

**IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF  
THE NORTH AMERICAN FREE TRADE AGREEMENT  
AND THE UNCITRAL ARBITRATION RULES**

**BETWEEN:**

**CHEMTURA CORPORATION  
(formerly Crompton Corporation)**

**Claimant/Investor**

**AND:**

**GOVERNMENT OF CANADA**

**Respondent/Party**

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**GOVERNMENT OF CANADA**

**COUNTER-MEMORIAL**

**October 20, 2008**

Departments of Justice and of  
Foreign Affairs  
& International Trade  
Trade Law Bureau  
Lester B. Pearson Building  
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## **OVERVIEW OF CASE**

1. Lindane is a pesticide in the organochlorine insecticide family that was first introduced in Canada in the 1930s. As of the late 1970s, evidence had begun to mount concerning lindane's damaging effects on humans, animals, and the environment. In 1975, the World Health Organisation and the Food and Agriculture Organisation reported that lindane accumulated in human tissue and could cause nervous system damage, convulsions, and even death. In the next two decades, scientific evidence against lindane grew exponentially. By the late 1990s, it was clear that lindane had serious neurotoxic effects on humans and animals, and that it accumulated in the environment, persisting indefinitely in the air, water, and soil.

2. As this evidence accumulated, States took steps domestically to limit or ban lindane use altogether. In the late 1970s, Canada and the United States began to progressively reduce or limit lindane uses. Internationally, lindane use peaked in 1968 and, by 2006, lindane was banned in 52 countries and its use was severely restricted in 33 other countries. In the same period, various international protocols were adopted committing the State Parties to reduce or ban lindane use.

3. By late 1997, Canada had withdrawn most uses of lindane but still permitted it to be used as an insecticide for seed treatment on certain crops. Lindane was used on canola, Canada's second most valuable crop. In the late 1990s, canola provided almost CDN \$2 billion dollars annually in farm cash receipts, of which roughly CDN \$600 million dollars was exported to the United States.

4. While Canada still allowed lindane use on agricultural products such as canola, the regulatory situation in the United States in the late 1990s was different. The U.S. Environmental Protection Agency (EPA) never had a registration or tolerance for lindane use on canola, and hence in 1997 export of lindane-treated canola or canola seed to the United States was arguably illegal. This issue arising from "asymmetric" regulation

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between Canada and the United States had apparently gone unnoticed by authorities for years, at least until the fall of 1997.

5. In September 1997, the Vice-President of Gustafson, a U.S. subsidiary of Chemtura, saw a golden opportunity to prevent imports of lindane-treated canola seed from Canada and to create market demand for its own lindane substitute product known as Gaucho. Chemtura's subsidiary alerted U.S. EPA and Customs officials to the fact that Canadian lindane-treated canola seed was entering the United States. It called on the U.S. government to stop this "illegal" importation. The EPA agreed, and advised that such imports would be stopped effective June 1, 1998.

6. Not surprisingly, the threat of a border closure for lindane-treated canola was catastrophic for Canadian canola farmers. Alarmed at the prospect of losing their largest export market, Canadian canola farmers called on their associations, the Canadian Canola Growers Association (CCGA) and the Canola Council of Canada (CCC), to do something. The CCGA and CCC immediately contacted the 4 Canadian registrants of lindane and asked them to voluntarily remove canola use from their lindane product registrations and product labels. The logic of this proposal was that if Canadian lindane producers agreed to remove lindane use on canola through a phase out, the United States could be prevailed upon to postpone its announced border action and allow a reasonable transition to lindane replacement products. The CCC and CCGA made it clear to the 4 registrants that failure to agree to such a transitional regime would result in the immediate and total closure of the border to lindane-treated canola, with devastating losses for Canadian canola growers (and of course for the companies that supplied them with lindane and lindane-treated seed). Chemtura Canada was one of these 4 Canadian lindane registrants asked by the CCC and CCGA to participate in this agreement. The CCC and the CCGA also asked the Pest Management Regulatory Agency to facilitate the proposed phase out by considering replacement product registrations.

7. By November 1998, the CCGA and CCC had negotiated a voluntary withdrawal agreement (VWA) with the 4 lindane manufacturers, including Chemtura. Essentially,

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the VWA required each manufacturer to ask the Canadian government regulator, the PMRA, to remove canola use from its product label by December 31, 1999. In turn, the PMRA would exercise regulatory discretion to permit a further two-year “phase out” period (to July 1, 2001), allowing depletion of existing product. As well, the PMRA agreed to review applications to register replacement treatments proposed by the 4 participating lindane manufacturers, although it could not guarantee the time required for, or the outcome, of such review. Canola industry stakeholders hoped that this plan would convince U.S. officials to forebear from the border closure and allow an orderly transition away from lindane. Ultimately this plan succeeded in doing so.

8. While none of the 4 lindane manufacturers were enamoured of this plan, they all agreed to it and ultimately took the benefit of it. Economically, their only other option was to lose product sales to Canadian canola farmers immediately and permanently. Chemtura commenced rearguard efforts in the fall of 1998 and throughout 1999 to renegotiate the VWA and to obtain preferential terms for itself. The PMRA refused to participate in this renegotiation and insisted that it could only facilitate the VWA if the CCC & CCGA could convince all 4 manufacturers unanimously to abide by it. Failing unanimity, the United States would impose a border closure.

9. Despite its threats to renege on the VWA and its efforts unilaterally to renegotiate that agreement, Chemtura ultimately agreed to the VWA with the CCGA and CCC. Chemtura therefore took the benefit of the VWA. It was the first of the 4 companies to obtain registration of a lindane replacement product and was given the opportunity to pursue its sales of lindane seed treatments on canola from 1999 until July 1, 2001, the end of the agreed phase-out period under the VWA.

10. While the VWA proceeded, the PMRA proceeded with its usual mandate of reviewing and regulating pesticides. Given increasing scientific knowledge of the toxic effects of lindane and the progressive retrenchment of lindane use internationally, the PMRA commenced a Special Review of lindane on March 15, 1999. The goal of the



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Special Review was to re-evaluate the risks and value of lindane in the light of current scientific knowledge.

11. The Special Review followed the procedure adopted by PMRA generally in re-evaluating pesticides, including an extensive review of available literature, cooperation with the U.S. EPA to take advantage of its studies, and PMRA's multi-pronged study considering potential risks of lindane use. Stakeholders, including Chemtura, were made aware of the broad scope of the lindane review and were given significant opportunities to submit relevant data and comment on the review. The Special Review concluded that continued registration of lindane was unacceptable on the basis of occupational health risks. Based on that conclusion, in October 2001 the PMRA advised registrants, including Chemtura, that all remaining agricultural uses of lindane generally would be suspended. The PMRA offered a three-year phase out of current products if registrants agreed to withdraw their lindane registrations immediately. Chemtura was the only manufacturer that refused this offer. As a result, PMRA was required by its governing legislation to cancel Chemtura's lindane registrations in February 2002.

12. Unhappy with the PMRA's decision, Chemtura then sought a Board of Review to reconsider the PMRA's Special Review of lindane. A Board of Review is available under PMRA's governing legislation and is designed to afford registrants the opportunity to challenge scientific determinations by the PMRA. The lindane Board of Review was convened and 3 neutral, external scientific experts were appointed to conduct a thorough review of the Special Review. Chemtura participated fully in the Board of Review, bringing 10 expert and fact witnesses, submitting documents and making argument. After 3 rounds of written submissions, 9 days of hearing and 8 months of deliberation, the Board of Review issued a report in August 2005 concluding that PMRA's conclusions were within scientifically acceptable parameters. However, the Board of Review recommended that the PMRA engage in further consultations with registrants, reconsider the risk factors it had applied, and reconsider ways to reduce exposure. This included consideration of lindane use restrictions the Claimant had raised for the first time in the course of the Board of Review proceedings.

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13. From 2005 to 2008, the PMRA did a full *de novo* review of lindane, taking into account the comments of the Board of Review. Chemtura participated in this *de novo* review, submitting new and updated data and comments, which PMRA studied. On April 30, 2008, the PMRA sent a draft Re-evaluation Notice (REN) to Chemtura and other stakeholders that accounted for the comments of the Board of Review and all stakeholders. The REN affirmed that lindane was unacceptable from an occupational exposure perspective (as had been concluded in the Special Review), and that the increasing body of scientific knowledge had established that lindane use was also unacceptable given environmental and carcinogenicity concerns.

14. Ironically, in the meanwhile the Claimant's home regulator, the U.S. EPA, came to the same conclusion as Canada. In 2002 the EPA maintained existing lindane registrations (which never included canola use) but made them subject to significant additional safety precautions. By 2006, the EPA determined that even these few remaining registrations could no longer be sustained given health and environmental concerns arising from lindane use. Lindane is currently being proposed for a full international ban under the United Nations *Convention on Persistent Organic Pollutants*.

15. Over the period described above, Chemtura initiated no less than 9 Federal Court judicial review applications challenging the PMRA's role in the VWA, the Special Review of lindane and the lindane Board of Review. Chemtura pursued only one of these applications, which dismissed Chemtura's request for an injunction. It abandoned all of its Federal Court applications before they were heard on the merits. Taking a similar approach to legal process, Chemtura has filed 3 Notices of Intent and 2 Notices of Arbitration under NAFTA Chapter 11 since November 6, 2001. These have variously alleged breaches of Articles 1102, 1103, 1105 and 1110, and have sought ever-escalating damages. In its NAFTA Memorial, Chemtura pursues breach of Articles 1110 and 1105, and a brand new theory of breach of Article 1103.

16. In this Counter-Memorial, Canada replies essentially that:

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- Canada did not expropriate the investment. There has been no substantial deprivation of Chemtura Canada, and in any event, the conduct of the PMRA is a valid (and non-compensable) exercise of police powers.
  - Further, Chemtura's conduct in triggering the U.S. border closure and its voluntary participation in the VWA estop it from pursuing expropriation claims with respect to lindane use on canola and canola seed.
  - Canada did not breach the minimum standard of treatment. The Claimant has not even attempted to establish the content of the minimum standard of treatment at customary international law.
  - In any event, the facts overwhelmingly demonstrate that Canada has accorded the Claimant ample due process, conducted itself lawfully and treated the Claimant fairly. The PMRA complied with Article 1105 in every respect.
  - The Claimant seeks to import a "free-standing" fair and equitable treatment clause into NAFTA through its most-favoured nation (MFN) obligation. Article 1103 is a limited MFN provision that applies to treatment, and does not import treaty standards at large. Even if it did, the PMRA accorded fair and equitable treatment to Chemtura at all relevant times, no matter how extensively one defines the scope of that phrase.
  - Finally, Chemtura claims damages founded on facts that have objectively been proved false, "but for" assumptions that are impossible and on a mechanically and technically flawed model. The LECG Report it submits is a hopelessly inadequate basis to award any damages, much less damages exceeding the USD \$82 million that Chemtura demands in this arbitration.

At the end of the day, Chemtura seeks to hold PMRA responsible for the fact that it can no longer profit from the sale of a toxic chemical that has been internationally banned based on demonstrated health and environmental concerns. The NAFTA does not protect or promote such investment, and this arbitration should be dismissed with costs to Canada.

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Materials Submitted by Canada

1. Canada's Counter-Memorial is accompanied by documentary annexes, a volume of appendices and compilation of relevant legal authorities. In addition, Canada submits eight affidavits and three expert reports in support of its Counter-Memorial:

- **BUTH AFFIDAVIT:** Joanne Buth was the Vice-President of Crop Protection at the Canola Council of Canada (CCC) from 1999-2006. Her affidavit addresses the implementation of the Voluntary Withdrawal Agreement (VWA) from her arrival at the CCC in 1999 until its completion in 2002.
- **CHAFFEY AFFIDAVIT:** Cheryl Chaffey was the Section Head of the PMRA's Health Re-evaluation Section during the review of lindane from 1999-2001. She describes the PMRA's toxicology assessment of lindane during the Special Review.
- **CHALIFOUR AFFIDAVIT:** Suzanne Chalifour was a Senior Evaluation Officer in the Product Sustainability and Coordination Division ("PSCD") of the PMRA. Her affidavit outlines the PMRA's pesticide registration process and discusses the applications for replacement products by Syngenta for Helix and by Chemtura for Gaucho.
- **COSTA REPORT:** Dr. Lucio Costa is a professor of Toxicology at the University of Washington in Seattle (WA, United States). He provides expert opinion on health, occupational and environmental issues related to lindane, and the regulatory science undertaken by the PMRA related to the de-registration of lindane in Canada.
- **FRANKLIN AFFIDAVIT:** Dr. Claire Franklin was the Executive Director of the PMRA from its creation in 1995 until 2003, overseeing all of the Agency's functions and ensuring cross-agency coordination. She addresses allegations that PMRA failed to bring its concerns regarding occupational exposure to Chemtura's attention during the Special Review of lindane and comments on a discussion with the Claimant regarding the PMRA's review of lindane products.
- **GOLDMAN REPORT:** Dr. Lynn Goldman is a pediatrician and a professor at the Johns Hopkins University Bloomberg School of Public Health (MD, United States). From 1993 to 1998, Dr. Goldman was the Assistant Administrator at the EPA's Office of Prevention, Pesticides, and Toxic Substances. She explains the legislative framework for pesticides in the U.S. and lindane's regulatory history, challenges assumptions of Paul Thompson, Edwin Johnson and James Aidala on the possibility of obtaining a registration and/or tolerance for lindane on canola and addresses the impact of the VWA on the impending U.S. border closure.

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- **KACZMAREK REPORT:** Brent Kaczmarek of Navigant Consultants reviewed the LECG analysis of economic losses claimed by Chemtura in this arbitration. He has provided an alternative assessment on the quantum of damages.
  - **REID AFFIDAVIT:** Jim Reid was the Chief of Compliance in regional operations of the PMRA from 1995-2002. His affidavit describes the PMRA's compliance and enforcement regime and explains the lindane compliance program (i.e. inventorying stocks of lindane seed treatment and lindane-treated seeds at seed treatment facilities) for the 2001 season.
  - **SEXSMITH AFFIDAVIT:** Wendy Sexsmith has held a number of positions at the PMRA during the relevant period: Director of the Alternative Strategies and Regulatory Affairs Division (1998-2000), Chief Registrar (2000-2003) and Acting Executive Director (2003-2005). Her affidavit considers the VWA from the PMRA's perspective, chronicles issues relating to the implementation of the PMRA's decision to withdraw all uses of lindane and weighs on the Board of Review process.
  - **WORGAN AFFIDAVIT:** John Worgan became involved in the re-evaluation of lindane in 2000, when he was moved to the PMRA's Exposure Re-evaluation Section. He provides an overview of pesticide regulation in Canada and the PMRA's re-evaluation program. Mr. Worgan also describes the Special Review of lindane, the Board of Review decision and the PMRA's implementation of the Board of Review's recommendations followed by a discussion of the PMRA's 2008 Re-Evaluation Note and current communications with the Claimant.
  - **ZATYLNLY AFFIDAVIT:** Tony Zatylny was the Vice President of Crop Production and Regulatory Affairs at the CCC from 1996-1999. His affidavit describes the development of the VWA and explains the purpose of the agreement.

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## STATEMENT OF FACTS

### I. BACKGROUND

#### A. The regulatory framework at issue

17. Due to their potential to damage human health and the environment, pest control products, more commonly termed 'pesticides', are among the most rigorously tested and regulated substances in the world. This high standard of scrutiny applies from the initial submission for registration and continues throughout the lifetime of a product registration.<sup>1</sup>

18. Canada is a world leader in the regulation of pest control products.<sup>2</sup> It participates alongside such nations as the United States, Australia, the United Kingdom, and States of Continental Europe in modern regulatory science practices designed to maximize protection of the public while permitting the most effective beneficial use of agro-chemicals and other products.<sup>3</sup> As the Claimant was well aware, given its longstanding participation in this industry in Canada,<sup>4</sup> no one has an inherent right to import, produce, or sell pesticides in Canada.

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<sup>1</sup> Affidavit of John Worgan, ¶¶ 9, 14. In this Counter-Memorial, Canada will refer to documentary exhibits of the affidavits using abbreviations based on the initials of the affiant. Exhibits are labelled in the format 'Exhibit AA-1', where 'AA' is the initials of the affiant and '1' is the document number. The abbreviations used are: CC = Cheryl Chaffey; CF = Claire Franklin; JR = Jim Reid; JB = JoAnne Buth, JW = John Worgan, LG = Lynn Goldman, SC = Suzanne Chalifour; TZ = Tony Zatylny; WS = Wendy Sexsmith.

<sup>2</sup> In this Counter-Memorial, Canada uses the terms 'pest control products' and 'pesticides' interchangeably.

<sup>3</sup> Regulatory science seeks to ensure a scientifically rigorous basis for public decision-making controlling the production and use of potentially dangerous substances, including pesticides. Regulatory scientists do not directly conduct laboratory experiments. Rather, they assess the soundness of scientific practice in reported experiments, and the conclusions set out therein. Taking into account such assessments, they collate data from a broad spectrum of scientific sources to make decisions about the eligibility of potentially dangerous substances for public use, including the restrictions to be placed on such use. Given the extensive range of studies they are called to assess, regulatory scientists must maintain a broad scientific knowledge of the area to be regulated, and must also be well-versed in the policy considerations underlying their review activities. Affidavit of Cheryl Chaffey, ¶¶ 27-32. Canada includes with its Counter-Memorial a Glossary of relevant terms at Appendix A.

<sup>4</sup> See Section II, C below.

19. During the time relevant to this dispute, the Pest Management Regulatory Agency (PMRA), an agency of Health Canada, a Canadian government Department, was the agency responsible for administering Canada's pest control legislation.<sup>5</sup> PMRA administered and implemented the *Pest Control Products Act (PCPA)*.<sup>6</sup>

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<sup>5</sup> The PMRA was created in 1995, integrating review functions that had previously been coordinated among several federal Departments, including Health, Agriculture, and Environment. The PMRA's primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products. See PMRA, "About PMRA", online at: <<http://www.pmra-arla.gc.ca/english/aboutpmra/about-e.html>> (Annex R-9). Consistent with this primary objective, the PMRA seeks to:

- (1) Minimize the health and environmental risks posed by pest control products and encourage the development and implementation of innovative, sustainable pest management strategies, among other things, by facilitating access to products that pose lower risks;
- (2) Encourage public awareness in relation to pest control products; and
- (3) Ensure that only those pest control products that are determined to be of acceptable value are approved for use in Canada.

Pursuant to the PMRA's operating policies, 'value', in respect of a pest control product, means the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration. The concept of value includes the products: a) efficacy; b) effect on host organisms in connection with which it is intended to be used; and c) health, safety and environmental benefits, and social and economic impact. See *Pest Control Products Regulations*, C.R.C., c.1253 at s. 18(c) (Annex R-2) ('PCPR'); see also PMRA, *Overview Document* at 7 (Annex R-29); *Pest Control Products Act*, R.S. 1985, c.P-9, s. 1 (Annex R-1) ('PCPA').

<sup>6</sup> The PMRA regulates pest control products in Canada through the *Pest Control Products Act* ('PCPA') (Annex R-1) as well as its accompanying regulations. The PCPA is the enacting legislation under two Regulations: The *Pest Control Product Regulations* ('PCPR') (Annex R-2); and the *Regulations Prescribing the Fees to be Paid for a Pest Control Product Application Examination Service Provided on Behalf of Her Majesty in Right of Canada, for a Right or Privilege to Manufacture or Sell a Pest Control Product and for Establishing a Maximum Residue Limit in Relation to a Pest Control Product*, SOR/97-173 (Annex R-3).

A new PCPA received Royal Assent on 12 December 2002, and came into force on 28 June 2006. All of the facts relevant to this arbitration arose under the original PCPA and references to the PCPA in this Memorial are to the pre-June 2006 legislation, unless otherwise indicated. In the period prior to its entry into force, the PMRA had already enacted at the level of agency policy many of the innovations legislatively enshrined in the 2006 version of the PCPA, including a program of systematic review of 'old' pesticides registrations, such as lindane: see Affidavit of John Worgan, ¶¶ 30,33.

20. PMRA controls the use, sale and import of all pest control products in Canada.<sup>7</sup> The PMRA exercises this authority through the registration (or non-registration) of products, as well as through renewals, discontinuances, cancellations or suspensions of registrations.<sup>8</sup> The Common Law also recognizes that the Minister does not have an enforceable obligation to take action in relation to every contravention. PMRA regulations allow a registrant to withdraw its product either partially (by applying to amend its registration under section 13) or entirely (by informing the Minister of its intention to discontinue sales of the control product, under section 16).<sup>9</sup> The PMRA is also authorized to conduct Special Reviews of currently-registered products where it believes that their confirmed use may pose a threat to public health or the environment.<sup>10</sup>

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<sup>7</sup> The *PCPA* and its accompanying Regulations regulate pest 'control products', defined in the *PCPA* as 'any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pest': *PCPA*, s. 2 (Annex R-1). Section 5(1) of the *PCPA* prohibits the importation or sale of any pest control product in Canada unless the product:

- (a) has been registered as prescribed;
- (b) conforms to prescribed standards; and
- (c) is packaged and labelled as prescribed.

Subject to certain specific exemptions, the *PCPR* impose detailed registration requirements for 'every control product imported into, sold or used in Canada or used or contained in another control product in Canada': *PCPR*, s. 6 (Annex R-2).

<sup>8</sup> *PCPR*, s. 14 (renewal), s. 16 (discontinuance), ss. 19-22 (cancellation), ss. 19-21 (suspension) (Annex R-2).

<sup>9</sup> *PCPR*: s. 13, s. 16 (Annex R-2).

<sup>10</sup> The burden remains on the registrant throughout the life of the registration to satisfy the Minister that the product continues to be acceptable for registration: *PCPR*, s. 19 (Annex R-2). In practice, the merits of maintaining existing registrations may be reviewed by a process known generically as 're-evaluation'. Affidavit of John Worgan, ¶ 26. The Minister can, at any time, request that the registrant provide information for that purpose, and may cancel or suspend registrations for cause, 'on such terms and conditions, if any, as he may specify': *PCPR*, s. 20 (Annex R-2). Under the Regulations, a registrant of a control product, when requested to do so by the Minister (acting through the PMRA), is required to satisfy the Minister that the availability of the control product will not lead to an unacceptable risk of harm to (a) things on or in relation to which the control product is intended to be used, or (b) public health, plants, animals or the environment are both examined: *PCPR*, s. 19 (Annex R-2). By conducting a re-evaluation, the PMRA seeks to ensure that a pesticide's continued use reflects current safety standards and value considerations. Re-evaluation may be pursued under s. 19 of the *PCPR* in at least two situations: periodically, where an existing registration has not been reviewed for several years; and in a Special Review, where re-evaluation of a currently-registered pesticide is prompted by specific concerns about the potential negative health and / or environmental impacts associated with continued registration of a pest control product. Affidavit of John Worgan, ¶ 28.



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21. This dispute concerns: (1) the PMRA's role in relation to a voluntary withdrawal agreement (VWA) for lindane use on canola seeds. The VWA negotiated in 1998 between Canadian canola farmers and lindane registrants, including Chemtura in response to an imminent ban on the importation of lindane-treated canola seeds by the United States; (2) the PMRA's related steps to register alternative, non-lindane-containing products for treatment of canola seeds; and (3) a Special Review of lindane for all uses, initiated by the PMRA in 1999, which determined that lindane was unsafe for all agricultural uses, and that all such registrations in Canada should be eliminated.

22. These exercises of authority were entirely legitimate agency actions, taken consistent with the PMRA's mandate. The Claimant has omitted key facts and distorted the events at issue in order to paint a picture of improper and discriminatory agency conduct. The real story is quite different. If anything, the Claimant reaped significant commercial benefit from the VWA. The VWA avoided an imminent U.S. border closure and extended Chemtura's sales by a further three years. Far from being discriminated against in the related review of potential lindane replacement products, Chemtura's replacement product was the first registered. The PMRA was also wholly justified in determining through a Special Review that the risks of lindane as a pesticide were too great to maintain its registrations.

23. Before going into the details of these events, however, it is important for the Tribunal to understand the status of lindane in 1998, when the events at issue began to unfold.

**B. By the late 1990s, lindane was the object of legitimate scrutiny nationally and internationally**

**1. The chemical lindane**

24. Lindane is a pesticide that was first introduced to the world market in the 1930's, and first registered on the Canadian market in 1938.<sup>11</sup> Although regarded as safe at the time of its introduction, beginning in the late 1960s, evidence started to mount of its

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<sup>11</sup> Affidavit of John Worgan, ¶ 19; Expert Report of Dr. Lucio Costa, ¶ 21 (*Dr. Costa Report*).

highly deleterious effects on human and animal health and the environment. As a result, nations around the world began to progressively limit and even ban its manufacture, use, and sale.<sup>12</sup>

25. Lindane is the common name of  $\gamma$ -HCH (gamma-HCH), one of eight isomers of 1, 2, 3, 4, 5, 6-hexachlorocyclohexane ( $C_6H_6Cl_6$ ). Isomers are chemical compounds with the same molecular formula but with differing molecular structures.<sup>13</sup>

26. HCH is among the oldest organochlorine insecticides.<sup>14</sup> The use of lindane as an insecticide began in the 1940s, when Technical HCH was registered with the U.S. Department of Agriculture ('USDA') as an agricultural insecticide.<sup>15</sup> In the same decade, the  $\gamma$  (gamma) isomer of HCH – lindane – was separately identified.<sup>16</sup> The isomer  $\gamma$ -HCH alone functions as a pesticide, while other HCH isomers do not.

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<sup>12</sup> Canada began imposing restrictions on lindane use as early as the 1970s. As discussed below, the pesticide lindane was one of the several hundred 'old' pesticides the PMRA considered in its re-evaluation exercise, beginning in the late 1990s: *Dr. Costa Report*, ¶ 47, 'General Considerations on lindane ( $\gamma$ -HCH)'; Affidavit of Cheryl Chaffey, ¶ 34.

<sup>13</sup> In the case of HCH, eight potential isomers are produced by photochemical chlorination of benzene, an organic chemical compound and known carcinogen with the molecular formula  $C_6H_6$ . The result is a product called Technical HCH, which is mainly made up of the isomers  $\alpha$ -HCH (alpha-HCH) (53-70 percent),  $\beta$ -HCH (beta-HCH) (3-14 percent),  $\gamma$ -HCH (gamma-HCH) (11-18 percent),  $\delta$ -HCH (delta-HCH) (6-10 percent) and  $\epsilon$ -HCH (epsilon-HCH) (3-5 percent). Lindane, or  $\gamma$ -HCH, is a white crystalline solid which is stable in light, heat, air, carbon dioxide and strong acids. See Commission for Environmental Cooperation, *North American Regional Action Plan (NARAP) on Lindane and other Hexachlorocyclohexane (HCH) Isomers*, 30 November 2006 (Exhibit CC-11) (NARAP); *Dr. Costa Report* ¶ 22.

<sup>14</sup> *Dr. Costa Report*, ¶ 21.

<sup>15</sup> NARAP, Section 3.3.6, *History and Current Status of Lindane Uses in the United States of America* (Exhibit CC-11). Until the 1960s, the pesticide typically used as 'lindane' was actually Technical HCH – that is, HCH in all of its potential isometric structures, or  $\alpha$ ,  $\beta$ ,  $\gamma$ ,  $\delta$  and  $\epsilon$ -HCH. And yet, as early as 1942, scientists had determined that of all the isomers making up Technical HCH, only  $\gamma$ -HCH (gamma-HCH) (lindane) had pesticidal properties.

<sup>16</sup> The launch of HCH as an insecticide during World War II coincided with the introduction of several other chlorinated insecticides, including DDT, chlordane, heptachlor, aldrin, dieldrin, and endosulfan. Organochlorine insecticides enjoyed wide use in agriculture and other applications from the 1940s to the 1970s: *Dr. Costa Report*, ¶ 22.

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**2. By the 1970s, scientists began to confirm that lindane and other HCH isomers are toxic and environmentally dangerous**

27. The properties that made organochlorine insecticides like lindane effective (generally low volatility, chemical stability, lipid solubility, slow rate of biotransformation and degradation) also brought about their demise. Over the past 30 years most organochlorines have been banned around the world because of their persistence in the environment, bioconcentration, and biomagnification in various food chains. Lindane is no exception.

28. In 1975, the World Health Organization (WHO) and Food and Agriculture Organization (FAO) jointly issued a Lindane Scientific Report indicating that lindane could accumulate in human tissue and had the potential to cause nervous system damage, convulsions and in some cases, even death.<sup>17</sup> Lindane has also been shown to cause nervous system damage in insects and mammals, leading to death.<sup>18</sup>

29. The U.S. Environmental Protection Agency (EPA), the Claimant's 'home' regulator has itself recognized the neurotoxic effects of lindane, as well as its renal and hepatic toxicity, and role as a potential endocrine disruptor in birds and mammals. The Agency for Toxic Substances and Disease Registry ('ATSDR') part of the U.S. Department of Health and Human Services, reported in 2005 that:

Animals that have been fed  $\gamma$ - and  $\alpha$ -HCH have had convulsions, and animals fed  $\beta$ -HCH have become comatose. All isomers [of HCH] can produce liver and kidney effects. Reduced ability to fight infection was reported in animals fed  $\gamma$ -HCH, and injury to

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<sup>17</sup> World Health Organization (WHO) and Food and Agriculture Organization (FAO), *Data Sheets on Pesticides No. 12; Lindane*, June 1975 (Exhibit CC-12).

<sup>18</sup> In insects, lindane binds to the chlorine channel on the gamma-amino butyric acid A (GABA-A) receptor complex in the central nervous system (CNS). The GABA-A acts to inhibit neurotransmission in the insect's CNS. By inhibiting the action of the GABA-A, lindane causes an overstimulation of the CNS (in essence, inhibiting an inhibitor), resulting in rapid convulsions and death of the insect. Lindane targets the same GABA-A receptor complex in mammals: primary effects of acute lindane exposure are neurotoxic. See *Dr. Costa Report*, ¶ 25.

the ovaries and testes was reported in animals given  $\gamma$ -HCH or  $\beta$ -HCH.<sup>19</sup>

30. With regard to effects on humans, the same ATSDR report noted that:

In humans, breathing toxic amounts of  $\gamma$ -HCH and/or  $\alpha$ ,  $\beta$ -, and  $\delta$ -HCH can result in blood disorders, dizziness, headaches, and possible changes in the levels of sex hormones in the blood. These effects have occurred in workers exposed to HCH vapors during pesticide manufacturing. People who have swallowed large amounts have had seizures; some have died.<sup>20</sup>

31. In 1997, the Joint Meeting on Pesticides Residues (JMPR), an FAO and WHO joint initiative, confirmed previous immunotoxicity concerns relating to lindane.<sup>21</sup>

32. In addition to sharing properties of bioaccumulation and environmental persistence with other organochlorines,<sup>22</sup> lindane produces significant amounts of toxic waste.<sup>23</sup> These wastes have generally been disposed of in open landfills or other disposal sites, often in the proximity of HCH manufacturing facilities. In the United States, more

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<sup>19</sup> Agency for Toxic Substances and Disease Registry, *Public Health Statement on Hexachlorocyclohexane*, 2005, section 1.5 (Exhibit CC-10) (*ATSDR Statement*).

<sup>20</sup> *ATSDR Statement* (Exhibit CC-10).

<sup>21</sup> Affidavit of Cheryl Chaffey, ¶ 47; Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues and WHO Core Assessment Group on Pesticide Residues, *Pesticide Residues in Food*, 1997 (Exhibit CC-15). In doing so, they applied a significant safety factor in analysing data from available studies to establish the allowable daily intake of lindane. The report observed immunotoxic effects at doses close to or even lower than the threshold employed by JMPR for allowable human intake levels. The JMPR therefore concluded that additional data on immunotoxicity was required.

<sup>22</sup> Like other isomers of HCH, lindane does not readily biodegrade in the environment, but instead can persist in the air, water and soil. Lindane can move by atmospheric transport to areas far removed from its original application. As a result of condensation in northern regions, lindane and other HCH isomers tend to settle and accumulate in the local food chain. Affidavit of Cheryl Chaffey, ¶ 38; *NARAP* (Exhibit CC-11).

<sup>23</sup> The remaining HCH isomers, while ineffective as pesticides, have even higher toxicity and environmental volatility than lindane. Moreover, while  $\gamma$ -HCH can be isolated from the other HCH isomers, they are necessary by-products of the photochemical chlorination of benzene through which  $\gamma$ -HCH is produced. Pure lindane (greater than 99 percent) is produced with a 10-15 percent yield from Technical HCH. In effect, this means that to produce one ton of  $\gamma$ -HCH, producers necessarily also generate 6-10 tons of additional, toxic, HCH isomers: Expert Report of Dr. Lynn Goldman, ¶ 8 (*Dr. Goldman Report*); U.S. EPA, *Assessment of Lindane and Other Hexachlorocyclohexane Isomers*, Docket No. EPA-HQ-OPP-2006-0034, 8 February 2006, at 11 (Annex R-45) (*EPA HCH Assessment*)

than 150 sites listed as 'Superfund' sites contain waste HCH isomers.<sup>24</sup> The 2006 NARAP on lindane noted that in places such as the Netherlands and Spain, mounds of waste HCH awaited burial in highly-controlled disposal sites (in the latter case, at an announced cost of 30 million Euros).<sup>25</sup>

33. By the late 1990s lindane production had not taken place in North America for decades.<sup>26</sup> However, use of lindane pesticides in Canada or in the United States necessarily entailed the generation of quantities of the other toxic HCH isomers in other parts of the world with less stringent safety and disposal standards. When not disposed of in secure sites, waste alpha- and beta-HCH generated in lindane production travels through the atmosphere to the north. In other words, use of lindane in Canada and the United States entails the eventual accumulation of HCH isomers in Northern Canada and Alaska.<sup>27</sup>

### **3. Early steps to restrict lindane use**

#### **a) International patterns**

34. In light of increasing evidence of its negative health and environmental impacts, global consumption of lindane has decreased steadily from its peak in 1968.

Governments around the world progressively restricted its use:

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<sup>24</sup> Superfund is the common name for the *Comprehensive Environmental Response, Compensation and Liability Act* (CERCLA) passed by the United States Congress in 1980. It is a U.S. Federal program to identify, prioritize and clean up sites containing toxic waste: see *Dr. Costa Report*, ¶ 27.

<sup>25</sup> NARAP, Annex A: Overview of Production, Residue Management, Formulation and Disposal, Part 1 – Case Studies on the Legacy of Lindane/HCH Isomer Production: Overview of Residue Management, Formulation and Disposal in the Netherlands and the Basque Country (Exhibit CC-11).

<sup>26</sup> Today, India is one of the last lindane production sites. Lindane was produced in Romania earlier this decade, but production in this country has been stopped due to Romania's accession to the EU, given the EU ban which took effect at the end of 2007: see Official Journal of the European Union, "Transitional Measures, Romania", 21 June 2005, online at: <<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:157:0138:0188:EN:PDF>> (Annex R-42). China, once a major manufacturer of the pesticide, ceased production of lindane in 2002: *Dr. Costa Report*, ¶ 40.

<sup>27</sup> Affidavit of Cheryl Chaffey, ¶ 40; Letter from Robert Dupree, Manager, Product Development & Regulatory Affairs, Crompton Canada (predecessor-in-title to Chemtura Canada) to Jeff Parsons, Re-evaluation Section, PMRA, 15 November 2001 (Exhibit JW-26B); EPA HCH Assessment (Annex R-45); U.S. EPA, *Addendum to the 2002 Lindane Reregistration Eligibility Decision (RED)*, Case No. 315, July 2006 (Exhibit JW-59) (*Lindane RED – 2006 Addendum*).

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- In 1968, Hungary restricted the use of lindane to grain treatment for winter wheat and nurseries;<sup>28</sup>
  - In 1971, lindane was banned in Japan;<sup>29</sup>
  - In 1974, mixed isomer-based lindane products were banned in Portugal;<sup>30</sup>
  - In 1979, the Netherlands prohibited the sale, stocking or use of pesticides containing HCH in all of its isometric forms;<sup>31</sup>
  - In 1986, South Korea banned the sale and use of lindane and Switzerland severely restricted its sale and use;<sup>32</sup>
  - In 1987, Cyprus restricted the use of lindane to wood protection and paints, eliminating agricultural use;<sup>33</sup>
  - In 1988, Finland prohibited the use of lindane as a pesticide;<sup>34</sup>
  - In both 1978 and 1988, the use of lindane was severely restricted within the European Community;<sup>35</sup>
  - In 1988, lindane was banned in Germany;<sup>36</sup>
  - In 1988, the former USSR prohibited the use of lindane as a pesticide, and severely restricted all other uses;<sup>37</sup>

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<sup>28</sup> Canadian Ministry of Indian Affairs and Northern Development, *Canadian Arctic Contaminants Assessment Report II: Sources, Occurrence, Trends and Pathways in the Physical Environment* (Ottawa: Government of Canada, 2003) at 51 (Annex R-36) (*Canadian Arctic Contaminants Report 2003*).

<sup>29</sup> UNEP, *Regionally Based Assessment of Persistent Toxic Substances: Central and North East Asia Regional Report*, December 2002, at 33 (Annex R-35) (*UNEP Central & NE Asia Report*).

<sup>30</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>31</sup> UNEP/FAO, *Programme for the Operation of Prior Informed Consent, Decision Guidance Documents: Lindane*, 1 January 1996 (Annex R-13) (*UN/FAO Decision Guidance Document*).

<sup>32</sup> *UN/FAO Decision Guidance Document* (Annex R-13); *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>33</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>34</sup> *UN/FAO Decision Guidance Document* (Annex R-13).

<sup>35</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>36</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>37</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

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- In 1989, lindane was banned in Sweden, and in Belgium its use was restricted to wood treatment and veterinary applications;<sup>38</sup>
  - In 1990, lindane was banned in New Zealand<sup>39</sup> and deregistered in Mongolia;<sup>40</sup>
  - In 1991, lindane was banned in Bangladesh and Hong Kong<sup>41</sup>, and its use was severely restricted in Belize and China;<sup>42</sup>
  - In 1992, lindane was banned in Austria and Brazil;
  - In 1993, lindane was banned in Bulgaria;<sup>43</sup>
  - In 1994, lindane was banned in Norway;<sup>44</sup>
  - In 1995, lindane was banned in Denmark and its use was severely restricted in Argentina;<sup>45</sup>
  - In 1997, the U.K. Pesticides Safety Directorate (PSD), the U.K.'s equivalent of the PMRA, initiated a review of lindane. By 1999, the PSD had decided to ban all forms of lindane seed treatment use, on the basis of unacceptable health risks to workers exposed to the chemical during seed treatment;<sup>46</sup>
  - In 1998, thirty-six countries signed the *Aarhus Protocol on Persistent Organic Pollutants* (Aarhus Protocol).<sup>47</sup> The Aarhus Protocol legally

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<sup>38</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>39</sup> *UN/FAO Decision Guidance Document* (Annex R-13).

<sup>40</sup> *UNEP Central & NE Asia Report* (Annex R-35).

<sup>41</sup> *UNEP Central & NE Asia Report* (Annex R-35).

<sup>42</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>43</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>44</sup> UNEP, *Reports on substances scheduled for re-assessments under the UNECE POPs Protocol: Technical Review Report on Lindane*, August 2004 (Annex R-39) (*UN Technical Review Report*).

<sup>45</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>46</sup> *Food and Environment Protection Act*, 1985, Control of Pesticides Regulations 1986 (UK), Evaluation on: The Review of Lindane, Part III, November 1999 (Exhibit CC-17).

<sup>47</sup> The Aarhus Protocol is one of eight protocols under the UN Economic Commission for Europe (UNECE) *Convention on Long Range Transboundary Air Pollution Chemicals* of 1979, signed by Canada, the U.S., European countries, Russia and the Commonwealth of Independent States. Canada ratified the Aarhus Protocol in 1998. The States Parties that signed in 1998 were: the European Community, the United States, the United Kingdom, France, Germany, Canada, Switzerland, Armenia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, Greece, Hungary, Iceland, Italy, Latvia,

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binds Parties to restrict or eliminate chemical substances contributing to damage caused by transboundary air pollution to human health and the environment. Lindane was listed in Annex 2 of the Aarhus Protocol. This listing restricted the use of lindane to only six specific uses and signatories committed to conducting a full reassessment of all restricted uses.

- In 1998, lindane was banned in France;<sup>48</sup>
- In 1998, the EU initiated a complete re-evaluation of lindane which resulted in an eventual Europe-wide ban on plant protection products containing lindane in 2000;<sup>49</sup> and
- At the same time, a number of European countries added lindane to the List of Chemicals for Priority Action under the *OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic*, further signalling international concern about the human health and environmental effects of lindane.<sup>50</sup>

**b) Lindane use was progressively retrenched in Canada and the United States from the 1970s onward**

35. The worldwide retrenchment of lindane use from the late 1960s to the late 1990s was mirrored by trends in North America.

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Liechtenstein, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Moldavia, Romania, Slovenia, Spain, Sweden and the Ukraine.

<sup>48</sup> *Canadian Arctic Contaminants Report 2003* at 51 (Annex R-36).

<sup>49</sup> This review followed upon Austria's 1991 examination of the health and environmental effects of lindane on behalf of the European Union. The initial report listed lindane as a carcinogenic substance with no safe exposure limit. A Europe-wide ban was enacted in 2004 and entirely implemented by 2007. Studies showed that exposure to the chemical causes damage to the immune system and nervous system, as well as causing hormone disruption, behavioural changes and birth defects.

<sup>50</sup> OSPAR Commission, *Hazardous Substances Series, Background Document on Lindane*, 2004 Update, (Annex R-37). Under the Convention, the Contracting Parties committed to preventing pollution of the maritime area by continuously reducing discharges, emissions and losses of hazardous substances. The OSPAR Commission concluded that "there is sufficient[ly] clear and scientifically proven evidence to justify that from the marine environmental point of view all open uses of lindane are to be banned".



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36. In 1947, the United States had 12 listed manufacturers of HCH. This increased to 16 in 1959, only to decline sharply to 3 in 1962. All U.S. production was suspended as of 1977.<sup>51</sup> Lindane was never produced in Canada or Mexico.

37. In Canada, lindane use was progressively restricted. The use of lindane on a range of fruit and vegetable crops, in outdoor foggers, and for the treatment of water for the control of mosquitoes ended in 1970.<sup>52</sup> In 1976, products containing technical HCH were no longer permitted. By the mid 1990s, all above-ground uses of lindane had been discontinued.<sup>53</sup>

38. In the United States, restrictions on certain lindane uses were proposed as a result of the 1977 U.S. EPA's "Rebuttable Presumption Against Registration" (RPAR) review of lindane, triggered by concerns about oncogenicity, fetotoxicity, teratogenicity, reproductive effects, potential to cause blood dyscrasias, and acute toxicity to wildlife.<sup>54</sup> On October 19, 1983, the EPA issued a Notice of Intent to Cancel Pesticide Products Containing Lindane. In 1985, the EPA issued a Lindane Registration Standard, which required registrants to carry out a number of studies to support their lindane registrations. The registrants' scientific lobbyist, the Centre International d'Études de Lindane (CIEL), was involved in conducting such studies and in negotiations with the EPA.

39. Between 1993 and 1998, as concerns regarding long-range transport and environmental impacts of lindane increased, registrants requested voluntary deletion of all uses of lindane in the United States, with the exception of seed treatment on a variety

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<sup>51</sup> California Environmental Protection Agency, *Public Health Goal for Lindane in Drinking Water*, February 1999 at 3 (Annex R-18).

<sup>52</sup> Affidavit of John Worgan, ¶ 21.

<sup>53</sup> As detailed in Section VI below, additional restrictions came in the current decade. Sales of all products registered for use on livestock (cattle, horse, sheep, goats and swine) and on tobacco were discontinued by registrants at the end of 2000. Affidavit of Cheryl Chaffey, ¶ 34; Affidavit of John Worgan, ¶ 21. In 2001, all remaining registrations of lindane in Canada were terminated by the PMRA, based on the results of its Special Review: *see* Section IV, below.

<sup>54</sup> *Dr. Costa Report*, ¶ 30.

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of crops.<sup>55</sup> There was no registration or even residue allowance (or tolerance) for lindane use on canola in the United States, as no registrant had even sought such a registration.

40. In 1997, the Northern Contaminants Program, which brought together relevant federal, provincial and territorial departments of the Canadian government as well as aboriginal groups and university researchers, published the Canadian Arctic Contaminants Assessment Report.<sup>56</sup> The Report identified HCH as the most-used persistent organochlorine and the most abundant organochlorine contaminant found in arctic air, water and snowfall.<sup>57</sup> Arctic wildlife, the food supply of many northern inhabitants, was also found to be contaminated with HCH. The publication of this report was followed by international calls for the immediate cancellation of all lindane use around the world.<sup>58</sup>

41. On April 7, 1997, Canada and the United States signed the *Canada-United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes*

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<sup>55</sup> Uses rescinded at this time included all existing livestock, pet care, turf, building sprays, timber, lumber and military uses for lindane. Between 1998 and 2002, the 19 remaining seed treatments had been reduced to only 6 (barley, corn, oats, rye, sorghum and wheat). These few remaining applications were suspended by the EPA in 2006: U.S. EPA, *Re-registration Eligibility Decision for Lindane*, 31 July 2002 at 3 (Annex R-34) (*Lindane RED*).

<sup>56</sup> As noted in the Affidavit of Cheryl Chaffey, ¶ 45, a Northern Contaminants Program (NCP) was established in 1991 in response to studies confirming pollution of the Arctic ecosystem. The three main contaminant groups of concern were persistent organic pollutants (POPs), heavy metals, and radionuclides. The NCP brought together several federal departments (including Indian and Northern Affairs Canada, Health Canada, Environment Canada, and Fisheries and Oceans Canada), as well as the territorial government departments (at the time, the Yukon and the Northwest Territories, now including the Inuit territory of Nunavut), northern Aboriginal organizations and university researchers. Their goal was (and remains) to work towards reducing and wherever possible eliminating contaminants in traditionally-harvested foods. See Northern Contaminants Program, *NCP Operational Management Guide: Introduction*, 20 March 2006 (Exhibit CC-13).

<sup>57</sup> See summary in Department of Indian And Northern Affairs Canada, *Canadian Arctic Contaminants Assessment Report* (Ottawa: Government of Canada, 1997) (Exhibit CC-14).

<sup>58</sup> Affidavit of Cheryl Chaffey, ¶ 46; see also for example Inuit Circumpolar Council (Canada), “Northern Contaminants and Global POPs Program”, online at: <<http://www.inuitcircumpolar.com/index.php?ID=161&Lang=En>> (Annex R-8).

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*Basin* (Great Lakes Binational Toxics Strategy).<sup>59</sup> The Strategy aimed to reduce or eliminate persistent toxic chemicals that bioaccumulate in the Great Lakes. Lindane and other HCH isomers were listed as Level II substances. This designation meant that lindane and other HCH isomers were identified by one or both countries as having the potential to persist in the environment, bioaccumulate and have toxic effects. Under the Strategy, both governments committed to pollution prevention for Level II substances.

42. As a result of these worldwide and North American developments, by 1998, Canada had committed itself to review the few remaining permitted uses of lindane. Indeed, based on the JMPR results, the PMRA had already begun to reassess its own database and safety thresholds for remaining lindane uses by the spring of 1998.<sup>60</sup> This coincided with a broader governmental initiative in the late 1990s to re-evaluate the registrations of all “old” pesticides, including lindane.<sup>61</sup>

## **II. THE CLAIMANT AS A LONGSTANDING REGISTRANT WAS FULLY AWARE OF CANADA’S REGULATORY PROCESS**

### **A. The Claimant’s business and activities in Canada**

43. Chemtura is a U.S. corporation established under the laws of New Jersey, and the successor-in-title to Crompton Corporation, the entity which initiated the present claims under Chapter 11 of the NAFTA. As the fourth-largest publicly traded pesticides manufacturer in the United States, Chemtura currently employs approximately 6,200

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<sup>59</sup> Affidavit of Cheryl Chaffey, ¶ 48; Great Lakes Binational Toxics Strategy, *Canada-U.S. Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes Basin*, Appendix I, Persistent Toxic Substances Focused on by the Canada-United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes (Exhibit CC-16).

<sup>60</sup> Affidavit of Cheryl Chaffey, ¶55; Exhibits CC-18, CC-19, CC-20; PMRA, Memorandum to Donald Grant, Director, HED from Susanne Geertsens, Evaluation Officer, HED, Lindane, 20 May 1998 (Exhibit CC-18); PMRA, Memorandum to Donald Grant, Director, HED from Ratna Bose, Evaluation Officer, Health Evaluation Division, Immunotoxicological Concern of Lindane, 24 June 1998 (Exhibit CC-19); Health Canada, Memorandum to Mary Jane Kelleher, Insecticide Section, PSCD from Donald Grant, HED, Lindane – ADI Assessment, 25 June 1998 (Exhibit CC-20).

<sup>61</sup> For more information on the re-evaluation (Special Review) process, *see* Section IV, below.

people internationally and had total sales of approximately US\$3.7 billion in 2006.<sup>62</sup> Besides pesticides, the Claimant's key products include plastic additives, flame retardants, pool and spa products, lubricants and urethane polymers for use in automotive, construction, consumer, packaging and industrial markets.<sup>63</sup>

44. In 1997 the Claimant was, through its Canadian subsidiary, Chemtura Canada,<sup>64</sup> one of four registrants in Canada of lindane-based pesticides. Chemtura Canada in turn held Gustafson Partnership, which it converted into a 50-50 partnership with Bayer CropSciences AG in November 1998. At the same time, Chemtura owned Gustafson Inc., (Gustafson) a U.S. corporation.<sup>65</sup>

45. During all periods relevant to this arbitration, Gustafson was owned wholly or in significant part by the Claimant.

46. Canada attaches to its Counter-Memorial Appendix D, a corporate chart summarizing the relations between the Claimant and its subsidiaries, including their various name-changes in the relevant period.

### **B. The Claimant invested in Canada over 50 years ago**

47. Chemtura's Canadian production facility operated under the Uniroyal name since at least the 1960s, although that facility had been in place since at least the early 1940s.

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<sup>62</sup> Chemtura Corporation, "About Chemtura", online at: <http://www.chemtura.com/corporate/v/index.jsp?vnextoid=4f997e765e59b010VgnVCM10000052d7010aRCRD&vnextchannel=4f997e765e59b010VgnVCM10000052d7010aRCRD&vnextfmt=default> (Annex R-6) (*Chemtura Website*).

<sup>63</sup> Lindane related products accounted for 4.4 percent, 3.8 percent and 2.5 percent of Chemtura's Crop Protection sales in 1998, 1999 and 2000, and less than 0.9 percent of Chemtura's total sales: Expert Report of Brent C. Kaczmarek, CFA, 20 October 2008, ¶ 66 (*Navigant Report*).

<sup>64</sup> Chemtura's website currently refers to its facilities in Elmira, Ontario and Westhill, Ontario as 'Chemtura Canada': see *Chemtura Website* (Annex R-6).

<sup>65</sup> Gustafson is a Delaware Corporation of which Crompton Corporation owned 50 to 100 % of the shareholders voting equity during the periods relevant to this claim. Crompton sold 50 % of its interest in Gustafson to Bayer CropScience AG ('Bayer') in November 1998 for US\$180 million, and sold the remaining 50 % to Bayer on March 31, 2004, for a further US\$129 million: see Crompton & Knowles Corporate 10-K Report for the year ended 26 December 1998 (Annex R-17); Crompton Corporate 10-K Report for the year ended 31 December 2004 (Annex R-40).

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Lindane formulations were only one of several of Chemtura Canada's pesticide product lines, which were, in turn, only a small minority of its overall Canadian business.<sup>66</sup>

48. The earliest Canadian registration of Chemtura's lindane products dates back to 1972. It registered at least four more lindane-based pest control formulations over the 1970s, under the trade names Vitaflo and Vitavax.<sup>67</sup> In 1979, Chemtura Canada gained PCPA registration of Vitavax RS Flowable (Vitavax) and in 1991, another lindane product called Cloak Seed Protectant Liquid (Cloak).<sup>68</sup>

49. The Claimant's lindane-based pesticides were applied to, among other products, canola.<sup>69</sup>

50. During the period relevant to this arbitration, the Claimant sold Vitavax and Cloak in Canada to seed treating companies and other users, including various agricultural retailers, seed companies, independent seed distributors and growers,<sup>70</sup> through Gustafson Partnership.

### **C. The Claimant was fully aware of Canada's regulatory process**

51. As a multi-billion-dollar, multinational, chemical company, Chemtura<sup>71</sup> cannot have been unaware of significant international trends against lindane use, as of the 1990s.

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<sup>66</sup> *Navigant Report*, ¶ 66.

<sup>67</sup> Affidavit of John Worgan, ¶ 24.

<sup>68</sup> *Crompton v. Canada*, Notice of Intent, 6 November 2001, ¶¶ 5, 8 (Annex R-137) (*NoI-1*). See Application for registration of Vitavax RS Flowable by Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 4 June 1979 (Annex R-12).

<sup>69</sup> They were also applied to a variety of other crops, including cabbage, cauliflower, broccoli, rutabagas and Brussels sprouts. See Product Label for Cloak Seed Protectant Liquid (Exhibit CC-26).

<sup>70</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Affidavit of Alfred F. Ingulli, Federal Court File No. T-585-01, 2 April 2001, ¶ 8 (Annex R-53) (*Ingulli 2 April 2001 Federal Court Affidavit*).

<sup>71</sup> The Claimant has variously been known as Uniroyal Chemical Inc., Crompton Corporation, and Chemtura Corporation. See corporate chart, Appendix D. For ease of reference, Canada will refer to Chemtura Corporation and its predecessors as 'Chemtura' throughout this Counter-Memorial.

52. Nor could the Claimant have been unaware that no one has an inherent right to sell pesticides in Canada. Pesticides can only be registered and sold pursuant to strict ongoing compliance with a detailed legislative and regulatory regime, to ensure that they are allowed for use only in the public interest, taking into account health, environmental, and competing value considerations, as these considerations evolve over time.

53. Registered products are regularly removed from the market, as new information becomes available regarding the potential impacts of a product; as improved replacement products are developed; and as standards evolve. This was true when the Claimant, through its Canadian subsidiary, first entered the pesticide business in Canada in the 1940s. It was true when the Claimant sought registration of its lindane-based products in Canada in the 1970s. It remains true to the present day. No commitment was made to Chemtura (or any other pesticide company) that its pest control products would be registered indefinitely in Canada or in any other country.

### **III. THE CANADIAN CANOLA INDUSTRY**

#### **A. Canola was Canada's second largest crop in 1997**

54. In 1997, canola was Canada's second most valuable crop, after wheat, providing canola growers with \$1.96 billion dollars in farm cash receipts. Canola was the third highest seeded acreage crop, after spring wheat and barley.<sup>72</sup> Canola provides a large domestic processing industry which was well established in 1997, crushing 3.2 million tonnes of a 6.2 million tonne crop.<sup>73</sup>

55. At that time, approximately 75 percent of canola seeds, meal and oil produced in Canada were exported to nations including the United States, Japan, Mexico and China.<sup>74</sup>

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<sup>72</sup> Statistics Canada, 'Farm Cash Receipts, January to December 1997', 23 February 1998, online at: <<http://www.statcan.ca/Daily/English/980223/d980223.htm#ART2>> (Exhibit JB-4). Canola was developed by Canadian plant breeders in the early 1970s by removing the anti-international component erucic and glucosinolates from rapeseed. The result was an oil see that was safe for animal and human consumption, and only had a 7 % or lower level of saturated fat. Affidavit of JoAnne Buth, ¶ 7.

<sup>73</sup> Affidavit of JoAnne Buth, ¶ 11.

<sup>74</sup> Canola Council of Canada, 'Oil and Meal Exports (Historic)', online at: <<http://www.canola-council.org/oilmealexports.aspx>> (Exhibit JB-7).

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U.S. exports alone represented 38 percent of the Canadian export market. The annual market value of Canada's canola sales to the United States exceeded CAD\$600M, including seed (for crushing in the U.S.), canola oil and meal.<sup>75</sup>

56. By the late 1990s, Canadian canola growers had established a Canadian Canola Growers Association (CCGA) which currently represents more than 75,000 canola growers across Canada. The CCGA represents the interests of all provincial canola growers' organizations with regard to national and international issues affecting its members. Another industry group of relevance is the Canola Council of Canada (CCC).<sup>76</sup>

**B. Several companies sold lindane-based products in Canada for use on canola in the late 1990s**

57. By the late 1990s, there were 4 registrants for lindane-based canola seed treatments: 1) Chemtura; 2) Rhône-Poulenc Canada Inc. of Mississauga, Ontario, (now Aventis CropScience) (Aventis); 3) Zeneca Agro of Calgary, Alberta (now Syngenta Crop Protection Inc.) (Syngenta); and 4) Interprovincial Cooperative Limited of Winnipeg, Manitoba (IPCO).<sup>77</sup>

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<sup>75</sup> Affidavit of JoAnne Buth, ¶ 14.

<sup>76</sup> Originally named the Rapeseed Association of Canada, the CCC was formed in 1968 and took its current name in 1972. It is a national, non-profit trade association funded by stakeholders in the canola industry. Its mission is to enhance the industry's ability to profitably produce and supply seed, oil and meal products that offer superior value to customers around the world. Members include canola growers, crop input manufacturers and suppliers, seed developers, grain handling companies, exporters, processors, food and feed manufacturers. See Affidavit of JoAnne Buth, ¶¶ 20-21.

<sup>77</sup> These products were, respectively, Foundation CST Canola and Mustard Seed Treatment (Rhône-Poulenc); Premiere Flowable Seed Treatment (Zeneca Agro); and IPCO Benelin Canada/Rape Seed Treatment (IPCO). Of these three registrants, IPCO was the only purely 'Canadian' business, being owned and operated by six major Canadian agricultural businesses: see Interprovincial Cooperatives Limited, "About Interprovincial Cooperatives Limited", online at: <[http://www.ipco.ca/Content.asp?content\\_id=193](http://www.ipco.ca/Content.asp?content_id=193)> (Annex R-7).

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#### IV. THE CLAIMANT VOLUNTARILY WITHDREW ITS REGISTRATION FOR LINDANE USE ON CANOLA IN LATE 1999

##### A. Overview

58. As of 1997, while canola remained a registered use for lindane seed treatment in Canada there was no equivalent lindane registration or residue tolerance in the United States. This meant that the export to the United States of Canadian canola seeds treated with lindane, and of products grown from treated seed, was arguably illegal under U.S. federal pesticides and food safety legislation. Yet the U.S. government was not preventing imports of lindane-treated canola seeds from Canada – and U.S. canola farmers were buying lindane-treated seed from Canada.

59. At the same time, Chemtura's U.S. subsidiary, Gustafson, had registered a lindane replacement product in the United States. This product, called Gaucho, did not contain lindane but was effective against the same pests. Gustafson called on the EPA to enforce U.S. legislation preventing the import of agricultural products treated with non-registered pesticides.<sup>78</sup> Prompted by a letter from Gustafson, the EPA announced that the U.S. border would be closed to lindane-treated canola after 1998.

60. Canadian canola growers – whose US\$600M export market was at stake – responded to this crisis by seeking the agreement of Canadian lindane registrants (including Chemtura) to voluntarily withdraw canola use from their lindane registrations. Hoping to stave off immediate application of the EPA's announced border action and ensure an orderly withdrawal from lindane, Canadian canola growers, in turn, asked the PMRA to facilitate their agreement with lindane registrants by permitting a three-year phase-out period for lindane use on canola, during which time registrants would submit replacement products for consideration.<sup>79</sup> As a result of this Voluntary Withdrawal

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<sup>78</sup> Gustafson was presumably losing market share as a result of imports of pre-treated Canadian canola seeds. Without the cross-border movement of lindane-treated seed, canola growers on both sides of the border would be forced to use Gustafson's replacement product.

<sup>79</sup> Given mounting international concerns about lindane, they had, in any event, anticipated the need to phase out use of this 'old' pesticide, and were concerned about the damage its continued use might cause to the 'healthy' image of canola.



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Agreement (VWA) Canadian canola growers achieved a 3 year phase-out of lindane use, rather than immediate termination. This benefitted all canola industry stakeholders, including the Claimant.

**B. A U.S. Chemtura subsidiary prompted the U.S. EPA to ban imports of lindane-treated canola, precipitating a crisis in the Canadian canola market**

61. In 1997, the EPA was contacted by Gustafson, at the time the Claimant's 100 percent-owned U.S. subsidiary.<sup>80</sup> By a letter dated September 17, 1997, Gustafson's Executive Vice President, E.L. Moore, alerted the EPA to the importation into the U.S. of Canadian lindane-treated canola seed. He asked the EPA to confirm that this importation was illegal and to remind U.S. Customs that it should be stopped. The letter stated:

Gustafson, Inc. has reason to believe that canola treated with Lindane was imported into the United States in quantities that would cover approximately 120,000 planted acres this year. Canola companies in the U.S. are being contacted by a Canadian company and being told that it is legal to import canola seeds treated with the active ingredients listed above. We expect importation of the treated seeds to grow to the equivalent of 700,000 acres next year.

*Gustafson believes the importation of the treated canola is illegal. We understand that no registration or tolerance exists in the United States for the use of Lindane on canola.*

From a recent telephone conversation with a USDA representative, we understand that they consider the importation of seed treated with a pesticide not registered in the U.S. and subsequent planting to be a "non-food use". Thus, U.S. Customs officials are apparently not stopping canola treated with unregistered pesticides at the border.

*We request that you consult with the USDA and customs to remind them of the Agency's policy concerning the importation of treated seeds and request that they stop the flow of canola treated with unregistered pesticides into the U.S. We also request a letter from*

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<sup>80</sup> Regarding the corporate affiliation between the Claimant and Gustafson, see Appendix D, Corporate Chart.

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your staff on this subject that we can share with the American Seed Trade Association and canola seed treaters and suppliers in the U.S.<sup>81</sup> (our emphasis)

62. At the time, Gustafson was producing a lindane alternative under the name of Gaucho, for sale to canola growers in the United States, where lindane had no legal registration for use on canola.<sup>82</sup> Sales of Canadian seeds treated with lindane therefore cut directly into Gustafson's U.S. Gaucho sales and profits.

63. Gustafson's letter now spurred the EPA to action.<sup>83</sup> On January 12, 1998, Anne Lindsay, Director, Field and External Affairs Division of U.S. EPA, wrote back to Gustafson, confirming that importation of canola treated with pesticides not registered in the U.S. (notably, lindane) was, indeed, illegal under the relevant U.S. legislation, and should be stopped at the U.S. border:

EPA's Office of General Counsel has reviewed your letter and concluded based on the limited information you provided, that importation of canola seeds such as you described would not be permissible under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). According to your information, the seed in question has been treated with pesticides that are not registered for use in the US and the seed itself is not a registered pesticide. Because the unregistered pesticide is applied to the seed for a pesticidal purpose, such treated seed is considered a non-exempt unregistered pesticide under FIFRA, and importation of the seed would not be legal. FIFRA does contain a treated article exemption but this exemption applies only to articles treated with the intention of protecting the article itself and treated only with pesticides registered for such use. Thus, the article exemption does not appear to apply to the cases you mentioned in which the seed

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<sup>81</sup> Letter from E.L. Moore, Executive Vice President, Gustafson, Inc., to Daniel M. Barolo, Director, Office of Pesticide Programs, U.S. EPA, 17 September 1997 (Exhibit TZ-2).

<sup>82</sup> Lindane-treated canola had regularly been sold to U.S. markets through the 1990s, despite the absence of a registration for lindane on canola in the United States, a requirement of section 3(a) of the *Federal Insecticide, Fungicide and Rodenticide Act*: U.S. *Federal Insecticide, Fungicide and Rodenticide Act*, 7 U.S.C. §136 *et seq.* (Annex R-5) (*FIFRA*). The introduction of the U.S. *Food Quality Protection Act of 1996* imposed more stringent limitations on pesticide residues in products destined for consumption and added a further new level of restriction: U.S. *Food Quality Protection Act of 1996*, Pub. L. No. 104-70, 110 Stat. 1489 (Annex R-4) (*FQPA*). See also *Dr. Goldman Report*, ¶ 17-22.

<sup>83</sup> *FQPA* (Annex R-4); Affidavit of Tony Zatylny, ¶ 18.

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was treated with pesticides unregistered in the U.S. for canola seed use.

Moreover, even assuming the seed was treated with a registered pesticide, and the treated article exemption could apply, a pesticide tolerance (maximum residue limit) or exemption from a tolerance could be necessary to avoid adulteration of food produced from such treated seed. *EPA requires tolerances to be established on the amount of pesticide residues that can lawfully remain in or on each treated food commodity. Canola seed treated with registered pesticides cannot legally be imported or otherwise distributed in the US unless a tolerance or exemption from a tolerance has been established to cover residues of the pesticides that could remain in the canola grown from the seed.*<sup>84</sup> (our emphasis)

64. The EPA's letter went on to outline the corresponding enforcement action required and in which it committed to participate:

If you have more detailed information about the specific cases of seed importation that you believe to be illegal, you should provide that information to EPA so that our Office of Enforcement and Compliance Assistance can pursue the matter. Without additional information, it is not possible for EPA to further investigate this matter. The Agency will discuss this issue with the appropriate authorities at USDA to be certain they are aware of FIFRA requirements applicable to treated seed. Further, we will bring the issue to the attention of the Food and Drug Administration (FDA), the agency responsible for monitoring imported food products that may contain pesticides. We would appreciate hearing from you if you can provide additional information that would be helpful to the three agencies.<sup>85</sup>

65. The EPA's letter in effect confirmed – at the prompting of the Claimant's subsidiary – that Canadian canola producers either had to renounce the use of lindane-based pesticides, or abandon \$600M in annual exports to the United States.

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<sup>84</sup> Letter from Anne Lindsay, Director, Field and External Affairs Division, U.S. EPA to E.L. Moore, Executive Vice President, Gustafson, Inc., 12 January 1998 (Exhibit WS-2).

<sup>85</sup> Letter from Anne Lindsay, Director, Field and External Affairs Division, U.S. EPA to E.L. Moore, Executive Vice President, Gustafson, Inc., 12 January 1998 (Exhibit WS-2).

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66. The CCC received a copy of Gustafson's letter from a third party.<sup>86</sup> The CCC immediately wrote to Gustafson (U.S.), highlighting the risk to the Canadian canola industry if its access to the U.S. market was threatened:

If your letter prompts a trade irritant, it will impact a trading relationship that in 1997 represented over 250,000 tonnes of seed (circa \$75 million), about 500,000 tonnes of canola oil (circa \$300 million) and nearly 1 million tonne of meal (circa \$200 million). Endangering a market that represents approximately \$600 million annually to Canadian producers and the Canadian industry...

67. Gustafson, however, ignored the concerns of the CCC. In fact, Gustafson Canada issued a press release to inform canola growers and seed suppliers that the importation of lindane-treated canola seed to the United States had been ruled illegal by the EPA.<sup>87</sup>

68. U.S. canola farmers wished to continue using Canadian lindane-treated canola seed, and their political representatives sent a letter to this effect to the EPA in early February 1998.<sup>88</sup> But they were also aware of the significant threat of a border closure and the consequent need to consider alternatives. If cut-off from access to Canadian lindane-treated seed, they would be forced to look to alternative pesticides.

69. By February 10, 1998, the U.S. Canola Association ('USCA') issued a Special News Alert, advising U.S. farmers of the illegality of planting Canadian-grown canola seed treated with lindane:

If residues of unregistered pesticides are found on the canola crop, the crop can be condemned and strict fines imposed. The only two products that are labelled for seed treatment and importation into the United States are **Benlate and Gaucho**. USCA urges growers

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<sup>86</sup> Affidavit of Tony Zatylny, ¶ 19; Letter from Dale Adolphe, President, CCC, to E.L. Moore, Gustafson, 27 January 1998 (Exhibit TZ-4).

<sup>87</sup> Affidavit of Tony Zatylny, ¶ 31; Gustafson Press Release, 26 February 1998 (Exhibit TZ-5).

<sup>88</sup> Letter from U.S. Senator Kent Conrad, U.S. Senator Byron Dorgan and U.S. Congressman Earl Pomeroy to Carol Browner, Administrator, U.S. EPA, 13 February 1998 (Exhibit TZ-6).

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to respect these laws and to plant only canola seed that has been treated with U.S.-registered products.<sup>89</sup>

70. Gustafson's letter of September 1997 had achieved its intended effect: pushing U.S. canola growers away from Canadian-grown seeds treated with lindane, towards its own product. On March 4, 1998, the EPA met with the CCC and the USCA to discuss the EPA's lindane policy. Then-Acting Director of the Office of Pesticide Programs at the EPA, Steve Johnson, stated at this meeting that the issue had become broader than canola seeds and the EPA confirmed that it would be closing the border to such trade. The EPA ban ultimately threatened all Canadian canola products grown from lindane-treated seeds: even the smallest residues resulting from seed treatment would, in theory, not conform to U.S. pesticide and food safety legislation. With a zero tolerance approach to lindane on canola in the United States, and in the absence of any registration, there was a real risk that products such as canola meal and oil could also be stopped at the border by the U.S. FDA.<sup>90</sup>

71. Once it became clear to the U.S. canola growers that the EPA was not going to change its mind about lindane-treated imports, their position hardened against any imports of canola grown from lindane-treated seeds. They feared that the import ban gave Canadian growers an unfair competitive advantage, since they alone would have access to lindane seed treatments. The U.S. farmers decided to "level the playing field" for a number of different canola products, by demanding a general ban on imports of Canadian canola products grown from lindane-treated canola seeds.<sup>91</sup>

72. The USCA therefore issued another statement on March 5, 1998, reaffirming its position that farmers should not plant canola seed treated with unregistered pesticides for

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<sup>89</sup> U.S. Canola Association *Special News Alert*, 10 February 1998 (Exhibit TZ-7); Affidavit of Tony Zatylny, ¶ 24. One of the two lindane replacement products referenced in U.S. Canola Association's memoranda was Gustafson's Gaucho pesticide.

<sup>90</sup> Affidavit of Tony Zatylny, ¶¶ 26 - 27.

<sup>91</sup> Affidavit of Tony Zatylny, ¶ 29.

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which tolerances have not been established.<sup>92</sup> They called on the EPA, seed companies and manufacturers and distributors of crop protection products to work with growers and help them to find adequate supplies of canola seed and approved pesticides for the 1998 crop. The statement also urged the EPA to mitigate the potential impact of a border closure on canola production, by expediting registrations for alternate products and establishing tolerances for pesticides for use on canola.

73. On March 12, 1998, the EPA announced that it would allow U.S. farmers to continue to import lindane-treated canola seed from Canada only until June 1, 1998.<sup>93</sup> Since the planting season would be over by that time, Canadian canola growers had some leeway to implement a plan of action, before the launch of the 1999 seed-buying and growing season. That is exactly what they proceeded to do.

**C. In light of the U.S. EPA's threatened ban on Canadian canola, the Canadian canola industry sought to phase out their use of lindane**

**1. Canadian canola industry stakeholders began to organize a voluntary withdrawal of lindane use on canola**

74. The impending U.S. ban created an immediate crisis for Canadian canola growers. In response, the CCC and CCGA mobilized all canola industry stakeholders to support a lindane phase-out. By voluntarily withdrawing their lindane use on canola, registrants would help Canadian canola growers demonstrate to the EPA their good faith in transitioning away from this pesticide. Such action, they hoped, would help persuade the EPA not to close the border immediately, and to allow a reasonable phase-out period.

75. To be effective, the plan required the buy-in of all four Canadian registrants of lindane-based pesticides used on canola: Chemtura, Aventis, Syngenta, and IPCO.

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<sup>92</sup> U.S. Canola Association News Release on planting canola seed treated with unregistered pesticides, 5 March 1998 (Exhibit TZ-9).

<sup>93</sup> Letter from Lynn Goldman and Steven Herman, EPA to Roger Johnson, Commissioner of Agriculture, North Dakota Department of Agriculture, 12 March 1998 (Exhibit TZ-8).

76. The pesticide producers realized that, should they refuse to take action as suggested by the CCC, the border closure would severely impact their pesticide sales to Canadian canola producers. Representatives from the CCC and the CCGA met with each of the registrants individually, to impress upon them the importance of the voluntary withdrawal.<sup>94</sup>

77. In parallel, canola growers sought assurances from the PMRA that it would facilitate the plan of voluntary withdrawal in three ways:

- First, by processing the registrants' requests to amend their lindane product registrations, removing the registered use on canola, and processing related label changes;
- Second, by agreeing to suspend strict enforcement of the revised registrations for a further phase-out period; and
- Third, by reviewing replacement products during the phase-out period, in the hope that one or several might gain approval.<sup>95</sup>

## 2. The PMRA monitored the growing canola crisis and the Canola Council's efforts to put in place a voluntary withdrawal

78. Early in 1998, the PMRA first learned of the issue that had arisen concerning Canadian canola exports to the United States.<sup>96</sup> An internal PMRA email notes as follows:

I had a call from EPA looking for a contact in the canola seed (for planting) industry. They indicated that they were concerned about the possible export into the USA from Canada of lindane treated seed. Lindane is not registered for this use in the USA. EPA seemed to feel they could deal with this directly with the treatment plants.

<sup>94</sup> Affidavit of Tony Zatylny, ¶¶ 35 - 36.

<sup>95</sup> Affidavit of Tony Zatylny, ¶ 42.

<sup>96</sup> By 1997, the PMRA had already begun to review its lindane database and respond to increasing domestic and international undertakings to re-evaluate remaining permitted uses in Canada. The PMRA had no settled view as to the need to withdraw these remaining uses, but it realized that the review in the current context was inevitable. Affidavit of Cheryl Chaffey, ¶ 55-57.

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In the effort of tracking down the correct person, I learned that this has all stemmed from a letter to EPA from Gustafsson [*sic*], a seed supplier from Texas, looking for a little market protection.

The Canola Council President, Dale Adolph [*sic*], referred me to Bill Leask as the person EPA should be talking to. Bill agreed to let his name be given to EPA, but also took the opportunity to pump me on the status of Gaucho, about which I know very little and told him so.<sup>97</sup>

79. Over the next several months, the PMRA continued to monitor the situation as Canadian canola growers sought to put in place a plan to voluntarily withdraw their use of lindane on canola.

80. The canola growers' associations asked the PMRA to keep the EPA apprised of their efforts and help them convince the EPA not to close the U.S. border. As noted in an internal email from Wendy Sexsmith, Director, Alternative Strategies and Regulatory Affairs of the PMRA in April 1998:

I have not received lindane email yet, but I spoke [*sic*] to Tony Zatylny [of the Canola Council of Canada] today and am now trying to get in touch with EPA. Apparently Rhône Poulenc has already removed lindane from Rovral, but are having some problems with formulation (they put water in place of lindane). May need some more work. Gustafson [*i.e.*, Gustafson Partnership, the Claimant's Canadian subsidiary] is considering and IPCO [Interprovincial Cooperative] is in favour of removing lindane. I am now going to try to sell this to EPA, with go ahead from Tony, as a way to stop the fuss. I will keep you posted...<sup>98</sup>

81. Although the EPA was in fact willing to tolerate a phase-out, the agreement hinged on the Canadian canola farmers' ability to convince the pesticide registrants to voluntarily withdraw the canola use on their lindane registrations in Canada.

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<sup>97</sup> E-mail from Janet Taylor, PMRA to Wayne Ormrod, Richard Aucoin, Suzanne Chalifour, J. Smith, and Mary Jane Kelleher, 6 February 1998; Affidavit of Wendy Sexsmith, ¶ 18 (Exhibit WS-7).

<sup>98</sup> E-mail from Wendy Sexsmith to Wayne Ormrod, 9 April 1998 (Exhibit WS-12); Affidavit of Wendy Sexsmith, ¶ 30.



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Negotiations between Canadian canola growers and the lindane registrants on the voluntary withdrawal continued through the spring and summer.<sup>99</sup>

**D. A Voluntary Withdrawal Agreement was finalized in late 1998**

**1. Lindane registrants and canola stakeholders confirmed the terms of their agreement**

82. By October 1998, the PMRA was officially contacted by CCGA president Eugene Dextrase confirming the terms of a voluntary agreement in principle. He advised as follows:

On behalf of the Canadian Canola Growers Association (CCGA) I would like to indicate that CCGA members have been in discussion with Lindane registrants for a voluntary removal of Lindane from canola seed treatments. It is our understanding that the Pest Management Regulatory Agency (PMRA) would as a result give priority to requests for the canola/rape claim removal from existing Lindane seed treatment formulations, as well as for Lindane-free seed treatment formulations for canola/rape. It is our understanding that any commercial stocks of seed treatments for canola containing Lindane will be used up. *We recognize the environmental and health issues that surround Lindane as well as the potential for negative perception about the healthiness of canola because of Lindane. To avoid any market impact growers have decided that they no longer wish to use this product.* However, if new products are not available on the market before these Lindane inventories are used up, canola growers can face sever [*sic*] economic loss. Therefore, the CCGA requests the PMRA to work with registrants and canola growers to establish a priority system for approving Lindane replacements.

It is my understanding that [lindane] registrants have already contacted or will be contacting PMRA to indicate their intent. These voluntary actions will help ensure that canola seed treatments without Lindane in the formulation will be available to growers for the 1999 season. You have the commitment of CCGA canola growers [*sic*] will work closely with the PMRA and

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<sup>99</sup> Affidavit of Wendy Sexsmith, ¶ 23. In particular, the CCC/CCGA held discussions with Chemtura over the summer of 1998 and in September 1998; Affidavit of Tony Zatylny ¶ 38.

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registrants to have Lindane replacement products available to growers in time for the 2000 crop.<sup>100</sup> (our emphasis)

83. On October 16, 1998, the PMRA received a letter from Don Wilkinson, IPCO's Manager, Sales & Development, officially notifying the PMRA of its intention to withdraw registration of IPCO Benolin-R, its only lindane-based seed product. As Mr. Wilkinson noted in his letter, IPCO's decision to seek voluntary withdrawal of its canola – lindane registration was to protect the interests of its clients, the canola producers:

The withdrawal of the registration will be effective at the end of the 1999 calendar year.

The withdrawal should also allow for two additional years of sale of product and treated seed at the wholesale and retail level until the end of the calendar year 2002. This will ensure minimal financial burden on wholesalers, retailers and farmers.

As you may be aware, this decision is not taken lightly and will inflict a significant financial penalty on IPCO in the short to mid-term. *This decision is being made, however, to ensure the financial security of canola producers in Canada.*

This offer to withdraw the registration of Benolin-R is made conditional upon a similar commitment being made by all other canola seed treatment registrants who use lindane for their seed treatments. We wish to reserve the right to cancel this request prior to December 31, 1999 if there is not total consensus among canola lindane seed treatment registrants.

*This is a significant decision for all concerned. I trust it will serve the valuable purpose intended.*<sup>101</sup> (our emphasis)

84. As IPCO's letter confirmed, voluntary lindane deregistration depended upon the commitment of all four pesticide manufacturers to respect its terms, if it was to preserve the Canadian Canola Growers' \$600M annual U.S. export market – and by extension, continued sales of pest control products to these canola producers.

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<sup>100</sup> Letter from Eugene Dextrase, President, CCGA to Dr. Claire Franklin, Executive Director, PMRA, 19 October 1998 (Exhibit WS-13).

<sup>101</sup> Letter from Don Wilkinson, Manager, Sales & Development, IPCO to Roy Lidstone, PMRA, 16 October 1998 (Exhibit WS-14).

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85. The PMRA was also contacted by Chemtura Canada.<sup>102</sup> Chemtura Canada's letter of October 28, 1998, clearly acknowledged that the impetus for the proposed VWA came from canola farmers:

Gustafson and other registrants of canola seed protectants have recently been contacted by the Canola Council of Canada and by the Canadian Canola Growers Association regarding an expressed concern over the threat of potential trade restrictions and negative controversy related to seed protectants used in the production of canola. *As a response to this threat, both the CCC and CCGA have requested that all registrants of canola seed protectants participate in a plan to voluntarily remove lindane as an insecticide for control of flea beetle in canola.*<sup>103</sup> (our emphasis)

86. Moreover, Chemtura Canada's letter clearly acknowledged the controversy then surrounding the continued use of lindane as a seed treatment, and the need to switch to replacement products:

*Lindane also has been the subject of controversy relating to concern over acceptable and unacceptable use patterns and the resultant effect on the environment. Seed treatment use for lindane has been identified as an acceptable use pattern under the United Nations draft "POPs Protocol", however issues at large concerning lindane in the environment remain controversial. Disassociation from lindane has been expressed by the CCC and CCGA as an opportunity to avoid controversy, thereby safeguarding the positive image of canola as a healthy product, and the image of the industry as a responsible industry.*

We are interested in input from the canola industry at large, recognizing that a decision on lindane and the mechanism to ensure a smooth transition to the availability of replacements can significantly impact canola production.<sup>104</sup> (our emphasis)

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<sup>102</sup> Letter from Bill Hallatt, Gustafson Partnership (business unit of Chemtura Canada), to PMRA, 28 October 1998 (Exhibit WS-15); Affidavit of Wendy Sexsmith, ¶ 36.

<sup>103</sup> Gustafson Partnership, *Update: The Use of Lindane Insecticide in Canola Seed Protection*, 28 October 1998 (Annex R-16).

<sup>104</sup> Gustafson Partnership, *Update: The Use of Lindane Insecticide in Canola Seed Protection*, 28 October 1998 (Annex R-16).

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87. By November 1998, the CCC/CCGA had organized a meeting involving all stakeholders to confirm the terms of the voluntary withdrawal. Chemtura Canada was among those invited, together with all other Canadian vendors of lindane-based pesticides. Dr. Claire Franklin, Executive Director of the PMRA, was also invited: this was to confirm the PMRA's agreement to facilitate the agreement of voluntary withdrawal between canola farmers and the four Canadian lindane-product registrants.<sup>105</sup>

88. On November 23, 1998, the Canola Council of Canada received a fax from the EPA confirming that, as things currently stood, Canadian canola seeds treated with lindane could not legally be imported into the United States:

First, I must confirm that canola seed treated with lindane cannot be imported into the United States. Growers making decisions on purchasing seed from Canada or other countries should not purchase seed treated with lindane for use in this country.

As of June 1998, U.S. Customs officials have closed the border to such seed<sup>106</sup>

89. This letter left little doubt that unless Canadian canola producers and lindane pesticide manufacturers could quickly put in place an agreement to voluntarily withdraw their use of lindane on canola, the U.S. government would cut them off from their main (U.S.) market as of the (imminent) 1999 growing season.

90. The CCC/CCGA-organized November 24, 1998 meeting was attended by, among others, Bill Hallatt of Gustafson Partnership, and Rob Dupree of Uniroyal Chemical (both predecessor entities of Chemtura Canada), along with representatives of the various Canadian canola producers, the other pesticide producers, and Wendy Sexsmith, at the time Director, Alternative Strategies & Regulatory Affairs of the PMRA.<sup>107</sup> At the meeting, the CCC reviewed the necessity and proposed terms of the voluntary withdrawal

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<sup>105</sup> Affidavit of Wendy Sexsmith, ¶ 39.

<sup>106</sup> Letter from Lynn R. Goldman, Assistant Administrator, U.S. EPA to Tony Zatylny, Canola Council of Canada, 23 November 1998 (Exhibit WS-16).

<sup>107</sup> Letter from Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, CCGA, to Dr. Claire Franklin, Executive Director, the PMRA, 26 November 1998 (Exhibit WS-17).

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agreement (VWA), and a plan of action for its implementation. The canola growers and lindane registrants agreed that the VWA would memorialize a progressive phase-out of lindane.

91. A letter dated November 26, 1998 from the CCGA confirmed the three key terms of the VWA that the stakeholders agreed upon at the meeting:

1. The registrants Interprovincial Cooperative Ltd., Rhône-Poulenc Seed Treatments, Uniroyal Chemical Ltd. [*i.e.*, Chemtura Canada] and Zeneca Agro will voluntarily remove canola/rapeseed claims from labels of registered canola seed treatments containing lindane by December 31, 1999.
2. All commercial stocks of products containing lindane for use on canola and lindane treated canola seed can not be used after July 1, 2001.
3. 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. The Canadian Canola Growers Association (CCGA) and the Canola Council of Canada (CCC) agree to work with the aforementioned bodies to facilitate these activities.<sup>108</sup>

92. Stakeholders<sup>109</sup> chose December 1999 as the date for ceasing production of lindane treatment products for canola because pesticide producers typically sell their treatment products up until that time of year. The remaining winter months are usually spent treating seeds. Treated seeds are then planted in the spring and early summer. Generally, by midsummer, no more canola planting occurs in Canada.<sup>110</sup>

93. This timeline also explains the July 2001 cut-off date for use of lindane-treated canola seeds: by that date, seed treatment and planting for that year would be completed.

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<sup>108</sup> Letter from Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, CCGA, to Dr. Claire Franklin, Executive Director, PMRA, 26 November 1998 (Exhibit WS-17).

<sup>109</sup> As defined in CCGA's 26 November 1998 letter (Exhibit WS-17): "Stakeholders mentioned in this letter includes: manufacturers, distributors, dealers, marketers and users of treated seed and/or seed treatment products; and Government pesticide and seed regulatory agencies".

<sup>110</sup> Affidavit of JoAnne Buth, ¶ 71.

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In essence, the VWA gave producers the benefit of three full planting seasons prior to complete elimination of lindane on canola. The provision was clear: no further use would be permitted after that date.<sup>111</sup>

94. The November 26, 1998, letter also recalled the meeting participants' agreement to a related work plan, including: (a) discussions in June and October 1999 to review progress on approvals of lindane replacement products (i.e. new insecticide products based on chemical actives that were effective on the same pests as lindane); (b) the development of a joint U.S. - Canada policy on the cross-border movement of pesticide-treated seed; (c) the impact of the VWA on the canola industry, other crops using lindane seed treatments and other pest management products; and (d) field results of newly-registered seed treatment products. The work plan foresaw progress in the coming year on the review of lindane replacement products. However, it set out no specific deadlines for, or guarantee of, registration.

95. Indeed, the November 26, 1998 letter set out an action time line only on the following issues:

- Registrants were to agree in writing to the VWA by December 31, 1998;
- By December 15, 1998, the CCGA was to issue a press release announcing the voluntary removal of canola and rapeseed from seed treatments containing lindane.<sup>112</sup>
- By December 31, 1998, any registrant wishing to gain approval for "lindane-free" seed treatment in time for the 1999 canola seeding had to make a formal request to the PMRA. A "lindane-free" seed treatment was an existing lindane-based insecticide-fungicide product from which lindane was simply removed, leaving a fungicide alone;
- In June and October 1999, stakeholder meetings were scheduled to review progress; and

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<sup>111</sup> Affidavit of Tony Zatylny, ¶ 51.

<sup>112</sup> This press release was ultimately issued on 15 February 1999. Affidavit of Tony Zatylny, ¶ 52; CCGA Press Release, *Canadian Canola Growers lead Industry to Develop New Seed Treatments*, 15 February 1999 (Exhibit TZ-14).

- Finally, November 1, 1999, was set as the deadline for formal requests from registrants to remove canola and rapeseed claims from seed treatments containing the active ingredient lindane.

96. At the close of its letter, the CCGA, "...respectfully request[ed] your [PMRA's] acceptance and support for the proposals outlined in this letter".<sup>113</sup>

97. The Claimant asserts that the agreement reached at the November 24, 1998 meeting did not reflect its own understanding of the VWA.<sup>114</sup> However, two of the Claimant's representatives were at that meeting, and the meeting's goal was clear – the parties were assembling to discuss and finalize a deal among canola farmers and pesticides producers that, by late November 1998, had been discussed for months. The Claimant's representatives agreed to the contents of the VWA.<sup>115</sup>

## **2. The U.S. government took note of the VWA**

98. As the foregoing demonstrates, the impetus behind the VWA was to convince the EPA not to immediately shut the U.S. border to canola products. By removing canola use from lindane product registrations in Canada, growers and pesticide producers hoped to convince the EPA of the good faith of their intention to cease applying lindane to canola products and, in this way, obtain the EPA's forbearance. Accordingly, the VWA was only workable if the EPA agreed to postpone its announced border action during the phasing-out period.

99. In the absence of official confirmation from the EPA, Canadian canola farmers were hoping at least for a sign that the VWA had been noted, suggesting the marketing of lindane-treated canola in the United States could proceed for the next few years undisturbed.

