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## 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	
	GOVERNMENT OF CANADA		
	POST-HEARING BRIEF		
	October 23, 2009		

Departments of Justice and of Foreign Affairs & International Trade Trade Law Bureau Lester B. Pearson Building 125 Sussex Drive Ottawa, Ontario K1A 0G2 CANADA

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#### I. INTRODUCTION

- 1. In its submissions, the Claimant alleged that Canada breached NAFTA in connection with the withdrawal of lindane use in Canada, and that Chemtura suffered loss as a result. Specifically, the Claimant alleged that Canada's Pest Management Regulatory Agency (PMRA) led a forced withdrawal of lindane product registrations for use on canola, and conducted an improper scientific review. The record and the hearing evidence have confirmed that to the contrary, there was no breach of NAFTA. First, the evidence confirms that PMRA's science-based decision making process, leading to suspension of lindane product registrations, was not in breach of NAFTA. Second, neither the parallel industry-led phase-out of lindane use on canola, nor its implementation, were a breach of NAFTA. Finally, no damages can flow from these facts. Chemtura's lindane sales ended in Canada based on the decision of its clients, the Canadian canola industry, to stop using its product. This in turn was substantially driven by Chemtura's failure to obtain a US registration for lindane use on canola, a fact with no causal link to Canada.
- 2. The following key points were confirmed at the September 2009 hearing, in support of these conclusions:
  - PMRA scientists undertook a Special Review of lindane pursuant to Canada's commitments under the Aarhus Protocol on Persistent Organic Pollutants, prompted by international and domestic concerns regarding the risks lindane presented to human health and the environment.
  - Regardless of what triggered the Special Review, it was an independent scientific assessment of lindane: its outcome was not dictated in advance and was the result of a scientific process. As Canada has noted, the role of a

Chapter 11 Tribunal is not to second-guess the 'correctness' of the science-based decision-making of highly specialised national regulatory agencies.

- The Claimant was given appropriate opportunities to participate in the Special Review process. In any event, the Board of Review process corrected any irregularities in the Special Review process and gave the Claimant full due process, including an opportunity to air its complaints about the Special Review and to submit new data.
- The Board of Review differed with PMRA scientists on certain points within the four corners of scientific debate, and made various recommendations, while finding Canada's result scientifically acceptable.
- The PMRA nonetheless conducted a *de novo* review, the lindane Reevaluation Note (REN), with a new scientific team. The REN took account of the Board's recommendations, offered the Claimant further procedural opportunities to air its complaints and to submit new data, and reached an independent scientific result which it has submitted to public scrutiny.
- As Canada took steps to review lindane, this pesticide has been deemed ineligible for registration and use in nearly every country in the world, based on the unacceptable risks it poses to human health and the environment.<sup>1</sup>
- 3. With regard to the parallel agreement of Voluntary Withdrawal Agreement relating to lindane use on canola (the 'VWA'), the hearing evidence confirmed the following key facts:

<sup>&</sup>lt;sup>1</sup> The most telling proof of this is the inclusion of lindane among chemicals designated for elimination, Schedule A of the Stockholm Convention on the persistent organics pollutants, 9 May 2009 (Exhibit CC-45).

- The VWA was an industry-prompted and industry-driven initiative, responding to a significant crisis that was largely of Chemtura's own making.
- The PMRA played at best a facilitating role under the VWA, and always on condition that the agreement was voluntary, and treated all stakeholders equally.
- The Claimant initially agreed to the terms of the VWA as proposed by the Canadian Canola Council, and stated its agreement publicly. It then spent the better part of a year attempting to force the PMRA to grant it preferential registration terms, failing which it threatened to repudiate the VWA, reckless to the consequences to the end-users of its lindane product. The PMRA consistently refused to grant the Claimant any preference over its competitors.
- The Claimant's alleged 'conditions' for participating in the VWA are not supported on the face of the October 27, 1999 letter, which it regards as the deal between itself and PMRA. That letter instead reiterates the key terms of the original VWA.<sup>2</sup> The only substantial point added in that letter concerned the possibility of reinstatement of Chemtura's lindane products for canola, if certain conditions were obtained. The PMRA extended this clarification to all four registrants.<sup>3</sup> The conditions for reinstatement never materialized.

<sup>&</sup>lt;sup>2</sup> Notably, Chemtura agreed to remove canola from its lindane product labels by December 31, 1999 and to a phase-out period for lindane use on canola, ending July 1, 2001; 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>&</sup>lt;sup>3</sup>Minutes of conference call, 22 October 1999 (Exhibit WS-87).