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<sup>113</sup> Letter from Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, CCGA, to Dr. Claire Franklin, Executive Director, PMRA, 26 November 1998 (Exhibit TZ-13).

<sup>114</sup> Claimant's Memorial, ¶ 72. The Claimant also incorrectly characterizes the VWA as a joint initiative of the CCGA and the PMRA, as opposed to a voluntary accord between pesticide producers which the PMRA had been invited to facilitate. Claimant's Memorial, ¶ 71.

<sup>115</sup> Affidavit of Tony Zatylny, ¶¶ 46 - 47; Affidavit of Wendy Sexsmith, ¶ 40.

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100. On December 2, 1998 Canada and the United States entered into a Record of Understanding (ROU). The ROU outlined a variety of actions designed to reduce current disagreements between the two countries concerning agricultural trade. Pest control products represented only one of 17 separate headings addressed. With regard to pest control, the ROU listed nine different points, mostly focussed on the coordination of pesticides registrations between the EPA and the PMRA. One point in the ROU referenced the VWA:

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 containing lindane for use on canola and lindane treated canola seed would not be used after July 1, 2001. This is contingent upon registrants requesting voluntary removal. EPA, PMRA, growers and registrants will continue to work together to facilitate access to replacement products.<sup>116</sup>

101. As the ROU clearly states, the voluntary agreement to remove canola from lindane product registrations, and the related label change, were part of an agreement reached between Canadian canola growers and pesticide producers. This was the only point in the ROU that memorialized private action, rather than any government initiative or program. From the perspective of canola growers, this reference served as official recognition of the VWA by the U.S. Government: more specifically, the ROU was viewed as an implicit commitment by the EPA not to stop lindane-treated canola products at the border during the transition phase of the VWA.<sup>117</sup> The Canadian farmers' request to voluntarily withdraw lindane seed treatments and the phase-out of use of lindane on canola was a helpful step forward in resolving a difficult situation.<sup>118</sup>

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<sup>116</sup> Record of Understanding between the Governments of Canada and the United States of America Regarding Areas of Agricultural Trade, 2 December 1998 (Exhibit WS-18).

<sup>117</sup> Affidavit of Tony Zatylny, ¶ 54.

<sup>118</sup> *Dr. Goldman Report*, ¶ 84.



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102. The reference to the VWA in the ROU is further confirmation of what had clearly been agreed at the November 24, 1998 meeting – in particular, the date for last use of lindane-treated seed (July 1, 2001).<sup>119</sup>

**E. Confirmation of the VWA terms**

**1. The registrants confirmed their consent to the VWA in writing**

103. In the wake of the CCGA's request to the PMRA for approval of the VWA, all four Canadian registrants of lindane treatment for canola wrote to the PMRA confirming their consent to the VWA.

104. Zeneca (Syngenta) wrote on December 10, 1998, confirming that at the CCC/CCGA meeting held on November 24, 1998, the registrants of lindane-based seed treatment for canola and rapeseed were requested to write a letter to the PMRA supporting the following lindane proposal:

- a) canola/rapeseed voluntarily removed from lindane labels by the end of 1999;
- b) all commercial stocks of lindane *and treated seed* used up by July 1, 2001; and
- c) canola council and CCGA commitment to work with registrants and regulatory agencies to get lindane replacements to market.<sup>120</sup> (our emphasis)

105. Zeneca noted that it “agrees in principle to the aforementioned proposal”, while noting that “We do expect the PMRA and the Canola Council of Canada to work with

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<sup>119</sup> In its Memorial, the Claimant claims that Canada ‘began efforts to obtain from industry a “voluntary” withdrawal of lindane use on canola by Canadian lindane registrants’ *after* the signing of the ROU on December 2, 1998. Claimant’s Memorial, ¶ 77. This claim is incorrect, first because the VWA was agreed to on 24 November 1998; and second, because the VWA was concluded between registrants and Canadian farmers on that date.

<sup>120</sup> Letter from Sesh Iyengar, Manager, Regulatory Affairs, Zeneca, to Dr. Claire Franklin, Executive Director, PMRA, 10 December 1998 (Exhibit WS-23).

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Zeneca for a timely registration for Premiere Z, a product in which we have replaced lindane with the active ingredient cyhalothrin-lambda.”<sup>121</sup>

106. Similarly, Rhône-Poulenc (Aventis) wrote the PMRA a letter on December 14, 1998:

... Rhône-Poulenc Canada has agreed to plans outlined to address the issue at the recent Canola Council stakeholders meeting held on November 24, 1998 in Ottawa...

[...]

Rhône-Poulenc Canada has agreed to the withdrawal of Lindane seed treatment products to be phased in *over the next two years*: firstly, to ensure that the Canadian Canola grower has access to the necessary crop protection tools; secondly, to give the PMRA and industry adequate time to register feasible alternatives to Lindane and; thirdly, to allow appropriate time for the utilization of Lindane seed treatment inventories. Therefore, as agreed at the November 24 meeting, Rhône-Poulenc Canada Inc. has committed to the voluntary removal of all Canola claims from its seed treatment labels which contain Lindane by December 31, 1999. *All commercial stock of our seed treatment products containing Lindane for use on Canola can be used until July 1, 2001, to allow for sale of current inventories of product and treated seed.* It is essential that we ensure that Canadian Canola growers have access to global markets as well as adequate crop protection tools to manage this transition and avoid any severe economic loss.<sup>122</sup> (our emphasis)

107. IPCO wrote to PMRA on January 21, 1999, confirming its adherence to the VWA and the motivations for their agreement:

We do understand the concerns of the canola production industry over the use of lindane products as seed treatment on their crop.

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<sup>121</sup> The application to register Premier Z was submitted December 1998 and later withdrawn by the applicant in July 2002. See Affidavit of Suzanne Chalifour, ¶ 24.

<sup>122</sup> Letter from Chris Dalton, General Manager, Rhône-Poulenc Canada [Aventis], to Dr. Claire Franklin, Executive Director, PMRA, 14 December 1998 (Annex R-313).

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We hope this industry move is a positive statement about our view of the value of this industry to everyone in Canada.<sup>123</sup>

**2. The Claimant immediately sought to unilaterally alter the agreed terms of the VWA**

108. For its part, the Claimant wrote to the PMRA concerning the VWA on December 17, 1998. The Claimant began its letter by acknowledging again that the CCGA and CCC were the source of the VWA:

The Canadian Canola Growers Association and Canola Council of Canada have requested on behalf of their members, that Uniroyal Chemical Co. and all other Canadian registrants voluntarily withdraw canola from the labels of seed protection products that contain lindane by the end of 1999.<sup>124</sup>

109. Although Chemtura generally took note that it was writing to confirm the terms of the VWA as requested by CCC and CCGA, Chemtura in fact, sought to unilaterally change material terms of that agreement, and impose for its own benefit new additional terms, notably:

- Chemtura demanded the PMRA's confirmation that various replacement products would be registered by the PMRA according to a schedule dictated by Chemtura;
- Chemtura demanded that it be able to use stocks of lindane seed treatment and lindane-treated seed after 1999 until their depletion, with no time limit; and
- Chemtura declared that if a tolerance was established in the U.S. for lindane on canola prior to the end of 1999, Chemtura would "reconsider its offer to voluntarily remove canola from the labels of its lindane based products."

110. Chemtura concluded its letter, signed by Alfred Ingulli, Executive Vice-President of the Claimant's Crop Protection Division, stating that:

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<sup>123</sup> Letter from Don Wilkinson, Manager, Product Development, IPCO to Roy Lidstone, PMRA, 21 January 1999 (Exhibit WS-21).

<sup>124</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) and Bill Hallatt, Product Development Manager, Gustafson Partnership (business entity of Chemtura Canada), to Dr. Claire Franklin, Executive Director, PMRA, 17 December 1998 (Exhibit WS-19).

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Gustafson Partnership / Uniroyal Chemical Co. shall be the final authority in the determination of satisfactory performance by any party in meeting the above provisions, and retains exclusive rights in its voluntary decision regarding the use or non-use of lindane in its products for use in canola.<sup>125</sup>

111. Despite having agreed to the terms of the VWA while in the presence of its clients the canola producers at CCC's November 24, 1998 meeting, Chemtura sought in its "confirming" letter to the PMRA (notably not copied to either the CCC or CCGA) to unilaterally impose much more extensive conditions in exchange for its continued adherence to its agreement with the canola growers. Remarkably, these conditions included imposing the PMRA's advance agreement to the registration of replacement products which Chemtura had not yet even formulated, let alone submitted to the PMRA. Chemtura's letters ignored the fact that the PMRA had clearly stated at the November 24, 1998 meeting, that the registration of replacement actives for lindane could not be guaranteed, and had not committed to a firm deadline for the completion of such reviews.<sup>126</sup>

112. Chemtura's letter further sought to unilaterally remove any time-limit from the use of lindane treatment and lindane-treated seeds, contrary to the July 1, 2001 deadline clearly set out in the VWA. In defiance of normal regulatory requirements for expansion of use on a product label, Chemtura also asserted that should a tolerance for lindane on canola later be obtained from the U.S. EPA, Chemtura could rescind its agreement to the VWA and unilaterally restore the lindane use on canola labels.

113. Chemtura's letter ignored the fact that it was its own government that had announced a ban on lindane-treated canola at the U.S. border – at the prompting of its own subsidiary. It further ignored that it was only through the voluntary withdrawal that the \$600 million annual Canadian canola export market would not be disrupted and all

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<sup>125</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) and Bill Hallatt, Product Development Manager, Gustafson Partnership (business unit of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 17 December 1998 (Exhibit WS-19).

<sup>126</sup> Affidavit of Wendy Sexsmith, ¶¶ 43 - 46.

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participants subjected to significant losses. Instead, Chemtura sought to use the crisis engineered by its own subsidiary to force the PMRA into accepting new registrations without any proper review. Chemtura's December 17, 1998 letter is alarming in its disregard for the PMRA, for its own clients, and for the safety of the Canadian public.

**3. Following further consultations, the PMRA confirmed its understanding of the VWA**

114. The PMRA did not immediately respond to Chemtura's December 17, 1998 letter or indeed to any of the confirming letters from the other registrants. As the PMRA had emphasized, it would only implement the VWA if it was voluntarily and equally adopted by all four lindane pesticide producers. Chemtura's letter suggested that the November 1998 consensus had already broken down.

115. The PMRA therefore contacted the CCC, noting Chemtura appeared to be attempting to change some of the terms of the VWA, and to impose additional conditions on the PMRA. If the VWA was to be preserved, only the CCC had the mandate and the ability to convince the Claimant to remain committed to the process.<sup>127</sup>

116. Wendy Sexsmith also called Chemtura Canada on January 5, 1999, to express the agency's concerns about the content of its December 17, 1998 letter. She noted that the PMRA was not in a position to commit to the schedule set down in its letter regarding the registration of replacement products, and that the Claimant was generally demanding outcomes and conditions that were beyond the power of the PMRA.<sup>128</sup>

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<sup>127</sup> This action is consistent with the PMRA's understanding that its role in the VWA was to facilitate voluntary agreement struck among canola growers and lindane registrants and not, as the Claimant has alleged, to enforce the agreement by relying on its ability to 'regulate the registrants out of business'. See Claimant's Memorial, ¶ 79; Affidavit of Wendy Sexsmith, ¶¶ 24-29.

<sup>128</sup> Affidavit of Wendy Sexsmith, ¶ 57.

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117. Chemtura Canada replied to the PMRA on January 11, 1999.<sup>129</sup> This letter focussed in particular on the process for registration of new replacement products.

Chemtura Canada noted, in particular:

You had expressed concern 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 harmonization 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 the PMRA towards 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. Uniroyal Chemical [*i.e.*, Chemtura Canada] has forwarded its submission for a “lindane free” product to PMRA prior to December 31, 1998 as per your direction and we look forward to its progress.

*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 seed protectant formulations. Considering the aspects of safety, environment, US 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? (our emphasis)*

118. This letter confirmed that the PMRA had *not* committed in November 1998 to any firm deadline or expedited review process for the Claimant's Gaucho-based formulations, contrary to the Claimant's later assertions in this regard.<sup>130</sup> The Claimant's letter also

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<sup>129</sup> Letter from Bill Hallatt, Product Development Manager, Gustafson Partnership (business unit of Chemtura Canada) to Wendy Sexsmith, PMRA, 11 January 1999 (Exhibit WS-20).

<sup>130</sup> Claimant's Memorial, ¶ 412.

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appeared to back down on demands that depended on the outcome of the U.S. review process, over which the PMRA obviously had no control.

119. As for the Claimant's attempt to unilaterally amend the terms of the VWA by extending the phase-out period for its lindane products in Canada, the PMRA's understanding was that, by early February 1999, Chemtura had backed down, as a result of the intervention of the CCGA and CCC. The Claimant apparently recognized that its demands would have destroyed the "truce" with the EPA and brought down the entire Canadian canola industry. In the meantime, as discussed in the previous section, the PMRA had received confirmation from the three other pesticide manufacturers that they would adhere to the VWA as agreed in the previous November.

## **F. Implementation of the VWA**

### **1. PMRA did not commit to lindane replacement product registration or to a binding timetable**

120. Terms of the VWA having apparently been settled, attention of the industry then turned to the registration of replacement products.

121. The issue of registering replacement products was of particular concern to the canola industry. The CCC and CCGA wrote to the PMRA on February 5, 1999, to support the request of pesticide producers that the PMRA register a number of different pesticide active ingredients to replace the seed treatment lindane.<sup>131</sup> The CCGA and CCC noted that a variety of benefits would flow from a greater number of choices and that they would continue to work with registrants and the regulatory agencies in this process. They therefore:

respectfully request[ed] that PMRA consider all submissions for lindane replacements as expeditiously as scientifically possible in view of the commitment that has been made to withdraw lindane from the market.

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<sup>131</sup> Letter from Tony Zatylny, Vice President, Crop Production, CCC, and Secretary/Treasurer, CCGA, to Dr. Claire Franklin, Executive Director, PMRA, 5 February 1999 (Exhibit WS-24).

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122. On February 9, 1999, the PMRA wrote back to the CCGA, officially responding to its letter of November 26, 1998, which contained the terms of the VWA.<sup>132</sup> Dr.

Franklin expressly reiterated these terms as originally stated:

1. The Canadian canola growers have requested Canadian registrants (Uniroyal, Interprovincial Cooperative Limited (IPCO), Zeneca, and Rhône-Poulenc) to agree voluntarily to remove canola/rapeseed claims from labels of registered canola seed treatments containing lindane by December 31, 1999.
2. All commercial stocks containing lindane for use on canola/rapeseed and lindane treated canola/rapeseed would not be used after July 1, 2001.
3. 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 Canadian Canola Growers Association (CCGA) and the Canola Council of Canada (CCC) agree to work with the aforementioned bodies to facilitate those activities.

123. The PMRA's February 9, 1999 letter was copied to representatives of all four Canadian registrants of lindane seed treatment for canola, including the Claimant (both its Canadian distributor and the Claimant itself). The PMRA noted that although (in its understanding) the registrants agreed to the terms, the VWA remained contingent upon the registrants requesting voluntary removal. Reflecting the discussions it had had with registrants in December 1998 and January 1999, the PMRA noted that all four of the registrants had indicated their agreement in principle with the three stated conditions of the VWA in writing and in discussions with PMRA staff.

124. The PMRA further referenced its ongoing efforts to facilitate access to replacement products and to work together with the EPA towards a harmonized policy on the movement of pesticide-treated seeds, as publicized in the ROU. Dr. Franklin specifically ensured no commitments were made regarding the registration of any one particular replacement product by a particular date:

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<sup>132</sup> Letter from Claire Franklin, Executive Director, PMRA, to Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, CCGA, 9 February 1999 (Exhibit WS-25).



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I understand your interest in having alternative products to fill the void that would be created by voluntary removal of lindane from current canola/seed dressing formulation(s). Recognizing the scope of this challenge, *the range of clients requesting fast track consideration*, and the importance of this issue to canola growers, *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.*<sup>133</sup> (our emphasis)

125. Dr. Franklin reiterated the PMRA's understanding, based on discussions with all of the registrants, that the registrants had agreed in principle to support the CCC and CCGA's request for the voluntary removal of canola and rapeseed from the labelling of lindane formulations. She described the mechanisms by which the agreement could be implemented:

In order to implement the plan to terminate the use of lindane as canola/rapeseed treatment by July 1, 2001, registrants must submit their application to amend their registrations to remove canola/rapeseed use from the product label by November 1, 1999, and begin to use the new label on products once the certificate of registration (December 31, 1999) is issued. In addition, they would have to provide by the same date, notice of discontinuation of sale as of December 31, 1999, of the product where there is only the canola/rapeseed use. This will allow the stocks with the canola/rapeseed treatment use to be exhausted.

126. Dr. Franklin's comments emphasized that the VWA of November 24, 1998 – entered into by lindane registrants to help preserve the business of their main clients, the canola growers – was entirely dependent upon the voluntary action of the registrants, including the Claimant.

127. On February 15, 1999, the CCGA issued a press release confirming the agreement to replace lindane products with new seed treatments by July 1, 2001. As the press

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<sup>133</sup> Letter from Claire Franklin, Executive Director, PMRA, to Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, CCGA, 9 February 1999 (Exhibit WS-25).

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release noted, this was to further the goal of managing canola pests in ways that reduced associated economic, environmental and health risks.<sup>134</sup>

128. On February 23, 1999, the PMRA wrote a further letter to the CCC and CCGA, concerning the two associations' joint letter of February 5, 1999 requesting an accelerated review of lindane replacement products.<sup>135</sup> As the PMRA noted, it currently had registration submissions in hand for three active ingredients that might emerge as viable alternatives for lindane in canola seed dressing applications: thiamethoxam (in Syngenta's Helix product, submitted for consideration in November 1998); imidacloprid (in Chemtura's Gaucho 75 ST, submitted for consideration in June 1998); and cyhalothrin-lambda (in Zeneca's Premiere Z, submitted in December 1998).<sup>136</sup>

129. The PMRA further noted that it had been approached by manufacturers regarding additional compounds that might be of future interest, but that these were some time away from actual submission. As the PMRA confirmed, the three currently-proposed replacement actives would receive priority review, subject to "continuing to advance only those that have a complete and reviewable submission, with a view to having at least one lindane alternative available for the 2000 crop year". The PMRA confirmed that in light of this objective:

The Agency will not entertain additional candidates within these time frames. To do so would jeopardize the chances of having any candidate emerge successfully and on time to be of value for the year 2000.

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<sup>134</sup> CCC press release, 15 February 1999 (Exhibit TZ-14).

<sup>135</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Tony Zatylny, Vice-President Crop Protection, CCC, 23 February 1999 (Exhibit WS-26).

<sup>136</sup> Affidavit of Suzanne Chalifour, ¶ 24. The Premiere Z application was withdrawn in July 2002. The Claimant's product Gaucho 75 ST had originally been submitted for registration to the PMRA on 3 September 1996, but for application on exported products only. The PMRA granted registration for this use on 4 August 1998: Letter from Jennifer Hamm Craig, PMRA, to Rob Dupree, Uniroyal Chemical (predecessor-in-title of Chemtura), 4 August 1998 (Exhibit SC-8). Meanwhile, on 16 June 1998, the Claimant had submitted a further request for registration of Gaucho 75 ST, this time for use on products for domestic use (in this way invoking a different standard of registration): Letter from Rob Dupree, Gustafson (a business unit of Chemtura), to Submission Screening Section, PMRA, 16 June 1998 (Exhibit SC-9). See Affidavit of Suzanne Chalifour, ¶¶ 25-29.

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130. The PMRA's letter reiterated that no registration application could be guaranteed success. The PMRA's resources were not endless. It therefore had to give priority to the three actives currently submitted for review, in the hope that one of them might provide a viable alternative to lindane during the phase-out period.<sup>137</sup>

**2. In March 1999, Chemtura made another attempt to renege on the VWA, then backed down**

131. The PMRA's reiteration of the VWA, in its letter of February 9, 1999, was accepted without comment by 3 of the 4 lindane pesticide manufacturers. Chemtura alone wrote back, again attempting to unilaterally impose particular terms to secure its agreement to the VWA.

132. In a letter to the PMRA of March 2, 1999, the Claimant stated, that "As a reminder, our company's offer to remove canola/rapeseed form [*sic*] the labels of Uniroyal Chemical seed treatments that contain lindane was subject to several provisions, including the issuance of several registrations, assuming of course, a clean PMRA review. Chemtura further took the position that it "will not voluntarily withdraw unless we have suitable alternative Uniroyal and Gustafson products registered to replace them".<sup>138</sup>

133. On March 25, 1999, the PMRA responded to the Claimant that it could not promise the registration of substitutes and that it had not made such a promise in connection with the VWA. The PMRA reiterated its general commitment to work with registrants to facilitate access to alternatives.<sup>139</sup> Dr. Franklin noted that the PMRA was working with registrants on a number of active ingredients that might emerge as viable alternatives for lindane on canola seed during applications. However, Dr. Franklin clearly stated:

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<sup>137</sup> Affidavit of Wendy Sexsmith, ¶¶ 66-67.

<sup>138</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), to Dr. Claire Franklin, Executive Director, PMRA, 2 March 1999 (Exhibit WS-27).

<sup>139</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA, to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 25 March 1999 (Exhibit WS-28).

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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.

134. With regard to the future use of lindane on canola, Dr. Franklin noted both that an EPA re-evaluation was underway and that a Special Review of lindane had been announced in Canada.<sup>140</sup> Thus, the ultimate fate of lindane as a registerable pesticide was, quite apart from the VWA, far from certain.

135. The PMRA heard nothing further from the Claimant and therefore reasonably assumed that the Claimant had abandoned its attempt to unilaterally change the terms of the VWA or impose additional obligations on the PMRA.

136. The PMRA turned its attention to the review of lindane replacement actives and of “lindane-free” (fungicide-only) products. Bill Hallatt of Gustafson Partnership wrote to Wendy Sexsmith in this regard on April 29, 1999. He confirmed, among other things, the Claimant’s understanding of the potential timing of this process:

In discussions held with Wendy Sexsmith of the Pest Management Alternatives Office [*sic*] last fall, when we were discussing possibilities, it was indicated to me that the registration of Gaucho could take as much as 18 months according to routine timelines, or might occur as early as June 1999.<sup>141</sup>

137. The Claimant had submitted Gaucho 75 ST for registration approval for domestic use on canola in June 1998.<sup>142</sup>

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<sup>140</sup> The PMRA’s Special Review of Lindane was launched on 15 March 1999 (Exhibit WS-32).

<sup>141</sup> Letter from Bill Hallatt, Gustafson Partnership (business unit of Chemtura Canada), to Dr. Claire Franklin, PMRA, 29 April 1999 (Exhibit WS-35).

<sup>142</sup> Letter from Rob Dupree, Gustafson Partnership (business unit of Chemtura Canada) to Submissions Screen Section, PMRA, 16 June 1998 (Exhibit SC-9). Gaucho 75 ST was the first lindane replacement product approved for use in Canada by the PMRA in July 1995. *See* Affidavit of Suzanne Chalifour, ¶ 29; Letter from Wayne Ormrod, PMRA to Rob Dupree, Gustafson (business unit of Chemtura Canada), 27 July 1999 (Exhibit SC-14).

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### 3. The PMRA and canola industry stakeholders continued to discuss implementation of the VWA

138. Canadian canola producers and lindane treatment registrants met on June 24, 1999 to monitor the implementation of the VWA and progress on lindane replacements.<sup>143</sup> The meeting was attended by Rick Turner of Gustafson Partnership (Chemtura Canada's distribution joint venture in Canada), and Rob Dupree of Uniroyal Chemical (predecessor of Chemtura Canada). At the meeting, Wendy Sexsmith of the PMRA gave an update on the status of the PMRA's lindane reviews and, more generally, current worldwide action against lindane.<sup>144</sup>

139. Participants also reviewed the agreed deadlines under the VWA. It was noted that "compliance will be started July 1, 2001."<sup>145</sup> The CCGA's representative reported that canola growers had been holding meetings to increase awareness of the deadline among the 75,000 to 80,000 growers they and the CCC represented. The main concern expressed in this regard was the unfairness that would result if one of the pesticide registrants continued to manufacture lindane product for canola use after December 31, 1999.

140. A representative of the pro-lindane lobby also attended this meeting and sought to assure canola producers that the outcome of current lindane reviews would be positive. Despite these assurances, the CCGA, among other things, noted that, given canola's perception as a healthy oil, it did not wish to create a perception of potential residues.<sup>146</sup>

141. The comment from the pro-lindane lobbyist prompted the question whether lindane producers could apply for a re-registration of its use on canola, if the data arising out of the Special Review showed no problem. Wendy Sexsmith confirmed that the

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<sup>143</sup> Memo from JoAnne Buth, CCC, to lindane registrants, canola association representatives, and PMRA attaching a draft meeting agenda and list of participants, 21 June 1999 (Annex R-20). This meeting had been agreed to in November 1998.

<sup>144</sup> Minutes of meeting organized by CCC/CCGA to monitor implementation of the VWA and progress on lindane replacements, 24 June 1999 (*24 June 1999 meeting*) (Exhibit WS-29).

<sup>145</sup> Minutes from lindane voluntary withdrawal & lindane replacement (Exhibit WS-29).

<sup>146</sup> Minutes from lindane voluntary withdrawal & lindane replacement (Exhibit WS-29).

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PMRA would review and evaluate any such submission. However, she added that no new submissions would be considered for registration during the course of the Special Review and only current uses would be extended on an annual basis. This was normal practice for a product under re-evaluation, given that a stable use pattern must be in place to carry out and complete a reassessment.<sup>147</sup>

142. Participants also reviewed the lindane replacement products currently under consideration by the PMRA. The PMRA confirmed its previous undertaking to give priority review to the first three replacement active submissions presented to it, as long as they were reviewable (*i.e.*, complete).

143. If Chemtura had wished to signal its continuing intention to repudiate the terms of the VWA, or resurrect its demands relating to the registration of replacement products, it certainly had the opportunity to speak up at this meeting – in full view of its clients, the canola farmers, whose livelihood Chemtura risked throwing into jeopardy by rejecting the VWA. Instead, Chemtura held silent – for the moment. Tellingly, the Claimant makes no mention of the June 24, 1999 meeting in either its Memorial or its timeline of key events.

#### **4. In the autumn of 1999, Chemtura again sought to unilaterally alter the terms of the VWA, but ultimately backed down**

144. While the PMRA was busy granting registration to Chemtura's replacement products, the date for implementation of the VWA approached. According to the agreed calendar, registrants had committed to submitting requests for voluntary deregistration of the canola use for their lindane products by November 1, 1999, with December 31, 1999 as the final official date for canola applications of its product. The CCC had scheduled a second follow-up meeting for October 5, 1999, to address any last-minute questions.<sup>148</sup>

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<sup>147</sup> Affidavit of Wendy Sexsmith, ¶ 73.

<sup>148</sup> Memorandum from JoAnne Buth, CCC to registrants, canola associations and PMRA attaching information and an agenda concerning the 5 October 1999 meeting, 10 September 1999 (Annex R-21).

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145. However, on October 1, 1999, Mr. Ingulli of the Claimant wrote again to the PMRA, rejecting the agreed terms of the VWA, issuing new threats and making new demands.<sup>149</sup>

146. Chemtura acknowledged that the PMRA had, by this point, registered the Claimant's submitted "Gaucho" lindane replacement products.<sup>150</sup> Although these registrations permitted these replacement products to be marketed, Chemtura now argued that these replacement registrations were only temporary. The PMRA had also reviewed and registered the Claimant's Vitavax product with lindane removed, making it a fungicide only. Chemtura now complained that Vitavax contained other active ingredients not registered in the United States.<sup>151</sup>

147. Mr. Ingulli cited these arguments as pretext for unilaterally extending the phase-out period for its canola use registrations by a full year:

To allow time for permanent registrations and tolerances to issue in the US and Canada and to allow time for data review, Uniroyal Chemical Co. will voluntarily remove canola from the product labels of Uniroyal Chemical Co. seed protectants that contain

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<sup>149</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 1 October 1999 (Exhibit WS-30); Affidavit of Wendy Sexsmith, ¶ 76. To recall, the Claimant had not replied to the PMRA's letter of 2 March 1999 in which the PMRA restated its understanding of the VWA terms, and in particular rejected Chemtura's attempt to dictate terms of registration of replacement products. The Claimant had also failed to raise any objection at the meeting between registrants, canola producers and the PMRA, on 24 June 1999.

<sup>150</sup> Affidavit of Suzanne Chalifour, ¶ 29.

<sup>151</sup> This argument ignored the fact that "temporary" registration was often initially granted to new product registrations, reflecting the fact that further data had to be submitted within one year of registration – and did not prevent Chemtura from marketing these replacement products. Affidavit of Suzanne Chalifour, ¶¶ 73-74. As for Vitavax, the binational registration status of other active ingredients had never been part of the terms of the VWA. Both of Chemtura's arguments were, therefore, without any merit. Chemtura's letter of 1 October 1999, also referred to "new lindane data on canola" that had recently been submitted for consideration by both the PMRA and EPA. Yet there had never been any agreement to hold off withdrawal of canola use registrations in Canada pending the issuance of any study results: to the contrary, such results might ultimately allow registrations to be restored, after voluntary suspension. Moreover, Chemtura's new arguments did not mean the EPA would suddenly be indifferent to imports of lindane-treated products into the U.S., pending any registration or tolerance in that country.

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lindane insecticide *by the end of December 31, 2000*, instead of the end of 1999...<sup>152</sup> (our emphasis)

148. Moreover, even this extended withdrawal would be subject to unilaterally-imposed conditions, including the registration for use on canola in the United States and Canada of entirely different chemical actives – the fungicides carbathiin and thiram – within the year; the granting of permanent registrations of its Gaucho formulations; the maintenance of registrations for its other lindane-based applications in Canada; and the ability to use stocks of lindane-based seed treatments produced up until the end of 2000 with no time limit, until depletion. If these conditions were not met, Chemtura refused to voluntarily request the amendment of its lindane product labels.

149. Mr. Ingulli's demands again ignored that:

- the EPA (not the PMRA, or any other Canadian government agency) was now prohibiting imports of Canadian canola treated with lindane, based on the application of U.S. pesticides and food safety legislation;
- without a VWA and its agreed phase-out period, there would be no market at all for lindane treatments among Canadian canola farmers: the U.S. border would have closed as announced on July 1, 1998;
- by repudiating the VWA, the Claimant would simply have hastened the destruction of the Canadian canola market – and, by extension, its own Canadian market for seed treatment products;
- this entire situation resulted from the action of its own subsidiary, Gustafson;
- since November 1998, the PMRA had repeated that it could not guarantee the timing or the outcome of new registrations; and
- by October 1, 1999, Chemtura itself had secured the only registration of a lindane replacement product in Canada, Gaucho.

150. Chemtura's letter of October 1, 1999 thus used the pressure of its threatened VWA withdrawal to unilaterally attempt to impose a dramatic extension of its lindane production (by a further full year) beyond what originally had been agreed (and several

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<sup>152</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 1 October 1999 (Exhibit WS-30).



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times reiterated) as of the November 24, 1998 meeting. Moreover, Mr. Ingulli's unilateral extension would have allowed Chemtura to stockpile extensive amounts of lindane treatment, to be used indefinitely into the future. Mr. Ingulli also sought to dictate the timing and the terms on which both the PMRA and the EPA would register replacement products.

151. Before the PMRA could respond, the scheduled CCC / CCGA monitoring meeting took place on October 5, 1999. At the meeting, Chemtura's representative, Mr. Dupree, announced that the Claimant was pulling out of the VWA. The CCC and CCGA sought to restore Chemtura's agreement, in light of the drastic consequences its refusal would have on the entire canola industry. As summarized in an October 14, 1999 letter from the CCC to the Claimant:

The U.S. has threatened several times over the last two years to take action against canola. However, due to the agreement on voluntary withdrawal Canada has been able to diffuse the situation.

In June 1999, all four registrants again confirmed their commitment to the voluntary withdrawal and on October 5, three of the registrants indicated that they would honour this agreement. Uniroyal [Claimant's predecessor-in-title] is the only registrant that has not confirmed its commitment to the voluntary withdrawal.

There has been continuing pressure on the FDA to monitor and potentially restrict the movement of canola exports. If the voluntary withdrawal does not proceed or is delayed it is anticipated that Senator Dorgan [of North Dakota] will move quickly to take border action, jeopardizing an industry worth over \$500 million in canola exports.<sup>153</sup>

152. As the representative of Chemtura's lindane pesticide clients in Canada, the CCC called on Chemtura to abide by its November 1998 undertaking, and commit again to removing canola from its labels within the time-frame originally agreed.<sup>154</sup>

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<sup>153</sup> Letter from Bruce Dalgarno, Chairman, CCC, to Mr. Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 14 October 1999 (Exhibit WS-31).

<sup>154</sup> Affidavit of Wendy Sexsmith, ¶ 83; Affidavit of JoAnne Buth, ¶ 53-55.

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153. The CCC further stated that:

If the U.S. Environmental Protection Agency (EPA) does grant a tolerance for lindane on canola, the lindane registrants can request that canola be re-instated on the Canadian labels through an administrative request to PMRA. Again, PMRA has indicated they will confirm this with you in writing. *If the review by PMRA and EPA does determine that lindane products meet the requirements for registration in both countries, the growers would support the re-instatement of the product for use on canola in Canada.*<sup>155</sup> (our emphasis)

154. In other words, the canola growers themselves, Chemtura's clients, only wished to continue using lindane in canola production if its safety had been confirmed by the relevant regulatory bodies in Canada and in the United States.

155. On October 8, 1999, Mr. Ingulli sent a follow-up letter to the PMRA, again failing to copy any of its clients, the Canadian canola growers.<sup>156</sup> Faced with the position of its own clients at the October 5, 1999 meeting, Chemtura had at least partially backed down. In particular, Mr. Ingulli dropped his demand for an extension of production to December 31, 2000, reiterating the original VWA termination date of December 31, 1999. However, Mr. Ingulli again sought to barter Chemtura's renewed commitment to the VWA against additional, preferential, conditions for the registration of Chemtura's replacement products. In the October 8, 1999 letter, these conditions were as follows:

1. All other registrants of products used to treat canola that contain lindane also agree to do the same.
2. PMRA and U.S. EPA shall coordinate the review of any new lindane data already submitted and/or to be submitted in accordance to any data call in or regulatory request and provide a scientific assessment of lindane. This is a necessary step.

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<sup>155</sup> Letter from Bruce Dalgarno, Chairman, CCC, to Mr. Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 14 October 1999 (Exhibit WS-31).

<sup>156</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 8 October 1999 (Exhibit WS-33).

3. In the event that *both* government agencies determine that lindane has adverse toxicological effects and deem it unsafe for use on canola as a seed treatment, Uniroyal [the Claimant's predecessor-in-title] will not recommence manufacture of lindane products for use on canola in 2000 and beyond.

4. In the event that PMRA determines that lindane is safe to be used on canola as a seed treatment or U.S. EPA should issue a canola tolerance or determine that lindane is exempt from requiring a tolerance in canola, [the Claimant] reserves the right to resume manufacturing of lindane products for use on canola.

156. Mr. Ingulli's letter of October 8, 1999 was followed by the CCC's October 15, 1999 letter, in which the CCC called on Chemtura to abide by its previous undertakings in the VWA, and asserted that canola producers would not use Chemtura's lindane product unless it passed scientific approval in both the United States and Canada.

157. On the same day (October 15, 1999), the PMRA responded to Mr. Ingulli's letters of October 1 and 8, 1999.<sup>157</sup> The PMRA noted its understanding that the second letter overrode the first. The PMRA also took note of Chemtura's renewed commitment to remove canola use from its lindane product labels by December 31, 1999, but also Chemtura's demand for new, additional, conditions from the PMRA. With regard to these, the PMRA confirmed as follows:

1. At the October 5, 1999, meeting that was held to discuss the status of the agreement [*i.e.*, the VWA], the other three registrants indicated that they remain in support of the voluntary agreement.
2. The PMRA and EPA are currently coordinating and collaborating on re-registration / re-evaluation activities, including the review of any new data.
3. Uniroyal will not recommence manufacture of lindane products for use on canola if through the re-registration/re-evaluation process in U.S. and Canada it is determined that continued use of lindane is unacceptable.

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<sup>157</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 15 October 1999 (Exhibit WS-36).

4. If after the re-registration / re-evaluation process is completed in the U.S. and Canada, use of lindane on canola is found to be acceptable, or if EPA issues a tolerance for lindane on canola, Uniroyal would be able to request an administrative reinstatement of products and users of lindane on canola that were voluntarily withdrawn.<sup>158</sup>

158. In other words, while confirming that its re-evaluation process was underway in co-ordination with the EPA, the PMRA made no firm commitment as to the outcome of that re-evaluation. The PMRA emphasized instead that renewal of lindane manufacturing in Canada could occur only if the re-evaluation in Canada, and in the United States, found continued use of the product acceptable. This position was entirely consistent with the Canadian regulatory regime, which Chemtura was attempting to ignore.

159. The fourth point of the PMRA's letter noted that Uniroyal would be able to "request" an administrative reinstatement of lindane products in Canada if the EPA issued a tolerance for lindane on canola. This assertion, though, was in the context of the PMRA's third point, that any renewed manufacturing of the product in Canada would ultimately be dependent upon the PMRA's re-evaluation. Thus, if the EPA were to grant Chemtura a tolerance on canola in advance of release of the PMRA's Special Review decision, Chemtura could, at most, apply for a temporary reinstatement of canola use on its labels. As the PMRA's third term set out, registration was ultimately subject to the results of the Special Review.<sup>159</sup>

160. Having responded to the Claimant's October 8, 1999 letter, the PMRA concluded by noting its understanding that the Claimant continued to support the VWA, and that the

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<sup>158</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 15 October 1999 (Exhibit WS-36).

<sup>159</sup> This was consistent with the position taken by the CCC in its letter to the Claimant on the same day, that canola growers would only renew their use of the product if it was deemed safe by the PMRA. It was also consistent with the PMRA's announcement of 15 March 1999: "The registration status of *all* lindane-containing products will depend on the outcome of this review" (our emphasis): PMRA, Special Review Announcement SRA99-01, *Special Review of Pest Control Products Containing Lindane*, 15 March 1999 (Exhibit WS-32) (*Lindane Special Review Announcement*). This statement had, as well, been recalled by the PMRA's Director, Alternative Strategies & Regulatory Affairs at the meeting of 24 June 1999. Affidavit of Wendy Sexsmith, ¶ 86.

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Claimant, along with other registrants, would be requesting voluntary removal by November 1, 1999.

161. Mr. Ingulli wrote back again on October 18, 1999. In his letter, Mr. Ingulli did not indicate that the PMRA was incorrect to assume that the Claimant's October 8, 1999 letter overrode that of October 1, 1999. Moreover, while committing to cease production of lindane products for canola by December 31, 1999, Chemtura now refused to remove this use from its label as of that date. This was a crucial point. If the seed treatment use for canola remained on the label, users would assume that canola remained a fully-supported application of lindane seed treatment, as opposed to an application that was being phased out. This violated not only the spirit, but the letter, of the VWA.

162. Moreover, Mr. Ingulli asserted that Chemtura would refrain from resuming manufacture of its lindane products for use on canola, "subject to those conditions as stated in my letter of October 8, 1999", while acknowledging the PMRA's clarifications in its October 15, 1999 response. Mr. Ingulli further sought clarification of Chemtura's ability to request an administrative reinstatement of products and uses of lindane on canola that were voluntarily withdrawn, as referenced at point 4 of the PMRA's October 15, 1999 letter.

163. Given that the 4 registrants had committed to notifying the PMRA of the voluntary withdrawal by November 1, 1999, Chemtura's latest effort to rewrite the VWA had reached a critical juncture. As the PMRA had repeatedly noted, it could only agree to implement the VWA if the agreement was universally adopted by the 4 registrants, on identical terms. Now, on the eve of implementing that agreement, Chemtura was again seeking to negotiate its own side agreement – in effect, trying to pressure the PMRA into accepting additional preferential conditions, in exchange for Chemtura's commitment to respect the VWA.

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164. Notwithstanding the inappropriateness of the Claimant's demands, the PMRA simply restated what was possible within its statutory and regulatory framework, while doing what it could to encourage Chemtura not to destroy the VWA.<sup>160</sup>

165. The PMRA wrote back to the Claimant on October 21, 1999, noting Chemtura's refusal to remove the canola seed treatment use from its lindane product label as of December 31, 1999.<sup>161</sup> The PMRA then expressly recalled the terms of the VWA, agreed by the Claimant along with other registrants in November 1998, which included the Claimant's agreement voluntarily to remove canola/rapeseed claims from labels of registered canola/rape seed treatments containing lindane by December 31, 1999. The PMRA noted that the 3 other registrants remained committed to the terms of the VWA.

166. The PMRA further noted that "with respect to PMRA's commitment to facilitate access to replacement products, Gaucho™ was registered for use in Canada in July 1999, as a result of a priority review; three lindane free formulations have been registered; and reviews are continuing on the two other products.

167. After reviewing the process for a request for reinstatement and the general context of the VWA, the PMRA summarized the situation as follows:

Given that the voluntary agreement continues to be supported by growers, the Canadian Seed Treatment Association, and other registrants; given that replacement products are available; given the high risk for the canola industry if the voluntary agreement does not remain in place; and given that the opportunity for a fast administrative re-instatement of use and products in Canada exists *if uses remain acceptable as a result of the re-evaluation*; I would strongly encourage [Claimant] to remain supportive of the

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<sup>160</sup> Affidavit of Wendy Sexsmith, ¶¶ 93-94.

<sup>161</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 21 October 1999 (Exhibit WS-38).

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voluntary agreement of November 1998, as originally written.<sup>162</sup>  
(our emphasis)

168. As its letter indicated, the PMRA was in no position to “impose” terms on Chemtura, and would only agree to accept the voluntary label changes if they were indeed voluntary and universal. The most it could do was point out the dire consequences of Chemtura’s position. The PMRA could not forfeit its regulatory role by allowing Chemtura to dictate the terms of new registrations, or by waiving the Special Review: hence the PMRA’s qualification, “if uses remain acceptable as a result of the re-evaluation”.

169. In light of Chemtura’s latest demands, the PMRA scheduled a conference call among all VWA members on October 22, 1999. During that call, the PMRA suggested that, at most, it could agree to accelerate reinstatement of the voluntarily-withdrawn products, if the ongoing reviews of lindane found that canola was an acceptable use. The PMRA extended this undertaking to all 4 registrants. Otherwise, the terms of the VWA itself were to be unchanged: notably, voluntary withdrawal of canola-use registrations for lindane products by December 31, 1999, and cessation of use of lindane-based products and lindane-treated seed by July 1, 2001.<sup>163</sup>

170. Mr. Ingulli wrote to the PMRA once again on October 26, 1999,<sup>164</sup> seeking to impose yet another series of conditions in exchange for its continued adherence to the VWA. These conditions included:

- universal agreement among registrants to voluntarily withdraw lindane from their product labels by the end of 1999;

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<sup>162</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 21 October 1999 (Exhibit WS-38).

<sup>163</sup> Affidavit of Wendy Sexsmith, ¶ 95.

<sup>164</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 26 October 1999 (Exhibit WS-39).

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- coordination and collaboration between the EPA and the PMRA on the review and re-evaluation of any new lindane data already submitted to, and/or to be submitted in accordance with, any data call-in or regulatory request. For the first time, picking up on the PMRA's comment of October 22, 1999 that the end of 2000 was the target completion date for its review, Mr. Ingulli demanded that this scientific assessment be provided by the end of 2000;
  - if both government agencies determined that lindane had adverse toxicological effects and deemed it unsafe for use on canola as a seed treatment, Uniroyal would not request the reinstatement of lindane use on canola in Canada;
  - if the PMRA determined that lindane was safe to be used on canola as a seed treatment or the EPA should issue a canola tolerance or exempt lindane from requiring a tolerance in canola, Chemtura would request from the PMRA the reinstatement of products and uses of lindane on canola that were voluntarily withdrawn. Mr. Ingulli demanded that any such request be agreed to by the PMRA within 30 days, without any other pre-conditions, including the possibility that the PMRA had not completed its re-evaluation of lindane prior to the EPA issuing a canola tolerance or an exemption from tolerance. Mr. Ingulli then claimed the right to re-launch its production of lindane-containing product for use on canola and rapeseed in Canada and the United States;
  - Chemtura demanded the continued registration of uses for all remaining crops listed on the product labels after the removal of canola/mustard seed;
  - Chemtura demanded that all stocks of products containing lindane for use on canola and rapeseed be allowed to be used after 1999 until depleted, with no time limit; and
  - finally, Chemtura demanded that all stocks of products containing lindane for use on canola and rapeseed that were produced prior to January 1, 2000 and that required rework could be reprocessed and used on canola and rapeseed.

171. By demanding these conditions on the eve of implementation of the VWA, Mr. Ingulli was attempting to barter Chemtura's agreement to the VWA for control over the conditions in which its lindane products would be registered. Moreover, Chemtura again sought to change one of the key provisions of the VWA: rather than agreeing to suspend use of all commercial stocks containing lindane for use on canola and rapeseed and lindane-treated canola and rapeseed after July 1, 2001, Chemtura now demanded that such products be permitted to be used "indefinitely".



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172. Chemtura's latest letter prompted another series of telephone calls between the PMRA and Chemtura, and between Chemtura and the CCC, in which Chemtura was asked again to respect the terms of the VWA.<sup>165</sup> Mr. Ingulli wrote still another letter to the PMRA on October 27, 1999.<sup>166</sup> In this final letter, the Claimant notably backed down on the sixth of its conditions. The October 26, 1999 letter had read, at point 6:

All stocks of products containing lindane for use on canola/rapeseed and lindane treated canola/rapeseed are allowed to be used after 1999 until they are depleted, with no time limit. Imposition of a time limit may create unnecessary economic loss and waste disposal issues for seed companies and canola producers.<sup>167</sup>

173. The October 27, 1999 letter read, instead, at point 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.

174. On October 28, 1999, the PMRA wrote back to the Claimant agreeing with the Claimant's letter of the previous day.<sup>168</sup>

175. The PMRA agreed to these provisions because it believed that the Claimant's letter of October 27, 1999 was consistent with the terms of the VWA, allowing that agreement to be preserved.<sup>169</sup> Notably, the Claimant had agreed to a voluntary withdrawal on the same timeline as originally agreed. As for the Claimant's additional

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<sup>165</sup> Affidavit of Wendy Sexsmith, ¶ 97.

<sup>166</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 27 October 1999 (Exhibit WS-40).

<sup>167</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 26 October 1999 (Exhibit WS-39).

<sup>168</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 28 October 1999 (Exhibit WS-41).

<sup>169</sup> Affidavit of Wendy Sexsmith, ¶ 99.

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conditions, the PMRA understood them to be consistent with the VWA, and with the PMRA's regulatory role:

- the PMRA was already collaborating with the EPA on the review of lindane. In October 1999, the PMRA expected that this review would be finished by late 2000;
- the Claimant's undertaking not to request reinstatement where both Canada and the United States deemed further lindane use unsafe was consistent with the PMRA's regulatory role. The PMRA had already confirmed in its October 15 and 21, 1999 letters that its treatment of such a request would be dependent on Canada's ultimate position on lindane, as determined in the Special Review;
- Chemtura's demand that lindane be reinstated in Canada if a lindane tolerance was allowed in the United States was acceptable. As the PMRA knew, the U.S. had refused to consider any new tolerances for lindane until after the outcome of its re-assessment of lindane.<sup>170</sup> Since the U.S. decision was not expected until late 2000, the granting of any tolerance could only come in 2001, at the earliest; By this time the PMRA's own Special Review was expected to be completed. Moreover, any "automatic" reinstatement of lindane in Canada would be subject to the ultimate outcome of the Special Review, as the PMRA had repeatedly stated. Thus, at best, if the PMRA ultimately reached a negative decision on lindane, any "automatic" reinstatement would be suspended;
- the demand for continuing registration of the Claimant's other lindane registrations was also not a problem, given that the PMRA had affirmed the continuing registration of these products in March 1999, pending the outcome of the Special Review. The PMRA had also repeatedly confirmed that all Canadian lindane registrations were subject to the Special Review. It did not occur to the PMRA that the Claimant was in fact demanding that the results of the Special Review should be ignored, *i.e.*, that its other registrations would be maintained indefinitely, whether or not the PMRA determined them to be unsafe; and
- finally, the Claimant appeared to be abiding by the July 1, 2001 deadline established in the VWA.

176. The PMRA therefore confirmed its agreement with the Claimant's October 27, 1999 letter. PMRA understood the VWA had been preserved. The future of the VWA

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<sup>170</sup> *Dr. Goldman Report*, ¶ 38.

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ultimately depended on the voluntary submission of label change request by registrants removing canola as a registered use.

177. As of its October 8, 1999 letter, Chemtura had abandoned any conditions relating to the registration or accelerated review of any of its lindane replacement products.

**G. Lindane use on canola was withdrawn from all registrations in late 1999 in accordance with the VWA terms**

**1. The CCC and other registrants confirmed the terms of the VWA as understood by the PMRA**

178. On October 29, 1999, the day after the PMRA's letter to the Claimant, the CCC released a memorandum to all 4 lindane product registrants, summarizing the removal process, the timelines, the re-instatement option arising out of the October 22, 1999 discussions with all registrants, and the requirements to request reinstatement. The memorandum noted that "All commercial stocks of products containing lindane and lindane treated canola/rapeseed must be used up by July 1, 2001".<sup>171</sup> Chemtura never challenged this deadline.

179. The other 3 registrants soon sent letters announcing their intention to voluntarily withdraw their canola registrations for lindane, as originally provided in the VWA. Zeneca wrote to this effect on October 29, 1999.<sup>172</sup> Aventis<sup>173</sup> and IPCO<sup>174</sup> wrote on November 1, 1999. The letters also took into account the last-minute discussions between the PMRA and the Claimant, since the PMRA provided the benefit of any such clarifications to all registrants, equally. As IPCO noted in its letter:

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<sup>171</sup> Memorandum from JoAnne Buth, CCC to lindane product registrants, *Voluntary Withdrawal of Canola/rapeseed from lindane containing product labels*, 29 October 1999 (Exhibit WS-42).

<sup>172</sup> Letter from Roy Lee Carter, Cereals and Oilseed Lead, Zeneca [Syngenta], to Dr. Claire Franklin, Executive Director, PMRA, 29 October 1999 (Exhibit WS-43).

<sup>173</sup> Letter from John Kelly, Rhône-Poulenc Canada Inc. [Aventis] to Wendy Sexsmith, PMRA, 1 November 1999 (Exhibit WS-44).

<sup>174</sup> Letter from Don Wilkinson, Manager, Regulatory Affairs, IPCO, to Roy Lidstone, PMRA, 1 November 1999 (Exhibit WS-45).

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If, in the meantime, *lindane is cleared by the special review* and tolerances are established for residues of oil and meal in the USA, IPCO expects to be able to re-instate the registration, as an administrative action under the Canadian PCP Act upon supply of spec sheets, current label and fees.<sup>175</sup> (our emphasis)

180. Aventis similarly noted:

*Should the re-evaluation of lindane prove favourable by the PMRA and the Environmental Protection Agency (EPA) in the United States, as per our agreement we reserve the right to apply for an administrative re-instatement of these products in an expedited manner.*<sup>176</sup> (our emphasis)

181. Syngenta, for its part, stated:

*If the re-evaluation of lindane in Canada, which we believe will be completed by December 2000, shows that the canola/rapeseed use can be reinstated, it will be a 30 day administrative process to meet this end.* (our emphasis)

182. In other words, all 3 of these registrants were confirming the PMRA's own understanding of its commitment to administrative re-instatement: that is, re-instatement would be granted for canola, but only if the results of the Special Review showed that continued use of lindane was safe. Ultimately, the Special Review of lindane reached precisely the opposite conclusion.

**2. The PMRA confirmed the Claimant's voluntary label change, reminding it of the conditions for restoration of lindane use on canola**

183. By mid-November, Mr. Rob Dupree of Chemtura Canada followed the lead of the other registrants, filing the required application for voluntary label change for all of the Claimant's lindane applications used on canola: Cloak, Vitavax RS Flowable (undyed),

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<sup>175</sup> Letter from Don Wilkinson, Manager, Regulatory Affairs, IPCO, to Roy Lidstone, PMRA, 1 November 1999 (Exhibit WS-45).

<sup>176</sup> Letter from John Kelly, Rhône-Poulenc Canada Inc., to Wendy Sexsmith, PMRA, 1 November 1999 (Exhibit WS-44).

and Vitavax RS Flowable.<sup>177</sup> As Mr. Dupree noted on the forms, the Claimant was requesting “minor label amendment” – removing canola use from the label instructions for these 3 products. Such amendments are processed under s.13 of the Regulations.<sup>178</sup>

184. On December 7, 1999, the PMRA replied to Mr. Dupree, confirming the amendment to the label pursuant to s.13 of the *PCPR*. Simultaneously, the PMRA reminded Chemtura of the ongoing Special Review of lindane, the rationale for this review, and the that applications to expand uses of products under review would not be considered use during this period:

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 mammals and all environmental media.

Canada, the United States, European countries and Russia have recently negotiated an international protocol on persistent organic pollutants (POPs) under the Convention on Long-Range Transboundary Air Pollution of the UN Economic Commission for Europe. This agreement established obligations aimed at restricting

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<sup>177</sup> Application for New or Amended Registration for Claimant's Cloak Product, submitted by Rob Dupree, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), to PMRA (Exhibit WS-46); Application for New or Amended Registration for Claimant's Vitavax RS Flowable Product, submitted by Rob Dupree, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), to PMRA (Exhibit WS-46A); Application for New or Amended Registration for Claimant's Vitavax RS Flowable (undyed) Product, submitted by Rob Dupree, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), to PMRA (Exhibit WS-46B).

<sup>178</sup> *PCPR*, s.13 (Annex R-2). In its Memorial, the Claimant has constructed an elaborate argument to the effect that the PMRA failed to respect the conditions of s.16 in relation to its voluntary deregistration of lindane use on canola. Claimant's Memorial, ¶¶ 83, 405. Yet Chemtura's application to amend its product labels failed to provide any of the information required for to a notice of discontinuation of sale under s.16. No date for discontinuation of sales was indicated. There was clearly no expectation that the registration status of the canola and rapeseed use would continue beyond 31 December 1999: the purpose of the application was to terminate that one use while maintaining other registered uses. The absence of information required for a section 16 procedure was not surprising, since the Claimant was not proceeding under s.16 of the Regulations, as it now alleges. It was proceeding under s.13. S.13 was also employed by Aventis and Syngenta, two of the other four Canadian registrants of lindane products who also had lindane products registered for uses other than canola. Under the terms of the VWA, IPCO stopped manufacturing its product altogether as of 31 December 1999. Thereafter, IPCO's sale of its remaining product and the use of the product continued in accordance with the terms of the VWA, with all sales and use ending as of July 1, 2001. Affidavit of Wendy Sexsmith, ¶¶ 118-119.

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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 United States and Mexico are considering taking regional action on lindane under the North American Agreement on Environmental Cooperation (NAAEC).

Accordingly the Pest Management Regulatory Agency will be conducting a Special Review of lindane-containing products *during which time no use expansions will be considered*. In addition, all new products, registration renewals, and amended registrations will be granted for a period not exceeding one year until this Special Review is complete. The registration status of all lindane-containing products will depend on the outcome of this review.<sup>179</sup> (our emphasis)

185. The PMRA could hardly have been clearer. A Special Review was underway. No expansions of registrations would be considered during this period. Moreover, all registrations depended on the ultimate outcome of the Special Review. This position was consistent with the PMRA's letters to the Claimant in October, and discussions with all registrants on October 22, 1999. It was also consistent with the understanding communicated by all other registrants in their letters of October 29 – November 1, 1999. The Claimant never suggested that these terms were, in any way, contrary to the exchange of letters between the Claimant and the PMRA of October 27-28, 1999.

### **3. The PMRA notified all four registrants**

186. On December 23, 1999, the PMRA wrote to all 4 Canadian registrants of lindane for canola use, confirming that all label amendments and notices of discontinuation of sale had been submitted and recalling the conditions agreed to by lindane registrants in the VWA of November 1998. In particular, the PMRA noted that “all commercial stocks containing lindane for use on canola/rapeseed and lindane treated canola/rapeseed would

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<sup>179</sup> See e.g. Letter from Roy Lidstone, PMRA, to Rob Dupree, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 7 December 1999 (Exhibit WS-47).

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not be used after July 1, 2001".<sup>180</sup> Again, the Claimant failed to challenge the PMRA's understanding of the withdrawal.

**H. The PMRA helped facilitate the July 1, 2001 deadline for the use of all remaining lindane for Canola**

**1. The PMRA's 2001 compliance activities focused on monitoring amounts of leftover lindane**

187. The Claimant has asserted that the PMRA, by threatening enforcement actions and other measures, deterred farmers from using lindane in the 2001 growing season. The PMRA's compliance program relating to lindane use on canola confirms that its approach was measured, and not designed to dissuade farmers from using the product.<sup>181</sup> To the contrary, it took steps to promote usage of existing stocks, even allowing treated seeds to be used up in the 2002 planting season.

188. The PMRA 2001 lindane/canola compliance program had two phases:

- 1) In the first phase, in the spring of 2001, the PMRA tried to determine how much lindane treatment remained in circulation, and the canola growers' level of awareness regarding the VWA. To do so, PMRA inspectors visited seed treatment facilities that were treating canola with lindane, inspecting the facilities, and filling in questionnaires. This phase lasted over April 2001, with a final report issued in May 2001. Teleconferences were held between the PMRA and industry players throughout the process.
- 2) The second phase came after July 1, 2001. From July to September 2001, the PMRA looked for evidence of left-over lindane product. They thereafter issued preliminary and then final reports. The PMRA did not impose a single fine for leftover lindane during this phase.

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<sup>180</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA, to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 23 December 1999 (Exhibit WS-48); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Don Wilkinson, IPCO, 23 December 1999 (Annex R-22); Letter from Dr. Claire Franklin, Executive Director, PMRA, to John Kelly, Rhône-Poulenc Canada, 23 December 1999 (Annex R-23); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Roy Lee Carter, Zeneca Agro, 23 December 1999 (Annex R-24).

<sup>181</sup> Affidavit of Jim Reid, ¶¶ 36-37.

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189. By the time the PMRA began actively monitoring amounts of lindane in circulation, in April 2001, Canadian canola farmers had decided whether to use lindane for that growing year. The same applied to the post-July 1, 2001 period.

**2. The PMRA make no “threats” regarding compliance with the VWA**

190. The PMRA has a modest compliance program based on carefully developed policy considerations. It conducted no compliance operations in relation to the VWA in either 1999 or 2000, while the CCC and CCGA reminded their members of the agreed deadline.<sup>182</sup> When asked about potential enforcement actions in late 2000 and early 2001, the PMRA repeatedly confirmed that its main intent was to monitor carry-over of lindane stock and treated seed after the agreed July 1, 2001 deadline. Its compliance program focused on these issues.

**a) The PMRA has only limited enforcement capacity**

191. The PMRA's compliance program has limited resources and enforcement powers.<sup>183</sup> Its actions are therefore carefully crafted to maximize compliance by focussing on the promotion of the safe use of pesticides.<sup>184</sup>

192. At all relevant times, the PMRA's compliance activity was guided by the PMRA's *Compliance and Enforcement Policy Guideline* (Guidelines), introduced in June 1998.<sup>185</sup> The Guidelines emphasize education and consultation, while allowing for inspections and investigation of suspected infractions. They also outline the potential for administrative penalties, fines and prosecution – but in practice these are relied upon only

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<sup>182</sup> Affidavit of Jim Reid, ¶ 27; Affidavit of JoAnne Buth, ¶ 64.

<sup>183</sup> In relation to the size of Canada's agricultural territory, the PMRA's compliance staff is quite limited. As of 2002, national compliance resources (including headquarters staff, field officers and inspectors, and laboratory technicians) amounted to, at most, 42 person-years (many inspectors were part-time). Affidavit of Jim Reid, ¶ 14. To recall, there were approximately 50,000 canola farmers in Western Canada. Affidavit of JoAnne Buth, ¶ 12.

<sup>184</sup> See generally Affidavit of Jim Reid, ¶¶ 4-23.

<sup>185</sup> Affidavit of Jim Reid, ¶ 4; PMRA, *Compliance and Enforcement Policy Guidelines*, 12 June 1998 (Exhibit JR-1).



as a last resort, after more collaborative approaches have been tried and have failed.<sup>186</sup> Specific activities are the result of an annual compliance planning process.<sup>187</sup>

**b) The PMRA engaged in no lindane compliance operations in 1998, 1999 or 2000**

193. Lindane treatment on canola was not on the PMRA's annual compliance agenda in 1998, 1999 or 2000.<sup>188</sup> During this period, the CCC, CCGA and subnational canola industry associations continued to advise their members of the VWA and the need to cease use of lindane products and of lindane-treated seed by July 1, 2001, in accordance with the terms of the VWA.<sup>189</sup>

194. The PMRA did not begin to discuss any compliance activities in relation to lindane use on canola until its planning session in the autumn of 2000, and did not begin to implement this program – focused on monitoring of remaining stocks – until April 2001. By that time, growers' decisions regarding the type of treated canola seeds to plant for that year would already have been taken.<sup>190</sup>

**c) The PMRA's 2001 compliance program focussed on monitoring leftover stocks**

195. Late in 2000, it had become clear to the canola growers and registrants that some lindane-based pesticides for use on canola, produced prior to the VWA cutoff date of December 31, 1999, would remain unused after the 2001 planting season (ending in May

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<sup>186</sup> Affidavit of Jim Reid, ¶¶ 6-12. The PMRA initiated at most 1 or 2 prosecutions a year with the potential to lead to penal fines. Affidavit of Jim Reid, ¶ 22. As for administrative fines, the PMRA would generally levy in the range of 20 per year, ranging from \$500 to \$2000. Affidavit of Jim Reid, ¶ 24-25.

<sup>187</sup> The PMRA compliance process followed a yearly three-part cycle: autumn (information – gathering); winter (planning); and spring/summer (implementation of target compliance actions). Affidavit of Jim Reid, ¶¶ 17-20.

<sup>188</sup> Affidavit of Jim Reid, ¶ 27; Outline of topics on PMRA Compliance Agenda, 1998 (Exhibit JR-6); Outline of topics on PMRA Compliance Agenda, 1999 (Exhibit JR-7); Table of Contents of PMRA Compliance Agenda, 2000 (Exhibit JR-8).

<sup>189</sup> Affidavit of JoAnne Buth, ¶ 56.

<sup>190</sup> Affidavit of Jim Reid, ¶ 28.

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or June 2001).<sup>191</sup> The fact that this was even raised as an issue reconfirms the general understanding among stakeholders that lindane-treated canola seed was not to be used after July 1, 2001, in accordance with the terms of the VWA.

196. The anticipated “overhang” was discussed at a November 2000 meeting between the PMRA, the CCGA, the CCC and the Canadian Seed Trade Association (CSTA), the organization that had requested the meeting.<sup>192</sup> The meeting was attended by both Wendy Sexsmith, Chief Registrar of the PMRA, and Jim Reid, the PMRA’s Chief Compliance Officer.<sup>193</sup>

197. In addition to discussing the issue of “overhang”, participants at the November 2000 meeting also engaged in a general discussion about PMRA compliance and enforcement policies.<sup>194</sup> Mr. Reid described the PMRA’s policy, referencing the PMRA’s Guidelines, and noting the fines established in the *PCPR*. This was a standard PMRA response.<sup>195</sup> No questions were raised about potential PMRA enforcement measures restricting the use of lindane seed treatments or treated seeds.<sup>196</sup>

198. Later, the Vice-President of the CCC, JoAnne Buth, produced a report of the meeting. The report included her views about the possible implications of matters discussed in the meeting. Ms. Buth’s report contained the following statements:

The lindane registration was amended as of December 31, 1999 – canola is no longer on the register of any label of products containing lindane.

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<sup>191</sup> At least two relevant factors affected lindane consumption in 2001, both of which the Claimant has failed to mention. These two factors are drought and a worldwide drop in canola prices. Canadian farmers, understandably sensitive to price changes and climatic challenges, shifted their production for that season to other, more promising crops. Their decisions collectively pushed planted canola acreage in Canada from 14 million in 1999, down to 9 million in 2001. Affidavit of JoAnne Buth, ¶ 70.

<sup>192</sup> Affidavit of Wendy Sexsmith, ¶ 124; E-mail from JoAnne Buth reporting on 12 November meeting between PMRA, CCGA, CCC and CSTA, 22 November 2000 (Exhibit WS-51).

<sup>193</sup> Affidavit of Wendy Sexsmith, ¶ 124; Affidavit of Jim Reid, ¶ 66.

<sup>194</sup> Affidavit of Wendy Sexsmith, ¶ 124.

<sup>195</sup> Affidavit of Jim Reid, ¶ 32.

<sup>196</sup> Affidavit of Wendy Sexsmith, ¶ 124.

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PMRA made a compliance policy decision to allow existing stocks to be used up until July 1, 2001. This is not uncommon and has been done with other products to use up existing stocks and minimize any disposal issues.

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 \$200,000.

*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.*

When I indicated that seed inventory may be as high as 10% of the seeded acreage (1 – 1.2 million acres), they did not think that this was unreasonable. However, they would like a better estimate of treated seed carryover before they are prepared to issue any letter or announcement. The impression I have is that it would be wise not to push them on a decision on this now, as they may not be prepared to make any adjustments to their policy until we have more information. If they are asked to confirm this in writing right now, I suspect that the answer will be that all existing stocks are to [*sic*] used up as of July 1, 2001.<sup>197</sup> (our emphasis)

199. The report confirms that the PMRA was not threatening enforcement action against anyone in 2001, and was actually engaged in a process of determining whether there could be an orderly exhaustion of stocks that might remain as of July 1, 2001.

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<sup>197</sup> E-mail from JoAnne Buth reporting on 12 November meeting between PMRA, CCGA and CCC, 22 November 2000 (Exhibit WS-51).

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200. In December 2000, the Canadian Association of Agri-Retailers published a “Lindane Alert”, stating that lindane could not be sold after July 1, 2001, and that fines could be as high as \$200,000.<sup>198</sup> Adam Vaughan, a representative of Chemtura Canada, brought this statement to the attention of the PMRA. The PMRA’s response was to confirm that the information was factual, and that its normal approach would be to investigate any unregistered sale or use of any control product. The PMRA also directed Mr. Vaughan’s attention to the Guidelines, which focus on compliance.<sup>199</sup>

201. Confirmation of the PMRA’s position was followed by a discussion between Mr. Vaughan and a PMRA enforcement officer, Ross Pettigrew. As Mr. Vaughan’s own notes of that meeting confirm, Mr. Pettigrew told the Claimant’s representatives that:

1. *PMRA does have the authority to impose fines but they probably would not. Generally, they only take people to court over things that intentionally cause harm or are dangerous, etc.*
2. *They will be focussing on making sure that there are no stockpiles of product and that nobody is intentionally treating and stockpiling seed for 2002.*
3. They WILL be doing inspections. PMRA will be contacting us in the future to give us more details about the inspections.
4. When I questioned him about how this is a violation of the PCP Act he said because it is using a product for an unregistered use (the registrations will be cancelled by that time).
5. The \$200,000 number probably came from someone asking the question, “What are the potential fines that PMRA could administer for a violation of the PCP Act?” *He felt*

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<sup>198</sup> Affidavit of Jim Reid, ¶ 45. Industry organizations have no obligation to inform the PMRA when making statements to their members; the PMRA thus typically would not even be aware such statements were to be made until their release, if at all. Nor was it the PMRA’s policy to interfere with third-party communications. Affidavit of Jim Reid, ¶ 42.

<sup>199</sup> Affidavit of Jim Reid, ¶45.

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*that the \$200,000 was put out as motivation to get the lindane used up and is not realistic.*<sup>200</sup> (our emphasis)

202. This report simply confirmed that, as a national regulator, the PMRA's standard policy was to admit the possibility of fines where a grower was wilfully violating the terms of the *PCPA*. This simply repeats the governing legislation. However, the PMRA, at the same time, also made clear that its focus was on monitoring remaining stocks.

203. Moreover, the PMRA itself had no interest in making such "threats". From a health and environmental perspective, it was preferable for remaining lindane stocks to be widely dispersed through use, rather than stockpiled in any one place with the potential to be destroyed as toxic waste.

204. The Claimant's allegations concerning the effect of alleged PMRA "threats" on lindane purchases are not supported by the affidavit of a single Canadian canola grower. To the contrary, Canada has provided the evidence of the President of the CCC, Ms. JoAnne Buth, which confirms that canola growers were aware of the PMRA's typical approach to compliance, and were not making decisions based on any fear of fines.<sup>201</sup>

205. Similarly, the Claimant, as a billion-dollar chemicals company long active in Canada, had intimate knowledge of the *PCPA* and *PMRA* compliance practice. It knew that continued use of any product outside of the registered label conditions could lead to fines. The VWA's end-date for use of lindane-treated seeds of July 1, 2001, as well as of the lindane products, had been repeatedly affirmed in communications. However, Chemtura also knew that the PMRA, in practice, rarely prosecuted infractions. Moreover, the PMRA had clearly stated with the outlines of its lindane compliance program that its interest in compliance activities was to determine amounts of hold-over of treated seed. This goal was never contradicted by any PMRA statements. Under the

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<sup>200</sup> E-mail from Adam Vaughan, Gustafson Partnership, to Bob Chyc, Fred Hnatiw, Kim Turner, Graham White and Rick Turner, Gustafson Partnership and Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 12 January 2001 (Exhibit JR-17).

<sup>201</sup> Affidavit of JoAnne Buth, ¶¶ 67-68.

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circumstances, the notion that Chemtura was afraid of the “chilling effect” of potential PMRA-imposed fines or prosecution is not credible.

**3. The Claimant ignores its multiple Federal Court proceedings, all of which it abandoned**

206. As of April 2001, the Claimant also began the first of a series of Federal Court applications challenging the withdrawal of lindane use in Canada, all of which it ultimately abandoned. The Claimant had sought judicial review of a variety of decisions taken by the PMRA, and was aware of such avenues of recourse (as its litigious behaviour confirms), yet abandoned each and every one of these applications, before a single ruling was issued. In this arbitration, the Claimant seeks review, at the international level, of decisions it declined to pursue domestically.

207. Given the numerous proceedings initiated by Chemtura, Canada has attached, at Appendix E, a separate narrative reviewing the details of each. The following paragraphs provide an overview of these actions.

**a) Chemtura brought a first application to throw out the VWA**

208. Chemtura's first of an eventual nine separate applications for judicial review was filed on April 4, 2001.<sup>202</sup> Chemtura sought prerogative relief, essentially allowing sale and use of lindane products both before and after July 1, 2001.<sup>203</sup>

209. Chemtura claimed that the PMRA had failed to comply with Section 16 of the *PCPR*.

**b) Chemtura unsuccessfully sought interim relief**

210. On April 10, 2001, Chemtura applied for interim relief in its pending review. In the motion, Chemtura requested an order prohibiting the PMRA from taking any actions

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<sup>202</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Notice of Application, Federal Court File No. T-585-01, 4 April 2001 (Annex R-54).

<sup>203</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Notice of Application, Federal Court File No. T-585-01, 4 April 2001 (Annex R-54).

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to limit the sale of its lindane products prior to July 1, 2001 or the use of those products after that date, restraining the PMRA from any other interference with the sale of lindane, and ordering the PMRA to declare that lindane products could be used after July 1, 2001.<sup>204</sup>

211. On the same day Counsel for Chemtura requested an expedited hearing of the motion.<sup>205</sup> Within a week, Chemtura advised that it would not, in fact, be prepared to proceed before April 23.<sup>206</sup> The motion was scheduled for May 1, 2001, in Ottawa.<sup>207</sup>

212. On May 4, 2001, Justice Tremblay-Lamer found that Chemtura had not proved it had suffered irreparable harm<sup>208</sup> and that any loss could be compensated monetarily.<sup>209</sup> As a result, the motion for interim relief was dismissed.<sup>210</sup> Of the nine applications Chemtura brought to the Federal Court, this motion is the only proceeding that Chemtura did not abandon before the Court had the opportunity to make a ruling.

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<sup>204</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Motion Record of the Applicant for Interlocutory Relief, Federal Court File No. T-585-01, 10 April 2001 (Annex R-56).

<sup>205</sup> Letter from Michael Phelan, Ogilvy Renault, to Annette Piette, Judicial Administrator, Federal Court Trial Division, 10 April 2001 (Annex R-57).

<sup>206</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Memorandum from L. Martel, Office of the Associate Chief Justice to A. LeGal, Intellectual Property and Admiralty, Federal Court File No. T-585-01, 17 April 2001 (Annex R-59).

<sup>207</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Notes from Telephone Call by the Office of the Associate Chief Justice/Judicial Administrator, Federal Court File No. T-585-01, 11 April 2001 (Annex R-58).

<sup>208</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Reasons for Order and Order of Justice Lamer-Tremblay, Federal Court File No. T-585-01, 4 May 2001, ¶¶ 39-41 (Annex R-62) (*Federal Court 2001 Reasons for Order*).

<sup>209</sup> *Federal Court 2001 Reasons for Order*, ¶¶ 43-45 (Annex R-62).

<sup>210</sup> *Federal Court 2001 Reasons for Order*, ¶ 46 (Annex R-62).

**c) The Claimant attempted to reinstate its lindane registrations on canola in the wake of its failure to secure interim relief**

213. Days after this ruling, on May 8, 2001, Chemtura filed a request with the PMRA for reinstatement of canola use on its lindane labels.<sup>211</sup>

214. The Claimant suggests that its request for reinstatement was justified, based on the delay in the Special Review of all lindane uses and on the “position taken by the Minister as to the legality of prior and future sales...”<sup>212</sup>

215. However, the Claimant fails to acknowledge that, as of May 2001, key conditions for eventual reinstatement of canola product labels had not been achieved:

- the PMRA had not yet reached a decision in the Special Review of lindane; and
- the EPA had failed to issue either a registration or a tolerance for lindane on canola.

216. The PMRA had repeatedly confirmed in 1999 that pending the results of the Special Review, no extensions of lindane use would be considered in Canada.<sup>213</sup> In any event, EPA approval had not been obtained as of May 2001 – nor, indeed, did EPA *ever* grant a registration or a tolerance for lindane use on canola in the United States.

217. For all of these reasons, the PMRA replied to the Claimant, in the language the Claimant itself cites<sup>214</sup>:

The PMRA believes that the conditions under which [Chemtura] can properly require reinstatement to its lindane product registrations of the canola/rapeseed use *have not yet been met* and

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<sup>211</sup> Letter from Rob Dupree, Manager, Regulatory Affairs & Registrations, Crompton Canada (predecessor-in-title to Chemtura Canada) to PMRA, 8 May 2001 (Exhibit WS-52).

<sup>212</sup> Claimant's Memorial, ¶ 149.

<sup>213</sup> *Lindane Special Review Announcement* at 3, 15 (Exhibit WS-32).

<sup>214</sup> Claimant's Memorial, ¶ 150.



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that to grant your request *at this time* would not be consistent with the terms of the voluntary agreement.<sup>215</sup> (our emphasis)

218. This was not a blanket refusal by the PMRA to reinstate the Claimant's registration of lindane for canola use in May 2001.<sup>216</sup> Rather, the PMRA treated the requests as premature, since the conditions for reinstating the amended registration (a clean result on scientific review) had not been achieved, either in Canada or in the United States. In fact, the PMRA retained the requests for decision when it could determine whether the conditions had been met or would not be met. The requests ultimately were refused, based on the results of the PMRA's Special Review of lindane.

**d) Crompton challenged the PMRA's decision to deny reinstatement in the Federal Court, but abandoned this application as well**

219. On June 21, 2001, Chemtura brought a second application to the Federal Court, seeking another declaration that the Minister had breached the Voluntary Withdrawal Agreement and an order of mandamus to reinstate the registrations and uses that had been cancelled by Chemtura pursuant to the voluntary withdrawal.<sup>217</sup>

220. As set out in detail in Appendix E to Canada's Counter-Memorial, the Claimant filed 5 other applications between December 2001 and March 2002, several of which

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<sup>215</sup> Letter from Wendy Sexsmith, Chief Registrar, PMRA to Rob Dupree, Manager, Regulatory Affairs & Registrations, Crompton Canada (predecessor-in-title to Chemtura Canada), 29 May 2001 (Exhibit WS-53).

<sup>216</sup> Affidavit of Wendy Sexsmith, ¶ 136.

<sup>217</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Notice of Application, Federal Court File No. T-1091-01, 21 June 2001 (Annex R-63).

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Chemtura discontinued shortly after they were filed.<sup>218</sup> The remaining applications were consolidated by the Court.<sup>219</sup>

221. After a few interlocutory motions concerning production of documents, Chemtura abandoned these consolidated proceedings. They were ultimately discontinued at Chemtura's instigation on October 3, 2006.<sup>220</sup>

**e) Chemtura initiated a first Chapter 11 claim**

222. While Chemtura was still pressing its claims before the Federal Court, on November 6, 2001, Chemtura served the Government of Canada with a Notice of Intent to submit a NAFTA Chapter 11 claim pursuant to Article 1116.<sup>221</sup> This Notice alleged that Canada had breached its obligations under NAFTA Articles 1102 (National Treatment), 1105 (Minimum Standard of Treatment), 1106 (Performance Requirements) and 1110 (Expropriation and Compensation). On April 4, 2002, Chemtura served Canada with a separate Notice of Intent, further alleging that Canada had breached Articles 1103 (Most Favored Nation Treatment) and 1104 (Standard of Treatment).<sup>222</sup>

223. In this initial Chapter 11 notice, the Claimant alleged that Canada had breached the VWA by stating that lindane-treated canola seeds could not be used after July 1, 2001, and by failing to complete the scientific review of lindane by December 2000. The Claimant also alleged that it had suffered damages as a result of PMRA's refusal to correct the "confusion in the market" created by the erroneous position attributed to it

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<sup>218</sup> Chemtura brought a third application relating to lindane on 7 December 2001, ultimately discontinued within three weeks; and a fourth application on 13 December 2001, also discontinued shortly after it was filed, on 2 January 2002.

<sup>219</sup> In November 2001 Chemtura sought to consolidate its first and second applications, a request granted in December 2001. In March 2002, Chemtura filed a further three applications for judicial review; these three applications concerned the PMRA's refusal to amend Chemtura's lindane labels to include canola uses, and the PMRA's decision by that time to suspend all remaining agricultural applications of lindane. These applications were eventually consolidated with the previous applications brought by Chemtura before the Federal Court relating to lindane.

<sup>220</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Notice of Discontinuance, Federal Court File No. T-585-01, 3 October 2006 (Annex R-122).

<sup>221</sup> *NoI-1* (Annex R-137).

<sup>222</sup> *Crompton v. Canada*, Notice of Intent submitted 4 April 2002 (Annex R-138) (*NoI-2*).

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regarding the use of lindane-treated seeds in the 2002 planting season. The Claimant sought damages of approximately USD \$100 million.

224. Counsel for the Claimant and Canada held consultations further to NAFTA Article 1118 on March 20, 2002. The Claimant served its Notice of Arbitration on October 17, 2002.<sup>223</sup>

**4. The PMRA ultimately agreed to extend planting of lindane-treated seed into the 2002 growing season**

**a) The PMRA pursued discussions with stakeholders concerning the potential to extend the phase-out period for planting treated seed**

225. As the Claimant's myriad Federal Court proceedings were unfolding in 2001, the PMRA and canola industry stakeholders monitored the final season of lindane use.

226. The issue of potential overhang of treated seed was first considered at a meeting between the PMRA and canola industry stakeholders in November 2000.<sup>224</sup> At that time, the PMRA simply noted that it would continue to monitor the situation. The fact that the CCC and other stakeholders were asking for the PMRA's permission potentially to extend the use of treated seed underscore, that it was understood that the deadline for its use was, indeed, July 1, 2001.

227. On March 23, 2001, the growers met again with the PMRA to seek an extension of time to use lindane-treated seed. The PMRA indicated that it would conduct an audit to determine the stocks of lindane product and lindane-treated seeds remaining, but did not make any commitment to extend the time limit.<sup>225</sup> The CSTA sent its members a

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<sup>223</sup> *Crompton v. Canada*, Notice of Arbitration submitted 17 October 2002 (Annex R-140) (*NoA-1*).

<sup>224</sup> Affidavit of Wendy Sexsmith, ¶ 124.

<sup>225</sup> Minutes of Lindane Meeting between PMRA and the Growers, 23 March 2001 (Exhibit WS-56).

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letter dated March 26, 2001, indicating that the July 1, 2001 deadline still applied unless the PMRA agreed to an extension.<sup>226</sup>

**b) The PMRA determined that treated seeds should be used up in the 2002 planting season**

228. In the course of its compliance audit from July to September 2001, the PMRA determined that there was some leftover treated seed.<sup>227</sup> This gave rise to a disposal problem: if all of the treated seed was simply dumped in one site, it could create a greater hazard than if it was widely dispersed.

229. Moreover, the results of the PMRA's Special Review of lindane, released in October 2001, raised specific concerns. As Canada will review in further detail below (*see* section VI, B, 5), through its Special Review the PMRA concluded that the continued registration of lindane treatments for agricultural applications posed too high a risk, based on the likely exposure of workers to the product during seed treatment.

230. When industry stakeholders returned in November 2001 to request permission to use their remaining treated seed, the PMRA was concerned that the requested extension might be used to re-launch seed treatments, and not simply to use up the existing stocks of treated seed. To alleviate these concerns, in a letter dated December 17, 2001 the CCC specified that the requested extension was not intended to include continued use of any remaining lindane product for treatment of seeds.<sup>228</sup>

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<sup>226</sup> E-mail from Judy Fredette, CSTA to CSTA Canola Seed and Seed Treatment Suppliers, 26 March 2001 (Annex R-28).

<sup>227</sup> Affidavit of Jim Reid, ¶ 36. According to the report issued at the completion of the lindane compliance program, 6,580 metric tonnes remained in the possession of registrants or seed treaters after July 1, 2001. *See* National Pesticides Compliance Program, Final Report, *Lindane Seed Treatment Use on Canola* (Program 2409), 2001 (Exhibit JR-13).

<sup>228</sup> Letter from JoAnne Buth, Vice-President, Crop Production, CCC, to Wendy Sexsmith, Chief Registrar, PMRA, 17 December 2001 (Exhibit WS-57).

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231. Chemtura wrote confirming its support for the CCC's request.<sup>229</sup> Chemtura "relinquish[ed] any right it may obtain in Canada to sell lindane products for the purposes of the seed treatment of canola seed for the 2002 planting season, regardless of the outcome of the pending litigation".<sup>230</sup>

232. After further consultation with the CCC, the PMRA decided to allow the remaining seed to be planted. The PMRA through consultations with CCC, who consulted broadly including with provinces, decided that dispersal through planting was the most effective means of eliminating any remaining treated seed, as otherwise it would be disposed of all in one place, creating a greater threat of toxicity.<sup>231</sup>

233. The PMRA's agreement to extend the phase-out period to the 2002 growing season meant that the remaining lindane-treated seeds were entirely used up over that last growing season.

#### **I. Registration of new products was fair and according to the VWA**

234. The Claimant complains about the PMRA's actions in registering lindane replacement products in the wake of its voluntary withdrawal of its lindane registration. The facts demonstrate that the registration of replacement products was expeditious, fair and consistent with the VWA and with generally applicable legal and regulatory standards.

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<sup>229</sup> Letter from Alfred Ingulli, Executive Vice President, Crompton to Wendy Sexsmith, PMRA, 24 January 2002 (Exhibit WS-59). Aventis expressed similar support for the Canola Council's plan in a letter of the following day: Letter from Chris Warfield, Aventis to Wendy Sexsmith, PMRA, 25 January 2002 (Annex R-31).

<sup>230</sup> This reflected the fact that, at the time, Chemtura had initiated various Federal Court actions seeking precisely this relief.

<sup>231</sup> Affidavit of Wendy Sexsmith, ¶ 145.

## 1. Initial registration is subject to stringent procedures

235. Every control product imported into,<sup>232</sup> sold or used in Canada or used or contained in another control product in Canada must be registered in accordance with the Regulations.<sup>233</sup>

236. Applications for a certificate of registration must be made to the Minister of Health with detailed information about the control product.<sup>234</sup> When the active ingredient in a control product has not previously been assessed under the *PCPA*, the applicant is required to provide much more scientific data.<sup>235</sup>

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<sup>232</sup> Control products may only be imported into Canada if accompanied by a declaration containing specific details about the shipment and signed by the importer. *See PCPR*, s. 55 (Annex R-2).

<sup>233</sup> *PCPR*, s. 6 (Annex R-2).

<sup>234</sup> *PCPR*, s. 7 (Annex R-2) provides that an application must include the following information:

- the name, address and signature of the applicant (or applicant's agent), the name and address of the manufacturer of the control product, and the place of manufacture;
- the brand name of the control product, the "product name" (which is to be "descriptive of the physical form and purpose of the control product" and should include "the common name of its active ingredient") [*PCPR*, s. 27(2)(a)], and both the content by percentage weight and specifications of each active ingredient;
- the name and address of the manufacturer of each ingredient of the control product;
- the size, type and specifications of the packaging [*PCPR*, s. 46], in which the control product is to be sold, including five copies of the proposed label, [*PCPR*, s. 10] (which must conform to an exacting set of standards) (*see PCPR*, ss. 27–39, "Labelling"); and
- a guarantee that the control product contains the specified active ingredient [*PCPR*, s. 27(2)(e)].

<sup>235</sup> *PCPR*, s. 9(2)(a) (Annex R-2) provides that scientific data includes (but is not limited to):

- data on the effectiveness of the control product for its intended purposes;
- data on the safety of occupational exposure to the product (manufacture, storage, display, distribution or use) and on the safety of the control product to the host (plant, animal or article) on which it is to be used;
- data on the effects of the control product on representative species of non-target organisms, and on the degree of persistence, retention and movement of the control product and its residues;
- suitable methods of analysis for detecting the active ingredient and measuring the specifications of the control product; and for detecting significant amounts (including its residues in food, feed and the environment under normal use);
- suitable methods for the detoxification/neutralization of the control product (in soil, water, air or on articles) and for disposing of it and its empty packages; and

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237. Additionally, when a control product is to be used on plants or animals grown for human consumption, applicants are required to provide yet further information, including:<sup>236</sup>

- animal tests for the purposes of assessing any risk to humans or animals; and
- data on how storing/processing food or feed the product was used on affects the dissipation or degradation of the control product and any of its residues.

238. At all times during the registration process, the Minister can ask registrants to provide any “such further or other information as will allow the Minister to determine the safety, merit and value of the control product”.<sup>237</sup>

239. When a chemical control product is registered, the Minister has discretion to set the term of validity of that registration for up to five years.<sup>238</sup> At the expiry of this term, registrants may apply to the Minister for another registration, subject to the same discretion on time limits.<sup>239</sup>

240. The Minister can refuse to register control products if the application is insufficient, the scientific data submitted is insufficient, the applicant fails to establish the product's value for the purposes claimed, or because the use of the control product would, in the Minister's opinion, lead to an unacceptable risk of harm to the things on which the control product is to be used, or to “public health, plants, animals or the environment.”<sup>240</sup>

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- data on the stability of the control product under normal conditions of storage and display and its compatibility with other control products with which it is recommended or likely to be mixed.

<sup>236</sup> *PCPR*, s. 9(2)(b) (Annex R-2).

<sup>237</sup> *PCPR*, s. 9(1) (Annex R-2). This data typically is to demonstrate that use of the product will not lead to an unacceptable risk of harm to either the things on which the product is to be used, or to “public health, plants, animals or the environment” (s.19).

<sup>238</sup> *PCPR*, s. 14(1) (Annex R-2).

<sup>239</sup> *PCPR*, s. 14(2) (Annex R-2).

<sup>240</sup> *PCPR*, s. 18 (Annex R-2).

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**2. The PMRA ensured accelerated registration of Chemtura's lindane replacement products, providing Chemtura a substantial first-to-market advantage**

241. The PMRA upheld its undertaking to review "lindane-free" formulations as well as the first 3 lindane replacement actives submitted to it by November 1998.<sup>241</sup>

242. "Lindane-free" products were registered products combining lindane with fungicide active ingredients, re-formulated by removing the lindane. These effectively became fungicide-only products. The CCGA letter of November 26, 1998 confirmed that any registrant wishing to gain approval for a "lindane-free" seed treatment in time for the 1999 canola seeding had to make a formal request to the PMRA by December 31, 1999. The Claimant's product of this nature, Vitavax rs Fungicide, was granted amended registration on May 3, 1999.

243. "Lindane replacement products" were products in which a different insecticide active ingredient was registered as an alternative to lindane. Review of these replacement products was a bigger undertaking, as it potentially involved the review by the agency of unregistered insecticide active ingredients, or of new uses of registered insecticide active ingredients.

244. These three products included Gaucho, proposed by Chemtura Canada.<sup>242</sup> This was the same Gaucho product sold by Gustafson, the Claimant's U.S. subsidiary and the company that had incited the EPA to ban imported lindane-treated canola into the United States.<sup>243</sup>

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<sup>241</sup> This was confirmed by the discussion at the June 24, 1999 meeting: Minutes of meeting organized by CCC/CCGA to monitor implementation of the VWA and progress on lindane replacements, 24 June 1999 (Exhibit WS-29).

<sup>242</sup> Imidacloprid, the active ingredient in Gaucho, was the first of a new class of insecticide active ingredient, the neonicotinoids. The active used in Syngenta's Helix product, thiamethoxam, was also a neonicotinoid. These products were developed as alternatives to older classes of pest control products such as the organophosphate and organochlorine insecticides. Affidavit of Suzanne Chalifour, ¶ 27.

<sup>243</sup> Affidavit of Suzanne Chalifour, ¶ 54.



245. Even before the growers, registrants, and the PMRA met to discuss the terms of the VWA, the PMRA had already granted registration to the Claimant's Gaucho 75 ST.<sup>244</sup> While this initial registration was for export only, it was the first lindane replacement product for canola to be available to Canadian seed treaters.<sup>245</sup> Chemtura was thus well-placed, even as of the summer of 1998, to offer a replacement product for lindane for the export market to the United States that was unaffected by asymmetrical registrations between Canada and the United States.

246. In June 1998, Chemtura applied to the PMRA to have its Gaucho 75 ST application expanded to include domestic use.<sup>246</sup> By early August 1998, the PMRA had completed its initial review of this request, and determined that it met the criteria for a Category A submission as a major new application – a more stringent standard of review reflecting the intended domestic use of the expanded registration.<sup>247</sup>

247. After exchanges concerning the data required for this submission, the PMRA agreed to waive certain data requirements<sup>248</sup> and by October 21, 1998, the application had been forwarded to the appropriate PMRA scientific sections for preliminary review.

248. On November 4, 1998, the Claimant submitted its application for registration of a second formulation, Gaucho 480 FL.<sup>249</sup>

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<sup>244</sup> This occurred on 4 August 1998: Letter from Jennifer Hamm Craig, PMRA, to Rob Dupree, Uniroyal Chemical, 4 August 1998 (Exhibit SC-8). In his witness statement, Mr. Ingulli alleges that "Gaucho, with the insecticide imidacloprid, had been registered by the PMRA for use on canola seed destined for export in November 1996." Mr. Ingulli's allegation is unsupported by the registration history (and indeed he himself cites nothing in support of his allegation), and is simply incorrect. *See* Witness Statement of Alfred Ingulli, ¶ 63.

<sup>245</sup> Letter from Jennifer Hamm Craig, PMRA, to Rob Dupree, Uniroyal Chemical, 4 August 1998 (Exhibit SC-8). This product was a wettable powder formulation.

<sup>246</sup> Letter from Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada), to Submission Screening Section, PMRA, 16 June 1998 (Exhibit SC-9).

<sup>247</sup> Letter from Roy Lidstone, PMRA, to Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada), 6 August 1998 (Exhibit SC-10). Each subsequent category of submission has a less onerous data requirement. *See* Affidavit of Suzanne Chalifour, ¶ 14. *See* PMRA, *Regulatory Proposal PRO96-01: Management of Submissions Policy*, 7 June 1996 (Exhibit SC-1).

<sup>248</sup> Letter from Richard McDonnell, PMRA, to Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada), 25 August 1998 (Exhibit SC-11).

249. The applications for Gaucho 480 FL and Gaucho 75 ST were considered together in the preliminary review for deficiency, and data deficiencies that had to be rectified for both submissions were identified together.<sup>250</sup> The reviews for Gaucho 75 ST and Gaucho 480 FL were synchronized as much as possible, since they mainly relied on the same data.<sup>251</sup> This practice of considering a later application or use change concurrently with a pre-existing application is known as “tailgating”.<sup>252</sup>

250. The PMRA completed its evaluation for temporary registration of both Gaucho 75 ST and 480 FL on July 27, 1999. After the Claimant supplied the PMRA with labels in accordance with the PMRA's requirements, it registered Gaucho 480 FL temporarily on October 26, 1999.<sup>253</sup> On November 25, 1999, the PMRA also registered Gaucho 75 ST temporarily.<sup>254</sup> These time-limited offers (one-year) of registration were contingent on

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<sup>249</sup> Letter from Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada), to Submission Screening Section, PMRA, 4 November 1998 (Exhibit SC-12). This application was submitted on behalf of Gustafson Canada, Inc. However, as it was a subsidiary of the Claimant at the time, we refer to “the Claimant” without differentiating between the two Canadian subsidiaries.

Unlike the powdered formulation Gaucho 75 ST, Gaucho 480 FL was a liquid formulation (as implied by the FL in its name, for “flowable”). Since the active ingredient, imidacloprid, was not currently registered for use on canola in Canada, the registration would be considered a major new use, a Category A.2 submission. See Affidavit of Suzane Chalifour, ¶ 28. Letter from Roy Lidstone, PMRA, to Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada), 23 December 1998 (Exhibit SC-13).

<sup>250</sup> Letter from Richard Aucoin, PMRA, to Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada), 29 March 1999 (Exhibit SC-54).

<sup>251</sup> Memorandum from Hemendra Mulye, PMRA, to Suzanne Chalifour, PMRA, 8 April 1999 (Exhibit SC-55).

<sup>252</sup> Tailgating refers to the practice of piggy-backing a review on an earlier application part-way through the review process (*e.g.*, to add a new use site, tank mix or application rate to earlier proposed uses claims). The PMRA has a “no tailgating” policy in place to help meet its performance standards, and to ensure that it uses its limited resources efficiently. When applicants are permitted to tailgate, evaluators often end up having to go back and repeat work which they have already completed, as changes to the formulation or use claims may mean that the conclusions reached in the previous evaluation are no longer entirely accurate (*e.g.*, the exposure assessment may differ). While the PMRA discourages tailgating, since it makes it difficult to meet performance standard commitments, on occasion, it has worked with registrants on a case-by-case basis. Affidavit of Suzanne Chalifour, ¶¶ 68, 71.

<sup>253</sup> PMRA Public Registry, entry for Gaucho 480 FL (Exhibit SC-16).

<sup>254</sup> Letter from Sean Muir, PMRA, to Rob Dupree, Gustafson Partnership (business unit of Chemtura Canada), 25 November 1999 (Exhibit SC-17).

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the receipt and acceptable review of residue data. Both registrations were valid until December 31, 2000.<sup>255</sup>

251. The Claimant also applied to the PMRA to amend the Gaucho 480 FL label to include use on more pests in the same month as it received temporary registration of that product.<sup>256</sup> This submission was accepted by PMRA as a “Category C” Submission.<sup>257</sup>

252. Gaucho 480 FL and Gaucho 75 ST remained the only Canadian-registered alternatives to lindane from October 1999 to November 2000. At that time, the PMRA registered a competitor product, Syngenta's Helix, following a two-year period of review. Chemtura obtained a first-to-the market advantage of over one year, and indeed of more than two years, given the PMRA's registration of Gaucho 75 ST for treatment of seed for export in August 1998.

### **3. The PMRA approved Helix, Syngenta's competing replacement product, 18 months after its approval of Chemtura's replacement formulations**

253. In November 1998, Syngenta (Novartis) submitted for registration review a lindane replacement product called Helix, based on the active ingredient thiamethoxam. The Claimant argues that Helix is not a “replacement product” because it was not submitted for registration by a former lindane registrant.<sup>258</sup> This narrow definition of replacement products is not accurate. Helix, as an insecticide that was effective against the same pests as lindane (*i.e.* flea beetles on canola) was considered a replacement product by canola producers.

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<sup>255</sup> Letter from Wayne Ormrod, PMRA, to Rob Dupree, Gustafson Partnership (business unit of Chemtura Canada), 27 July 1999 (Exhibit SC-14); Letter from Wayne Ormrod, PMRA, to Sue-Chi Shen, Gustafson Partnership (business unit of Chemtura Canada) 27 July 1999 (Exhibit SC-15).

<sup>256</sup> The Claimant argues that when its competitor, Syngenta, was permitted to add a new use-site to a temporarily-registered product, Syngenta was receiving preferential treatment. Claimant's Memorial, ¶ 251. Yet the Claimant received exactly the same treatment.

<sup>257</sup> Letter from Sean Muir, PMRA, to Bob Chyc, Gustafson Partnership (business unit of Chemtura Canada), 16 December 1999 (Exhibit SC-18).

<sup>258</sup> Claimant's Memorial, ¶ 234.

254. In the year following its initial submission in November 1998, the PMRA repeatedly asked Novartis (Syngenta) for more information to ensure the data met the high standards of a Category A submission. This practice was consistent with the PMRA's standard screening procedure.<sup>259</sup>

255. In early January 2000 the PMRA, the EPA, and Novartis met to discuss the occupational exposure data for Helix.<sup>260</sup> At this meeting, the PMRA and the EPA decided that the surrogate occupational exposure study submitted by Novartis was not adequate to determine whether Helix would be safe for workers, and required a full Helix exposure study.<sup>261</sup>

256. The PMRA issued a public Regulatory Note in mid-February, 2000, addressing the delay in the registration of Helix to allow for completion of the non-substitute occupational exposure study, which the PMRA and the EPA had deemed necessary to “fully characterize worker exposure to Helix in commercial seed treatment plants”.<sup>262</sup>

257. The resulting delay came at a time of considerable pressure from growers to register alternatives to lindane. The year 2000 was the second-last season of the phase-out of lindane under the VWA. This meant that lindane would only be available for one more season. Although the PMRA had registered 2 versions of the Claimant's replacement product (Gaucho 75 ST and 480 FL) as of November 1999, canola producers

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<sup>259</sup> PMRA, *Regulatory Proposal PRO96-01: Management of Submissions Policy*, 7 June 1996 (Exhibit SC-1).

<sup>260</sup> See PowerPoint slides of Presentation by the PMRA to Syngenta and the EPA, “Helix Operator Exposure Assessment – Background” (Exhibit SC-39). This meeting was pursuant to the Mandate of the Joint Review of Chemical Pesticides Subcommittee, which was operating under the NAFTA Technical Working Group (TWG) on pesticides. Helix was one of a number of pesticides being reviewed as a work-share under this project. Imidacloprid, the active ingredient in Gaucho, was also reviewed collaboratively by the EPA and the PMRA. See U.S. EPA, *Joint Reviews – Conventional Chemicals Project Sheet*, November 2007 (Exhibit SC-36); See also Affidavit of Suzanne Chalifour, ¶¶ 42-47.

<sup>261</sup> Letter from Judy Shaw, Manager, Governance & Public Affairs, Novartis, to Jeff Parsons, PMRA, 10 January 2000 (Exhibit SC-41).

<sup>262</sup> PMRA Regulatory Note Reg2000-01, *Delay on Helix Registration Decision*, 16 February 2000 (Exhibit SC-42).

were finding it a relatively ineffective insecticide.<sup>263</sup> The PMRA continued to insist on appropriate review standards for this new active, even if it delayed the registration of Helix by another season.

258. In the midst of the registration process, the PMRA asked Syngenta to submit a half-rate Helix product. This product had the same formulation as the first product, but had a lower concentration of the active ingredients (reducing the amount of exposure to people and the environment, yet also potentially affecting the length of time that the product would be effective). The day after the Regulatory Note was released, Judy Shaw of Novartis wrote to the PMRA's Wendy Sexsmith, expressing her understanding that the registration for half-rate Helix (Helix 156 FS) could be submitted for registration along with the pre-existing registration for Helix 289 FS (later known as Helix XTra).<sup>264</sup>

259. On November 27 and 29, 2000, Helix and Helix XTra were registered for use in Canada.<sup>265</sup> The PMRA released a Regulatory Note concerning the registration of the 2 Helix products in February 2001. These products, like the Claimant's Gaucho 75 ST and 480 FL, were granted only temporary registration, pending additional toxicology and value studies to be conducted by the registrant.<sup>266</sup>

#### **4. Gustafson submitted a complete application for Gaucho CS FL nearly two years later than Syngenta's Helix submission**

260. On March 21, 2000, the Claimant submitted a registration application for Gaucho CS FL which, unlike its previous Gaucho formulations, mixed the insecticide

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<sup>263</sup> Affidavit of JoAnne Buth, ¶ 31; See also PMRA Regulatory Note REG2000-01, *Delay on Helix Registration Decision*, 16 February 2000 (Exhibit SC-42); and *EPA Federal Register*, Vol. 64, No. 240, p. 70018, 15 December 1999 (Exhibit SC-37).

<sup>264</sup> Letter from Judy Shaw, Manager, Government & Public Affairs, Novartis, to Wendy Sexsmith, PMRA, 17 February 2000 (Exhibit SC-57).

<sup>265</sup> PMRA Public Registry entry for Helix (Exhibit SC-43); PMRA Public Registry entry for Helix XTra (Exhibit SC-44).

<sup>266</sup> PMRA Regulatory Note REG2001-03, *Thiamethoxam, Helix, Helix XTra*, 9 February 2001 (Exhibit SC-45). With the new *PCPA*, which came into force on June 28, 2006, provisions in the former regulations regarding temporary registrations have been repealed and replaced by provisions reflecting certain policies associated with "conditional registrations"; Affidavit of Suzanne Chalifour, ¶ 50.

imidacloprid with a fungicide (a so-called “all in one” formulation). In the cover letter attached to the registration application, the Claimant indicated that the product was a lindane replacement product, and requested expedited review of the submission by September 15, 2000, “in the same timeframe as per the original agreement”.<sup>267</sup> Given the date of its letter (March 2000), the Claimant’s expectation at the time appeared to be that the “timeframe as per the original agreement” was six months (as opposed to the three months it now claims).<sup>268</sup> This expectation found no support in any of the PMRA’s communications concerning the registration of replacement products or active ingredients. It was also much shorter than even the process for Gaucho 480 FL, which fell under the PMRA’s undertaking to review in priority the 3 formulations submitted to it by the end of 1998: even that process took nearly a year.<sup>269</sup>

261. Chemtura’s real expectation had been confirmed by Mr. Hallatt in his April 29, 1999 letter, where he confirmed Wendy Sexsmith’s comment of November 1998 that the review of replacement products could take up to 18 months.<sup>270</sup>

262. On April 20, 2000, the PMRA confirmed that it had only committed to fast-tracking the applications for lindane-free products.<sup>271</sup> The PMRA noted that it had not committed to expedite the review of all lindane replacement products, and that it was important for the PMRA to respond to all requests in an equitable manner. The PMRA also re-stated its consistent position that, whatever process may be used to register

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<sup>267</sup> Letter from Adam Vaughan, Gustafson Partnership (business unit of Chemtura Canada), to PMRA, 21 March 2000 (Exhibit SC-23).

<sup>268</sup> Claimant’s Memorial, ¶ 225.

<sup>269</sup> The application for Gaucho 480 FL was submitted in November 1998, and the product was granted temporary registration in October 1999.

<sup>270</sup> Letter from Bill Hallatt, Gustafson Partnership, to Dr. Claire Franklin, PMRA, 29 April 1999 (Exhibit SC-53).

<sup>271</sup> This was consistent with the message Dr. Franklin had communicated in her letter of 9 February 1999 and 25 March 1999. See Letter from Dr. Claire Franklin, Executive Director, PMRA, to Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, 9 February 1999 (Exhibit WS-25); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 25 March 1999 (Exhibit WS-28).

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replacement products, it would not entail a predetermined position to register any products before a review had been completed.<sup>272</sup>

263. After this initial exchange, Mr. Ingulli wrote to the PMRA's Executive Director, Dr. Claire Franklin, expressing "surprise" that PMRA did not consider it had a commitment to expedite the review of Gaucho CS FL.<sup>273</sup> Mr. Ingulli cited his letter of December 17, 1998, in which he had requested expedited review of a lindane replacement insecticide-fungicide product, as evidence that such a term was an element of the VWA.

264. In response, Dr. Franklin wrote to Mr. Ingulli, indicating that the PMRA had "opened the door" to lindane replacement products for a short period of time, rather than creating an open-ended promise to expedite review of any lindane-free canola product. Dr. Franklin reminded Mr. Ingulli that three products had been submitted for registration under the limited agreement to expedite and that, in fact, the only registered replacement product to date was Chemtura's Gaucho.<sup>274</sup> As Canada has demonstrated, Gaucho 75 ST was registered for export use in August 1998, and for domestic use in November 1999, and Gaucho 480 FL was registered for use in Canada in October 1999.

265. Dr. Franklin also drew Mr. Ingulli's attention to her letter of February 9, 1999, which carefully reiterated the agreed terms of the VWA (and did not include any agreement to expedite the registration of replacement products), and clarified that the PMRA and the EPA had committed to facilitate the registration of replacement products through joint review, rather than through a perpetual commitment to expedited registrations.

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<sup>272</sup> Letter from Gil Flores, PMRA, to Adam Vaughan, Gustafson Partnership (business unit of Chemtura Canada), 20 April 2000 (Exhibit SC-24).

<sup>273</sup> Letter from Alfred Ingulli, Executive Vice President, Crompton (predecessor-in-title to Chemtura), to Dr. Claire Franklin, Executive Director, PMRA, 15 May 2000 (Exhibit SC-25).

<sup>274</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA, to Alfred Ingulli, Executive Vice President, Crompton, 21 June 2000 (Exhibit SC-22).

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266. The following month, Mr. Ingulli asked to meet Dr. Franklin face-to-face, in order to discuss “the difference of opinion that exists around Uniroyal’s commitment to a voluntary removal of canola from our lindane containing seed treatment label and our understanding of the PMRA’s commitment in return”, as well as some new data that the Claimant and affiliates wished to share with the PMRA.<sup>275</sup>

267. At the time Mr. Ingulli was requesting a meeting to discuss the PMRA’s consideration of lindane alternatives, the PMRA completed its initial screening for deficiencies of the Gaucho CS FL submission. This screening determined that there was data missing. The PMRA therefore sent a Deficiency Review Note to the Claimant, listing the outstanding data requirements.<sup>276</sup> The Claimant responded to the Note on September 7, 2000, with information to correct the identified deficiencies.<sup>277</sup> These delays, which were in the Claimant’s hands, added to the overall timeline for the completion of the registration review.<sup>278</sup>

268. Representatives from the Claimant and the PMRA met on October 4, 2000 to discuss a variety of issues, including the registration of replacement products.<sup>279</sup> Following this meeting, on October 6, 2000, the Claimant wrote to the PMRA, indicating that the “misunderstanding” regarding priority review of replacement products was

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<sup>275</sup> Letter from Alfred Ingulli, Executive Vice President, Crompton, to Dr. Claire Franklin, Executive Director, PMRA, 28 July 2000 (Exhibit SC-26).

<sup>276</sup> Letter from Sean Muir, PMRA, to Adam Vaughan, Gustafson Partnership (business unit of Chemtura Canada), 27 July 2000 (Exhibit SC-29).

<sup>277</sup> Letter from Adam Vaughan, Gustafson Partnership (business unit of Chemtura Canada), to Sean Muir, PMRA, 7 September 2000 (Exhibit SC-30); Internal Memorandum re: *Gaucho CS FL Formula Modification* from John Kibbee, Gustafson Partnership Formulation Group, to Adam Vaughan, Gustafson Partnership (business unit of Chemtura Canada), 24 August 2000 (Exhibit SC-31).

<sup>278</sup> In September 2000, the Claimant submitted its application to register another Gaucho product, Gaucho 600 FL. This product was similar to the previously-registered Gaucho 480 FL, but had a higher concentration of the active ingredient, and therefore required the application of less product per unit of seed. This product was eventually registered, in 2003, bringing the Claimant’s total number of registered Gaucho products to four. Letter from Wendy Sexsmith, PMRA, to Adam Vaughan, Gustafson Partnership (business unit of Chemtura Canada), 5 February 2003 (Exhibit SC-21).

<sup>279</sup> Alfred Ingulli handwritten notes from meeting with Dr. Claire Franklin, Executive Director, PMRA, 4 October 2000 (Exhibit SC-27). See also Affidavit of Dr. Claire Franklin, ¶¶ 32-34.



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“behind us now”, and expressing a wish to move forward on the submission for Gaucho CS FL in the most expedient manner possible.<sup>280</sup>

269. As proposed in its letter of October 6, 2000, Gustafson Partnership submitted its acute toxicity studies for Gaucho CS FL, along with product chemistry studies and additional efficacy reports and summaries, by the end of October. The PMRA did not have all data required to complete its review of Gaucho CS FL until over a month after the Claimant's initial September 15, 2000 deadline for registration.<sup>281</sup>

270. On October 26, 2000, the same day that it submitted its toxicity studies and efficacy reports for the Gaucho CS FL registration, the Claimant also notified the PMRA about an optional tank mix for Gaucho CS FL.<sup>282</sup> This change amounted to a new application rate to the proposed use claims. Although contrary to the PMRA's no-tailgating policy, this inclusion of two rates of application was permitted by the PRMA, like the amendment to the Helix registration.<sup>283</sup>

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<sup>280</sup> Letter from Rick Turner, President, Gustafson Partnership (business unit of Chemtura Canada), to Wendy Sexsmith, PMRA, 6 October 2000 (Exhibit SC-28). Contrary to the Claimant's current allegations, the Claimant's letter expressly waived all claims to an expedited review, stating that “it has been brought to our attention by PMRA that this submission will not be given priority review status. It is unfortunate that there has been a misunderstanding”. Claimant's Memorial, ¶¶ 225, 411-412. This letter confirms that the issue had been addressed at the meeting, contrary to Mr. Ingulli's allegation that the PMRA “refused to discuss” replacement products. Witness Statement of Alfred Ingulli, ¶ 158. Indeed, the Claimant went on to ask for an exception to the normal data call-in process, and proposed a timeline for the provision of new information which would include the submission of a new acute toxicity study by 31 October 2000, and completion of the review by 1 October 2001 (in time for the 2001-2002 seed treatment season).

<sup>281</sup> The Claimant suggests that the extension of time granted to Syngenta for submission of the Helix occupational exposure study was highly unusual, but the late submission confirms that Claimant itself received similar treatment. Claimant's Memorial, ¶ 238.

<sup>282</sup> This change would involve mixing the product with Gaucho 480 FL, in order to increase the amount of imidacloprid (the lindane-replacement insecticide active) without increasing the amounts of carbathiin and thiram (the fungicide actives). Letter from Adam Vaughan, Gustafson Partnership (business unit of Chemtura Canada), to Sean Muir, PMRA, 26 October 2000 (Exhibit SC-34).

<sup>283</sup> Affidavit of Suzanne Chalifour, ¶ 72.

271. The process for the registration of Gaucho CS FL continued through late 2000 and into 2001. Further deficiencies were identified and further data requested.<sup>284</sup> All of these data call-ins took time, and increased the overall time for review of this application.

272. The claimant contends that the PMRA took considerably longer to process the application to register Gaucho CS FL than the applicable performance standard of 462 days to process a Category B.2.6 submission for a new end-use product which was a new combination of active ingredients.<sup>285</sup> However, PMRA performance standards do not include time periods when a submission is pending response from the applicant. This submission was awaiting a response from the applicant for almost 200 of those days beyond the performance standards.<sup>286</sup>

273. Furthermore, many amendments and changes were allowed during the level D review timeframe which ordinarily should have been considered in a separate submission once a decision had been made regarding the initial application. These additions and changes also slowed the registration review process but ultimately saved the claimant more time than had the amendments been considered as separate submissions.<sup>287</sup>

## 5. Helix and Gaucho were treated equally

274. The Claimant alleges that the PMRA granted preferential terms of registration to its competitor Syngenta's replacement product Helix, prejudicing Chemtura's position in the lindane replacement-products market.<sup>288</sup> This is untrue. As demonstrated, the PMRA

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<sup>284</sup> Internal Memorandum re: *Gaucho CS Flowable* from Suzanne Chalifour, PMRA, to Leo Bouthillier, PMRA, 18 December 2000 (Exhibit SC-46). See Affidavit of Suzanne Chalifour, ¶ 60.

<sup>285</sup> See Exhibit D1 of the Witness Statement of John Kibbee.

<sup>286</sup> Affidavit of Suzanne Chalifour, ¶ 59. Second level A (7 days), B (45 days) and level C (120 days) reviews of this application were required to address the applicant's response to deficiencies. The PMRA took only a portion of the allotted time, as these levels were completed in only 75 days. When these delays and additional performance times are considered, the PMRA did meet performance standards for its review of the submission. Affidavit of Suzanne Chalifour, ¶ 60.

<sup>287</sup> Affidavit of Suzanne Chalifour, ¶ 61.

<sup>288</sup> Claimant's Memorial, ¶¶ 209-210, 254.

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registered Gaucho formulations a year before it registered Syngenta's Helix. Further, the registration process for Helix proceeded in accordance with normal PMRA policy.<sup>289</sup>

275. Over the course of their respective registration reviews, Helix and Gaucho received the same treatment. In particular:

- *Tailgating*. To manage its resources effectively, the PMRA typically discourages the practice of joining a new product review to an ongoing review of a related product. The PMRA relaxed this policy both for Gaucho and for Helix.<sup>290</sup>
- *Time to submit additional data*. The PMRA provides a defined time in the review process to address data deficiencies in a registration submission. The PMRA granted extensions to both Gaucho and Helix.<sup>291</sup>
- *Temporary registration*. The PMRA initially registered both Gaucho and Helix products on a temporary basis, consistent with its standard practice. Both were allowed to add new uses despite this temporary status.<sup>292</sup>

276. The Claimant cites other instances of Helix's registration as evidence of preferential treatment. It has in each case mischaracterized the relevant facts:

- *Coloured seed*.<sup>293</sup> A PMRA Regulatory Directive says that canola seed treatments should be light blue.<sup>294</sup> However, in 2002 it was generally agreed that this policy was inflexible and out of date with evolving seed coating practices. The decision to allow a green-coloured Helix, which is consistent with the requirement in the *Seeds Regulations* that treated seeds be dyed a "conspicuous colour."<sup>295</sup> was reached in accordance with current practice, and after consultation with several stakeholders, (including Syngenta, Bayer Corporation and the CCC). Stakeholders, including the Canadian Grain Commission and Gustafson, expressed concern about the use of a green dye,

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<sup>289</sup> Affidavit of Suzanne Chalifour, ¶¶ 40-49.

<sup>290</sup> Affidavit of Suzanne Chalifour, ¶¶ 69-72.

<sup>291</sup> Affidavit of Suzanne Chalifour, ¶¶ 73-84.

<sup>292</sup> Affidavit of Suzanne Chalifour, ¶¶ 73-84.

<sup>293</sup> Claimant's Memorial, ¶¶ 244-246.

<sup>294</sup> Regulatory Directive 94-06, Colour Standards for Seed Treatment Products and Labelling of Treated Seed, 30 March 1994 (Exhibit SC-68).

<sup>295</sup> *Seeds Regulations*, C.R.C. c. 1400, s. 20 (Exhibit SC-67).

and so PMRA overturned this decision and Syngenta was asked to remove the green colourants from their formulations.<sup>296</sup>

- *Groundwater warnings.*<sup>297</sup> All proposed pesticide products are given a pre-market assessment based on sound scientific principles current at the time of review. These risk assessment methods, policies, and labelling statements evolve over time in response to developments in science. The continual updating of assessment methods accounts for the differences in the environmental statements noted on clothianidin (Prosper) and thiamethoxam (Helix) end-use product labels. Environmental labelling statements were standardized formally in 2003, and water exposure modelling started in mid-2001. These will be periodically modified as additional information becomes available. Later registered thiamethoxam products have label statements warning against leaching to groundwater.<sup>298</sup>
- *Product efficacy.* The value assessment in the Regulatory Note concluded that both Helix and Helix XTra provided very good and consistent early-season control of flea beetles on canola and mustard. Regarding fungicides, the value assessment determined that the product should be used at a full rate to ensure effectiveness.<sup>299</sup>
- *Product Stewardship.* Occupational exposure mitigation measures were considered and implemented in the Helix registration. It is common practice for the PMRA to consider such measures in the case of a new registration, where the product is not yet in use. In the case of re-evaluation of an existing registration, the PMRA does not offer identical opportunities, given that the product is in current use and may be causing health or environmental harm.<sup>300</sup>

## V. THE PMRA DECIDED ON SCIENTIFIC GROUNDS TO WITHDRAW ALL LINDANE AGRICULTURAL USES

### A. Overview

277. Having described the events relating to the VWA and related issues regarding the use of lindane in canola, in the section that follows Canada will review the facts concerning the PMRA's Special Review of Lindane.

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<sup>296</sup> Affidavit of Suzanne Chalifour, ¶ 94.

<sup>297</sup> Claimant's Memorial, ¶ 242.

<sup>298</sup> Affidavit of Suzanne Chalifour, ¶ 97.

<sup>299</sup> Affidavit of Suzanne Chalifour, ¶ 88; PMRA Regulatory Note REG2001-03, *Thiamethoxam, Helix, Helix XTra*, 9 February 2001 (Exhibit SC-45).

<sup>300</sup> Affidavit of Suzanne Chalifour, ¶¶ 98-101.

**B. The lindane Special Review was conducted in a fair and scientifically sound manner and determined that lindane was a dangerous product that should be deregistered**

**1. Multiple developments indicated a need for such review, launched by the PMRA in 1999**

278. On March 15, 1999 the PMRA announced a Special Review of Lindane. Pursuant to the *PCPA*, a Special Review is a re-evaluation of an existing pesticide registration undertaken when the PMRA has reason to believe that active ingredient risks are causing harm to human health or the environment.<sup>301</sup>

279. The Special Review of lindane was launched after nearly 3 decades of progressive retrenchment of lindane registrations, in Canada and around the world. A long series of events in 1997 and 1998 prompted the Special Review of lindane. These included:

- In 1997, the Northern Contaminants Program had published the Canadian Arctic Contaminants Assessment Report, identifying hexachlorocyclohexanes (HCHs, otherwise known as lindane and its isomers) as the most abundant organochlorine contaminant found in arctic air, water and snowfall, eliciting international demands to further ban lindane use;<sup>302</sup>
- In 1997, Canada and the United States had signed the *Canada-United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes Basin*, under which lindane and other HCH isomers were listed as Level II substances, *i.e.*, identified as having the potential to persist in the environment, bioaccumulate and have toxic effects. Under the Strategy, both governments committed to pollution prevention for Level II substances;<sup>303</sup>

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<sup>301</sup> Affidavit of John Worgan, ¶ 23. A Special Review is launched for pest control products for which:

- a potentially serious adverse effect has been identified in a review document, in an international forum or through submitted data;
- national or international commitments require the PMRA to address a particular aspect of health or environmental safety; or
- emerging issues indicate that a regulatory follow-up is required.

See *PCPR*, s. 19 (Annex R-2).

<sup>302</sup> Affidavit of Cheryl Chaffey, ¶ 47.

<sup>303</sup> Affidavit of Cheryl Chaffey, ¶ 48.

- The Joint Meeting on Pesticides Residues (JMPR) had, in 1997, confirmed previous immunotoxicity concerns relating to lindane.<sup>304</sup> Based on the JMPR results, the PMRA, by the spring of 1998, had already begun to reassess its own database and safety thresholds for remaining lindane uses,<sup>305</sup>
- In 1998, Canada ratified the Aarhus Protocol to the UN Economic Commission for Europe (UNECE) *Convention on Long Range Transboundary Air Pollution Chemicals*. The Protocol listed lindane as a pollutant, and required signatories to review lindane;<sup>306</sup>
- In 1998, a number of European countries added lindane to the List of Chemicals for Priority Action under the *OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic*, further signalling the international focus on the human health and environmental effects of lindane;
- The EPA launched a re-evaluation of remaining lindane uses in 1998; and
- Finally, on January 15, 1999, the Commission for Environmental Cooperation (CEC), an organization established under the North American Agreement on Environmental Cooperation (NAAEC),<sup>307</sup> was presented with a nomination by the United States for a North American Regional Action Plan (NARAP) concerning lindane.<sup>308</sup>

280. All of these steps and related concerns laid the groundwork for the PMRA announcement of a Special Review of Pesticide Control Products Containing Lindane (Special Review) on March 15, 1999.<sup>309</sup>

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<sup>304</sup> Affidavit of Cheryl Chaffey, ¶ 47; Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues and WHO Core Assessment Group on Pesticide Residues, *Pesticide Residues in Food*, 1997 (Exhibit CC-15).

<sup>305</sup> Affidavit of Cheryl Chaffey, ¶ 55; PMRA Memorandum to Donald Grant, Director, HED from Suzanne Giertson, Evaluation officer, HED, *Lindane*, 20 May 1998 (Exhibit CC-18); PMRA Memorandum to Donald Grant, Director, HED from Ratna Bose, evaluation officer, HED immunotoxicological cancer of lindane, 24 June 1998 (Exhibit CC-19); Health Canada, memorandum to Mary Jane Kelleher, insecticide section, PSCD, from Donald Grant, HED, *Lindane – ADI assessment*, 25 June 1998 (Exhibit CC-20).

<sup>306</sup> As of July 1998, before the VWA was confirmed, the PMRA had already set up a Project Team to work out a plan of Special Review of lindane and had developed a rough schedule, intended to comply with Canada's Aarhus commitments. PMRA, *Project Sheet on the Special Review of Lindane*, July 1998 (Annex R-15).

<sup>307</sup> The NAAEC is the environmental side agreement to the NAFTA which facilitates cooperation between the NAFTA State Parties on environmental issues. Affidavit of Cheryl Chaffey, ¶ 53.

<sup>308</sup> Affidavit of Cheryl Chaffey, ¶ 53.

<sup>309</sup> *Lindane Special Review Announcement*, 15 March 1999 (Exhibit WS-32).

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## 2. The PMRA launched an extensive program of re-evaluation in the late 1990s

281. The Special Review of lindane fell under the general category of pesticide re-evaluations, i.e. reviews of currently-registered pesticides to determine whether such registrations continued to meet current safety standards. The lindane Special Review was launched at a time when the PMRA was initiating a major general program of re-evaluation of older registrations. The Special Review, as a type of re-evaluation, became subject to the policies developed in the context of that much larger program.

282. As of 1999, approximately 550 pesticide active ingredients were registered under the *PCPA* for use in Canada.<sup>310</sup> At the time of their initial registrations – which, in some cases, could go back decades – these pesticides were considered acceptable on the basis of an assessment of their safety and value. But the science underlying these assessments is continually evolving, and new methodologies and tools are integrated into regulatory risk assessments. Furthermore, re-evaluation of older pesticides can take into consideration the full extent of the current use patterns of the active ingredients, the diversity of their end-use products, and their market penetration. Such parameters would not have been fully apparent at the time of initial registration.

283. In the twentieth century, most re-evaluations of existing pesticide registrations in Canada proceeded on an *ad hoc* basis.<sup>311</sup> However, resource considerations and practical

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<sup>310</sup> Affidavit of John Worgan, ¶ 27.

<sup>311</sup> Agriculture Canada, the department responsible at that time for administering the *PCPA*, reviewed this history on 20 May 1986 in its Memorandum to Registrants R-1-226: Agriculture Canada, Memorandum to Registrants R-1-226, *Re-evaluation of Registered Products*, 20 May 1986 (Exhibit JW-4).

The first compounds re-evaluated in Canada were the organochlorines, in relation to environmental persistence and accumulation in food chains, effects on birds and fish, and possible carcinogenicity. This resulted in severe restrictions on the use pattern or outright deregistration of aldrin, dieldrin, heptachlor endrin, BHC, toxaphene, DDT and others. Reviews of the mercurials, arsenicals, and many of the carbamates and organophosphates followed. A review of the EBDC's was initiated in response to concerns regarding safety of breakdown products after cooking. More recently, 2, 4-D has been re-evaluated, with establishment of a standard for a maximum level of certain dioxins potentially present in the technical ingredient.

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difficulties – notably, delays caused by lengthy periods of data-collection from registrants – significantly slowed this process. As a result, the responsible agencies undertook a policy review in the early 1990s, to determine a more effective strategy.<sup>312</sup>

284. Canada's review of its pesticides re-evaluation policy was extensive, drawing on a multi-stakeholder review<sup>313</sup> that was adopted by the mid-1990s in a formal governmental proposal.<sup>314</sup> This policy-building process was part of a major overhaul of Canada's pest management system.<sup>315</sup> This overhaul notably included the formation of the PMRA as a branch of Health Canada in 1995.<sup>316</sup>

285. The extensive policy consideration in the 1990s led to the launch of the PMRA's systemic re-evaluation program in 1999, which would eventually encompass over 400 "old" pesticides, including lindane.

286. The policy process of the 1990s incorporated public input on the conduct of Canada's re-evaluation program. By December 1999 the PMRA had published for public

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Lindane is an organochlorine, among the first "old" pesticides that the PMRA had targeted for re-evaluation, even before a systematic re-evaluation programme was launched in the late 1990s. Memorandum R-1-226 proposed a mechanism to prioritize 452 active ingredients for re-evaluation, including lindane. Agriculture Canada and Health Canada subsequently engaged in this prioritization exercise, and began re-evaluating a series of older registrations.

<sup>312</sup> Affidavit of John Worgan, ¶ 32.

<sup>313</sup> Stakeholder participants included Crop Life Canada, the industry association that represented the major pesticide registrants, including Chemtura Canada. See Pesticide Registration Review Team, *Recommendations for a Revised Federal Pest Management Regulatory System*, Final Report (Blue Book), December 1990 (Exhibit CF-1).

<sup>314</sup> Government of Canada, *Government Proposal for the Pest Management Regulatory System*, Final Report (Purple Book), October 1994 (Exhibit CF-2); see also Affidavit of Dr. Claire Franklin, ¶¶ 9-16.

<sup>315</sup> Canada's renewed policy focus on re-evaluation was further encouraged by the introduction in the United States in 1996 of the *FQPA* (Annex R-4). The *FQPA* instituted important new policies, including consideration of aggregate exposure and cumulative risk (*i.e.*, the risk of additive exposures from chemicals that produce the same toxic effects), and additional safety factors to protect sensitive subpopulations, notably children, from exposure to pesticide residues. The *FQPA* provided a further impetus to the PMRA to review its policies and reconsider earlier registrations. The application of a higher safety factor, in particular, proved important in the PMRA's review of occupational health risks relating to lindane.

<sup>316</sup> Affidavit of Dr. Claire Franklin, ¶ 10; Pesticide Registration Review Team, *Recommendations for a Revised Federal Pest Management Regulatory System*, Final Report (Blue Book), December 1990 (Exhibit CF-1).



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comment a regulatory proposal document, *A New Approach to Re-evaluation*, PRO99-01.<sup>317</sup> The public comment process solicited responses from industry stakeholders like Chemtura. Having taken into consideration such comments, the PMRA in 2001 published a Regulatory Directive outlining the Agency's current re-evaluation program, *PMRA Re-evaluation Program*, DIR2001-03 (DIR2001-03).<sup>318</sup> The policies in this program document had been implemented since the launch of the PMRA's program in 1999 and were applied in the Special Review of lindane.<sup>319</sup>

**3. Special Reviews were a sub-set of the PMRA's more general re-evaluation programs, applied in cases of identified concern**

287. The Special Review of lindane therefore took place in the context of the PMRA's new re-evaluation program. It applied the policies adopted on a agency-wide basis that were intended to ensure the efficiency and efficacy of the PMRA's overall re-evaluation effort.<sup>320</sup>

288. A "Special Review" is a specific sub-category of re-evaluation, to which particular considerations apply.<sup>321</sup> Re-evaluation is a scheduled cyclical review of a product to ensure an existing registration meets current safety standards. By contrast, a Special Review is triggered by specific health, environment or value concerns identified

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<sup>317</sup> PMRA, Regulatory Proposal PRO99-01, *A New Approach to Re-evaluation*, 3 December 1999 (Exhibit JW-7).

<sup>318</sup> PMRA Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, 30 March 2001 (Exhibit JW-8).

<sup>319</sup> Affidavit of John Worgan, ¶ 76; Affidavit of Cheryl Chaffey, ¶ 76.

<sup>320</sup> At the time, the PMRA had little experience with the re-evaluation process: now, ten years later, the PMRA has a much better idea of the time it takes to conduct a re-evaluation. The time the PMRA spent on the Special Review of lindane is consistent with the time now typically required to review information and reach a regulatory decision for a re-evaluation.

<sup>321</sup> Affidavit of John Worgan, ¶¶ 28, 74.

for a pest control product.<sup>322</sup> Because it is prompted by specific concerns, a Special Review does not necessarily entail a complete re-evaluation of a product's database, although in practice the range of review remains broad.<sup>323</sup>

289. Since the human and other resources required to conduct the Special Review, and the review procedures applied, are essentially the same as those in a re-evaluation, the PMRA's Special Review policy closely reflects the approach the PMRA adopted under PRO99-01 and DIR2001-003 for re-evaluations generally.<sup>324</sup>

**4. The Special Review of lindane took place in the context of the PMRA's general re-evaluation of old pesticides, and applied policies developed for that process**

290. The Claimant has suggested that approaches taken in the scientific re-evaluation of lindane were evidence of PMRA bias.<sup>325</sup> To the contrary, in its re-evaluation of lindane the PMRA was implementing sound policies arising out of its extensive policy review. These policies reflected the PMRA's balancing of competing interests, in the proper exercise of its public mandate.

291. The PMRA was facing an enormous task in seeking to systematically review all of its older registrations. Pursuing an approach arising out of the policy reviews of the 1990s, the 2001 Regulatory Directive confirmed that all technical active ingredients

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<sup>322</sup> Given that it is prompted by particular concerns, a Special Review differs in some ways from a routine re-evaluation, and even more so from the review of a newly-proposed product. In the case of a Special Review, the product is already being used, and has given rise to public health or environmental concerns. By contrast, in the case of a new registration (for example, Syngenta's registration process for Helix), the product is not in circulation. A potential registrant may submit further studies to convince the PMRA of the safety of its product. The prospective registrant generates the study at its own expense, and there is no public risk.

<sup>323</sup> Special Reviews have been completed by the PMRA for a number of active ingredients including carbofuran (1995), lindane (1999-2001) and tributyltins paints (2000-2002). All of these Special Reviews resulted either in phase out or cancellation of all products (tributyltins and lindane) or at least partial phase-outs (carbofuran). Affidavit of John Worgan, ¶ 75.

<sup>324</sup> In effect, this meant that the lindane Special Review followed general PMRA re-evaluation policy regarding 1) reliance to the extent possible on international reviews; 2) refraining from full-scale data call-ins, supplementing existing and available data-bases as required; and 3) pursuit of the review only until a finding justifying suspension of the product.

<sup>325</sup> Claimant's Memorial, ¶¶ 73, 431.

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registered prior to December 31, 1994 were to be re-evaluated: a total of 401 target actives. In an average year, applying current policies, the PMRA has the resources to pursue re-evaluations of between 40 to 50 active ingredients at most.<sup>326</sup>

292. A substantial amount of the policy thinking in the 1990s, therefore, centred on how to review the enormous number of “old” registrations in a cost-effective, efficient, and scientifically effective manner. The PMRA was conscious of the need to complete the re-evaluation in a reasonable amount of time, and to take account of competing demands on public resources. But this was not simply a matter of money; it also reflected a concern that, without reasonable steps to accelerate the process, products potentially causing harm to human health and the environment would remain in use for a much longer time.<sup>327</sup>

293. Such considerations prompted the adoption of a series of re-evaluation policies reflected in PRO99-01 and in DIR2001-03,<sup>328</sup> notably:

- 1) reliance on existing reviews of other national regulators;
- 2) use of existing data-sets; and
- 3) pursuit of reviews only until the finding of an “unacceptable” result in one or more areas.

**a) Reliance on existing reviews**

294. The PMRA decided that in conducting re-evaluations, it would be most efficient to rely, as much as possible, on recent re-evaluations conducted by equivalent OECD

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<sup>326</sup> Even this rate depends on policies designed to achieve effective and safe review results within a reasonable time frame. The experience of the early 1990s had demonstrated how the process could fall victim to delay, as the review process struggled to keep up with the mounting tide of studies concerning new and current registrations. Affidavit of John Worgan, ¶ 70.

<sup>327</sup> Affidavit of John Worgan, ¶ 40.

<sup>328</sup> PMRA, Regulatory Proposal PRO99-01, *A New Approach to Re-evaluation*, 3 December 1999 (Exhibit JW-7); PMRA Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, 30 March 2001 (Exhibit JW-8).

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regulators.<sup>329</sup> The *PCPA* and its associated Regulations provide the Minister of Health with broad discretionary authority to determine what information requirements should be applied in the evaluation and re-evaluation of pest control products.<sup>330</sup> Re-evaluations were not intended to be conducted in a vacuum, ignoring equivalent reviews, or building up the required sets of data without reference to existing sources, in a completely *de novo* process. A process of this nature would be expensive and time-consuming to both the PMRA and industry and could delay decisions needed to protect the health of Canadians and their environment well beyond the time taken in other countries with comparable pest management regimes.<sup>331</sup>

295. The PMRA's policy approach was further supported by the systematic pesticides re-evaluation process that had been initiated by the EPA in the late 1980s, generating an enormous collection of studies and updated databases, the reviews of which were available to the PMRA. The studies required by the EPA were relied upon by national regulators around the world.<sup>332</sup>

296. The PMRA's policy decision was supported by parallel efforts under the NAFTA to increase harmonization of the pesticide review functions between NAFTA partners. Such practices have been promoted by the NAFTA TWG.<sup>333</sup>

297. While the PMRA decided to rely as much as possible on international reviews in its wholesale re-evaluation effort, it did not rely blindly on existing reports, nor did it always make the same decisions as the EPA, or any other national agency.<sup>334</sup> In practice, the PMRA frequently looks beyond the analysis in any given OECD study to the

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<sup>329</sup> Affidavit of Dr. Claire Franklin, ¶ 12; Affidavit of John Worgan, ¶¶ 47, 80; Affidavit of Cheryl Chaffey, ¶ 30.

<sup>330</sup> The Minister's general authority to determine the information required to support a registration was found in s. 5-9 of the *PCPR* (Annex R-2). Affidavit of John Worgan, ¶ 43; (Exhibit JW-3A).

<sup>331</sup> Affidavit of Dr. Claire Franklin, ¶ 14.

<sup>332</sup> Affidavit of John Worgan, ¶ 44.

<sup>333</sup> NAFTA TWG on Pesticides, *A North American Initiative for Pesticides; Operation of the NAFTA Technical Working Group on Pesticides*, 6 November 1998 (Exhibit JW-9).

<sup>334</sup> Affidavit of John Worgan, ¶¶ 53-54; Affidavit of Cheryl Chaffey, ¶ 66.

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underlying data, testing its conclusions and confirming its consistency with the PMRA's own standards and policies.

298. The PMRA would, in particular, apply its own standards concerning the acceptable measure of risk, and the application of uncertainty and safety factors to account for uncertainties in the database.<sup>335</sup> Application of such policies can lead to differences in supported (*i.e.*, registerable) uses and required mitigation measures.

**b) Reliance on existing data-sets**

299. Consistent with its policy (DIR 2001-03), the PMRA's re-evaluation program of the late 1990s relied as much as possible on the databases built up by other national agencies. This information was complemented by the PMRA's existing registrant data concerning a pesticide under review, and by specific data requests that the PMRA might call for in the context of a particular re-evaluation.

300. The PMRA had seen in its re-evaluation exercises in the late 1980s and early 1990s that initiating a "data call-in" at the same time as a re-evaluation resulted in excessive delays to the re-evaluation process.<sup>336</sup>

301. In any event, extensive data calls-ins had already been conducted by equivalent regulators on many of the relevant pesticides. By the late 1990s, mostly as a result of the re-registration initiatives led by the EPA, registrants had generated and submitted a large number of studies on individual active ingredients and their associated products. These

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<sup>335</sup> Canadian-specific policies include the Federal Government's Toxic Substances Management Policy (TSMP), and PMRA's Formulants Policy, application of which can result in regulatory decisions that are more restrictive than those of the EPA. Affidavit of John Worgan, ¶ 56; Environment Canada, *Toxic Substances Management Policy*, 1995 (Annex R-41); PMRA, *Regulatory Proposal PRO2000-04, Formulants Policy*, May 2000 (Annex R-27).

<sup>336</sup> A "data call-in" is a request to registrants for additional data concerning an active, beyond that which registrants have already provided in the course of initial registration or during the period of subsequent use. Data call-ins tended to create an "endless regress", as the submission of new data would lead to the re-assessment of all previously-confirmed data, during which new data would be generated, leading to further general re-assessments, leading to further delays. Affidavit of John Worgan, ¶ 70.

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studies had brought historical pesticide databases closer to the modern standards required for new products.<sup>337</sup>

302. The PMRA also had existing data-sets submitted by registrants at the outset or in the course of periodic re-registration in its own databases. This data was, in theory, supposed to be sufficient to support each registration.<sup>338</sup>

303. The PMRA's general approach to data call-ins did not prevent it from requesting specific studies from registrants for re-evaluation.<sup>339</sup> This occurred in the case of lindane. The EPA had launched a re-evaluation of lindane in 1998, one year before the start of the PMRA's own Special Review, and therefore had an up-to-date database and their evaluation of the data was at the PMRA's disposal. However, in the course of the Special Review, the PMRA supplemented that data-base in several different ways, to satisfy itself that its conclusions were scientifically well-grounded.

**c) Pursuit of reviews until reaching a negative conclusion**

304. In a typical re-evaluation, the PMRA will examine a product's potential threat to human health or the environment by considering its environmental fate, toxicity, and presence in standard and specific environments, among other factors.<sup>340</sup> Any one of these factors is sufficient grounds for deeming a pesticide unacceptable for continued registration.

305. While the different aspects of re-evaluation typically proceed in parallel, they do not necessarily proceed at the same speed or achieve results at the same time. It is typical

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<sup>337</sup> Affidavit of John Worgan, ¶ 45.

<sup>338</sup> While the PMRA would draw on other agency databases, in doing so it was constrained by its own legislative framework. In particular, the *PCPA* statutorily barred the PMRA from referring to proprietary data generated by one registrant when re-evaluating another registrant's product. In this way, its process differed from that of the EPA, which did have this statutory power. This again affected the different initial outcomes of the PMRA and the EPA's respective lindane reviews.

<sup>339</sup> Claimant's Memorial, ¶ 426.

<sup>340</sup> Affidavit of John Worgan, ¶ 60.

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in an evaluation for one PMRA scientific group to reach its conclusions before other aspects of the re-evaluation have been concluded.

306. Prompted by efficiency and resource considerations, the PMRA policy therefore provided for the pursuit of all reviews during a re-evaluation only to the point where a “negative” result showing significant concern (i.e. justifying deregistration) had been reached on any one ground. At this point, since that one ground would ultimately result in the deregistration of the product, investigation of the other potential grounds would be halted. This practice allowed resources to be re-allocated to review other “old” actives subject to re-evaluation.

307. This is exactly what occurred in the case of lindane. In its re-evaluation of lindane, the PMRA considered the safety of lindane from multiple points of view (including environmental persistence and compartment, short- and long-term toxicology, carcinogenicity, etc.). However, PMRA scientists considering the occupational health risks reached a negative answer first. As a result, having discovered a sufficient reason to withdraw the chemical, all other aspects of the investigation were suspended.

**5. The PMRA’s Special Review of lindane took place in coordination with EPA’s parallel lindane re-registration review process**

308. The PMRA’s process in the Special Review was shaped by its overarching goal of co-ordinating and harmonizing pesticide regulation as much as possible between Canada and the United States.<sup>341</sup>

**a) The EPA and the PMRA explored a coordinated approach to pesticide regulation**

309. In 1998, while the stakeholders were negotiating the VWA, the PMRA and the EPA sought to address the more systemic issue of registration asymmetries between the

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<sup>341</sup> Affidavit of John Worgan, ¶ 48; Affidavit of Cheryl Chaffey, ¶ 63.

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United States and Canada. As of February 1998, efforts were already underway to harmonize pesticide registrations between Canada and the United States.<sup>342</sup>

310. The problem of asymmetrical pesticide registrations was not easy to resolve. As confirmed by Canada's review of the *PCPA* framework, pesticide registration systems in most countries are very precise. Registrations are permitted or denied in accordance with each federal regulator's internal policies. Such policies depend upon, among other things, conclusions regarding appropriate safety standards and risk-management, on which reasonable scientists can differ. Countries may reach different conclusions based on the same data.

311. Neither the EPA nor the PMRA could *sua sponte* decide to register a pesticide. Each relied on applications of would-be registrants, who had to generate appropriate data to support each registration. Such applications were often not pursued in parallel by chemical companies in Canada and the United States. The PMRA generally counselled agricultural industry stakeholders to work together with chemical companies to ensure parallel registrations were in place, but the decision about which registrations to pursue, and when, was ultimately in the hands of the pesticide companies themselves.<sup>343</sup>

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<sup>342</sup> As noted in the USCA's Special News Alert, the harmonization issue was not limited to lindane:

Canada has several pesticides labeled for use on canola as plant protectants. USCA has been working to gain approvals from EPA and FDA to allow the maximum residue tolerance used in Canada to serve as the maximum allowable tolerance for canola seeds imported into the U.S. for processing. This policy would eliminate restrictions on the free flow of canola planting seed between the U.S. and Canada.

At the same time, USCA has been working closely with the Canola Council of Canada, EPA, the Pesticide [*sic*] Management Regulatory Agency, and pesticide manufacturers throughout the NAFTA Technical Working Group (TWG) to harmonize the use of canola protection products by U.S. and Canadian producers. USCA is making progress towards achieving equality with Canada on pesticide standards and regulations governing registration. At the last TWG, EPA and PMRA agreed to pursue harmonization for Muster, to be followed by other products.

U.S. Canola Association, *Special News Alert*, 10 February 1998 (Exhibit TZ-7).

<sup>343</sup> The only unusual aspect of lindane in this regard was that its registration had been pursued in this case in Canada, and not in the United States. This deviation from the normal course of events reflected canola's Canadian origins.



**b) The EPA and the PMRA coordinated their reviews of lindane**

312. In light of the PMRA's goal of co-ordinating and harmonizing pesticide regulation as much as possible between Canada and the United States, the Special Review proceeded in conjunction with the parallel review of lindane by the EPA. As the EPA's review had begun in 1998, it made sense for the PMRA to take account of the evaluations the EPA had generated, rather than to initiate another complete data call-in, as the EPA had done so only months before.<sup>344</sup> This approach also reflected the PMRA's commitment in connection with the VWA, to work as much as possible in tandem with the EPA and coordinate their respective reviews of lindane.

313. Working in tandem with the EPA's lindane review also meant that rather than engaging in direct review of all relevant studies, the PMRA first considered EPA's recent reviews on the same studies.<sup>345</sup> The EPA provided their reviews to the PMRA as they were generated and the PMRA used EPA reviews of individual toxicity studies, consistent with the VWA commitment for the two agencies to collaborate. The PMRA staff were not simply taking the EPA's reviews at face value; nor were they relying exclusively on EPA-generated reviews.<sup>346</sup>

314. Despite this joint review procedure, each agency continued to apply its own policies and, in particular, safety standards to the data under review. In this sense, each

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<sup>344</sup> It also reflected general PMRA policy regarding data call-ins, in the context of re-evaluations. Affidavit of John Worgan, ¶ 70.

<sup>345</sup> The PMRA had started identifying missing information required for review as early as 1998. However, the PMRA ultimately addressed these data-gaps by relying on reviews arising out of the EPA's already ongoing lindane re-evaluation. Affidavit of Cheryl Chaffey, ¶¶ 63-71.

<sup>346</sup> The Claimant's suggestion that the PMRA entirely relied upon the EPA to review the science is false. Claimant's Memorial, ¶ 86. The PMRA staff examined the underlying studies and data on which the EPA had relied. They also looked to reviews from other regulatory or international authorities for additional data, requested specific data from registrants and supplemented this activity with a review of the scientific literature. Affidavit of Cheryl Chaffey, ¶ 66.

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Agency retained its autonomous decision-making power. This was evidenced in particular by the use of different safety factors.<sup>347</sup>

## **6. The Scope of the Special Review**

315. The Claimant suggests that the PMRA limited the scope of issues to be considered in the Special Review of lindane, and caught the Claimant “off guard” when lindane use was rescinded on the basis of occupational health risk.<sup>348</sup> This is unsupportable. First, the scope of the Special Review was expressly confirmed from the start to be broad. Second, the Claimant received confirmation within two months of its launch that the Special Review would include an occupational health review. And third, the PMRA specifically raised concerns about the occupational health database at a meeting between Chemtura Canada and the PMRA’s Executive Director more than a year before Special Review results were released in draft.

### **a) The broad scope of the Special Review was confirmed from the start**

316. The Special Review announcement of March 15, 1999 clearly identified the concerns that initially triggered the Special Review:

- 1) Lindane’s persistence, potential for long-range transport and widespread occurrence in the environment;
- 2) The many unanswered questions regarding the potential impact on humans and wildlife; and

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<sup>347</sup> This led to a difference between the PMRA’s result in 2001 (suspending use of lindane on grounds of occupational health risk) and that of the EPA in 2002, which maintained existing registrations conditional upon significant additional safety precautions and the delivery of further data. The EPA by 2006 had suspended even these few remaining registrations, citing the same occupational health risks that had prompted the PMRA’s 2001 decision.

<sup>348</sup> Claimant’s Memorial, ¶¶ 176-177.

- 3) Canada's agreement to an international protocol on persistent organic pollutants.<sup>349</sup>

317. The purpose of such announcements is to advise a range of stakeholders that a Special Review is being launched. It is not meant to provide detailed procedures or schedules for the review.<sup>350</sup>

318. Contrary to the Claimant's suggestion that the scope of the Special Review was limited,<sup>351</sup> the Special Review announcement of March 15, 1999<sup>352</sup> expressly noted "*the scope of issues surrounding Lindane is potentially broad*". It went on to note that "[t]he PMRA's current understanding of Lindane are [sic] complex and merit [sic] a Special Review at this time. As a better understanding of the potential for adverse effects becomes known, *the scope of this review may change.*" This clearly signalled that the scope of the Special Review remained open-ended.<sup>353</sup>

**b) The PMRA expressly noted it would be proceeding with exposure assessments under the Special Review**

319. Apart from the language of the Special Review notice, early on the PMRA expressly indicated to the Claimant that it was considering human health and exposure as part of its review. At a meeting held between the PMRA, Chemtura and CIEL on May 11, 1999, Chemtura's own notes confirm the PMRA's indication that it would focus on chemistry aspects "for now", and "the health and environmental risks in the fall of

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<sup>349</sup> This makes it difficult to understand Chemtura's allegation that the Special Review announcement cited only "unspecific environmental concerns". Claimant's Memorial, ¶ 142. The announcement cited specific concerns (biopersistence, long-range volatility) which were not limited to the environment, but also specifically referenced lindane's potential impact on human health.

<sup>350</sup> Affidavit of John Worgan, ¶ 125. The level of detail in the lindane Special Review public announcement document was consistent with those for other Special Reviews (*e.g.*, tributylins) and re-evaluations (*e.g.*, organophosphates) released around the same time. See PMRA, Special Review Announcement SRA2000-01, *Special Review of Organotin Antifouling Paints for Ships Hulls*, 9 May 2000 (Exhibit JW-16); PMRA, Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*, 29 June 1999 (Exhibit JW-17).

<sup>351</sup> Claimant's Memorial, ¶ 176.

<sup>352</sup> *Lindane Special Review Announcement* (Exhibit WS-32).

<sup>353</sup> As the PMRA noted in the Special Review announcement, "the registration status of all lindane-containing products will depend on the outcome of this review (our emphasis). See *Lindane Special Review Announcement* (Exhibit WS-32).

1999”.<sup>354</sup> Chemtura would have known that “health and environmental risks” included occupational and dietary risks.<sup>355</sup>

320. Indeed, the minutes of this meeting further reference the ongoing U.K. Pesticides Safety Directorate’s occupational risk concerns: “PSD [*the Pesticides Safety Directorate, the UK national pesticides regulator*] in UK: Lindane under review. PSD has raised some concerns regarding operator exposure.”<sup>356</sup> The PMRA cannot have been expected to ignore this in its own review. Indeed, Chemtura was more than aware of the U.K.’s occupational safety concerns. The group representing lindane registrants, the Centre International de Études du Lindane, or CIEL, had made representations before the U.K. equivalent of the PMRA.<sup>357</sup> As occupational risk had been the basis for removal of lindane for seed treatment in the U.K., it was entirely foreseeable to a sophisticated registrant such as Chemtura that the PMRA would take this issue seriously. This was particularly true since the U.K. shortly thereafter called for the immediate revocation of the sale and use of lindane seed treatment products based upon occupational exposure concerns.<sup>358</sup>

**c) The PMRA expressly raised specific occupational health concerns with Chemtura**

321. Moreover, the PMRA expressly raised occupational health a year before the release of the Special Review, identifying it as a concern. As the Claimant admits,<sup>359</sup> at

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<sup>354</sup> Minutes of meeting between PMRA, Chemtura and CIEL, 11 May 1999 (Exhibit JW-19). Indeed, the minutes of this meeting further reference the ongoing U.K. Pesticides Safety Directorate’s occupational risk concerns: UK Department of Environment, Food and Rural Affairs, *Evaluation on the Review of Lindane*, November 1999 (Exhibit CC-17). Affidavit of Cheryl Chaffey, ¶ 96.

<sup>355</sup> Affidavit of John Worgan, ¶ 128.

<sup>356</sup> Minutes of meeting between PMRA, Chemtura and CIEL, 11 May 1999 (Exhibit JW-19).

<sup>357</sup> U.K. Department of Environment, Food and Rural Affairs, *Evaluation on the Review of Lindane*, November 1999 (Exhibit CC-17).

<sup>358</sup> Affidavit of Cheryl Chaffey, ¶ 96; Ministry of Agriculture, Fisheries and Food (U.K.) News Release: Review of the Pesticide Lindane, 18 June 1999 (Exhibit CC-32).

<sup>359</sup> Claimant’s Memorial, ¶ 186.

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an October 4, 2000 meeting,<sup>360</sup> 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” and that extrapolating from databases might not be appropriate. In essence, the PMRA was indicating that the available exposure data had limitations. The notes from that meeting further confirm that the PMRA had raised the results of the lindane assessment by the U.K.’s national pesticides regulator, which had decided to ban lindane based upon occupational exposure concerns.<sup>361</sup> This was a full year before the PMRA completed the Special Review.<sup>362</sup>

322. The PMRA’s concern with worker exposure was expressly noted in the personal notes of Mr. Alfred Ingulli, the Chemtura senior executive present at the meeting. These notes state:

#### Concerns of PMRA

- Worker Exposure. Told PMRA that EPA reviewed and accepted seed treat[ment] worker exposure study.<sup>363</sup>

323. Mr. Ingulli was referencing the Claimant’s own 1992 Dupree study.<sup>364</sup> Chemtura notably did not even propose to submit any newly-generated occupational exposure data or studies, despite the opportunity to do so presented by the October 4, 2000 meeting with the PMRA’s Executive Director. Ironically, when the PMRA released the results of its occupational assessment based upon the Dupree study a year later, Chemtura criticized

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<sup>360</sup> The meeting of October 4, 2000 was called at Chemtura’s request and attended by Dr. Claire Franklin, then PMRA’s Executive Director. Issues discussed at such a meeting would, of necessity, be important to the Agency. Affidavit of Dr. Claire Franklin, ¶ 25.

<sup>361</sup> Minutes of meeting between Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title to Chemtura Canada) and Dr. Claire Franklin, Executive Director, PMRA, 4 October 2000 (Exhibit JW-23).

<sup>362</sup> Affidavit of Dr. Claire Franklin, ¶ 31; Letter from Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada) to Janet Taylor, PMRA, 6 October 2000 (Exhibit JW-20).

<sup>363</sup> Minutes of meeting between Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title to Chemtura Canada) and Dr. Claire Franklin, Executive Director, PMRA, 4 October 2000 (Exhibit JW-23).

<sup>364</sup> Letter from Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada) to Janet Taylor, PMRA, 6 October 2000 (Exhibit JW-20).

the PMRA for not using more up-to-date data, arguing that their Dupree study did not account for current use patterns.<sup>365</sup> It is striking that the Claimant has declined to call Mr. Dupree as a witness in these proceedings.

## **7. The Special Review represented a substantial investment of the PMRA's scientific resources**

### **a) The process of the Special Review**

324. The PMRA's Special Review of lindane followed the PMRA's standard pattern of pesticide review: a toxicological assessment,<sup>366</sup> together with a parallel assessment of potential human exposure by all routes (in this case, dietary and occupational exposure),<sup>367</sup> as well as investigations of the product's potential environmental impact and an assessment of its value.<sup>368</sup> The PMRA then combined information from the assessments and performed a risk assessment to determine whether, taking account of

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<sup>365</sup> Affidavit of John Worgan, ¶ 131.

<sup>366</sup> See generally Affidavit of Cheryl Chaffey, ¶¶ 8-17 for a detailed description of the nature of toxicology and exposure assessments. Ms. Chaffey was one of the lead scientists involved in the Special Review of lindane. Essentially, toxicology involves considering:

- the different effects of various routes of exposure on test subject (oral, dermal, inhalation – in other words, exposure to a pesticide through swallowing, through the skin, or by breathing it in);
- the different effects of various durations of exposure: single exposures (also called “acute” exposures) or repeated exposures. The latter exposures could take place over a limited period of time (such as a short-term period of several weeks to several months) or on a chronic basis (such as lifetime daily exposure);
- the different effects of increasing and varying doses of a pesticide; and
- the various types of toxicity demonstrated (for example, cancer, damage to the nervous system, to the liver, or to other organs, known as “endpoints”).

These studies follow PMRA guidelines and regulatory directives. Regulatory Directive DIR2005-01, *Guidelines for Developing a Toxicological Database for Chemical Pest Control Products*, 27 May 2005 (Exhibit CC-1); PMRA, *Data Requirements for Use Site Category 10 - Seed Treatments for Food and Feed* (Exhibit CC-3). The PMRA's toxicologists aim to determine the lowest level of exposure at which an adverse effect can be determined for particular “endpoints” in the body, due to some form of exposure to a toxin. The level of exposure just below this critical endpoint is called the “no observed adverse effect level”, or “NOAEL”. The PMRA then conducts a risk assessment, to ensure that human exposure is below the NOAEL.

<sup>367</sup> PMRA studied the likely human exposure to the pesticide, in either general or specific (e.g., occupational) environments.

<sup>368</sup> Affidavit of Cheryl Chaffey, ¶ 72.

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appropriate margins of uncertainty and safety, the expected exposure exceeded the dosage understood to be safe. With regard to these margins, the PMRA follows standard international practice by applying uncertainty and safety factors to the NOAELs for identified critical endpoints (sites of specific damage, such as damage to the liver, kidneys or reproductive organs). Uncertainty and safety factors are numerical adjustments used to extrapolate from data generated in animal testing to estimate the allowable human exposure below which an adverse effect will likely not occur. These factors are intended to be conservative: the minimum factor is typically 100.

325. This basic international standard is the product of two uncertainty factors: a factor of 10 for inter-species difference (that is, general risk assessment practices assume that the human is 10 times more sensitive than the laboratory animal), and a factor of 10 for intra-species variability (that is, there could exist a 10-fold difference in response between an average person and a sensitive person on account of their age, gender, health status, genetic makeup etc.).

326. Additional uncertainty and safety factors are frequently applied, taking into account, for example, problems with the quality of data in the underlying test studies or concerns with respect to the seriousness of the endpoints affected. Therefore, where a rat may be safely exposed to 1 unit of a chemical, the PMRA will assume that the equivalent human NOAEL level is at most 0.01 (one-hundredth of the rat dose) and in some cases less.

327. In the case of both dietary and occupational risk assessment, the PMRA will apply uncertainty and safety factors to the NOAEL to yield either an acceptable daily intake, or an allowable Margin of Exposure (MOE). If potential daily exposure exceeds the allowable, the PMRA will consider the risk to be unacceptable.

328. The PMRA's analysis is then refined to determine whether any steps can be taken to mitigate exposure. This analysis is limited by the data actually available to confirm exposure estimates under the proposed "mitigation measures". If, despite such further

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checks, the PMRA still ends up with potential exposures that exceed the allowable daily intake or target margin of exposure, then it has to take stronger regulatory action.<sup>369</sup>

329. Each component of the parallel review – the toxicological, exposure and risk assessments – underwent internal peer review by senior scientists.<sup>370</sup> It was only at this stage – in the late summer of 2001 – that the PMRA had confirmation that the level of occupational exposure was unacceptable.

**b) Resources invested in the Special Review of lindane**

330. The PMRA spent 108 person-days (or approximately 5 working months) on the toxicological review of lindane alone.<sup>371</sup> Person-days expended in other aspects of the Special Review were equally substantive.<sup>372</sup>

**c) Toxicology and exposure assessments in the context of the Special Review of lindane**

331. In conducting its toxicology and exposure assessment analysis in the lindane Special Review, the PMRA assessed the core toxicology data by reviewing EPA documents, supplemented by other international reviews and published literature.<sup>373</sup>

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<sup>369</sup> See Affidavit of Cheryl Chaffey, ¶ 25.

<sup>370</sup> The process involved evaluating the PMRA's own records for past reviews, evaluating available reviews from other reputable regulatory groups (in particular, EPA), discussing findings with EPA counterparts, evaluating the scientific literature and, on the basis of this collective information, producing the PMRA's own updated review. This was followed by at least two levels of peer review. This overall approach was consistent with PMRA Regulatory Directive DIR2001-03, the then-current statement of PMRA practices for such reviews. PMRA Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, 30 March 2001 (Exhibit CC-8). Although the Directive was released in 2001, it codified regulatory practice in place since 1999. Affidavit of John Worgan, ¶ 26.

<sup>371</sup> Affidavit of Cheryl Chaffey, ¶ 72.

<sup>372</sup> Canada specifically rejects the Claimant's suggestion that the PMRA had "put no resources towards completing the lindane scientific review" because "everyone at PMRA felt the issue would go away". Claimant's Memorial, ¶¶ 145, 398. The Claimant's allegation relies on Mr. Ingulli, who himself is reporting what another Chemtura employee, Fred Hnatiw, believes he heard from a PMRA employee, Mr. Pettigrew. The E-mail Mr. Ingulli himself relies upon was internal to Chemtura, and expressly asked, "Rob let me know if you read the meeting the same way I do", signalling Mr. Hnatiw's own uncertainty about what had been said. The narrative of the meeting with Mr. Pettigrew was never submitted to the PMRA for review or comment. In any event, Mr. Pettigrew was a regional compliance officer at the PMRA at the time – he had no direct knowledge of or involvement in the scientific review of lindane.

<sup>373</sup> Affidavit of Cheryl Chaffey, ¶¶ 66, 74.



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From this body of evidence, the PMRA identified the toxic effects associated with lindane exposure and the NOAELs for the critical endpoints to be used for conducting the risk assessments for different routes and durations of exposure. The PMRA also identified special concerns at this stage, such as the sensitivity of the young, that would need to be considered during risk assessment.

332. While identifying potential hazards of lindane from the toxicology database and from available reviews, the PMRA's Special Review team proceeded in parallel with the occupational exposure assessment:

- The first step was to identify and characterise potential routes and durations of exposure.<sup>374</sup>
- The second step was to identify and evaluate relevant exposure studies.<sup>375</sup>
- The third step was to use all relevant identified data to estimate unit exposure values for each exposure scenario.<sup>376</sup>

333. Meanwhile, other elements of the PMRA's review, including an evaluation of lindane as a potential carcinogen, and an assessment of its environmental impact, proceeded in parallel. However, since the PMRA first reached a negative decision regarding continued use of lindane based on occupational exposure risks for non-cancer endpoints, these other avenues of research were set aside, and the resources reallocated to

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<sup>374</sup> The PMRA examined the use patterns of lindane specified on the then-current labels, and characterised the work activities (tasks, equipment used, quantity of chemical handled, etc.) of people likely to be exposed to the pesticide, to assess their probable routes and durations of exposure. In the case of lindane, important groups included the seed treatment workers exposed to lindane during commercial and "on-farm" seed treatments; and the exposure of farmers planting seed treated with lindane. Affidavit of Cheryl Chaffey, ¶ 75.

<sup>375</sup> The available data came from passive dosimetry studies conducted during seed treatment and seed planting (*i.e.*, studies of the amount of dermal and inhalation exposure to which workers were subjected while treating or planting seeds), reflecting the kinds of uses allowed in then-current registrations. The PMRA considered all exposure studies available to registrants at the time of the Special Review. PMRA Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, 30 March 2001 (Exhibit CC-8). See Affidavit of Cheryl Chaffey, ¶ 76.

<sup>376</sup> Unit exposure values are the amount of anticipated exposure per kg of chemical handled for each exposure scenario. This is the usual method employed by the PMRA and other regulatory agencies, as it maximises the use of available data by allowing exposure values obtained in a specific study situation to be extrapolated to other similar scenarios. PMRA Registration No. 11422, *Registration for Vitaflo Pesticide*, 30 January 1996 (Exhibit CC-24). See Affidavit of Cheryl Chaffey, ¶ 78.

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other re-evaluations.<sup>377</sup> In so doing, the PMRA was simply applying the policies it had developed for re-evaluations generally that sought to maximize use of the PMRA's limited resources in the context of its massive re-evaluation scheme.<sup>378</sup>

**8. The Special Review was delayed despite the PMRA's ongoing efforts**

334. The Special Review of lindane was initially expected to reach its conclusions by the end of 2000. However, the PMRA repeatedly made it clear that late December 2000 was a "target date".<sup>379</sup>

335. The issuance of the Special Review actually took about ten months longer than expected, as it was released in draft in late October 2001. This was in part simply an issue of workload. The PMRA does not have endless resources or unlimited numbers of scientific evaluators, and was just beginning the re-evaluation program of over 400 existing registrations.

336. However, it was the linkage of the PMRA's process to that of the EPA that was the primary source of delay.<sup>380</sup> The PMRA scientists involved in the Special Review were speaking on a regular basis with their counterparts at the EPA. Yet despite the fact that the relevant reviews were originally anticipated in 2000, the reviews used by the PMRA were generated by the EPA over the course of two years, with the last toxicology review report generated as late as August 30, 2001.<sup>381</sup>

337. Indeed, these circumstances were alluded to in Wendy Sexsmith's letter of May 29, 2001 to Chemtura Canada:

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<sup>377</sup> Affidavit of John Worgan, ¶ 62.

<sup>378</sup> Affidavit of John Worgan, ¶ 64.

<sup>379</sup> *Lindane Special Review Announcement* (Exhibit WS-32); Affidavit of John Worgan, ¶ 116; Affidavit of Wendy Sexsmith, ¶ 133.

<sup>380</sup> By coordinating its own review with that of the EPA, the PMRA was fulfilling a specific request of lindane registrants and end-users.

<sup>381</sup> This may have been the result of changing priorities within the EPA. Affidavit of John Worgan, ¶ 118.

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Regarding the allegation that the Minister has breached the terms of your company's letter of October 27, 1999 in relation to the conducting of the special review of lindane products in a timely manner, it is important to note that the condition set forth in your company's letter stipulated that, *in conducting the special review, the PMRA was to coordinate and collaborate with the EPA in its re-evaluation of lindane products*. The PMRA has been pursuing the matter in that manner diligently, and continues to do so. I am confident that your company is aware of the considerable progress that has been made to date. That the anticipated completion of the special review by the end of 2000 has not materialized does not indicate any failure or fault on the part of the PMRA in relation to its undertaking. *As you are probably aware, failure to meet the target date for completion of the special review has been due, in large measure, to factors beyond the PMRA's control.*<sup>382</sup> (our emphasis)

338. Once the last awaited EPA review was received, the Special Review team proceeded to the risk assessment phase, which concluded in October 2001. Risk assessments are conducted by the PMRA to take into account country-specific conditions of use. Consequently, the PMRA's dependence on EPA timelines ceased at this point and its Special Review team was able to conclude its review prior to the United States.<sup>383</sup>

339. The delay in the Special Review caused no prejudice to the Claimant. The Claimant assumes an earlier review would have resulted in a positive outcome,<sup>384</sup> but there is no basis whatsoever for this assumption. Had the Special Review results been released earlier, the Claimant's remaining registered uses of lindane would simply have been discontinued sooner. Instead, the Claimant effectively gained an additional year to sell its lindane products in Canada.

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<sup>382</sup> Letter from Wendy Sexsmith, PMRA to Rob Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada), 29 May 2001 (Exhibit WS-53).

<sup>383</sup> The EPA only issued its own first Re-registration Eligibility Decision on lindane in 2002, five years after beginning its review in 1998. *Lindane RED* (Annex R-34). It thereafter pursued data review in the 2002-2005 period. The EPA finally cancelled lindane seed treatments altogether by 2006. *Lindane RED – 2006 Addendum* (Exhibit JW-59); U.S. EPA Lindane Cancellation Order, Federal Register, Vol. 71, No. 239 at 74905-7, 13 December 2006 (Annex R-49).

<sup>384</sup> Claimant's Memorial, ¶¶ 399-400.

**9. Chemtura had obvious opportunities to participate in the Special Review process, but failed to take advantage of these**

340. Contrary to its allegation in this arbitration,<sup>385</sup> the Claimant had several opportunities to participate in the Special Review, but failed to take advantage of these. The first example is the meeting between the PMRA and the Claimant, on May 10-11, 1999.

341. The meeting took place at the request of the Claimant's lobbyist, CIEL, and allowed a full opportunity at the outset of the Special Review for the Claimant to present its point of view.<sup>386</sup> Mr. Johnson – one of the Claimant's witnesses in this matter – summed up the contemporary impression of the Claimants' representatives in his notes of the May 10-11, 1999 meetings:

In summary, the PMRA staff was very open in the discussion and interested in our presentations on data and canola tolerance. We will be able to maintain an open relationship and dialogue with them as the special review proceeds.<sup>387</sup>

342. The Board of Review noted in its Final Report, that “there was a lack on Chemtura's part to make efforts to inquire and consult with the regulator” and that Chemtura “did not engage PMRA in any meaningful way in respect of updates to the process, interim findings or potential data gaps”.<sup>388</sup>

343. The PMRA's Executive Director met with a Chemtura Senior Executive regarding the Special Review in October 2000, over a year before the issuance of the

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<sup>385</sup> Claimant's Memorial, ¶¶ 432-439.

<sup>386</sup> Letter from Edwin Johnson, Technology Science Group, to Richard Aucoin, PMRA, 20 April 1999 (Exhibit CF-8); Minutes of meeting between PMRA, Chemtura and CIEL, 11 May 1999 (Exhibit JW-19).

<sup>387</sup> Minutes of meeting between PMRA, Chemtura and CIEL, 11 May 1999 (Exhibit JW-19).

<sup>388</sup> Lindane Review Board, *Report of the Lindane Board of Review*, 17 August 2005, ¶¶ 109, 110 (Exhibit WS-71) (*Board of Review Report*).

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PMRA's results. If Chemtura had specific concerns about the Special Review, it obviously had the opportunity to raise them at that meeting.<sup>389</sup>

344. Indeed, the only information that Chemtura provided to the PMRA, the Dupree Study, was used and considered by the PMRA in the Special Review.<sup>390</sup>

### **10. The PMRA ultimately determined that occupational risks of lindane use were unacceptable**

345. After the last awaited EPA information was received in August 2001, the PMRA was able to finalize its toxicological analysis, and compare this with its exposure assessment results. It was at this risk assessment and characterisation stage, when the toxicology and the exposure analysis were brought together, that the PMRA confirmed there was unacceptable risk with occupational exposure (*i.e.*, exposure to the product during seed treatment and seed planting activities).<sup>391</sup> The PMRA therefore determined, in

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<sup>389</sup> See generally Affidavit of Dr. Claire Franklin.

<sup>390</sup> See Affidavit of Dr. Claire Franklin, ¶ 474; Affidavit of Cheryl Chaffey, ¶¶ 101-102 and 120.

<sup>391</sup> As explained above, the risk assessment and characterisation involved calculating Margins of Exposure (MOEs) for each exposure scenario. The objective was to ensure that the difference between the estimated exposures, and the doses that caused no effects in laboratory animals, was sufficiently large to account for any uncertainty in extrapolating animal results to humans and in the variability in the human population, and to account for identified concerns relating to sensitivity of the young, immunotoxicity and endocrine toxicity.

In this case, the sum of the uncertainty and safety factors (and hence the target MOE) was 1000. Yet calculated MOEs were much less than the target of 1000. For example:

- for commercial seed treatment, calculated MOEs were 2 for canola and mustard and 30 for wheat;
- for on-farm seed treatment of wheat, the calculated MOE was 7; and
- for seed planters, calculated MOEs ranged from 2 to 3.

These MOEs were so far below the target MOE of 1000 that it was obvious that the application of additional personal protective equipment (PPE) would not adequately mitigate the risks. Some PPE, such as protective overalls and gloves for the commercial seed treaters, was already reflected in the assessment, and it was obvious that any adjustment of the exposure estimates to reflect additional PPE would not result in substantial refinements. Affidavit of Cheryl Chaffey, ¶ 89.

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October 2001, that the findings warranted the termination of the lindane registrations through a phase-out of its remaining uses.<sup>392</sup>

**a) Stakeholders were given the opportunity to comment on the Special Review**

346. The PMRA provided stakeholders, including the Claimant, an advance draft release of the Occupational Risk Assessment (Special Review) of lindane in late October 2001 and met with registrants on November 5, 2001 to discuss its findings.<sup>393</sup>

347. The PMRA met with the lindane manufacturers on October 30, 2001 and with registrants of end-use products on November 5, 2001, to review the PMRA's draft risk assessment results.<sup>394</sup> Registrants were provided an opportunity to comment on the toxicology, occupational exposure and risk assessments and were given an opportunity to provide additional or new data information for the PMRA to consider.<sup>395</sup>

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<sup>392</sup> To recall, this conclusion was reached after having specifically raised the worker exposure issue with the Claimant a full year before, at the October 4, 2000 meeting; at which time the Claimant's proposal that the PMRA rely on its 1992 Dupree study for worker exposure data suggested it represented current use patterns, contrary to the Claimant's assertions in its Memorial. Claimant's Memorial, ¶ 195. See Affidavit of Dr. Claire Franklin, ¶ 29.

<sup>393</sup> Affidavit of John Worgan, ¶ 159.

<sup>394</sup> Minutes of meeting between PMRA, Inquinosa, Kanoria Chemicals, TR-Metro Chemicals and Ogilvy Renault, 30 October 2001 (Exhibit JW-24); Minutes of Meeting of 5 November 2001 (Exhibit JW-25).

<sup>395</sup> PMRA E-mail to O. Swenson, AGSCO INC., I. Schmidt, United Agri Products Canada Inc., R. Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada), R. Lindstone, Aventis and L. Caron, NORAC Concepts, 6 November 2001 (Exhibit JW-26); PMRA E-mail to O. Swenson, AGSCO INC., I. Schmidt, United Agri Products Canada Inc., R. Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada), D. Wilkinson, IPCO, J. Shaw, Syngenta, R. Lindstone, Aventis and L. Caron, NORAC Concepts, 27 November 2001 (Exhibit JW-26A). Some respondents indicated that they had data/information applicable to the occupational risk assessment but not considered by the PMRA. The PMRA was prepared to accept data/information which registrants wished to submit for consideration in the occupational risk assessment, and requested that any such data/information be submitted by 3 December 2001.

348. In response to the PMRA's request, Chemtura submitted comments on the PMRA assessment.<sup>396</sup> It also submitted an alternative occupational risk assessment of its own.<sup>397</sup>

349. However, this study was based on the same data relied on by the PMRA (including the Claimant's Dupree study), simply substituting the Claimant's views for those of the PMRA. Moreover, the Claimant's study contained a calculation error which, when corrected, showed even the Claimant had come up with a negative answer, despite using more lenient standards.<sup>398</sup>

**b) The PMRA considered comments by stakeholders, but maintained its conclusions**

350. In a teleconference with Chemtura and other registrants on December 13, 2001, the PMRA provided a response to the comments and information Chemtura and others had provided on the draft risk assessment.<sup>399</sup> None of the information sent provided any reason to change its occupational risk assessment; nor did any of the information submitted demonstrate that the PMRA's concerns could be adequately addressed through the imposition of protective measures or restrictions in use to minimize exposure.

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<sup>396</sup> Report from Crompton Canada (predecessor-in-title to Chemtura Canada), *Preliminary Consolidated Comments on the PMRA Occupational Exposure Risk Assessment and Proposed Regulatory Action on Lindane*, sent with letter from Rob Dupree, Crompton Canada to Jeff Parsons, PMRA, 15 November 2001 (Exhibit JW-26B).

<sup>397</sup> Report by Stefan Korpalski, Uniroyal Chemical (predecessor-in-title to Chemtura Canada), *Handler Exposure Assessment for Lindane as a Commercial Seed Treatment*, 30 November 2001, sent with letter from Rob Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada) to Jeff Parsons, PMRA, 6 December 2001 (Exhibit JW-26C).

<sup>398</sup> The Claimant incorrectly suggests this document demonstrated acceptable levels of worker exposure. Claimant's Memorial, ¶ 201. In fact, Chemtura's submission was simply an alternative risk assessment, based on the same exposure studies used by the PMRA. For commercial seed treaters, the Claimant used the Dupree 1992 study and the EPA's unit exposure numbers for that study, which were very similar to the PMRA's numbers. (Which again runs contrary to the assertions in the Claimant's Memorial, ¶195 that this study was out-of-date). However, Chemtura made a serious error in its risk calculations. By performing erroneous metric conversions of an EPA exposure number for commercial seed treaters (EPA March and July 2001), Chemtura cited the exposure for commercial loader/applicators as 13.9 µg/kg, when in fact the correct exposure value was 139 µg/kg. This means that its own calculated Margins of Exposure (MOEs) were actually much lower than presented in its assessment. Had they been correctly calculated, even based on the Claimant's much more lenient risk assessment, seed treater risks would have been unacceptable. Affidavit of John Worgan, ¶ 163; Affidavit of Cheryl Chaffey, ¶ 101.

<sup>399</sup> Affidavit of John Worgan, ¶ 164.

351. All of the data submitted to the PMRA at this time consisted of data that the PMRA had already collected and considered in the course of its own review. While Chemtura proposed the use of personal protective equipment (PPE) at this point, it did not, for example, propose extensive restrictions on the use pattern of the active (for example, use in closed transfer systems, where the pesticide is never in the open air during seed treatment). And contrary to the Claimant's allegation,<sup>400</sup> other registrants did not provide data "which indicated the occupational risks were far below those reported by the PMRA". Indeed, as the Claimant itself notes in its consolidated comments, the industry consultant Technology Sciences Group, Inc. (TSG) expressly observed that "the re-evaluation is comprehensive in that most relevant data is cited...".<sup>401</sup>

352. During the December 13, 2001 call (after the period in which Chemtura was to submit any new data), Chemtura informed the PMRA of the availability of a new immunotoxicity study, called the Huntingdon study, which had been commissioned by CIEL.<sup>402</sup> However, the PMRA's worker exposure concerns related to endocrine toxicity and sensitivity of the young. Thus, even if the study had satisfactorily addressed immunotoxic concerns relating to lindane, it would not have changed the results of the Special Review.<sup>403</sup>

353. The Claimant has complained that the overall period for comment was too short.<sup>404</sup> Yet the comment period granted in the Special Review of lindane was consistent with that used for other re-evaluations done at the same time, and with the PMRA policy

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<sup>400</sup> Claimant's Memorial, ¶ 202.

<sup>401</sup> The TSG comments went on to note that the PMRA's study was "...limited due to reliance upon the reviews of other bodies, particularly the U.S. EPA", see Report of Gary Burin, Technology Sciences Group, Comments on PMRA Lindane Re-evaluation Monograph, 13 November 2001 (Annex R-30). But the PMRA's use of EPA studies was part of a deliberate and scientifically sound policy that made particular sense in the context of a mass re-evaluation exercise.