- To the extent PMRA agreed to take steps to facilitate the VWA for example, by allowing a phase-out of lindane use on canola to July 1, 2001, and reviewing replacement products – the steps it took were squarely within the PMRA's regulatory mandate and powers, and PMRA substantially fulfilled its commitments.
- The PMRA's scientific review of lindane was undertaken well in advance of the October 27, 1999 letter, and would have proceeded in any event. To the extent the PMRA's review was delayed, it was due to issues beyond its control – notably, the collaboration with US EPA, upon which the Claimant equally insisted.
- Despite having made no specific commitments concerning the timing of its review of lindane replacement products in connection with the VWA, the PMRA accelerated the review of the two lindane replacement products, Gaucho 75 ST and Gaucho 480, that Chemtura submitted in connection with the VWA. Chemtura in this way achieved a substantial first-to-market advantage, that it failed to exploit. The PMRA made no open-ended commitment to fast-track all versions of Chemtura's replacement products. The Claimant's October 27, 1999 letter made no reference to replacement products. Chemtura eventually filed an 'all-in-one' version of Gaucho that had substantial deficiencies, and that PMRA reviewed in good faith.
- 4. None of the actions at issue amount to a breach of Articles 1105, 1103, or 1110.
- 5. With regard to damages, the hearing evidence confirmed the following:
  - The Canadian canola industry as of 1998 no longer wished to use lindane

without it being registered in both the US and Canada.

- The US EPA never granted a registration or tolerance for lindane use on canola, despite substantial efforts on Chemtura's part.
- In consequence, the Canadian market for lindane was effectively ended as of 2001 (the end of the VWA phase-out period), irrespective of the results of PMRA's Special Review.
- As for the (minor) non-canola uses of lindane, the Claimant was offered but refused a phase-out period for sale of its remaining product.
- 6. Claimant's expert in calculating alleged damages assumed away not only Canada's alleged measures, but all of the significant negative market factors affecting lindane sales as of 1998. In addition, Chemtura seeks to avoid responsibility for the incoherence of its own business strategy; poor coordination between its U.S. head office and its Canadian and U.S. subsidiaries; failure to adequately prepare for and manage the consequences of scientific change; and notably, failure to develop and properly market new, safer pest control products, despite the near-universal scientific consensus that lindane use presents unacceptable risk to human health and to the environment.
- 7. As a final point, Canada wishes to comment on the credibility of the evidence heard at the hearing. Canada's witnesses systematically confirmed the evidence Canada had put forward in its written submissions. Canada's witnesses notably confirmed the integrity of PMRA's science-based decision-making process; the driving role played by the Canadian Canola Council in the achievement of the Voluntary Withdrawal Agreement; and the Claimant's failure to make any headway in convincing its own home regulator, the EPA, that lindane use on canola was safe.

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8. By contrast, over the course of the hearing, Chemtura's witnesses systematically resiled from their witness statements, or demonstrated that they had taken various positions in the absence of key facts.<sup>4</sup> As for the documentary evidence upon which Chemtura relied, again and again, Canada's witnesses rejected the Claimant's misreadings and partial references to the record. By the end of the hearing, as detailed in the present Memorial, the allegations put forward in the Claimant's opening statement had been systematically discredited.

<sup>&</sup>lt;sup>4</sup> For example, despite alleging in his first witness statement that "I was involved extensively with the subject-matter of this proceeding" (¶4), Mr. Ingulli revealed his systemic lack of knowledge of the issues addressed in his (broad-ranging) witness statements, including PMRA re-evaluation policy regarding the database (Hearing Transcript, Vol. 1, pp. 201-202), Chemtura's failure to suggest mitigation measures at the end of the Special Review (p. 214), or the position of the US EPA on the canola registration (pp. 245-50). He also admitted that the PMRA had the regulatory authority to undertake the steps it did in connection with the VWA (Hearing Transcript Vol. 1, p.237), the concerns of the Canola Council of Canada lead to the VWA (Hearing Transcript Vol. 1, p. 234), and that an agreement in principle was reached in November 1998 concerning the VWA (Hearing Transcript Vol. 1, p. 257). Mr. Thomson admitted contrary to his first witness statement (¶41) that the PMRA had raised worker exposure during the Special Review: Hearing Transcript Vol. 2, pp. 282-287, (Paul Thomson). Contrary to his claimed expectation, Mr. Thomson admitted that this registration could not have been obtained up to and including 2006, at which point the EPA withdrew support even for existing (non-canola) lindane registrations: Hearing Transcript, Vol. 2, pp. 300-301, (Paul Thomson). Mr. Kibbee for his part admitted contrary to his witness statement that Chemtura understood Gaucho 75ST and 480FL – not Gaucho CSFL – would be expedited: Hearing Transcript, Vol. 2, pp. 360-364 (John Kibbee); that Helix was a replacement product; that Chemtura was responsible for some of the delays in processing its Gaucho CSFL application: Hearing Transcript, Vol. 2, pp. 370-376 (John Kibbee); that this application was granted many of the "advantages" allegedly given to Helix: Hearing Transcript, Vol. 2, pp. 376-378, 379-381, (John Kibbee). Mr. Johnson was similarly misleading when he wrote in his First Statement that "as a practical matter, given the situation in Canda, Crompton did not aggressively purse" a time limited tolerance with the EPA (First Witness Statement of Edwin Johnson ¶ 28). This is debunked by his own oral testimony when he said, starting in 1999, Chemtura was "constantly calling on the EPA trying to get them to move. We called them regularly, sent memos over to the managers at EPA" (Hearing Transcript, Vol. 2, p. 446 (Edwin Johnson)) to grant an import tolerance. The EPA's response – "[t]hey didn't say anything, or they said not now" (Hearing Transcript, Vol. 2, p. 447 (Edwin Johnson) - is unsurprising given Dr. Goldman's testimony that such tolerances are granted only in very rare instances (Hearing Transcript, Vol. 5, pp. 1192-93 (Dr. Goldman)).