<sup>402</sup> Report of Dr. M. G. Wing, Huntingdon Life Sciences Laboratory, *Investigation of the Immunotoxic Potential of Lindane: Peripheral Blood Lymphocyte Analysis on Samples from Mouse Carcinogenicity Study*, 17 January 2000 (Annex R-25).

<sup>403</sup> Affidavit of John Worgan, ¶ 168.

<sup>404</sup> Claimant's Memorial, ¶ 191.



in the context of the Special Review.<sup>405</sup> As of November 2001, the Claimant had had over two years' notice that the Special Review was ongoing, and could assess for itself the state of the database: the Claimant's representative CIEL had submitted a data list to the PMRA in May 1999.<sup>406</sup> Moreover, when the PMRA raised the issue of occupational data in October 2000, the Claimant encouraged the PMRA to rely on its 1992 Dupree study.<sup>407</sup> It is thus very misleading for the Claimant to suggest that it only had "one month" in total to submit further data.

354. It must also be recalled that this was a comment period relating to a Special Review, where the PMRA had reason to believe that continued use of the product could damage human health and the environment. The PMRA had sound policy reasons to avoid a lengthy comment-period, particularly when a registrant like Chemtura had done relatively little over the two-year Special Review period to participate (as the Board of Review itself would later find).<sup>408</sup> The Claimant glosses over this wider context when it suggests that it was given only "4 weeks to comment".<sup>409</sup>

355. It would be far more accurate to note that as of October 2001, lindane had been the subject of mounting scientific criticism and of progressive national restrictions for 30 years; the target of international action for at least 25 years; had been reduced to only a few remaining uses as of the late 1990s; and had just gone through an over two-year review process in which the Claimant was aware of issues raised regarding lindane use, including worker exposure concerns, and had ample time to comment. The comment period provided after October 30, 2001 was not the launch of discussions about the safety of lindane. It was the tail-end.

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<sup>405</sup> The comment period for Diazinon was 60 days; Affidavit of John Worgan, ¶ 169. See PMRA, Re-evaluation Note REV2005-06, *Preliminary Risk and Value Assessments of Diazinon*, 30 June 2005 (Annex R-43).

<sup>406</sup> Minutes of meeting between PMRA, Chemtura and CIEL, 11 May 1999 (Exhibit JW-19).

<sup>407</sup> Letter from Rob Dupree, Uniroyal, to Janet Taylor, PMRA, 6 October 2000 (Exhibit CF-10); Affidavit of Dr. Claire Franklin, ¶ 29.

<sup>408</sup> *Board of Review Report*, ¶¶ 83-92 (Exhibit WS-71).

<sup>409</sup> Claimant's Memorial, ¶ 192.

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**C. Chemtura opted not to withdraw its lindane registrations voluntarily in the wake of the Special Review**

**1. The PMRA advised all lindane registrants of identical terms of progressive lindane withdrawal**

356. As a result of the Special Review of lindane, the PMRA advised the registrants of lindane seed treatment products that all uses of their products would be phased out over a period of 1 to 3 years.

357. The PMRA in particular advised the Claimant on December 19, 2001 that the termination of all its lindane seed treatment products was warranted.<sup>410</sup>

358. The PMRA proposed a voluntary discontinuation pursuant to s.16 of the *PCPA* Regulations to all registrants. The PMRA proposed 2 phase-out periods, one for the wireworm-related applications and the other for flea beetle applications. Both were progressive, and gave stakeholders an extended period to use up existing stocks, and to modify their practices. It requested additional information on each registrant's products in order to assess the feasibility of its proposed time-line.

359. Both phase-outs called for any remaining product or treated seed outstanding at the end of the respective phase-out periods to be disposed of at the expense of the owner.

**2. The Claimant rejected the PMRA's regulatory action**

360. On January 17, 2002, the PMRA reiterated to the Claimant that it was prepared to accept the phase-out of Chemtura's lindane products according to the proposed schedule only if the Claimant notified the Minister by January 31, 2002 of its agreement to voluntarily withdraw all of its remaining lindane registrations.<sup>411</sup>

361. The Claimant forwarded sales figures and inventory information in accordance with the PMRA's request on January 17, 2002. The Claimant further asserted that, "[i]n

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<sup>410</sup> Letter from Janet Taylor, PMRA, to Rob Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada), 19 December 2001 (Annex R-60).

<sup>411</sup> The PMRA's request was consistent with s. 16 of the *PCPR* (applicable here in the case of a phase-out of all uses, as opposed to the earlier partial deregistration of canola use under s. 13).

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providing this information, [Chemtura] in no way concurs with the PMRA's proposal for voluntary discontinuance under the [PCPA]. Given the terms of the December 19 letter from the PMRA, there is no basis for immediate suspension under the Act<sup>412</sup>." Thus, the Claimant expressly rejected both the PMRA's scientific conclusions, and a voluntary withdrawal.

**3. The PMRA was unable to provide the Claimant the extended phase-out provided by statute for voluntary deregistration**

362. On February 11, 2002, the PMRA advised the Claimant that, in light of the results of the Special Review and the Claimant's decision not to voluntarily discontinue its sales of its lindane products, the registrations of such products were terminated through suspension.<sup>413</sup>

363. In a different letter on the same date, the PMRA refused the Claimant's request of May 8, 2001 to amend its labels respecting these same products by reinstating canola and rapeseed.<sup>414</sup> Since lindane use was to be phased out altogether, Chemtura's request for a label amendment to add canola was obviously misplaced.

364. On February 21, 2002, the PMRA advised the Claimant that its registrations for its remaining lindane products were terminated through suspension.<sup>415</sup>

365. In the case of a voluntary suspension under s.16 of the *PCPR*, the PMRA has the statutory right to permit a long phase-out period. By so exercising its discretion, the PMRA was not in any way "agree[ing] to cease enforcing the law" as the Claimant

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<sup>412</sup> Letter from Rob Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada) to Janet Taylor, PMRA, 28 January 2002 (Exhibit WS-62). (our emphasis)

<sup>413</sup> Letter from Janet Taylor, Health Canada, Manager Registered Product Evaluation, to Rob Dupree, Crompton, 11 February 2002 (Annex R-307).

<sup>414</sup> Letter from Wendy Sexsmith, PMRA to Rob Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada), 11 February 2002 (Annex R-308).

<sup>415</sup> These products include: *Vitaflo DP Systemic Fungicide & Insecticide*, Reg. No. 11422; *Vitavax Dual Solution Systemic Fungicide & Insecticide*, Reg. No. 14115; *Vitavax Dual Powder Seed Protectant*, Reg. No. 15537.

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alleges.<sup>416</sup> However, where a registrant refuses to proceed on a voluntary basis, the PMRA has no further statutory flexibility, and is obliged to suspend registrations under s.20 of the *PCPR*, which does not provide for a phase-out.

366. Chemtura's case was distinct from that of all other lindane registrants in Canada because all other registrants agreed to the voluntary suspension of their registrations in the wake of the Special Review. Thus, the PMRA could offer them a phase-out period under Section 16 of the Regulations.<sup>417</sup> Chemtura also could have benefited from this phase-out, but lost this opportunity by refusing to voluntarily withdraw its registrations.

#### **4. Claimant initiated a second Chapter 11 matter**

367. On September 19, 2002, in addition to serving Canada with an amendment to its existing Chapter 11 claim, the Claimant also served Canada with an additional Notice of Intent, further to Articles 1116, 1117 and 1119 of the NAFTA. This latest Notice of Intent alleged that Canada breached its obligations under Articles 1102, 1103, 1104, 1105, 1106 and 1110 of the NAFTA entitling Chemtura to claim damages under Articles 1116 and 1117.

368. In this latest Notice of Intent, the Claimant alleged that the PMRA's suspensions of its products on February 11, 2002,<sup>418</sup> and February 21, 2002,<sup>419</sup> respectively, without the right to a phase-out, were contrary to Canada's NAFTA obligations. These suspensions, the Claimant alleged, were effected notwithstanding its full-compliance with the PMRA's request for sales and inventory information in order to be granted the right to phase use out gradually. But Chemtura failed to mention its own refusal to voluntarily withdraw its lindane registrations despite the PMRA's findings that occupational risks were unacceptable.

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<sup>416</sup> Claimant's Memorial, ¶ 443.

<sup>417</sup> *PCPR*, s. 16 (Annex R-2).

<sup>418</sup> *NoI-2*, ¶ 6 (Annex R-138). These products include: *Vitavax RS Flowable*, *Vitavax RS Powder*, *Cloak Seed Treatment*, *Vitavax RS Flowable (undyed)*, and *Vitavax RS Dynaseal*.

<sup>419</sup> *NoI-2*, ¶ 7 (Annex R-138). These products include: *Vitaflo DP Systemic*, *Vitavax Dual Solution Systemic* and *Vitavax Dual Powder Seed Protectant*.

369. Chemtura sought damages of an additional \$100 million (USD) in this claim.

370. On January 20, 2003, counsel for the Claimant and Canada held consultations further to NAFTA Article 1118 in relation to this second claim. The Notice of Arbitration in relation to this claim was served on Canada on February 10, 2005.<sup>420</sup>

**D. A Board of Review scientifically evaluated the PMRA's conclusions supporting a full lindane ban**

**1. The nature of Board of Review proceedings**

371. Having failed to avail itself of a voluntary withdrawal and the related phase-out period for non-canola uses, the Claimant, exercising its right as a registrant under Section 23 of the *PCPA* Regulations,<sup>421</sup> requested the constitution of 4 separate Boards<sup>422</sup> to review 4 decisions made by the PMRA regarding the Claimant's lindane registrations.<sup>423</sup>

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<sup>420</sup> *Crompton v. Canada*, Notice of Arbitration submitted 16 February 2005 (Annex R-141) (*NoA-2*).

<sup>421</sup> Under s. 23 of the *PCPR*, a Review Board is a scientific body constituted to assist the Minister of Health in evaluating a decision made by the PMRA and challenged by an affected registrant. *PCPR*, s. 23 (Annex R-2). The members of the Board must be experts in their field, and independent from the PMRA and Health Canada. The Board's findings are recommendations only and not binding on the Minister. According to s. 24 of the Regulations, the Minister is required to appoint a Review Board upon receipt of such a request.

<sup>422</sup> In the more than 30 year history of the regulations prior to the Chemtura Review Board requests, only 2 registration decisions under the *PCPA* had been challenged through the Review Board process. Affidavit of Wendy Sexsmith, ¶ 160.

<sup>423</sup> The Claimant's four requests related to:

- the PMRA's refusal to reinstate the canola uses for lindane that the Claimant had discontinued pursuant to the VWA. The Claimant sent this request to the PMRA on February 18, 2002;
- the PMRA's decision to terminate through suspension the Claimant's registrations for the remaining (non-canola) uses for the same five products that were the subject-matter of the first request. The Claimant sent this request on February 18, 2002 as well;
- the PMRA's decision to suspend three further lindane product registrations that were used on wheat, barley, oats, rye, and flax. The Claimant sent this request on March 14, 2002; and
- the PMRA's decision to suspend the registration for the lindane base product, lindane technical. The Claimant sent this request on September 29, 2003.

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Each was based on the finding that, pursuant to the Special Review, occupational health risks dictated that the lindane product registrations could no longer be supported by the Minister.

372. In its letters requesting the constitution of a Review Board, counsel for the Claimant indicated that it intended to raise “the legal (including jurisdictional), scientific and factual basis and/or authority to suspend the registration of the above-referenced control products in the current circumstances” before the Board of Review.<sup>424</sup>

**2. The Claimant was responsible for the delay in constituting the Board of Review**

373. On May 6, 2002, the Minister of Health notified the Claimant that its requests for a Review Board had been forwarded to the PMRA for appropriate action. On June 3, 2002, the Claimant responded, questioning the involvement of the PMRA in the appointment of the Review Board:

We are unclear as to the meaning or intent of your letter. It would appear that either you intend the PMRA to appoint the Board for the purpose of conducting the reviews contemplated by the Regulations or that you intend the PMRA itself to conduct the review. Either interpretation offends principles of fairness and reasonable administrative decision-making.<sup>425</sup>

374. On June 12, 2002, 9 days after sending the letter to the Minister, the Claimant brought an application in the Federal Court of Canada challenging the Minister's decision to refer the Review request to the PMRA. The Claimant argued that the involvement of

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*See* letters from Michael Phelan, Ogilvy Renault LLP on behalf of Crompton Canada (predecessor-in-title to Chemtura Canada) to the Hon. Anne McLellan, Minister of Health, requesting formation of a Review Board of, respectively, 18 February 2002 (Exhibit WS-64) (a second identical letter was sent the same day, pursuant to the Minister's other 11 February 2002 decision.); 14 March 2002 (Exhibit WS-65); and 29 September 2003 (Exhibit WS-66).

<sup>424</sup> Pursuant to the *PCPR*, the application that triggers the Board of Review determines the subject-matter of the inquiry. *PCPR*, s. 25(1) (Annex R-2).

<sup>425</sup> Letter from Michael Phelan, Ogilvy Renault, to the Honourable Anne McLellan, Minister of Health, 3 June 2002 (Exhibit WS-69).

the PMRA in this process was prejudicial and that the Minister had erred in jurisdiction and at law by involving it in the appointment.<sup>426</sup>

375. Following receipt of the application for judicial review, the Minister postponed appointing the Board pending the Court's consideration of the Claimant's case. Close to a year passed before the Claimant's application was scheduled to be heard by the Federal Court in Vancouver, British Columbia. After causing all of this delay, at the hearing, counsel for the Claimant advised the Court that it had no objection to the PMRA being involved in selecting the Board members. The Court therefore adjourned the matter indefinitely.<sup>427</sup>

376. On January 8, 2004, Chemtura Canada filed a motion for discontinuance in this matter.<sup>428</sup>

Since the Respondent has appointed a Review Board as originally requested by the Applicant and the Applicant has been successful in obtaining the relief it sought in the application, the Applicant wishes to discontinue this proceeding.

### **3. The Board of Review**

#### **a) The Board of Review was constituted in accordance with the Regulations**

377. After the Federal Court hearing on May 6, 2003, the Minister and the PMRA moved forward with the establishment of the Board.<sup>429</sup> With the agreement of the Claimant, the Minister determined that it would establish 3 review Boards, for each of the

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<sup>426</sup> *Crompton Co./Cie v. Attorney General of Canada*, Notice of Application, Federal Court File No. T-899-02, 12 June 2002 (Exhibit WS-70).

<sup>427</sup> The Claimant was not forced to bring Federal Court proceedings in order to push the Minister to appoint a Board as the Claimant suggests (Claimant's Memorial, ¶ 263). To the contrary, the Claimant challenged a proceeding already begun, and then dropped its objections after a year of wasted and entirely unnecessary procedural opposition to the constitution of the Board.

<sup>428</sup> *Crompton Co./Cie v. Attorney General of Canada*, Notice of Motion, Court File No. T-899-02, 8 January, 2004 at 3, ¶ (k) (Annex R-104A).

<sup>429</sup> *Crompton Co./Cie v. Attorney General of Canada*, Report of Counsel for the Respondent to the Court Pursuant to the Order of the Honourable Justice Frederick E. Gibson of 6 May 2003, Court File No. T-899-02, 15 May 2003 (Exhibit WS-67) (*15 May 2003 Report of Respondent's Counsel*).

3 initial requests, but that the same members would be appointed to each Board, and that they would be asked to consolidate the matter – effectively operating as one Board.<sup>430</sup>

The Claimant's 2003 request for the review of lindane technical, which was initiated after the Board was constituted, was also consolidated with the other requests.<sup>431</sup>

**b) The 3 Board members were highly qualified scientists**

378. In its search for qualified panellists, the PMRA sought individuals who:

- had the expertise to evaluate the scientific information on which the regulatory decisions were based and provide a peer review of these decisions;
- were not employed by the Government of Canada or any of its Agencies;
- were not in a position of conflict with respect to their responsibilities as Review Board members; and
- were available to undertake and complete their responsibilities without undue delay.<sup>432</sup>

379. The PMRA contacted a number of potential candidates who met these criteria and who had scientific expertise in: a) toxicology; b) worker exposure assessment; and c) risk assessment.<sup>433</sup> Out of these possible panellists, the 3 Board members were selected.

380. On August 23, 2003, the PMRA contacted the Board members to confirm their participation, and to establish their mandate.<sup>434</sup> The Board members were all experienced toxicologists.<sup>435</sup>

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<sup>430</sup> 15 May 2003 Report of Respondent's Counsel, ¶ 12 (Exhibit WS-67).

<sup>431</sup> Board of Review Report, ¶ 9 (Exhibit WS-71).

<sup>432</sup> 15 May 2003 Report of Respondent's Counsel, ¶ 18 (Exhibit WS-67).

<sup>433</sup> *Crompton Co./Cie v. Attorney General of Canada*, A Second Progress Report of Counsel for the Respondent to the Court Pursuant to the Order of the Honourable Justice Frederick E. Gibson of 6 May 2003, court file No. T-899-02, 27 June 2003, ¶¶ 2-3 (Exhibit WS-72).

<sup>434</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Dr. Len Ritter, Canadian Network of Toxicology Centres, 26 August 2003 (Exhibit WS-73); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Dr. Joe Frank, California Department of Pesticides Regulation, 26 August 2003 (Exhibit WS-74); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Dr. Robert Sielken, Sielken Associates, 26 August 2003 (Exhibit WS-75).



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381. On October 22, 2003, the Minister informed counsel for Chemtura Canada that the Review Board had been appointed.<sup>436</sup> Shortly thereafter, Chemtura Canada contacted the chair of the Board and confirmed its acceptance of the Board's appointment.<sup>437</sup> The work of the Board was delayed for some months, first by the Claimant's (subsequently abandoned) Federal Court proceeding, and then by the process of appointing independent counsel for the Board, to ensure that there was no conflict from government lawyers representing both the Board and the Minister of Health.

**c) The Board established reasonable terms of reference**

382. The PMRA wrote letters to the Board outlining its mandate, which reflected s. 25 of the Regulations. The PMRA's letters also established that the subject-matter of the hearings was identical to the scope of inquiry identified by the Claimant in all of its requests for appointment of a Board: "the legal (including jurisdictional), scientific and factual basis and/or authority to suspend the registration of the above-referenced control products in the current circumstances".<sup>438</sup>

**d) The Board of Review was transparent and open**

383. The Board officially began its work in May 2004.<sup>439</sup> On July 28, 2004, the Board published notice of its proceedings in major English and French newspapers in Canada. The notice, which fulfilled the requirement in s. 25 of the Regulations that the Board give "all other persons who may be affected by the subject matter of the hearing" an

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<sup>435</sup> The Board members were: Leonard Ritter, Ph.D. of the Canadian Network of Toxicology Centres (presiding member); Joseph P. Frank, D.Sc. of the California Department of Pesticides; and Robert L. Sielken Jr., PhD of Sielken Associates.

<sup>436</sup> Letter from the Honourable Anne McLellan, Minister of Health, to Michael Phelan, Ogilvy Renault, 22 October, 2003 (Exhibit WS-76).

<sup>437</sup> Letter from Michael Phelan, Ogilvy Renault, to Dr. Len Ritter, Canadian Network of Toxicology Centres, 30 October 2003 (Exhibit WS-77).

<sup>438</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Dr. Len Ritter, Canadian Network of Toxicology Centres, 26 August 2003 (Exhibit WS-73); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Dr. Joe Frank, California Department of Pesticides Regulation, 26 August 2003 (Exhibit WS-74); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Dr. Robert Sielken, Sielken Associates, 26 August 2003 (Exhibit WS-75).

<sup>439</sup> *Board of Review Report*, ¶ 10 (Exhibit WS-71).

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opportunity to be heard,<sup>440</sup> was also distributed to 30 environmental, health, labour and consumer groups, academics, pesticide manufacturers and users who comprise the Pest Management Advisory Council.<sup>441</sup> The notice read as follows:

NOTICE is hereby given that the Minister of Health for Canada has established a Review Board pursuant to the *Pest Control Products Regulations*, C.R.C., c. 1253 at the request of Crompton Co.\Cie to conduct a hearing concerning the decisions made on February 11 and 21, 2002 under the *Pest Control Products Act*, R.S., c. P-10, to suspend or refuse the amendment of registrations of pest control products containing lindane.

Any person who may be affected by those decisions and wishes to make representations to the Review Board at the hearing must contact counsel for the Review Board in writing at the address below no later than August 30, 2004. Affected persons are requested to indicate the nature of their interest in these matters and whether they wish to participate in these proceedings. The Review Board may decide the manner in which affected persons will be allowed to participate in these proceedings.

The hearing will be held at the City of Ottawa, Province of Ontario, at a time to be determined by the Board. Affected persons should be aware that no funding exists for the payment of any costs related to their participation in this proceeding.<sup>442</sup>

**e) The Board adopted a fair procedure**

384. Since the *PCPA* Regulations do not prescribe any timeframes or rules, the Review Board developed its own Rules of Procedure.<sup>443</sup> The Rules of Procedure established the following timeline:

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<sup>440</sup> *PCPR*, s. 25 (Annex R-2).

<sup>441</sup> *Board of Review Report*, ¶ 11 (Exhibit WS-71). The Pest Management Advisory Council “is a multi-stakeholder group that fosters communication and dialogue among stakeholders and with the PMRA, and provides advice to the Minister of Health on policies and issues relating to the federal pest management regulatory systems”. See PMRA, “Pest Management Advisory Council (PMAC)”, online at: <<http://www.pmra-arla.gc.ca/english/advbod/pmace.html>> (Annex R-10).

<sup>442</sup> Notice of Review Board Hearing into the use of Lindane Seed Treatment Products, Lindane Review Board, 28 July 2004 (Annex R-123).

<sup>443</sup> Lindane Review Board Rules of Procedure, 16 September 2004, ¶ 5 (Annex R-125).

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- August 30, 2004: Notices from affected persons to be submitted to the Review Board;
  - September 20, 2004: Review Board announces decisions regarding standing of affected persons, and the role they will be permitted to play in the review process;<sup>444</sup>
  - November 1, 2004: Written submissions, witness statements and experts' reports to be filed with the Review Board, by those contesting the Minister's decisions, and any Party directed by the Review Board to file at that time;
  - November 22, 2004: Written submissions, witness statements and experts' reports to be filed with the Review Board, by those supporting the Minister's decisions, and any Party directed by the Review Board to file at that time;
  - December 6, 2004: Reply submissions by those contesting the Minister's decisions to be filed with the Review Board;
  - December 20, 2004: Review Board announces witnesses it will call to hear evidence at the hearing and the order of evidence and questions to be followed at the hearing; and
  - January 10-13 and 24-27, 2005: Hearing.<sup>445</sup>

#### **4. The Board of Review offered the Claimant a full opportunity to be heard**

385. The Board of Review gave the Claimant a full and thorough hearing of its complaints about the Special Review.

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<sup>444</sup> On 20 September 2004, the Board of Review issued a preliminary decision regarding disclosure of documents in the Minister's Possession: Decision of the Lindane Review Board Regarding Disclosure of Documents in the Minister's Possession, 20 September 2004 (Annex R-126). This was in response to an application filed by the Claimant on 29 July 2004 seeking to compel the Minister to produce certain documents. Letter from Gregory Kane, Stikeman Elliott and Charles O'Connor, McKenna, Long & Aldridge to Gerry Stobo, Borden Ladner Gervais, 29 July 2004 (Annex R-124). The Board decided that its mandate, as established by the Regulations, included the contemplation of new information that was not part of the initial Special Review. Decision of the Lindane Review Board regarding a Motion to Extend Time for Filing, Lindane Review Board, 16 November 2004, ¶ 18 (Annex R-129) (*Review Board Filing Extension Decision*). However, the Board concluded that it did *not* have jurisdiction to compel the production of documents, as this power did not fall within the scope of its mandate, which was to "inquire into the subject matter and give affected persons an opportunity to be heard." *Review Board Filing Extension Decision*, ¶ 18 (emphasis in original).

<sup>445</sup> Lindane Review Board Rules of Procedure, 16 September 2004, ¶ 7 (Annex R-125).

386. The Claimant first provided the Review Board with the written testimony of five witnesses, both independent and from within its organization,<sup>446</sup> as well as a report prepared by a five-member panel of experts in “medicine, toxicology, risk assessment, and related fields” constituted at the Claimant’s request, criticizing the findings and methods of the Special Review.<sup>447</sup> Through its witnesses’ testimony, the Claimant attacked the ways in which the PMRA had framed its study, and the conclusions that the Agency had reached.

387. The Claimant also included copies of 8 scientific studies, addressing both lindane toxicology and occupational health assessment, which were relied upon by its expert panel and cited in their reports and testimony. The Claimant also relied on studies that had not been completed at the time of the Special Review, and put a proposal to the Board for lindane registration that was much narrower in scope, and included much greater mitigation measures, than that which it had requested at the time of the Special Review.<sup>448</sup>

388. The Claimant further changed its position by requesting the continued registration of only its 2 liquid lindane products, suddenly dropping its claim for the re-registration of its dust formulations.<sup>449</sup> Since the Claimant had not suggested these mitigation measures

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<sup>446</sup> Letter from Gregory Kane, Stikeman Elliott and Charles O’Connor, McKenna, Long & Aldridge to Gerry Stobo, Borden Ladner Gervais, 29 October 2004 (Annex R-124).

<sup>447</sup> Report of an Expert Panel, *Occupational Exposures and Risks from uses of Lindane as a Seed Treatment in Canada*, Lindane Review Board, 27 October 2004 at 2 (Annex R-127).

<sup>448</sup> The Claimant’s “Report of an Expert Panel”, filed as part of its submission to the Board of Review, outlined a wide array of potential mitigation measures allegedly making lindane use safe for workers, including the use of personal protective equipment and closed systems for seed treatment, designed to bring the level of worker exposure to lindane within acceptable parameters. In the witness statement of Stefan Korpalski, the Claimant for the first time proposed that these mitigation measures, among others, could be added to the labels of its lindane product. For example, Korpalski proposed label changes that required lindane seed-treatment to take place in a closed treatment system, and provided new scientific studies to support this proposal. See Witness Statement of Stefan Korpalski, Lindane Board of Review, 26 October 2004 (Annex R-128).

<sup>449</sup> Witness Statement of Stefan Korpalski, Lindane Board of Review, 26 October 2004, at 3-4 (Annex R-128). Concerning the dust formulations, see Letter from Michael Phelan, Ogilvy Renault LLP (on behalf of Crompton Canada (predecessor-in-title to Chemtura Canada)) to the Hon. Anne McLellan, Minister of Health, requesting formation of a Review Board, 18 February 2002 (Exhibit WS-64), which lists five registered lindane products as the subject-matter of the requested Board of Review.

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at the time of the Special Review, they had not been considered when the PMRA had conducted its analysis of the safety of lindane for workers.<sup>450</sup>

389. After the Claimant filed its initial written submission, the PMRA was given an extra month to prepare its response,<sup>451</sup> as the Claimant's filing relied in part on proprietary studies which Chemtura had not previously provided to the PMRA and which, in some cases, had not even been conducted at the time of the Special Review.<sup>452</sup>

390. The PMRA's written submissions, which were filed on December 20, 2004, addressed the regulatory framework for the Special Review, and the reasons underpinning the PMRA's decisions both during the Special Review and after the results of the Review were released.<sup>453</sup> The PMRA filed a comprehensive statement "intended to assist the Board of Review by providing a summary guide to the Minister's view of the issues, and of the evidence on either side of the debate that will be conducted before the Board".<sup>454</sup>

391. In its reply, filed on January 4, 2005, two of the Claimant's witnesses, as well as the Panel of Experts (collectively), provided further statements that directly addressed the witness statements provided by PMRA in its submission. Through this process, the Claimant had an opportunity to critique the studies upon which the PMRA had relied in the Special Review. Its expert panel was also given a further opportunity to explain why its conclusions, where they differed, were preferable to those reached by the PMRA.<sup>455</sup>

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<sup>450</sup> Affidavit of Cheryl Chaffey, ¶ 123.

<sup>451</sup> The Claimant's time for filing a written reply was also extended by a month, from the initially scheduled date of 6 December 2004, until 4 January 2005. *Review Board Filing Extension Decision*, 16 November 2004, ¶ 5 (Annex R-129).

<sup>452</sup> *Review Board Filing Extension Decision*, ¶ 4 (Annex R-129).

<sup>453</sup> Submission of the Minister of Health to the Lindane Review Board, 20 December 2004 (Annex R-130).

<sup>454</sup> Submission of the Minister of Health to the Lindane Review Board, 20 December 2004, ¶ 1 (Annex R-130).

<sup>455</sup> Statement by Gary Burin in Reply to the PMRA Witness Statement of Cheryl Chaffey, 4 January 2005 (Annex R-132); Statement by Stefan Korpalski in Reply to the PMRA Witness Statement of Mary Mitchell, 4 January 2005 (Annex R-133); Reply by the Expert Panel to the PMRA Witness Statements (Cheryl Chaffey and Mary Mitchell), 4 January 2005 (Annex R-131).

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The Claimant also submitted 2 additional scientific reports addressing the proper framework for assessing toxicity, which had not been previously available.<sup>456</sup>

392. The Review Board held its hearings in Ottawa, beginning on January 10, 2005. During the 9 days of hearings, the Board heard all 13 witnesses, and over 2000 pages of transcript were produced.<sup>457</sup>

393. During the oral hearing, the witnesses were examined by their respective counsel, and cross-examined by opposing counsel. The members of the Board also questioned the witnesses to obtain relevant information, and to explore issues that were not fully examined in the written statements.<sup>458</sup>

394. Both parties' final submissions were filed on February 15, 2005.<sup>459</sup> The Claimant's submission alleged that the Special Review was unfair.<sup>460</sup> This was the first time that such concerns had been raised directly in the Claimant's 3 opportunities to make written submissions, and their inclusion at this final stage precluded the PMRA from providing a written response. The Claimant also argued that safety factors lower than those employed by the PMRA would have been appropriate for assessing the occupational risk associated with lindane.<sup>461</sup>

395. The PMRA's submission summarized its position regarding the Special Review and highlighted the fact that the proposal for product registration presented to the Board of Review by Crompton was much narrower in scope than the one that the PMRA had

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<sup>456</sup> Table of Contents of Reply by Crompton, Lindane Review Board, 5 January 2005 (Annex R-134).

<sup>457</sup> *Board of Review Report*, ¶ 17 (Exhibit WS-71).

<sup>458</sup> For example, the Board asked specific questions about the scientific methods used in one of the tests a witness had quoted in his statement. Transcript of Testimony of Gary Burin, Lindane Review Board, 11 January 2005 at 225-232 (Annex R-135).

<sup>459</sup> *Board of Review Report*, ¶ 18 (Exhibit WS-71).

<sup>460</sup> Final Submission of Crompton Co./Cie. (predecessor-in-title to Chemtura Canada) to the Lindane Review Board, 14 February 2005 at 16-22 (Annex R-136).

<sup>461</sup> Final Submission of Crompton Co./Cie. (predecessor-in-title to Chemtura Canada) to the Lindane Review Board, 14 February 2005 at 26-39 (Annex R-136).

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been addressing at the time it discontinued the Claimant's lindane uses, both in terms of label warnings and the number of products it was seeking to register.<sup>462</sup>

### 5. The Board of Review issued a series of recommendations

396. On August 17, 2005, the *Report of the Lindane Board of Review*, was released. In its Report, the Board made the following six recommendations:

- “[T]he Board recommends that during its deliberations, PMRA should seek and consider input from Crompton as well as other interested parties.”<sup>463</sup>
- “The Board recommends that [its finding that] the evidence for sensitivity of the young ... is suggestive as opposed to conclusive [and] be taken into account when considering the need for an additional uncertainty factor”.<sup>464</sup>
- The Review Board's finding that “the evidence for Lindane related immunotoxicity is not compelling ... should be taken into account when considering the need for additional uncertainty factors”.<sup>465</sup>
- Because “[t]he 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”.<sup>466</sup>
- Since “the Board finds that a conclusion of common toxicological endpoints and aggregated exposure for both inhalation and dermal exposure, as conducted by the PMRA, is not sufficiently supported by the evidence and available data, ... the Board recommends that ... the Minister direct PMRA officials to review both the final JMPR report, as well as the original dermal toxicity study on which it is based, to determine whether the liver toxicity data, discussed in the draft JMPR report can be supported, so as to arrive at an independent conclusion as to liver toxicity, and the appropriateness of aggregation of dermal and inhalation exposure”.<sup>467</sup>

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<sup>462</sup> Crompton Co./CIE and The Minister of Health as Represented by the PMRA, Final Submission of the PMRA on behalf of the Minister of Health to the Lindane Review Board, 14 February 2005, ¶ 3 (Annex R-309).

<sup>463</sup> *Board of Review Report*, ¶¶ 214, 227 (Exhibit WS-71).

<sup>464</sup> *Board of Review Report*, ¶ 217 (Exhibit WS-71).

<sup>465</sup> *Board of Review Report*, ¶ 219 (Exhibit WS-71).

<sup>466</sup> *Board of Review Report*, ¶¶ 222, 162 (Exhibit WS-71).

<sup>467</sup> *Board of Review Report*, ¶¶ 223 – 224 (Exhibit WS-71).

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- “[T]he Board recommends that PMRA reconsider potential opportunities for mitigating its concern for health related issues associated with the use of Lindane.”<sup>468</sup>

397. Rather than a wholesale condemnation of the PMRA’s Special Review process, the Board overall considered that the PMRA could have adopted a less conservative approach; that the Claimant itself had failed to fully participate in or follow the Special Review;<sup>469</sup> and that the PMRA should take into account information that the Claimant had generated for the first time during the Board of Review proceedings.

398. As for some of the Board’s specific findings, Canada will address these in the order they are raised at &381 of the Claimant’s Memorial:

- **Sensitivity of the Young:** Regarding the Board of Review’s finding that sensitivity in the young cannot clearly be refuted, but that the evidence in support is suggestive rather than conclusive – the PMRA’s guiding principle is the “precautionary principle”, as the national regulator. The regulator does not need conclusive evidence prior to taking regulatory action.<sup>470</sup>

The *PCPA* sets an even higher standard regarding protection from unacceptable risk than does the precautionary principle. The new Act defines the standard in subsection 2(2) as follows:

For purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

That standard was applied under the former Act and formalized in the new Act.

- **Uncertainty Factors:** The Claimant suggests the Board criticized the PMRA’s use of uncertainty factors. The PMRA in the Special Review applied uncertainty factors consistent with its contemporary regulatory practice.

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<sup>468</sup> *Board of Review Report*, ¶¶ 214, 129 (Exhibit WS-71).

<sup>469</sup> *Board of Review Report*, ¶¶ 109 – 110 (Exhibit WS-71).

<sup>470</sup> Affidavit of Cheryl Chaffey, ¶ 131 (for this and the balance of the PMRA’s responses to points raised by the Board of Review).



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Moreover, the factors applied by the PMRA were not inconsistent with those applied by other international bodies.

- **Immunotoxicity Studies:** Regarding immunotoxicity, the PMRA was criticized for relying on studies published in the open scientific literature, which the Board claimed the PMRA would not normally do. The scientific literature represents a valuable source of independent research that can play a significant role in an assessment. While the literature is rarely consulted for new submissions due to the lack of research on products that have not entered the marketplace, it is routine for the PMRA to consider research from the literature in the re-evaluation of any product. The PMRA acknowledged concerns raised by the Board regarding product purity in the immunotoxicity studies and in fact, placed less reliance on this finding in the recent assessment. In any event, the PMRA's 2001 assessment would have remained unchanged, even if one had removed this concern from the considerations. The concerns that the PMRA had for endocrine toxicity and sensitivity of the young were enough in the PMRA's view to warrant the additional factor of 10 used in the occupational risk assessment.<sup>471</sup>
- **Additional Adjustment Factors:** Regarding the uncertainty factor, the Board of Review itself suggested an "adjustment" factor over the base factor of 100. This of course, contrasted with the reduction of the basic standard uncertainty factor of 100 to 32 proposed by the Claimant. The PMRA acknowledged during the hearing that an additional factor of only 3 would be deemed acceptable to some toxicologists. However, this does not mean it was acceptable to PMRA, especially given the mandate and mission of the PMRA and the precautionary approach at the core of its guiding legislation.
- **Toxicity Conclusions:** The Board of Review found that there was insufficient support that the same organ (*i.e.*, the liver) was a target in both the dermal and inhalation toxicity studies. It made this finding based on data that was *not* available to PMRA during the Special Review. The common findings in the liver allowed PMRA to combine the risk assessments for the dermal and inhalation route of exposure. In any event, even having considered this additional data in its Re-evaluation Note exercise, the PMRA's interpretation of those studies remains unchanged.
- **New Studies:** The Board of Review in referencing exposure evaluations arising out of particular studies, cited studies not available to PMRA at the time of the Special Review, and submitted by the Claimant only *after* the end of the Special Review. In any event, PMRA took such studies into account in the REN and reached the same conclusions as in 2001.

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<sup>471</sup> Transcript, Lindane Review Board, 26 January 2005, Vol. 7, at 1375 (Exhibit CC-39).

- **Mitigation Measures:** The Board of Review was not conclusive regarding its response that the risk of exposure might come within an acceptable range. In the text the Claimant cites at 407 of its Memorial, the Board concludes that if various additional factors are taken into account, target and actual margins of exposure “*may begin to approach acceptable margins*” (our emphasis). This is hardly a definitive statement. And indeed, in the Re-evaluation Note following the Board of Review, the PMRA did take the considerations of the Board into account and found that occupational risk remained unacceptable.
- **Imminent Concerns:** Finally, with regard to the Board of Review’s excerpts at Annex C of the Claimant’s Memorial, it is important to note the Board’s acknowledgement that some of the concerns raised by the PMRA could give rise to concerns of an imminent nature. A national regulator was obviously within its rights to act on such concerns.

399. The Board of Review’s fundamental conclusion was that the PMRA’s Special Review results (suspending the use of lindane due to occupational exposure concerns) were within generally accepted scientific parameters.<sup>472</sup>

400. As the toxicology expert, Dr. Costa, notes in his independent report:

... the Board did not find that the PMRA made several unacceptable scientific findings or critical mistakes (cfr. Thompson, 2008, Chemtura 2008a). On the contrary, as said (par. 113), the Board stated that the “risk assessment and conclusions were generally within acceptable scientific parameters” (Board, 2005; par. 115), and that “the risk assessment process ... was adequate ... and consistent with existing regulations as they applied to lindane registrations of the time” (Board, 2005; par. 128).<sup>473</sup>

**E. The PMRA implemented the Board of Review’s recommendations, confirming its original decision to withdraw all lindane uses**

401. Following the Board of Review proceedings, the PMRA renewed its review of lindane, addressing all of the Board of Review’s recommendations. It launched a review *de novo* that culminated in the 2008 lindane Re-evaluation Note (REN). The PMRA thus exceeded the Board’s recommendations by a substantial measure. The net result of the

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<sup>472</sup> Board of Review Report, ¶ 115 (Exhibit WS-71).

<sup>473</sup> Dr. Costa Report, ¶ 116.

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PMRA's lengthy and careful post-Board re-evaluation of lindane was to confirm the correctness of its decision in the original Special Review. Indeed, the lindane Re-evaluation simply expanded the scientific rationale for suspending lindane use.

**1. The PMRA immediately sought to implement the Board of Review's recommendations**

402. After receiving the Review Board's Report in August of 2005, the PMRA spent the autumn of 2005 examining the Board's findings, and developing a strategy that would best incorporate the recommendations of the Board in its re-evaluation.

403. On September 15, 2005, prompted by the release of the Board of Review's Report, Chemtura's lawyer, Gregory Kane, wrote a letter to Health Minister Dosanjh in which he requested action:

[Chemtura] respectfully urges you to exercise your discretion on an expeditious basis pursuant to ss 25(3) of the Pest Control Products Regulations ("the Regulations") by implementing the recommendation made by the Review Board which directs the Pest Management Regulation [*sic*] Agency ("PMRA") to consult with [Chemtura] in order to take into account any relevant mitigation measures available and to consider the possibility of a mitigation strategy that might result in labels and use practices acceptable to PMRA with respect to the use of seed treatment products containing Lindane.

...

The ultimate recommendation of the Review Board while largely scientific in nature is also characterised by legal fairness relative to the regulatory process. *Implementing the Review Board recommendation will remedy the past situation in which Crompton was not provided with a fair opportunity to present its case in an effort to achieve the registration of Lindane's seed treatment products.*<sup>474</sup> (our emphasis)

404. After consultation with the office of the Minister of Health, the PMRA's executive director, Karen Dodds, wrote to Mr. Kane and the Review Board's lawyer,

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<sup>474</sup> Letter from Stikeman Elliott LLP to the Honourable Ujjal Dosanjh, Minister of Health, 15 September 2005 (Exhibit JW-33).

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Gerry Stobo, on January 17, 2006, announcing the PMRA's intention to implement the Review Board's recommendations:

Please note that Health Canada's Pest Management Regulatory Agency (PMRA) intends to reconsider the occupational risk assessment of lindane by taking into account the new exposure study generated by Crompton [Chemtura] since the Special Review, the Board's opinions and other information presented at the hearings, and will reconsider the original data and any supporting data relevant to the aggregate dermal and inhalation risk assessment.

Further, PMRA is currently reviewing its policy regarding the use of uncertainty and safety factors in risk assessment. This process includes public consultation. Should the outcome of the public consultations result in changes to the current policy, the PMRA will adjust the safety factors applied to lindane accordingly.<sup>475</sup>

405. This letter initiated the PMRA's discussion with the Claimant concerning the scope of the re-evaluation activity, and specifically indicated that the re-evaluation would be linked to the PMRA's ongoing review of the use of "uncertainty and safety factors"<sup>476</sup> in pesticide regulation.<sup>477</sup>

## **2. The PMRA notified the Claimant, former lindane registrants, and the general public of the review**

406. In his capacity as the Director of the PMRA's Re-evaluation Management Division (REMD), on February 28, 2006, John Worgan wrote to all former lindane

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<sup>475</sup> Letter from Karen Dodds, Executive Director, PMRA to T. Gregory Kane, Stikeman Elliott LLP, 17 January 2006 (Exhibit JW-34).

<sup>476</sup> The phrase "safety factors" has sometimes been used interchangeably with "uncertainty factors" depending on the regulatory authority involved. See PMRA, Regulatory Proposal PRO2007-01, *Use of Uncertainty and Safety Factors in the Human Health Risk Assessment*, 25 July 2007, at 2 (Exhibit JW-36) (Regulatory Proposal PRO2007-01).

<sup>477</sup> The PMRA's policy review on "uncertainty and safety factors" began in 2005, in order to update the Canadian Government's understanding of sources of uncertainty in scientific data and to develop guidance for using these factors (numerical adjustment) in estimating allowable human exposure. Uncertainty and safety factors reflecting both uncertainties and level of concern would be applied to all future pesticide assessments based on the outcomes of this policy discussion. Even at this early stage, then, the PMRA showed a willingness to address the Board's recommendations concerning increasing consultation with the registrants and reviewing the uncertainty and safety factors that it would apply to its re-assessment of lindane. See Affidavit of John Worgan, ¶ 190.

registrants, identifying the steps that the PMRA would take to implement the Review Board's recommendations:

As you are aware, the Lindane Board of Review submitted its report to the Minister of Health on 18 August 2005. In its review of the October 2001 lindane decision, the Board made a number of comments and recommended that the Minister of Health direct Health Canada's Pest Management Regulatory Agency (PMRA) to consult with Crompton [Chemtura] in order to evaluate, for the uses affected by the October 2001 decision, possible mitigation strategies that might result in acceptable labels and use.<sup>478</sup>

407. That letter was one of the PMRA's earliest acknowledgements of the Review Board's recommendations for increased consultation with registrants and the re-examination of potential mitigation measures with respect to lindane use.<sup>479</sup>

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<sup>478</sup> Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to Patti Turner, Crompton Canada (predecessor-in-title of Chemtura Canada), 28 February 28, 2006 (Exhibit JW-37); Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to Industries Quimicab Del., Inquinosa Noroeste, S.A., 28 February 2006 (Exhibit JW-38); Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to C.V. Srikanth, Kanoria Chemicals & Industries Ltd., 28 February 2006 (Exhibit JW-39); Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to Orval Swenson, Agsco Inc., 28 February 2006 (Exhibit JW-40); Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to Don Wilkinson, Interprovincial Cooperative Ltd., 28 February 2006 (Exhibit JW-41); Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to Louis Caron, Nora Concept, Inc., 28 February 2006 (Exhibit JW-42); Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to Duane Fairbairn, Syngenta Crop Protection Canada Inc., 28 February 2006 (Exhibit JW-43); Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to Irwin Schmidt, United Agri Products Canada Inc, 28 February 2006 (Exhibit JW-44) (*John Worgan 28 February 2006 Letters*).

<sup>479</sup> Mr. Worgan made pledges similar to those contained in the January 17, 2006 letter from Karen Dodds:

To meet the Board's recommendations the PMRA is ready to act in the following areas:

- 1) reconsider the occupational risk assessment of lindane by taking into account the new exposure study generated by Chemtura since the Special Review, the Board's opinions and other information presented at the hearings;
- 2) reconsider the original data and any supporting data relevant to the aggregate dermal and inhalation risk assessment; and
- 3) initiate communications with Chemtura, other former registrants of lindane products, and other interested parties, as appropriate, to seek input into risk assessments and to discuss viable mitigation measures that may address health-related concerns for workers.

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408. On page two of this letter, Mr. Worgan continued that, “[w]ith this letter, the PMRA announces the beginning of the follow-up review of the occupational risk assessment for lindane and the initiation of the work needed to complete the re-evaluation of the other risks associated with the use of lindane products, including dietary, cancer and environmental risks”.<sup>480</sup>

409. Finally, Mr. Worgan “ask[ed] all former registrants of affected lindane products to submit any relevant data or information that could be used in the above reviews... within 60 days of this letter” (this submission period was later extended by 90 days to July 31, 2006 to account for the concerns of former registrants who felt they needed more time to submit data).<sup>481</sup>

410. On the same day, Dr. Dodds, Executive Director of the PMRA, wrote a letter to Chemtura’s lawyer, responding to an earlier inquiry from Chemtura dated February 13, 2006. In her letter she advised Mr. Kane that:

[t]he PMRA has communicated to Crompton [Chemtura] and all the other registrants of Lindane products affected by the 2001 decision the steps that it intends to follow to address the recommendations of the Lindane Board of Review in the letter dated February 28, 2006. The PMRA is also in the process of publishing a public document to communicate to all interested parties an update on the review process of Lindane.<sup>482</sup>

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The PMRA is currently reviewing its policy regarding the use of uncertainty and safety factors in risk assessment. This process includes public consultation. Should the outcome of the public consultations result in changes to the current policy, the PMRA may consider adjusting the uncertainty factors applied to lindane accordingly. See *John Worgan 28 February 2006 Letters* (Exhibits JW-37 to JW-44).

<sup>480</sup> *John Worgan 28 February 2006 Letters* (Exhibits JW-37 to JW-44).

<sup>481</sup> E-mail from Marisa Romano Re-evaluation Co-ordination Section, PMRA to Patti Turner, Crompton Canada (predecessor-in-title to Chemtura Canada); Orval Swenson, Research Director, AGSCO Inc.; Don Wilkinson, Manager, Regulatory Affairs, IPCO Ltd.; Duane Fairbairn, Syngenta Crop Protection Canada Inc.; Irwin Schmidt, United Agri Products Canada Inc; I. Caron, NORAC Concepts Inc.; and Delpac, Kanoria Chemicals & Industries Limited, 28 April 2006 (Exhibit JW-52) (*Marisa Romano 28 April 2006 E-mail*).

<sup>482</sup> Letter from Karen Dodds, Executive Director, PMRA to T. Gregory Kane, Stikeman Elliott LLP, 28 February 2006 (Exhibit JW-46).

411. During March and April of 2006, five former lindane registrants responded to the PMRA's request for consultation and input regarding new lindane studies.<sup>483</sup> Some of the former registrants requested clarification regarding the type of data being sought by the PMRA and virtually all of them asked for a more protracted response time than the 60 days outlined in Dodd's letter.

412. On April 26, 2006, the PMRA released a public Information Note on its website regarding the status of lindane use in Canada.<sup>484</sup> The Note outlined the PMRA's intended responses to the Review Board's recommendations, in particular concerning the need for further consultation with registrants:

The PMRA acknowledges that at the time lindane was re-evaluated, it was practice to allow for a short consultation period with the registrant at the end of the assessment. The PMRA's re-evaluation process has since been revised and now includes a longer opportunity for dialogue with registrants and other stakeholders throughout the process consistent with the recommendations of the Board.<sup>485</sup>

413. To address the issues raised by the Board in the case of lindane, the PMRA initiated communications with all affected former registrants of lindane products and other interested parties, as appropriate, to seek input into the risk assessment and to explore possible measures that address health-related concerns for workers.<sup>486</sup>

414. On page three of that same Information Note, the PMRA then announced its plan to re-evaluate lindane use:

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<sup>483</sup> Letter from Orval Swenson, Research Director, AGSCO Inc. to Maria Luisa Romano, Re-evaluation Co-ordination Section, 24 March 2006 (Exhibit JW-47); Letter from Benoit Caron, NORAC Concepts Inc. to Maria Luisa Romano, Re-evaluation Co-ordination Section, PMRA (Exhibit JW-48); Letter from Patricia Turner, Regulatory/Registration Scientist, Chemtura Canada, to John Worgan, PMRA, 12 April 2006 (Exhibit JW-49); Letter from Don Wilkinson, IPCO Ltd., to Marisa Romano, PMRA, 26 April 2006 (Exhibit JW-50); Letter from D.K. Jain, Kanoria Chemicals & Industries Ltd., to Marisa Romano, PMRA, 27 April 2006 (Exhibit JW-51).

<sup>484</sup> An Information Note of this type is commonly issued to inform the public about ongoing regulatory activities of the PMRA. See PMRA, *Information Note on Lindane*, 26 April 2006, (Exhibit JW-53) (*Lindane Information Note – April 2006*).

<sup>485</sup> *Lindane Information Note – April 2006* (Exhibit JW-53).

<sup>486</sup> *Lindane Information Note – April 2006* at 2 (Exhibit JW-53).

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To ensure that the risk management decision on the use of lindane products is made with a clear understanding of all the risks, the PMRA is completing the special review of Lindane. This includes completing the human health risk assessment of areas not addressed in the previous evaluation (e.g., carcinogenicity) as well as finalizing the environmental risk assessment in collaboration with Environment Canada and the United States Environmental Protection Agency.<sup>487</sup>

415. On April 28, 2006 the PMRA's re-evaluation coordinator at the time, Marisa Romano, emailed former lindane registrants to indicate that the deadline for submission of information to PMRA would be extended to July 31, 2006.<sup>488</sup>

416. On May 10, 2006, a draft work plan was developed to coordinate the work of the evaluation team.<sup>489</sup>

417. In response to various inquiries from former lindane registrants (including the Claimant) about the type of information that the PMRA was seeking, Ms. Romano wrote an email on June 20, 2006 to the registrants explaining that the initiation of PMRA's re-assessment of its uncertainty and safety factor policy had actually predated the Board's recommendation for the same:

The PMRA started a review of the policy regarding the use of uncertainty and safety factors in risk assessment before the Lindane Board of Review report was received. Therefore, this activity has been initiated by the PMRA independently from the outcome of the Board. This process will include public and stakeholder consultation.<sup>490</sup>

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<sup>487</sup> *Lindane Information Note – April 2006* at 3 (Exhibit JW-53).

<sup>488</sup> *Marisa Romano 28 April 2006 E-mail* (Exhibit JW-52).

<sup>489</sup> Minutes from PMRA Lindane Team Meeting, 10 May 2006 (Exhibit JW-54).

<sup>490</sup> E-mail from Marisa Romano Re-evaluation Co-ordination Section, PMRA to Patti Turner, Crompton Canada (predecessor-in-title to Chemtura Canada); Orval Swenson, Research Director, AGSCO Inc.; Don Wilkinson, Manager, Regulatory Affairs, IPCO Ltd.; Duane Fairbairn, Syngenta Crop Protection Canada Inc.; Irwin Schmidt, United Agri Products Canada Inc; I. Caron, NORAC Concepts Inc.; and Delpac, Kanoria Chemicals & Industries Limited, 20 June 2006 (Exhibit JW-55) (*Marisa Romano 20 June 2006 E-mail*).



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### 3. The PMRA considered evidence Claimant had failed to submit during the Special Review

418. During the lindane re-evaluation period, the PMRA was proactive in soliciting input from Chemtura and other former registrants. It maintained regular and timely correspondence with the registrants to answer their questions, to provide greater detail about the types of data being sought by the PMRA during the review, and to keep them apprised of the PMRA's ongoing policy review on safety factors.<sup>491</sup>

419. In total, the PMRA examined three sets of lindane studies that Chemtura had formerly submitted to the U.S. EPA, as well as Chemtura's new occupational exposure study.<sup>492</sup>

420. On July 14, 2006, the Claimant sent the PMRA its first substantive response to an earlier request for updated data on lindane by providing it with permission to access documents and studies that it had provided to the U.S. EPA. The Claimant also provided the PMRA with copies of studies and access to documents to assist its re-evaluation of lindane.<sup>493</sup>

421. On July 21, 2006, the Claimant provided the PMRA with its second instalment of studies and data on lindane, including a report entitled "Lindane Risk Mitigation Summary" that recommended six risk mitigation measures that it suggested could be taken to ensure that lindane was used safely. In that same letter, the Claimant noted that

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<sup>491</sup> See correspondence: *Marisa Romano 28 April 2006 E-mail* (Exhibit JW-52); *Marisa Romano 20 June 2006 E-mail* (Exhibit JW-55).

<sup>492</sup> Letter and accompanying lindane data from Patti Turner, Regulatory/Registration Scientist, Crompton Canada (predecessor-in-title of Chemtura Canada) to Maria Luisa Romano, Re-evaluation Coordination Section, PMRA, 14 July 2006 (Exhibit JW-56); Letter and accompanying lindane data from Patti Turner, Regulatory/Registration Scientist, Crompton Canada (predecessor-in-title of Chemtura Canada) to Maria Luisa Romano, Re-evaluation Coordination Section, PMRA, 21 July 2006 (Exhibit JW-57); Letter and accompanying lindane data from Patti Turner, Regulatory/Registration Scientist, Crompton Canada (predecessor-in-title of Chemtura Canada) to Maria Luisa Romano, Re-evaluation Coordination Section, PMRA, 4 August 2006 (Exhibit JW-60).

<sup>493</sup> Letter of Authorization from Will Cummings, Regulatory Manager, Chemtura Corporation to the PMRA, 14 July 2006 (Annex R-310).

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it expected to have “a new occupational exposure study for on-farm seed treating” available for distribution in early 2007.<sup>494</sup>

422. On August 4, 2006, the Claimant provided the PMRA with its third instalment of studies on lindane, along with a list of studies that were still outstanding.<sup>495</sup>

423. On August 31, 2006, the Science Management Committee (SMC) of the PMRA met and decided that “a new work plan [would] be developed outlining the PMRA schedule and including consideration of the new surrogate exposure study and a deadline for completion”.<sup>496</sup> The Lindane team met on September 27, 2006 to discuss the work plan.<sup>497</sup>

424. Again, in another example of the ongoing dialogue between the PMRA and the Claimant, on October 18, 2006, the PMRA wrote to Chemtura to advise that it was “interested in receiving a copy of a new occupational exposure study for on-farm seed treating which [had been] expected to be available in the first quarter of 2007”.<sup>498</sup>

#### **4. Claimant repeatedly requested and was granted extensions for the submission of new evidence, delaying the issuance of the Re-evaluation Note**

425. During the next four months, the PMRA granted the Claimant a series of deadline extensions to ensure that its occupational exposure study would be included in the re-

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<sup>494</sup> Letter and accompanying lindane data from Patti Turner, Regulatory/Registration Scientist, Crompton Canada (predecessor-in-title of Chemtura Canada) to Maria Luisa Romano, Re-evaluation Coordination Section, PMRA, 21 July 2006 (Exhibit JW-57).

<sup>495</sup> Letter and accompanying lindane data from Patti Turner, Regulatory/Registration Scientist, Crompton Canada (predecessor-in-title of Chemtura Canada) to Maria Luisa Romano, Re-evaluation Coordination Section, PMRA, 4 August 2006 (Exhibit JW-60). Meanwhile, on 2 August 2006, the EPA released an addendum to its 2002 Lindane Reregistration Eligibility Decision (RED) which concluded that, based on a risk-benefit analysis, lindane was ineligible for re-registration in the U.S.

<sup>496</sup> PMRA, Science Management Committee Briefing, Lindane, 31 August 2006 (Exhibit JW-61).

<sup>497</sup> Minutes from PMRA Lindane Team Meeting, 27 September 2006 (Exhibit JW-62).

<sup>498</sup> Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to Patricia Turner, Chemtura Canada, 18 October 2006 (Exhibit JW-63).

examination of lindane.<sup>499</sup> In total, the PMRA granted the Claimant four extensions, representing over ten months of extra time.<sup>500</sup>

## 5. March 2007 to the release of the Re-evaluation Note

426. After the arrival of the Claimant's study, it took the PMRA approximately one year to undertake a broad range of consultations with stakeholders and government departments, and to undertake the necessary scientific study in order to re-examine its assessment of lindane (pertaining to health, environmental, and occupational effects).

427. The PMRA engaged in extensive actions on the lindane REN between March 2007 and April 2008.

428. During the spring of 2007, the Health Evaluation Division (HED) considered the Claimant's worker exposure study.<sup>501</sup> In the summer of 2007, the Science Management Committee considered preliminary findings for the health and environmental

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<sup>499</sup> Beginning on 7 November 2006, Chemtura wrote to the PMRA "formally requesting that PMRA delay the Special Review of Lindane in order to allow for consideration of [their] new occupational exposure study", which was expected "to be completed by January 15, 2007". Letter from Patti Turner, Registration Manager, Crompton Canada (predecessor-in-title to Chemtura Canada) to Mr. Shuhua Liu, Re-evaluation Co-ordination Section, PMRA, 7 November 2006 (Exhibit JW-64). On 13 December 2006, the PMRA advised Chemtura that they had accepted their request and that "[a]s a result, the target completion date of this special review [would] be postponed to the spring 2007". Letter from John Worgan, Director, Re-evaluation Management Division, PMRA to Patricia Turner, Chemtura Canada, 13 December 2006 (Exhibit JW-65). On 22 December 2006, the PMRA released another Information Note advising that "on November 7, 2006, a registrant [Chemtura] requested that the PMRA delay completing the special review of Lindane in order to allow for consideration of its new occupational exposure study... [and] [a]s a result, the target completion date for this special review will be postponed to spring 2007", see PMRA, Information Note, Lindane, 22 December 2006, (Exhibit JW-66) (*Lindane Information Note - December 2006*). On 31 January 2007, the PMRA's Shuhua Liu advised his colleagues of having "received a phone call from Patricia Turner of Chemtura informing the PMRA that the exposure study which they committed to submit by January 31, 2007 [would] not be ready until as late as February 20, 2007, i.e., they request[ed] a delay for 3 weeks". E-mail from Shuhua Liu, Re-evaluation Co-ordination Section, PMRA, 31 January 2007 (Exhibit JW-67). On 2 February 2007, the PMRA granted a further extension on the submission of their exposure study to 20 February 2007. Shuhua indicated to Chemtura that the PMRA "accepts this request but asks that Chemtura not delay the submission of the study further". E-mail from Shuhua Liu, Re-evaluation Co-ordination Section, PMRA, 2 February 2007 (Exhibit JW-68).

<sup>500</sup> Marisa Romano extended the original deadline for new data submissions from 28 April 2006 to 31 July 2006, adding an additional 90 days from the original submission deadline.

<sup>501</sup> E-mail from Kim Irwin, PMRA to Andrew Russell, Health Canada, 19 March 2007 (Exhibit JW-69); e-mail from Andrew Russell, Health Canada to Kim Irwin, Lynda MacMillan, Derek Francois et al., PMRA, 12 April 2007 (Exhibit JW-70).

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assessments, while work on assessments continued.<sup>502</sup> By the autumn of 2007, a draft REN had been generated and was being revised.<sup>503</sup>

429. On December 3, 2007, the Claimant's Patti Turner emailed a request for an update on the status of the review. Lynn Ovenden (the PMRA's new re-evaluation coordinator) replied on December 5, 2007, stating that the PMRA was "targeting spring 2008" as an approximate time for completion.<sup>504</sup>

430. By December 2007, the lindane evaluation team had generated a complete revised draft of the REN, which was circulated for comment.<sup>505</sup>

431. From January to March, 2008, HED integrated the most up-to-date PMRA policy on the use of uncertainty and safety factors (referred to above) to the re-assessment of lindane.<sup>506</sup>

## **6. General policy review of uncertainty and safety factors**

432. From March 2007 to April 2008, the re-examination of lindane was also brought into conformity with the PMRA's general policy review for the identification of appropriate uncertainty and safety factors in the regulation of pesticides.

433. In order to understand the context of the policy review, it is helpful to go back to February 28, 2006 when the PMRA advised the stakeholders (including the Claimant) of

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<sup>502</sup> PMRA, Science Management Committee Briefing, 28 June 2007 (Exhibit JW-73).

<sup>503</sup> Minutes from PMRA, Science Management Committee Meeting, 4 October 2007 (Exhibit JW-74).

<sup>504</sup> E-mail from Lynn Ovenden, Re-evaluation Coordinator, PMRA to Patti Turner, Registration Specialist, Crompton Canada (predecessor-in-title to Chemtura Canada), 5 December 2007 (Exhibit JW-76).

<sup>505</sup> E-mail from Pierre Brassard, PMRA to Barbara Njie, Lynn Ovenden and Stephen Croteau, PMRA, 7 December 2007 (Exhibit JW-77); e-mail from Karen O'Keefe, PMRA to Janice Squires, Barbara Njie and Lynn Ovenden, PMRA, 14 December 2007 (Exhibit JW-79); e-mail from Lynn Ovenden, PMRA to Hang Tang and Barbara Njie, PMRA, 4 January 2008 (Exhibit JW-80).

<sup>506</sup> This policy is explained in *Science Policy Note SPN2008-01* (Exhibit JW-81).

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its plan to apply any updated policies developed under the PMRA's review on uncertainty and safety factors to the re-evaluation of lindane.<sup>507</sup>

434. In evaluating the health risk of a pest control product, the PCPA requires that a scientifically based approach be used.<sup>508</sup> Once the hazard of a pesticide is determined, it is PMRA policy to apply both traditional uncertainty factors<sup>509</sup> and, as required, additional uncertainty/safety factors<sup>510</sup> to the appropriate "endpoint" in the toxicology data base to ensure an adequate margin of safety between the identified toxicological hazard and the potential human exposure.<sup>511</sup>

435. The Board of Review in its decision on lindane had recommended that the PMRA re-consider its approach to safety margins, suggesting in particular that the PMRA's additional safety factor might be too conservative in the evaluation of lindane. This recommendation added to the impetus behind the PMRA's re-evaluation of the use of uncertainty and safety factors.

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<sup>507</sup> The degree to which safety and uncertainty factors are applied in any risk assessment is determined by a scientific finding of the health hazard of a given pesticide and the uncertainties in the available toxicological database. The risk of a pesticide is considered along with the efficacy of a pesticide. Tolerances for risk may be set lower in cases where there are safe and cost-effective substitutes available in the marketplace. *PCPA* (2002), s. 4(2)(b) requires the Minister to "seek to minimize health and environmental risks posed by pest control products". In other words, the risks must not only be acceptable they must also be minimized where possible.

<sup>508</sup> *PCPR*, s. 19 (Annex R-2).

<sup>509</sup> The traditional uncertainty factors are internationally agreed upon and used. They are standardized to include a default 10-fold factor to account for variability between species (interspecies factor). Another default 10-fold is used to account for variability within a species (intraspecies factor). As a result, the acceptable dose for human exposure is at minimum 100X lower than the dose that caused no effects in animals.

<sup>510</sup> It is policy at the PMRA to apply additional factors in conjunction with the traditional uncertainty factors where necessitated on the findings in the animal toxicity data base. These findings could include additional uncertainties in the available data base, the need to protect sensitive subpopulations (*e.g.*, pregnant females and infants) and /or the seriousness of the effects observed. When the PMRA identifies the need for additional factors to obtain a larger than minimum margin-of-safety (>100) it is PMRA policy to apply these additional factors where relevant to both the dietary/non-occupational risk assessments as well as the occupational risk assessments to protect all workers including pregnant and lactating females in the workplace.

<sup>511</sup> "Endpoint" refers to either a chemical concentration that produces the Lowest Observed Adverse Effect Level ("LOAEL") or No Observed Adverse Effect Level ("NOAEL") depending on the study methodology used.

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436. On July 25, 2007, the PMRA issued a public consultation document concerning the application of uncertainty factors and safety factors in the human health risk assessment of pesticides.<sup>512</sup> The purpose of the document was indicated on page 2:

The purpose of this document is twofold. First, it provides stakeholders with an overview of historical and current Canadian pesticide regulatory practices concerning the application of uncertainty and safety factors to mammalian toxicology data [...]. Second, this document is intended to solicit feedback from interested stakeholders on issues and considerations regarding the future application of uncertainty and safety factors by the PMRA.<sup>513</sup>

437. Later on page four, the rationale for the use of safety factors was explained:

Absolute certainty of safety is not attainable in view of the requisite extrapolation of the results of toxicity studies conducted in a homogeneous laboratory animal population to a heterogeneous human population. Although the process of risk assessment strives to use the best scientific information available, the use of factors to account for uncertainties in the assessment or concerns for human health is critical in securing assurances of reasonable certainty of no harm to human health.<sup>514</sup>

438. During July and August 2007, the PMRA's second draft environmental assessment monograph was peer-reviewed internally and by Environment Canada before it was finalized.<sup>515</sup>

439. On December 11-12, 2007, the PMRA held a stakeholder workshop in order to present and collectively discuss proposals identified in the policy evaluation of the use of uncertainty and safety factors.<sup>516</sup>

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<sup>512</sup> *Regulatory Proposal PRO2007-01* (Exhibit JW-36).

<sup>513</sup> *Regulatory Proposal PRO2007-01* at 2 (Exhibit JW-36).

<sup>514</sup> *Regulatory Proposal PRO2007-01* at 4 (Exhibit JW-36).

<sup>515</sup> Affidavit of John Worgan, ¶ 227.

<sup>516</sup> Health Canada, Presentation to PMRA Advisory Council, Public Consultation Document PRO2007-01, Use of uncertainty and safety factors in the human health risk assessment of pesticides, 11 December 2007 (Exhibit JW-78).

440. On March 31, 2008, the PMRA published an update on the status of this policy,<sup>517</sup> referring to the stakeholder feedback the agency had received following the publication of the *Regulatory Proposal* issued on July 25, 2007. That document provided a detailed description of the proposed approach that the PMRA would use with regard to uncertainty and safety factors as a result of the consultative process.<sup>518</sup> This policy after extensive consultation continued to apply the additional factor 10, on top of the base factor of 100, that the PMRA had applied in the Special Review.

441. By April 1, 2008, HED had completed the human health risk assessment for lindane, integrating the revised approach to the application of uncertainty factors and the new PCPA factor.<sup>519</sup>

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<sup>517</sup> PMRA, Regulatory Proposal PRO2008-01, *Consultation Update on PRO2007-01, Regulatory Proposal for the Use of Uncertainty and Safety Factors in the Human Health Risk Assessment*, 31 March 2008 (Exhibit JW-82).

<sup>518</sup> With the assistance of 24 written responses from industry stakeholders, the medical profession, public health officials, academia, user groups, and various levels of government received over a 90 day commenting period, the PMRA proposed adopting and / or continuing to:

- use 10-fold uncertainty factors for both interspecies extrapolation and interspecies variability;
- where necessary, use additional uncertainty factors up to 10-fold each for data deficiencies, when toxicity data from a short-term study is used to assess risk for a longer term exposure or when a critical study does not demonstrate a dose level without toxic effects
- retain an additional factor (PCPA factor) up to 10-fold in both dietary and non-dietary residential risk assessment (i.e. the general population) where there are residual concerns with the adequacy of the database with respect to the toxicity to infants or children or where there are prenatal or postnatal toxicity concerns; the latter encompasses potential sensitivity of the young and seriousness of the toxic effects;
- where appropriate, apply the same standard of protection to workers as that applied to the general population; and
- use an upper limit of 3000 as an overall assessment factor (i.e. all factors combined) in quantitative risk assessments.

<sup>519</sup> PCPA factors of 3-fold and 10-fold were applied to the acute and chronic dietary risk assessments, respectively. These additional factors were applied to account for the sensitivities of vulnerable subpopulations (pregnant females and infants) as well as any residual concerns and uncertainties pertinent to these subpopulations, the determination of which was based on the available information. The PMRA applies more caution in areas where there is less scientific certainty, which could be the result of gaps in scientific knowledge, or where there is a greater level of concern for the scientific findings themselves. In the occupational risk reassessment, an additional factor of 10-fold was used to address the same considerations that supported the use of the PCPA factor in the chronic dietary risk reassessment, given that the workforce could include pregnant or lactating women.

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442. On July 29, 2008, the PMRA published the results from its policy review on the use of uncertainty factors.<sup>520</sup>

**7. The PMRA ultimately issued a draft Re-evaluation Note in April 2008, again allowing for comments by registrants**

443. The culmination of the PMRA's re-assessment of lindane was the April 2008 draft of the REN which it released to the Claimant on April 28, 2008 and then to all other former registrants on May 5, 2008. The former registrants were once again asked for their input on the document within 60 days.<sup>521</sup>

**8. The Re-evaluation Note reached the same conclusions as the original Special Review**

444. In the end, the conclusion of the REN scientific team was the same as the conclusion made in the 2001 Special Review: lindane was found to be unsafe for further use in Canada. This time, however, the conclusion was based on findings across a larger spectrum of inquiries into areas such as carcinogenicity, dietary risk occupational risk, and environmental harm.

445. The PMRA reviewed all areas raised in the Review Board recommendations. The evidence for sensitivity of the young was re-examined and previous concerns for this aspect identified in 2001 were confirmed in the 2008 review. During the re-examination, PMRA also found that, while lindane could potentially affect the immune system, the effect was likely secondary to other toxicity and did not warrant an additional uncertainty factor. Further to the Board's recommendations, the REN team reviewed the final JMPR report and the original dermal toxicity study, among other studies. Based on the selection of a different endpoint for inhalation risk in the REN, the PMRA did not undertake an aggregate assessment. The REN team also reviewed more recent studies.

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<sup>520</sup> PMRA, Science Policy Note SPN2008-01, *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides* (Exhibit JW-81) (Science Policy Note SPN2008-01).

<sup>521</sup> PMRA, *Re-Evaluation Note REV2008, Draft Lindane Risk Assessment*, 14 April 2008 (Exhibit JW-92) (Re-evaluation Note REV2008).



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446. The scope of the present lindane review was stated in the REN:

This risk assessment also takes into account a new, more restricted use pattern, including application in closed systems, as proposed by former registrants. The PMRA reconsidered the original data, completed the human health risk assessment in areas not finalized in the previous evaluation (*e.g.*, carcinogenicity) and finalized the environmental risk assessment.<sup>522</sup>

447. In other words, the PMRA addressed mitigation, as recommended by the Board of Review, but still found that lindane fell outside of the parameters of acceptable risk.<sup>523</sup>

448. As a result of the release of the REN, on May 14, 2008, the Claimant requested copies of the unpublished information referenced in the REN document.<sup>524</sup>

449. On June 27, 2008, the Claimant responded to the PMRA regarding the findings outlined in the REN.<sup>525</sup>

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<sup>522</sup> *Re-evaluation Note REV2008* at 2 (Exhibit JW-92).

<sup>523</sup> The REN, concluded as follows regarding the feasibility of possible mitigation procedures:

Risk-reduction measures to address some of the potential risks from use of lindane are identified in this assessment but are not proposed for implementation. It is not feasible to reduce risks sufficiently to address the levels of concern which have been identified for:

Human Health

Even with maximum personal protective equipment (PPE) and engineering controls, risks to workers handling lindane and lindane treated seed were unacceptable.

Environment

As a seed treatment, there are no effective measures from an environmental perspective to mitigate the volatilization, atmospheric transport, bioaccumulation and toxicity of lindane.

There are no known reported measures that would effectively mitigate the release of the waste chemicals produced in the manufacture of lindane.

*See Re-evaluation Note REV2008* at 2 (Exhibit JW-92).

<sup>524</sup> Letter from Patricia Turner, Registration Specialist, Chemtura Canada to Lynn Ovenden, Re-evaluation Management Directorate, PMRA, 14 May 2008 (Exhibit JW-93).

<sup>525</sup> Letter and accompanying REN feedback from Patricia Turner, Registration Specialist, Chemtura Canada Co. to Lynn Ovenden, Project Manager, Re-evaluation Coordination Section, PMRA, 27 June 2008 (Exhibit JW-95).

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450. Following this PMRA responded to the Claimant on August 6, 2008 concerning the dialogue that had taken place between the Agency and the former registrants since the Board of Review Report in August 2005. A second letter followed, on September 30, 2008, in which the PMRA dealt with substantive scientific concerns that the Claimant had expressed in its June 27, 2008 letter.

## **VI. WORLDWIDE REJECTION OF LINDANE ACCELERATED DURING THE PERIOD AT ISSUE**

### **A. The PMRA's decision reflected a global rejection of lindane**

451. As Canada has demonstrated earlier in this Counter-Memorial, up to the late 1990s, lindane had already been the subject of substantial restrictions and international action.<sup>526</sup> These trends continued and intensified during the period at issue in this arbitration:

- By 2002, the European Union – traditionally, the world's primary user of lindane - had entirely prohibited the use and marketing of lindane as a plant protection product.<sup>527</sup> The EU imposed a ban on lindane use and production by the end of 2007.<sup>528</sup> In addition, European countries further banned its use for public health and veterinary purposes by late 2007.<sup>529</sup>
- On February 24, 2004, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals for Pesticides in International Trade (the PIC Convention) entered into force. The Convention applies to pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons. Canada ratified the PIC Convention on August 26, 2002. Lindane is listed in Annex III of the PIC Convention. In effect, this means that lindane is subject to the prior informed consent procedure (the PIC procedure). The PIC procedure creates a mechanism for obtaining and disseminating the decision of an importing

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<sup>526</sup> See section B, *above*.

<sup>527</sup> UN Technical Review Report (Annex R-39); European Communities Commission Decision Concerning the Non-Inclusion of Lindane in Annex I to Council Directive 91/414/EEC and the Withdrawal of Authorisations for Plant-Protection Products Containing this Active Substance (2000/801/ED) (20 December 2000) (Annex R-317).

<sup>528</sup> Regulation (EC) No 850/2004 of the European Parliament and of the Council, on Persistent Organic Pollutants and amending Directive 79/117/EEC (Exhibit CC-41).

<sup>529</sup> UN Technical Review Report (Annex R-39).

country as to whether it wishes to receive future shipments of particular chemicals. The Convention also creates legally-binding obligations for Parties exporting banned or severely restricted chemicals to comply with these decisions.

- As of 2006, lindane was banned in 52 countries, and its usage was severely restricted in 33 others. Production of lindane had become a dying industry.<sup>530</sup>
- By November 30, 2006, all three North American governments had signed the *North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane Isomers*, a strategy to eliminate uses of lindane that carried unacceptable risks.<sup>531</sup>
- Most recently, in December 2007, the Secretariat of the Stockholm Convention on Persistent Organic Pollutants issued a communication confirming the recommendations of the Persistent Organic Pollutants Review Committee to add lindane to Annex A of the Convention, and inviting States Parties to prepare themselves for discussion of this issue at the fourth meeting of the Conference of the Parties.<sup>532</sup> By listing a chemical in Annex A of the Stockholm Convention, States Parties agree to prohibit and/or take the legal and administrative steps necessary to eliminate its production and use.<sup>533</sup>

## **B. The U.S. in particular implemented a near-total ban on lindane**

### **1. The U.S. had already banned significant uses of lindane by 1998-99**

452. The United States was subject to the same international concerns that prompted Canada's Special Review and subsequent ban on lindane. Against this backdrop of mounting domestic and international concerns, the EPA initiated a re-evaluation of lindane in 1998. The results of the EPA's regulatory review of lindane were eventually

<sup>530</sup> NARAP at Annex B (Exhibit CC-11).

<sup>531</sup> NARAP (Exhibit CC-11). Specifically, Canada committed to assess and manage the risks associated from pharmaceutical drug use, the only current use of lindane in Canada. Mexico agreed to eliminate all agricultural, veterinary, and pharmaceutical uses of lindane through a prioritized phase-out approach. And the United States committed, *inter alia*, to monitor food for residues, to work with pharmaceutical companies to develop alternative treatments for lice and scabies, and to promote reductions of use and emissions in China and India. The NARAP Implementation Task Force anticipates completion of the action plan within 8-10 years of its authorization.

<sup>532</sup> Communiqué from the Secretariat of the Stockholm Convention on Persistent Organic Pollutants to Stockholm Convention Official Contact Points, 15 December 2007 (Annex R-52).

<sup>533</sup> Stockholm Convention on Persistent Organic Pollutants, 22 May 2001 (*entered into force* 17 May 2004) (Annex R-38).

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published in what the EPA terms a “Re-registration Eligibility Decision” (RED) of 2002,<sup>534</sup> and a 2006 Addendum to the 2002 RED.<sup>535</sup>

453. Notwithstanding the EPA’s ongoing RED process, in 1999 the CIEL and its member company Inquinosa S.A. sought a tolerance for lindane use on canola, bucking the general trend toward voluntary cancellation of lindane products by registrants. The EPA recommended against the proposed tolerance, requiring “new nature of the residue studies”, (i.e. studies that characterize the chemical remaining in plants or animals following the use of a pesticide) further field trials and the cancellation of all remaining food/feed uses of lindane. Although the EPA included the risk assessment for lindane use on canola seeds in the RED, this was for informational purposes and “the decision whether to grant the petition and register canola as a new use [wa]s outside the scope of this RED and w[ould] be made separately by the Agency”. This tepid reply hardly supports the assertion that “a favourable assessment of lindane in the RED process would have opened the door for a canola registration and/or tolerance”.<sup>536</sup>

## **2. By 2001-2002 U.S. registrations of lindane was further restricted**

454. In the summer of 2001, the EPA released for public comment its Preliminary Risk Assessment that was developed as part of its lindane RED. During that same period, a second wave of voluntary U.S. cancellations came at the request of technical registrants (*i.e.*, a company in whose name a pesticide is registered). By the time the 2002 RED was released, the only food/feed uses of lindane still supported for re-registration were six seed treatments: barley, corn, oats, rye, sorghum and wheat.

455. On July 31, 2002, the EPA’s Re-registration Eligibility Decision on lindane was issued.<sup>537</sup> The human health and ecological risk assessments for lindane indicated risk

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<sup>534</sup> *Lindane RED* (Annex R-34).

<sup>535</sup> *Lindane RED – 2006 Addendum* (Exhibit JW-59).

<sup>536</sup> Claimant’s Memorial, ¶ 283.

<sup>537</sup> *Lindane RED* (Annex R-34).

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concerns. For instance, the 2002 RED started that “there is some evidence that lindane may act as an endocrine disruptor; however, further investigation is necessary to ascertain the relevance and impact of such findings on public health.”<sup>538</sup> Additionally, the Agency made a number of changes to the terms and conditions of the remaining seed treatment registrations to prevent unreasonable adverse effects on the environment pending the submission of additional data requested by the EPA in order to assess potential dietary risks. The EPA requested these additional studies because the nature of residues was not adequately understood. Additionally, measures were called for to mitigate occupational exposure concerns, including: the prohibition of certain uses, reductions in the maximum application rate, additional safety equipment, and restrictions on the timing of usage.<sup>539</sup> In light of these findings, the Claimant’s allegation that “apart from minor label changes, the RED did not identify any remaining risk concerns with lindane”<sup>540</sup> is misleading.<sup>541</sup> Furthermore, the EPA did an assessment of canola in its 2002 RED for “informational purposes”. This assessment showed that occupational exposure for commercial treaters did not meet targets and were therefore of concern.

456. Contrary to what the Claimant alleges in its Memorial, it was far from a foregone conclusion that “once the EPA issued its RED on July 31, 2002, it would have been open to Chemtura to actively pursue a registration and/or tolerance for lindane on canola”.<sup>542</sup> The EPA noted that:

the establishment of new tolerances for the seed treatment uses of lindane [wa]s conditioned on: 1) the receipt and review of additional data to characterize lindane metabolites; and 2) EPA’s ability to make a determination that establishing the new tolerances meets the safety standard in the FFDCA. Because EPA does not know what the data will indicate about lindane metabolites, and for other reasons explained more fully below, EPA is unable to

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<sup>538</sup> See *Dr. Goldman Report*, ¶ 27; *Lindane RED* at 9 (Annex R-34).

<sup>539</sup> *Dr. Goldman Report*, ¶¶ 24, 87.

<sup>540</sup> Claimant’s Memorial, ¶ 184.

<sup>541</sup> See *Dr. Goldman Report*, ¶¶ 23-29.

<sup>542</sup> Claimant’s Memorial, ¶ 294.

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determine whether it will be able to make a determination that new tolerances for lindane would be safe.<sup>543</sup>

457. The approval of new registrations or tolerances for lindane on canola in the United States was an unlikely possibility, as it was heavily conditioned on events that never occurred.

### 3. The EPA continued to consider further data

458. Following the 2002 RED, Chemtura continued to actively pursue its application for tolerance and/or registration of lindane use on canola in the United States by submitting the generic data requirements, *i.e.*, the data required of a company seeking a re-registration or tolerance for a pesticide.<sup>544</sup>

459. Meanwhile, the United States was negotiating the *North American Regional Action Plan* on lindane (NARAP). The United States itself had in January 1999 nominated lindane for a NARAP in recognition that lindane and other HCH isomers constituted a risk to human health and the environment. The NARAP provides a strategy for NAFTA governments to address exposure risks. The United States committed to monitor food for residues, to work with pharmaceutical companies to develop alternative treatments for lice and scabies, and to promote reductions of lindane use and emissions in China and India.

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<sup>543</sup> *Lindane RED* at 43 (Annex R-34).

<sup>544</sup> Claimant's Memorial, ¶¶ 293, 295. The EPA had requested a plant metabolism study, a seed leaching study and an anaerobic aquatic metabolism study. The EPA also issued generic and product-specific call-ins (DCIs) for lindane in February 2004, triggering another wave of voluntary cancellations of lindane uses by registrants (Goldman, ¶ 42). An additional generic DCI for lindane was issued in September 2004, requiring an occupational exposure (seed treating) study as confirmatory data. *Dr. Goldman Report*, ¶ 42. The existence of these DCIs evidence that the EPA may have been concerned not only about seed tolerances but also worker exposures associated with this registered use of lindane. The RED had also provided that all other existing tolerances for lindane were no longer needed since the lindane products registrations for which those tolerances had been originally established were cancelled. The EPA cancelled those registrations on September 21, 2005. End users were given a period of time within which to exhaust their existing stocks.

460. The NARAP broadened the scope of inquiry for the EPA's risk assessment of lindane to other HCH isomers.<sup>545</sup> This new direction was reflected in a report prepared by the EPA in February 2006 entitled "Assessment of Lindane and Other Hexachlorocyclohexane Isomers" (HCH Assessment).<sup>546</sup> The Agency turned its attention to "risks resulting from human and environmental exposures to other HCH isomers of environmental significance produced as by-products during the manufacture of lindane".<sup>547</sup> Pure lindane is produced at a 10-15 percent yield from technical HCH so that, for every ton of lindane that is produced, approximately 6-10 tonnes of X- and B-isomers are produced.<sup>548</sup> These other HCH isomers were also relevant because the EPA was unable to confirm the method of waste disposal after the lindane manufacturing process.<sup>549</sup> In April 2006, Michael Boucher wrote to the EPA on behalf of Chemtura Corporation disputing the findings of the Assessment.<sup>550</sup> Nevertheless, despite its initial criticisms, Chemtura USA Corp. voluntarily requested cancellation of its lindane product registrations in July 2006.<sup>551</sup>

#### **4. By 2006 the U.S. EPA imposed a total lindane ban on agricultural uses**

461. Following these voluntary cancellation requests, the EPA released the "Addendum to the 2002 Lindane Reregistration Eligibility Decision" on August 2,

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<sup>545</sup> Technical HCH is a manufactured chemical that comprises a mixture comprising of all 6 isomers, contains about 60-70 percent alpha-HCH, 5-12 percent beta-HCH and 10-15 gamma-HCH. Gamma-HCH (*i.e.*, lindane), the only HCH isomer with insecticidal properties, is extracted from the mixture and purified. Approximately 99 percent of pure lindane is produced at a 10-15 percent yield from technical HCH, thereby producing significant amounts of toxic waste.

<sup>546</sup> *EPA HCH Study* (Annex R-45); *see also Lindane RED – 2006 Addendum* (Exhibit JW-59).

<sup>547</sup> *EPA HCH Study* at 2 (Annex R-45).

<sup>548</sup> *See Dr. Goldman Report*, ¶ 8; *EPA HCH Study* at 11 (Annex R-45).

<sup>549</sup> A modern process to treat waste isomers is "cracking" which involves the production of other chemicals such as trichlorobenzene and hydrochloric acid which can be sold. *See Dr. Goldman Report*, ¶ 8.

<sup>550</sup> Michael Boucher (on behalf of Chemtura U.S.), Reply of Chemtura Corporation to EPA's Assessment of Lindane and other Hexachlorocyclohexane Isomers, 10 April 2006 (Annex R-46).

<sup>551</sup> Shortly after, other lindane producers AGSCO Inc., Drexel Chemical Co. and JLM International Inc., followed suit.

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2006.<sup>552</sup> The 2006 Addendum refined the scope of enquiry regarding the linkage between lindane use and HCH pollution which led to a better awareness of the overall effects of lindane. Citing health concerns, the Agency concluded that the six lindane seed treatment uses were ineligible for registration because the risks outweighed the benefits of the use. The Addendum stated that:

Lindane primarily affects the nervous system. In acute, subchronic, and developmental neurotoxicity studies and chronic toxicity/oncogenicity studies, lindane was found to cause neurotoxic effects. Lindane also appears to cause renal and hepatic toxicity. In addition, there is evidence that lindane may act as an endocrine disruptor.<sup>553</sup>

462. The EPA found that the overall costs of continued registration of lindane for seed treatment uses were high because human health and environmental reasons:

The seed treatment use will only add to the existing sources of lindane exposure. Ongoing releases of lindane into the environment are of concern due to the environmental fate characteristics of the chemical. Lindane is persistent and mobile and will accumulate in human fat tissue. This potential for ongoing and future exposure to lindane is of particular concern for nursing infants because of the potential for exposure to lindane via breast milk.<sup>554</sup>

463. In other words, the EPA was citing the same factors raised by the PMRA in its Special Review of 2001. The availability of alternative seed treatments was also a factor that militated in favour of de-registering lindane. On balance, the EPA concluded that “these costs of continued lindane registration far outweighed the benefits of the seed treatment use”.<sup>555</sup>

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<sup>552</sup> *Lindane RED – 2006 Addendum* (Exhibit JW-59). See also U.S. EPA, “Lindane Voluntary Cancellation and RED Addendum Fact Sheet”, July 2006, online at: <[http://www.epa.gov/pesticides/reregistration/REDS/factsheets/lindane\\_fs\\_addendum.htm](http://www.epa.gov/pesticides/reregistration/REDS/factsheets/lindane_fs_addendum.htm)> (Annex R-47).

<sup>553</sup> *Lindane RED – 2006 Addendum* at 4 (Exhibit JW-59).

<sup>554</sup> *Lindane RED – 2006 Addendum* at 16 (Exhibit JW-59).

<sup>555</sup> *Lindane RED – 2006 Addendum* at 17 (Exhibit JW-59).



## VII. THE CLAIMANT VOLUNTARILY WITHDREW ITS LINDANE REGISTRATIONS IN THE UNITED STATES

464. For the sake of efficiency, the EPA does not undertake long, complicated and burdensome pesticide cancellation actions when it is able to reach an agreement with a pesticide registrant to voluntarily cancel a pesticide.<sup>556</sup>

465. The Claimant itself submitted its voluntary request to cancel all remaining U.S. lindane registrations on July 20, 2006.<sup>557</sup> In its letter, the Claimant waived the 180-day comment period resulting in a default 30-day comment period ending September 22, 2006.<sup>558</sup> The Agency did not receive any public comment and granted the Claimant's request to cancel five registrations.<sup>559</sup> The effective date of the cancellation order was July 1, 2007.

466. Needless to say, by that point the Claimant's attempt to further expand the registration or tolerance (adding canola use) was a dead letter. There is no credibility to the Claimant's allegation that it is reasonable to expect that it would have been granted a

<sup>556</sup> See *Dr. Goldman Report*, ¶ 60.

<sup>557</sup> Letter from Willard Cummings, Chemtura U.S., to Michael Goodis, U.S. EPA, 20 July 2006 (Annex R-311). The Claimant's remaining registrations were:

No.	EPA Reg.	Chemtura Product Name
	400-490	Gustafson Flowable Lindane 40%
	400-532	Sorghum Guard
	400-538	Gustafson Lindane 30C Flowable
	400-539	Gustafson Captan Lindane 12.5-25
	400-540	Gustafson Vitavax-Thiram-Lindane Flowable Fungicide Insecticide

<sup>558</sup> The Claimant also asked the EPA to "issue a cancellation order that w[ould] allow continued sale and/or use of *existing stocks* of Products until such stocks [were] exhausted." Further, the Claimant asked the EPA to complete a scientific review of the seed treatment worker exposure study it had submitted to support the lindane seed treatment uses and to provide its review. The EPA did not respond to this request in correspondence confirming the cancellation of the Claimant's lindane registrations.

<sup>559</sup> Letter from Michael Goodis, U.S. EPA, to Willard Cummings, Chemtura U.S., 4 October 2006 (Annex R-312).

tolerance or registration for lindane use on canola at this time.<sup>560</sup> The Claimant voluntarily withdrew its registrations just in advance of the 2006 Addendum, following EPA practice of allowing registrants to bow out gracefully rather than seeing their products cancelled. A company that has worked long and hard to maintain a pesticide on the market through not only an expensive and arduous register process, but also prior to that, a Special Review, does not easily yield to a volume cancellation process, unless they are absolutely certain they will lose.<sup>561</sup>

467. On December 13, 2006, the EPA announced the issuance of final orders cancelling the registration of all pesticide products containing lindane.<sup>562</sup> In a news release dated December 15, 2006, the EPA stated that it “expects the cancellation of these uses to result in no significant loss to U.S. agriculture due to the successful development and registration of safer alternative pesticides in recent years”. The release concluded that “lindane is a toxic, persistent and bio-accumulative pesticide that has been of international as well as domestic concern”.<sup>563</sup>

468. The last remaining U.S. tolerances on lindane were revoked on September 19, 2007.<sup>564</sup>

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<sup>560</sup> *Claimant's Memorial*, ¶ 295 (*Nor a fortiori does its allegation that such a registration would have been granted through to 2022*).

<sup>561</sup> *See Dr. Goldman Report*, ¶ 63.

<sup>562</sup> Cancellation of manufacturing-use product registrations was effective on October 4, 2006 and the last date of use was July 1, 2007. Cancellation of end-use product registrations (*i.e.*, for dealers and users) was effective on July 1, 2007 and the last day of use is October 1, 2009. U.S. EPA Lindane Cancellation Order, Federal Register, Vol. 71, No. 239 at 74905-7, 13 December 2006 (Annex R-49).

<sup>563</sup> U.S. EPA, “Pesticide News Story: Remaining Lindane Registrations Cancelled”, 15 December 2006, online at: <[http://www.epa.gov/oppfead1/cb/csb\\_page/updates/2006/lindane-order.htm](http://www.epa.gov/oppfead1/cb/csb_page/updates/2006/lindane-order.htm)> (Annex R-50).

<sup>564</sup> The tolerances were related to the presence in the fat of cattle, goats, hops, horses and sheep. U.S. EPA Tolerance Actions, Federal Register, Vol. 72, No. 181 at 53449-55, 19 September 2007 (Annex R-51).

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## ANALYSIS

### I. APPLICABLE PRINCIPLES OF NAFTA INTERPRETATION

#### A. NAFTA investors have limited access to arbitration

469. The NAFTA is an international treaty among Canada, the United States and Mexico (“the Parties”). Each State to this treaty assumes obligations toward the others with respect to a range of matters. Chapter 11 of the NAFTA imposes obligations on the Parties concerning foreign investment. Other chapters address diverse matters including trade in goods, cross-border trade in services, competition policy, the temporary entry of business personnel, and procedures for the review of anti-dumping and countervailing duty orders.

470. As a general matter, only a Party to the NAFTA has the right to enforce the obligations therein. Private parties, even if they are nationals of a NAFTA country, do not have such rights.<sup>565</sup> However, certain chapters of the NAFTA create dispute settlement mechanisms that grant private parties limited access to international jurisdiction. Chapter 11 of the NAFTA creates one such mechanism.<sup>566</sup>

471. Chapter 11 is divided into three Sections: Section A (Investment), Section B (Settlement of Disputes) and Section C (Definitions). Section A sets out the substantive obligations that each Party owes the other Parties with respect to measures relating to investors and their investments. These obligations apply only with respect to investments

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<sup>565</sup> See NAFTA, Articles 2004 and 2018 (allowing only a State-to-State panel constituted pursuant to Chapter 20 to require compliance with a NAFTA obligation); NAFTA, Article 2021 (prohibiting a domestic right of action to enforce NAFTA obligations).

<sup>566</sup> NAFTA, Article 1115.

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made in host NAFTA countries by investors of other NAFTA countries. They do not relate to domestic investments or to cross-border trade.<sup>567</sup>

**B. Investors must meet all requirements to bring a Chapter 11 arbitration**

472. This Tribunal has been constituted pursuant to Section B. As a creature of the NAFTA, it must operate within the limits of its jurisdiction stated by the NAFTA.

473. Article 1101 limits the Tribunal's subject matter jurisdiction to "measures adopted or maintained by a Party relating to: (a) investors of another Party; (b) investments of investors of another Party in the territory of the Party; and (c) with respect to Articles 1106 and 1114, all investments in the territory of the Party".

474. Further, pursuant to Articles 1116 and 1117, the Tribunal may only hear claims if the investor alleges that it or its investment has suffered loss or damage as a result of measures in breach of an obligation under Section A, Article 1503(2), or in certain circumstances, Article 1502(3)(a).

475. An investor cannot bring claims under Chapter 11 for violations of another NAFTA chapter, other rules of international law, or private agreements between the investor and a NAFTA Party.<sup>568</sup>

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<sup>567</sup> *Canadian Cattlemen for Fair Trade v. United States* (UNCITRAL) Award on Jurisdiction (28 January 2008), ¶ 111 ("the only investors who may avail themselves of the protections of Chapter Eleven ... are actual or prospective foreign investors in another NAFTA party.") (*Canadian Cattlemen – Jurisdiction Award*) (Annex R-163); *Bayview Irrigation District v. Mexico* (ICSID No. ARB(AF)/05/1) Award (11 June 2007), ¶ 96 ("The ordinary meaning of the text of the relevant provisions of Chapter Eleven is that they are concerned with *foreign* investment, not domestic investments.") (Annex R-157) (*Bayview – Award*). On 5 May 2008, the Ontario Superior Court of Justice dismissed an application by the Claimant to set aside this award (*Bayview Irrigation District et al. v. Mexico*, Ont. Sup. Ct. (5 May 2008)) (Annex R-158) (*Bayview – Set Aside*).

<sup>568</sup> *Waste Management Inc. v. Mexico* (ICSID No. ARB(AF)00/3) Award (30 April 2004), ¶ 73. "It is always necessary for a claimant to assert as its cause of action a claim founded in one of the substantive provisions of NAFTA referred to in Articles 1116 and 1117" (Annex R-300) (*Waste Management II-Award*).

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476. Articles 1116(2) and 1117(2) are temporal limits on jurisdiction, requiring that an investor make a claim within three years of the date on which the investor first acquired knowledge of the alleged breach and loss therefrom.

477. An investor seeking to access international jurisdiction pursuant to Section B must also meet all of the procedural conditions precedent to submitting a dispute to arbitration. Articles 1118 to 1121 of the NAFTA describe these conditions.

478. The Tribunal can treat Section B of Chapter 11 of the NAFTA as constituting Canada's consent to arbitration only if all these requirements have been met. International law does not give an investor the benefit of the doubt with respect to the existence of a State's consent to arbitration.<sup>569</sup> Rather, the investor bears the burden of proving that "the requirements of Article 1101 are fulfilled, that a claim has been brought by a claimant in accordance with Article 1116 or 1117, and that all preconditions and formalities under Articles 1118 to 1121 are fulfilled."<sup>570</sup>

479. The Claimant must also prove the merit of its claims. Article 24(1) of the UNCITRAL Arbitration Rules incorporates the general rule that, "[E]ach party shall have the burden of proving the facts relied on to support his claim or defence." As the Tribunal in *Thunderbird* explained, "the party alleging a violation of international law giving rise to international responsibility has the burden of proving its assertion."<sup>571</sup> To meet this burden Chemtura must present persuasive evidence and legal argument to demonstrate that its claims are within the jurisdiction of this Tribunal, are timely and that Canada's actions were inconsistent with NAFTA Articles 1103, 1105, and 1110.

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<sup>569</sup> *Fireman's Fund Insurance Company v. Mexico* (ICSID No. ARB(AF)/02/1) Decision on the Preliminary Question (17 July 2003), ¶ 64 (Annex R-189) (*Fireman's Fund – Preliminary Award*).

<sup>570</sup> *United Parcel Service v. Canada*, (UNCITRAL), Award on Merits and Dissenting Opinion (24 May 2007), ¶ 120 (Annex R-297) (*UPS-Award*); *ADF Group Inc. v. United States* (ICSID No. ARB (AF)/00/1) Award (9 January 2003), ¶ 185 (Annex R-143) (*ADF – Award*).

<sup>571</sup> *International Thunderbird Gaming Corporation v. Mexico* (UNCITRAL) Arbitral Award, 26 January 2006, ¶ 95 (Annex R-287) ("*Thunderbird-Award*"); See also, *S.D. Myers v. Canada* (UNCITRAL) First Partial Award (13 November 2000), ¶ 316 (Annex R-267) (*S.D. Myers-First Partial Award*).

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Chemtura must also prove that the damages claimed were caused by the breaches alleged and are reasonable and accurate.

480. Moreover, identification of the investment at issue is an integral part of the analysis. The effects of “any measures” or “treatment” by Canada are only relevant insofar as they affect the covered investment.<sup>572</sup>

### C. The Tribunal decides on the basis of applicable law

481. In considering whether the Claimant has met its burden of proof, Article 1131 requires the Tribunal to “decide the issues in dispute in accordance with this Agreement and applicable rules of international law... [and any] interpretation by the [Free Trade Commission].”<sup>573</sup> It has no power to decide issues based on any other law or to decide matters *ex aequo et bono*.

482. The applicable rules of international law consist in part of the rules of treaty interpretation described below. Other general rules of international law, including the rules concerning state responsibility, are also potentially applicable. However, these rules cannot replace or modify the specific rules in the NAFTA which is *lex specialis* among the Parties.<sup>574</sup>

483. Article 1131 of the NAFTA also requires this Tribunal to apply any interpretation of the NAFTA issued by the Free Trade Commission (FTC). Article 1131(2) states that an interpretation by the FTC of a provision of the NAFTA “shall be binding” on a Chapter 11 Tribunal. The FTC issued such *Notes of Interpretation of Certain Chapter Eleven Provisions* on July 31, 2001.<sup>575</sup> These Notes addressed procedures for public

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<sup>572</sup> The question of what constitutes the Claimant's investment is examined below and is section II.

<sup>573</sup> NAFTA, Articles 102, 1131(1).

<sup>574</sup> *UPS-Award*, ¶¶ 55, 59 (Annex R-297).

<sup>575</sup> NAFTA Free Trade Commission, *Notes of Interpretation of Certain Chapter Eleven Provisions*, 31 July 2001, online at: <<http://www.international.gc.ca/trade-agreements-accords-commerciaux/disp-diff/nafta-interpr.aspx?lang=en>> (Annex R-242) (*NAFTA – Notes of Interpretation*).

access to documents, and Article 1105 of the NAFTA. NAFTA tribunals have consistently found the FTC Notes to be binding.<sup>576</sup>

#### **D. NAFTA is interpreted pursuant to the Vienna Convention on the Law of Treaties**

484. Article 102 of the NAFTA requires the NAFTA to be interpreted and applied “in accordance with applicable rules of international law.” Article 38(1) of the *Statute of the International Court of Justice (ICJ Statute)* identifies the sources for applicable rules of international law.<sup>577</sup> The primary sources are applicable treaties, customary international law, and “the general principles of law recognized by civilized nations.”<sup>578</sup> A subsidiary source is “judicial decisions and the teachings of the most highly qualified publicists.”<sup>579</sup>

485. The rules of international law applicable to NAFTA disputes include the rules of interpretation codified in Articles 31 and 32 of the *Vienna Convention on the Law of Treaties (Vienna Convention)*.<sup>580</sup> Articles 31 and 32 of the Vienna Convention provide as follows:

#### **Article 31 General rule of interpretation**

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:

<sup>576</sup> See, e.g., *Thunderbird-Award*, ¶ 192 (Annex R-287); *Methanex v. United States*, (UNCITRAL) Award of the Tribunal on Jurisdiction and the Merits (3 August 2005), Part IV, Ch. C, ¶ 20 (Annex R-235) (*Methanex-Award*).

<sup>577</sup> *Methanex-Award*, Part II, Ch. B, ¶ 3 (Annex R-235); *Thunderbird-Award*, ¶¶ 89-90 (Annex R-287).

<sup>578</sup> *Statute of the International Court of Justice*, Art. 38(1)(a)-(c) (Annex R-206) (*ICJ Statute*).

<sup>579</sup> *ICJ Statute*, Art. 38(1)(d) (Annex R-206).

<sup>580</sup> *Vienna Convention on the Law of Treaties*, 23 May 1969, Can. T.S. 1980 No. 37 (also published at 1155 U.N.T.S. 331, (1969) 8 ILM 679), Arts. 31-32 (Annex R-299) (*Vienna Convention*); See also *Thunderbird-Award*, ¶ 91 (Annex R-287); *Methanex-Award*, Part II, Ch. B, ¶ 15 (Annex R-235).

(a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;

(b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

3. There shall be taken into account, together with the context:

(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;

(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;

(c) any relevant rules of international law applicable in the relations between the parties.

4. A special meaning shall be given to a term if it is established that the parties so intended.

### **Article 32**

#### **Supplementary means of interpretation**

Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:

(a) leaves the meaning ambiguous or obscure; or

(b) leads to a result which is manifestly absurd or unreasonable.

486. NAFTA Chapter 11 tribunals uniformly agree that Articles 31 and 32 of the *Vienna Convention* are part of customary international law, and apply to disputes under the NAFTA.<sup>581</sup>

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<sup>581</sup> *Methanex-Award*, Part IV, Ch. B, ¶ 29 (Annex R-235); *S.D. Myers-First Partial Award*, ¶¶ 200-202 (Annex R-267); *Pope & Talbot, Inc v. Canada* (UNCITRAL) Interim Award (26 June 2000), ¶¶ 64-69 (Annex R-259) (*Pope & Talbot-Interim Award*).



## 1. Article 31 describes the primary means of interpreting the NAFTA

487. Article 31(1) of the *Vienna Convention* makes the ordinary meaning of the text itself the starting point for interpretation. As the NAFTA Tribunal in *ADF* recently explained, “the rules of interpretation found in customary international law enjoin us to focus first on the actual language of the provision being construed.”<sup>582</sup>

488. The text of the NAFTA must also be interpreted in the appropriate context. Each provision must be interpreted in the context of the entire NAFTA and the Tribunal must read all provisions harmoniously and as a whole.<sup>583</sup> The context of each provision also includes the structure of the provision, the Chapter in which it is contained and the NAFTA as a whole.<sup>584</sup>

489. The text of the NAFTA must also be interpreted in the light of the object and purpose of the Agreement.<sup>585</sup> In a Chapter 11 dispute, the Preamble of the NAFTA and Article 102 provide the Tribunal with an appropriate starting point for understanding the object and purpose of the NAFTA.<sup>586</sup>

490. As the Preamble makes clear, the NAFTA represents a balance struck by the Parties between promoting trade and economic development while protecting the public interest and welfare.<sup>587</sup> For example, while the Parties intended to “ensure a predictable commercial framework for business planning and investment” the Preamble also notes the Parties’ intent to “preserve their flexibility to safeguard the public welfare; promote

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<sup>582</sup> *ADF – Award*, ¶ 147 (Annex R-143).

<sup>583</sup> *ADF – Award*, ¶ 147 (“[A NAFTA] provision under examination must of course be scrutinized in context; but that context is constituted chiefly by the other relevant provisions of NAFTA”) (Annex R-143).

<sup>584</sup> *Canfor Corporation v. United States; Tembec et al. v. United States and Terminal Forest Products Ltd. v. United States* (Consolidated UNCITRAL) Decision on Preliminary Question (6 June 2006), ¶ 122 (“Article 1901(3) can be properly understood only within the context of the structure of Chapter Nineteen as a whole.”) (Annex R-165) (*Canfor – Preliminary Question*).

<sup>585</sup> *Vienna Convention*, Article 31 (Annex R-299); *See also* NAFTA Article 102.

<sup>586</sup> *S.D. Myers-First Partial Award*, ¶ 196 (Annex R-267).

<sup>587</sup> *S.D. Myers-First Partial Award*, ¶¶ 196, 220 (Annex R-267).

sustainable development; strengthen the development and enforcement of environmental laws and regulations; and protect, enhance and enforce basic workers' rights."<sup>588</sup> The NAFTA was not intended by the Parties to be a one-sided agreement favouring only commercial interests.

491. NAFTA Chapter 11 Tribunals have adopted this understanding of the object and purpose of the NAFTA, and applied it in their interpretation of the Treaty's provisions. In *Waste Management II*, the Tribunal noted that the NAFTA does not provide an insurance policy against business risk, nor does it protect investors from the ordinary disappointments of business operations.<sup>589</sup> Simply put, the NAFTA does not mandate that every regulatory action of the government inure to the benefit of the investor or that the investor will never be disappointed in its dealings with public authorities.<sup>590</sup> The NAFTA Tribunal in *GAMI* summarized this by noting that the NAFTA does not "constitute[s] a guarantee of economic success."<sup>591</sup>

492. NAFTA Chapter 11 Tribunals have also cautioned against using statements as to the object and purpose of the treaty as anything more than an interpretive tool. In *ADF*, the Tribunal explained that the general provisions stating the object and purpose of the NAFTA "may frequently cast light on a specific interpretive issue; but [are] not to be regarded as overriding and superseding the [text]."<sup>592</sup> This rule is also made clear by Article 102 itself, which provides that the objectives of the NAFTA are "elaborated more specifically through its principles and rules."

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<sup>588</sup> NAFTA, Preamble.

<sup>589</sup> *Waste Management II-Award*, ¶ 160 ("It is not the function of Article 1110 to compensate for failed business ventures...") (Annex R-300).

<sup>590</sup> *Azinian, Davitian, & Baca v. Mexico* (ICSID No. ARB (AF)/97/2) Award (18 October 1999), ¶ 83 (Annex R-154) (*Azinian – Award*); ("It is a fact of life everywhere that individuals may be disappointed in their dealings with public authorities...NAFTA was not intended to provide foreign investors with blanket protection from this kind of disappointment, and nothing in its terms so provides.").

<sup>591</sup> *GAMI Investments, Inc. v. Mexico* (UNCITRAL) Final Award (15 November 2004), ¶ 85 (Annex R-196); ("No one has suggested that NAFTA entitles an investor to act on the basis that a regulatory scheme constitutes a guarantee of economic success.") (*GAMI-Final Award*).

<sup>592</sup> *ADF – Award*, ¶ 147 (Annex R-143).

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## 2. Article 32 describes supplementary means of interpretation

493. Pursuant to Article 32 of the *Vienna Convention*, a Tribunal can rely on supplementary means only if interpreting a NAFTA provision in accordance with Article 31 leads to a result which is ambiguous or obscure, or leads to a manifestly absurd or unreasonable conclusion. Article 32 of the *Vienna Convention* provides that supplementary material includes “the preparatory work of the treaty and the circumstances of its conclusion.”<sup>593</sup>

### E. Definition of investment

494. NAFTA Chapter 11 defines “investment” in Article 1139. It provides:

**investment** means:

- (a) an enterprise;
- (b) an equity security of an enterprise;
- (c) a debt security of an enterprise
  - (i) where the enterprise is an affiliate of the investor, or
  - (ii) where the original maturity of the debt security is at least three years,

but does not include a debt security, regardless of original maturity, of a state enterprise;

- (d) a loan to an enterprise
  - (i) where the enterprise is an affiliate of the investor, or
  - (ii) where the original maturity of the loan is at least three years,

but does not include a loan, regardless of original maturity, to a state enterprise;

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<sup>593</sup> *Vienna Convention*, Article 32 (Annex R-299).

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- (e) an interest in an enterprise that entitles the owner to share in income or profits of the enterprise;
  - (f) an interest in an enterprise that entitles the owner to share in the assets of that enterprise on dissolution, other than a debt security or a loan excluded from subparagraph (c) or (d);
  - (g) real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes; and
  - (h) interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory, such as under
    - (i) contracts involving the presence of an investor's property in the territory of the Party, including turnkey or construction contracts, or concessions, or
    - (ii) contracts where remuneration depends substantially on the production revenues or profits of an enterprise;

but investment does not mean:

- (i) claims to money that arise solely from
  - (i) commercial contracts for the sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the territory of another Party, or
  - (ii) the extension of credit in connection with a commercial transaction, such as trade financing, other than a loan covered by a subparagraph (d); or
- (j) any other claims to money,

that do not involve the kinds of interests set out in subparagraphs (a) through (h).

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495. This definition is exhaustive (“investment means...”), and not illustrative. The Claimant must prove that the interest which it alleges is an investment falls squarely within this definition.

496. The Claimant appears to define its investment as Crompton Canada. It states:

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, 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.<sup>594</sup>

497. Despite expressly defining the investment for purposes of Article 1139 as Crompton Canada, the Claimant refers inconsistently to different facets of its Canadian subsidiary as the affected investment throughout its Memorial. For example, the Claimant variously alleges that Canada took measures affecting its “seed treatment investment”,<sup>595</sup> that its affected investment is its “lindane seed treatment investment”,<sup>596</sup> its “lindane seed treatment business” or “lindane business.”<sup>597</sup> At yet another point in its Memorial, the Claimant suggests that its “lindane product business” is not an investment in its own right, but is “a significant proportion of its investment [...] in Canada”.<sup>598</sup> Finally, in the context of Article 1110, the Claimant argues that:

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.<sup>599</sup>

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<sup>594</sup> Claimant’s Memorial, ¶ 304.

<sup>595</sup> Claimant’s Memorial, ¶¶ 298 and 487.

<sup>596</sup> Claimant’s Memorial, ¶ 495.

<sup>597</sup> Claimant’s Memorial, ¶¶ 520 and 524.

<sup>598</sup> Claimant’s Memorial, ¶ 518.

<sup>599</sup> Claimant’s Memorial, ¶ 519. In the case of market share, *see also* ¶ 518.

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498. These phrases are used interchangeably throughout the Claimant's Memorial, ultimately confusing what the Claimant, in fact, alleges as its investment.

499. The Claimant's shifting and imprecise definition of its investment is especially problematic in the context of expropriation.

## **II. ARTICLE 1110 – CANADA DID NOT EXPROPRIATE THE CLAIMANT'S INVESTMENT**

### **A. Summary of Canada's position regarding expropriation**

500. The Claimant has not established its expropriation claim against Canada under Article 1110 of the NAFTA for four reasons:

*First*, only Chemtura Canada, the Claimant's enterprise as a whole, qualifies as an investment capable of being expropriated. Elements of the value of the enterprise such as goodwill, market share, and customers are not investments under Article 1139 and hence cannot be expropriated investments for the purposes of NAFTA.

*Second*, there has not been a substantial deprivation of the Claimant's investment. Indeed, the VWA for canola and the PMRA's subsequent decision to phase out lindane use more generally (based on the Special Review) had a limited impact on Chemtura Canada, and certainly nothing approaching substantial deprivation. Moreover, Canada never controlled the Claimant's investment, directed its operations, took proceeds of sales, intervened in management or shareholder activities, or otherwise interfered with it in any way that can be characterised as expropriation or an action tantamount to expropriation. To the contrary, the Claimant: i) controlled all aspects of Chemtura Canada's operations at all relevant times; ii) was granted an extended phase-out period during which it could deplete its lindane stock; iii) was permitted to sell two replacement

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pesticide products in Canada even before the beginning of the phase-out period; and iv) was consistently profitable before, during, and after the ban on lindane was instituted.

*Third*, even if this Tribunal finds that the Claimant was substantially deprived of its investment, there was still no expropriation because the PMRA's decision to phase out all agricultural applications of lindane was a valid exercise of Canada's police powers to protect public health and the environment. The PMRA's decision to de-register lindane fits within the police powers doctrine in that it was: i) not made in an arbitrary manner since it respected due process and was based on valid science; ii) non-discriminatory; iii) not excessive and; iv) made in good faith to combat the serious occupational exposure risks posed by lindane.

*Fourth*, at international law, an act of compulsion by the expropriating State is essential to a finding of expropriation. No such compulsion existed here. Indeed, because the Claimant consented to the VWA in November 1998 and took the benefit of it, it is now precluded by international law from establishing a claim for expropriation against the PMRA.

501. For all of these reasons, the Tribunal should dismiss the Claimant's Article 1110 claim.

**B. Expropriation: definition and methodology**

502. NAFTA Article 1110(1) states that:

1. No Party may directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment ("expropriation"), except:
  - (a) for a public purpose;

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- (b) on a non-discriminatory basis;
  - (c) in accordance with due process of law and Article 1105(1);  
and
  - (d) on payment of compensation in accordance with  
paragraphs 2 through 6.

503. The NAFTA does not define “expropriation.” As a result, NAFTA Tribunals have defined expropriation on a case-by-case basis, referring to applicable rules of international law.<sup>600</sup> A three-step methodology has emerged from these cases that asks the following questions:

- 1) Is there is an investment capable of being expropriated?
- 2) If so, has that investment been expropriated?
- 3) If so, was the investment expropriated in a manner consistent with the conditions found in Articles 1110(1)(a) to (d), therefore constituting a lawful expropriation?

504. In this arbitration, the answer to question 1) is yes, though only with respect to the Claimant’s enterprise, Chemtura Canada. Elements such as goodwill, market share, and customers are not investments as defined by NAFTA Article 1139. For three reasons, the answer to question 2) is no. Since the answer to question 2) is no, question 3) is irrelevant. Canada addresses these three questions in detail below.

**C. The three-part expropriation analysis derived from the NAFTA case law**

**1. Chemtura Canada is the only investment capable of being expropriated in this case**

505. The first step in determining whether Article 1110 has been breached is to determine whether there is an interest capable of being expropriated. It is important not to conflate the first and second steps of this test: the Tribunal must be satisfied that an

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<sup>600</sup> NAFTA Article 1131. *Pope & Talbot-Interim Award* (Annex R-259); *Metalclad v. Mexico* (ICSID No. ARB(AF)/97/1) Award (30 August 2000) (Annex R-233) (*Metalclad – Award*); *Methanex-Award* (Annex R-233).



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investor possesses an expropriable interest before it can consider whether that interest has in fact been expropriated.

506. Article 1110 expressly requires an “investment” to have been expropriated. If the alleged interest is not within the scope of the definition of “investment” in NAFTA Article 1139, then it cannot be the subject of an expropriation claim under Article 1110.

Canada's position is that the Claimant has pleaded only one interest that is capable of fitting within the definition of investment in NAFTA Article 1139. That interest is succinctly described by the Claimant in paragraph 304 of its Memorial: “Crompton Canada constitutes an “investment” within the meaning of Article 1139 of NAFTA”.

**a) The enterprise as a whole must be considered**

507. When addressing whether the Claimant's investment has been expropriated, the Tribunal must consider Chemtura Canada as a whole enterprise; the Claimant cannot artificially isolate aspects of its business and claim that these pieces constitute a stand-alone investment under Article 1139.

508. The proposition that an investment must be considered as a whole is supported by both NAFTA and non-NAFTA investment awards. Those awards have consistently held that, while subsidiary elements of an investment are relevant to a determination of its value, they are not, in themselves, investments.

509. For instance, in *Feldman v. Mexico*, the Mexican government denied Feldman tax rebates on cigarettes exported to the United States. The Tribunal looked at the Claimant's entire business when determining whether he had suffered a substantial deprivation of the investment. Although Feldman was effectively precluded from exporting cigarettes by the actions of Mexico, the Tribunal found that he was “free to pursue other continuing lines of business activity”. The essential issue in determining if there had been a substantial taking was whether the Claimant still had control of its

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investment, and the Tribunal found that the deprivation of one product line “does not amount to Claimant’s deprivation of control of his company”.<sup>601</sup>

510. In determining whether the investor had an expropriable investment, the claimant in *Methanex v. United States* argued unsuccessfully that its customer base, goodwill, and market share were investments as defined in Article 1139 of the NAFTA. The Tribunal acknowledged that “the restrictive notion of property as a material “thing” is obsolete and has ceded its place to a contemporary conception which includes managerial control over components of a process that is wealth producing”.<sup>602</sup> However, the Tribunal concluded that these elements were not, in and of themselves, investments. Again, while a product line may be a relevant element in the valuation of an enterprise, it is not itself a stand-alone investment.

511. Outside of the NAFTA context, other international investment tribunals have also found that an investment must be considered as a whole, and that discrete parts of a larger investment cannot be parsed for the purposes of analyzing the obligations a State has assumed under a bilateral investment treaty (BIT).

512. For instance, in *Eastern Sugar v. Czech Republic*, the dispute concerned government regulation of the sugar industry in the Czech Republic, and various measures taken by the Czech Republic to harmonize its rules with the agricultural policies of the European Union. In this case, the Tribunal decided that the Article of the Czech Republic-Netherlands BIT addressing expropriation “is applicable only if there was a substantial deprivation of *the entire investment or a substantial part* of the investment”.<sup>603</sup> Since the Claimant was not alleging that its whole investment had been affected, but only that its sugar quota had been affected, it failed to identify an expropriable investment, and there was no expropriation.

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<sup>601</sup> *Feldman v. Mexico* (ICSID No. ARB(AF)/99/1) Award (16 December 2002), ¶ 142 (Annex R-187) (*Feldman-Award*).

<sup>602</sup> *Methanex-Award*, Part IV – Chapter D, at 7-8, ¶ 17 (Annex R-235).

<sup>603</sup> *Eastern Sugar B.V. v. Czech Republic* (UNCITRAL), Partial Award (27 March 2007), ¶ 210 (Annex R-179) (*Eastern Sugar – Partial Award*) (our emphasis).

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513. A similar result occurred in *Joy Mining v. Egypt*.<sup>604</sup> There the Claimant had contracted to provide mining equipment to Egypt's mining authority for a specific project. Problems in the operation of the project led to the dispute before an ICSID Tribunal. The Claimant argued that its contract was an investment under the United Kingdom-Egypt BIT, and that the Egyptian government's refusal to release bank guarantees violated the treaty. The Tribunal considered that the essential question was whether the bank guarantees were an investment,<sup>605</sup> and concluded that "a given element of a complex operation should not be examined in isolation because *what matters is to assess the operation globally or as a whole*".<sup>606</sup> (our emphasis). As such, the bank guarantees could not be considered an affected investment, and the dispute was not within the scope of the BIT.

**b) What is not an investment under Article 1139**

514. In its Memorial, the Claimant appears to allege that customers, goodwill, and market constitute its investment under the NAFTA.<sup>607</sup> It is unclear whether the Claimant is arguing that these elements are investments in and of themselves, or that they are merely parts of the value of Chemtura's "Canadian investment", which it has defined as its wholly-owned subsidiary. If the Claimant is arguing that these elements are stand-alone investments, Canada submits that that argument must fail because such interests do not fit within the definition of investment in Article 1139.

515. The terms included in Article 1139's definition of investment provide clear indicia of what this Tribunal may consider as an "investment": these include an enterprise, an equity security, a debt security, a loan, or an interest entitling its owner to share in income, profits, or assets upon dissolution. These items share attributes in that they are concrete, definite interests that are liable to be bought, sold, traded, or borrowed

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<sup>604</sup> *Joy Mining v. Egypt* (ICSID Case No. ARB/03/11) Award on Jurisdiction (6 August 2004) (Annex R-211) (*Joy Mining-Award on Jurisdiction*).

<sup>605</sup> *Joy Mining-Award on Jurisdiction*, ¶ 42 (Annex R-211).

<sup>606</sup> *Joy Mining-Award on Jurisdiction*, ¶ 54 (Annex R-211) (our emphasis).

<sup>607</sup> Claimant's Memorial, ¶ 519. In the case of market share, *see also* ¶ 518.

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against. The NAFTA Parties have assigned a core meaning to what comprises an investment under Article 1139, which does not include customers, goodwill, or market share.

516. The Claimant has not indicated in its Memorial which paragraph of Article 1139 includes customers, goodwill, or market share as investments. On a plain reading of Article 1139, it is obvious that these concepts are not investments under paragraphs (a) to (f) of that Article. As such, Canada assumes that the Claimant is relying on Article 1139 (g) and (h), and will therefore analyze those alleged “investments” under those headings.

517. Even under those broad categories, however, the Claimant’s characterization of customers, market share, and goodwill as NAFTA investments still fails. NAFTA Articles 1139(g) and (h) define investment as:

- (g) real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes; and
- (h) interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory, such as under
  - (i) contracts involving the presence of an investor’s property in the territory of the Party, including turnkey or construction contracts, or concessions, or
  - (ii) contracts where remuneration depends substantially on the production, revenues or profits of an enterprise.

518. NAFTA Article 1139(g) lists real estate and tangible or intangible property as covered investments. The ordinary meaning of “property” is a thing or possession that a person or entity owns. At international law, “property” consists of a bundle of rights including the right to use, the right to enjoy and the right to destroy or dispose of the

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property (*i.e.*, *usus, fructus, abusus*).<sup>608</sup> In a similar manner, the *Shorter Oxford Dictionary* defines “property” as “that which one owns; a thing or things belonging to a person or persons” and “the condition or fact of owning or being owned; the (exclusive) right to the possession, use or disposal of a thing, ownership.”<sup>609</sup> Generally, property can be acquired, owned, and alienated by its owner.

519. Customers, goodwill, and market share are not within the ordinary meaning of tangible or intangible property. No one, including the Claimant, can own, acquire, possess, use, rent, mortgage, dispose of or otherwise alienate customers, goodwill, or market share. Nor does the Claimant manage or control these so-called investments. They are elements of a business, and could even be considered benefits that flow from its success, but they are not interests that constitute stand-alone investments and they do not attract protection under NAFTA Chapter 11.

520. Similarly, the ordinary meaning of the terms used in Article 1139(h) would not include the interests alleged by the Claimant. The *Shorter Oxford Dictionary* defines “interest” as a “right or a title, esp. to a share in property.”<sup>610</sup> The things described as investments by the Claimant are clearly not legal concerns, rights or titles. In the same vein, “commitment” denotes an obligation that restricts freedom of action, while the verb “commit” refers to conduct in the nature of a pledge, undertaking, or guarantee.<sup>611</sup> Again, the alleged investments are not of the same nature as an obligation, pledge, undertaking, or guarantee.

521. Articles 1139(h)(i) and (ii) provide relevant context for the interpretation of “interests arising from the commitment of capital.” Articles 1139(h)(i) and (ii) narrow

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<sup>608</sup> Higgins, Rosalyn, *The Taking of Property by the State: Recent Developments in International Law* (1982) 176 REC. DES COURS 259 at 270 ff (Annex R-204) (*Higgins*); Wortley, B.A., *EXPROPRIATION IN PUBLIC INTERNATIONAL LAW* (New York: Cambridge University Press, 1959) at 50 (Annex R-303) (*Wortley*); *LIAMCO v. Libya*, 62 I.L.R. 140 (1981) at 89-92 (Annex R-220) (*LIAMCO*).

<sup>609</sup> SHORTER OXFORD ENGLISH DICTIONARY, 5th ed. (Oxford University Press, 2002) at 2369 (Annex R-275) (*SHORTER OXFORD*).

<sup>610</sup> *SHORTER OXFORD*, at 1400 (Annex R-275).

<sup>611</sup> *SHORTER OXFORD*, at 460-461 (Annex R-275).

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the potential scope of “interests arising from the commitment of capital” by limiting them to interests “such as” contracts and concessions. The *ejusdem generis* rule of interpretation would restrict the scope of the word “interests” to things like “contracts” and “concessions”.<sup>612</sup> Customers, goodwill or market share are not remotely like interests that arise from contracts or concessions.

522. Nothing in the object and purpose of the NAFTA justifies expanding the definition of investment to include the interests alleged by the Claimant. In particular, the NAFTA’s objective to “increase substantially investment opportunities in the territories of the Parties”<sup>613</sup> is not a licence to transform benefits flowing from a successful investment into a stand-alone investment for the purposes of investor promotion and protection.

523. The expansive definition of investment implied by the Claimant’s arguments has been considered and rejected in international jurisprudence, including NAFTA Chapter 11 arbitrations, other international case law, and doctrine.

524. For instance, in *Methanex v. United States*, the Tribunal rejected the Claimant’s argument that customer base, goodwill, or market share could be considered as stand-alone investments:

The USA is correct that Article 1139 does not mention the items claimed by Methanex. But in *Pope & Talbot Inc. v. Canada*, the tribunal held that “the Investor’s access to the U.S. market is a property interest subject to protection under Article 1110.” Certainly, the restrictive notion of property as a material “thing” is obsolete and has ceded its place to a contemporary conception which includes managerial control over components of a process that is wealth producing. In the view of the Tribunal, items such as goodwill and market share may, as Professor White wrote, “constitute [] an element of the value of an enterprise and as such may have been covered by some of the compensation payments”.

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<sup>612</sup> The *ejusdem generis* rule means that general words following special words are limited to the *genus* indicated by the special words. See Lord McNair, *THE LAW OF TREATIES* (Oxford: Oxford University Press, 1961) at 393-410 (Annex R-231) (*McNair*).

<sup>613</sup> NAFTA Article 102(1)(c).

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Hence in a comprehensive taking, these items may figure in valuation. But it is difficult to see how they might stand-alone, in a case like the one before the Tribunal.<sup>614</sup>

525. In reaching its conclusion, the *Methanex* Tribunal relied in part on the writings of Professor Gillian White, who addressed the type of rights that were protected against expropriation. She wrote:

A property right, in order to qualify for the protection of the international law rules must be an actual legal right, as distinct from a mere economic or other benefit, such as a situation created by the law of a State in favour of some person or persons who are therefore interested in its continuance. ... [T]he notion of goodwill is too vague to be regarded as a separate property right apart from the enterprise to which it is attached. This assumption gains support from the complete absence of any reference to goodwill or business reputation in any of the post-war decrees or compensation agreements examined by the writer. The most that can be said is that goodwill constitutes an element of the value of an enterprise and as such may have been covered by some of the compensation payments.<sup>615</sup>

526. The Permanent Court of International Justice has also rejected claims based on the expropriation of customer base, goodwill, or market share. In the *Oscar Chinn* case, the government of the Belgian Congo substantially reduced transport tariffs in an effort to combat a widespread economic downturn. Chinn owned a river transport business that was severely affected by the tariff reduction, and ultimately he went out of business. Nonetheless, the Permanent Court of International Justice refused to order reparations for Chinn's loss, concluding that it was:

...unable to see in [Mr. Chinn's] original position – which was characterized by the possession of customers and the possibility of making a profit – anything in the nature of a genuine vested right.

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<sup>614</sup> *Methanex-Award*, Part IV – Chapter D at 7-8, ¶ 17 (Annex R-235).

<sup>615</sup> White, Gillian, NATIONALISATION OF FOREIGN PROPERTY (London: Stevens & Sons Ltd., 1961), at 49 (Annex R-301) (*White*).

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Favourable business conditions and goodwill are transient circumstances, subject to inevitable changes.<sup>616</sup>

527. Customers, goodwill, and market share are also “transient circumstances” that are subject to change. They are not stand-alone investments for the purposes of NAFTA Article 1139. They are merely benefits that add value to the enterprise but do not constitute investments in and of themselves. As a result, the Tribunal should dismiss the claims for breach of Chapter 11 based on these alleged rights without further consideration of their merits.

**c) What does constitute an investment under Article 1139**

528. In contrast to the customers, goodwill, and market share discussed above, the Claimant's Canadian corporation, Chemtura Canada, does fit within Article 1139's definition of investment. In particular, Chemtura Canada fits squarely under Article 1139(a).

529. It is only when an investor demonstrates that it possesses interests within the meaning of the definition of “investment” in Article 1139 that the Tribunal can proceed to the second step of determining whether such “investments” have in fact been expropriated. Canada submits that the Claimant's only qualifying investment, Chemtura Canada, has not been expropriated.

**2. Canada did not expropriate Chemtura's investment**

530. It is clear that Canada did not expropriate the Claimant's investment, Chemtura Canada, for three reasons: a) the Claimant was not substantially deprived of its investment; b) the deregistration of lindane was a valid exercise of police powers by Canada designed to protect the health of its citizens; and c) there can be no expropriation where the Claimant consented to the impugned government action, which is precisely what the Claimant did under the VWA with respect to ending lindane use on canola.

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<sup>616</sup> *The Oscar Chinn Case, (UK v. Belgium)* (1934) P.C.I.J. (Series A/B) No. 63, at 88 (Annex R-253) (*Oscar Chinn Case*).



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**a) There was no substantial deprivation**

**(1) Definition of substantial deprivation**

531. Both the Claimant and Canada agree that a substantial deprivation of the investment is required for a finding of expropriation under Article 1110.<sup>617</sup> As Professor Higgins notes, “[w]here physical property has been concerned, the issue has been fairly clear: interferences which significantly deprive the owner of the use of his property amount to a taking of that property”.<sup>618</sup>

532. In this instance, it is evident that there has been no direct expropriation. The Claimant contends that the measures at issue either indirectly expropriated or were tantamount to an expropriation of its investment.

533. NAFTA Tribunals have clearly decided that “tantamount to expropriation” simply means equivalent to expropriation, and does not expand the scope of expropriation beyond its meaning at international law.<sup>619</sup>

534. Numerous tribunals have considered the definition of indirect expropriation. In *Starrett Housing*, for instance, the Iran-United States Claims Tribunal described indirect expropriation in the following manner, using a formulation that has been relied on by numerous subsequent investment arbitration tribunals:

It is recognized in international law that measures taken by a State can interfere with property rights to such an extent that these rights are rendered so useless that they must be deemed to have been expropriated, even though the State does not purport to have expropriated them and the legal title to the property formally remains with the original owner.<sup>620</sup>

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<sup>617</sup> Claimant's Memorial, ¶ 503.

<sup>618</sup> *Higgins*, at 324 (Annex R-204).

<sup>619</sup> *Pope & Talbot-Interim Award*, ¶ 104 (Annex R-259); *S.D. Myers-First Partial Award*, ¶ 285 and Separate concurring opinion (13 November 2000), ¶ 217 (Annex R-267); *Feldman-Award*, ¶¶ 98-100 (Annex R-187).

<sup>620</sup> *Starrett Housing Corporation v. Iran*, Interlocutory Award No. ITL 32-24-1 (19 December 1983), 4 Iran-U.S. C.T.R. 122, 154, at 28, 36 (Annex R-282) (*Starrett Housing – Interlocutory Award*).

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535. Contrary to what the Claimant alleges in its Memorial, there has been no substantial deprivation in this case.

536. To succeed, Chemtura must demonstrate that the impugned government measure interferes with the investment sufficiently “to support a conclusion that the property has been “taken” from the owner”.<sup>621</sup>

537. Most cases have focused on what level of deprivation is deemed “substantial” for the purposes of finding an expropriation. If there has been a deprivation, the question becomes whether that deprivation is substantial.

538. For example, in *Pope & Talbot*, the Tribunal rejected the investor’s claim of expropriation because the alleged interference did not amount to a “substantial deprivation”.<sup>622</sup> Citing both the *Harvard Draft* and the *Third Restatement*, the *Pope & Talbot* Tribunal held that:

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 Investor’s Counsel conceded, correctly, that under international law, expropriation requires a “substantial deprivation.” The Export

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<sup>621</sup> *Pope & Talbot-Interim Award*, ¶ 102 (Annex R-259).

<sup>622</sup> *Pope & Talbot-Interim Award*, ¶ 102 (Annex R-259).

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Control Regime has not restricted the Investment in ways that meet these standards.<sup>623</sup>

539. The level or degree of deprivation is critical to a finding of expropriation. It is not mere interference or some deprivation that is required but rather a finding of substantial deprivation. For instance, in finding that Canada's export quotas imposed under the *Softwood Lumber Agreement 1996* did not amount to a substantial deprivation of the investment, the *Pope & Talbot* Tribunal concluded that, "mere interference is not expropriation; rather, a significant degree of deprivation of fundamental rights of ownership is required".<sup>624</sup>

540. To assess whether the requisite degree of deprivation had been established, the *Pope & Talbot* Tribunal looked at the usual indicia of effective control over an investment. These include whether the investor, notwithstanding the measures complained of, still directed day-to-day operations, operated at a profit, and employed officers who were not supervised by the State, and whether the State took proceeds of sales, interfered with management or shareholder functions, the payment of dividends or the appointment of directors and managers.<sup>625</sup>

541. The Tribunal in *Waste Management II* also looked at the usual indicia of effective control in finding that there had been no expropriation in that case. In concluding that the investor's investments had not been expropriated, the *Waste Management II* Tribunal

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<sup>623</sup> *Pope & Talbot-Interim Award*, ¶ 102 (Annex R-259). Article 10(3) of the Harvard Draft *Convention on the International Responsibility of States for Injury to Aliens* defined a taking as "any unreasonable interference with the use, enjoyment or disposal of property as to justify an inference that the owner will not be able to use, enjoy, or dispose of the property within a reasonable period of time after the inception of such interference." See Sohn, Louis B. & R.R. Baxter, *Responsibility of States for Injuries to the Economic Interests of Aliens* (1961) 55:3 AM J. INT'L L. 545 at 553 (Annex R-277) (*Sohn & Baxter*). The Third Restatement states that: A State is responsible under international law for "taking by the state of the property of a national of another state that (a) is not for a public purpose, or (b) is discriminatory, or (c) is not accompanied by provision for just compensation." It goes on to state that, similar to NAFTA Article 1110(a) through (d), the application of §712(a) through (c) is not part of the test to determine whether expropriation has occurred. *American Law Institute*, RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES (1986) at §712, Comment (e) (Annex R-289) (*U.S-Third Foreign Relations Restatement*).

<sup>624</sup> *Pope & Talbot-Interim Award*, ¶ 102 (Annex R-259).

<sup>625</sup> These criteria are generally considered at international law to determine whether there has been a substantial deprivation. See, for example, *Pope & Talbot-Interim Award*, ¶ 100 (Annex R-259).

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noted that there had been no taking of physical assets and that the investor had control over and use of its investment. It also noted the degree of deprivation required to constitute expropriation: “[I]t is not the function of Article 1110 to compensate for failed business ventures, absent arbitrary intervention by the State amounting to a virtual taking or sterilising of the enterprise”.<sup>626</sup>

542. The *S.D. Myers* Tribunal also recognized that the degree of deprivation was an important factor on which a determination of expropriation must turn. It required a “lasting removal” of the use of the economic right, though the Tribunal accepted that it need not be a complete or permanent deprivation in all contexts. It held that:

An expropriation usually amounts to a lasting removal of the ability of an owner to make use of its economic rights although it may be that, in some contexts and circumstances, it would be appropriate to view a deprivation as amounting to an expropriation, even if it were partial or temporary.<sup>627</sup>

543. Similarly, the Tribunal in *Fireman's Fund* held that, “[t]he taking must be a substantially complete deprivation of the economic use and enjoyment of the rights to the property, or of identifiable distinct parts thereof (*i.e.*, it approaches total impairment)”.<sup>628</sup>

544. The Tribunal in *Metalclad* also required a significant degree of deprivation for a finding of expropriation under Article 1110. It held that a measure must have “the effect of depriving the owner, in whole or in significant part, of the use or reasonably-to-be-

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<sup>626</sup> *Waste Management II-Award*, ¶¶ 156-160 (Annex R-300).

<sup>627</sup> *S.D. Myers-First Partial Award*, ¶ 283 (Annex R-267).

<sup>628</sup> *Fireman's Fund – Award*, ¶ 176 (Annex R-188).

expected economic benefit of property even if not necessarily to the obvious benefit of the host State".<sup>629</sup>

545. Most recently, the Tribunal in *Archer Daniels Midland Co. v. Mexico* summarized the test for an expropriation as follows:

... the severity of the economic impact is the decisive criterion in deciding whether an indirect expropriation or a measure tantamount to expropriation has taken place. An expropriation occurs if the interference is substantial and deprives the investor of all or most of the benefits of the investment. There is a broad consensus in academic writings that the intensity and duration of the economic deprivation is the crucial factor in identifying an indirect expropriation or equivalent measure.<sup>630</sup>

546. This view is consistent with arbitral awards on expropriation claims brought pursuant to BITs. For example, in *EnCana*, the Tribunal held that,

[A]lthough the EnCana subsidiaries suffered financially from the denial of VAT and the recovery of VAT refunds wrongly made, they were nonetheless able to continue to function profitably and to engage in the normal range of activities, extracting and exporting oil (the price of which increased during the period under consideration). *There is nothing in the record which suggests that the change in VAT laws or their interpretation brought the companies to a standstill or rendered the value to be derived from their activities so marginal or unprofitable as effectively to deprive them of their character as investments.*<sup>631</sup> (Emphasis added)

<sup>629</sup> *Metalclad – Award* ¶ 103 (Annex R-233). In an application to set aside the Tribunal's decision, the B.C. Supreme Court questioned the breadth of this definition but did not reverse it. ("The Tribunal gave an extremely broad definition of expropriation for the purposes of Article 1110. In addition to the more conventional notion of expropriation involving a taking of property, the Tribunal held that expropriation under the NAFTA includes 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 or reasonably-to-be-expected economic benefit of property. This definition is sufficiently broad to include a legitimate rezoning of property by a municipality or other zoning authority. However, the definition of expropriation is a question of law with which this Court is not entitled to interfere under the *International CAA*"): *Mexico v. Metalclad*, 2001 BCSC 664, 2 May 2001 (B.C. Sup. Ct), ¶ 99 (Annex R-234) (*Metalclad – Set Aside*).

<sup>630</sup> *ADM v. Mexico* (ICSID No. ARB (AF)/04/05) Award (21 November 2007), ¶ 240 (Annex R-146) (*ADM – Award*).

<sup>631</sup> *EnCana Corporation v. Republic of Ecuador* (UNCITRAL) Award (3 February 2006), ¶ 174 (Annex R-183) (*EnCana – Award*).

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547. The *EnCana* holding demonstrates how significant the deprivation must be to establish expropriation. Indeed, the Tribunal there held that despite suffering significant financial effects due to the government VAT measure at issue, the claimant was not so adversely affected as to warrant a finding of expropriation.

548. Similarly, the Tribunal in *CMS Gas Transmission Co.* put it this way: “[t]he essential question is therefore to establish whether the enjoyment of the property has been effectively neutralized”.<sup>632</sup> Again the degree of deprivation is far from trivial. It is not merely interference; rather, it is the effective neutralization of the enjoyment of the property.

549. In *PSEG*, the Tribunal relied on the serious deprivation formula in *Pope & Talbot* to conclude:

The Tribunal has no doubt that indirect expropriation can take many forms. Yet, as the tribunal in *Pope & Talbot* found, there must be some form of deprivation of the investor in control of the investment, the management of day-to-day operations of the company, interfering with the administration, impeding the distribution of dividends, interfering in the appointment of officials and managers, or depriving the company of its property or control in total or in part.<sup>633</sup>

550. The *PSEG* Tribunal's holding is instructive not only because it again demonstrates the very high degree of interference required to amount to expropriation, but also because it reaffirms the importance of considering matters such as control of the investment, management of day-to-day operations, administration, distribution of dividends, and the appointment of officers.

551. Further, a diminution of value or profits, on its own, does not constitute an expropriation. Addressing indirect expropriation, Higgins noted that “[t]he tendency has

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<sup>632</sup> *CMS Gas Transmission Company v. Argentine Republic* (ICSID No. ARB/01/8) Final Award (12 May 2005), ¶ 262 (Annex R-172) (*CMS – Final Award*).

<sup>633</sup> *PSEG Global Inc. and Konya Elektrik Uretim ve Ticaret Limited Sirketi v. Republic of Turkey* (ICSID No. ARB/02/5) Award (17 January 2007), ¶ 278 (Annex R-261) (*PSEG – Award*).

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been, if the essential property rights remain intact, to refuse compensation even if substantial loss can be shown. Diminution of value by itself appears to be insufficient to occasion a duty to compensate”.<sup>634</sup>

552. These principles are consistent with the holding that the NAFTA does not amount to an investor's insurance policy against economic loss of any kind. Indeed, as the Tribunal in *Feldman v. Mexico* concluded:

[T]he Tribunal is aware that not every business problem experienced by a foreign investor is an indirect or creeping expropriation under Article 1110, or a denial of due process or fair and equitable treatment under Article 1110(1)(c). As the *Azinian* tribunal observed, “It is a fact of life everywhere that individuals may be disappointed in their dealings with public authorities... It may be safely assumed that many Mexican parties can be found who had business dealing with governmental entities which were not to their satisfaction...”

[...]

To paraphrase *Azinian*, not all government regulatory activity that makes it difficult or impossible for an investor to carry out a particular business, change in the law or change in the application of existing laws that makes it uneconomical to continue a particular business, is an expropriation under Article 1110. Governments, in their exercise of regulatory power, frequently change their laws and regulations in response to changing economic circumstances or changing political, economic or social considerations. Those changes may well make certain activities less profitable or even uneconomic to continue.<sup>635</sup>

553. Consequently, even if the Claimant here can prove that it suffered a temporary setback due to regulatory measures designed to protect Canadian citizens from hazardous pesticides, it cannot rely on the NAFTA to claim compensation under Article 1110. NAFTA does not provide such blanket guarantees of uninterrupted business success.

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<sup>634</sup> *Higgins*, at 278, 271 (Annex R-204); See also *ADM– Award*, ¶ 248 (Annex R-146).

<sup>635</sup> *Feldman– Award*, ¶ 112 (Annex R-187). See also McLachlan, Campbell, Laurence Short & Matthew Weiniger, *INTERNATIONAL INVESTMENT ARBITRATION: SUBSTANTIVE PRINCIPLES* (Oxford; Oxford University Press, 2007) at 306 (Annex R-230) (*McLachlan, Shore & Weiniger*).

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**(2) The facts alleged do not support a claim of substantial deprivation**

554. In its Memorial the Claimant alleges that the PMRA's "measures clearly interfered with the substantial proportion of the Investor's business in Canada".<sup>636</sup> Of course, an interference is not sufficient to establish expropriation.

555. Instead, Chemtura must prove a taking by Canada that resulted in a substantial deprivation of its enterprise. Throughout its Memorial, the Claimant tries to divide the enterprise into various elements, and repackage them as stand-alone investments to suit its claim on the merits. Canada does not contest that these elements may be relevant to determining the investment's value in a damages analysis; however, they are not "investments" for the purposes of determining whether there has been a "substantial taking," which would meet the definition of expropriation in Article 1110 of NAFTA.

556. If the Claimant was permitted to redefine mere *indicia* of its investment's value as stand-alone investments whenever it suited its purpose, the result would be a moving target that could be reduced to fit the parameters of the substantial deprivation test in all cases. As a result, the question of whether there has been a substantial deprivation would always be answered in the affirmative. In turn, this would render the substantial deprivation analysis meaningless and would contradict the established practice of tribunals determining whether there has been an expropriation. As discussed above, Canada's position is that the Claimant's investment can only be Chemtura Canada.

557. By the Claimant's own evidence, it is clear that lindane product sales represented only a small portion of Chemtura Canada's overall business. Indeed, it is significant that the Claimant's own damages expert, LECG, concluded in its report that, "prior to the [PMRA's] measures [Chemtura]'s lindane products represented a small share of its overall business".<sup>637</sup> The report explains that, "[p]rior to the measures in 1999, lindane based products represented around 6.3 percent of [Chemtura]'s overall Canadian business

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<sup>636</sup> Claimant's Memorial, ¶ 520.

<sup>637</sup> LECG Report, ¶ 57.



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measured by output (pounds) and approximately 17.6 percent measured by net sales”.<sup>638</sup> Indeed, LECG rejected a book value approach to valuation in part because “[Chemtura]’s lindane products represented a small share of its overall business...”.<sup>639</sup>

558. In any event, the VWA was a voluntary agreement which benefitted Chemtura, and was not a taking against its will. Under the VWA, the Claimant was offered not only a phase-out period for lindane use on canola but also had review of its lindane replacement products expedited, and it obtained the first registered alternative product. Chemtura willingly took the benefit of the VWA, which extended the Claimant’s use of lindane on canola for an additional three years.<sup>640</sup> In the absence of the VWA, the U.S. EPA would have closed the U.S. border to lindane-treated canola seeds after the 1998 planting season and there would have been no sales, no transition period, and no special assistance by the PMRA in registering the Claimant’s substitute products.

559. After the Special Review, the PMRA offered the Claimant a phase-out period for lindane use generally but the Claimant refused.

560. Consequently, because the Claimant continued to sell alternative pesticides in Canada after lindane was banned, and because pesticides were only a small part of the Claimant’s business in the first place, the most that it can reasonably claim is that its income with respect to its lindane business was eliminated, not its income with respect to its pesticide business more generally (*i.e.* those remaining and new products other than lindane sold by Chemtura Canada).

561. The de-registration of lindane did not approach the standard of a “substantial deprivation” of the Claimant’s investment. The PMRA’s decision to de-register lindane did not render Chemtura’s investment “useless.” Nor is the Claimant incapable of using,

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<sup>638</sup> *LECG Report*, fn. 27. Note also that the VWA actually came into existence in November 1998, not 1999. The *Navigant Report* notes at ¶ 51 that lindane-based products represented 18.9 percent, 17.6 percent and 9.7 percent of gross sales of Crompton Canada in 1998, 1999 and 2000 respectively.

<sup>639</sup> *LECG Report*, ¶ 57.

<sup>640</sup> Affidavit of John Worgan, ¶ 120.

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enjoying, or disposing of its property in that the Claimant continues to produce and sell pesticides in Canada and to earn considerable profits from its Canadian investments.<sup>641</sup> In short, the evidence here shows that none of the PMRA's actions interfered with the Claimant's ownership of its investment.<sup>642</sup>

562. Chemtura Canada is still owned by the Claimant, which continues to own all of its trade registrations, operate all of its physical plants, and run a profitable enterprise.

563. As in *Pope & Talbot*, the Claimant here has remained in control of its investment throughout the relevant period.<sup>643</sup> There has been no interference with its management or any other action to remove the Claimant from full ownership and control of its investment. In like circumstances, the *Pope & Talbot* Tribunal concluded that:

[w]hile this interference has, according to the Investor, resulted in reduced profits for the Investment, it continues to export substantial quantities of softwood lumber to the U.S. and to earn substantial profits on those sales.

Even accepting (for the purpose of this analysis) the allegations of the Investor concerning diminished profits, the Tribunal concludes that the degree of interference with the Investment's operations due to the Export Control Regime does not rise to an expropriation (creeping or otherwise) within the meaning of Article 1110.<sup>644</sup>

564. The situation here is analogous to that in *Pope & Talbot*. Even if the Claimant's Canadian investment temporarily suffered diminished profits as a result of the de-registration of lindane, the degree of interference with the investment's operations due to the actions of the PMRA "does not rise to an expropriation [...] within the meaning of Article 1110".

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<sup>641</sup> *Navigant Report*, Exhibit NCI-3.

<sup>642</sup> Affidavit of JoAnne Buth, ¶ 70 Ms. Buth explains that "between 1999 and 2001, Canadian canola acreage dropped from 14 to 19 million acres. This decline in canola production was unrelated to the PMRA's enforcement activities. Rather, it was attributable to a combination of a drop in the world market price of canola and to a drought, primarily in Saskatchewan, in 2000 and 2001."

<sup>643</sup> *Pope & Talbot—Interim Award*, ¶ 100 (Annex R-259).

<sup>644</sup> *Pope & Talbot—Interim Award*, ¶ 102 (Annex R-259). See also *ADM—Award*, ¶ 248 (Annex R-146).

**b) The de-registration of lindane was a valid exercise of Canada's police powers**

565. Even if this Tribunal finds that there has been a substantial deprivation of the Claimant's investment, the Claimant's expropriation claim still fails because the de-registration of lindane in early 2002 constitutes a valid exercise of Canada's police powers.<sup>645</sup> The police powers doctrine is a vital component of the international law governing State practice with respect to foreign investment. Indeed, as Aldrich notes, international legal authorities have regularly concluded that "[l]iability does not arise from actions that are non-discriminatory and are within the commonly accepted taxation and police powers of states".<sup>646</sup>

566. The doctrine is consistently said to apply to measures adopted by States to protect public health and the environment. The doctrine's *raison d'être* in that context is straightforward. As Newcombe explains:

*[F]ew international jurists would seriously suggest that if a government, acting in good faith and non-discriminatorily, bans a carcinogenic pesticide, compensation would be due to the affected investor for an expropriation, even where the pesticide company's business is based solely on the manufacture and distribution of the banned pesticide. The general rationale for non-compensation is that property rights have inherent limitations – they are never absolute. Property is a social institution that serves social functions. Property cannot be used in a way that results in serious harms to public order and morals, human, health or the environment. A comparative study of domestic legal systems would surely confirm this as a general principle of law.<sup>647</sup> (our emphasis)*

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<sup>645</sup> It should be recalled that the first withdrawal of lindane (for canola) concerned the 1998 VWA between the Claimant and the CCGA. But it is the second, more general withdrawal of lindane – based on the science of the Special Review – that implicates the police powers doctrine.

<sup>646</sup> Aldrich, George H., *What Constitutes a Compensable Taking of Property? The Decisions of the Iran– United States Claims Tribunal* (1994) 88 AM. J. INT'L L. 585 at 609 (Annex R-147) (Aldrich). See also Newcombe, Andrew, *The Boundaries of Regulatory Expropriation in International Law* (2005) 20:1 ICSID REV. 1 at 22 (Annex R-244) (Newcombe).

<sup>647</sup> Newcombe, at 21 (Annex R-244).

567. The police powers doctrine has a long history. For instance, in 1941, John Herz concluded that:

...even in the era of most radical non-intervention policy there were always certain cases in which state interference with private property was not considered expropriation entailing an obligation to pay compensation but a necessary act to safeguard public welfare: e.g., measures taken for reasons of police, that is, for the protection of public health or security against internal or external danger.

The right of the state to interfere with private property in the exercise of its police power has been recognized by general international law as referring to foreign property also: interference with foreign property in the exercise of police power is not considered expropriation. The state is deemed to be free to take all necessary steps in this respect without incurring any of the obligations which generally accompany ordinary expropriation. Again it is very difficult to draw a sharp line of demarcation between the exercise of the right of eminent domain and that of police power [...] Suffice it to say here that, in spite of difficulties of demarcation, the distinction between measures of police and expropriation for public utility is one of positive international law, recognized by state practice as well as by almost unanimous opinion of theorists.<sup>648</sup>

568. Along the same lines, the 1961 *Harvard Draft* stated the following:

An uncompensated taking of property of an alien or deprivation of the use or enjoyment of property of an alien which results from the execution of the tax laws; from a general change in the value of currency; *from the action of the competent authorities of the State in the maintenance of public order, health, or morality*; or from the valid exercise of belligerent rights; or is otherwise incidental to the normal operation of the laws of the State shall not be considered wrongful, provided: (a) it is not a clear and discriminatory violation of the law of the State concerned; (b) it is not the result of a violation of any provision of Articles 6 to 8 of this Convention [relating to “Denial of Access to a Tribunal or an Administrative Authority” “Denial of a Fair Hearing” and “Adverse Decisions and

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<sup>648</sup> Herz, John, *Expropriation of Foreign Property* (1941) 35:2 AM. J. INT'L. L. 243 at 251-252 (Annex R-203) (*Herz*). Herz's footnote cites the cases of *Parsons* and *Chorzow Factory* and authors Kaeckenbeeck, Foulke, Brierly, Verdross, Lauterpacht, Fachiri, Borchard, and Jessup.

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Judgments”]; (c) it is not an unreasonable departure from the principles of justice recognized by the principal legal systems of the world; and (d) it is not an abuse of the powers specified in this paragraph for the purpose of depriving an alien of his property.<sup>649</sup> (Emphasis added)

569. Similarly, in 1962, Christie wrote that:

[t]he conclusion that a particular interference is an expropriation might also be avoided if the State whose actions are the subject of complaint had a purpose in mind which is recognized in international law as justifying even severe, although by no means complete, restrictions on the use of property. Thus, the operation of a State's tax laws, changes in the value of a State's currency, actions in the interest of the public health and morality, will all serve to justify actions which because of their severity would not otherwise be justifiable; subject to the proviso, of course, that the action in question is not what would be “commonly” called discriminatory either with respect to aliens or with respect to a certain class of persons, among whom are aliens, residing in the State in question.<sup>650</sup>

570. In the same text, Christie concludes that:

[t]he refusal to permit the alienation of real property, or of personal property not easily removable from the State issuing the prohibition, would seem, under some circumstances, to amount to an expropriation for which, accordingly, compensation is payable. *If, however, such prohibition can be justified as being reasonably necessary to the performance by a State of its recognized obligations to protect the public health, safety, morals or welfare, then it would normally seem that there has been no “taking” of property.*

[...]

A State's declaration that a particular interference with an alien's enjoyment of his property is justified by the so-called “police power” does not preclude an international tribunal from making an independent determination of this issue. But, if the reasons given are valid and bear

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<sup>649</sup> See *Harvard Draft* (Annex R-277).

<sup>650</sup> Christie, G.C., *What Constitutes a Taking of Property Under International Law?* (1962) 38 BRIT Y.B. INT'L. L. 307 at 331 (Annex R-169) (*Christie*).

some plausible relationship to the action taken, no attempt may be made to search deeper to see whether the State was activated by some illicit motive.<sup>651</sup>

571. It is therefore an accepted principle of international law that States are not liable to compensate foreign investors for economic losses incurred as a result of measures designed to protect public health and the environment that fall within the police powers of a State.<sup>652</sup> Friedman explains the doctrine this way:

State practice contains numerous examples of the suppression of particular activities which may be carried out ... In the first place, the activity may be regarded as harmful at a given time although it was perfectly legal hitherto and may indeed become so again ... In all these cases where a particular activity was suppressed, with a resulting destruction of important corporeal and incorporeal property rights, no compensation was paid to those suffering damage in consequence of the measures taken.<sup>653</sup>

572. Both old and new case law supports the application of the police power doctrine in an investment law context. Notably, it was applied by joint claims commissions early in the last century. For instance, in 1903, the *Bischoff Case* confirmed that: “Certainly during an epidemic of an infectious disease there can be no liability for the reasonable exercise of police power, even though a mistake is made”.<sup>654</sup> In that case, a carriage belonging to the claimant, wrongly believed to have transported two persons afflicted

<sup>651</sup> *Christie*, at 336-338 (Annex R-169) (our emphasis). See also, *Aldrich* at 609 (Annex R-147): “[I]liability does not arise from actions that are non-discriminatory and are within the commonly accepted taxation and police powers of states. Liability is not affected by the fact that the state has acted for legitimate economic or social reasons and in accordance with its laws.”

<sup>652</sup> See Friedman, S., *EXPROPRIATION IN INTERNATIONAL LAW* (London: Stevens, 1953) at 50-51 (Annex R-193) (*Friedman*). Brownlie, Ian, *PRINCIPLES OF PUBLIC INTERNATIONAL LAW*, 6th ed. (New York: Oxford University Press, 2003) at 512 (“Cases in which expropriation is allowed to be lawful in the absence of compensation are within the narrow concept of public utility prevalent in laissez-faire economic systems, *i.e.* exercise of police power, health measures, and the like.”) (Annex R-162). See also *Newcombe*, at 22 (Annex R-244). *RESTATEMENT (SECOND) OF THE LAW OF FOREIGN RELATIONS* § 197(1) (1965) (“Conduct attributable to a state and causing damage to an alien does not depart from the international standard of justice indicated in s. 165 if it is reasonably necessary for (a) the maintenance of public order, safety, or health,...”) (Annex R-290) (*U.S. – Second Foreign Relations Restatement*).

<sup>653</sup> *Friedman*, at 50-51 (Annex R-193).

<sup>654</sup> *Bischoff Case*, Arbitral Decision (1903), United Nations, 10 R.I.A.A., Vol. X. at 420-1 (Annex R-160) (*Bischoff Case*).

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with smallpox, was taken by the police during an epidemic of smallpox. The police later offered to return the carriage but the claimant refused to accept it without compensation because it had been damaged.<sup>655</sup>

573. The 1925 *Parsons Case* also affirmed this doctrine in the following circumstances:

This is a claim for the value of a stock of liquors destroyed by order of the Provost Marshal General, under the authority of the Military Governor General at Manila, during the Philippine insurrection. We are satisfied that the destruction was a matter of police entirely within the powers of the military government and quite justified by the circumstances.<sup>656</sup>

574. The police powers doctrine has also been applied by the Iran-U.S. Claims Tribunal. In *Sea-Land Services v. The Government of the Islamic Republic of Iran, Ports and Shipping Organization*, the claimant argued that the government interfered with its activities, notably when it restricted the types of cargo that could be unloaded at a port, limiting such to foodstuff and medicine.<sup>657</sup> The Tribunal considered this to be “a reasonable and legitimate measure during a time of civil unrest. There is nothing to suggest that it did not apply equally to other carriers”.<sup>658</sup> In *Emanuel Too v. Greater Modesto Insurance Associates*, the claimant argued that the seizure of its liquor licence by the U.S. Internal Revenue Service to satisfy overdue taxes constituted an expropriation. The Tribunal explained, however, that:

a State is not responsible for loss of property or for other economic disadvantage resulting from bona fide general taxation or any other action that is commonly accepted as within the police power of States, provided it is not discriminatory and is not designed to

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<sup>655</sup> The Tribunal in this case held that some of the damages were recoverable because of the unreasonable length of time involved. See below on the limits of the police power doctrine.

<sup>656</sup> *J. Parsons (Great Britain) v. United States*, Arbitral Decision (30 November 1925) VI., R.I.A.A., at 165-66 (Annex R-254).

<sup>657</sup> *Sea-Land Service, Inc. v. Iran*, Award No. 135-33-1 (22 June 1984), 6 Iran-U.S. C.T.R. 149 at 165 (Annex R-273) (*Sea-Land Award*).

<sup>658</sup> *Sea-Land Award*, at 165 (Annex R-273).

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cause the alien to abandon the property to the state or to sell it at a distress price.<sup>659</sup>

575. More recently, tribunals applying BITs have also confirmed the applicability of the police powers doctrine. For instance, in *Lauder (U.S.) v. Czech Republic*, the Tribunal stated that the “detrimental effect on the economic value of property is not sufficient; Parties to the Treaty are not liable for economic injury that is the consequence of bona fide regulation within the accepted police powers of the State”.<sup>660</sup> The Tribunal in *Saluka v. The Czech Republic* supported the same proposition:

In the opinion of the Tribunal, the principle that a State does not commit an expropriation and is thus not liable to pay compensation to a dispossessed alien investor when it adopts general regulations that are “commonly accepted as within the police power of States” forms part of customary international law today. There is ample case law in support of this proposition. As the tribunal in *Methanex Corp. v. USA* said recently in its final award, “[i]t is a principle of customary international law that, where economic injury results from a *bona fide* regulation within the police powers of a State, compensation is not required”.<sup>661</sup>

576. The police powers doctrine is also clearly relevant in the application of NAFTA Chapter 11. First, the text of the NAFTA itself preserves a State’s sovereign right to protect public health and the environment. The preamble of the NAFTA points to the signatories’ resolve to “PRESERVE their flexibility to safeguard the public welfare; ... STRENGTHEN the development and enforcement of environmental laws and regulations ... [and] UNDERTAKE each of the preceding in a manner consistent with environmental protection and conservation”.<sup>662</sup>

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<sup>659</sup> *Emanuel Too v. Greater Modesto Insurance Associates, et al.*, Award No. 460-880-2 (29 December 1989), 23 Iran–U.S. C.T.R. 378, ¶ 26 (Annex R-182) (*Emanuel Too– Award*).

<sup>660</sup> *Lauder (U.S.) v. Czech Republic* (UNCITRAL) Final Award (3 September 2002), ¶ 198 (Annex R-215).

<sup>661</sup> *Saluka Investments B.V. v. Czech Republic* (UNCITRAL) Partial Award (17 March 2006), ¶ 262 (Annex R-270) (*Saluka – Partial Award*).

<sup>662</sup> NAFTA Article 102.



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577. In a similar vein, Article 1101(4) requires that Chapter 11 be construed so as not “to prevent a Party from providing a service or performing a function such as ... social welfare ... [or] health”.

578. Similarly, Article 1114(1) states that “[n]othing in this Chapter shall be construed to prevent a Party from adopting, maintaining or enforcing any measure otherwise consistent with this Chapter that it considers appropriate to ensure that investment activity in its territory is undertaken in a manner sensitive to environmental concerns”.

579. Article 1114(2) includes the NAFTA signatories’ acknowledgement that:

... it is inappropriate to encourage investment by relaxing domestic health, safety or environmental measures. Accordingly, a Party should not waive or otherwise derogate from, or offer to waive or otherwise derogate from, such measures as an encouragement for the establishment, acquisition, expansion or retention in its territory of an investment of an investor.

580. Taken as a whole, these NAFTA provisions demonstrate that the NAFTA signatories clearly did not intend for non-discriminatory regulatory measures that are designed to protect public health and the environment – such as the PMRA’s decision to de-register lindane – to constitute expropriation.

581. NAFTA tribunals have recognized, implicitly and explicitly, that the police powers doctrine applies to Chapter 11 NAFTA cases. For example, the Tribunal in *Feldman* recognized the police powers principle in all but name when it stated as follows:

The Tribunal notes that the ways in which governmental authorities may force a company out of business, or significantly reduce the economic benefits of its business, are many. [...] At the same time, governments must be free to act in the broader public interest through protection of the environment, new or modified tax regimes, the granting or withdrawal of government subsidies, reductions or increases in tariff levels, imposition of zoning restrictions and the like. Reasonable governmental regulation of this type cannot be achieved if any business that is adversely affected may

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seek compensation, and it is safe to say that customary international law recognizes this.<sup>663</sup>

582. Similarly, in *S.D. Myers*, the Tribunal noted that:

The general body of precedent usually does not treat regulatory action as amounting to expropriation. Regulatory conduct by public authorities is unlikely to be the subject of legitimate complaint under Article 1110 of the NAFTA, although the Tribunal does not rule out that possibility.<sup>664</sup>

583. Even the *Pope & Talbot* Tribunal, which cautioned that “the exercise of police powers must be analyzed with special care”,<sup>665</sup> accepted that the doctrine was valid in the NAFTA context.

584. In *Fireman's Fund v. Mexico*, the Tribunal raised the issue of “whether the measure is within the recognized police power of the host State” as one of the factors that helps a Tribunal to “distinguish between a compensable expropriation and a non-compensable regulation by a host State”.<sup>666</sup>

585. The NAFTA case most directly applicable to the present matter is *Methanex v. United States*.<sup>667</sup> Methanex's claim was summarized by the Tribunal in the following paragraph:

...Methanex claims that a substantial portion of its investments, including its share of the California and wider U.S. oxygenate markets, was taken by a discriminatory measure and handed to the US domestic ethanol industry. It submits that this was “tantamount ... to expropriation” within Article 1110. It also submits that the various exceptions listed in Article 1110 have

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<sup>663</sup> *Feldman– Award*, ¶ 103 (Annex R-187).

<sup>664</sup> *S.D. Myers– First Partial Award*, ¶ 281 (Annex R-267). See also *S.D. Myers v. Canada* (UNCITRAL) Separate concurring opinion (13 November 2000), ¶ 214 (Annex R-267), where, in a separate opinion, Arbitrator Schwartz was more explicit stating that the principle embraced actions done in the “ordinary course of protecting health, safety, the environment, and other public welfare concerns”.

<sup>665</sup> *Pope & Talbot–Interim Award*, ¶ 99 (Annex R-259).

<sup>666</sup> *Fireman's Fund – Award*, ¶ 176(j) (Annex R-188).

<sup>667</sup> *Methanex v. United States*, (UNCITRAL) Fourth Submission of the Government of Canada Pursuant to NAFTA Article 1128 (30 January 2004) (Annex R-236) (*Methanex – Fourth Canadian 1128 Submission*).

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been met, i.e. the US measures were not intended to serve a public purpose, were not in accordance with due process of law and Article 1105, and that no compensation has been paid.<sup>668</sup>

586. The Tribunal entirely rejected Methanex's expropriation claim. It began by making the following pronouncement about a government's power to enact regulations without being subject to expropriation claims:

In the Tribunal's view, Methanex is correct that an intentionally discriminatory regulation against a foreign investor fulfils a key requirement for establishing expropriation. But as a matter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process, and which affects, inter alios, a foreign investor or investment is not deemed expropriatory and compensable unless specific commitments had been given by the regulating government to the then putative foreign investor contemplating investment that the government would refrain from such regulation.<sup>669</sup>

587. The Tribunal then referred to the *Revere Copper & Brass, Inc. v. OPIC*<sup>670</sup> and *Waste Management v. Mexico*<sup>671</sup> decisions where government authorities *had* made representations with respect to the investment that were reasonably relied on by and to the detriment of the investor.

588. However, in two paragraphs that can be applied equally to the Claimant's expropriation claim here, the *Methanex* Tribunal concluded as follows:

No such commitments were given to Methanex. Methanex entered a political economy in which it was widely known, if not notorious, that governmental environmental and health protection institutions at the federal and state level, operating under the vigilant eyes of the media, interested corporations, non-governmental organizations and a politically active electorate, continuously monitored the use and impact of chemical compounds and commonly prohibited or restricted the use of some

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<sup>668</sup> *Methanex– Award*, Part IV, Ch. D, ¶ 1 (Annex R-235).

<sup>669</sup> *Methanex– Award*, Part IV, Ch. D, ¶ 4 (Annex R-235).

<sup>670</sup> *Revere Copper & Brass, Inc. v. Overseas Private Invest. Corp.* (1978) 56 ILR 258 (Annex R-263) (*Revere Copper*).

<sup>671</sup> *Waste Management II– Award*, ¶ 98 (Annex R-300).

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of those compounds for environmental and/or health reasons. Indeed, the very market for MTBE in the United States was the result of precisely this regulatory process. Methanex appreciated that the process of regulation in the United States involved wide participation of industry groups, non-governmental organizations, academics and other individuals, many of these actors deploying lobbyists. Methanex itself deployed lobbyists. Mr. Wright, Methanex's witness, described himself as the government relations officer of the company.

Methanex entered the United States market aware of and actively participating in this process. It did not enter the United States market because of special representations made to it. Hence, this case is not like *Revere*, where specific commitments respecting restraints on certain future regulatory actions were made to induce investors to enter a market and then those commitments were not honoured.<sup>672</sup>

589. The present case is directly analogous. The Claimant began its lindane sales in Canada in the 1970s without any commitment from Canada, either then or any time thereafter, that its regulating body would forebear from regulating the Claimant's conduct. To the contrary, the Claimant was aware from the start i) of the legislative regime governing manufacture and sale of pesticides; ii) that it was entering a highly regulated field; iii) that its products, once registered, would be subject to periodic review; iv) that scientific views on pesticides were subject to change; and v) that ultimately it sold its product in Canada only upon sufferance, so long as the Minister of Health remained convinced that it was safe.<sup>673</sup>

590. No person or company, including the Claimant here, has an unfettered right to produce or sell pesticides in Canada.<sup>674</sup> As the PMRA's Director General of Re-Evaluation, John Worgan, points out in his affidavit, "[f]rom the start of its activity in Canada, Chemtura, as well as other pesticide companies, was subject to an extensive set

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<sup>672</sup> *Methanex–Award*, Part IV, Ch. D, ¶ 5 (Annex R-235).

<sup>673</sup> *Navigant Report*, ¶¶ 78-79 and Exhibit NCI-6.

<sup>674</sup> Affidavit of John Worgan, ¶¶ 9-18.

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of regulatory obligations. Pesticides have always been and continue to be among the most rigorously tested and regulated substances in the world.”<sup>675</sup>

591. Nor can it be said that it would have been reasonable for the Claimant to have expected that there would never be any change in the status of the products under the regulatory scheme governing the sale and use of lindane in Canada. As Mr. Worgan states, under the *PCPA*, the “burden ... remains on the registrant throughout the life of the registration to satisfy the Minister that the product continues to be acceptable for registration”.<sup>676</sup>

592. In this case, there is not even inferential evidence that the PMRA, or any other government entity, “induced” the Claimant to invest by representing that it would be entitled to operate outside of the regulations governing pesticides in Canada or that those regulations would remain unchanged for any length of time, let alone indefinitely. Chemtura Canada and its predecessor company opted to do business in Canada of their own accord and with full knowledge of the prevailing regulatory regime.

593. Regarding the registration of replacement products, the PMRA’s Chief Registrar, Wendy Sexsmith, notes in her affidavit that “I made no specific commitments regarding the timing of the PMRA’s review of new products, and emphasized that the outcome of such reviews could not be guaranteed”.<sup>677</sup> Or, as Dr. Claire Franklin explained in her February 9, 1999 letter to all registrants:

I understand your interest in having alternative products to fill the void that would be created by voluntary removal of lindane from current canola / seed dressing formulation(s). Recognizing the scope of this challenge, the range of clients requesting fast track consideration, and the importance of this issue to canola growers, we are in the process of developing an orderly approach to this

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<sup>675</sup> Affidavit of John Worgan, ¶ 9.

<sup>676</sup> Affidavit of John Worgan, ¶ 14.

<sup>677</sup> Affidavit of Wendy Sexsmith, ¶¶ 44. See also ¶¶ 47, 64.

special needs situation. It will be important to respond to all of these requests in an equitable manner.<sup>678</sup>

**(1) A valid application of the police powers doctrine**

594. Various authors and tribunals have expressed concern that the police powers doctrine operate within certain limits so that it is not abused by governments who might enact police measures as a pretext to an expropriation.<sup>679</sup> Factors considered in this context include whether the measure is arbitrary, discriminatory, excessive, and whether it was adopted in good faith.<sup>680</sup>

595. In the present case, the PMRA's decision to de-register lindane constitutes a valid exercise of Canada's police powers because the decision: i) was not arbitrary; ii) was non-discriminatory; iii) was not excessive; and iv) was made in good faith.

**(a) The de-registration of lindane was not arbitrary**

<sup>678</sup> Letter from Dr. Claire Franklin to registrants, 9 February 1999 (Exhibit WS-25).

<sup>679</sup> Bindschedler, Rudolf L., *La protection de la propriété privée en droit international public* (1956) 90 REC. DES COURS 173 at 213 (Annex R-159) (*Bindschedler*) "Les mesures dites de police ont souvent aussi, dans les Etats de l'Est, été le prétexte à ce qui pratiquement équivalait à une confiscation. (...) L'exercice arbitraire de compétences qui en soi appartiennent à l'Etat, ainsi que l'utilisation d'institutions juridiques dans des buts qui leur sont étrangers ne sont rien d'autre que des *abus de droit*. Or, l'abus de droit n'est pas protégé par le droit international". *Wortley*, at 110 (Annex R-303), states under the 'health and planning legislation' heading that: "A foreigner may not receive any compensation for the indirect loss resulting to him from an act done for the public benefit. But the act must not be done carelessly or abusively, for, as has been shown, the principle of good faith and the doctrine of abuse of rights are becoming of importance in both national and international law". Fouilloux, Gerard, *LA NATIONALISATION ET LE DROIT INTERNATIONAL PUBLIC* (Paris: Librairie générale de droit et de jurisprudence, 1962) 173-174 (Annex R-191) (*Fouilloux*); Laviee, Jean-Pierre, *PROTECTION ET PROMOTION DES INVESTISSEMENTS: ÉTUDE DE DROIT INTERNATIONAL ÉCONOMIQUE* (Paris: Presses universitaires de France, 1985) at 165, 169 (Annex R-217) (*Laviee*); *Emanuel Too – Award* (Annex R-182); *Saluka – Partial Award*, ¶ 258 (Annex R-270).

<sup>680</sup> *Harvard Draft* (Annex R-277); *Wortley*, at 46 (Annex R-303). Where, in a discussion of taxation relevant to police powers, *Wortley* mentions arbitrariness and discrimination as factors. *Christie*, at 331 (Annex R-169). Where discrimination is mentioned, and at 338, where there is a discussion of the validity and plausible relationship of the reasons with the action taken. *Fouilloux*, at 173-174 (Annex R-191); Noting excessiveness and arbitrariness as factors. *See also U.S.– Third Foreign Relations Restatement* (Annex R-289) ("A State is not responsible for loss of property or for other economic disadvantage resulting from *bona fide* general taxation, regulation, forfeiture for crime, or other action of the kind that is commonly accepted as within the police powers of States, if it is not discriminatory, ... and is not designed to cause the alien to abandon the property to the state or sell it at a distress price"), S.712, cmt.g. (p.201); *Newcombe*, at 21-27 (Annex R-244).

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596. The *ELSI* case, decided by the ICJ, is often cited for the proposition that: “[a]rbitrariness 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 juridical propriety”.<sup>681</sup> In the context of police powers, the *Harvard Draft*, cited above, echoes this requirement.<sup>682</sup>

597. Here, the evidence demonstrates that there was nothing arbitrary about the process undertaken by the PMRA during its extensive reviews of lindane. A non-exhaustive list of examples of how the Claimant was afforded due process in this case includes:

- The Claimant was given ample opportunity to provide input during the Special Review during in-person meetings and the regular exchange of correspondence on the substance of the Review;
- The Claimant took full advantage of its invitation to provide submissions to the lindane Board of Review;
- The Claimant initiated various Federal Court proceedings and later abandoned them;
- The PMRA and the Claimant frequently corresponded in creating the draft Re-Evaluation Note on lindane; and
- As evidenced by their letters to and from the PMRA in the summer and fall of 2008, the Claimant continues to take advantage of the opportunity to discuss and debate the PMRA's evaluation of lindane.

598. More particularly, the evidence demonstrates that the PMRA's decision to de-register lindane was not taken arbitrarily but was instead based on valid scientific considerations raised in the Special Review about lindane's unacceptable risks to workers through occupational exposure. The REN expanded on the scope of the PMRA's scientific enquiry by identifying further environmental and carcinogenic concerns

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<sup>681</sup> *Elettronica Sicula S. p. A. (ELSI) (United States v. Italy)* [1989] I.C.J Rep. 15, ¶ 128 (Annex R-181) (*ELSI*).

<sup>682</sup> *Harvard Draft* (Annex R-277).

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regarding lindane. Any one of those issues constituted sufficient grounds for de-registering lindane.

599. In the conclusion of his expert report, Dr. Costa makes three critical points: i) the international concerns about lindane are widely-held and long-standing; ii) the PMRA's Special Review and REN were both based on credible science; and iii) the REN addressed the concerns raised in the Board of Review's report:

Like several other organochlorine insecticides in the past thirty years, lindane has been under scrutiny by national and international regulatory agencies for quite some time, because of concerns for possible adverse human health and environmental/ecological effects.

As part of its process of re-evaluating "older" pesticides, and because of increasing international concerns, in 2001 PMRA conducted a risk assessment of lindane. The conclusions of the Special Review was that occupational exposure to lindane would constitute an unacceptable risk to workers, and, therefore, that all lindane registrations should be revoked. *Though the scientific process that led to such a decision has been criticized, it is my opinion that PMRA's evaluation is within the boundaries of acceptable and credible science.* Though PMRA applied a conservative approach to its evaluation, this can be justified on the basis of its mission and duty, as the pesticide regulatory agency of Canada, to assure full protection of the Canadian people and their environment.