- 9. In this Post-hearing Memorial Canada summarizes and organizes the evidence from the witness hearing of September 2009, with particular reference to questions posed by the Tribunal on the final hearing day. Canada primarily focuses on issues relating to Article 1105: how the standard applies to the substance of decision rendered by specialized state regulatory agencies and how it applies to the specific allegations at issue here. The Post-Hearing Memorial also briefly comments on Canada's continued objection to the claim brought under Article 1103 and on the Article 1110 claim. Finally, it considers the implications of the hearing evidence for damages.
- 10. Consistent with the Tribunal's directions, in setting out the above, Canada has sought to avoid repeating its prior written submissions. The evidence set out in this Posthearing Memorial is intended to be read in conjunction with the equivalent sections of Canada's Memorials. This Posthearing Memorial is not intended to replace nor indeed to summarize Canada's full case based upon the written record. That case is set out in Canada's Counter-Memorial and Rejoinder and in their supporting witness statements, expert reports and contemporary documents, upon which Canada expressly relies.

# II. A HIGH THRESHOLD EXISTS FOR THE BREACH OF ARTICLE 1105(1) OF THE NAFTA

- A. Minimum Standard of Treatment as Applied to the Substance of Decisions Rendered by Specialized Regulatory Agencies of a State
- 11. At the evidentiary hearing, the Tribunal asked a question regarding the extent of the authority of a Chapter 11 Tribunal in relation to the decisions of a regulatory agency of a State which has a particular statutory mandate in a particular field of expertise. The Tribunal was interested in the relationship between Article 1105 and that special mandate, and in particular as to whether there exists under Article 1105 a "margin of regulatory appreciation" as exists at the domestic level in relation to the substance of

decisions (here related to the safety of pesticides).<sup>5</sup> In answer to that question, Canada notes:

- 1. NAFTA Chapter 11 Tribunals do not have the authority to review the substance of decisions made by specialized regulatory agencies; and
- 2. NAFTA Chapter 11 Tribunals should consider the process that led to a science-based decision to rule on a breach of MST.
  - 1) NAFTA Chapter 11 Tribunals do not have the authority to review the substance of decisions made by specialized regulatory agencies
- 12. Chemtura's claim challenges the science-based decision-making process that led to the ban of lindane as constituting a violation of Article 1105. For instance, the Claimant challenges the choice of safety factors and the evaluation of mitigation measures by the PMRA.<sup>6</sup> It alleges that the science used by the PMRA was not "rigorous." The Tribunal should refuse the Claimant's invitation to delve into the science underlying the PMRA's decision. Chapter 11 Tribunals are not tasked with a substantive evaluation of regulatory science.
- 13. Canada has discussed at length previously the standard applicable under Article 1105 and the high threshold required to find a breach of MST.<sup>8</sup> A substantive evaluation of the science underlying a product ban, here the pesticide lindane, is not compatible with that mandate.

<sup>&</sup>lt;sup>5</sup> Hearing Transcript, Vol. 6, p. 1406 (Professor Crawford).

<sup>&</sup>lt;sup>6</sup> Hearing Transcript, Vol. 1, p. 63 (Opening Statement); Hearing Transcript, Vol. 1, p. 251 (Alfred Ingulli).

<sup>&</sup>lt;sup>7</sup> Hearing Transcript, Vol. 1, p. 251 (Alfred Ingulli).

<sup>&</sup>lt;sup>88</sup> See Canada's Counter-Memorial, pp. 240-303 (for a discussion of the high threshold, see  $\P\P$  676-688); Canada's Rejoinder, pp. 49-86 (also see  $\P\P$  130-134).