Some deficiencies in the 2001 Special Review, as pointed out by the Board of Review, were addressed in the 2008 Re-evaluation Note, which, upon a revised and more comprehensive risk assessment of lindane, arrived at the same 2001 conclusion that lindane exposure would represent an unacceptable risk. *It is my opinion that this latter assessment, which considered exposure studies not available at the time of the 2001 Special Review, is also in keeping with scientifically credible and acceptable regulatory practices.*<sup>683</sup> (Emphasis added)

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<sup>683</sup> Dr. Costa Report, ¶¶ 157-159.



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600. John Worgan also sets out the scientific basis of the Special Review on lindane in his affidavit where he outlines the toxicological, occupational, carcinogenicity, safety margin evaluation, and other aspects of the PMRA's inquiry.<sup>684</sup>

601. Dr. Costa also took issue with how the Claimant characterized the Board of Review's findings:

It is, however, my opinion that the Board did not find that the PMRA made several unacceptable scientific findings or critical mistakes (cfr. Thompson, 2008; Chemtura 2008a). On the contrary, as said (par. 113), the Board stated that the "risk assessment and conclusions were generally within acceptable scientific parameters" (Board, 2005; par. 115), and that "the risk assessment process ... was adequate ... and consistent with existing regulations as they applied to lindane registrations of the time" (Board, 2005; par. 128).<sup>685</sup>

602. The culmination of the PMRA's post Board of Review response was the comprehensive REN. Regarding that document, Dr. Costa concluded as follows:

The 2008 REN provided a logical follow-up to the 2001 Special Review. The availability of new exposure studies allowed PMRA to carry out new occupational exposure risk assessments. Separate determinations of MOEs were done with regard to dermal and inhalation occupational exposures. Acute and chronic dietary exposure risk assessments, a cancer risk assessment, and an evaluation of environmental / ecological risks were also included. The 2008 REN thus built on the 2001 Special Review, by the filling of all gaps and addressing the issues raised by the Board of Review, and provided an overall comprehensive risk assessment of lindane.

Given the choice of PMRA to maintain a total UF (or MOE) of 1000, a decision which is within an acceptable and credible scientific standard for a national pesticide regulator, the occupational concerns were judged to remain unacceptable. The process that led to the 2008 REN shows, in my opinion, a logical coherence on the part of PMRA, and its responsiveness to the

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<sup>684</sup> Affidavit of John Worgan, ¶¶ 94 – 103; see also Affidavit of Cheryl Chaffey, ¶¶ 6-7, 27.

<sup>685</sup> *Dr. Costa Report*, ¶ 116.

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recommendations of the Board, which ultimately led to a better and more comprehensive risk assessment of lindane.<sup>686</sup>

603. It is significant that the PMRA's decision to de-register lindane has been supported not only by its own subsequent re-assessment of lindane but also by virtually every other national regulatory agency worldwide.<sup>687</sup> As Dr. Costa concludes in his expert report, the PMRA's "decision of revoking lindane's registrations has also been reached by the United States (USEPA, 2006b) and by over fifty other countries. It was also reiterated by the Stockholm Convention on POPs, which in 2007 recommended placing lindane in Annex A, *i.e.* the list of chemicals for which elimination is sought".<sup>688</sup>

604. Or, as John Worgan concludes in his affidavit, "it would be far more accurate to note that as of October 2001, lindane had been the subject of mounting scientific criticism and of progressive national restrictions for 30 years, the target of international conventions for at least 25 years, had been reduced to only a few remaining uses as of the late 1990s..."<sup>689</sup>

605. The threshold for demonstrating the validity of the science underlying the PMRA's decisions should not be so high as to require a Tribunal to second-guess the regulatory science upon which policy decisions are made by the State. Elected governments charge officials with taking decisions based on their judgments of the risks involved, in conformity with the regulatory framework established for that purpose.

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<sup>686</sup> *Dr. Costa Report*, ¶¶ 150-151.

<sup>687</sup> *Dr. Costa Report*, ¶ 45: the "list of international activities [concerning the banning of lindane] brings attention to the fact that lindane has been on the radar screen for quite some time all over the world. Initiatives and actions by individual countries should thus be judged, in my opinion, also at the light of this international background."

<sup>688</sup> *Dr. Costa Report*, ¶ 160. See also the UK and EC decisions referenced in the Affidavit of Dr. Claire Franklin, ¶¶ 20-21.

<sup>689</sup> Affidavit of John Worgan, ¶ 172. Similarly, in her witness statement, Cheryl Chaffey notes that: "In the case of lindane, concerns had been mounting for a long time. Lindane had been registered in various forms in Canada for several decades since 1938. But between the 1970s and the 1990s, the overall scope of this registration had consistently been reduced, on the basis of increasing evidence of negative health and environmental impacts. Canada first started restricting lindane use as early as the 1970s." Affidavit of Cheryl Chaffey, ¶ 34 and at ¶¶ 27-32.

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606. The award in *Methanex* affirms that a Tribunal should concern itself primarily with an evaluation of the scientific method, rather than with evaluating *de novo* the scientific conclusions reached by government bodies or agents. As noted by the Tribunal, often there will be disagreements founded on valid scientific grounds. However, if the science relied on by the State has been validated *inter alia* by a process of hearings and peer-reviews, a Tribunal under NAFTA Chapter 11 should be satisfied that the decision was not arbitrary.

607. The Tribunal in *Methanex* concluded as follows:

Having considered all the expert evidence adduced in these proceedings by both Disputing parties, the Tribunal accepts the UC [University of California] Report as reflecting a serious, objective and scientific approach to a complex problem in California. Whilst it is possible for other scientists and researchers to disagree in good faith with certain of its methodologies, analyses and conclusions, the fact of such disagreement, even if correct, does not warrant this Tribunal in treating the UC Report as part of a political sham by California [as alleged by Methanex]. In particular, the UC Report was subjected at the time to public hearings, testimony and peer-review; and its emergence as a serious scientific work from such an open and informed debate is the best evidence that it was not the product of a political sham engineered by California, leading subsequently to the two measures impugned by Methanex in these arbitration proceedings. Moreover, in all material respects, the Tribunal is not persuaded that the UC Report was scientifically incorrect: the Tribunal was much impressed by the scientific expert witnesses presented by the

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USA and tested under cross-examination by Methanex; and the Tribunal accepts without reservation these experts' conclusions.<sup>690</sup>

608. The same thing can be said about the scientific basis upon which the PMRA decided to de-register lindane: from the Special Review, through the Board of Review, to the ongoing Re-Evaluation Note, the science on which the PMRA based its conclusions has been subject repeatedly to public hearings, peer-reviews, and rigorous cross examination. Throughout it all, the soundness of the science behind both the PMRA's original (2001) and its ultimate (2008) decisions regarding lindane has not been credibly impugned.

609. Indeed, Canada has demonstrated through the evidence provided by the PMRA and independent expert Dr. Costa that the Special Review was conducted in a thoroughly scientific manner. And although the Board of Review would have been less conservative in the application of some risk factors, it never suggested that the PMRA's process was a "sham".

610. The Claimant's attempt to impugn the PMRA's scientific conclusions based on the EPA's results is also without merit. In fact, by 2006, the EPA had reached the same conclusion reached by the PMRA in its Special Review – lindane was unsafe for further registration.<sup>691</sup>

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<sup>690</sup> *Methanex– Award*, Part III, Ch. A, ¶ 51, (Annex R-235). See also Gantz, D., *Potential Conflicts Between Investor Rights and Environmental Regulation under NAFTA's Chapter 11* (2001) 33 GEO. WASH. INT'L L. REV. 651 at 656-657 (Annex R-197), where he observes: "Given that the potential danger of a substance to humans can seldom be established with absolute certainty, questions necessarily remain as to the level of scientific "proof" that should be required before government action is taken, the extent of the risk assessment that may be required, and, indeed, the level of protection against perceived risks to humans that is necessary. Using the popular terminology, when does the "precautionary principle" justify regulatory action because waiting to act until there is clear scientific proof of danger may pose unacceptable risks for the public?" See also Hunter, David, James Salzman & Durwood Zaelke INTERNATIONAL ENVIRONMENTAL LAW AND POLICY (New York: Foundation Press, 1998) at 360 (Annex R-205), where the authors explain that the precautionary principle "evolved from the recognition that scientific certainty often comes too late to design effective legal and policy responses for preventing potential environmental threats. Most environmental issues involve complex analyses of scientific, technical and economic factors. We rarely have anything approximating perfect knowledge when law-makers are asked to make decisions whether to respond to a specific threat."

<sup>691</sup> Affidavit of John Worgan, ¶ 144; *Dr. Goldman Report*, ¶¶ 55, 57.

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611. The PMRA's application of its re-evaluation policies was similarly not done in an arbitrary fashion. As Mr. Worgan explains in his affidavit, though the PMRA's i) reliance on existing reviews of other national regulators, ii) use of existing data sets, and iii) pursuit of reviews only until an "unacceptable" finding was made, have all been criticized by the Claimant, "I can confirm that these were not applied on an arbitrary basis in the re-evaluation of lindane, but reflected systemic PMRA re-evaluation procedure, founded on sound public policy considerations".<sup>692</sup>

612. Moreover, the PMRA's decision was vindicated by similar decisions from equivalent regulators throughout the world.<sup>693</sup> The Claimant's insistence that lindane should not be banned in Canada completely ignores the knowledge accumulated internationally about the product and the actions of national governments and international bodies to protect citizens from its hazardous effects.

**(b) The de-registration of lindane was not discriminatory**

613. The police powers doctrine cannot be relied on if the State discriminates against an alien on the basis of nationality. Wortley expresses this principle of nationality-based discrimination in the following way:

Even genuine health and planning legislation (...) may be abusively operated, for example, if health or quarantine regulations are imposed not bona fide to protect public health, but with the real, though unfavoured, purpose of ruining a foreign trader. When the evidence of such indirect motive is clear, the foreign State concerned may properly protest on the ground that the trader is being unjustifiably deprived of his rights<sup>694</sup>

614. The *Emanuel Too* case, cited above, questioned whether the measure at issue was discriminatory and concluded that: "The IRS's action was a result of the Claimant's failure to pay taxes withheld by him on his employees' salaries. Nowhere does the

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<sup>692</sup> Affidavit of John Worgan, ¶ 42.

<sup>693</sup> Affidavit of John Worgan, ¶ 25.

<sup>694</sup> *Wortley*, at 110 (Annex R-303).

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Claimant suggest that this tax levy was imposed against him because he was an Iranian national”.<sup>695</sup>

615. In the present case, it is telling that the Claimant has failed to pursue the Article 1102 argument pleaded in its Notices of Intent and Arbitration. Clearly, it could not make out a case of discriminatory treatment on the basis of nationality here because there was no discrimination.

616. In fact, the evidence shows that all the lindane registrants in Canada were treated equally, and that the Claimant was not singled out for discriminatory treatment by the PMRA during the time leading to and including the de-registration of lindane.

617. The PMRA also demonstrated equality of treatment with respect to the VWA and its implementation. As Wendy Sexsmith notes in her affidavit, “recognizing that only a universally accepted plan would lead to a solution, the PMRA emphasized that it would facilitate the voluntary withdrawal only if all four lindane registrants participated in the plan, and were treated on an equal basis”.<sup>696</sup>

618. The PMRA's equality of treatment approach was challenged on more than one occasion by the Claimant's demands for preferential treatment and concessions from the PMRA with respect to the phase out of its lindane products for use on canola and the registration of new replacement products.<sup>697</sup> The PMRA, however, did not waiver in its commitment to fairness.<sup>698</sup> As Wendy Sexsmith notes in her affidavit, “[a]lthough the PMRA wanted to do what it could within its regulatory framework to help stave off the crisis Chemtura had created, it could not guarantee registrations of alternative products

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<sup>695</sup> *Emanuel Too – Award*, ¶ 27 (Annex R-182).

<sup>696</sup> Affidavit of Wendy Sexsmith, ¶ 28.

<sup>697</sup> Affidavit of Wendy Sexsmith, ¶¶ 75-96.

<sup>698</sup> Affidavit of Wendy Sexsmith, ¶¶ 97 – 100.

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without adequate review, and in disregard of all other competing demands on PMRA resources”<sup>699</sup>.

619. With respect to the Claimant’s allegation of preferential treatment given to Syngenta in its Helix registration application, again the evidence shows that, to the contrary, Helix was the subject of vigorous review and Helix and Gaucho applications received equal treatment.<sup>700</sup>

620. As for the suspension of the Claimant’s remaining lindane-based product registrations based on the Special Review, that too was carried out without favouritism. Indeed, the Claimant was offered the same phase-out conditions as the other remaining registrants. The evidence shows that the option of voluntary withdrawal, of which it bitterly complains, was put in place to allow registrants a chance to bow out gracefully when an active had been deemed unsafe. The Claimant, however, refused this option. The PMRA was left with no option under its governing legislation but to suspend the Claimant’s registrations immediately. Had the Claimant instead agreed to abide by the terms of the proffered voluntary withdrawal, it would have been granted the same phase-out period enjoyed by the other registrants. As Wendy Sexsmith explains in her affidavit:

That is what occurred with the other remaining lindane registrants, who voluntarily withdrew in light of the PMRA’s Special Review findings. Chemtura was advised that it could have had the advantage of this phase-out regime, but instead it chose to opt out, with the consequences that followed.<sup>701</sup>

621. The Claimant now urges this Tribunal to reward it for its own reckless behaviour. Canada submits that its claims are meritless and should be rejected.

**(c) The de-registration of lindane was not excessive**

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<sup>699</sup> Affidavit of Wendy Sexsmith, ¶ 82.

<sup>700</sup> See generally Affidavit of Suzanne Chalifour.

<sup>701</sup> Affidavit of Wendy Sexsmith, ¶ 158.

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622. The definition of “excessive” is highly fact-dependent. In the *Bischoff Case*, for example, the State was “liable for damages for the detention of the property for an unreasonable length of time and injuries to the same during that period”.<sup>702</sup>

623. The *Loewen* case is instructive because the Tribunal found that the “Claimants had a very strong case for arguing that the damages awarded, both compensatory and punitive, were excessive, and that the amounts were so inflated as to invite the inference that the jury was swayed by prejudice, passion or sympathy”.<sup>703</sup> Even though that comment was made in the context of a denial of justice claim under Article 1105, the same point applies in the police powers context. Indeed, a Tribunal in a police powers context should seek to identify indicia that the impugned measure or process were so out of bounds as to compel the inference that an expropriation had occurred.

624. The Claimant here alleges that i) the uncertainty or safety factors used during the Special Review and REN were excessively conservative, and that ii) the suggested mitigation measures were not adequately addressed.<sup>704</sup>

625. In her affidavit, Cheryl Chaffey, one of the lead scientists involved in the Special Review of lindane, responds to both allegations. First, regarding the uncertainty factor chosen by the PMRA, Ms. Chaffey notes the following:

The PMRA’s uncertainty/safety factor was considered conservative by the Board of Review, but I note that this was only a matter of degree. While the PMRA applied an overall factor 1000 reflecting an additional factor of 10, the Board of Review recommended “an adjustment factor other than the additional 10x maximum default”. In other words, the Board concluded that an additional factor of some magnitude was warranted above the basic standard of 100. I would add that the PMRA’s approach to risk assessment, while consistent with internationally recognized practices, represents a precautionary approach that reflects the

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<sup>702</sup> *Bischoff Case*, at 420 (Annex R-160).

<sup>703</sup> *Loewen Group, Inc. and Raymond L. Loewen v. United States* (ICSID No. ARB/98/3) Award on Merits (25 June 2003) (Annex R-221) (*Loewen – Award on Merits*).

<sup>704</sup> Claimant’s Memorial, ¶ 194.



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health-protective mandate of the PMRA. By contrast, the Claimant's hired panel of experts suggested (quite improperly in my view) that an overall factor of merely 32 was sufficient. In my many years in pesticide regulation, I had not encountered the application of such a low factor for a pesticide where the health assessment was based on animal data. The Board made it clear that the Claimant's data were inadequate to support a reduction of the basic standard of 100.<sup>705</sup>

626. On the issue of the PMRA's rejection of mitigation measures regarding lindane, Ms. Chaffey explains why the Claimant's complaints are unfounded:

There were suggestions that exposure could be mitigated by increased personal protective equipment (PPE), but as I have explained, it was clear that these measures would not come close to reducing actual exposure enough to exceed the target MOE of 1000. Neither the Claimant nor any other registrant suggested generating new exposure data, restricting lindane use to highly engineered closed treatment systems, or abandoning dust formulations, such as "powder" or dust for formulations, which gave rise to particular exposure concerns.

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Even if PMRA had applied a lower overall factor to yield a target MOE such as 300, the calculated margins of exposure (MOE) were so far below this that it was obvious the application of additional personal protective equipment would not adequately mitigate the risks. It is possible that the inhalation exposure estimates could have been reduced by mandating the use of respiratory protective equipment, but exposure to the pesticide through skin contact (*i.e.*, dermal exposure) would still have been of concern.<sup>706</sup>

627. Ms. Chaffey's positions above are supported by Dr. Costa who, in his expert report, concludes that "on the basis of current available information and regulatory practices in 2001, PMRA's choice of default 100X UF was scientifically justified and in line with the PMRA's internal policies, and the policies of other international regulatory agencies".<sup>707</sup> Dr. Costa concludes that "[i]t is my opinion that the 2008 REN provided a

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<sup>705</sup> Affidavit of Cheryl Chaffey, ¶ 115.

<sup>706</sup> Affidavit of Cheryl Chaffey, ¶¶ 100, 116.

<sup>707</sup> *Dr. Costa Report*, ¶ 70.

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logical follow-up to the 2001 document, and that its assessment of lindane is within an acceptable and credible scientific standard for a national pesticide regulator".<sup>708</sup>

628. It is undeniable that the PMRA's Special Review had a very sound and defensible basis. The differences in optimal risk factors suggested by the PMRA (and Dr. Costa), as compared to those suggested by the Board of Review, are relatively small differences of degree based on complex science and expert assessment. More importantly, the existence of such a difference in views between scientists does not approach the threshold of excessiveness.

629. Finally, the Tribunal should not be expected to rule on the "correct" risk factor. The PMRA is charged by its constituent legislation to make such decisions and has the expertise to do so. In this case, the PMRA applied the risk factors it considered most appropriate, reconsidered its view in light of the Board of Review and Chemtura's submissions, and maintains its view. A NAFTA Tribunal is neither equipped nor mandated to arbitrate that kind of debate.

**(d) The decision to de-register lindane was made in good faith**

630. Finally, to fit within the police powers exception, a governmental measure must be enacted in good faith. As the Tribunal in *Methanex* concluded, the California ban did not constitute a Chapter 11 expropriation in part because the Tribunal found, in regard to the scientific issues related to MTBE, that "this policy was motivated by the *honest belief, held in good faith* and on reasonable scientific grounds, that MTBE contaminated groundwater and was difficult and expensive to clean up".<sup>709</sup> (our emphasis)

631. Bin Cheng similarly explains that "the public welfare of the community is considered by international law to be of such overriding importance that it is allowed to

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<sup>708</sup> *Dr. Costa Report*, ¶ 4.

<sup>709</sup> *Methanex– Award*, Part III, Chapter A, ¶ 102 (Annex R-235) (our emphasis). See also Paulsson, Jan, *Indirect Expropriation: is the right to regulate at risk?*, Paper presented at OECD, ICSID & UNCTAD Symposium *Making the most of International Investment Agreements: A Common Agenda*, Paris (12 December 2005) at 5 (Annex R-256).

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derogate from the principle of respect of private rights. Such derogation is, however, conditional upon the presence of a genuine public need, and is *governed by the principle of good faith.*<sup>710</sup> (our emphasis)

632. There is no evidence indicating that the PMRA's Special Review or REN were anything other than good faith attempts to re-evaluate the safety of lindane-based on a broad spectrum of scientific issues (including occupational exposure, environmental effects, carcinogenicity, and endocrine disruption) grounded in valid scientific methods and sound policy.

633. As Cheryl Chaffey notes in her affidavit, the Claimant's charges of bad faith on the part of the PMRA are groundless since the "Special Review followed the PMRA's standard pattern of pesticide review" where parallel studies were conducted in a manner consistent with the then current statement of PMRA practices and "[w]e spent 108 person-days (or approximately 5 working months) on the toxicology review alone".<sup>711</sup>

634. Specifically with respect to the Special Review, the Claimant alleges that the PMRA i) failed to bring to its attention that occupational health was an issue and ii) failed to request in a timely manner the relevant data concerning the same.<sup>712</sup> The evidence, however, demonstrates that neither allegation is true.

635. First, regarding the Claimant's allegation that the PMRA switched the focus of the Special Review occupational concerns in the middle of the review to without advising the registrants, again the documentary and affidavit evidence shows this to be false. From the initial announcement of the Special Review, the PMRA signalled that "the scope of this review may change".<sup>713</sup>

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<sup>710</sup> Cheng, Bin, GENERAL PRINCIPLES OF LAW AS APPLIED BY INTERNATIONAL COURTS AND TRIBUNALS (Cambridge: Grotius Publications, 1987) at 39-40 (Annex R-167) (*Cheng*).

<sup>711</sup> Affidavit of Cheryl Chaffey, ¶ 72.

<sup>712</sup> Claimant's Memorial ¶¶ 187, 188, 178.

<sup>713</sup> Affidavit of John Worgan, ¶ 126.

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636. As early as its May 10 – 11, 1999 meeting with the registrants, the PMRA indicated that it would be considering occupational health concerns, citing the recent occupational concerns raised by the U.K. Pesticides. The Claimant's Mr. Ingulli was present at a meeting with the PMRA on October 4, 2000 where the PMRA's occupational concerns were specifically raised by the PMRA's Executive Director.<sup>714</sup>

637. More generally, as John Worgan explains in his affidavit:

In a typical review, the PMRA will set out to consider a product's potential threat to health and to the environment. Any one of these factors can lead to a finding that a product is unsafe for continued registration... Each of these findings, on its own, would justify cancellation.

According to standard PMRA re-evaluation practice, each type of scientific review typically proceeds in parallel with the others. But these different studies do not necessarily proceed at the same speed or achieve results at the same time. It is in fact typical in an evaluation for one the PMRA scientific group to reach its conclusions under one area, before studies under other areas have been concluded.

Prompted by the efficiency and resource considerations ... the PMRA may pursue all reviews during a re-evaluation only to the point where a "negative" result had been reached on any one area showed significant concerns that justified deregistration. At this point, investigation of the other potential grounds would be halted, and other evaluation resources re-allocated to other actives.

Given the resource constraints under which the PMRA was operating and the enormous re-evaluation task at hand, this policy decision made a lot of sense...

This is exactly what occurred in the case of lindane. In the Special Review, PMRA considered the safety of lindane from multiple points of view (including environmental persistence and compartment, dietary risk, occupational risk, etc.). However, PMRA scientists considering the occupational health risks reached a negative answer first. Having discovered a sufficient reason to withdraw the chemical, all other aspects of the investigation were

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<sup>714</sup> Affidavit of Claire Franklin, ¶¶ 22-29.

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suspended, so that human resources could be reallocated to other re-evaluations.<sup>715</sup>

638. Second, regarding the timeliness of the call-in for data, the Special Review was conducted in the context of a general policy re-evaluation that guided the PMRA's approach to data collection and was familiar to the Claimant. For instance, rather than requiring the industry to provide new data, the PMRA made efforts to use the EPA's re-evaluation data base that had been generated as of the year prior to the start of the Special Review (1998) and was then up to date. As John Worgan explains in his affidavit,

“[b]y relying on available EPA's work, the PMRA could avoid going through an extensive data call-in, while leaving the PMRA free to consider new studies not already included in existing reviews in their re-evaluation assessments. It would have been wasteful and unnecessarily time-consuming for the PMRA to effectively “re-invent the wheel” in these circumstances.<sup>716</sup>

639. The policy decision to rely on foreign reviews was supported by i) the PMRA's governing legislation, ii) the practice of other national regulators<sup>717</sup>, and iii) practical constraints in the context of a full-scale review of over 400 old actives, of which lindane was only one.<sup>718</sup> The PMRA's approach – which applied across the board and not merely to lindane – permitted the PMRA to arrive at decisions on the health risks of pesticides in a more efficient and timely manner, though not in the absence of evidence as alleged by the Claimant.<sup>719</sup> Indeed, reliance on recent reviews of equivalent regulators and existing data call-ins was efficient, but it did not prevent the PMRA from questioning and

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<sup>715</sup> Affidavit of John Worgan, ¶¶ 60 – 64.

<sup>716</sup> Affidavit of John Worgan, ¶¶ 46 – 47. See also 67 – 71.

<sup>717</sup> Affidavit of John Worgan, ¶ 47.

<sup>718</sup> Affidavit of Dr. Claire Franklin, ¶ 14; Affidavit of John Worgan ¶¶ 43 – 50; Affidavit of Cheryl Chaffey, ¶ 61.

<sup>719</sup> See Affidavit of Cheryl Chaffey, ¶ 63 where she notes that the EPA had a 10 year head start on pesticide studies and that its relative size to the PMRA made it a valuable data resource.

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supplementing the existing record each time it deemed it to be necessary in the exercise of sound regulatory science and policy.<sup>720</sup>

640. Third, contrary to what the Claimant alleges in its Memorial, the PMRA also expedited the registration of the Claimant's replacement products, in this way mitigating the effect that a ban on lindane should have on its operations.<sup>721</sup> The PMRA had reviewed and approved the submitted formulations of the Claimant's replacement Gaucho product by the summer of 1999, a full 18 months before any other companies' products gained approval. It was not the PMRA's fault that the Claimant waited until the autumn of 2000 to submit data sets for its all-in-one product. Any delays were thus due either to the complexity of the applications or to the Claimant's own dilatoriness.<sup>722</sup>

641. By facilitating the VWA and fast-tracking the registration of replacement pesticides, the PMRA provided a "soft landing" for the industry as it moved away from lindane use.<sup>723</sup> The PMRA, in other words, did its very best to ensure that the de-registration of lindane would not have a sudden adverse impact on the industry. Indeed, if the PMRA had not facilitated the VWA, a "crash landing" would have occurred as a result of the immediate closure of the border to canola.

642. Fourth, the evidence regarding compliance with its labelling and usage decisions also shows that the PMRA made efforts to inform the lindane industry of its compliance framework and that it did not threaten in advance to take compliance action, including issuing fines, for contraventions of the *PCPA*.<sup>724</sup> The Claimant's allegation that the PMRA somehow "invented" the July 1, 2001 deadline is demonstrably false – the PMRA

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<sup>720</sup> Unlike the EPA, the PMRA could not use data sets provided by other companies concerning products other than the one currently being reviewed, a fact of which the Claimant was aware as early as the May 10-11, 1999 meeting between the PMRA and registrants. Moreover, the difference between the data relied on by the EPA, as opposed to that relied on by the PMRA, was that the two agencies laboured under different statutory regimes.

<sup>721</sup> Affidavit of Suzanne Chalifour, ¶ 24.

<sup>722</sup> Affidavit of Suzanne Chalifour, ¶ 58.

<sup>723</sup> Affidavit of Wendy Sexsmith, ¶¶ 24-25.

<sup>724</sup> Affidavit of Jim Reid, ¶¶ 42-43.

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was simply abiding by the terms that were agreed to by the Claimant itself with its customers in 1998.

643. The Claimant suggests that the Special Review was pursued in bad faith to avoid a “trade irritant” with the United States. However, as Wendy Sexsmith notes in her affidavit, the Claimant’s argument is entirely false, and is based on another false premise. By the time the Special Review was launched, on March 15, 1999, Canadian canola growers had already expressed their desire to transition away from lindane use, through the Voluntary Withdrawal Agreement.<sup>725</sup> Moreover, Sexsmith continues:

[w]hile the Claimant suggests that the Special Review of lindane was somehow launched in order to give a veneer of science to the withdrawal of lindane on pure “trade” grounds, the situation was in fact entirely the opposite: by the time the U.S. border issue arose, lindane was already well in the PMRA’s sights. Indeed, according to the PMRA’s regulatory framework, a Special Review can only be conducted where the PMRA has reason to believe that a registered active may pose a threat to the environment and / or to human health. That is exactly the situation we were in, by the late 1990s.<sup>726</sup>

644. In her affidavit, Cheryl Chaffey corroborates the good faith-basis of the Special Review:

[h]aving been directly involved in the PMRA’s scientific review of lindane under the Special Review between 1999 and 2001, I can confirm we undertook a full good-faith scientific effort to study the merits of continued use of lindane, and were confident of our conclusion that it posed an unacceptable risk for continued use for seed treatment.<sup>727</sup>

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<sup>725</sup> Affidavit of Wendy Sexsmith, ¶ 24.

<sup>726</sup> Affidavit of Wendy Sexsmith, ¶ 148. *See also Dr. Costa Report*, ¶¶ 41-45, where Dr. Costa outlines the various international conventions and protocols where lindane is either banned or listed as a chemical of concern.

<sup>727</sup> Affidavit of Cheryl Chaffey, ¶ 58.

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645. As Canada has demonstrated, the PMRA was already re-assessing its lindane database and considering a Special Review as early as 1998 and had preliminary plans in place in July 1998, several months before the VWA commenced.<sup>728</sup>

646. Finally, as to the Claimant's allegation that it was denied an opportunity to participate in the PMRA's regulatory process, the evidentiary record shows otherwise.<sup>729</sup>

647. Indeed, even if this Tribunal were to find that the PMRA did not offer enough opportunity for the registrants to participate in the Special Review or to comment on its results – which Canada denies – there is no denying the good faith of Canada's effort to address the Claimant's concerns through a full-scale review process by way of the Board of Review. Moreover, the Claimant's allegation that the PMRA was somehow forced to convene the Board of Review is demonstrably false. To the contrary, the Claimant's ultimately abandoned Federal Court proceedings that held up matters for more than a year.<sup>730</sup>

648. The PMRA's good faith was further demonstrated when it launched a review *de novo* of lindane that took into account the Board of Review's recommendations. And then the results of the REN ended up vindicating the results of the Special Review.

649. In short, there is ample evidence of good faith on the PMRA's part with respect to the de-registration of lindane, and absolutely no evidence of bad faith.

650. In conclusion, Canada has provided substantial authority for the application of the police power doctrine under NAFTA Chapter 11. It has also demonstrated that Canada's measures were well within the limits of that doctrine.

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<sup>728</sup> Affidavit of Cheryl Chaffey, ¶¶ 55-57.

<sup>729</sup> Affidavit of John Worgan, ¶¶ 213, 250 and 251, *see generally*; Affidavit of Claire Franklin.

<sup>730</sup> Affidavit of Wendy Sexsmith, ¶ 168.



**c) Chemtura consented to the VWA and therefore cannot now claim expropriation**

651. Finally, a finding of expropriation cannot be made when the conduct complained of was consented to by the party alleging the expropriation. This principle is squarely at issue with respect to the Claimant's allegations surrounding the VWA.

652. In *International Investment Arbitration*, McLachlan, Shore and Weiniger make the following important point about consent in the context of an expropriation claim:

Whether a State has by actions or inactions committed what might be considered an expropriatory measure, *if the investor has effectively consented to such actions or inactions, a finding of indirect expropriation will generally not be made.* That is, the investor must be the subject of a compulsory measure. The *Tradex* Tribunal held "As expropriation by definition is a compulsory transfer of property rights..., an agreement reached in consent with the foreign investor and signed by it as in the Dissolution Agreement dated 21 April 1992 can hardly be seen as an act of expropriation in itself".<sup>731</sup> [our emphasis]

653. In *Tradex*, a Greek company, Tradex, entered into a joint venture with a state-owned Albanian company for the commercial and agricultural use of 1170 hectares of Albanian farmland. Tradex alleged that its investment had been expropriated by the Albanian government because: i) some of the subject land was transferred to local villagers; ii) other land was occupied by either local villagers and / or their livestock; and iii) various Tradex crop supplies and cattle were stolen by the villagers.

654. A year later, and in view of those circumstances, Tradex and the Albanian corporation entered into an agreement to dissolve the joint venture. Tradex nevertheless later claimed that "the dissolution of the Joint Venture, though effected by consent between Tradex and its partner in the Joint Venture, was forced upon Tradex and constitutes an expropriation".<sup>732</sup>

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<sup>731</sup> *McLachlan Shore & Weiniger*, at 292 (Annex R-230).

<sup>732</sup> *Tradex Hellas S.A. v. Republic of Albania* (ICSID No. ARB/94/2) Award (29 April 1999), ¶ 177 (Annex R-288) (*Tradex– Award*).

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655. The *Tradex* Tribunal, however, did not accept Tradex's coercion argument. Instead, as noted above, the Tribunal concluded that, "[a]s expropriation by definition is a compulsory transfer of property rights..., an agreement reached in consent with the foreign investor and signed by it as in the Dissolution Agreement dated 21 April 1992 can hardly be seen as an act of expropriation in itself."<sup>733</sup>

656. The fundamental proposition that an expropriation requires a compulsory transfer is also found in the *Amoco* case where the Tribunal stated: "Expropriation, which can be defined as a *compulsory transfer* of property rights, may extend to any right which can be the object of a commercial transaction, *i.e.*, freely sold and bought, and thus has a monetary value"<sup>734</sup> (our emphasis)

657. A situation analogous to *Tradex* arose in this case where the Claimant alleges that it was coerced into entering the VWA with the CCC & CCGA. The evidence, however, clearly points to the contrary. Indeed, it was the CCC & CCGC – with the agreement of the four lindane registrants operating in Canada (including the Claimant) – who asked the PMRA to facilitate the 1998 VWA between the CCGA and the registrants that gradually eliminated the use of lindane on canola in Canada. The initiative was taken to avoid immediate retaliatory action from the US EPA. As Chemtura acknowledged in its October 28, 1998 letter to the PMRA, "[a]s a response to this threat [closure of the U.S. border to lindane treated seeds], both the CCC and CCGC have requested that all registrants of canola seed protectants participate in a plan to voluntarily remove lindane as an insecticide for control of flea beetle in canola"<sup>735</sup>.

658. The evidence demonstrates that the VWA represented a solution that was sensible, even self-interested, from the registrants and canola growers' perspectives. The

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<sup>733</sup> *Tradex– Award*, ¶ 177 (Annex R-288).

<sup>734</sup> *Amoco International Finance Corporation v. Iran*, Partial Award No. 310-56-3 (14 July 1987), 15 Iran– U.S. C.T.R. 189, ¶ 108 (*Amoco – Partial Award*) (Annex R-150) (emphasis added). *See also* Foighel, Isi, NATIONALIZATION: A STUDY IN THE PROTECTION OF ALIEN PROPERTY IN INTERNATIONAL LAW (London: Stevens, 1957) at 15 (Annex R-190); *See, White*, at 43 (Annex R-301).

<sup>735</sup> Affidavit of Wendy Sexsmith, ¶ 36; *see also*, Affidavit of JoAnne Buth, ¶¶ 36-37.

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alternative would have been the immediate closure of the U.S. border and the elimination of the \$600 million canola export market which would have had devastating consequences for Canadian canola farmers and their related industries (such as pesticide producers).<sup>736</sup> The evidence also shows that, as a direct result of the VWA, lindane registrants were legally able to sell their pesticides in Canada for an additional three years.

659. In short, it made good economic sense for the Claimant to enter the VWA willingly. Most importantly, the evidence shows that, though it bickered about some of the Agreement's terms, the Claimant did indeed enter the VWA willingly and without any coercion by Canada.<sup>737</sup> Chemtura clearly had the capacity to say "no" to the VWA. It did not. Instead, it took the benefit of the VWA. Having done so, the Claimant cannot now allege expropriation and its Article 1110 claim should be dismissed.

**3. There is no expropriation and hence no basis to consider Article 1110(a) to (d)**

660. The third step in a NAFTA expropriation analysis – considering whether the alleged expropriation was a lawful one consistent with the conditions found in Articles 1110(1)(a) to (d) – is reached only if an expropriation has been found. As such, the conditions laid out in Article 1110 are not relevant to a finding of whether the investment was in fact expropriated. In particular, no obligation to compensate exists *unless and until* there has been a finding that the investment has been expropriated by the government measure at issue.

661. The Tribunal in *Fireman's Fund* affirmed that it is incorrect to begin an expropriation analysis by turning to the four conditions of paragraphs (a) to (d) of Article 1110. It sensibly stated that:

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<sup>736</sup> Affidavit of Tony Zatylny, ¶¶ 26-28.

<sup>737</sup> The Voluntary Withdrawal Agreement – concerned as it was with lindane use on canola – presented only the first part of the withdrawal of lindane from the Canadian market. The second, wider de-registration was instituted by the PMRA as a result of its Special Review in 2001.

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That would indeed be putting the cart before the horse (“*poner la carreta delante de los caballos*”). Paragraphs (a) through (d) do not bear on the question as to whether an expropriation has occurred. Rather, the conditions contained in paragraphs (a) through (d) specify the parameters as to when a State would not be liable under Article 1110.<sup>738</sup>

662. In its Memorial, the Claimant mistakenly conflates the determination of whether an expropriation has occurred with the conditions of legality found in paragraphs 1110(a) to (d).<sup>739</sup> That is not an appropriate analysis. In this case, there is no basis to address the question of expropriation consistent with the criteria in Article 1110(1)(a) to (d) because there has been no expropriation at all.

#### **D. Conclusion of Canada's Article 1110 expropriation argument**

663. In conclusion, the Claimant has failed to establish its Article 1110 expropriation claim against Canada for the following reasons:

- 1) Only Crompton Canada, the Claimant's enterprise as a whole, qualifies as an investment. Elements of the value of an enterprise such as goodwill, market share, and customers are not stand-alone investments under Article 1139 and hence cannot be expropriated investments for the purposes of NAFTA;
- 2) The PMRA's actions in relation to lindane did not substantially deprive the Claimant of its investment;
- 3) The PMRA's decision to suspend registration of lindane based on the concerns identified in its Special Review was a valid exercise of Canada's police power which recognized the government's right to protect public health and the environment;
- 4) The Claimant consented to the VWA and is therefore estopped from claiming expropriation relating to that agreement.

664. Canada therefore asks this Tribunal to dismiss the Claimant's expropriation claim.

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<sup>738</sup> *Fireman's Fund –Award*, ¶ 174 (Annex R-188).

<sup>739</sup> Claimant's Memorial, ¶¶ 521-532.

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### III. ARTICLE 1105 - CANADA HAS FAR EXCEEDED THE MINIMUM STANDARD OF TREATMENT

#### A. Summary of Canada's position regarding the minimum standard of treatment

665. The Claimant has not established either the content of the minimum standard of treatment under Article 1105 or a breach of that standard. Its claim under the provision must be dismissed for two reasons:

- *First*, Article 1105 establishes the minimum standard of treatment at customary international law (MST). The Claimant bears the burden of proving the content of MST through evidence of both State practice and *opinio juris*. It has not even attempted to do so. Instead, Chemtura imports idiosyncratic content into Article 1105 that is not comprehended by the customary international law standard.
- *Second*, none of the measures at issue come near to establishing a breach of MST, applying either the correct interpretation of the customary standard or the Claimant's version. Canada accorded the highest standard of treatment in this case.

#### B. Article 1105 accords the minimum standard of treatment of aliens under Customary International Law

##### 1. The text of Article 1105

666. NAFTA Article 1105 reads:

##### **Article 1105: Minimum Standard of Treatment**

1. 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.
2. Without prejudice to paragraph 1 and notwithstanding Article 1108(7)(b), each Party shall accord to investors of another Party, and to investments of investors of another Party, non-discriminatory treatment with respect to measures it adopts or maintains relating to losses suffered by investments in its territory owing to armed conflict or civil strife.

3. Paragraph 2 does not apply to existing measures relating to subsidies or grants that would be inconsistent with Article 1102 but for Article 1108(7)(b).

667. As explained in Canada's *Statement on Implementation* for NAFTA, issued in 1994, Article 1105 was "intended to assure a minimum standard of treatment of investments of NAFTA investors" and "provides for a minimum absolute standard of treatment, based on long-standing principles of customary international law."<sup>740</sup>

**2. The note of interpretation confirmed the proper interpretation of Article 1105**

668. The proper interpretation of Article 1105 was confirmed by the NAFTA Free Trade Commission in its binding Note of Interpretation of July 31, 2001. The Note of Interpretation reads as follows:

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 investors 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).<sup>741</sup>

669. The Note of Interpretation represents the definitive meaning to be given to Article 1105(1). It is binding on tribunals constituted under NAFTA Chapter Eleven.<sup>742</sup> In fact,

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<sup>740</sup> Canada, Department of Foreign Affairs, *Statement on Implementation: North American Free Trade Agreement*, vol. 128, no. 1 (Ottawa: Canada Gazette, 1994) at 149 (*Canada – Statement on Implementation*) (Annex R-248).

<sup>741</sup> NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter Eleven Provisions, 31 July 2001, at B. (*NAFTA – Notes of Interpretation*) (Annex R-242).

<sup>742</sup> NAFTA Article 1131(2).

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NAFTA Tribunals have acknowledged the binding effect of the Note and applied it uniformly.<sup>743</sup>

### 3. Article 1105 imposes an objective minimum standard of treatment

670. As stated in its title and confirmed by the Note of Interpretation, Article 1105 imposes an international minimum standard, ensuring that treatment by a State does not fall below an established threshold level. The *S.D. Myers* Tribunal explained the *raison d'être* of such a provision as follows:

[This clause] is necessary to avoid what might otherwise be a gap. A government might treat an investor in a harsh, injurious and unjust manner, but do so in a way that is no different than the treatment inflicted on its own nationals. The “minimum standard” is a floor below which treatment of foreign investors must not fall, even if a government were not acting in a discriminatory manner.<sup>744</sup>

671. The reference to customary international law in the Note of Interpretation demonstrates, contrary to the Claimant's suggestion,<sup>745</sup> that the NAFTA Parties did not create an open-ended obligation for future definition by Tribunals based on their subjective understanding of the minimum standard of treatment. Article 1105 is, rather, an “objective” standard of treatment for investors. As stated by the *Mondev* Tribunal, it is not for the Tribunal to “apply its own idiosyncratic standard in lieu of the standard laid down in Article 1105(1).”<sup>746</sup>

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<sup>743</sup> (*Mondev – Award*), ¶¶ 100-125 (Annex R-238); *ADF – Award*, ¶¶ 175-178 (Annex R-143); *Loewen – Award on Merits*, ¶¶ 124-128 (Annex R-221); *Waste Management II – Award*, ¶¶ 90-91 (Annex R-300); *Methanex – Award*, III, Chap. C ¶¶ 20-24 (Annex R-236); *Thunderbird – Award*, ¶¶ 192-193 (Annex R-287).

<sup>744</sup> *S.D. Myers – First Partial Award*, ¶ 259 (Annex R-267).

<sup>745</sup> Claimant's Memorial, ¶ 349.

<sup>746</sup> *Mondev – Award*, ¶ 120 (Annex R-238).

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#### 4. The minimum standard of treatment must be established by Customary International Law

672. Article 1105 defines the minimum standard of treatment by reference to customary international law. The Note of Interpretation establishes that “international law” in Article 1105 means the “*customary* international law minimum standard of treatment of aliens” (emphasis added). In other words, a violation of Article 1105 occurs only if Chemtura establishes the existence of a rule that is recognized as part of the customary international minimum standard for the treatment of aliens, and proves a breach of that rule.

673. As the *Loewen* Tribunal noted, fair and equitable treatment and full protection and security are “not free-standing obligations”; “[t]hey constitute obligations only to the extent that they are recognized by customary international law.”<sup>747</sup> The point was also emphasized by Mr. Justice Tysoe on the application to the British Columbia Supreme Court to set aside the *Metalclad* arbitral award:

What the *Myers* Tribunal correctly pointed out is that in order to qualify as a breach of Article 1105, the treatment in question must fail to accord to international law. Two potential examples are “fair and equitable treatment” and “full protection and security”, but those phrases do not stand on their own. For instance, treatment may be perceived to be unfair or inequitable but it will not constitute a breach of Article 1105 unless it is treatment which is not in accordance with international law. In using the words “international law”, article 1105 is referring to customary international law which is developed by common practice of countries.<sup>748</sup>

674. Moreover, as the Note of Interpretation confirms, the references to “fair and equitable treatment” and “full protection and security” are illustrative examples; they are not evidence that the NAFTA Parties intended to exceed the customary international minimum standard of treatment in Article 1105. As the *UPS* Tribunal noted, “the

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<sup>747</sup> *Loewen – Award on Merits*, ¶ 128 (Annex R-221).

<sup>748</sup> *Metalclad – Set-Aside*, ¶ 62 (Annex R-234).



obligation to accord fair and equitable treatment is not in addition to or beyond the minimum standard.”<sup>749</sup> Similarly, the *Mondev* Tribunal stated:

The FTC interpretation makes it clear that in Article 1105(1) the terms “fair and equitable treatment” and “full protection and security” are, in the view of the NAFTA Parties, references to existing elements of the customary international law standard and are not intended to add novel elements to that standard.<sup>750</sup>

675. Dolzer and Schreuer have recently commented in the same sense:

...in the context of NAFTA, the three state parties decided that the standards of “fair and equitable treatment” and “full protection and security” must be understood to require host states to observe customary international law and not more demanding autonomous treaty-based standards.<sup>751</sup>

##### **5. Article 1105 establishes a high threshold for violation**

676. NAFTA authorities have repeatedly asserted that the threshold for proof of a violation of Article 1105 is high. This is consistent with the submissions of Canada in the past as well as in the present case.

677. For example, this high threshold was recognized in *S.D. Myers*, where the Tribunal stated:

The Tribunal considers that a breach of Article 1105 occurs only when it is shown that an investor has been treated *in such an unjust or arbitrary manner that the treatment rises to the level that is unacceptable from the international perspective*. That determination must be made in the light of the high measure of deference that international law generally extends to the right of domestic authorities to regulate matters within their own borders...<sup>752</sup> (our emphasis)

<sup>749</sup> *UPS v. Canada* (UNCITRAL) Award on Jurisdiction (22 November 2002), ¶ 97 (Annex R-298) (*UPS – Jurisdiction Award*).

<sup>750</sup> *Mondev – Award*, ¶ 122 (Annex R-238).

<sup>751</sup> Dolzer, Rudolf & Christoph Schreuer, *PRINCIPLES OF INTERNATIONAL INVESTMENT LAW* (Oxford: Oxford University Press, 2008) at 16 (Annex R-177) (*Dolzer & Schreuer*).

<sup>752</sup> *S.D. Myers – First Partial Award*, ¶ 263 (Annex R-267).

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678. In *Mondev*, the Tribunal, relying in part on the *ELSI* case decided by the International Court of Justice (ICJ), also provided for the application of a high threshold:

In the *ELSI* case, a Chamber of the Court described as arbitrary conduct that which displays “a wilful disregard of due process of law... which shocks, or at least surprises, a sense of judicial propriety.”... The Tribunal would stress that the word “surprises” does not occur in isolation. The test is not whether a particular result is surprising, but whether the shock or surprise occasioned to an impartial tribunal leads, on reflection, to justified concerns as to the judicial propriety of the outcome, bearing in mind on the one hand that international tribunals are not courts of appeal, and on the other hand that Chapter 11 of NAFTA (like other treaties for the protection of investments) is intended to provide a real measure of protection. In the end the 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”<sup>753</sup> (our emphasis)

679. The *ADF* Tribunal, also consistent with *ELSI*, confirmed that simple illegality is not enough to establish a violation of Article 1105(1).<sup>754</sup> Rather, a judicial or administrative ruling must be “grossly unfair or unreasonable” to breach Article

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<sup>753</sup> *Mondev – Award*, ¶ 127 (Annex R-238).

<sup>754</sup> *ELSI* [1989] I.C.J. Rep. 15, ¶ 124 (Annex R-181); *See also* Freeman, Alwyn V., *THE INTERNATIONAL RESPONSIBILITY OF STATES FOR DENIAL OF JUSTICE* (Toronto: Longmans, Green and Co., 1938) (Annex R-192), on “denial of justice”, who emphasized again the very high threshold for a violation of the minimum standard of treatment:

The protection which must be furnished by the local courts under the State's general duty does not require letter-perfect compliance with the provisions of domestic law. Denial of justice is an international wrong and will exist only where an international duty has been unfulfilled. Now an infraction of the local law may or may not entail a violation of the State's international obligations. Whether it does or does not always depends upon the nature of the specific rule which is violated. But the mere fact that in the administration of justice some local prescription has gone by the boards does not make out an international delinquency. It is therefore not enough, in support of a charge of denial of justice, to allege and prove that the acts complained of were contrary to domestic law; but it must be further shown, as a general proposition, that the resultant judicial protection has been internationally inadequate, i.e. that the law of nations was thereby violated at the same time.

1105(1).<sup>755</sup> Contrary to what the Claimant suggests,<sup>756</sup> the ADF Tribunal did not find that the government has “act[ing] beyond the scope of lawful authority” established a breach of Article 1105:

...the Tribunal has no authority to review the legal validity and standing of the U.S. measures here in question under U.S. internal administrative law. We do not sit as a court with appellate jurisdiction with respect to U.S. measures. Our jurisdiction is confined by NAFTA Article 1131(1) to assaying the consistency of the U.S. measures with relevant provisions of NAFTA Chapter 11 and applicable rules of international law. *The Tribunal would emphasize, too, that even if the U.S. measures were somehow shown or admitted to be ultra vires under the internal law of the United States, that by itself does not necessarily render the measures grossly unfair or inequitable under the customary international law standard of treatment embodied in Article 1105(1).* An unauthorized or ultra vires act of a governmental entity of course remains, in international law, the act of the State of which the acting entity is part, if that entity acted in its official capacity. *But something more than simple illegality or lack of authority under the domestic law of a State is necessary to render an act or measure inconsistent with the customary international law requirements of Article 1105(1), even under the Investor's view of that Article.*<sup>757</sup> (emphasis added)

680. The Tribunal in *Waste Management II* summarized consideration of the standard as follows:

[...] 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 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

<sup>755</sup> *ADF – Award*, ¶ 189 (Annex R-143): “We do not believe that the refusal of the FHWA to follow prior rulings, judicial or administrative is, in itself, in the circumstances of this case, *grossly unfair or unreasonable*.”

<sup>756</sup> Claimant's Memorial, ¶ 348.

<sup>757</sup> *ADF – Award*, ¶ 190 (Annex R-143).

judicial proceedings or a *complete lack of transparency and candour* in the 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.<sup>758</sup> (our emphasis)

681. Further, in that case, the Tribunal concluded that the respondent State entity would have had to act in a “*wholly arbitrary way*” or in a way that was “*grossly unfair*” to find a breach of Article 1105.<sup>759</sup> The Tribunal went so far as to say that non-payment of a debt would breach Article 1105 only if it amounts to an “*outright and unjustified repudiation of the transaction*”.<sup>760</sup>

682. The Claimant also relegates to a footnote more recent NAFTA characterizations of the minimum standard of treatment under Article 1105, which confirm the high threshold required. The award in *GAMI* noted that:

[...] a claim of maladministration would likely violate Article 1105 if it amounted to an “*outright and unjustified repudiation*” of the relevant regulations.<sup>761</sup> (our emphasis)

683. In 2006, the *Thunderbird* Tribunal also observed that under NAFTA “the threshold for finding a violation of the minimum standard of treatment still remains high.”<sup>762</sup> That Tribunal held that conduct must be manifestly arbitrary or unfair in order to breach the minimum standard of treatment under Article 1105:

The Tribunal cannot find sufficient evidence on the record establishing that the SEGOB proceedings were arbitrary or unfair, *let alone as manifestly arbitrary or unfair as to violate the minimum standard of treatment*.<sup>763</sup> (our emphasis)

<sup>758</sup> *Waste Management II – Award*, ¶¶ 98-99 (Annex R-300).

<sup>759</sup> *Waste Management II – Award*, ¶ 115 (Annex R-300) (emphasis added).

<sup>760</sup> *Waste Management II – Award*, ¶ 115 (Annex R-300) (emphasis added).

<sup>761</sup> *GAMI – Final Award*, ¶103 (Annex R-196).

<sup>762</sup> *Thunderbird – Award*, ¶ 194 (Annex R-287).

<sup>763</sup> *Thunderbird – Award*, ¶ 197 (Annex R-287).

684. The *Thunderbird* Tribunal acknowledged that the administrative proceedings in question there “may have been affected by certain procedural irregularities.”<sup>764</sup> However, the Tribunal held that it could not find “any administrative irregularities that were *grave enough to shock a sense of judicial propriety and thus give rise to a breach of the minimum standard of treatment*”:<sup>765</sup>

[...] 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*.<sup>766</sup> (our emphasis)

685. *Thunderbird* also confirmed that administrative proceedings are subject to a lesser level of scrutiny:

As acknowledged by *Thunderbird*, the SEGOB proceedings should be tested against the standards of due process and procedural fairness *applicable to administrative officials. The administrative due process requirement is lower than that of a judicial process.*” (our emphasis)

686. In an administrative context, mere procedural errors, even if they lead to an apparently arbitrary or unfair result, “[do] not attain the minimum level of gravity required under Article 1105 of the NAFTA [...]”.<sup>767</sup>

687. The Claimant extensively cites NAFTA Tribunals’ comments that customary international law is not frozen in time.<sup>768</sup> Canada has never disagreed with this position. As Canada stated in its Article 1128 submission in the *ADF* case:

Canada’s position has never been that the customary international law regarding the treatment of aliens was “frozen in amber” at the

<sup>764</sup> *Thunderbird – Award*, ¶ 200 (Annex R-287).

<sup>765</sup> *Thunderbird – Award*, ¶ 200 (Annex R-287).

<sup>766</sup> *Thunderbird – Award*, ¶194 (Annex R-287).

<sup>767</sup> *Thunderbird – Award*, ¶ 200 (Annex R-287).

<sup>768</sup> Claimant’s Memorial, ¶¶ 337-341.

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 minimum standard of treatment is still high*.<sup>769</sup>

688. In short, NAFTA Tribunals have consistently identified and applied a high threshold for breach of the customary international minimum standard of treatment.

## 6. The Claimant's summary of NAFTA rulings is inaccurate and unreliable

689. The Claimant purports to carefully survey the rulings of NAFTA tribunals on Article 1105 since the issuance of the Note of Interpretation.<sup>770</sup> Yet its summary of these decisions is inexact and unreliable:

- The Claimant cites language from *Mondev* criticizing behaviour that is “clearly improper and discreditable”, but immediately adds its own (self-generated) gloss, “*i.e.* lack of sufficient evidence to support the decision and/or basing the decision on irrelevant considerations”. Neither of these criteria were mentioned in *Mondev*;
- With regard to “lack of due process,” the Claimant wrongly alleges that it is sufficient to find “a denial of the right to be heard”. The Claimant ignores the comments of the *Waste Management* and *Thunderbird* Tribunals, which required an offence to due process “leading to an outcome which offends a sense of judicial propriety – as might be the case with a *manifest failure of natural justice* in judicial proceedings”<sup>771</sup>, or “a *gross denial of justice or manifest arbitrariness falling below international standards*”<sup>772</sup>;

<sup>769</sup> *ADF – Award* (Annex R-143); *ADF Group Inc. v. United States* (ICSID No. ARB (AF)/00/1) Second Submission of Canada Pursuant to NAFTA Article 1128 (19 July 2002), ¶ 33 (Annex R-144). The *Neer* reference is a classic articulation of the content of the “minimum standard of treatment” in relation to physical integrity of non-nationals on the territory of another State: “[T]he treatment of an alien, in order to constitute an international delinquency, should amount to an outrage, to bad faith, to wilful neglect of duty, or to an insufficiency of governmental action so far short of international standards that every reasonable and impartial man would readily recognize its insufficiency.” *L. F. H. Neer and Pauline Neer (United States) v. Mexico* (1926) 4 R.I.A.A. 60 at 61-2 (Annex R-243).

<sup>770</sup> Claimant's Memorial, ¶ 351.

<sup>771</sup> *Waste Management II – Award*, ¶ 98 (Annex R-300).

<sup>772</sup> *Thunderbird – Award*, ¶ 194 (Annex R-287).

- The Claimant also fails to consider how the standard of “due process” is to be adjusted in the administrative context: as the *Thunderbird* Tribunal noted, “The administrative due process requirement is lower than that of a judicial process”<sup>773</sup>;
- With regard to “legitimate expectations”, the *ADF* Tribunal considered the claimant’s arguments on alleged legitimate expectations, but simply rejected them on the facts, without engaging in any review of “legitimate expectations” as a doctrine;<sup>774</sup>
- As for “transparency”, the Claimant cites *Metalclad* in support of this allegation. *Metalclad* both predates the Note of Interpretation, and was expressly set aside on this point by Mr. Justice Tysoe of the British Columbia Supreme Court;
- While the Claimant suggests “acting beyond the scope of lawful authority” is sufficient to breach Article 1105, NAFTA tribunals have instead sanctioned an “*outright and unjustified repudiation* of the relevant regulations”<sup>775</sup>. The *ADF* Tribunal expressly rejected the argument that acting outside of lawful authority is in itself a breach of the customary international law standard under Article 1105(1), suggesting that the decision had to be “*grossly unfair or inequitable*”;<sup>776</sup>
- The Claimant gratuitously adds “failing to act in good faith” to its list, but no Chapter 11 Tribunal has found that Article 1105 is breached by alleged failure to act in good faith;<sup>777</sup> and
- Finally, the Claimant argues that the NAFTA decisions it cites “establish the principle” that “the governmental action at issue need not necessarily shock an observer; it may be sufficient if an observer is surprised by the impropriety of the governmental action”.<sup>778</sup> Yet, as the *Mondev* decision stated, the *ELSI* reference to “surprise” “does not occur in isolation”, and must lead the

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<sup>773</sup> *Thunderbird– Award*, ¶ 200 (Annex R-287).

<sup>774</sup> *ADF – Award*, ¶ 189 (Annex R-143). The Claimant incorrectly states that the *ADF* Tribunal was building on the *Waste Management II* (Annex R-300) approach. This is incorrect as *ADF* was released prior to *Waste Management II*.

<sup>775</sup> *GAMI– Final Award*, ¶ 103 (Annex R-196).

<sup>776</sup> *ADF – Award*, ¶ 190 (Annex R-143).

<sup>777</sup> Claimant’s Memorial, ¶333

<sup>778</sup> Claimant’s Memorial, ¶ 342.

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tribunal to decide that the impugned decision was “*clearly improper and discreditable*”.<sup>779</sup>

690. The Claimant's summary does not accurately list the types of behaviour already sanctioned under Article 1105. In particular, it attempts to reduce significantly the threshold for breach of Article 1105 and suggests that relatively inconsequential conduct is sufficient to establish a violation of the provision. The Claimant's list fails to reflect both the actual decisions of NAFTA Chapter 11 Tribunals, and the customary international minimum standard of treatment embodied in Article 1105.

**7. Canada's conduct has respected the minimum standard of treatment**

691. Canada conducted itself in a manner that respected, and indeed substantially surpassed, the customary international minimum standard of treatment.

**a) The PMRA acted in an entirely proper and creditable manner**

- (1) The withdrawal of lindane use on canola was a voluntary, industry-led initiative

692. Canada's actions relating to the VWA were entirely proper and creditable. The Claimant's allegations to the contrary are founded on the flawed premise that Canada “required” it to participate in the voluntary agreement to withdraw lindane use on canola in Canada.<sup>780</sup> That is untrue.

693. The impetus for the VWA was not Canada. In fact, the VWA was precipitated by the Claimant's U.S. subsidiary, Gustafson, which sought to gain a competitive edge by taking advantage of the fact that lindane-treated seed was being imported into the United States, apparently contrary to EPA rules. By making this complaint, Chemtura effectively killed the Canadian market for lindane use on canola as of 1998 and provoked the crisis leading to stakeholders demanding a VWA.

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<sup>779</sup> *Mondev – Award*, (Annex R-238) ¶ 127.

<sup>780</sup> Claimant's Memorial, ¶¶ 366-376.



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694. The record is abundantly clear that Canadian canola growers asked the PMRA to support a voluntary industry-led agreement (the VWA). The stakeholders came to the PMRA (not vice versa), urging them to facilitate the VWA and thereby assist them in avoiding an immediate border closure and financial ruin.

695. Further, the PMRA agreed to facilitate the VWA only if all lindane producers concurred with it. Obviously partial withdrawal would have been both ineffective and inequitable. The producers, including Chemtura, were free at any time to refuse to be part of the VWA and it is disingenuous to suggest otherwise. The reason they did not do so was not pressure brought about by Canada, but rather the entreaties of their clients, the Canadian canola farmers, and the fact that doing so would have caused them to lose a significant market and incur financial loss. As the PMRA did not “require” the voluntary withdrawal of lindane on canola, it cannot be accused of doing so based upon on “irrelevant considerations”.

696. The Claimant misstates the regulatory grounds under which the VWA proceeded. As the Claimant itself admitted in November 1999<sup>781</sup>, the VWA did not constitute a “cancellation” of the Claimant’s product under Section 16 of the Regulations.<sup>782</sup> Chemtura requested, as the VWA expressly envisioned, an administrative amendment, removing one use (canola) pursuant to Section 13 of the Regulations. It was neither improper nor discreditable for the PMRA to accept and process the requested amendment. To the contrary, to do so was to fulfill the PMRA’s legislated duty.

697. Nor was it improper or discreditable for the PMRA to:

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<sup>781</sup> Affidavit of Wendy Sexsmith; Application of Rob Dupree of Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to PMRA requesting minor label change for *Cloak*, 1 November 1999 (Exhibit WS-46), Application of Rob Dupree of Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to PMRA requesting minor label change for *Vitavax RS Flowable*, 1 November 1999 (Exhibit WS-46A) and Application of Rob Dupree of Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to PMRA requesting minor label change for *Vitavax RS Flowable (undyed)*, 1 November 1999 (Exhibit WS-46B).

<sup>782</sup> Claimant’s Memorial, ¶ 372.

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- exercise its Common-Law regulatory discretion by refraining from strict enforcement of the terms of the amended lindane label during the agreed phase-out period; or
  - make limited commitments to reviewing potential replacement products, without prejudice to the ultimate acceptability of such products.<sup>783</sup>

698. In both instances, the PMRA complied with its statutory mandate and acted in the public interest while attempting to assist the industry. Its conduct was a responsible and balanced reaction to a difficult situation not of its making.

699. The Claimant also seriously mischaracterizes the Record of Understanding (“ROU”) of December 1998.<sup>784</sup> As Canada has demonstrated, the ROU importantly confirmed to the Canadian canola industry that the U.S. Government had taken note of its agreement with Canadian lindane registrants to phase out the use of lindane.<sup>785</sup> Industry stakeholders took this as a sign that the relevant U.S. agencies would hold off their announced plan to close the U.S. border to lindane-treated canola effective June 1998, allowing instead an orderly phase-out over several years. It is strictly untrue that the PMRA in any way “imposed” the VWA through the ROU or otherwise. Again, as the ROU recorded a voluntary agreement, it was of course open to the Claimant to walk away from the VWA at any time. The Claimant did not – presumably, realizing that to do so would simply put its own remaining lindane sales in Canada in immediate jeopardy.

700. Moreover, the Claimant has misstated the basic terms of the VWA and its relation to the PMRA’s parallel Special Review of lindane.<sup>786</sup> The PMRA repeatedly clarified that any arrangement under the VWA was ultimately subject to the results of its own

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<sup>783</sup> Affidavit of Wendy Sexsmith, ¶ 119, 27.

<sup>784</sup> Claimant’s Memorial, ¶¶ 372-373.

<sup>785</sup> Affidavit of Tony Zatylny, ¶ 54.

<sup>786</sup> Claimant’s Memorial, ¶¶ 374-375.

Special Review.<sup>787</sup> This understanding was confirmed both by canola growers, and by the other registrants.<sup>788</sup> The PMRA's position was also consistent with its legislative responsibility to ensure that pesticides are used in Canada only if they are safe and have value.

701. If the Claimant truly believed the PMRA had taken a "decision" to "require" the voluntary withdrawal, based upon "irrelevant considerations", it could have pursued domestic judicial review of this alleged "decision". The grounds it complains of in this case are uniquely within the mandate of judicial review of administrative action conferred on the Federal Court of Canada.<sup>789</sup> They certainly do not rise to the level of international wrongs.

702. Instead of pursuing judicial review or other domestic corrective mechanisms, the Claimant commenced but then abandoned 9 separate applications for judicial review before the Federal Court of Canada. It did so before any rulings could be issued or indeed evidence heard – with the exception of its injunction application of April 2001, which was dismissed.<sup>790</sup> Chemtura is now seeking relief from this Tribunal for alleged international wrongs when it failed to pursue effective and available remedies before Canada's sophisticated domestic courts.

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<sup>787</sup> Affidavit of Wendy Sexsmith, ¶ 105; PMRA, *Special Review of Pest Control Products Containing Lindane SRA99-01*, 15 March 1999 (Exhibit WS-32); Minutes of meeting of 24 June 1999 (Exhibit WS-29); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 15 October 1999 (Exhibit WS-36).

<sup>788</sup> Letter from John Kelly, Rhône-Poulenc Canada Inc., to Wendy Sexsmith, PMRA, 1 November 1999 (Exhibit WS-44); Letter from Don Wilkinson, Manager, Regulatory Affairs, IPCO, to Roy Lidstone, PMRA, 1 November 1999 (Exhibit WS-45); Letter from Roy Lee Carter, Cereals and Oilseed Lead, Zeneca, to Dr. Claire Franklin, Executive Director, PMRA, 29 October 1999 (Exhibit WS-43).

<sup>789</sup> Federal Courts Act, R.S., 1985, c. F-7, s. 1; c. 8, s. 14., s.18.1(4) (Annex R-305).

<sup>790</sup> *Crompton v. Canada*, Notice of Discontinuance, 28 December 2001 (Annex R-72); *Crompton v. Canada*, Notice of Discontinuance, 2 January 2002 (Annex R-73); *Crompton v. Canada*, Notice of Discontinuance, 10 February 2004 (Annex R-111); *Crompton v. Canada*, Notice of Discontinuance, 27 September 2006 (Annex R-121); *Crompton v. Canada*, Notice of Discontinuance, 3 October 2006 (Annex R-122); See generally Appendix E.

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703. Chemtura's suggestion that Canada compelled it to participate in the VWA is contrived and without any factual foundation.

- (2) The PMRA's decision to withdraw lindane use was based on extensive scientific review and substantial evidence

704. Canada's actions in connection with its parallel scientific review of lindane in the Special Review were also proper and creditable. The Claimant's attempt to impugn the PMRA's decision ignores growing international efforts to curb the use of lindane described earlier<sup>791</sup>, and the extensive scientific review that led to withdrawal of the remaining agricultural registrations of lindane in Canada.

705. The PMRA has demonstrated through the evidence of its witnesses Cheryl Chaffey and John Worgan, and through the independent review of Dr. Lucio Costa, that its October 2001 decisions in the Special Review were taken after a detailed, professional and impartial scientific process, applying carefully developed PMRA policies.<sup>792</sup>

706. One such policy was to rely on existing data as opposed to time-consuming data call-ins. As the PMRA has demonstrated, its lindane Special Review relied on the extensive EPA database collected in a lindane review launched a year before that of the PMRA, as well as the EPA's studies based on this database.<sup>793</sup> Reliance on this database responded to gaps in the PMRA's own data identified earlier in the process.<sup>794</sup> The EPA data was supplemented as required by the PMRA's specific requests for data. The scope of the data employed reflected sound PMRA policies in the context of its general

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<sup>791</sup> By the late 1990s lindane use had been progressively restricted around the world for nearly three decades. Efforts were mounting to implement international bans on this chemical. Affidavit of Cheryl Chaffey, ¶ 41-54. Canada had made specific commitments to scientifically review its remaining registered uses of lindane before the VWA was even agreed to. *See Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants* (Exhibit JW-10).

<sup>792</sup> *See* Affidavit of Cheryl Chaffey, ¶ 58-98; Affidavit of John Worgan, ¶ 33-139; *Dr. Costa Report* ¶ 3, 70-73, and 158.

<sup>793</sup> Affidavit of Cheryl Chaffey, ¶ 63-67.

<sup>794</sup> Affidavit of Cheryl Chaffey, ¶ 68-69.

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programme of re-evaluation.<sup>795</sup> Delays in the conclusion of the Special Review were due to the PMRA's reliance on the EPA reviews, the last of which was not provided until August 2001.<sup>796</sup>

707. The Claimant's attempt to exploit an alleged difference of result between the PMRA and the EPA<sup>797</sup> is without any merit: the EPA's 2002 conclusion to allow the few remaining existing registrations of lindane was conditional upon the application of substantial additional safety measures and did not extend to unregistered uses, notably canola. As confirmed by Dr. Lynn Goldman, a long-time senior employee of the EPA, by 2006, the EPA found even these few remaining applications ineligible for continued registration, referencing the same health considerations relied on by the PMRA in its Special Review.<sup>798</sup>

708. Moreover, the Claimant's specific allegation that the PMRA "failed to request information from registrants"<sup>799</sup> in the course of the Special Review is disingenuous. As Canada has demonstrated, in October 2000, over a year before the release of the Special Review, the Executive Director of the PMRA met with the Claimant's senior management and specifically listed PMRA concerns, notably occupational exposure. Occupational exposure risks became the basis of the PMRA's decision to suspend lindane.<sup>800</sup> Both at the meeting and in the written response it provided a few days later, the Claimant insisted that the PMRA rely on the Claimant's own 1992 occupational

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<sup>795</sup> Affidavit of Cheryl Chaffey, ¶ 69.

<sup>796</sup> Affidavit of Cheryl Chaffey ¶¶ 82-84.

<sup>797</sup> Claimant's Memorial, ¶ 378.

<sup>798</sup> *Dr. Goldman Report*.

<sup>799</sup> Claimant's Memorial, ¶ 380.

<sup>800</sup> Affidavit of Dr. Claire Franklin, ¶¶ 26-27.

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exposure study.<sup>801</sup> Once the PMRA's Special Review decision was released, the Claimant criticized the PMRA for its reliance on this very same study.<sup>802</sup>

709. The Claimant's further suggestion that the PMRA ordered deregistration of the Claimant's remaining lindane product registrations "without a right of phase-out" is false.<sup>803</sup> After the PMRA had released the results of the Special Review, the Claimant was offered the opportunity to voluntarily withdraw its products in late 2001 in accordance with Section 16 of the Regulations, which would have permitted a phase-out period.<sup>804</sup> The regime of voluntary withdrawal exists precisely to allow registrants to bow out gracefully where the PMRA finds its registration can no longer be supported, rather than face immediate cancellation. The PMRA made this offer to all then remaining registrants; all but the Claimant accepted the offer, and were granted a phase-out period. The Claimant flatly refused, defying the PMRA's scientific analysis.<sup>805</sup> Faced with the Claimant's refusal, the PMRA had no other choice under its governing legislation than to suspend the Claimant's registrations, effective immediately.<sup>806</sup> The Claimant knew the applicable statutory scheme, knew its options and chose not to take the benefit of the phase-out period.

710. The Special Review's process and conclusions were subject to a full scientific review by an independent Board of Review. Contrary to the Claimant's suggestion,<sup>807</sup> the

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<sup>801</sup> See Meeting notes of Alfred Ingulli, 4 October 2000 (Exhibit SC-27); Letter from Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada) to Janet Taylor, PMRA, 6 October 2000 (Exhibit JW-20).

<sup>802</sup> Claimant's Memorial, ¶ 195; Report from Crompton Canada (predecessor-in-title to Chemtura Canada), *Preliminary Consolidated Comments on the PMRA Occupational Exposure Risk Assessment and Proposed Regulatory Action on Lindane*, sent with letter from Rob Dupree, Crompton Canada, to Jeff Parsons, PMRA, 15 November 2001 (Exhibit JW-26B).

<sup>803</sup> Claimant's Memorial, ¶ 383.

<sup>804</sup> Letter from Janet Taylor, PMRA, to Rob Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada), 19 December 2001 (Exhibit WS-60).

<sup>805</sup> Letter from Rob Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada) to Janet Taylor, PMRA, 28 January 2002 (Exhibit WS-62).

<sup>806</sup> Affidavit of Wendy Sexsmith, ¶ 158.

<sup>807</sup> Claimant's Memorial, ¶ 379.

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PMRA moved promptly to constitute this Board, but was delayed in this effort by the Claimant's related Federal Court challenge. The Claimant ultimately dropped this challenge, expressly endorsing the fairness of the Board of Review process, having caused over a year of needless delay.<sup>808</sup>

711. The Claimant seeks to impugn the PMRA's Special Review by selective references to Board of Review findings.<sup>809</sup> Yet the Board of Review never suggested that the PMRA's process was anything other than scientifically motivated and in good faith. The Board of Review did not conclude that the Special Review was a "seriously flawed analysis".<sup>810</sup> The fundamental finding of that Board was that the PMRA's risk assessment and conclusions were within acceptable scientific parameters.<sup>811</sup> The extensive, highly technical discussions before the Board of Review concerning the conduct of the Special Review could not have occurred if the latter had been, as the Claimant suggests, simply the veneer over a purely "political" decision.

712. As for other passages from the Board of Review's decision selectively cited by the Claimant,<sup>812</sup> the PMRA in each case had sound scientific and policy reasons for its approach.<sup>813</sup>

713. Nevertheless, to demonstrate its willingness to consider the Board of Review's suggestions and the additional evidence that the Claimant submitted for the first time during the Board of Review, the PMRA between 2005 and 2008 engaged in a review *de*

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<sup>808</sup> Affidavit of Wendy Sexsmith, ¶¶ 167-169.

<sup>809</sup> Claimant's Memorial, ¶¶ 380-381.

<sup>810</sup> Claimant's Memorial, ¶ 383.

<sup>811</sup> *Report of the Lindane Board of Review*, ¶¶ 110-111, (Exhibit JW-26D).

<sup>812</sup> Claimant's Memorial, ¶ 381.

<sup>813</sup> Affidavit of Cheryl Chaffey, ¶ 131.

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*novo* of lindane,<sup>814</sup> leading to its REN. Over the course of the REN process, the PMRA gave the Claimant multiple opportunities to submit further data, despite the extensive delays these caused.<sup>815</sup>

714. The lindane REN simply confirmed the PMRA's original negative findings about worker risk. Moreover, it confirmed further concerns about lindane's endocrine toxicity, neurotoxicity, and impact on the young.<sup>816</sup> Additionally, the REN found suggestive evidence that lindane causes cancer in animals and found that lindane and its isomers bioconcentrate and bioaccumulate in the environment at levels that give rise to concerns.<sup>817</sup> The Claimant fails to refer to these conclusions in its Memorial.<sup>818</sup>

715. Nothing in the above suggests that the PMRA's conduct was even remotely "improper" or "discreditable". To the contrary, the PMRA conducted itself as a responsible and sophisticated national regulator, acting fairly towards stakeholders, while respecting its fundamental obligation to protect the safety of the public.

**b) The PMRA consistently acted within the scope of its authority**

716. Canada's behaviour in no way represented an "outright and unjustified repudiation" of relevant laws or regulations. To the contrary, Canada consistently acted

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<sup>814</sup> PMRA, Information Note, *Lindane* (Exhibit JW-53) did not "acknowledge the deficiencies raised by the Review Board". Claimant's Memorial, ¶ 382. Rather, the PMRA noted in this document that when lindane was re-evaluated, it was practice to allow for a short consultation period with the registrant at the time of the assessment. The PMRA also noted that it conducted a workers' risk assessment based on the data available at the time of the Special Review. These data notably included the Claimant's study, upon which Chemtura encouraged the PMRA to rely in October 2000, over a year before the conclusions of the Special Review were released.

<sup>815</sup> Affidavit of John Worgan, ¶ 214.

<sup>816</sup> Affidavit of John Worgan ¶ 240; *see also* PMRA, Re-evaluation Note REV2008, *Draft Lindane Risk Assessment*, 14 April 2008 (Exhibit JW-92) (*PMRA Draft Re-evaluation Note REV2008*).

<sup>817</sup> PMRA Draft Re-evaluation Note REV2008, (Exhibit JW-92).

<sup>818</sup> Claimant's Memorial, ¶ 275.



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within the scope of its legislative authority. The Claimant's allegations to the contrary are incorrect.<sup>819</sup>

717. As Canada has noted, the PMRA's actions in relation to the voluntary withdrawal of lindane use on canola were entirely within the scope of its legislation, regulations and mandate.

718. The Claimant's arguments in this regard<sup>820</sup> are again based on the false premise that the PMRA "imposed" a "cancellation" of its products on the Claimant under the VWA. As Canada has shown, the VWA was an agreement between canola farmers and the four Canadian registrants of canola lindane products to voluntarily remove the canola designation from their lindane product labels. It was designed to avoid immediate retaliatory action by the U.S. EPA, and to grant all stakeholders a reasonable phase-out period; and succeeded in doing so.

719. At most, the PMRA played a facilitating role in this agreement. Notably, the PMRA agreed to exercise its administrative discretion by allowing canola to be treated with lindane up to July 1, 2001, despite its voluntary removal from lindane labels in December 1999, rather than strictly enforcing the voluntary partial deregistration.<sup>821</sup>

720. Once the agreed phase-out period had ended, it was also within the PMRA's regulatory mandate to require compliance with the actual registered uses of lindane.

721. Finally, it was also within the PMRA's authority and mandate to determine that lindane was unsafe for further registration. The PMRA did so through a good-faith scientific review conducted according to carefully developed, agency-wide policies and

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<sup>819</sup> Claimant's Memorial, ¶ 440 ff, 381.

<sup>820</sup> Claimant's Memorial, ¶ 441.

<sup>821</sup> The PMRA also made limited commitments to review replacement products, while carefully refusing to prejudge the outcome of such reviews. *See* Affidavit of Wendy Sexsmith, ¶¶ 26-27, 39, 47, 57, 64, 68. The review of replacement products was entirely within its powers, and the PMRA conducted this review in a manner consistent with its policies and regulatory discretion. Again, ironically, Chemtura benefited from this exercise of discretion and was the first of the registrants to have a replacement product on the market due to the diligence of the PMRA. *See* Affidavit of Suzanne Chalifour ¶¶ 55, Affidavit of Wendy Sexsmith ¶77.

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procedures. Once the PMRA had determined through the Special Review that agricultural uses of lindane could no longer be supported, it was entirely within the PMRA's legislative mandate to require suspension of remaining product registrations. This suspension would have been subject to a phase-out period, had the Claimant not flatly refused to adhere to the requested voluntary withdrawal.

**c) The PMRA acted fairly, treating all with equality**

722. Canada also behaved fairly throughout this matter. The Claimant's allegations of "gross unfairness" withstand no scrutiny.<sup>822</sup>

723. The PMRA treated the Claimant and all concerned registrants equally and fairly under the VWA. It gave all parties equal notice of its position with regard to the VWA. The PMRA underlined that it would only agree to facilitate this voluntary arrangement if it was indeed voluntary, and applied equally to all registrants<sup>823</sup>. It administered the voluntary phase-out of canola from lindane product labels in an even-handed manner that saw all 4 of the registrants cease sales of this product on the same day, after a three-year transition period. The PMRA repeatedly emphasized that it sought to deal with the review of potential lindane replacement products in an equitable manner. Even at that, it ultimately registered the Claimant's tendered Gaucho products by October 1999, a full year before any competitor product. The PRMA's review of replacement products took place according to PMRA policies. To the extent the PMRA showed any flexibility in their application, the Claimant benefitted in equal measure.

724. The Claimant complains of "widespread confusion" regarding the July 1, 2001 deadline.<sup>824</sup> The July 1, 2001 end-date for phase-out of lindane use was clear from the start. The PMRA engaged in no "enforcement" actions beyond verifying the amounts of lindane left in the market as of April 2001, when most decisions about lindane purchases for the 2001 planting season had already been taken. The head of the CCC has rejected

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<sup>822</sup> Claimant's Memorial, ¶¶ 440-446.

<sup>823</sup> Affidavit of Wendy Sexsmith, ¶ 28.

<sup>824</sup> Claimant's Memorial, ¶ 446.

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the Claimant's allegation that canola farmers were dissuaded from using lindane based on a fear of PMRA "threats", and has noted that canola production dropped in 2001 due to extraneous factors (drought, prices).<sup>825</sup>

725. The Claimant's complaint that the delay in the Special Review was somehow deliberate is unsubstantiated and false.<sup>826</sup> Substantial resources were dedicated to the Special Review, with the target goal of completing this work by the end of 2000.<sup>827</sup> The release of the Special Review was primarily delayed by a slow-down in delivery of reports from the EPA: a collaboration that the Claimant had demanded and that was consistent with sound scientific practice.<sup>828</sup> The PMRA proceeded with the Special Review of lindane in good faith, and came to a scientifically sound conclusion to withdraw all agricultural lindane applications in a reasonable time-frame.

726. The PMRA's suspension of the Claimant's remaining lindane product registrations based on the Special Review was perfectly consistent with the PMRA's statutory mandate to prevent public use of pesticides deemed unsafe, and was applied equally to all lindane product registrants. The PMRA repeatedly noted that the ultimate fate of all lindane registrations depended on the outcome of the Special Review. Along with all remaining lindane registrants the Claimant was offered, but refused, a reasonable phase-out period.

727. The Claimant selectively cites from Board of Review comments regarding the Special Review in an attempt to confirm that the Special Review was "unfair". Yet the very fact the Board of Review process took place is fatal to the Claimant's charge. The Board of Review provided the Claimant an extensive opportunity to make representations about the Special Review, and to submit new data. The mitigation measures the Board references were not even proposed to the PMRA by the Claimant during the Special

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<sup>825</sup> Affidavit of JoAnne Buth, ¶ 70.

<sup>826</sup> Claimant's Memorial, ¶¶ 399-400.

<sup>827</sup> Affidavit of Cheryl Chaffey, ¶¶ 72, 80; Affidavit of John Worgan ¶ 116.

<sup>828</sup> Affidavit of Cheryl Chaffey, ¶ 82.

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Review.<sup>829</sup> Moreover, the Board of Review's fundamental conclusion was that the PMRA's decision was within acceptable scientific parameters.

**d) The Claimant enjoyed extensive opportunities to be heard**

728. There was also no “manifest failure of natural justice” in this matter, or “gross denial of justice”. To the contrary, the Claimant enjoyed extensive due process opportunities. Its allegations to the contrary are baseless.<sup>830</sup>

729. In the context of the VWA, Canada engaged in multiple stakeholder meetings, communications and in extensive specific exchanges with Chemtura.<sup>831</sup>

730. In connection with the Special Review, rights of due process were even more extensive.

731. The Claimant specifically alleges that the PMRA failed to provide it due process by not revealing the full range of concerns in the Special Review to the Claimant, and failing to collect “relevant” data from the Claimant, contrary to usual practice.<sup>832</sup> These allegations are false. Canada has demonstrated that the scope of the Special Review was open-ended when it was first announced, and that representatives of the Claimant attended two meetings with the PMRA where the scope of the Special Review, and the

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<sup>829</sup> Affidavit of Cheryl Chaffey, ¶ 123.

<sup>830</sup> Claimant's Memorial, ¶ 424 ff.

<sup>831</sup> Affidavit of Wendy Sexsmith, ¶ 39; *see e.g.* Letter from Bill Hallatt, Gustafson Partnership, to Wendy Sexsmith, PMRA, 11 January 1999 (Exhibit WS-20); Letter from Alfred Ingulli, Uniroyal, to Dr. Claire Franklin, PMRA, 2 March 1999 (Exhibit WS-27); Letter from Dr. Claire Franklin, PMRA, to Alfred Ingulli, Uniroyal, 25 March 1999 (Exhibit WS-28); Letter from Alfred Ingulli, Uniroyal, to Dr. Claire Franklin, PMRA, 1 October, 1999 (Exhibit WS-30); Letter from Alfred Ingulli, Uniroyal, to Dr. Claire Franklin, PMRA, 8 October 1999 (Exhibit WS-33); Letter from Bill Hallatt, Gustafson to Dr. Claire Franklin, PMRA, 29 April 1999 (Exhibit WS-35); Letter from Dr. Claire Franklin, PMRA, 15 October 1999 (Exhibit WS-36); Letter from Alfred Ingulli, Uniroyal to Dr. Claire Franklin, PMRA, 18 October 1999 (Exhibit WS-37); Letter from Dr. Claire Franklin, PMRA, to Mr. Alfred Ingulli, Uniroyal, 21, October 1999 (Exhibit WS-38); Letter from Alfred Ingulli, Uniroyal, to Dr. Claire Franklin, PMRA, 26 October 1999 (Exhibit WS-39); Letter from Alfred Ingulli, PMRA, to Dr. Claire Franklin, PMRA, 27 October 1999 (Exhibit WS-40); Letter from Dr. Claire Franklin, PMRA, to Alfred Ingulli, Uniroyal, 28 October 1999 (Exhibit WS-41); and Minutes of Lindane Voluntary Withdrawal and Lindane Replacement meeting, 24 June 1999 (Exhibit WS-29).

<sup>832</sup> Claimant's Memorial, ¶ 426.

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specific need for occupational and other health exposure assessments, were discussed.<sup>833</sup> In response to the later meeting where the PMRA's Executive Director specifically raised this concern, (which took place a full year before the PMRA released its results) the Claimant encouraged the PMRA to rely on its 1992 Dupree occupational exposure study, demonstrating its awareness of the concern and its opportunity to submit relevant information.<sup>834</sup>

732. When the PMRA released the results of the Special Review of lindane, it first requested comments and further input from Chemtura, agreed to extend the comment period, and took into account Chemtura's views on the potential for mitigation measures, and its submission of an alternative risk assessment before confirming its decision.<sup>835</sup>

733. Chemtura thereafter availed itself of its right to seek review of the PMRA's conclusions before a Board of Review. When Canada sought to appoint that Board, Chemtura raised objections before the Federal Court, which it abandoned a year later. Before the Board of Review, Chemtura was given a full opportunity to make written and oral submissions, and to adduce further factual and expert evidence.

734. The Board of Review proceedings definitively put to rest any notion that the Claimant failed to be granted "due process" with regard to the safety of its lindane products in Canada.<sup>836</sup>

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<sup>833</sup> Affidavit of Cheryl Chaffey, ¶¶ 93-98.

<sup>834</sup> Affidavit of Claire Franklin, ¶¶ 24-29.

<sup>835</sup> Affidavit of Cheryl Chaffey, ¶¶ 99-102; Affidavit of John Worgan, ¶¶ 106, 159-169; Claimant's Memorial, ¶ 428.

<sup>836</sup> The Claimant also relies on findings of the Board of Review to justify its complaint. In this regard Canada would note:

Concerning mitigation measures raised by the Claimant during the comment period of the Special Review – after the PMRA had relayed its initial conclusions regarding occupational risk, in October 2001, it invited registrants to submit any comments or additional data that the PMRA might not have considered. No new data were submitted. The Claimant suggested that exposure could be mitigated by increased personal protective equipment. But it was clear that the proposed measures would not come close to reducing actual exposure enough to exceed the target MOE of 1000. Neither the Claimant nor any other registrant suggested generating new exposure data, restricting lindane use to highly engineered closed treatment systems, or abandoning dust formulations.

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735. Following the Board of Review's Report, the PMRA decided to launch a review *de novo* of lindane, in which the Claimant was granted multiple opportunities to make submissions, including the submission of substantial new data, resulting in substantial delays to the REN.<sup>837</sup> The Claimant also had an opportunity to review and comment on the PMRA's draft REN. The Claimant made comments that the PRMA took into account.<sup>838</sup>

736. On April 30, 2008, the PMRA delivered its draft lindane REN to former registrants (including the Claimant) for review and comment. The Claimant replied on June 27, 2008. The PMRA took these comments into account, responding to the Claimant's comments on the procedure on August 6, 2008, and on the substance of the Claimant's comments on September 30, 2008.<sup>839</sup> The PMRA has also offered to meet in person with the Claimant to discuss its views.<sup>840</sup>

737. Moreover, as demonstrated by its nine separate Federal Court procedures, the Claimant clearly had the opportunity to pursue judicial review of each aspect of the PMRA's decision-making process in respect both of the VWA and of the Special Review.<sup>841</sup> And yet the Claimant abandoned each and every one of these applications before the substance of the dispute could be heard. The only one of these proceedings

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The Claimant did submit an internal exposure assessment on December 3, 2001. The Claimant alleged that it demonstrated acceptable levels of worker exposure. This was not based on any new data, and was simply an alternative risk assessment based on the same exposure studies used by the PMRA. The Claimant relied among other things on its 1992 Dupree study, submitted to the PMRA in October 2000 and later denounced by the Claimant. The Claimant also committed a serious error in risk calculations when converting data from an EPA study, stating an exposure level as 13.9 µg/kg, when the correct value was actually an exposure of 139µg/kg. This meant that the Claimant's own calculated Margins of Exposure were actually much lower than as presented in their assessment. Even by their own calculations, seed treatment risks would have been unacceptable.

<sup>837</sup> Affidavit of John Worgan, ¶¶ 213-214.

<sup>838</sup> Affidavit of John Worgan, ¶¶ 239, 247-251.

<sup>839</sup> Affidavit of John Worgan, ¶ 250; Letter from John Worgan, PMRA to Patricia Turner, Chemtura Canada, 6 August 2008 (Exhibit JW-97), Letter from John Worgan, PMRA to Patricia Turner, Chemtura Canada, 30 September 2008 (Exhibit JW-99).

<sup>840</sup> Affidavit of John Worgan ¶¶ 250-251; Letter from John Worgan, PMRA to Patricia Turner, Chemtura Canada, 30 September 2008 (Exhibit JW-99).

<sup>841</sup> See Appendix E, Federal Court Proceedings.

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that was actually heard in part by a Federal Court judge related to the Claimant's request to enjoin the final date of use for lindane on canola. It was rejected by the Court.<sup>842</sup>

738. The existence of domestic review mechanisms with the capacity to correct erroneous or unsubstantiated decisions is an important indicator that due process has been accorded and that there has been no denial of justice. As the *Pope & Talbot* Tribunal noted in rejecting that Claimant's accusation of "administrative unfairness", while there was no internal appellate system, "the Investment... was able to resort to judicial review if it chose".<sup>843</sup>

739. Similarly, the *Mondev* Tribunal commented on the significance of the right to judicial recourse in that case:

On the approach adopted by Mondev NAFTA Tribunals would turn into courts of appeal, which is not their role. Conceivably these might be a problem if the appellate decision took into account some entirely new issue of fact essential to the decision and there was a substantial failure to allow the affected party to present its case. But LPA had (and exercised) the right to apply for a hearing and then to seek *certiorari* to the Supreme Court. In these circumstances there was no trace of procedural denial of justice.<sup>844</sup>

740. In short, there is no basis for a finding that Canada's conduct constituted a "manifest failure of natural justice".

**C. Expansions in the content of Customary International Law must be proved by the Claimant**

741. The Claimant's further complaints regarding Canada's conduct are based on grounds that form no part of the minimum standard of treatment at customary

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<sup>842</sup> *Crompton Co./Cie v. Minister of Health and Minister of Agriculture and Agri-Food*, Reasons for Order and Order of Justice Lamer – Tremblay, Federal Court File T-585-01, 4 May 2007 (Annex R-63).

<sup>843</sup> *Pope & Talbot Inc. v. Canada* (UNCITRAL) Award on the Merits (10 April 2001) ¶ 183 (Annex R-319).

<sup>844</sup> *Mondev – Award*, ¶ 136 (Annex R-238).

international law. As set out in the section that follows, the Claimant bears the burden of proving any expansion in the content of customary international law.

**1. Customary International Law requires proof of state practice and *opinio juris***

742. It is fundamental that a customary international law standard is proved by evidence of (1) State practice, coupled with (2) *opinio juris*.<sup>845</sup>

743. This is confirmed by Article 38 of the Statutes of the International Court of Justice which establishes among the sources of international law, “international custom, as evidence of a general practice accepted as law”.<sup>846</sup> The definition reflects the classic two-part test (consistent State practice and *opinio juris*) that has been repeatedly confirmed by the ICJ itself.<sup>847</sup> In the context of the NAFTA, the *UPS* Tribunal has acknowledged that “...to establish a rule of customary international law two requirements must be met: consistent state practice and an understanding that that practice is required by law”.<sup>848</sup>

744. Arbitral awards do not constitute a formal source of State practice. As explained by Lauterpacht, “[d]ecisions of international courts are not a source of international law ... [t]hey are not direct evidence of the practice of States or of what States conceive to be the law.”<sup>849</sup> Arbitral decisions are relevant only to the extent that they contain valuable analysis of State practice. They may provide a useful tool for determining the content of

<sup>845</sup> International Law Association, STATEMENT OF PRINCIPLES APPLICABLE TO THE FORMATION OF GENERAL CUSTOMARY INTERNATIONAL LAW, Final Report of the Committee, London Conference (2000), at 8 (Annex R-207) (*ILA – Statement of Principles*).

<sup>846</sup> *ICJ Statute*, Article 38 (emphasis added).

<sup>847</sup> See e.g. *The Case of the S.S. “Lotus”* (France v. Turkey) (1927) P.C.I.J. (Series A) No. 10, at 18, 28 (Annex R-225); *North Sea Continental Shelf Cases* (*Federal Republic of Germany v. Denmark / Federal Republic of Germany v. Netherlands*), Judgment [1969] I.C.J. Rep. 3, at 44 (Annex R-247) (*North Sea Continental Shelf*).

<sup>848</sup> *UPS – Jurisdiction Award*, ¶ 84 (Annex R-298). See also *Case Concerning the Continental Shelf*, (*Libyan Arab Jamahiriya v. Malta*) [1985] I.C.J. Rep. 13, ¶ 27 (Annex R-174).

<sup>849</sup> Sir Hersch Lauterpacht, *THE DEVELOPMENT OF INTERNATIONAL LAW BY THE INTERNATIONAL COURT* (London: Stevens, 1958), at 20-21 (Annex R-216).



customary international law in this way. They do not in themselves constitute the practice of States.

745. The Claimant comments that “the task of identifying particular conduct which is unfair or inequitable thereby giving rise to a breach of minimum standard has... been left to arbitral tribunals.”<sup>850</sup> This analysis is incorrect. It wrongly suggests that NAFTA Chapter 11 Tribunals are mandated to assess the conduct of State Parties based on their own subjective sense of what might constitute a “minimum standard” and divorced from an objective and uniformly shared legal definition. As noted above, the minimum standard is an objective standard whose content is defined by customary international law.

## 2. The Claimant bears the burden of proving Customary International Law

746. The burden of proving the existence of a rule of customary international law rests on the party that alleges it.<sup>851</sup> The principle has been consistently upheld by both international tribunals and legal scholars.<sup>852</sup> It has also been specifically acknowledged in the NAFTA context.<sup>853</sup> The *UPS* Tribunal among others stated that:

[T]he obligations imposed by customary international law may and do evolve. The law of state responsibility of the 1920s may well

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<sup>850</sup> Claimant's Memorial, ¶ 343.

<sup>851</sup> *Case Concerning Rights of Nationals of the United States of America in Morocco (France v. United States)*, [1952] I.C.J. Rep. 176 (Annex R-265) (quoting *The Asylum Case (Colombia v. Peru)*, 1950 I.C.J. Rep. 266 (Annex R-153): “The Party which relies on a custom of this kind must prove that this custom is established in such a manner that it has become binding on the other Party.”).

<sup>852</sup> Nguyen Quoc Dinh, Dallier, Patrick & Pellet, Alain, *DROIT INTERNATIONAL PUBLIC*, 6th ed. (Paris: Librairie générale de droit et de jurisprudence, 1999), at 330 (Annex R-245): “c’est à [la partie] qui s’appuie sur une coutume d’en établir l’existence et la portée exacte”; Ian Brownlie, *PRINCIPLES OF PUBLIC INTERNATIONAL LAW* at 330 (Annex R-162) (“In practice the proponent of a custom has a burden of proof the nature of which will vary according to the subject-matter and the form of the pleadings.”) (*Brownlie 6<sup>th</sup> ed.*).

<sup>853</sup> For instance, the *ADF* Tribunal stated: “The Investor, of course, in the end has the burden of sustaining its charge of inconsistency with Article 1105(1). That burden has not been discharged here and hence, as a strict technical matter, the Respondent does not have to prove that current customary international law concerning standards of treatment consists only of discrete, specific rules applicable to limited contexts.” *See, ADF – Award*, ¶ 185 (Annex R-143).

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have been superseded by subsequent developments. It would be remarkable were that not so. *But relevant practice and the related understandings must still be assembled in support of a claimed rule of customary international law.*<sup>854</sup> (our emphasis)

747. In fact, the Article 1105 claim in *UPS* failed on the ground that the claimant there had “not attempted to establish that that state practice reflects an understanding of the existence of a generally owed international legal obligation”.<sup>855</sup>

748. Similarly, in the present case, the Claimant has not even acknowledged its obligation to prove customary international law, let alone discharged it. Having failed to offer any evidence of State practice and *opinio juris* supporting its expansive reading of either “minimum standard of treatment” or of “fair and equitable treatment”, the Claimant’s argument to extend these obligations must fail.

### **3. An expanded scope for the customary minimum standard cannot be proven simply by counting BITs**

749. The Claimant cites the comments of some recent arbitral decisions, referring to the entry into force of various BITs over the past few decades, as evidence of the increased scope of international customary protection of investments.<sup>856</sup> The Claimant argues that the comments of various NAFTA tribunals “establish the principle” that “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””.<sup>857</sup>

750. NAFTA decisions do not support the notion that customary international law has expanded to the extent suggested by the Claimant. The Claimant notably fails to cite the decision of the *ADF* Tribunal on this point:

We are not convinced that the Investor has shown the existence, in current customary international law, of a general and autonomous

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<sup>854</sup> *UPS – Jurisdiction Award*, ¶ 84 (Annex R-298).

<sup>855</sup> *UPS – Jurisdiction Award*, ¶ 86 (Annex R-298).

<sup>856</sup> See Claimant’s Memorial, ¶ 338, citing *Mondev – Award*, ¶ 117 (Annex R-238).

<sup>857</sup> Claimant’s Memorial, ¶ 342.

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requirement (autonomous, that is, from specific rules addressing particular, limited, context) to accord fair and equitable treatment and full protection and security to foreign investments. The Investor, for instance, has not shown that such a requirement has been brought into the corpus of present day customary international law by the many hundreds of bilateral investment treaties now extant. It may be that, in their current state, neither concordant state practice nor judicial or arbitral case law provides convincing substantiation (or, for that matter, refutation) of the Investor's position. It may also be observed in this connection that the Tribunal in *Mondev* did not reach the position of the Investor, while implying that the process of change is in motion...<sup>858</sup>

751. In any event, Canada rejects the notion that the signature of BITs containing reference to "fair and equitable treatment" has altered the minimum customary standard of treatment at international law.

752. Article 38 of the *ICJ Statute* distinguishes "treaties" from customary international law. It cannot be assumed that the State Parties are codifying a customary international obligation every time they set out a specific commitment in a treaty.<sup>859</sup> The *Mondev* Tribunal acknowledged that "[i]t is often difficult in international practice to establish at what point obligations accepted in treaties, multilateral or bilateral, come to condition the content of a rule of customary international law binding on States not party to those treaties."<sup>860</sup> As the *UPS* Tribunal noted, "in terms of *opinio juris* there is no indication that [the BITs] reflect a general sense of obligation".<sup>861</sup>

753. Moreover, the creation of custom is not a mere mechanical exercise of counting treaties. The simple existence of treaties on a subject-matter cannot lead to any definitive

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<sup>858</sup> *ADF – Award*, ¶ 183 (Annex R-143).

<sup>859</sup> See Sornarajah, M., *THE INTERNATIONAL LAW ON FOREIGN INVESTMENT*, 2nd ed. (New York: Cambridge University Press, 2004) at 233: "knowing the confused state of the law, [countries] entered into such treaties so that they could clarify the rules that they would apply in cases of any disputes which may arise between them." (Annex R-278) (*Sornarajah*).

<sup>860</sup> *Mondev – Award*, ¶ 111 (Annex R-238).

<sup>861</sup> *UPS – Jurisdiction Award*, ¶ 97 (Annex R-298).

conclusions regarding the existence of a customary rule.<sup>862</sup> As the International Law Association (ILA) recently noted, “[t]here is no *presumption* that a succession of similar treaty provisions gives rise to a new customary rule with the same content.”<sup>863</sup>

754. The requirement of proving consistent State practice is particularly apposite where, as in the case of BITs, the alleged customary rule is thought to have emerged recently, and quickly. As the ICJ noted in the *North Sea Continental Shelf Case*, State practice must be “both extensive and virtually uniform” where it is asserted that a rule of customary international law has emerged in a short period of time.<sup>864</sup> Yet the diversity of scope and content in BITs has been noted by many authors.<sup>865</sup>

755. As for *opinio juris*, the requirement for this element has been repeatedly noted by tribunals in the context of investor-State disputes.<sup>866</sup> In the NAFTA context, all three

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<sup>862</sup> Faruque, Abdullah Al, *Creating Customary International Law Through Bilateral Investment Treaties: A Critical Appraisal* (2004) 44 INDIAN J. INT’L L. 292, at 300 (Annex R-186) (*Faruque*); McLachlan, Campbell, *Investment Treaties and General International Law* (2008) 57 I.C.L.Q. 361, at 400 (Annex R-229) (*McLachlan*).

<sup>863</sup> Principle no. 25 adopted by the *ILA – Statement of Principles*, at 47 (Annex R-207) (emphasis added). The ILA specifically addressed the question of the impact of BITs on custom: “The question of the legal effect of a succession of similar treaties or treaty provisions arises particularly in relation to bilateral treaties, such as those dealing with extradition or investment protection. (...) [T]here seems to be no reason of principle why these agreements, however numerous, should be *presumed* to give rise to new rules of customary law or to constitute the State practice necessary for their emergence. (...) Some have argued that provisions of bilateral investment protection treaties (especially the arrangements about compensation or damages for expropriation) are declaratory of, or have come to constitute, customary law. But (...) there seems to be no special reason to *assume* that this is the case, unless it can be shown that these provisions demonstrate a widespread acceptance of the rules set out in these treaties *outside the treaty framework*.” (at 47-48) (emphasis in the original)

<sup>864</sup> *North Sea Continental Shelf*, at ¶ 75 (Annex R-247).

<sup>865</sup> *Sornarajah*, at 206 (Annex R-278) (“there is so much divergence in the standards in the [BITs] that it is premature to conclude that they give rise to any significant rule of international law”); Kishoiyian, Bernard *The Utility of Bilateral Investment Treaties in the Formulation of Customary International Law* (1994) 14:2 NW. J. INT’L L. & BUS. 352 at 372-373 (Annex R-213) (“a close analysis of the various BITs ... has revealed that there not sufficient consistency in the terms of the investment treaties to find in them support for any definite principles of customary international law”); Mendelson, Maurice, *The Runaway Train: the Continuous Nationality Rule from the Panevezys–Salduvis Railway Case to Loewen* in: T. Weiler, ed., *INTERNATIONAL INVESTMENT LAW and ARBITRATION: LEADING CASES FROM THE ICSID, NAFTA, BILATERAL TREATIES and CUSTOMARY INTERNATIONAL LAW* (London: Cameron May, 2005) 97 at 141 (Annex R-232); *McLachlan*, at 393 (Annex R-229); *Faruque*, at 301-310 (Annex R-186).

<sup>866</sup> *Amoco – Partial Award*, ¶ 252 (Annex R-150); *See also UPS – Jurisdiction Award*, ¶ 84 (Annex R-298).

NAFTA Parties rejected the *Pope* Tribunal's equation of customary international law with BITs, which failed to mention the *opinio juris* requirement. The *Mondev* tribunal reviewed this:

In their post-hearing submissions, all three NAFTA Parties challenged holdings of the Tribunal in *Pope & Talbot* which find that the content of contemporary international law reflects the concordant provisions of many hundreds of bilateral investment treaties. In particular, attention was drawn to what those three States saw as a failure of the *Pope & Talbot* Tribunal to consider a necessary element of the establishment of a rule of customary international law, namely *opinio juris*. These States appear to question whether the parties to the very large numbers of bilateral investment treaties have acted out of a sense of legal obligation when they include provisions in those treaties such as that for "fair and equitable" treatment of foreign investment.<sup>867</sup>

**4. All three NAFTA States have expressly rejected the notion that BITs establish customary international law**

756. Canada, the United States and Mexico have consistently rejected the notion that BITs establish customary international law. For instance, in the context of the *Loewen* case, Mexico made the following submission pursuant to Article 1128:

Mexico is particularly concerned about the suggestion that the fact that the mere existence of some 1800 BITs in the world means that somehow that the corpus of these treaties creates customary

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<sup>867</sup> *Mondev – Award*, ¶ 11 (Annex R-238). See also the Tribunal's reference to the U.S. position that the *Pope* Tribunal had "erred in its automatic equation of customary international law with the content of BITs, without regard to any question of *opinio juris*." (¶ 106). In the context of the *Loewen* case, Mexico made the following observation: "The [*Pope*] Tribunal did not refer to the essential additional requirement of *opinio juris*. In Mexico's respectful view, the *Pope & Talbot* Tribunal's failure to observe basic principles of treaty interpretation and its treatment of proving the existence of a customary international law rule does not commend its Awards to this Tribunal. Its Awards have been wrongly decided and should be disregarded." See *Loewen Group, Inc. and Raymond L. Loewen v. United States* (ICSID No. ARB/98/3) Mexico's Article 1128 Submission Concerning Loewen Corporate Restructuring (2 July 2002), ¶ 39-40 (Annex R-223); *Loewen Group, Inc. and Raymond L. Loewen v. United States* (ICSID No. ARB/98/3) Second Submission of the Government of Canada Pursuant to NAFTA Article 1128 (27 June 2002), ¶ 25-26 ("the *Pope & Talbot* Tribunal referred to no *opinio juris* surrounding these agreements and appeared unaware that such a sense of legal obligation is required before a customary norm can be found. The *Pope & Talbot* Tribunal failed to establish that fundamental pre-conditions to the creation of customary obligations had been met. Therefore, Canada submits that the *Pope and Talbot* Tribunal's conclusions with respect to the status of BITs as crystallizations of customary law should not be followed.") (Annex R-222) (*Loewen – Canada's Second 1128 Submission*).

international law obligations. The fact that States may agree to the same or similar obligations through different treaties involving different parties, or even the same obligations through multilateral treaties is not sufficient on its own to build customary international law.<sup>868</sup>

[i]t is impossible to infer from the existence of a large number of BITs alone that any particular provision therein represents a rule of customary international law merely by reason of its commonality.<sup>869</sup>

757. The same position was adopted by the United States<sup>870</sup> and Canada<sup>871</sup> in the *Loewen* case as well as by the United States in the *Glamis* case.<sup>872</sup>

##### **5. Awards under different treaties are only relevant if they apply the customary international law minimum standard of treatment**

758. As a general matter, tribunals' articulations of customary international law are only valid to the extent they are firmly grounded in State practice, and *opinio juris*.

759. Non-NAFTA cases interpreting minimum treatment provisions that are not based on the customary international law minimum standard of treatment are of little or no guidance in interpreting NAFTA Article 1105.

760. Further, non-NAFTA decisions relied upon by the Claimant are striking in their absence of any analysis or evidence justifying the content that they ascribe to their

<sup>868</sup> *Loewen – Mexico's 1128 Submission*, ¶ 33 (Annex R-223).

<sup>869</sup> *Loewen – Mexico's 1128 Submission*, ¶ 39 (Annex R-223).

<sup>870</sup> *Loewen Group, Inc. and Raymond L. Loewen v. United States* (ICSID No. ARB/98/3) Response of the United States of America to the June 27 and July 2, 2002 Submissions of the Governments of Canada and Mexico Pursuant to NAFTA Article 1128 (19 July 2002), at 3 (“no rule of customary international law relevant to this NAFTA proceeding is established by the various bilateral investment agreements between States not parties to the NAFTA.”) (Annex R-224).

<sup>871</sup> *Loewen – Canada's Second 1128 Submission*, ¶ 11 (Annex R-222) (“Canada submits that the provisions at issue in this case contained in the more than 1800 BITs and in the ICSID Convention in existence have not been transformed into rules of customary international law consistent with Article 38(1)(b) of the ICJ Statute.”).

<sup>872</sup> *Glamis v. United States*, United States' Rejoinder Memorial (15 March 2007) at 142 ff (Annex R-201).

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standard of treatment. The comments of these Tribunals do not define the international minimum standard of treatment under Article 1105 and ignore the rigorous standard required to prove customary international law.

761. Thus, the Tribunal in *Occidental* makes a bald and unsubstantiated statement 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.”<sup>873</sup> It is unclear that the Tribunal’s comment refers to a customary international minimum standard of treatment. The *Occidental* Tribunal does not even attempt to demonstrate the basis of its assertion on State practice. Indeed, the Tribunal’s comment does not reflect any customary international standard known at law. Instead, it simply refers to the opinions of the various tribunals. The Tribunal in *Azurix* for its part states “...whichever side of the argument one takes, the answer to the question may in substance be the same” without considering the high threshold required by customary international law.<sup>874</sup> The *TecMed* Tribunal expressly emphasizes that its analysis is based on an “autonomous interpretation, taking into account the text of Article 4(1) of the Agreement according to its ordinary meaning”, adding only tangentially “or from international law and the good faith principle...”.<sup>875</sup>

762. Indeed, UNCTAD has observed that the broad interpretation of fair and equitable treatment by some tribunals has caused some States to redraft their BIT models.

UNCTAD comments:

The debate regarding the fair and equitable treatment clause in the context of Chapter 11 of NAFTA has shown the risks of including language in BITs providing for unqualified fair and equitable treatment of foreign investment. The wording of this clause might be broad enough to be invoked in respect of virtually any adverse

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<sup>873</sup> *Occidental Exploration and Petroleum Company v. The Republic of Ecuador* (LCIA Case No. UN3467) Final Award (1 July 2004) (Annex R-249) (*Occidental – Award*).

<sup>874</sup> *Azurix v. Argentine Republic* (ICSID No. ARB/01/12) Award (14 July 2006) (Annex R-155) (*Azurix – Award*).

<sup>875</sup> *Técnicas Medioambientales Tecmed, S.A. v. Mexico* (ICSID No. ARB(AF)/00/2) Award (29 May 2003) (Annex R-285) (*Tecmed – Award*).

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treatment of an investment, thus making the fair and equitable treatment provision among those most likely to be relied upon by an investor in order to bring a claim under the investor–State dispute settlement proceedings. *It is therefore not surprising that some countries have begun to consider redrafting their BIT models to clarify the scope and content of the fair and equitable treatment standard.*<sup>876</sup>

763. Another recent UNCTAD study has confirmed this trend in investor-State decision-making as a response to arbitral decision-making:

The inclusion of language clarifying the content and scope of the minimum standard of treatment in new [international investment agreements] may be particularly relevant to counterbalance two recent trends in [investor–State dispute settlement] practice. First, the clarification concerning the meaning of customary international law included in, for example, Annex A of the Australia–United States FTA is important for providing guidance as to how to interpret the fair and equitable treatment standard properly. *Some recent arbitration panels have granted themselves a certain degree of freedom in this respect.* Given the evolutionary nature of customary international law, the content of the fair and equitable treatment standard no longer requires bad faith or “outrageous” behaviour on behalf of the host country. *By eliminating these requirements, some arbitral decisions had the effect of equating the minimum standard under customary international law with the plain meaning approach to the text. However, it is not self-evident that customary international law has evolved to such a degree.*<sup>877</sup>

764. Failing to apply the customary international law minimum standard of treatment, the decisions cited by the Claimant do not offer guidance as to the proper interpretation of Article 1105.

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<sup>876</sup> UNCTAD, BILATERAL INVESTMENT TREATIES 1995–2006: TRENDS IN INVESTMENT RULEMAKING, UN Doc. UNCTAD/ITE/IIT/2006/5 (2007), at 32 (Annex R-295) (*UNCTAD – BITs*).

<sup>877</sup> UNCTAD, INVESTOR-STATE DISPUTE SETTLEMENT AND IMPACT ON INVESTMENT RULEMAKING, UN Doc. UNCTAD/ITE/IIA/2007/3 (2007), at 75 (Annex R-296) (*UNCTAD – Dispute Settlement*).



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**D. The Claimant's attempt to expand the scope of these obligations is unfounded in law**

765. The Claimant bears the burden of demonstrating that the standard it proposes indeed forms part of customary international law. It has not even attempted to do so. The Claimant instead seeks altogether to ignore the Article 1105 reference to a minimum standard of treatment **(1)**; it also seeks to transform the general principle of good faith into a substantive obligation not found in the customary international standard **(2)**; it attempts to transform the customary international minimum standard into a variable yardstick, expanded or diminished depending on the State in question **(3)**; seeks to impose a “stand still” obligation and other unreasonable expectations **(4)**; and alleges an obligation of “total transparency” that is not founded in law **(5)**. These arguments do not alter the customary minimum standard found in Article 1105, with which Canada has complied

**1. The Claimant cannot legitimately ignore the express language of Article 1105 and the Note of Interpretation**

766. The Claimant attempts to alter the scope of Article 1105 by simply ignoring the textual references to the “minimum standard of treatment”, citing commentary unrelated to this standard.<sup>878</sup>

767. This ignores the requirements of the *Vienna Convention*. As the *Myers* Tribunal noted:

Article 1105(1) expresses an overall concept. The words of the article must be read as a whole. The phrases... fair and equitable treatment... and... full protection and security... cannot be read in isolation. They must be read in conjunction with the introductory phrase... “treatment in accordance with international law”.<sup>879</sup>

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<sup>878</sup> Claimant's Memorial, ¶ 333.

<sup>879</sup> *S.D. Myers – First Partial Award*, ¶ 262 (Annex R-267).

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768. The Claimant seeks support in the writings of Dolzer and Stevens as well as Mann.<sup>880</sup> Both references are unhelpful. First, the Claimant cites Dolzer and Stevens selectively, failing to include the following passage: “However, in the North American Free Trade Agreement (NAFTA), the fair and equitable standard is explicitly subsumed under the minimum standard of customary international law”.<sup>881</sup>

769. The Claimant also relies on an early article by Mann claiming that “A tribunal would not be concerned with a minimum... standard.”<sup>882</sup> Mann was not addressing the situation where the minimum standard of treatment under international law was specified as the governing law, as it is under NAFTA Article 1105. The Claimant also fails to note that Mann significantly nuanced his views in the quoted article, shortly after its publication. As J.C. Thomas has observed:

The irony of the intense debate that Mann’s arguments spawned in North America twenty years after his note was published is that only one year after he argued that fair and equitable treatment should reach “conduct which goes far beyond the minimum standard” and should afford protection to a much greater extent than the treatment required by customary international law, Mann published the fourth edition of his treatise on the law of money. As a treatise, and not an argument, this work had a different and more conservative analysis of fair and equitable treatment.

In *The Legal Aspects of Money*, Mann’s view of the obligation was much narrower than the argument that he had advanced a year earlier:

“In some cases, it is true, treaties merely repeat, perhaps in slightly different language, what in essence is a duty imposed by customary international law; the foremost example is the familiar provision whereby states undertake to accord “fair and equitable treatment” to each others” nationals, and which in law is unlikely

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<sup>880</sup> Claimant’s Memorial, ¶ 350.

<sup>881</sup> *Dolzer & Schreuer*, at 60 (Annex R-177).

<sup>882</sup> Claimant’s Memorial, ¶ 350.

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to amount to more than a confirmation of the obligation to act in good faith, or to refrain from abuses or arbitrariness.”<sup>883</sup>

770. Similarly, the Claimant alleges, “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”.<sup>884</sup> Its comment is imprecise and misleading. As confirmed by the Note of Interpretation, the proper analysis of Article 1105(1) is to address the extent to which State conduct violates the (proven) customary international minimum standard of treatment. To the extent the phrase “fair and equitable treatment” is taken as only illustrative of a minimum standard, any meaning ascribed to the illustrative example cannot exceed the boundaries of that customary minimum standard.

## **2. The doctrine of “good faith” informs existing obligations rather than creating new ones**

771. The Claimant also attempts to expand the customary international minimum standard of treatment in Article 1105 by reference to an international obligation to act in good faith.<sup>885</sup> The Claimant appears to be equating “good faith” and “fair and equitable treatment”, arguing that by including a reference to “fair and equitable treatment” in Article 1105, Canada is obliged to uphold a standard in excess of the minimum standard of treatment because “good faith” has been interpreted more expansively. The Note of Interpretation has categorically confirmed this as incorrect.

772. In any event, while good faith is indeed a principle at international law, it is not in itself a source of substantive obligations.

773. In the particular context of Article 1105, the duty to act in good faith is relevant only when invoked in connection with a subject matter that already forms part of the customary international law minimum standard of treatment of aliens. This was

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<sup>883</sup> Thomas, J.C., *Reflections on Article 1105 of NAFTA: History, State Practice and the Influence of Commentators* (2002) 17:1 ICSID REV. 21 at 58 (Annex R-286).

<sup>884</sup> Claimant’s Memorial, ¶ 332.

<sup>885</sup> Claimant’s Memorial, ¶ 333 ff.

confirmed by the ICJ in the *Case Concerning Border and Transborder Armed Actions (Nicaragua v. Honduras)*:

The principle of good faith is, as the Court has observed, “one of the basic principles governing the creation and performance of legal obligations” (Nuclear Tests, I.C.J. Reports 1974, p. 268, para. 46; p. 473, para. 49); it is not in itself a source of obligation where none would otherwise exist.<sup>886</sup>

774. The good faith undertaking cannot expand the obligations under Article 1105. The obligations can be expanded only to the extent that they have become part of customary international law.

775. The Claimant has, of course, entirely failed to demonstrate that the standard it alleges reflects customary international law. The Claimant has also failed to allege a single specific instance of Canada failing to act in good faith, much less prove such an allegation. To the contrary, Canada acted in complete good faith throughout, consistent with its statutory mandate and in the best interests of all stakeholders.

### 3. The customary international minimum standard applies equally to all States

776. Among the Claimant's manifold errors in analysing the customary international law minimum standard of treatment is its suggestion that the level of protection offered by this standard should vary in accordance with the level of development of the country in question.<sup>887</sup> Canada rejects this interpretation. The customary international law

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<sup>886</sup> *Case Concerning Border and Transborder Armed Actions (Nicaragua v. Honduras)*, Jurisdiction and Admissibility, Judgment, [1988] I.C.J. Rep. 69, at 105-106, ¶ 94 (Annex R-246); also applied in *Land and Maritime Boundary (Cameroon v. Nigeria)*, [1998] I.C.J. Rep. 275, ¶ 39 (Annex R-214). The principle has also been applied by international arbitration tribunals: see *Canfor – Preliminary Question*, ¶ 182 (Annex R-165). The parties have debated at some length about the relevance of good faith in the present case. Good faith is a basic principle for interpretation of a treaty. It is stated in so many words in Article 31(1) of the Vienna Convention (“A treaty shall be interpreted in good faith . . .”). Good faith is also a basic principle in the performance of a treaty by States. Article 26 of the Vienna Convention provides: “Every treaty in force is binding on the parties to it and must be performed by them in good faith.” In the words of the ICJ: “The principle of good faith is, as the Court has observed, one of the basic principles governing the creation and performance of legal obligations . . . it is not in itself a source of obligation where none would otherwise exist.”

<sup>887</sup> Claimant's Memorial, ¶¶ 353-356.

minimum standard of treatment is exactly as its name describes it – a minimum standard universally applicable as an absolute, below which no State should fall. The international standard is entirely distinct from domestic legal regimes: “For the determination of the existence of an unlawful act in international law... municipal law, as such, is wholly irrelevant”.<sup>888</sup>

777. The Claimant’s reasoning would displace the international customary minimum standard in favour of a variable standard. And yet the essence of the customary international standard is precisely the contrary:

The international minimum standard is a norm of customary international law which governs the treatment of aliens, by providing for a minimum set of principles which States, *regardless of their domestic legislation and practices*, must respect when dealing with foreign nationals and their property.<sup>889</sup>

778. The examples that the Claimant cites in favour of an allegedly “mobile” minimum standard of treatment offer no support. Neither *Generation Ukraine v. Ukraine* nor *X v. Central European Republic* stands for the proposition that conduct required under customary international law varies depending on the host country’s level of development.<sup>890</sup> Indeed, *Generation Ukraine* did not even include a “fair and equitable treatment” claim, and *Central European Republic* did not reach the merits.<sup>891</sup>

779. The *Genin* Tribunal noted that “[w]hile the exact content of this standard is not clear, the Tribunal understands it to require an “international minimum standard” that is

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<sup>888</sup> *Cheng*, at 172 (Annex R-167).

<sup>889</sup> OECD, *FAIR AND EQUITABLE TREATMENT STANDARD IN INTERNATIONAL INVESTMENT LAW*, (2004) Working Papers on International Investment No. 2004/3, at 8 n. 32 (emphasis added) (Annex R-251), citing *Brownlie 6th ed.*, at 502 (Annex R-162).

<sup>890</sup> *Generation Ukraine v. Ukraine* (ICSID No. ARB/00/9) Award (13 September 2003), ¶ 5.1 (Annex R-199); *X v. Central European Republic* (SCC Case 29/2002) Award (2003), reprinted in *Stockholm Arb. Rep.* 141, 165 (2004) (Annex R-304).

<sup>891</sup> Nor does the article on which the Claimant relies support its proposition; rather, the article simply describes recent arbitral divergence of view on the point, and suggests the need for clarification: See Gallus, Nick, *The Influence of the Host State’s Level of Development on International Investment Treaty Standards of Protection* (2005) 6:5 J. WORLD INVEST & TRADE 711, at 728 (Annex R-195).

separate from domestic law, but that is, indeed, a minimum standard".<sup>892</sup> In the same way, the *Saluka* Tribunal noted that the customary minimum standard:

... provides a minimum guarantee to foreign investors, even where the State follows a policy that is in principle opposed to foreign investment; in that context, the minimum standard of "fair and equitable treatment" may in fact provide no more than "minimal" protection.<sup>893</sup>

780. The mutable standard that the Claimant seeks to impose on Article 1105 is not, as it alleges, "consistent with the NAFTA framework": to the contrary, it contradicts the express position of the NAFTA State Parties in the Note of Interpretation, affirming the customary international minimum standard of treatment as the appropriate standard under Article 1105.

#### **4. Article 1105 does not impose a "standstill" obligation on States**

##### **a) There is no "standstill" obligation under the minimum standard of treatment or at all**

781. Having failed to prove an expanded minimum treatment obligation in customary international law, the Claimant asserts a "standstill" obligation: that Article 1105 prevents a State from changing its laws or regulatory regime as of the time an investment is made. This, of course, is contrary to the longstanding principle of public international law that a foreign investor assumes the risk of investing in a foreign country, including that the legal regime in place in that country may change.<sup>894</sup>

In application of a generally accepted principle, any person taking up residence or investing capital in a foreign country must assume the concomitant risks and must submit, under reservation of any

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<sup>892</sup> *Genin v. Republic of Estonia* (ICSID No. ARB/99/2) Award (25 June 2001), ¶ 367 (emphasis in original) (Annex R-200).

<sup>893</sup> *Saluka – Partial Award*, ¶ 292 (Annex R-270).

<sup>894</sup> Indeed, it is for precisely this reason that investors seek stabilization clauses in the contractual context.

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measures of discrimination against him as a foreigner, to all the laws of that country.<sup>895</sup>

782. The applicability of a “standstill” principle has been particularly challenged in the regulatory context, where investors should expect that the situation will change and evolve. As Professor Schreuer writes:

It is clear that a reasonable evolution of the host State’s law is part of the environment with which investors must contend. For instance, an adjustment of environmental regulations to internationally accepted standards or general improvements in labour law for the benefit of the host State’s workforce would not lead to a violation of the fair and equitable treatment standard if applied in good faith and without discrimination.<sup>896</sup>

783. The Investor invokes the concept of “legitimate expectations” to effect a “standstill” obligation through Article 1105. However, customary international law does not recognize “legitimate expectations” as the source of State obligations. Two recent decisions of ICSID Annulment Committees support this proposition.

784. In February 2007, the *MTD* Annulment Committee noted:

For example the *TECMED* Tribunal’s apparent reliance on the foreign investor’s expectations as the source of the host State’s obligations (such as the obligation to compensate for expropriation) is questionable. The obligations of the host State towards foreign investors derive from the terms of the applicable investment treaty and not from any set of expectations investors may have or claim to have. A tribunal which sought to generate from such expectations a set of rights different from those contained in or enforceable under the BIT might well exceed its powers, and if the difference were material might do so manifestly.<sup>897</sup>

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<sup>895</sup> *Cheng*, at 36-37 (Annex R-167), quoting *Standard Oil v. Germany* (1926) 7 R.I.A.A. 301 (Annex R-281).

<sup>896</sup> Schreuer, Christoph, *Fair and Equitable Treatment in Arbitral Practice* (2005) 6:3 J. WORLD INVMT & TRADE 357, at 374 (Annex R-271).

<sup>897</sup> *MTD Equity Sdn. Bhd. & MTD Chile S.A. v. Chile* (ICSID No. ARB/01/7) Decision on Annulment (21 March 2007), ¶ 67 (Annex R-239).

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785. In August 2007, the *CMS* Annulment Committee noted: “[a]lthough legitimate expectations might arise by reason of a course of dealing between the investor and the host State, these are not, as such, legal obligations”.<sup>898</sup>

786. These recent decisions undermine the *Tecmed* award, which had become for some the high water mark for its alleged interpretation of the concept of “legitimate expectations”. The Claimant relies heavily on *Tecmed* as well as on other awards, including *Occidental*, *LG & E* and *Sempra*, all of which cite *Tecmed*. Unfortunately, none of these awards justifies their interpretation beyond general references to good faith or to preambular language referring to the stability of the legal framework.<sup>899</sup>

787. The concept of “legitimate expectations” has not figured prominently in Chapter 11 cases. The Tribunal in *Thunderbird* went the furthest when it stated:

Having considered recent investment case law and the good faith principle of international customary law, the concept of “legitimate expectations” relates, within the context of the NAFTA framework, to a situation where a Contracting Party’s conduct creates reasonable and justifiable expectations on the part of an investor (or investment) to act in reliance on said conduct, such that a failure by the NAFTA Party to honour those expectations could cause the investor (or investment) to suffer damages.<sup>900</sup>

788. The *Waste Management II* Tribunal, noted that “[i]n 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”.<sup>901</sup>

789. In *Methanex*, while in the different context of expropriation, the Tribunal also noted that:

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<sup>898</sup> *CMS Gas Transmission Company v. Argentine Republic* (ICSID No. ARB/01/8) Annulment Proceeding (25 September 2007), ¶ 89 (Annex R-171).

<sup>899</sup> Claimant’s Memorial, ¶ 359.

<sup>900</sup> *Thunderbird – Award*, ¶ 147 (notes omitted) (Annex R-287).

<sup>901</sup> *Waste Management II – Award* (Annex R-300).



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But as a matter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process and, which affects, *inter alios*, a foreign investor or investment is not deemed expropriatory and compensable *unless specific commitments had been given by the regulating government to the then putative foreign investor contemplating investment that the government would refrain from such regulation.*<sup>902</sup> (emphasis added)

790. The NAFTA cases cited above when addressing legitimate expectations do so only in the context of there being specific *representations* or *commitments* by the State. In other words, the concept of “legitimate expectations” must be based on objective rather than subjective expectations.<sup>903</sup>

791. Further, in the cases that have applied this concept, even broadly, outside the NAFTA context, it has been with regard to undertakings that induced an investor to make its investment in the first place. As the *Enron* Tribunal noted:

What seems to be essential, however, is that these expectations derived from the *conditions* that were *offered* by the State to the

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<sup>902</sup> *Methanex – Award*, Part IV, Chapter D, at 4 (Annex R-236).

<sup>903</sup> See also, *M.C.I. Power Group L.C. and New Turbine, Inc. v. Ecuador* (ICSID No. ARB/03/6) Award (26 July 2007) (Annex R-226). The *M.C.I.* Tribunal stated that “the alleged legitimate expectations of an investor with respect to the behaviour required of a host State cannot include merely subjective assessments...” (¶ 349). The Tribunal also indicated that “[t]he legitimacy of the expectations for proper treatment entertained by a foreign investor protected by the BIT does not depend solely on the intent of the parties, but on certainty about the contents of the enforceable obligations”.[cite] The Tribunal in *Saluka – Partial Award*, even while interpreting a fair and equitable treatment obligation that contains no reference to international law, warned that: “(T)he scope of the Treaty’s protection of foreign investment against unfair and inequitable treatment cannot exclusively be determined by foreign investors subjective motivations and considerations. Their expectations, in order for them to be protected, must rise to the level of legitimacy and reasonableness *in light of the circumstances*. No investor may reasonably expect that the circumstances prevailing at the time the investment is made remain totally unchanged. In order to determine whether frustration of the foreign investor’s expectations was justified and reasonable, the host State’s legitimate right subsequently to regulate domestic matters in the public interest must be taken into consideration as well.”, ¶ 305 (Annex R-270). As the Tribunal in *S.D. Myers – First Partial Award* has stated, the determination of a breach of the obligation of “fair and equitable treatment” by the host State: “...must be made in the light of the high measure of deference that international law generally extends to the right of domestic authorities to regulate matters within their own borders.”, ¶ 263 (Annex R-267).

investor *at the time of the investment* and that such conditions were *relied upon* by the investor *when deciding to invest*.<sup>904</sup>

792. As the Tribunal in *Sempra* noted:

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*.<sup>905</sup>

793. Even the *Tecmed* Tribunal comments were with reference to "...international investments treatment that does not affect the basic expectations that were taken into account by the foreign investor *to make the investment*".<sup>906</sup>

**b) The Claimant could not legitimately expect that a "stand-still" obligation existed respecting regulation of lindane**

794. The facts of this case illustrate perfectly why a general "stand-still" obligation cannot be part of the minimum standard of treatment contained in Article 1105. In the regulatory framework at issue here, Chemtura was well aware that the appreciation of its product by the domestic regulator could change, based among other things on the evolution of science, emerging information regarding the negative effects of a pesticide, and shifts in public tolerance for the use of chemicals.

795. The Claimant never suggests that Chemtura Canada was "guaranteed" that the regulatory environment under which it would operate would be frozen or that any

<sup>904</sup> *Enron Corporation Ponderosa Assets, L.P. v. Argentine Republic* (ICSID No. ARB/01/3) Award (22 May 2007), ¶ 262 (Annex R-184) (emphasis added).

<sup>905</sup> *Sempra Energy International v. Argentina* (ICSID No. ARB/02/15) Award, (26 September 2007), ¶ 299 (Annex R-274). The *LG&E* Tribunal similarly noted: "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 investment*..." *LG&E Energy Corp. LG&E Capital Crop. and LG&E International Inv. v. Argentina* (ICSID No. ARB/02/1) Decision on Liability (3 October 2006), ¶ 130 (Annex R-219). The Tribunal in *Occidental – Award*, ¶ 191 caveated its own comments on the content of "fair and equitable treatment" as specific to promises made at the time the investment was made: "... there is certainly an obligation not to later the legal and business environment in *which the investment was made*. In this case, it is the latter question that triggers a treatment that is not fair and equitable." (Annex R-249). Finally, in the context of the NAFTA, the Tribunal in *GAMI – Final Award*, ¶ 93, noted that "NAFTA arbitrators have no mandate to evaluate laws and regulations that predate the decision of a foreigner to invest." (Annex R-196).

<sup>906</sup> *Tecmed – Award*, ¶ 154 (Annex R-285) (our emphasis).

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promises were made concerning the longer-term registrability of lindane. To the contrary, the Claimant's Canadian subsidiary was heavily regulated from the start and operated in a regulatory environment where the registration of any particular pesticide was subject to ongoing review and approval by the Minister, which could be withdrawn. The sale of pesticides in Canada is always "on sufferance" and may be revoked where the Minister no longer believes that continuing registration is of value to the Canadian public, based on a variety of factors, including health and environmental considerations. The Claimant knew this at all times.

796. It is clear that the Claimant was aware of the increasing restrictions placed on lindane in the 1990s. In its 1996 10-K, Chemtura refers to U.S. Congressional action limiting pesticide residues on food and increasing consumer safety. The Claimant also recognized that the EPA was required to review all tolerances for all pesticides within 10 years. Chemtura was also aware that the EC was in the process of reviewing all existing active ingredient pesticides. Further, the Claimant was aware of increasingly strict environmental, health and safety laws and their enforcement. It expected stricter requirements to put into question the handling, manufacture, use, emission and disposal of certain products that may result in the modification, reduction or suspension of certain operations.<sup>907</sup>

797. Moreover, any "expectation" on Chemtura's part for a continuing positive review of lindane would be unreasonable, given the mounting international action against the chemical during the 1990s and 2000s.

798. In conclusion, no "stand-still" obligation exists under Article 1105, nor does the concept of "legitimate expectations" incorporate such an obligation. "Legitimate expectations" have only been recognized under certain conditions which do not exist in this case, namely:

- The alleged "expectations" were not based on pre-investment conditions;

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<sup>907</sup> *Navigant Report*, Exhibit NCI-6.

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- The alleged “expectations” were not based on representations or commitments by the State; and
  - The Claimant did not rely on any such representations or commitments when investing.

**c) The July 1, 2001 deadline for withdrawal was universally acknowledged**

799. The Claimant’s factual allegations regarding its alleged “legitimate expectations” are without merit.<sup>908</sup>

800. Chemtura points to no specific undertakings made by Canada at any time inducing the launch of a lindane product line. The only reasonable expectation the Claimant could have, in a highly regulated industry, was that the conditions permitting the sale of its product in Canada might change.

801. Chemtura’s allegations of disappointed “expectations” are based on its own subjective understanding of exchanges between itself and the PMRA concerning the VWA. These exchanges came in 1998-1999, decades after the start of Chemtura Canada’s activities in Canada, including the launch of its lindane products in the 1970s. The alleged “commitments” relating to the VWA were not an inducement to invest, but, rather, an attempt to address the market crisis generated by the Claimant itself, through its U.S. subsidiary. The PMRA acted consistently with the VWA by facilitating the phase-out of lindane and reviewing replacement products in accordance with the stakeholders’ agreement. To the extent Chemtura had an opportunity to re-instate its product, the fundamental conditions for that reinstatement (notably, positive safety reviews for lindane use on canola) were never met.

802. The first of the Claimant’s alleged “expectations” concerned the end-date for lindane use, under the VWA, and actions by the PMRA to “enforce” this agreed deadline.<sup>909</sup> On both fronts, the Claimant’s allegations are unfounded.

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<sup>908</sup> Claimant’s Memorial, ¶¶ 384 ff.

<sup>909</sup> Claimant’s Memorial, ¶¶ 388-394.

803. The deadline of July 1, 2001 to cease both sales of lindane treatment, and use of lindane-treated seeds, was established in the VWA from the start.<sup>910</sup> The date was acknowledged in writing by stakeholders in the VWA, and thereafter repeatedly recalled over the course of 1999.<sup>911</sup> Contrary to the Claimant's allegations, the date of July 1, 2001 for cessation of use of both lindane treatment and lindane-treated seed made perfect sense: the last date for planting treated seed was typically June of any given year. It was reasonable for the last date of a three-year phase-out to fall just after the planting season.<sup>912</sup> To say in this context that "there was no suggestion of any restriction on the sale of treated seed or the planting of such seed" after July 1, 2001<sup>913</sup> is at best, wilful blindness on the Claimant's part.

804. Rather than being in any way confused about the July 1, 2001 deadline, Chemtura's senior executives instead repeatedly sought to deliberately alter that date. They did so reckless to the potential consequences to Chemtura's own clients, the canola industry, and in violation of Chemtura's undertakings. Moreover, the end-date of July 1, 2001 was confirmed in the CCC memorandum of October 29, 2001, and again in the PMRA's letters in connection with the voluntary suspension of regulations that came shortly thereafter<sup>914</sup>. The Claimant never wrote back denouncing these reiterations of what had been clear all along. Contrary to the Claimant's suggestion, all four registrants respected the July 1, 2001 date.

805. The Claimant also misstates the statutory basis of its partial registration amendment and related label change (relying on section 16, *PCPR* rather than 13), to

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<sup>910</sup> Letter from Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, CCGA, to Dr. Claire Franklin, Executive Director, PMRA, 26 November 1998 (Exhibit JB-9).

<sup>911</sup> See e.g. Letter from Claire Franklin, Executive Director, PMRA, to Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, CCGA, 9 February 1999 (Exhibit WS-25); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 23 December 1999 (Exhibit WS-48).

<sup>912</sup> Affidavit of JoAnne Buth, ¶ 71.

<sup>913</sup> Claimant's Memorial, ¶ 391.

<sup>914</sup> Memorandum from JoAnne Buth to lindane product registrants, 29 October 1999 (Exhibit WS-42); Letter from Dr. Claire Franklin, Executive Director, PMRA, to Alfred Ingulli, Executive Vice President, Uniroyal (predecessor-in-title to Chemtura Canada), 23 December 1999 (Exhibit WS-48).

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wrongly suggest that the three-year phase-out period agreed to under the VWA was unexpectedly imposed.<sup>915</sup> Yet its own submission to the PMRA in 1999 requesting the voluntary label change referenced section 13 of the Regulations, as did the PMRA's responses. In any event, under the VWA the Claimant was allowed a full three-year phase-out period for lindane use on canola. This certainly would have been enough to "exhaust" stocks, and compares favourably to the case of DEET the Claimant cites.<sup>916</sup>

806. In sum, the Claimant's argument that the July 1, 2001 date was somehow an "additional restriction unilaterally imposed" by the PMRA (or otherwise) after October 1999<sup>917</sup> is patently false.

807. The Claimant's attempt to argue PMRA's alleged "enforcement" action breached its expectations is also without substance.

808. In stating that its sales of lindane products "virtually ceased in the spring of 2001",<sup>918</sup> the Claimant is also failing to inform the Tribunal that in the typical planting year, purchases of lindane seed mainly take place over the winter and are applied to seed that is planted from spring to early summer.<sup>919</sup> The sales pattern in 2001 was exactly what one should expect in any typical year. Additionally, due to drought and the dropping price of canola, fewer acres of canola were planted in 2001, leading to a reduced demand for pesticide products for canola from farmers.<sup>920</sup> This had nothing to do with any alleged "enforcement" action on the part of Canada.

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<sup>915</sup> Claimant's Memorial, ¶ 393.

<sup>916</sup> The Claimant refers to cases of voluntary withdrawal where use has been extended. Claimant's Memorial, ¶ 393. This comparison is wrong on at least two levels. In the first place, these cases were not, as in the case of lindane under the VWA, ones of partial deregistration. More importantly (as is obvious on the face of the cited examples), they were cases where replacement products were not yet available. Yet by July 1, 2001 the PMRA had registered the Claimant's Gaucho product, among others. See Affidavit of Suzanne Chalifour, ¶ 30.

<sup>917</sup> Claimant's Memorial, ¶ 389.

<sup>918</sup> Claimant's Memorial, ¶ 394.

<sup>919</sup> Affidavit of JoAnne Buth, ¶ 71.

<sup>920</sup> Affidavit of JoAnne Buth, ¶ 70.

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809. The Claimant should in any event have expected canola farmers to begin transitioning away from the use of lindane over the course of the 1999-2001 growing seasons. The CCC had been informing its members of the phase-out plan since 1998, and recalling the end-date of July 1, 2001.<sup>921</sup> The Claimant was unreasonable in its approach to the repeatedly-confirmed “phase-out” by July 1, 2001. The Claimant appears to have approached 1999-2001 as a “max-out” period: producing and selling as much of its lindane product in these years as it possibly could. The Claimant has provided no evidence of any efforts it made during this period to market its replacement product, Gaucho.

810. Canada has demonstrated that the PMRA in no way threatened canola sellers with fines or otherwise dissuaded growers from using lindane during the VWA phase-out period. The PMRA did not even include lindane in its compliance plans for the 1999 and 2000 seasons.<sup>922</sup> In the 2001 season, the PMRA publicly implemented a compliance review aimed at monitoring the amounts of lindane treatment product and lindane-treated seeds that might be left over after July 1, 2001.<sup>923</sup> It hoped in this way to determine whether there was a disposal issue to be addressed. The PMRA's presence would also provide limited dissuasion against stockpiling.

811. It is commonly known among growers that PMRA only exercises its statutory right to prosecute in extremely limited and egregious circumstances, and indeed has only limited powers to impose fines.<sup>924</sup> The Claimant's suggestion that Canadian canola farmers were “very concerned” about potential imposition of fines has no basis.<sup>925</sup> The

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<sup>921</sup> Affidavit of JoAnne Buth, ¶ 70.

<sup>922</sup> Affidavit of Jim Reid, ¶ 27.

<sup>923</sup> National Pesticides Compliance Program, Final Report, Lindane Seed Treatment Use on Canola (Program 2409), 2001 (Exhibit JR-13).

<sup>924</sup> Affidavit of Jim Reid, ¶ 23.

<sup>925</sup> Claimant's Memorial, ¶ 390.

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national representative of Canada's canola industry stakeholders has expressly debunked the Claimant's allegation.<sup>926</sup>

812. Finally, the debate about the use of lindane-treated canola seed after July 1, 2001, became a moot point. After confirming amounts of lindane-treated seed left over after July 1, 2001, the PMRA determined that the best course of disposal was to extend use of these seeds into the 2002 planting season.

**d) The PMRA issued its scientific assessment in good time**

813. The Claimant's alleged expectations concerning release of the PMRA's scientific assessment are equally unfounded.<sup>927</sup>

814. As of the date of the VWA (November 24, 1998), when the conditions of the voluntary withdrawal of lindane use on canola were confirmed between canola farmers and lindane producers, the PMRA's Special Review of lindane had not even been publicly announced. It thus necessarily could not have been part of the alleged "conditions" the Claimant now cites for that agreement.

815. Moreover, when the PMRA's Special Review of lindane was actually announced on March 15, 1999, the PMRA carefully noted that December 2000 was simply the "target date" for completion of its review.<sup>928</sup> Again at the canola stakeholders' meeting of June 24, 1999, the date was announced as a "target".<sup>929</sup> The "target" for completion was recalled in a registrant teleconference of October 22, 1999.<sup>930</sup>

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<sup>926</sup> Affidavit of JoAnne Buth, ¶¶ 63-68.

<sup>927</sup> Claimant's Memorial, ¶¶ 395-400.

<sup>928</sup> PMRA, Special Review Announcement SRA99-01, Special Review of Pest Control Products Containing Lindane, 15 March 1999 (Exhibit WS-32) (PMRA Special Review Announcement SRA099-01).

<sup>929</sup> Minutes of meeting organized by CCC/CCGA to monitor implementation of the VWA and progress on lindane replacements. 24 June 24 1999 (Exhibit WS-29).

<sup>930</sup> Affidavit of Wendy Sexsmith, ¶ 95.



816. Each time the Claimant sought to extract preferential terms from the PMRA in relation to the VWA (in December 1998, in March 1999, and again in early October 1999), the Claimant never mentioned the Special Review of lindane as a “condition”.<sup>931</sup>

817. Picking up on the PMRA’s comment of October 22, 1999, the Claimant suddenly noted in its letter of October 27, 1999 that the Special Review was to be completed by the end of 2000, on a collaborative basis with the U.S. EPA.<sup>932</sup> In the context of the PMRA’s repeated assertions that late 2000 was a “target” date, and knowing that the PMRA’s timing relied on elements beyond its control (notably, the pace of the EPA’s parallel review), any subjective expectation that this date was set in stone was unreasonable at best.

818. The PMRA pursued its review of lindane in good faith as of 1999, devoting substantial resources in the expectation that the review would be completed by late 2000.<sup>933</sup> The PMRA was delayed in issuing its results principally due to its work-sharing approach with the EPA.

819. Moreover, the Claimant’s expectations regarding the outcome of the Special Review in 2000 were themselves deeply unreasonable. The Claimant argues that “once a proper assessment had been completed”, it was “confident that the Lindane Products would be accepted for use on canola...”.<sup>934</sup> As Canada has point out, the Special Review of lindane was taking place in a context in which lindane use had already been restricted

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<sup>931</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) and Bill Hallatt, Product Development Manager, Gustafson Partnership (business entity of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 17 December 1998 (Exhibit WS-19); Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 2 March 1999 (Exhibit WS-27). Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to Dr. Claire Franklin, 10 October 1999 (Exhibit WS-30).

<sup>932</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 27 October 1999 (Exhibit WS-40).

<sup>933</sup> Canada did not wait until after July 1, 2001 to devote resources to the Special Review, as the Claimant alleges at ¶ 398: *see* Affidavit of Cheryl Chaffey, ¶ 72.

<sup>934</sup> Claimant’s Memorial, ¶ 395.

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or banned in many countries; in which most uses of lindane had already been banned or otherwise discontinued in Canada; and when lindane had been targeted for elimination internationally.<sup>935</sup> By the late 1990s, lindane was (with good reason) literally under siege. The Claimant's "confidence" in a positive outcome of the lindane review was entirely misplaced.

820. There is no evidence that, had the PMRA been able to complete the Special Review any earlier, its outcome would have been any different. The slight delay to the issuance of the PMRA's Special Review results caused the Claimant no prejudice whatsoever. Had the PMRA issued its results earlier, the Claimant's lindane products would simply have come under general ban in 2001, rather than in 2002. The Claimant's speculations on what "would have happened" in the case of an earlier result are based on a false premise.<sup>936</sup>

**e) The PMRA terminated the Claimant's registrations based on a scientific review, in accordance with Canadian law**

821. The Claimant further alleges that its expectations were disappointed in that the PMRA suspended its lindane registrations in February 2002 "without first conducting a proper scientific assessment."<sup>937</sup> The Claimant's statement is once again incorrect. As Canada has demonstrated, the PMRA did indeed conduct a "proper" scientific review of lindane under the Special Review, consistent with its re-evaluation policies, and deploying substantial resources.<sup>938</sup> It did so in collaboration with the EPA as the Claimant demanded and gave the Claimant the opportunity to participate in a manner consistent with its re-evaluation policies – an opportunity which, according to the Board of Review, the Claimant failed to exploit.<sup>939</sup>

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<sup>935</sup> Affidavit of Cheryl Chaffey, ¶¶ 41-55.

<sup>936</sup> Claimant's Memorial, ¶¶ 399-400.

<sup>937</sup> Claimant's Memorial, ¶ 401 ff.

<sup>938</sup> Affidavit of Cheryl Chaffey, ¶¶ 58-98; Affidavit of John Worgan, ¶ 33-139.

<sup>939</sup> Board of Review Report, ¶¶ 109-110 (Exhibit WS-71).

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822. The Special Review reached conclusions which, even after intense scientific attack by the Claimant before the Board of Review, were deemed within acceptable scientific parameters.<sup>940</sup> The Board of Review's alleged "criticisms" of the Special Review in fact reflected different degrees of emphasis within the four corners of a reasonable scientific debate.<sup>941</sup>

823. The PMRA demonstrated its good faith by taking account of the Board of Review's comments in an extensive, *de novo* review of lindane. This extensive effort simply confirmed the correctness of the PMRA's decision in 2001. In the meanwhile, the EPA had effectively endorsed the PMRA's position, and lindane had been further banned in other major jurisdictions, such as the European Union.<sup>942</sup>

824. From the initial launch of the Special Review in March 1999, and throughout 1999, the PMRA confirmed that "all uses" of lindane were ultimately subject to the results of the Special Review.<sup>943</sup> This point was reiterated in the parties' June 1999 meeting and in the PMRA's letters of October 1999 to the Claimant.<sup>944</sup> All three of the other registrants sent letters to the PMRA in November 1999 confirming that the reinstatement of lindane use on canola would be subject to the results of the Special

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<sup>940</sup> Board of Review Report, ¶ 115 (Exhibit WS-71).

<sup>941</sup> Affidavit of Cheryl Chaffey, ¶ 131.

<sup>942</sup> Regulation EC No 850/2004 of the European Parliament and the Council, on Persistent Organic Pollutants and amending directive 79/117/EEC, 29 April 2004 (Exhibit CC-41).

<sup>943</sup> PMRA Special Review Announcement SRA099-01 (Exhibit WS-32).

<sup>944</sup> Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 8 October 1999 (Exhibit WS-33); Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 15 October 1999 (Exhibit WS-36); Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 21 October 1999 (Exhibit WS-38); Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 28 October 1999 (Exhibit WS-41).

Review.<sup>945</sup> The Claimant is the only party that allegedly believed the contrary. This subjective impression cannot form the basis of a legal obligation.

825. Moreover, the Claimant's complaints about the consequences of the Special Review – the cessation of its product registrations in February 2002 – cannot be reconciled with its own admission that it rejected the extended phase-out period offered to it by the PMRA in December 2001.<sup>946</sup> Notwithstanding its decision to seek review of the PMRA's decision on scientific grounds, it was patently unreasonable for the Claimant to throw over the phase-out opportunity offered to it by the PMRA. As the Claimant notes, other registrants of lindane were offered the phase-out opportunity on the same terms the PMRA had proposed to the Claimant, and took advantage of that offer.<sup>947</sup> To provide this opportunity in light of its Special Review findings was consistent with the PMRA's statutory mandate and in particular, the provisions of Section 16 of the Regulation. The Claimant has itself cited other examples of similar phase-outs.<sup>948</sup> The only reason the Claimant did not also enjoy that opportunity was because it refused the PMRA's offer, in full knowledge of the consequences.<sup>949</sup>

826. The Claimant returns to its selective quotation of the Board of Review's findings concerning the Special Review,<sup>950</sup> in an attempt to discredit the science applied in the Special Review. The Claimant relies on two proposals, an occupational health study and additional safety measures, which were first introduced during the Board of Review process. Thus, it would have been impossible for the PMRA to rely on such information as it was unavailable at the initial review. In any event, the new information was taken

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<sup>945</sup> Letter from John Kelly, Rhône-Poulenc Canada Inc., to Wendy Sexsmith, PMRA, 1 November 1999 (Exhibit WS-44); Letter from Don Wilkinson, Manager, Regulatory Affairs, IPCO, to Roy Lidstone, PMRA, 1 November 1999 (Exhibit WS-45); Letter from Roy Lee Carter, Cereals and Oilseed Lead, Zeneca, to Dr. Claire Franklin, Executive Director, PMRA, 29 October 1999 (Exhibit WS-43).

<sup>946</sup> Claimant's Memorial, ¶¶ 403-404.

<sup>947</sup> Claimant's Memorial, ¶ 406.

<sup>948</sup> Claimant's Memorial, ¶ 393.

<sup>949</sup> Letter from Rob Dupree, Crompton Canada (predecessor-in-title to Chemtura Canada) to Janet Taylor, PMRA, 28 January 2002 (Exhibit WS-62).

<sup>950</sup> Claimant's Memorial, ¶ 407.

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into account by the PMRA in the REN.<sup>951</sup> The conclusions it reached merely confirmed the correctness of its October 2001 decision.

827. In sum, the PMRA's decision to ban lindane was taken on a legitimate scientific basis, consistent with PMRA re-evaluation policy and based on a valid and resource-intensive scientific review, which the PMRA willingly submitted to the scrutiny of an expert Board of Review. To the extent that Board suggested the PMRA could have taken additional factors into account, the PMRA did so in a completely new review, which merely confirmed the PMRA's original decision.

**f) The PMRA reviewed lindane replacements in a manner consistent with its limited undertakings**

828. The Claimant's alleged expectations regarding the review of replacement products rely on misstatements of the PMRA's undertakings in this regard, all of which the PMRA respected.<sup>952</sup>

829. As Canada has demonstrated, at the time the VWA was concluded in November 1998, the PMRA was careful not to commit in advance either to the timing or to the ultimate approval of lindane replacement products, beyond a limited commitment to review "lindane free" formulations, *i.e.* existing products in which the lindane active would simply be removed leaving a fungicide alone.<sup>953</sup> In subsequent correspondence, the PMRA reiterated that it could not commit to specific dates or outcomes for the review of the Claimant's proposed lindane replacement products.<sup>954</sup> The PMRA in fact registered the Claimant's "lindane-free" product by May 1999.<sup>955</sup>

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<sup>951</sup> Affidavit of John Worgan, ¶¶ 199-207.

<sup>952</sup> Claimant's Memorial, ¶ 409.

<sup>953</sup> Affidavit of Wendy Sexsmith, ¶ 45.

<sup>954</sup> Letter from Dr. Claire Franklin, PMRA to Gene Dextrase, President and Bruce Dalgarno, Past President, CCGA, 9 February 1999 (Exhibit WS-25); Letter from Dr. Claire Franklin, PMRA to Tony Zatylny, CCC, 23 February 1999 (Exhibit WS-26); and Letter from Dr. Claire Franklin, PMRA to Alfred Ingulli, Uniroyal, 25 March 1999 (Exhibit WS-28); Affidavit of Wendy Sexsmith, ¶¶ 25,40, 57, 62, 69.

<sup>955</sup> Affidavit of Suzanne Chalifour, ¶ 22.

830. By November 1999, the PMRA had granted conditional approval to the submitted formulations of Chemtura's lindane-replacement product Gaucho.<sup>956</sup> Disregarding the PMRA's fulfillment of its undertaking, Chemtura insisted that the PMRA should commit to approving products it had not even submitted to the PMRA.<sup>957</sup> The PMRA rejected this suggestion, and in the letters that followed, the Claimant abandoned its demand – its letter of October 27, 1999 notably fails to make any reference to the timing or outcome of replacement product registrations.<sup>958</sup>

831. Chemtura's allegation that it had "made it clear that it required an expedited registration of an all-in-one lindane product replacement" as a "condition" for its adherence to the VWA ignores the above facts.<sup>959</sup> There is no basis for the Claimant's allegation that it "expected" expedited review within three months. Indeed, the Claimant's own contemporaneous evidence contradicts the notion that this was its true "expectation" at the time.<sup>960</sup> When it eventually partially submitted its "all-in-one" Gaucho CS FL (insecticide / fungicide) formulation, in March 2000, the Claimant's comments suggested it expected a six-month review process at the fastest.<sup>961</sup> After a meeting with the PMRA in early October 2000, the Claimant conceded its misunderstanding in anticipating "fast track" for this late-submitted formulation.<sup>962</sup>

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<sup>956</sup> Affidavit of Suzanne Chalifour, ¶ 29.

<sup>957</sup> Letter from Alfred Ingulli, Executive Vice President, Uniroyal Chemical (Predecessor-in-title of Chemtura Canada) to Dr. Claire Franklin, Executive Director, PMRA, 1 October 1999 (Exhibit WS-30).

<sup>958</sup> 18 October 1999 (Exhibit WS-37); 21 October 1999 (Exhibit WS-39); 26 October 1999 (Exhibit WS-40). The Claimant complains that these registrations were "temporary" (Claimant's Memorial ¶ 247) but fails to note that this was standard PMRA procedures (affecting the Helix registrations as well) that did not prevent the Claimant from marketing its product and that all registrations have been made temporary, pending steps to be taken following the coming into force of the PCPA (2002): *See* Affidavit of Suzanne Chalifour, ¶¶ 50, 78.

<sup>959</sup> Claimant's Memorial, ¶ 411.

<sup>960</sup> Letter from Bill Hallatt, Gustafson (a business unit of Chemtura), to Dr. Claire Franklin, Executive Director, PMRA, 29 April 1999 (Exhibit WS-35); Affidavit of Wendy Sexsmith, ¶ 72.

<sup>961</sup> Affidavit of Suzanne Chalifour, ¶ 62; Letter from Adam Vaughan, Gustafson Partnership (business unit of Chemtura Canada), to PMRA, 21 March 2000 (Exhibit SC-23).

<sup>962</sup> Letter from Rick Turner, President, Gustafson Partnership (business unit of Chemtura Canada), to Wendy Sexsmith, PMRA, 6 October 2000 (Exhibit SC-28).

832. The Claimant's further expectations regarding the registration of Gaucho CS FL are equally unfounded.<sup>963</sup> The fundamental point is that the Claimant submitted this formulation only in March 2000.<sup>964</sup> Even then, the Claimant failed to submit a complete data package for this formulation until the autumn of 2000.<sup>965</sup> By contrast, Syngenta's Helix product was submitted for review by the PMRA in 1998. By the time Gaucho CS FL was entirely before the PMRA, Helix had already been under review for two years. Yet Chemtura (unreasonably) expected its late-submitted application to be reviewed and approved *before* Helix.

833. As for alleged "unfair" registration advantages granted to Syngenta's Helix, this allegation is belied by the fact that the PMRA registered the Claimant's submitted "simple" formulations of Gaucho (the only ones the Claimant had actually submitted to that point) by November 1999, over a year before Helix.<sup>966</sup> The Claimant was in this way offered a significant first-to-market advantage. Gaucho's reception in the Canadian canola market is not within the PMRA's control.<sup>967</sup> As Canada has shown, each and every one of the alleged "preferential advantages" offered to Syngenta in the Helix registration process was either standard procedure, or was provided to the Claimant as well.<sup>968</sup> This entire process took over two years. This is hardly evidence of "preferential" treatment.

834. In summary, the facts concerning Chemtura's allegedly thwarted "expectations" occurred decades after its investment in Canada. The concept of "reasonable expectations" therefore cannot apply, even if that concept is reflected the customary international minimum standard of treatment, which it is not. Moreover, close

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<sup>963</sup> Claimant's Memorial, ¶ 412 ff.

<sup>964</sup> Affidavit of Suzanne Chalifour, ¶¶ 33-34; Letter from Adam Vaughn, Gustafson, to PMRA, 21 March 2000 (Exhibit SC-23).

<sup>965</sup> Affidavit of Suzanne Chalifour, ¶ 37.

<sup>966</sup> See Affidavit of Suzanne Chalifour, ¶¶ 52-56.

<sup>967</sup> Affidavit of JoAnne Buth, ¶ 31; Affidavit of Suzanne Chalifour, ¶ 47.

<sup>968</sup> See generally Affidavit of Suzanne Chalifour, ¶¶ 64-84.

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examination of Chemtura's "expectations" confirms that they were in each case subjective, unreasonable and unfounded.

**5. The customary international minimum standard does not include a requirement of "total transparency"**

**a) There is no such requirement under Article 1105**

835. The Claimant further attempts to rely on non-Chapter 11 decisions to import into Article 1105 a requirement of "total transparency" as articulated by the *Tecmed* Tribunal.<sup>969</sup> That alleged requirement bears no relation to the customary international minimum standard of treatment, and is irrelevant to Article 1105.

836. The Claimant's suggestion that transparency has been recognized as an element of fair and equitable treatment by arbitral tribunals<sup>970</sup> begs the question of the relevance of such findings to the analysis of the minimum standard of treatment under Article 1105. The arbitral awards the Claimant cites in support of this proposition all, with the exception of *Metalclad*, come from outside the Article 1105 minimum standard of treatment / customary international law context.<sup>971</sup> The Claimant has entirely failed to prove that transparency forms part of the minimum standard of treatment at customary international law.

837. As for *Metalclad*, this case was decided before the Note of Interpretation. Moreover, the Claimant fails to note that the decision was expressly set aside on this very point. Justice Tysoe of the B.C. Supreme Court partly overturned the *Metalclad* Tribunal on the ground that it exceeded the scope of Chapter 11. Justice Tysoe specifically held that the so-called transparency obligation was not part of customary international law and was not covered by Article 1105:

On my reading of the Award, the Tribunal did not simply interpret Article 1105 to include a minimum standard of transparency. *No*

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<sup>969</sup> Claimant's Memorial, ¶ 360.

<sup>970</sup> Claimant's Memorial, ¶ 361.

<sup>971</sup> Claimant's Memorial, ¶ 362 and note 299.



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*authority was cited or evidence introduced to establish that transparency has become part of customary international law. (...).*<sup>972</sup>

In the present case, however, the Tribunal did not simply interpret the wording of Article 1105. Rather, it misstated the applicable law to include transparency obligations and it then made its decision on the basis of the concept of transparency.<sup>973</sup>

838. Justice Tysoe also expressly stated that no transparency obligation exists under NAFTA Chapter 11. To the contrary, transparency is covered under Chapter 18 (Publication, Notification, and Administration of Laws) of the NAFTA,<sup>974</sup> which is not part of the investor-State dispute settlement provisions under the NAFTA.

839. Justice Tysoe's partial set-aside was pursuant to NAFTA Article 1136(3), authorizing review of final awards under applicable (domestic) legislation rendered in cases applying the UNCITRAL or ICSID Additional Facility Rules; such set-aside decisions are persuasive guidance.

#### **b) Canada in any event acted transparently**

840. The Claimant's suggestion that its treatment lacked transparency<sup>975</sup> is in any event baseless.

841. The Claimant first relies on the end-date for lindane use as an example of the alleged "lack of transparency". The July 1, 2001 deadline was established in the VWA as confirmed by the CCGA's November 26, 1998 letter, and reiterated time and again. The Claimant's suggestion that this date was somehow "imposed" by the PMRA after the fact in an arbitrary manner or at all, is flatly contradicted by the documented history of this matter.

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<sup>972</sup> *Metalclad – Set Aside*, ¶ 68 (emphasis added) (Annex R-234).

<sup>973</sup> *Metalclad – Set Aside*, ¶ 70 (Annex R-234).

<sup>974</sup> *Metalclad – Set Aside*, ¶¶ 71-72 (Annex R-234).

<sup>975</sup> Claimant's Memorial, ¶ 434 ff.

842. The PMRA was equally transparent in its consideration of replacement products.<sup>976</sup> The PMRA was clear that it could not make specific commitments as to the outcome of its reviews, that it did not have endless resources to review replacement products, and that it would therefore review the first three replacement actives submitted to it in priority.<sup>977</sup>

843. The PMRA's processes for registration of replacement products were also made clear to stakeholders as they progressed.<sup>978</sup> The Claimant's only specific argument in this regard is that the PMRA has not yet issued a Regulatory Decision Document for Helix or Helix XTra.<sup>979</sup> Yet Regulatory Decision Documents are only issued when a product is eligible for permanent registration. Helix, like many other products, has not yet entered that process. When the new *PCPA* came into force in 2006, all temporary registrations were transferred to conditional registrations. At that time, the conditions of registration were posted on the internet, and PMRA began to systematically review these registrations to determine if they meet the conditions attached to them. Syngenta has applied to have the Helix registration converted from Conditional to Full.<sup>980</sup>

844. Both the Regulatory Note concerning the delay of Helix registration,<sup>981</sup> and the Note that was issued when Helix was temporarily registered<sup>982</sup> are publicly available and comprehensive documents that explain a great deal about the decisions taken in this process, and the reasons behind them.<sup>983</sup>

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<sup>976</sup> Claimant's Memorial, ¶ 438.

<sup>977</sup> Affidavit of Wendy Sexsmith, ¶ 82; Letter from Dr. Claire Franklin, Executive Director, PMRA, to Tony Zatylny, CCC, 23 February 1998 (Exhibit WS-26).

<sup>978</sup> Minutes of meeting organized by CCC/CCGA to monitor implementation of the VWA and progress on lindane replacements, 24 June 1999 (Exhibit WS-29).

<sup>979</sup> Claimant's Memorial, ¶ 438.

<sup>980</sup> Affidavit of Suzanne Chalifour, ¶ 82.

<sup>981</sup> PMRA Regulatory Note Reg2000-01, *Delay on Helix Registration Decision*, 16 February 2000 (Exhibit SC-42).

<sup>982</sup> PMRA Regulatory Note REG2001-03, *Thiamethoxam, Helix, Helix XTra*, 9 February 2001 (Exhibit SC-45).

<sup>983</sup> See for e.g., Affidavit of Suzanne Chalifour, ¶¶ 85-88.

845. The Special Review of lindane<sup>984</sup> itself proceeded in accordance with the PMRA's general re-evaluation policy, which was publicized for comment in the same year as the launch of the Special Review.<sup>985</sup> The Special Review was publicly announced on March 15, 1999.<sup>986</sup> The PMRA in addition held a two-day meeting with the Claimant within weeks of the launch of the Special Review, to discuss its procedure, concerns and expected schedule. The Claimant's own witness Mr. Johnson noted at the time of this meeting:

In summary, the PMRA staff was very open in the discussion and interested in our presentations on data and canola tolerance. We will be able to maintain an open relationship and dialogue with them as the special review proceeds.<sup>987</sup>

846. The Board of Review found that Chemtura subsequently failed to adequately follow the Special Review process.<sup>988</sup>

847. The Claimant and the PMRA's Executive Director, Dr. Claire Franklin, met to discuss the Special Review on October 4, 2000, over a year before the ultimate release of the Special Review results.<sup>989</sup> At this meeting, the PMRA raised specific concerns regarding occupational safety data, giving the Claimant the opportunity to submit further data.<sup>990</sup> The Claimant in response encouraged the PMRA to rely on its 1992 Dupree

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<sup>984</sup> Claimant's Memorial, ¶ 437.

<sup>985</sup> PMRA, Regulatory Proposal PRO99-01, *A New Approach to Re-evaluation*, 3 December 1999 (Exhibit JW-7); Affidavit of John Worgan, ¶¶ 33-72.

<sup>986</sup> PMRA Special Review Announcement SRA099-01, 15 March 1999 (Exhibit WS-32).

<sup>987</sup> Edwin Johnson notes from meeting with PMRA, 11 May 1999 (Exhibit CC-23).

<sup>988</sup> Crompton and The Minister of Health as Represented by PMRA and The Sierra Club of Canada, Report of the Lindane Board of Review, ¶¶ 110 & 111, 17 August 2005 Exhibit JW-26D, ¶ 109-110.

<sup>989</sup> Affidavit of Dr. Claire Franklin, ¶ 24.

<sup>990</sup> As confirmed by Mr. Ingulli's handwritten meeting, 4 October 2000 (Exhibit CF-12); and Letter from Rob Dupree, Uniroyal Chemical (predecessor-in-title to Chemtura Canada) to Janet Taylor, PMRA, 6 October 2000 (Exhibit CF-10).

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study – although it later criticized the PMRA for doing so – failing to submit any new data.<sup>991</sup>

848. The PMRA also invited comments at the end of the Special Review, and took them into consideration before confirming its conclusions.<sup>992</sup>

849. In response to the Claimant's further complaints, the PMRA organized a Board of Review process at which the Claimant's further evidence (which it had failed to generate during the Special Review) was given a full and complete hearing.<sup>993</sup>

850. The PMRA thereafter engaged in a further re-evaluation of lindane, according to a publicly announced process.<sup>994</sup> This re-evaluation among other things took account of the additional information the Claimant had submitted (for the first time) before the Board of Review. The results of its re-evaluation were released in April 2008, at which time the PMRA again requested comments of the Claimant.<sup>995</sup> The Claimant delivered such comments, and the PMRA took them into consideration and provided a reply in writing, proposing a meeting in person with the Claimant.<sup>996</sup>

851. All of these actions took place in accordance with the PMRA's publicly available statutes, regulations, and review procedures.<sup>997</sup> It is difficult to imagine how more transparency could have been offered. That said, the level of transparency by PMRA throughout more than meets Canada's international obligations.

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<sup>991</sup> Letter from Rick Turner, President, Gustafson Partnership (business unit of Chemtura Canada), to Wendy Sexsmith, PMRA, 6 October 2000 (Exhibit CF-16); Claimant's Memorial ¶ 195.

<sup>992</sup> Affidavit of John Worgan, ¶¶ 159-165; *see also* Exhibit JW-24; Exhibit JW-25; Exhibit JW-26; Exhibit JW-26A; Exhibit JW-26B; and Exhibit JW-26C.

<sup>993</sup> Affidavit of Wendy Sexsmith, ¶¶ 176-179.

<sup>994</sup> Affidavit of John Worgan, ¶¶ 185-238.

<sup>995</sup> PMRA, Re-Evaluation Note REV2008, *Draft Lindane Risk Assessment*, 14 April 2008 (Exhibit JW-92).

<sup>996</sup> Letter from John Worgan, Director General, Re-evaluation Management Division, PMRA to Patricia Turner, Registration Specialist, Chemtura Canada, 6 August 2008 (Exhibit JW-97).

<sup>997</sup> Affidavit of John Worgan, ¶¶ 25-28.

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**IV. ARTICLE 1103 – THE CLAIM UNDER ARTICLE 1103 IS NOT PROPERLY BEFORE THE TRIBUNAL, ERRS IN LAW AND FAILS ON THE FACTS**

**A. Summary of Canada's position**

852. Chemtura's Article 1103 claim must be dismissed for three reasons:

*First*, Canada never consented to arbitrate this claim, which has been pleaded for the first time in Chemtura's Memorial.

*Second*, the Claimant fails to establish any of the legal elements necessary for breach of Article 1103. In particular, it fails to prove that a "treatment" was accorded, that the treatment was "with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments," that such treatment was accorded "in like circumstances," and that it was "less favourable" than the treatment accorded to investors or investments of a non-Party.

*Third*, the facts in this arbitration clearly demonstrate that Canada acted in a fair, transparent and just manner, regardless of how broadly one construes fair and equitable treatment in this arbitration.

**B. This is a new claim that Canada never consented to arbitrate**

853. The Claimant filed three Notices of Intent and two Notices of Arbitration in this proceeding. The first Notice of Intent did not even advance a claim under Article 1103.<sup>998</sup>

854. The second Notice of Intent was a 1.5 page letter purporting to add a vaguely pleaded Article 1103 claim.<sup>999</sup> The third Notice of Intent incorporated by reference and

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<sup>998</sup> *NoI-1* (Annex R-137).

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repeated the inadequate Article 1103 claim stated in the second Notice of Intent, but with respect to further factual allegations.<sup>1000</sup> It never explained how Article 1103 would apply.

855. The first Notice of Arbitration made the bald allegation that Canada failed to accord the Claimant “treatment no less favourable than that accorded investors from non-Party nations by discriminating against Crompton to the advantage of MFN formulators.”<sup>1001</sup> This Notice of Arbitration never identified an “MFN formulator”, much less did it hint at how less favourable treatment was accorded. The second Notice of Arbitration repeated this allegation and added an equally bald allegation that Article 1103 was “breached when other registrants and other companies (including those from Most Favoured Nations) were accorded more favourable treatment.”<sup>1002</sup>

856. The Claimant’s Memorial advances an Article 1103 claim that cannot be traced in any way to its Notices of Intent and Arbitration but rather represents an entirely new most-favoured-nation (MFN) theory. Claimant’s new theory asserts that 16 of Canada’s post-NAFTA BITs contain a “free-standing” fair and equitable treatment obligation that is more favourable than NAFTA’s minimum standard of treatment and hence must be

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<sup>999</sup> *NoI-2* stated that: unidentified other companies were accorded unspecified but more favourable terms under the VWA; Crompton was accorded unidentified but less favourable treatment than unspecified other businesses; the substitute products of competitors were somehow treated better than Crompton’s substitute product; and Crompton’s registration was improperly suspended, presumably (although never stated) in a less favourable manner than for some other unidentified registrant. (Annex R-138).

<sup>1000</sup> *NoI-3* (Annex R-139).

<sup>1001</sup> *NoA-1*, ¶ 33 (Annex R-140).

<sup>1002</sup> *NoA-2*, ¶¶ 28-30 (Annex R-141).

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applied to the Claimant by operation of NAFTA Article 1103.<sup>1003</sup> In other words, it seeks to import more favourable treaty standards.

857. Canada never consented to arbitrate Chemtura's newly invented Article 1103 claim and the Tribunal should refuse to entertain it. Article 1122 expressly conditions Canada's consent to arbitration on fulfillment of Articles 1119 to 1121. Article 1119(c) requires a claimant to specify the issues and the factual basis for the claim. Chemtura never specified the issue it now raises under Article 1103, nor did it ever plead the factual basis for such a claim.

858. It is inequitable and contrary to the express provisions of NAFTA Chapter 11 to allow a Claimant to raise new claims after it has filed its Notices of Intent and Arbitration. This is especially the case where, as here, the three-year period for initiating a NAFTA claim<sup>1004</sup> has expired. Chemtura's new Article 1103 claim should be dismissed without further consideration.

**C. Chemtura fails to prove any of the legal elements of a claim pursuant to Article 1103**

859. Should the tribunal (wrongfully) permit the Claimant's new Article 1103 claim to go forward, it must fail on the merits. The Claimant has not proved any of the legal elements required for an Article 1103 claim to succeed.

860. Article 1103 is a carefully worded provision that limits the scope of MFN in NAFTA Chapter 11. It guarantees MFN treatment to investors and investments of another NAFTA Party in the following terms:

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<sup>1003</sup> Claimant's Memorial, ¶¶ 450-451 and generally ¶¶ 450-494. The Claimant's labelling of the fair and equitable treatment ("FET") standard in Canada's post-NAFTA BITs as "free-standing" is misleading. Typically, clauses that accord "fair and equitable treatment" *simpliciter*, without further qualification or descriptor, are referred to as "free-standing" FET clauses. The FET clause in Canada's post-NAFTA BITs is definitely not of this variety. Rather, it accords "fair and equitable treatment in accordance with the principles of international law" (or "in accordance with international law"). The Claimant's argument is also based on the incorrect assumption that the FET standard in Canada's post-NAFTA BITs is not the minimum standard of treatment under customary international law.

<sup>1004</sup> NAFTA Articles 1116(2) and 1117(2).

1. Each Party shall accord to Claimants of another Party treatment no less favourable 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 favourable 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.

861. In other words, MFN treatment is owed only with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments, not with respect to all manner of treatment by host states, much less with respect to other treaty standards. It is a limited MFN obligation, not a general obligation.

### 1. Interpretive principles

862. Article 1103, like all of NAFTA, must be interpreted according to Article 31 of the *Vienna Convention* according to “the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose.”

863. The wording of Article 1103 is especially important in construing the breadth of the NAFTA's MFN obligation. As stated in the *Ambatielos* case, “...the most-favoured-nation clause can only attract matters belonging to the same category of subject as that to which the clause itself relates.”<sup>1005</sup>

864. Likewise, the scope of an MFN clause is confined to matters that are *ejusdem generis* with those matters covered by the basic treaty.<sup>1006</sup> Again, the wording of the

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<sup>1005</sup> *The Ambatielos Claim (Greece v. United Kingdom)* (1956) 12 R.I.A.A. 107 (Annex R-148); affirmed in *Emilio Agustín Maffezini v. Spain* (ICSID No. ARB/97/7) Decision of the Tribunal on Objections to Jurisdiction (25 January 2000), at ¶ 49 (Annex R-227) (*Maffezini – Jurisdiction*).

<sup>1006</sup> *Maffezini – Jurisdiction*, at ¶ 56 (Annex R-227). The Tribunal in *Plama Consortium Ltd. v. Republic of Bulgaria* (ICSID No. ARB/03/24) Decision on Jurisdiction (8 February 2005), ¶ 189 (Annex R-257) defined the *ejusdem generis* principle as follows: “when a general word or phrase follows a list of specifics, the general word or phrase will be interpreted to include only items of the same type as those listed...”. (*Plama – Jurisdiction*).



specific MFN clause in the basic treaty defines the breadth of treatment that can be incorporated from a third-party treaty.

865. The negotiating texts of Article 1103 demonstrate that the NAFTA Parties intentionally drafted a limited MFN obligation. The Parties rejected a proposal to adopt a broad MFN obligation (“in respect of all matters covered by this Agreement”<sup>1007</sup>) early in the NAFTA negotiations. Instead, the negotiations focused on the terms triggering application of Article 1103.<sup>1008</sup>

866. Limited MFN clauses have a narrow reach. As summarised by Noah Rubins:

...MFN clauses of limited scope are intended to cover the investment activities of the investment or its investment vehicle, *i.e.* matters related to making money, and not matters related to vindicating rights through international arbitration.<sup>1009</sup>

867. The BIT cases relied on by the Claimant use broad MFN language.<sup>1010</sup> Such cases are not helpful in construing the specific language of Article 1103. Canada submits that a limited MFN clause like Article 1103 does not accord MFN treatment to treaty standards at large.

<sup>1007</sup> Georgetown Composite Negotiating Text, INVEST.116, January 16, 1992, p. 6, Art. 108 (Annex R-241).

<sup>1008</sup> For a chronology of the negotiating drafts for Article 1103, *see*: Kinnear, Meg, Andrea Bjorklund, and John Hannaford, INVESTMENT DISPUTES UNDER NAFTA, AN ANNOTATED GUIDE TO NAFTA CHAPTER 11, at 1103-1 – 1103-6 (Annex R-212).

<sup>1009</sup> Rubins, Noah- *MFN Clauses, Procedural Rights, and a Return to the Treaty Text*, in Grierson Weiler, T. J. (ed.), INVESTMENT TREATY ARBITRATION AND INTERNATIONAL LAW, 214-216, and generally 213-229 (Annex R-266). In *Plama – Jurisdiction*, the Tribunal held that the wording of NAFTA Article 1103 would exclude incorporation of dispute settlement provisions through an MFN clause, ¶¶ 201-203 (Annex R-257).

<sup>1010</sup> The scope of the MFN clause in *Maffezini – Jurisdiction* was “all matters subject to this Agreement...”, ¶ 38 (Annex R-227); in *Siemens* the Tribunal noted expressly that the MFN clause was very general, applying to treatment and activities: *Siemens A.G. v. Argentine Republic* (ICSID No. ARB/02/8) Decision on Jurisdiction (3 August 2004), ¶ 85 (Annex R-276) (*Siemens – Jurisdiction*); the MFN clauses in *MTD* and *Telenor* simply required parties to accord “treatment no less favourable”: *MTD Equity Sdn. Bhd v. Chile*, ICSID No. ARB/01/7, 25 May 2004, ¶ 27 (Annex R-240), request for annulment dismissed March 21, 2007 (Annex R-239); *Telenor Mobile Communications A.S. v. Hungary*, ICSID No. ARB/04/15, Sept. 13, 2006, ¶ 84 (Annex R-323); *Salini Costruttori S.p.A. and Italstrade S.p.A. v. Jordan* (ICSID Case No. ARB/02/13) Decision on Jurisdiction (29 November 2004), ¶ 117 (Annex R-269).

868. The Investor tries to avoid the plain language of Article 1103 by asserting that an MFN obligation “should be applied broadly” or “interpreted liberally” to achieve its liberalising purpose.<sup>1011</sup> Such an approach contradicts Article 31 of the *Vienna Convention* and seeks to use purpose to read out the express words of the basic treaty. This approach has been resoundingly rejected by Tribunals applying MFN provisions as well as other BIT obligations, and must be rejected in this case.<sup>1012</sup>

869. The objectives of a treaty cannot override express treaty language. While NAFTA shares the objectives of promotion and protection of investment common to all BITs, it seeks to balance economic expansion through trade and investment with other shared values. Thus, the Preamble to NAFTA states the resolve of the Parties to promote trade but “in a manner consistent with environmental protection and conservation”, that preserves “flexibility to safeguard the public welfare”, that promotes “sustainable development” and that strengthens “the development and enforcement of environmental laws and regulations.”<sup>1013</sup>

870. Similarly, Article 102 of NAFTA stipulates that the objectives of the treaty are more specifically elaborated through its rules, including MFN treatment, thus sending the treaty interpreter back to the particular wording of Article 1103.

## 2. The elements of Article 1103

871. Article 1103 lists several elements that are preconditions to its application. Each of the elements in Article 1103 must be given meaning. The Claimant bears the burden

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<sup>1011</sup> Claimant's Memorial, ¶¶ 457, 455-458 and 486. The quote from Scott Vesel at ¶ 457 of the Claimant's Memorial actually supports Canada's position that the text of the MFN provision is determinative and that Parties may limit an MFN clause (“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 chose.”) (emphasis added).

<sup>1012</sup> The Tribunal in *Siemens – Jurisdiction*, ¶ 81 (Annex R-276) stated that a BIT must be “interpreted neither liberally nor restrictively, as neither of these adverbs is part of Article 31(1) of the *Vienna Convention*.”

<sup>1013</sup> NAFTA Preamble, clauses 11-14.

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of proving that each element of Article 1103 is satisfied, as well as the facts that establish its breach.

872. Article 1103 does not apply to all treatment. Rather, Article 1103 applies to *treatment no less favourable* than that it [the NAFTA Party] 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*.<sup>1014</sup> MFN treatment in Chapter 11 is only available for treatment meeting all the elements of Article 1103.

873. In this arbitration, therefore, Chemtura must establish four elements, specifically that Canada accorded it, or its investment, (1) “treatment” (2) relating to “the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments” that was (3) “less favourable” than the treatment accorded (4) “in like circumstances” to investors or investments of another Party or a non-Party.

874. The Investor fails to prove even one of these elements and suggests an interpretation that would render each element superfluous.

#### **a) Treatment**

875. First, Chemtura must establish that Canada accorded “treatment” to investors or investments of a non-Party. It never does so. The Claimant does not argue that a Canadian measure accorded more favourable treatment to an investor or investment of a non-Party. Rather, it alleges that a more favourable standard exists in a BIT with a non-NAFTA State and it seeks to incorporate that standard into NAFTA.

876. The ordinary meaning of treatment is “behaviour in respect of an entity or a person.”<sup>1015</sup> A treaty standard is not behaviour in respect of an entity or person.

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<sup>1014</sup> Emphasis added.

<sup>1015</sup> *Siemens – Jurisdiction*, ¶ 85 (Annex R-276).

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877. In addition, for the purposes of NAFTA Chapter 11, treatment must be read in the context of Article 1101(1). Article 1101(1) states that Chapter 11 applies to “measures adopted or maintained by a Party” relating to investments or investors. Read together, Articles 1101 and 1103 make it clear that “treatment” means treatment through adopting or maintaining measures.

878. In turn, NAFTA Article 201 defines measure as including any “law, regulation, procedure, requirement or practice.” Each of these items relates to action taken by a single NAFTA government in its domestic jurisdiction. By comparison, a treaty is an international instrument concluded by two or more States. A treaty does not fall within the definition of measure and is not treatment for the purposes of Chapter 11.<sup>1016</sup>

879. The NAFTA Parties were aware of the difference between treatment accorded under a treaty as compared to the treaty itself, and used this language purposively. Thus, in Annex IV of NAFTA, each Party took an exception to Article 1103 for “treatment accorded *under* all bilateral and multilateral agreements” in force or signed before NAFTA, as well as an exception for “treatment accorded *under* agreements” dealing with certain subjects and entered into after NAFTA.<sup>1017</sup>

880. Canada also notes the recent award in *Soci t  G n rale v. Dominican Republic* which supports the Respondent’s arguments in this arbitration. In that case, the investor invoked an MFN clause to import a substantive provision (a definition of “investment”) from a non-Party treaty into the BIT applicable to the dispute. The Tribunal rejected this based on the fact that a treaty definition did not constitute “treatment” for the purposes of an MFN obligation. It held:

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<sup>1016</sup> The Tribunal in *Pope & Talbot* held, to like effect, that the *Softwood Lumber Agreement*, a treaty between Canada and the United States, could not be challenged under Chapter 11 because it was not a measure; only treatment accorded under the treaty was liable to challenge under Chapter 11: *Pope & Talbot Inc. v. Canada* (UNCITRAL) Award In Relation To Preliminary Motion By Government of Canada To Dismiss The Claim Because It Falls Outside The Scope And Coverage Of NAFTA Chapter 11 (26 January 2000), ¶¶ 35-37 (Annex R-260).

<sup>1017</sup> NAFTA Annex IV, Schedule of Canada, ¶¶ 1 and 2; NAFTA Annex IV, Schedule of Mexico, ¶¶ 1 and 2; NAFTA Annex IV, Schedule of the United States, ¶¶ 1 and 2 (emphasis added).

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Each treaty defines what it considers a protected investment and who is entitled to that protection, and definitions can change from treaty to treaty. In this situation, resort to the specific text of the MFN Clause is unnecessary because it applies only to the treatment accorded to such defined investment, but not to the definition of “investment” itself.<sup>1018</sup>

881. Canada submits that the same reasoning applies in this case.

882. While treatment may be accorded pursuant to a treaty, this does not convert a treaty standard into treatment for the purposes of Article 1103. Put another way, the obligation in Article 1103 to accord MFN treatment applies to the measures a NAFTA Party adopts or maintains, and not to the treaties that it enters into.

**b) With respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments**

883. Second, Article 1103 requires the Claimant to demonstrate that the more favourable treatment was accorded “with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.”

884. The availability of a fair and equitable treaty obligation in a BIT does not fit in this list of actions related to operating an investment. Even if it were to be viewed as “treatment,” it would not be treatment with respect to any of the types of conduct listed in Article 1103.

**c) In like circumstances**

885. Third, Article 1103 requires a comparison of treatment accorded to investors or their investments that are in like circumstances. The “in like circumstances” language of Article 1103 (like Article 1102) compels a fact-specific analysis of comparators accorded treatment in like circumstances.

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<sup>1018</sup> *Société Générale v. Dominican Republic*, (LCIA Case No. UN 7927), Award on Preliminary Objections in Jurisdiction (19 September 2008), ¶ 41 (Annex R-322).

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886. No NAFTA case to date has applied the “in like circumstances” test in Article 1103. However, awards applying the identically worded “in like circumstances” analysis of Article 1102 invariably undertake a fact-specific analysis of the relevant comparators. In that context the *Loewen* Tribunal commented that:

[A] critical problem in the application of Article 1102 to the facts of this case is that we do not have an example of “the most favorable treatment accorded, in like circumstance” by a Mississippi court to investors and investments of the United States.... What Article 1102(3) requires is a comparison between the standard of treatment accorded to a claimant and the most favorable standard of treated accorded to a person in like situation to that claimant. There are no materials before us which enable such a comparison to be made.<sup>1019</sup>

887. The Investor never proffers any comparative analysis of persons “in like circumstances”. Instead, it compares treaty provisions (Article 1105 vs. post-NAFTA BITs) rather than treatment accorded, and never identifies the relevant circumstances, nor how they are like. This falls woefully short of meeting the Investor’s burden of proof to demonstrate treatment accorded in like circumstances.

**d) No less favourable**

888. Fourth, even if NAFTA Article 1103 permitted incorporation of a treaty standard from a third-Party BIT, Chemtura would have to prove that the minimum standard of treatment in NAFTA Article 1105 is less favourable than the fair and equitable treatment standard in Canada’s post-NAFTA BITs.

889. The Investor alleges that 16 Canadian BITs entered into between October 1994 and May 1999 contain a “free-standing fair and equitable treatment standard”, and that these 16 provisions offer more favourable treatment than is available under NAFTA

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<sup>1019</sup> *Loewen -Award on Merits*, ¶ 140 (Annex R-221).

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Article 1105 (and the Note of Interpretation).<sup>1020</sup> This argument is unsupported and unsustainable.

890. Article 1105 of NAFTA is titled “Minimum Standard of Treatment” and states:

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.

891. The July 31, 2001 Note of Interpretation addressing Article 1105 clarified and reaffirmed the meaning of Article 1105; it did not amend or alter that provision.<sup>1021</sup> As discussed earlier, the 2001 Note left no doubt that Article 1105 articulated a standard based on customary international law, not a new standard.

892. Canada's post-NAFTA BITs referred to by the Investor oblige each BIT party to “accord investments or returns of investors of the other Party fair and equitable treatment in accordance with international law” (or “principles of international law”). These are obviously standards that form part of international law, despite the Claimant's mischaracterization of them as “free-standing” fair and equitable treatment obligations.

893. From a textual perspective, the post-NAFTA BITs (“fair and equitable treatment in accordance with international law”) are practically identical to Article 1105 (“treatment in accordance with international law, including fair and equitable treatment.”)

894. Further, Canada has consistently expressed its position that the post-NAFTA BITs are based on NAFTA and are consistent with it. Canada's Department of Foreign Affairs

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<sup>1020</sup> Claimant's Memorial, ¶¶ 451, 487-494, fn. 367.

<sup>1021</sup> Article 1131(2) allows interpretation of a provision of NAFTA. The preamble to this *Note of Interpretation* specifically states that “the Free Trade Commission hereby adopts the following interpretations of Chapter Eleven in order to clarify and reaffirm the meaning of certain of its provisions...”.

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and International Trade website clearly identifies the 16 BITS referred to by the Investor as “NAFTA-based agreements.”<sup>1022</sup>

895. The 2001 Note of Interpretation reflects Canada's long-held and public view that Article 1105 accorded the customary international law minimum standard of treatment. In fact, Canada's Statement on Implementation of NAFTA, issued on entry into force of the NAFTA and well before the 2001 Note of Interpretation, expressly stated that:

Article 1105, which provides for treatment in accordance with international law, is intended to assure a minimum standard of treatment of investments of NAFTA investors.... this article provides for a minimum absolute standard of treatment, based on long-standing principles of customary international law.<sup>1023</sup>

896. There is no difference in the standards of treatment afforded under NAFTA Article 1105 (as reaffirmed in the Note of Interpretation) and the post-NAFTA BITS – both accord the customary international law minimum standard of treatment.

897. As a result, neither provision accords more or less favourable treatment; there is no difference in the treatment accorded to investors or investments under these provisions. The Investor's Article 1103 claim must therefore be rejected.

898. The argument made by Chemtura pursuant to Article 1103 has been resoundingly rejected in NAFTA cases. The Claimant in *UPS v. Canada* raised exactly the same argument based on the very same post-NAFTA BITS entered into by Canada. The *UPS* Tribunal dismissed the claim.<sup>1024</sup>

899. This argument was also advanced in *ADF* and in *Methanex* with respect to post-NAFTA BITS entered into by the United States. The U.S. BIT provisions in question were very similar to the provisions in Canada's 16 post-NAFTA BITS.

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<sup>1022</sup> Canadian Department of Foreign Affairs, “Listing of Canada's Existing FIPAs”, online at: <[http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/fipa-apie/fipa\\_list.aspx?lang=eng](http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/fipa-apie/fipa_list.aspx?lang=eng)> (Annex R-306).

<sup>1023</sup> Note of Interpretation- NAFTA, 68 at 149 (Annex R-248).

<sup>1024</sup> *UPS-Award*, ¶¶ 182-184 (Annex R-297).



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900. Like Canada, the United States demonstrated that the fair and equitable treatment obligation in its post-NAFTA BITs was consistent with Article 1105 and that it had publicly asserted this fact at all relevant times. In particular, the American Letters of Submittal for these BITs expressly stated that the guarantee of fair and equitable treatment in accordance with international law set out a minimum standard of treatment based on customary international law.<sup>1025</sup>

901. The *Methanex* Tribunal did not comment on this argument in its final award. However, the *ADF* Tribunal commented at length on the argument and dismissed it.

902. In *ADF* the Investor alleged that the 1998 U.S.-Albania BIT provided a fair and equitable treatment standard that was more favourable than NAFTA Article 1105 as interpreted in the NAFTA 2001 Note of Interpretation. It claimed the benefit of this allegedly better standard based on Article 1103.<sup>1026</sup>

903. The *ADF* Tribunal dismissed the Investor's argument that the BIT was more favourable than NAFTA Article 1105. It held that:

The Investor's theory assumes the validity of its own reading of the relevant clauses of the treaties with Albania and Estonia. That reading... is that the "fair and equitable treatment" and "full protection and security" clauses of the two treaties establish broad, normative standards of treatment distinct and separate from the specific requirements of the customary international law minimum standard of treatment. We have, however, concluded that the Investor has not been able persuasively to document the existence of such autonomous standards, and that even if the Tribunal assumes hypothetically the existence thereof, the Investor has not

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<sup>1025</sup> *ADF Group Inc. v. United States*, Rejoinder of Respondent United States of America on Competence and Memorial, March 29, 2002, 38-45 (Annex R-145); *Methanex v. United States*, Response of Respondent United States to Methanex's Submission Concerning the NAFTA Free Trade Commission's July 31, 2001 Interpretation (26 October 2001), at 8-12 (Annex R-237).

<sup>1026</sup> *ADF – Award*, ¶¶ 75-80; 193 (Annex R-143). The fair and equitable treatment standard in the U.S. – Albania treaty is strikingly similar to the provisions in Canadian post-NAFTA BITs cited by Chemtura. Article II(3)(a) of the U.S.– Albania BIT stated that "[E]ach Party shall at all times accord to covered investments fair and equitable treatment...and shall in no case accord treatment less favourable than that required by international law." ¶ 77.

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shown that the U.S. measures are reasonably characterised as in breach of such standards.<sup>1027</sup>

904. This reasoning applies with equal force to Chemtura's argument in this case. Chemtura has neither documented the existence of autonomous standards nor has it identified any Canadian measures that could reasonably be characterised as a breach of such standards.

905. The Investor's reliance on the holding of the *Pope & Talbot* tribunal on Article 1103<sup>1028</sup> is severely misplaced for the following reasons: (1) no Article 1103 claim was before the *Pope* Tribunal and Article 1103 was not briefed by the disputing Parties; (2) the comments are pure *obiter dicta*; (3) the additive theory of Article 1105 espoused by the *Pope* Tribunal based on Article 1103 has been uniformly rejected in subsequent awards and the subsequent Note of Interpretation; (4) the dicta in *Pope* relies on the factually incorrect premise that Canada accorded "broader rights" to other countries; and (5) it also contradicts the express language of Article 1105 ("*including* fair and equitable treatment...").

906. The Claimant relies on non-NAFTA cases construing very differently worded MFN provisions that are broader than Article 1103. The cases cited by Chemtura do not support the argument advanced by Chemtura, and are difficult, if not impossible, to reconcile. At most, these cases reinforce the fundamental point made by Canada in this submission: the breadth of an MFN clause is a function of the specific words used in the clause. The MFN obligation in Article 1103 is a limited one that applies to treatment, and does not bring treaty standards into NAFTA.

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<sup>1027</sup> *ADF – Award*, ¶ 194 (Annex R-143).

<sup>1028</sup> Claimant's Memorial, ¶ 473.

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**D. Chemtura fails to prove that any of the measures at issue in this arbitration would breach the alleged “free-standing” fair and equitable treatment obligation**

907. Even if the Tribunal were to agree that Article 1103 incorporates the alleged “free-standing” fair and equitable treatment standard, the Investor must still meet its burden of proof to demonstrate that Canada’s measures violated this standard.

908. The Claimant has not, and cannot, meet this burden. The facts of this case overwhelmingly demonstrate that Canada acted in a fair, even-handed and just manner. Even on the most liberal and “free” free-standing approach to FET, there was no breach.

909. The facts relevant to whether Canada acted in a fair and equitable manner are thoroughly canvassed in the factual section and in the Article 1105 section of this Counter-Memorial. Canada adopts these in the context of Article 1103 and as a result will not repeat them. In summary, however:

- Canada acted within the scope of its statutory authority at all times. In particular, it was within the PMRA’s mandate and legislative discretion to facilitate the VWA, to offer a reasonable phase-out period for lindane use on canola, and to suspend remaining agricultural applications of lindane based on health concerns identified in the Special Review.
- Canada accorded due process to Chemtura at all times. In the context of the VWA, Canada engaged in multiple stakeholder meetings and in extensive specific exchanges with Chemtura. Chemtura initiated (then abandoned) judicial review of the PMRA’s actions in nine Federal Court applications. PMRA requested comments and further input from Chemtura concerning the Special Review, extended the comment period, and took into account Chemtura’s views before confirming its decision. Chemtura thereafter obtained review of the PMRA’s conclusions before a Board of Review. Before the Board of Review, Chemtura was given a full opportunity to make submissions, and to adduce further evidence. The PMRA addressed the Board of Review’s recommendations by launching a review *de novo* of lindane, at which it reviewed the evidence Chemtura had submitted, and allowed Chemtura to make further substantial submissions. After the PMRA’s resulting Re-evaluation Note (REN) was released, the PMRA gave Chemtura the opportunity to comment, responded to those comments in writing, took Chemtura’s comments into account, and has proposed a face-to-face meeting with Chemtura to discuss its response.

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- Canada's conduct and mandate were fully transparent at all times. The PMRA's statutory mandate and governing regulations and directives, notably concerning its re-evaluation procedures, are a matter of public record. Canada explained the basis for its actions to Chemtura at all times. In particular, the terms of the VWA were repeatedly confirmed through discussions and at meetings in which the Claimant directly participated. The Special Review was initiated by public notice. The PMRA met with Chemtura within weeks of this notification, discussing its approach in a two-day meeting and thereafter Chemtura met the PMRA's Executive Director to discuss the Special Review and replacement products reviews. At that meeting, the PMRA raised specific concerns, notably occupational exposure risk, and gave Chemtura the opportunity to submit further data on this issue, which the PMRA took into account in its Review. The Board of Review conducted itself according to clear procedure. The PMRA implemented Board of Review recommendations in its lindane REN applying publicly-announced procedures.
  - Canada met all reasonable expectations in the circumstances. Chemtura knew that it was investing in a heavily regulated field in which the continuing registration of its pesticide products could not be guaranteed. The PMRA conducted itself consistently with the VWA, engaged in a good-faith Special Review of lindane and reached its decision based on legitimate scientific considerations and policies.
  - Canada preserved a stable, predictable business environment for Chemtura at all times. The VWA avoided a U.S. border closure, and granted Chemtura 3 additional years to sell its lindane product. During this period, the PMRA provided Chemtura substantial opportunities for fast-track review of its original replacement product submissions, resulting in registration of Chemtura's submitted applications over a year before those of its competitors. During the VWA, the PMRA took no steps to dissuade canola farmers from using up Chemtura's lindane product, and indeed, extended the right to use lindane-treated seed into a fourth growing season. When the PMRA reached a negative conclusion in the Special Review of lindane, Chemtura was offered, but refused, a multi-year phase-out for its remaining lindane-product registrations.
  - Canada acted in complete good faith at all times, consistent with its statutory mandate and in the best interests of all stakeholders.

910. The standard set by Canada in the events at issue in this arbitration manifestly exceeds any standard of treatment expected at international law.

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## **E. Conclusion**

911. Chemtura's claims based on Article 1103 must be rejected. The Claimant has asserted a new claim in its Memorial that Canada never agreed to arbitrate. Moreover, this new claim fails as a matter of law. Article 1103 is a limited MFN provision that applies to a narrow category of treatment defined by the wording of that Article. Treaty standards do not fall within its definition of treatment. In any event, the fair and equitable standard under Article 1105 of NAFTA, as reaffirmed by the 2001 Note of Interpretation, is the same as the standard accorded in Canada's post-NAFTA BITs. Finally, Canada fully complied with the obligation to accord fair and equitable treatment, no matter how broadly that obligation is defined.

## **V. RELIEF REQUESTED**

### **A. Damages**

#### **1. Summary of Canada's position**

912. The Claimant's request for damages should be dismissed, for at least three reasons:

*First*, any loss sustained by the Claimant was not caused by the breaches alleged.

*Second*, Chemtura failed to mitigate, and in large degree contributed to, its own loss.

*Third*, the LECG Report is based on untrue facts, unsupportable assumptions and a technically unsound model. It cannot be used as a basis to award or quantify Chemtura's damages.

#### **2. The law on damages**

913. NAFTA Article 1135 authorizes a Tribunal to award damages for breach of Chapter 11. It reads:

Article 1135: Final Award

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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.

### **3. General principles governing damages**

#### **a) Burden of proof**

914. The Investor bears the burden of proving the quantum of damages, that the Respondent's breach caused its loss and that the damages are recoverable at law.<sup>1029</sup> As the Tribunal stated in *UPS v. Canada*:

A Claimant must not only show that it has persuasive evidence of damage from the actions alleged to constitute breaches of NAFTA obligations but also that the damage occurred as a consequence of the breaching Party's conduct within the specific time period subject to the Tribunal's jurisdiction.<sup>1030</sup>

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<sup>1029</sup> *Cheng*, at 328-329, (Annex R-167); *S.D. Myers – First Partial Award*, ¶ 316 (Annex R-267).

<sup>1030</sup> *UPS – Award*, ¶ 38 (Annex R-297).

915. Chemtura fails to prove that Canada caused its loss and bases its claim on speculative and misleading assumptions that ignore proven facts. Chemtura has failed to discharge its burden of proof in any respect.

#### b) Causation

916. Damages can only be awarded if they were caused by the breach found by the Tribunal. Article 31(1) of the International Law Commission Draft Articles on the Responsibility of States (*ILC Draft Articles*) includes this fundamental principle: “[T]he responsible State is under an obligation to make full reparation for the injury caused by the internationally wrongful act.”<sup>1031</sup>

917. NAFTA Articles 1116 and 1117 provide likewise, requiring that the damage be incurred “by reason of, or arising out of” the breach. All NAFTA damage awards have applied this requirement. For example, in *S.D. Myers*, the Tribunal noted that compensation was due “only in respect of harm that is proved to have a *sufficient causal link* with the specific NAFTA provision that has been breached”.<sup>1032</sup>

918. Damages must be the proximate, direct and immediate consequence of any breach found. Tribunals will not award compensation for claims that are inherently speculative, contingent, remote or uncertain.<sup>1033</sup>

<sup>1031</sup> See RESPONSIBILITY OF STATES FOR INTERNATIONALLY WRONGFUL ACTS 2001, *Report of the International Law Commission*, Fifty-Third Session (23 April-1 June and 2 July-10 August 2001), Supp. No. 10 (A/56/10), United Nations, New York (Annex R-208 ) (*ILC Draft Articles*). Article 31(2) of the *ILC Draft Articles* affirms this, stating: “[I]njury includes any damage, whether material or moral, caused by the internationally wrongful act of a State.” See also, *ILC Draft Articles* 31, Commentary 9 &10; *Whiteman*, at 1830: damages are “disallowed when they are ‘not the natural consequence’ of the wrongful act for which the respondent government is liable under international law” (Annex R-302).

<sup>1032</sup> *S.D. Myers – Second Partial Award*, ¶¶ 140-145 (Annex R-268) (our emphasis). See also, *ADM – Award*, ¶¶ 275, 282: need to prove a “sufficiently clear link” between wrongful act and alleged injury, (Annex R-146); *Feldman – Award*, ¶ 194: the amount of loss or damage must be “adequately connected” to the breach (Annex R-187); *Pope & Talbot v. Canada (UNCITRAL) Award in Respect of Damages* (31 May 2002), ¶ 80: investor required to prove the loss or damage claimed was causally connected to the breach alleged. (Annex R-258) (*Pope & Talbot – Damages Award*).

<sup>1033</sup> *ILC Draft Articles*, Article 31, Commentary 10 (Annex R-208). See also, *Whiteman*, at 1766 (Annex R-302); *Amoco – Partial Award*, at ¶ 238 (Annex R-150).

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919. The bulk of Chemtura's claim is for lost profit. While available in principle, claims for lost profit are inherently speculative and should be awarded only if "an anticipated income stream has attained sufficient attributes to be considered legally protected interests of sufficient certainty to be compensable."<sup>1034</sup> The claim for lost profit by Chemtura in this arbitration is especially speculative, based on a number of implausible assumptions. For example, it ignores the objective fact that lindane was increasingly banned around the world due to scientific evidence of its harmful effects, and that lindane was made ineligible for registration in the United States in 2006. Given these facts, the potential for future profit from lindane sales was limited or nil. Canada submits that there is no viable basis upon which to award Chemtura lost profit in this case.

920. The Claimant also fails to prove its loss was caused by Canada. It bases its damages claim on a remote, improbable and unsupported set of assumptions that have no direct link to the loss claimed.

921. In particular, Chemtura's allegation that its damages were caused by the VWA is false. The VWA actually extended the sales of lindane treated canola seed and enabled the Claimant to transition from production of lindane treatments to alternatives, two of which the PMRA registered prior to the phase-out period expiring. If the VWA and its phase-out period had not been in place, the border would simply have been closed at an earlier date by the United States, as of June, 1998.<sup>1035</sup> By facilitating the VWA, PMRA saved 3 years of sales for Chemtura and other registrants. This amount should be set off from damages claimed.

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<sup>1034</sup> *ILC Draft Articles*, Article 36, Commentary 27: "...lost profits have not been as commonly awarded in practice as compensation for accrued losses. Tribunals have been reluctant to provide compensation for claims with inherently speculative elements." (Annex R-208). See also, *ADM – Award*, at ¶ 285 (Annex R-146); *LG&E Energy Corp., LG&E Capital Corp. and LG&E International Inc. v. Argentine* (ICSID Case No. ARB/02/1) Award (25 July 2007), at ¶ 51 (Annex R-218) (*LG&E – Award*). See *Whiteman*, at 1837 (Annex R-302).

<sup>1035</sup> Affidavit of Tony Zatylny, ¶ 28.



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922. In any event, the VWA was an agreement between Chemtura and its own clients, the Canadian canola growers. PMRA only facilitated the VWA and hence did not cause any loss allegedly flowing from the VWA.

923. The destruction of the lindane-treated canola market in Canada was precipitated by the Claimant alerting U.S. authorities to the fact that lindane-treated canola seeds were being imported into the United States without a lindane tolerance. The EPA never issued a tolerance for lindane on canola and in 2006 the EPA effectively banned the use of lindane in the United States altogether.<sup>1036</sup>

924. In addition, the market for lindane-treated seed turned away from the Claimant's product because alternatives were available that did not pose health or environmental risk and would not tarnish the healthy image of canola.<sup>1037</sup> The decision not to use lindane-treated canola seed was made by the Claimant's clients. This was an industry decision with no causal connection to the actions of the PMRA.

925. Moreover, quite apart from the VWA, lindane was phased out in Canada as of 2002 for all products due to the Special Review. The fact that the Special Review was finished in October 2001 instead of December 2000 did not cause any loss to the Claimant. This ten month delay actually extended the life of lindane in Canada for another year.

926. In summary, the Claimant fails to come to grips with the real cause of its loss: that it was selling a hazardous chemical with adverse health and environmental effects.

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<sup>1036</sup> In the U.S., the 2002 RED allowed current registered lindane seed treatments (which did not include canola) if a variety of additional safety conditions were respected. The 2006 Addendum to the RED made all lindane seed treatment uses ineligible for registration. *See Dr. Goldman Report*, ¶¶ 57-59.

<sup>1037</sup> Letter from Eugene Dextrase, President, CCGA to Dr. Claire Franklin, Executive Director, PMRA, 19 October 1998 (Exhibit WS-13).

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**c) Mitigation of loss**

927. The investor must mitigate its loss. Where the investor fails to mitigate its loss, the claim will be reduced accordingly.<sup>1038</sup> This general principle is reflected in the Commentary to *ILC Draft Article 31*: “a failure to mitigate by the injured party may preclude recovery to that extent.”<sup>1039</sup>

928. An investor fails to mitigate if it does not make business decisions that would have reduced its loss when it was reasonable and possible to do so.<sup>1040</sup>

929. The Claimant failed to mitigate its loss in various ways. First, the Claimant had enough product in 1999 to see it through the 1999, 2000 and 2001 growing seasons.<sup>1041</sup> Knowing that the VWA committed to terminating use by 2001, the Claimant should have anticipated a shift away from lindane after 1999 and focussed on production and marketing of lindane replacement products.

930. Second, the PMRA expedited the review of the two Gaucho formulations that Chemtura submitted in 1998, at the time of the VWA. This meant that the Claimant had at least two lindane replacement products to sell in time for the 2001 growing season. If any loss was suffered from the transition to replacement products during this period, it was not due to PMRA's actions. PMRA ensured that the Claimant had products to mitigate any loss it may have suffered.

931. The fact that Claimant's replacement products were inadequate<sup>1042</sup> was not Canada's fault. If the Claimant believed that simple formulation Gaucho was an inferior

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<sup>1038</sup> *Whiteman*, at 199 (Annex R-302). See also, *Case Concerning the Gabčíkovo–Nagymaros Project (Hungary v. Slovakia)*, Judgment of 25 September 1997, [1997] I.C.J. Rep. 7, at ¶ 80 (Annex R-194) (*Gabčíkovo–Nagymaros*).

<sup>1039</sup> *ILC Draft Articles*, Article 31 (Commentary) (Annex R-208).

<sup>1040</sup> *Amco Asia Corporation Pan American Development Ltd. and PT Amco Indonesia v. Indonesia* (ICSID No. ARB/81/8) Decision on Supplemental Decision and Rectification of the Award (17 October 1990), ¶¶ 78- 79 (Annex R-151) (*Amco – Rectification*).

<sup>1041</sup> *LECG Report*, ¶ 43.

<sup>1042</sup> See Claimant's Memorial, ¶¶ 60, 212-214, 411. Affidavit of JoAnne Buth, ¶ 31.

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product, it should have focused on improving it or developing an all-in-one formulation earlier, as Syngenta had.<sup>1043</sup> Moreover, claiming that the product was inadequate is difficult to reconcile with the fact that the Claimant had been marketing the same Gaucho replacement product in the United States since 1994.<sup>1044</sup>

932. Third, given the health and environmental concerns plaguing lindane around the world, including in Canada and the United States, the Claimant should have focussed on developing and marketing effective alternatives earlier.<sup>1045</sup> Instead, it chose to continue fighting the PMRA, insisting that, despite the science, lindane was safe enough to continue using.

933. The Claimant also failed to mitigate any loss from its remaining non-canola lindane products when it refused the phase-out period offered after the Special Review was completed. The Claimant knew that it could take advantage of a voluntary discontinuation, but refused to do so. Any damages that Chemtura suffered from the termination of its non-canola lindane product market could have been mitigated to a great extent by taking advantage of the phase-out regime, as did the other registrants.

934. Finally, the Claimant admits that Gustafson did not sell any lindane replacement products for non-canola uses.<sup>1046</sup> This is a failure on the Claimant's part to mitigate its alleged loss in the non-canola market.

935. Any award to Chemtura should be reduced to reflect its failure to mitigate loss although it was reasonable and possible to do so.

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<sup>1043</sup> Affidavit of JoAnne Buth, ¶¶ 60-62.

<sup>1044</sup> At the time Gustafson tipped off the EPA about illegal lindane treated seed imports, it held the U.S. registration for a replacement product, Gaucho: *see* Affidavit of Suzanne Chalifour, ¶ 54.

<sup>1045</sup> Affidavit of Suzanne Chalifour, ¶ 54.

<sup>1046</sup> *LECG Report* footnote 30.

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**d) Claimant's responsibility for its own loss**

936. If a Claimant contributes to causing the loss alleged, either by carelessness, negligence or wilful conduct, the damages will be diminished or disallowed.<sup>1047</sup>

937. This general principle is reflected in Article 39 of the *ILC Draft Articles* under the heading *Contribution to the Injury*. It states that, “account shall be taken of the contribution to the injury by wilful or negligent action or omission of the injured State or any person or entity in relation to whom reparation is sought.”<sup>1048</sup>

938. In *MTD v. Chile*<sup>1049</sup>, the claimant incurred loss due to a series of bad business decisions which increased its risks in the transactions at issue. The Tribunal held that the respondent State could not be liable for these unwise business decisions, regardless of the treatment accorded by the State, and it reduced the damages awarded by 50 percent on this account. The Annulment Committee reviewing this award affirmed the principle that damages should be reduced to reflect the claimant's contribution to loss and declined to annul this portion of the award.<sup>1050</sup>

939. Similarly, in *Bogdanov v. Moldova*<sup>1051</sup>, the claimant was held partially responsible for the loss suffered because it made an unwise business decision and failed in its due diligence before signing the contract at issue. As a result, the Tribunal reduced its damages award accordingly.

940. Canada submits that Chemtura significantly contributed to its loss and hence damages should be reduced accordingly.

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<sup>1047</sup> *Whiteman*, at 216 (Annex R-302).

<sup>1048</sup> *ILC Draft Articles*, Article 39, Commentary 2: “...the conduct of the injured State, or of any person or entity in relation to whom reparation is sought, should be taken into account in assessing the form and extent of reparation. This is consonant with the principle that full reparation is due for the injury – but nothing more – arising in consequence of the internationally wrongful act.” (Annex R-208).

<sup>1049</sup> *MTD – Award*, ¶¶ 242-3 (Annex R-240).

<sup>1050</sup> *MTD – Annulment*, ¶¶ 93-101 (Annex R-239).

<sup>1051</sup> *Bogdanov v. Republic of Moldova*, Arbitration Institute of the Stockholm Chamber of Commerce (Sept. 22, 2005), ¶ 5.2 (Annex R-161).

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941. The Claimant precipitated the events leading to the closure of the U.S. border to lindane treated canola seed by alerting U.S. authorities that such seed was crossing the border. It did so for what appears to be an attempt to force canola growers into using one of its own Gaucho products.<sup>1052</sup> This back-fired, resulting in a situation where only the VWA protected it from an immediate border closure. Any award of damages should be significantly discounted to reflect the Claimant's role in its loss.

942. In any event, the VWA was voluntary. Chemtura could have refused to participate in it if it wished. While it complained about the VWA and suggested changes, ultimately it did not object to the VWA and certainly Chemtura took the benefit of it. It cannot now dissociate itself from the VWA.

943. In addition, the complaint by Chemtura that Syngenta had a superior product on the market prior to Chemtura is the result of the Claimant's own bad business decisions. Syngenta had the business acumen to develop an all-in-one product before Chemtura. By not investing in the development of such a product earlier, especially given the inevitable trajectory of scientific knowledge about the risks of lindane, Chemtura contributed to the losses it alleges.<sup>1053</sup>

944. The Claimant also contributed to its loss in the non-canola market by refusing to take advantage of the voluntary discontinuance and phase-out regime after the Special Review.

945. Finally, there are several examples of the Claimant's contributory negligence during the Special Review and Review Board process. For instance, Chemtura failed to take advantage of opportunities to participate during the Special Review process. With respect to the Review Board process, Chemtura's application for judicial review of the appointment of Review Board Members delayed the proceedings by a full year. The

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<sup>1052</sup> Affidavit of Tony Zatylny, ¶ 19.

<sup>1053</sup> Moreover, the Claimant has provided no proof that it tried to market Gaucho in Canada, as it had successfully done in the United States since 1994.

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application was discontinued by Chemtura a year later, with Chemtura agreeing that the process was fair.<sup>1054</sup>

946. Cumulatively, this conduct by the Claimant contributed in significant part to its loss and any award should be discounted to reflect its role.

**e) Double recovery**

947. A claimant cannot obtain double recovery. If an investor recovers on account of more than one obligation or more than one head of damages, the total award cannot exceed the investor's actual loss. As the Tribunal noted in *S.D. Myers*, "damages for breach of one NAFTA provision can take into account any damages already awarded under a breach of another NAFTA provision."<sup>1055</sup>

**4. Standard of compensation for expropriation**

948. The other provision in NAFTA Chapter 11 that addresses damages is Article 1110. The Article, entitled "Expropriation and Compensation", provides a complete code to address expropriation under Chapter 11. The scope of compensation for an expropriation is found in Article 1110(2) – (6), which reads:

(2) Compensation shall be equivalent to the fair market value of the expropriated investment immediately before the expropriation took place ("date of expropriation"), and shall not reflect any change in value occurring because the intended expropriation had become known earlier. Valuation criteria shall include going concern value, asset value including declared tax value of tangible property, and other criteria, as appropriate, to determine fair market value.

(3) Compensation shall be paid without delay and be fully realizable.

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<sup>1054</sup> Affidavit of Wendy Sexsmith, ¶ 168.

<sup>1055</sup> *S.D. Myers – First Partial Award*, ¶ 316 (Annex R-267). See also, *Redfern, Alan and Martin Hunter*, *LAW AND PRACTICE OF INTERNATIONAL COMMERCIAL ARBITRATION*, 4<sup>th</sup> ed. (London; Sweet & Maxwell, 2004, ¶¶ 500-501: "...in the case of successful claims for expropriation and other treaty breaches, compensation will not be cumulative." (Annex R-262).

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(4) If payment is made in a G7 currency, compensation shall include interest at a commercially reasonable rate for that currency from the date of expropriation until the date of actual payment.

(5) If a Party elects to pay in a currency other than a G7 currency, the amount paid on the date of payment, if converted into a G7 currency at the market rate of exchange prevailing on that date, shall be no less than if the amount of compensation owed on the date of expropriation had been converted into that G7 currency at the market rate of exchange prevailing on that date, and interest had accrued at a commercially reasonable rate for that G7 currency from the date of expropriation until the date of payment.

(6) On payment, compensation shall be freely transferable as provided in Article 1109.

949. Fair market value in Article 1110(2) reflects an objective standard requiring quantification of the loss based on a sale between a willing buyer and seller. The Tribunal in *Enron Corporation Ponderosa Assets, L.P. v. Argentine Republic* set out the generally accepted definition of fair market value:

[T]he price at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, absent compulsion to buy or sell, and having the parties reasonable knowledge of the facts, all of it in an open and unrestricted market.<sup>1056</sup>

950. Fair market value can be assessed in a number of ways, including those listed in Article 1110(2) (“going concern value, asset value including declared tax value of tangible property, and other criteria”). The choice of valuation methodologies depends on the specific facts of a case and should result in quantification that most accurately reflects actual loss.

951. While the Investor suggests that it has quantified fair market value in its claim for loss, it ignores the fact that lindane was increasingly being regulated or banned internationally and that the market for lindane treatment was shrinking rapidly. In the

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<sup>1056</sup> *Enron – Award*, ¶ 361 (Annex R-184).

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circumstances, it is hard to imagine a willing buyer paying more than a nominal amount in respect of lindane product sales by the investment.<sup>1057</sup>

## 5. Compensation for non-expropriation breaches

952. NAFTA Tribunals assessing non-expropriatory breach generally have relied on customary international law principles to determine damages for such breaches. These Tribunals have concluded that such an assessment is fact-driven and discretionary.<sup>1058</sup>

953. At customary international law, an award of damages seeks to put the investor in the position it would have been had the breach not occurred.<sup>1059</sup> This reflects the principle in *Chorzow Factory* 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.”<sup>1060</sup>

954. The Claimant states that the fair market value standard of compensation applicable to a breach of Article 1110 should apply equally to a breach of Articles 1105 or 1103 because the result was complete loss of the investment.<sup>1061</sup>

955. This position ignores the text of NAFTA: unlike Article 1110, Article 1135 does not prescribe fair market value.<sup>1062</sup> Fair market value may be an appropriate standard for

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<sup>1057</sup> *Navigant Report*, ¶¶ 10-22.

<sup>1058</sup> *ADM – Award*, ¶ 283 (Annex R-146); *S.D. Myers – Second Partial Award*, ¶ 144 : “...the NAFTA deals explicitly with the measure of damages for an expropriation and those provisions are not controlling in this case” [breach of Article 1102] (Annex R-268 ); *S.D. Myers – First Partial Award*, ¶¶ 305-309: “...the drafters of the NAFTA intended to leave it open to tribunals to determine the measure of compensation appropriate to the specific circumstances of the case, taking into account the principles of both international law and the provisions of NAFTA.” (Annex R-267); *Feldman – Award*, at ¶ 194: “...in case of discrimination that constitutes a breach of Article 1102, what is owed by the responding Party is the amount of loss or damage that is adequately connected to the breach.” The same holds for any possible breach of Article 1105. (Annex R-187).

<sup>1059</sup> *ILC Draft Articles*, Article 31 (Annex R-208).

<sup>1060</sup> *Chorzów Factory*, ¶ 29 (Annex R-168).

<sup>1061</sup> Claimant's Memorial, ¶ 546.

<sup>1062</sup> See *S.D. Myers – First Partial Award*, ¶ 307: “In fact, the drafters of NAFTA did not state that the “fair market value of the asset” formula applies to all breaches of Chapter 11. They expressly attached it to expropriations.” (Annex R-267).



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non-expropriatory breach if that breach directly caused total loss of the investment.<sup>1063</sup>

Otherwise, “in the absence of discrimination that also constitutes indirect expropriation or is tantamount to expropriation, a claimant would not be entitled to the full market value of the investment which is granted by NAFTA Article 1110.”<sup>1064</sup>

956. In this instance, Chemtura asserts that the non-expropriatory breach caused a total loss of the investment, but never explains how the alleged breaches of Articles 1105 or 1103 could cause a total loss of the investment. In the circumstances of this case, it is difficult to imagine, for example, how the failure to incorporate a “free-standing” fair and equitable clause or to complete the Special Review of lindane ten months earlier caused a total loss of the Investment.

957. Canada submits that Chemtura has failed completely to prove an Article 1105 or 1103 breach that directly caused loss to the Claimant, nor has it proved the quantum of any such loss. As a result, no award should be made for breach of these provisions.

## 6. LECG Report

958. Chemtura claims USD \$83,139,672 in damages entirely on the basis of the LECG Report. That report adopts an inappropriate valuation method, incorrect facts, and implausible “but-for” assumptions. It is highly speculative and inaccurate for reasons which are canvassed below.

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<sup>1063</sup> See *Feldman – Award*, ¶ 194 (Annex R-187). See also *Metalclad – Award*, ¶ 113: where damages for 1105 are deemed the same as Article 1110 since *Metalclad* completely lost its investment. (Annex R-233). See also *CMS – Final Award*, ¶ 410: “While this standard [FMV] figures prominently in respect to expropriation, it is not excluded that it might also be appropriate for breaches different from expropriation if their effect results in important long-term losses.” (Annex R-172); *Azurix – Award*, ¶ 424 (Annex R-155); *LG&E – Award*, ¶ 39 where Tribunal discusses the fact that FMV was used for breaches other than expropriation when the result of the breach was tantamount to expropriation. (Annex R-218).

<sup>1064</sup> *Feldman – Award*, ¶ 194 (Annex R-187). See also, *GAMI – Final Award*, ¶¶ 83-84: “A complaint of alleged unfair and inequitable treatment must be connected with a demonstration of specific and quantifiable prejudice by the Claimant.” (Annex R-196).

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**a) LECG does not use an appropriate valuation method**

959. LECG claims that it performed a DCF analysis to quantify fair market value.<sup>1065</sup> A DCF analysis is inherently speculative, based on various assumptions about risk and performance in the future. In this instance, LECG compounds the speculative nature of DCF analysis by basing its assumptions on facts that are patently incorrect and assumptions that are totally implausible. The result is a report that cannot be relied upon by this Tribunal.

960. In particular, the assumption that Chemtura's ability to generate profits in the past accurately reflects its ability to generate profits in the future on the sale of lindane-based products<sup>1066</sup> is to put on blinders about the world in which Chemtura was doing business.

961. In the eyes of a reasonable businessperson, Chemtura had little, if any, prospect of continuing to generate profits on lindane-based products in the future. It was selling a chemical that was hazardous to human health and the environment and therefore increasingly banned internationally; was completely banned in Canada by 2002; never had a canola tolerance from the United States, which threatened a border closure if canola was imported; was completely banned by the United States (a major market) by 2006; was losing market-share over concern about the toxic image projected by lindane; and for which there were viable substitute products. In these circumstances, the likelihood of generating profit from lindane-based products was not just speculative, it was nil.<sup>1067</sup> As put succinctly in the Navigant Report, "[T]he changing market environment between 1998 and 2002....would make any attempt to establish the fair market value of the Claimant's investment an entirely speculative exercise....the value of the Claimant's lindane-based product line would necessarily be zero as of 1 January 2003."<sup>1068</sup>

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<sup>1065</sup> *LECG Report*, ¶¶ 59-66.

<sup>1066</sup> *LECG Report*, ¶ 59.

<sup>1067</sup> *The Navigant Report* reviews the value of canola's lindane line at various key events in the case. It concludes that a reasonable businessperson would not have viewed Chemtura's lindane line as viable at any point from 1998 onwards: *Navigant Report*, ¶¶ 107-121.

<sup>1068</sup> *Navigant Report*, ¶ 106.

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962. Further, although LECG claims to do a DCF analysis, it does not implement a DCF approach in the traditional sense. Rather, it uses a two-step approach, calculating historical lost cash flow plus future lost cash flow based on a June 30, 2008 valuation date.<sup>1069</sup>

963. The LECG approach does not yield reliable results for two main reasons. First, since lindane treated seed was not sold after 2002, there is no reliable market experience in the post-2002 environment on which to base its assumptions. Second, all of the requisite variables that must be known and factored into the LECG analysis are not present. For example, there is no reliable way to identify the market share Chemtura would gain; the price at which it could have sold lindane; the impact of competing substitute products, the size of the market for lindane, the effect of trade association views on lindane use; the effect of the U.S. regulatory situation until 2006 when it totally banned lindane; or the cost of producing lindane.<sup>1070</sup> The LECG approach is therefore speculative and unreliable.

964. LECG selects a valuation date of June 30, 2008 in its report.<sup>1071</sup> A valuation date of January 1, 2003 would be more accurate because estimates of lost cash flow should be discounted to the date of the alleged harm or the start of the projection period, which the Claimant admits is January 1, 2003.<sup>1072</sup> Even with this modification, the LECG model overstates damages due to its reliance on market data and financial results of Chemtura during the pre-1998 period (and the VWA period) and due to the completely different market environment by 2002.<sup>1073</sup>

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<sup>1069</sup> *Navigant Report*, ¶¶ 26-28, 87-88.

<sup>1070</sup> *Navigant Report*, ¶¶ 33-36, 90-100.

<sup>1071</sup> *LECG Report* ¶ 66.

<sup>1072</sup> *LECG Report*, ¶¶ 34, 88-98. Canada, at this point in time, has no way of determining whether this date is in fact the date when losses begin to accrue. Once document disclosure has occurred in this arbitration, Canada will be in a position to better assess the validity of this date.

<sup>1073</sup> *Navigant Report*, ¶ 98.

**b) LECG accepts facts known to be incorrect as its factual foundation**

965. The LECG Report is based on facts dictated by Counsel for the Claimant that contradict reality and rewrite history.<sup>1074</sup> The damages assessment which is based on these facts is inaccurate and wildly speculative. Canada rebuts these incorrect facts in the same order as they are listed in the instruction letter to LECG.

**(1) The VWA did not commit to complete the scientific review of lindane by late 2000**

966. LECG accepts that Canada breached its commitment to complete the “scientific review” by late 2000.<sup>1075</sup> This is false.

967. The terms of the VWA were clear in the November 26, 1998 letter.<sup>1076</sup> Canada never undertook to complete the Scientific Review on lindane by late 2000 and could not logically have done so, given that the Special Review of lindane had not even formally been announced by that time.<sup>1077</sup> The PMRA had emphasized that the late December 2000 date was a target-date only.<sup>1078</sup> The Claimant knew that the Special Review was complex, had a broad scope, and could evolve.<sup>1079</sup>

<sup>1074</sup> *LECG Report*, Exhibit D, Instruction Letter of May 28, 2008 from Somers to LECG.

<sup>1075</sup> *LECG Report*, Exhibit D, ¶ 1(a).

<sup>1076</sup> Letter from Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, CCGA, to Dr. Claire Franklin, Executive Director, PMRA, 26 November 1998 (Exhibit JB-9). This letter memorialized the meeting that took place two days earlier and was copied to Chemtura.

<sup>1077</sup> The Special Review was announced on March 15, 1999. *See* PMRA, Special Review Announcement SRA99-01, *Special Review of Pest Control Products Containing Lindane*, 15 March 1999 (Exhibit JW-14).

<sup>1078</sup> Affidavit of Cheryl Chaffey, ¶ 80; Affidavit of John Worgan, ¶ 11; Affidavit of Wendy Sexsmith ¶¶ 89-90.

<sup>1079</sup> Affidavit of Cheryl Chaffey, ¶ 78-79; Affidavit of Dr. Claire Franklin, ¶ 15.

968. The Claimant insisted that PMRA and EPA coordinate on the review and re-evaluation of data by the end of 2000.<sup>1080</sup> Obviously PMRA could not control EPA's timing, and Chemtura knew this.

969. Moreover, the date on which the Special Review was completed (October 30, 2001) is irrelevant to the damages assessment. The additional ten months merely delayed the suspension or termination of lindane use by the Claimant and did not cause any loss.

970. The results of the Special Review on lindane would have been identical if it had been completed by late 2000. If anything, the delay gave the Claimant more time to market its lindane products.

**(2) The PMRA's scientific review of lindane was fair, transparent and scientifically sound**

971. LECG accepts that the "scientific review" was flawed and provided no meaningful opportunity to participate. This is false.<sup>1081</sup>

972. Chemtura was advised that the scope of the Special Review was potentially broad and would include an occupational health review.<sup>1082</sup> PMRA invested significant resources in the Special Review, which followed standard PMRA re-evaluation policy.

973. Comprehensive toxicology and exposure assessments were also performed. Five months were spent on the toxicology review alone. Although stakeholders were invited

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<sup>1080</sup> Interestingly, despite what Chemtura claims in its Memorial, it appears the Claimant (in this case, the Canadian subsidiary, Gustafson Partnership) knew that PMRA had only limited control over the process: see Affidavit of Wendy Sexsmith, ¶ 59. See Letter from Bill Hallatt, Product Development Manager, Gustafson Partnership, to Wendy Sexsmith, PMRA, 11 January 1999 (Exhibit WS-20). In this letter, the Claimant admits it is only asking for things within Chemtura's control. In another letter however, the Claimant (Chemtura), however, consistently fought this aspect of the commitment, insisting, for example, that if the EPA agreed to the use of lindane, the PMRA should reinstate lindane products for use on canola; Affidavit of Wendy Sexsmith, ¶ 96. This is in contrast to the other registrants, who understood that the process involved two independent national regulators, working in tandem; Affidavit of Wendy Sexsmith, ¶¶ 102-105.

<sup>1081</sup> LECG Report, Exhibit D, ¶ 1 (b).

<sup>1082</sup> PMRA expressly raised specific occupational health concerns with Chemtura a year before the Special Review.

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to participate during the process, Chemtura never did.<sup>1083</sup> Stakeholders were given the opportunity to comment on the conclusions of the Special Review. Chemtura did so, although it did not suggest the significant mitigation measures it advocated at a much later date.<sup>1084</sup>

974. When the Claimant was dissatisfied with the results of the Special Review, it requested that a Board of Review be established. The Minister of Health established the Lindane Review Board in May 2004 and moved of his own accord to appoint the Board (which Chemtura opposed in Federal Court).<sup>1085</sup>

975. The Lindane Review Board was established in a fair and transparent manner and in accordance with section 24 of the *PCPA* Regulations<sup>1086</sup>. The PMRA and Chemtura had three rounds of written submissions and an opportunity to present new evidence.<sup>1087</sup> The three Board members were highly qualified scientists, and during the nine days of hearings, the Board heard all 13 witnesses and produced over 2000 pages of transcript.<sup>1088</sup>

976. The Board of Review confirmed the Special Review's conclusion: "the risk assessment conducted by PMRA, and the conclusions reached, were generally within acceptable scientific parameters."<sup>1089</sup>

977. Therefore, the Claimant not only took part in the Special Review, but then exercised its right of statutory review and received a full and thorough evaluation of the Special Review process and scientific results. Furthermore, the PMRA and the Minister

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<sup>1083</sup> Affidavit of John Worgan, ¶¶ 173-178.

<sup>1084</sup> Affidavit of John Worgan, at ¶¶ 173, 175, 208.

<sup>1085</sup> The action that delayed the Review Board process for a year. The Claimant later dropped the action, conceding that the process for the establishment of the Board was fair. Affidavit of Wendy Sexsmith, ¶¶ 160-169.

<sup>1086</sup> Affidavit of Wendy Sexsmith, ¶¶ 170-175

<sup>1087</sup> Affidavit of Wendy Sexsmith ¶ 178.

<sup>1089</sup> *Board of Review Report*, ¶ 115 (Exhibit WS-71).

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accepted the Board of Review's recommendations, and implemented them during a follow-up *de novo* scientific review.

978. The *de novo* review has so far culminated in the Lindane Risk Assessment Draft Re-Evaluation Note published in April, 2008.<sup>1090</sup> The Draft concludes that “the pesticide lindane poses unacceptable risk of harm to human health and the environment.” This assessment confirms the earlier decision by PMRA in the Special Review to withdraw registrations for lindane from use in Canada.<sup>1091</sup>

**(3) PMRA was clear on the meaning of the July 1, 2001 deadline**

979. LECG accepts that the PMRA misinformed growers about the July 1 deadline.<sup>1092</sup> This is false.

980. The VWA states as a condition: “All commercial stocks of products containing lindane for use on canola and lindane treated canola seed cannot be used after July 1, 2001.”<sup>1093</sup> The wording is clear and unequivocal. Neither stocks of products containing lindane *nor* lindane treated canola seed could be used after July 1, 2001. This clearly worded condition was repeated in subsequent letters from the PMRA<sup>1094</sup> and from concerned stakeholders.<sup>1095</sup>

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<sup>1090</sup> PMRA, Re-Evaluation Note REV2008, Draft Lindane Risk Assessment, 14 April 2008 (Exhibit JW-92) (*PMRA Re-evaluation Note REV2008*).

<sup>1091</sup> See *PMRA Re-evaluation Note REV2008*, p. 1 (Exhibit JW-92).

<sup>1092</sup> *LECG Report*, Exhibit D, ¶ 1(c).

<sup>1093</sup> Letter from Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, CCGA, to Dr. Claire Franklin, Executive Director, PMRA, 26 November 1998 (Exhibit JB-9).

<sup>1094</sup> See Letter from Claire Franklin, Executive Director, PMRA, to Gene Dextrase, President, CCGA, and Bruce Dalgarno, Past President, 9 February 1999 (Exhibit WS-25); Letter from Dr. Claire Franklin, Executive Director, PMRA to Alfred Ingulli, Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 21 October 1999 (Exhibit WS-38).

<sup>1095</sup> Memorandum from JoAnne Buth, CCC to lindane product registrants, *Voluntary Withdrawal of Canola/rapeseed from lindane containing product labels*, 29 October 1999 (Exhibit WS-42); Affidavit of Wendy Sexsmith, ¶¶ 54-108, 141-145.

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981. The Claimant also alleges that PMRA threatened the imposition of fines. However, the focus on the compliance program for lindane was to determine whether there would be enough stock left after the phase-out period to cause a disposal problem, not on prosecution or the imposition of fines.<sup>1096</sup>

**(4) PMRA expedited review of replacement products and Chemtura was the first on the market as a result**

982. LECG accepts that PMRA failed to expedite Chemtura's replacement products.<sup>1097</sup> This is false.

983. The PMRA made no express time-commitment to review lindane replacement products nor did it make an open-ended commitment to review all formulations.<sup>1098</sup>

984. In any event, by October 1999, PMRA had reviewed and registered two of the Claimant's lindane replacement products, as well as one lindane-free versions of existing formulations.<sup>1099</sup> PMRA registered Chemtura Gaucho lindane-replacement formulations first, prior to Syngenta's Helix product.<sup>1100</sup>

985. Chemtura's real complaint is that its all-in-one replacement, Gaucho CS FL, was not registered in time for the 2001 planting season. No commitment to do so was ever made. Further, Chemtura can only blame itself for not having formulated and registered

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<sup>1096</sup> Affidavit of Jim Reid, ¶12. Deletion of Lindane Seed Treatment Use on Canola, National Pesticides Compliance Program, Program 2409, 2001 (Exhibit JR-12); Final Report, Lindane Seed Treatment Use on Canola, National Pesticides Compliance Program, Program 2409, 2001 (Exhibit JR-13).

<sup>1097</sup> *LECG Report*, Exhibit D, ¶ 1(d).

<sup>1098</sup> Affidavit of Wendy Sexsmith, ¶ 44: "I made no specific commitment regarding the timing of the PMRA's review of new products, and emphasized that the outcome of such reviews could not be guaranteed."

<sup>1099</sup> Affidavit of Wendy Sexsmith, ¶ 94; Affidavit of Suzanne Chalifour, ¶55.

<sup>1100</sup> Affidavit of Wendy Sexsmith, ¶ 82; Affidavit of Suzanne Chalifour, ¶ 25.



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such a product earlier. These were business decisions by the respective companies involved and had nothing to do with PMRA's actions.<sup>1101</sup>

986. Even LECG suggests that Chemtura's failure to perform well in the replacement market is partly explained by the fact that its product was not dual-use, and was not attributable to actions by PMRA.<sup>1102</sup>

**(5) PMRA had no choice but to deregister  
Claimant's lindane product registrations in  
February 2002**

987. LECG accepts that PMRA deregistered Chemtura's remaining lindane registrations in 2002.<sup>1103</sup> This is misleading since Chemtura refused a phase-out for these registrations, leaving PMRA no other choice.

988. After the Special Review, the PMRA proposed a voluntary discontinuance of lindane seed treatment products pursuant to the *PCPA* Regulations.<sup>1104</sup> A three year phase-out was offered to companies that voluntarily rescinded their remaining lindane registrations.

989. When the Claimant refused to voluntarily discontinue<sup>1105</sup>, PMRA had no choice but to suspend registrations unilaterally.

**c) LECG'S "but for" assumptions are flawed**

990. LECG builds its valuation on assumptions provided by Chemtura's counsel that are highly improbable.<sup>1106</sup> These assumptions, layered on top of an incorrect factual

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<sup>1101</sup> However, even Syngenta's Helix wasn't registered in time to be effectively marketed for the 2001 growing season. See Affidavit of JoAnne Buth, ¶ 61.

<sup>1102</sup> *LECG Report* ¶¶ 48-51.

<sup>1103</sup> *LECG Report*, Exhibit D, ¶ (1).

<sup>1104</sup> *PCPR*, s.14 (Annex R-2).

<sup>1105</sup> Affidavit of Wendy Sexsmith, ¶¶ 149-158.

<sup>1106</sup> *LECG Report*, ¶¶ 68-71 and Exhibit D, ¶¶ 2-6.

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foundation, weaken the LECG conclusions even further. LECG's "but-for" world is an impossible fantasy. Canada addresses these assumptions below.

**(1) Chemtura would not have been able to reintroduce lindane**

991. On the instructions of counsel for Chemtura, LECG assumes that Chemtura would have reintroduced lindane products in Canada if the scientific review had been completed by late 2000.<sup>1107</sup>

992. As explained above, Canada made no commitment to complete the Special Review by the end of 2000.

993. More importantly, it is foolish to suggest that if the Special Review had been completed 10 months earlier, the results would have been different. The science would not have been more favourable to Chemtura several months earlier.

994. In addition, by 1998, Canadian canola growers were increasingly concerned that the environmental and health issues surrounding lindane negatively affected the image of canola as a healthy product, and decided that they no longer wished to use lindane products.<sup>1108</sup> This decision would not have been affected by the Special Review being completed 10 months earlier.

995. Nor would an earlier review in Canada have altered the fact that the United States never had a tolerance for lindane treated canola and was ready to close the border to imports of such canola. From an economic perspective, it made no sense for Canadian canola growers to continue to use lindane-treated seeds if there were asymmetric regulations between the United States and Canada.<sup>1109</sup>

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<sup>1107</sup> *LECG Report*, ¶¶ 44-47 and Exhibit D, ¶ 2.

<sup>1108</sup> See Letter from Eugene Dextrase, President, CCGA to Dr. Claire Franklin, Executive Director, PMRA 19 October 1998 (Exhibit WS-13). See also Affidavit of JoAnne Buth, ¶¶ 24-25; Affidavit of Tony Zatylny, ¶ 33.

<sup>1109</sup> Affidavit of JoAnne Buth, ¶ 37.

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**(2) Canada is not responsible for Claimant's decision to abandon efforts to pursue registration for lindane products for canola use in the United States**

996. On the instructions of counsel for Chemtura, LECG assumes that Chemtura would not have voluntarily discontinued efforts to pursue registration in the United States if PMRA had not terminated lindane use on canola seed in 2001 and 2002. Counsel further instructs LECG that Chemtura would have obtained a tolerance for lindane on canola by 2003 and a full registration by 2007 in the United States.<sup>1110</sup> These are also absurd assumptions that weaken the LECG report.

997. Canada has no control over, and is not responsible for, the Claimant's decision to abandon pursuing registration for lindane products for canola use in the United States. This decision was made solely by the Claimant.

998. It is equally outlandish to suggest that the Claimant's efforts to pursue a registration for lindane products from the EPA would have proven successful. The science on which these decisions are based has nothing to do with Canada's conduct, and the EPA made its decision independently of Canada.<sup>1111</sup>

**(3) The Special Review covered lindane products for both canola and non-canola crops**

999. Counsel for Chemtura also instructed LECG to assume that completion of a "fair report" by late 2000 would have enabled Chemtura to continue sale of lindane for non-canola products in 2002.<sup>1112</sup> This is a further unfounded assumption.

1000. The Special Review addressed lindane use on all products, including canola and non-canola seeds. The Special Review would have occurred regardless of Chemtura's tip-off to the EPA that canola seeds treated with lindane were crossing the U.S. border.<sup>1113</sup>

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<sup>1110</sup> *LECG Report*, ¶¶ 44-47 and Exhibit D, ¶ 3.

<sup>1111</sup> *Dr. Goldman Report* ¶¶ 57-59

<sup>1112</sup> *LECG Report*, Exhibit D, ¶ 4.

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1001. In fact, the Special Review was part of a comprehensive PMRA programme to systematically review all of existing registrations.<sup>1114</sup> The PMRA had been reviewing its lindane database since the issuance of the JMPR report in 1997 and had been planning on reviewing lindane as of July 1998 in response to the Aarhus Protocol commitment.

**(4) Chemtura withdrew from the U.S. registration process because the results of the Addendum were imminent**

1002. LECG assumes, on counsel instructions, that Chemtura withdrew from the U.S. registration process in 2006 because of the termination of the lindane market in Canada and the cost of EPA information requests.<sup>1115</sup> Again, it is absurd for the Claimant to blame Canada for its decision not to pursue registration in the United States. It is even more absurd to assume that had it pursued registration in the United States it would have been successful. The problem was not Canada's conduct, but rather that science objectively demonstrates that lindane is a hazardous substance.

1003. It is clear that Chemtura voluntarily withdrew from the U.S. registration process because it knew the results of the Addendum were about to be made public. The EPA's process resulted in a complete ban of lindane (on canola and non-canola products). Chemtura had provided all the data requested to support its registration request to the EPA but ultimately, to no avail. The EPA concluded that lindane was unsafe.<sup>1116</sup>

**(5) The Claimants suggested period of damages is completely untenable**

1004. Finally, LECG's but-for world includes a claim for profits until 2022.<sup>1117</sup>

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<sup>1113</sup> Affidavit of Cheryl Chaffey, ¶ 57.

<sup>1114</sup> Affidavit of Cheryl Chaffey, ¶¶ 33-38, 55-57.

<sup>1115</sup> *LECG Report*, Exhibit D, ¶ 5.

<sup>1116</sup> *Dr. Goldman Report*, ¶ 57-59

<sup>1117</sup> *LECG Report*, Exhibit D, ¶ 6.

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1005. Of course, by July 2006, lindane was no longer eligible for registration in the United States.<sup>1118</sup> Lindane was being progressively banned across the world due to new data that questioned the safety of the product. The U.S. ban in 2006 was not due to Chemtura's withdrawal from the registration process in that country. The assumption that an EPA tolerance or registration would have been granted and continued to 2022 completely ignores reality and the clear direction of science on lindane use.<sup>1119</sup>

**d) The LECG report has numerous mechanical and technical errors**

1006. The Claimant's damage claim is also based on a technically flawed LECG Report.

1007. The report of Navigant Consulting Inc., submitted by Canada, describes numerous errors in the LECG Report which further demonstrate "the pervasive problems inherent in LECG's damages methodology and their flawed instructions and assumptions."<sup>1120</sup> These include:

- LECG does not rely on proper documents such as audited financial statements or internal management reports. It relies on one spreadsheet attached to an e-mail that contains numerous errors, including years with 15 (rather than 12) months and profitability information attributed to the wrong year;<sup>1121</sup>
- LECG assumes that Chemtura would export to and make profit from sales to countries that do not have lindane tolerances, have minimal lindane tolerances, or have banned lindane altogether. This assumption is applied for the entire period to 2022, hence it ignores existing lindane bans (for example in the United States) as well as the likelihood of lindane bans being implemented before 2022.<sup>1122</sup>

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<sup>1118</sup> In Canada, lindane was phased out for canola products into the 2002 growing season (to allow for any hangover product to be used up) and for non-canola products, its use was not permitted after the Special Review process ended.

<sup>1119</sup> *Dr. Goldman Report*, ¶¶ 84-86.

<sup>1120</sup> *Navigant Report*, ¶ 122.

<sup>1121</sup> *Navigant Report*, ¶¶ 123-125.

<sup>1122</sup> *Navigant Report*, ¶¶ 126-129.

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- LECG fails to set-off profit earned through sales of lindane replacement products;<sup>1123</sup>
  - LECG calculated Chemtura's market share based on flawed information and ignoring exports to the United States. It concludes that Chemtura had market share between 57.6% (2000) to an astonishing 115.1% (1996);<sup>1124</sup>
  - LECG increases the per unit sales price of lindane product by almost 100% in its projection of future sales. This contradicts Chemtura's own sales statistics which demonstrate that prices have remained stable over time;<sup>1125</sup>
  - LECG assumes the sale of Gustafson does not represent fair market value without any basis for doing so, and calculates sales related to Gustafson as if it had abandoned sales of lindane replacement products from 2003 onward;<sup>1126</sup>
  - LECG incorrectly uses the Weighted Average Cost of Capital (WACC) as the discount rate, notwithstanding that there is no evidence justifying use of the cost of debt rather than the cost of equity;<sup>1127</sup>
  - LECG makes numerous data-entry, formula and logic errors in implementing its damages model.<sup>1128</sup>

## **B. Interest**

### **1. Summary of Canada's position**

1008. If the Tribunal finds that the Claimant suffered damages as a result of a breach of NAFTA by Canada, it has discretion to award interest if necessary to effect full reparation for the breach found.

1009. An award of interest should be made at the prevailing Canadian or U.S. treasury bill rate in the relevant period, as this benchmark represents a commercially reasonable rate. Interest should accrue from the date of the award. Simple, rather than compound, interest should be awarded.

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<sup>1123</sup> *Navigant Report*, ¶¶ 130-131.

<sup>1124</sup> *Navigant Report*, ¶¶ 132-136.

<sup>1125</sup> *Navigant Report*, ¶¶ 137-138.

<sup>1126</sup> *Navigant Report*, ¶¶ 139-144.

<sup>1127</sup> *Navigant Report*, ¶¶ 145-151.

<sup>1128</sup> *Navigant Report*, ¶¶ 153-159.

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## 2. The law with respect to awards of interest

1010. NAFTA provides little guidance with respect to the award of interest under Chapter 11. Article 1135(1)(a) of the NAFTA simply provides: “[W]here a Tribunal makes a final award against a Party, the Tribunal may award, separately or in combination [ . . . ] monetary damages and *any applicable interest*” [emphasis added].

1011. In addition, NAFTA Article 1110(4) provides that compensation for breach of Article 1110 “shall include interest at a commercially reasonable rate”. NAFTA provides no further guidance on awards of interest. The UNCITRAL Arbitration Rules are also silent regarding awards of interest.

1012. At international law, there is no automatic right to an award of interest on damage, and whether an award of interest is appropriate turns on the circumstances of each case and, in particular, on whether interest is necessary to ensure full reparation for any breach found.<sup>1129</sup> The Commentary on the *ILC Draft Articles* specifically provides, “[I]nterest is not an autonomous form of reparation, *nor is it a necessary part of compensation in every case*” (emphasis added).<sup>1130</sup>

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<sup>1129</sup> *Crawford* (Annex R-175): “Although the trend of international decisions and practice is towards greater availability of interest as an aspect of full reparation, an injured State has no automatic entitlement to the payment of interest. The awarding of interest depends on the circumstances of each case; in particular, on whether an award of interest is necessary in order to ensure full reparation. This approach is compatible with the tradition of various legal systems as well as the practice of international tribunals.” See also, *ILC Draft Articles*, Article 38(1): “interest on any principal sum due under this chapter [on reparation for injury] shall be payable when necessary in order to ensure full reparation. The interest rate and mode of calculation shall be set so as to achieve that result.” (Annex R-208).

<sup>1130</sup> *ILC Draft Articles*, Article 38, Commentary 1. The ILC goes on to note at ¶ 7: “Although the trend of international decisions and practice is towards greater availability of interest as an aspect of full reparation, an injured State has no automatic entitlement to the payment of interest. *The awarding of interest depends on the circumstances of each case; in particular, on whether an award of interest is necessary in order to ensure full reparation.*” (emphasis added) (Annex R-208).

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### 3. Calculation of any award of interest

#### a) Applicable interest rate

1013. If this Tribunal determines that interest should be awarded, Canada submits that the rate should be a “commercially reasonable rate”. This is a logical benchmark and reflects the standard in Article 1110(4).

1014. Investment tribunals frequently use the interest rate on government treasury bills as a proxy for a commercially reasonable rate. The treasury bill rate is easily quantifiable and reflects a guaranteed risk-free government return rate, making it free from speculation. For example, the Tribunal in *Feldman*<sup>1131</sup> awarded interest based on the rate paid for federal treasury certificates or bonds issued by the Mexican Government. A similar approach was taken by a non-NAFTA tribunal in *CMS v. Argentina*.<sup>1132</sup>

1015. LECG has chosen Chemtura Canada's WACC as a pre-award interest rate. This is inappropriate because it inherently holds Canada responsible for the risk profile of the company's capital. A more appropriate rate would be an unbiased commercial lending rate such as a treasury bond rate for either Canada or the United States.<sup>1133</sup>

#### b) Date on which interest begins to accrue

1016. The NAFTA does not specify the date from which interest starts to accrue. The *ILC Draft Articles* provide some guidance, stating that “[i]nterest runs from the date when the principal sum should have been paid until the date the obligation to pay is fulfilled”.<sup>1134</sup>

1017. The Claimant's valuation expert asserts: “[e]ven though Canada's measures start in late 2001, damages to Claimant start to materialize by the end of February 2002 for

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<sup>1131</sup> *Feldman – Award*, at ¶ 211 (Annex R-187).

<sup>1132</sup> *CMS – Final Award*, at ¶ 471 (Annex R-172).

<sup>1133</sup> *Navigant Report*, ¶ 152.

<sup>1134</sup> *ILC Draft Articles*, Article 38, Commentary 2 (Annex R-208).



Crompton's non-canola lindane business and in January 2003 for Crompton's canola lindane business".<sup>1135</sup>

1018. The Claimant took six years between filing its initial notice of intent and the constitution of a panel in this case. Such delay should not be rewarded through an award of interest. At the earliest, interest should commence on the date of the award.

### c) Simple or compound interest

1019. The Claimant argues that it is "entitled" to pre-award compound interest from the date of expropriation.<sup>1136</sup> This is incorrect. As a general principle, simple interest should be awarded when it will adequately compensate the claimant's loss.<sup>1137</sup> Otherwise, the Tribunal risks awarding compensation "out of proportion to the possible loss that was incurred".<sup>1138</sup>

1020. In the NAFTA context, the tribunals in *Pope*,<sup>1139</sup> *Myers*<sup>1140</sup> and *Metalclad*<sup>1141</sup> awarded compound interest. On the other hand, the tribunals in *Feldman*<sup>1142</sup> and *ADM*<sup>1143</sup>

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<sup>1135</sup> *LECG Report*, ¶ 70. It is notable that the Claimant fails to link this loss to any specific event within the years cited (Claimant's Memorial, ¶ 561).

<sup>1136</sup> Claimant's Memorial, ¶ 572.

<sup>1137</sup> *Chorzów Factory*, ¶ 47 (Annex R-168).

<sup>1138</sup> *CME – Final Award*, ¶ 644 (Annex R-170), drawing from several Iran– U.S. Claims Tribunal cases, including: *Anaconda– Iran, Inc. v. Iran* Interlocutory Award No. ITL 65-167-3 (10 Dec. 1986), 13 Iran– U.S. C.T.R. 199 (Annex R-152); *Sylvania Technical Systems, Inc. v. Iran*, Award No. 180-64-1 (27 June 1985), 8 Iran– U.S. C.T.R. 298 (Annex R-284).

<sup>1139</sup> *Pope & Talbot – Damages Award*, ¶ 90: 'In the circumstances, acting pursuant to Article 1131, the Tribunal awards interest on the principal sum at the rate of 5% per annum compounded quarterly as an appropriate rate, starting at December 1, 1999.' (Annex R-258).

<sup>1140</sup> *S.D. Myers – Second Partial Award*, ¶ 307: "The Tribunal determines that CANADA shall pay to SDMI compound interest on the sum awarded in Chapter VI above at the Canadian prime rate plus 1% over the period referred to above." (Annex R-268).

<sup>1141</sup> *Metalclad – Award*, ¶ 128: "So as to restore the Claimant to a reasonable approximation of the position in which it would have been if the wrongful act had not taken place, interest has been calculated at 6% p.a., compounded annually." (Annex R-233).

<sup>1142</sup> *Feldman – Award*, ¶ 205: 'The total revised award indicated above of \$9,464,627.50 Mexican Pesos is increased by simple interest calculated from the date the rebates should have been paid (see below) to the date of this decision [ . . . ].' See also ¶ 206. (Annex R-187).

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awarded simple interest. In *CME v. Czech Republic*, in the non-NAFTA context, the Tribunal awarded simple interest because it adequately “compensate[d] the loss of use of the principal amount of the award in the period of delay”.<sup>1144</sup>

1021. Canada submits that the circumstances of this case dictate against an award of compound interest, if interest is awarded. The guiding principle should be what is required to effect reparation of the loss occasioned by the breach.

1022. The Claimant has not demonstrated that it borrowed money or otherwise incurred debt as a result of Canada's conduct, nor has it justified in any other way why an award of compound interest would be apt. Moreover, the Claimant has continued to function as a profitable company. Because compound interest is not necessary to effect full reparation in this case, simple, rather than compound interest is appropriate.

#### **4. Conclusion on interest**

1023. The Claimant has not proved any loss that would justify an award of interest. An award of interest is not necessary to fully repair the loss, if any, in this case. If interest is awarded, it should be at the Canadian or U.S. treasury bill rate in the relevant period. It should run from the date of the award and should be simple, rather than compound, interest.

### **C. Costs**

#### **1. The UNCITRAL Arbitration Rules**

1024. Article 1135(1) of NAFTA states that a Tribunal is to “award costs in accordance with the applicable arbitration rules.”

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<sup>1143</sup> *ADM – Award*, ¶ 296, 298: “The Tribunal believes that only simple interest, rather than compound, should be awarded. [. . .] The Claimants’ investment would have generated a certain cash flow and profits for ALMEX. However, since this is not an expropriation case, but rather concerns the appropriate compensation to be paid to Claimants for the injury caused as a result of the Respondent’s breach of the national treatment and performance requirements obligations under Chapter Eleven, the Tribunal’s view is that simple interest is appropriate in the present case.” (Annex R-146).

<sup>1144</sup> *CME – Final Award*, ¶ 647 (Annex R-170).

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1025. The applicable arbitration rules in this case are the UNCITRAL Arbitration Rules. Articles 38 and 40 of the UNCITRAL Rules govern costs. Article 38 gives the Tribunal authority to fix the costs of an arbitration, and provides an exhaustive definition of the categories of costs that can be awarded by a Tribunal. It covers both arbitration and legal costs.

1026. More specifically, Articles 38(a)-(d) and (f) of the UNCITRAL Rules cover arbitration costs. Arbitration costs include the fees and costs of the arbitrators, experts and assistants hired for the arbitration, as well as the fees and costs of the arbitration facilities. If the arbitration is administered by an arbitral institution, institutional costs are also part of the arbitration costs.<sup>1145</sup>

1027. Article 38(e) covers legal costs.<sup>1146</sup> Legal costs are the costs of preparing and presenting the case, including counsel fees, witness fees, as well as the costs incurred by experts hired by the parties.

1028. Article 40 sets out the presumptions and tests to be applied by the Tribunal in awarding costs. It reads:

(1) Except as provided in paragraph 2, the costs of arbitration shall in principle be borne by the unsuccessful party. However, the arbitral tribunal may apportion each of such costs between the parties if it determines that apportionment is reasonable, taking into account the circumstances of the case.

(2) With respect to the costs of legal representation and assistance referred to in article 38, paragraph (e), the arbitral tribunal, taking into account the circumstances of the case, shall be free to determine which party shall bear such costs or may apportion such costs between the parties if it determines that apportionment is reasonable...

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<sup>1145</sup> See Kinneer, Meg N., Andrea K. Bjorklund & John F.G. Hannaford, INVESTMENT DISPUTES UNDER NAFTA: AN ANNOTATED GUIDE TO NAFTA CHAPTER 11, Kluwer Law International (2006, updated to 2007), at 33-1135 (Annex R-212) (*Kinneer*).

<sup>1146</sup> *S. D. Myers, Inc. v. Canada*, (UNCITRAL) (Final Award on Costs) (30 December 2002) at ¶ 24 (Annex R-321) (*S.D. Myers – Costs*).

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1029. Article 40(1) creates a rebuttable presumption in favour of the unsuccessful party paying arbitration costs, but allows a tribunal to decide otherwise in appropriate circumstances. By contrast, Article 40(2) includes no such presumption. It is therefore in the Tribunal's discretion to determine how to award legal costs, including by apportionment when reasonable under the circumstances.<sup>1147</sup>

## 2. The circumstances of the case

1030. In applying the UNCITRAL Rules, tribunals typically have assessed the success of the parties in the arbitration as well as the circumstances of the case. The circumstances of a case include the behaviour of the parties during the arbitration, the nature of the issues raised, and in some instances, the circumstances leading to the arbitration.

1031. In *Azinian*, the claim failed entirely. The Tribunal recognized that the losing party usually bear the costs of arbitration and contributes to the legal costs. However, four factors mitigated against such an award: (1) NAFTA was a novel mechanism; (2) the Claimants presented their case in an efficient and professional manner; (3) the Respondent in some ways invited litigation; and (4) the person most accountable for the Claimants' wrongful behaviour would be least likely to be affected by an award of costs.<sup>1148</sup> As a result, the Tribunal made no award of costs and required each side to pay its own.

1032. In *Pope & Talbot*,<sup>1149</sup> the starting point for costs was the mixed success of the parties on the merits. The Tribunal also considered the fact that the issues raised were

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<sup>1147</sup> For more about the difference between these two provisions, see: *Kinnear*, at 32-1135 (Annex R-212); Dore, Isaak I., *ARBITRATION AND CONCILIATION UNDER THE UNCITRAL RULES: A TEXTUAL ANALYSIS* (Boston: Martinus Nijhoff Publishers, 1986), at 66 (Annex R-316); Nurick, Lester, *Costs in International Arbitrations*, (Spring 1992) 7:1, ICSID REV. 59 (Annex R-318); Berger, Klaus Peter, *INTERNATIONAL ECONOMIC ARBITRATION* (Boston: Kluwer Law and Taxation Publishers, 1993), at 617 (Annex R-313).

<sup>1148</sup> *Azinian – Award*, ¶ 126 (Annex R-154).

<sup>1149</sup> *Pope & Talbot Inc. v. Canada* (UNCITRAL) (Award on Costs) (Nov. 26, 2002), at ¶¶ 7-9 (Annex R-320) (*Pope & Talbot – Costs*).

important, novel and difficult;<sup>1150</sup> and the behaviour of the parties during document production.<sup>1151</sup> Due to these circumstances, each Party was to bear its own arbitration and legal costs.

1033. Similarly, in *S.D. Myers*<sup>1152</sup>, the Tribunal, noted that “[s]uccess is rarely an absolute commodity.”<sup>1153</sup> The Tribunal affirmed that the conduct of the disputing parties during the course of the proceedings was to be taken into account, including for example, the fact that the arbitration was hard fought and there was a postponement of the hearing. Legal and arbitration costs were apportioned accordingly.

1034. In *Methanex*<sup>1154</sup>, the Claimant was unsuccessful at both stages of the claim and the Tribunal concluded that on the facts of the case, there was no reason to apportion the arbitration costs. In addition, the Respondent was awarded its legal costs as the Tribunal did not consider apportionment appropriate under Article 40(2) of the UNCITRAL Rules.

1035. In *Thunderbird*<sup>1155</sup> and *Canfor*<sup>1156</sup>, both Tribunals relied heavily on the rebuttable presumption in Article 40(1), calling it the general rule of “costs follow the event”. In *Thunderbird*, the Tribunal did not find the behaviour of the disputing parties significant enough to disregard the general rule of costs following the event.<sup>1157</sup> In *Canfor*, the

<sup>1150</sup> *Pope & Talbot – Costs*, ¶ 15 (Annex R-320).

<sup>1151</sup> *Pope & Talbot – Costs*, ¶ 11 (Annex R-320).

<sup>1152</sup> *S.D. Myers – Costs*, ¶¶ 15-19 (Annex R-321).

<sup>1153</sup> *S.D. Myers – Costs*, ¶ 16 (Annex R-321). The Claimant succeeded in the merits stage, but not completely. In the Damages Phase the Claimant was awarded only a small percentage of the amount claimed.

<sup>1154</sup> *Methanex – Award* (Annex R-235).

<sup>1155</sup> *Thunderbird – Award* (Annex R-287).

<sup>1156</sup> *Canfor Corp, Tembec Inc., Terminal Forest Prods. Ltd. v. United States* (ICSID) Joint Order on the Costs of Arbitration and the Termination of Certain Arbitral Proceedings (19 July 2007) (Annex R-314) (*Canfor – Costs*) The U.S. District Court for the District of Columbia, in a Memorandum Opinion of 14 August 2008 granted the United States its motion to dismiss Tembec's application to vacate the cost award of 19 July 2007.

<sup>1157</sup> *Thunderbird – Award*, ¶ 218 (Annex R-287). In applying the four factors of *Azinian – Award*, the Tribunal decided the fact that the parties presented their case in an efficient and professional manner

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Tribunal also suggested following the general rule unless there were “exceptional circumstances”<sup>1158</sup>.

1036. Most recently, in *Fireman's Fund*<sup>1159</sup>, the Tribunal deviated from the rule of costs following the event, despite the fact that the Respondent was successful in the claim. This was because the Preliminary Question was lost on a technicality and the Claimant made “respectable claims”, some over which the Tribunal had no jurisdiction.<sup>1160</sup>

1037. Similar considerations have been invoked in cases outside of the NAFTA context. In *Generation Ukraine*,<sup>1161</sup> the Claimant had presented its case in a convoluted, repetitive and legally incoherent fashion and its presentation of damages had relied on the “flimsiest foundation”.<sup>1162</sup> As a result, the unsuccessful Claimant had to pay not only the Respondent's arbitration costs, but a substantial portion of the Respondent's legal costs as well.

1038. More recently, in *Plama Consortium*<sup>1163</sup>, the Tribunal made an award of costs in the Respondent's favour due not only to the fact that it was the successful party, but because of the behaviour of the Claimant. In this case, the Tribunal looked not only at the behaviour of the Claimant during the arbitration process, but took into account the circumstances of events leading to the case. The Tribunal found that the Claimant was guilty of fraudulent misrepresentation in obtaining its investment and this fact influenced

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was not a decisive factor for awarding costs in deviation of the general principle. With respect to the other three, the Tribunal concluded that the NAFTA Chapter 11 mechanism was no longer novel and that the other two factors were not applicable to the case. (Annex R-154).

<sup>1158</sup> *Canfor – Costs*, ¶ 139 (Annex R-314).

<sup>1159</sup> *Fireman's Fund – Award*, ¶ 221: “On the basis of the principle set forth in [International Thunderbird], it would mean that costs should be awarded in favour of Mexico. However, the circumstances of the present case are such that the Tribunal believes that it is justified to deviate from that principle.” (Annex R-188).

<sup>1160</sup> *Fireman's Fund – Award*, ¶ 221 (Annex R-188).

<sup>1161</sup> *Generation Ukraine – Award* (Annex R-199).

<sup>1162</sup> *Generation Ukraine – Award* (Annex R-199), ¶ 24.4 (Annex R-199). *See* ¶¶ 24.1-24.8 for entire cost discussion.

<sup>1163</sup> *Plama Consortium Limited v. Republic of Bulgaria* (ICSID Case No. ARB/03/24), Award (27 August 2008), ¶ 322.

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its decision that the Claimant was to bear both arbitration and legal costs incurred by the Respondent.

**3. An award of costs should reflect the circumstances of the case**

1039. Although the “success” of the parties has yet to be determined in this arbitration, and the arbitration is in its early stages, Canada submits it should be awarded its costs regardless of the outcome of the arbitration. The following circumstances support this request:

- The need for a VWA and the steps required to implement it were caused by the Claimant’s own subsidiary alerting the U.S. authorities to the border issue in order to obtain a commercial benefit in the U.S. market;
- The Claimant endangered other registrants in the canola industry by trying to break with its VWA commitments. Its consistent attempts to re-write the VWA and change its terms potentially undermined the agreement and caused considerable insecurity to the Canadian canola industry.
- The Claimant has benefited from an extraordinary amount of due process at the cost of PMRA and Canada: the Special Review, the Board of Review, the REN and nine abandoned Federal Court applications.
- As canvassed in this submission the Claimant has presented the facts in a skewed and inaccurate fashion.
- Canada has expended significant resources on legal process with Chemtura throughout the events in question. Such monies could otherwise be dedicated to protecting public health and safety, and Canada suggests that an award of costs in the circumstances of this case would remedy this to some extent.

1040. Canada respectfully submits that these factors, among others, should be taken into consideration in any assessment of arbitration and legal costs. Canada will make detailed submissions on costs at the conclusion of the hearing.

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**VI. REQUEST FOR RELIEF**

For the foregoing reasons, Canada respectfully requests that this Tribunal render an award:

- i) Dismissing the claims of Chemtura in their entirety;
- ii) Ordering that Chemtura bear the costs of the arbitration in full and indemnify Canada for its costs of legal representation.

THE WHOLE RESPECTFULLY SUBMITTED THIS 20th DAY OF OCTOBER 2008.



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Meg Kinnear  
Christophe Douaire de Bondy  
Stephen Kurelek  
Yasmin Shaker  
Christina Beharry  
Carolyn Elliott-Magwood

On behalf of the Respondent, Canada