- 14. Even in the context of domestic administrative law review of decisions of regulatory agencies, courts in different countries do not perform the type of substantive review suggested by the Claimant. They refrain from such scrutiny (often under the heading of "margin of appreciation"), because they recognize the fact that regulatory agencies are best placed to understand the often complex regulatory schemes they are mandated to implement, the fact that regulatory agencies develop specialised experience and expertise, and the fact that the questions at issue are not easily managed in a judicial context or easily subjected to a legal review (e.g. risk assessment decisions).
- 15. A *fortiori*, an international tribunal, that does not have a scientific mandate but rather is tasked to rule on the breach of MST under NAFTA, should not pronounce itself on the "correctness" of the science of a domestic regulatory agency underlying a product ban. It is a long held principle of international law that States have the sovereign right to decide how best to protect the health and safety of their citizens. The State has the right to set the level of protection it considers appropriate. In this case, the determination of safety factors, for example, is not open to challenge on the basis that they are "unfair" or "too conservative". Further, an international tribunal does not have the authority to second-guess the value and policy judgments that go into science-based decision-making (for example related to risk management). Finally, NAFTA tribunals do not have the authority or expertise to decide amongst a range of acceptable scientific outcomes, which one a State should have chosen.
  - 2) NAFTA Chapter 11 Tribunals should consider the process that lead to a science-based decision to rule on a breach of MST
- 16. The Tribunals in *Methanex* and *Glamis* were both faced with arguments that involved challenges to the scientific basis of decisions made by States. In both cases, the

<sup>&</sup>lt;sup>9</sup> See below at III, A, 2, b).

Tribunals did not base their ruling on the "correctness" of the science, rather limited themselves to considering the science-based process by which the decision was reached.

17. In the context of an Article 1105 claim, the Tribunal in *Glamis* did not attempt to rule on the "correctness" of the science underlying the cultural review of the Imperial mining project. The Tribunal stated:

"In evaluating each of these arguments, the Tribunal is mindful of Respondent's statement that 'it is simply not this Tribunal's task to become archaeologists and ethnographers and to draw a definitive conclusion as to the location of the Trail of Dreams.' The Tribunal agrees with this statement. It is not the role of this Tribunal, or any international tribunal, to supplant its own judgment of underlying factual material and support for that of a qualified domestic agency. Indeed, our only task is to decide whether Claimant has adequately proven that the agency's review and conclusions exhibit gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons so as to rise to the level of a breach of the customary international law standard embedded in Article 1105."

- 18. When applying this standard, the Tribunal added: "Without delving into the veracity of the facts and conclusions presented by Respondent and its witnesses, the Tribunal notes that Respondent submitted evidence that the decisions were reached based upon Section 106-mandated studies and the guidance of professional archeologists [sic] and researchers." It also emphasised the technical background, qualifications and expertise of the professionals involved and the substantial evidentiary support for their conclusions in ruling in favor of the United States. 12
- 19. While in *Methanex* the Tribunal was considering an Article 1102 claim, its approach to scientific evidence is equally relevant. In particular, the Tribunal looked for

<sup>&</sup>lt;sup>10</sup> Glamis Gold, Ltd. v. United States, (UNCITRAL) Award (8 June 2009), ¶ 779 (Annex R-345) ("Glamis Award") (Annex R-345).

<sup>&</sup>lt;sup>11</sup> *Glamis Award*, ¶ 781 (Annex R-345).

<sup>&</sup>lt;sup>12</sup> *Glamis Award*, ¶ 783 (Annex R-345).

indications that the scientific conclusions underlying the ban of MTBE "were so faulty that the Tribunal may reasonably infer that the science merely provided a convenient excuse for the hidden regulation of methanol producers."<sup>13</sup> To reach the conclusion that this was not the case, the Tribunal considered a number of process-based criteria. The Tribunal stated:

"Having considered all the expert evidence adduced in these proceedings by both Disputing Parties, the Tribunal accepts the UC 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. 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." <sup>14</sup>

- 20. Taken together, these cases support an approach that does not evaluate the *substance* of regulatory science but rather considers the science-based decision-making *process* to ascertain whether it suggests that there was gross denial of justice, a complete lack of due process, manifest arbitrariness, etc. Similarly, in order to determine whether the ban on lindane and the process that led to it constitute a violation of MST, this Tribunal should consider process-based criteria.
- 21. The evidence heard during the hearing and outlined in detail below demonstrates the serious, objective and scientific approach used by the PMRA (e.g. there was no

13 Methanex v. United States (UNCITRAL) Award of the Tribunal on Jurisdiction and the Merits (3 August 2005), Part IV, Chapter E, ¶ 19 (Annex R-235) ("Methanex- Award").

14 Methanex – Award, Part III, Chapter A, ¶ 101, (Annex R-235). The Tribunal went on to add that, it was not persuaded that the UC Report was scientifically incorrect. This comment was clearly an obiter as it was not the basis for the conclusion.

predetermined outcome; scientific conclusions were subjected to peer-review), the openness of the process (e.g. there were many communications with stakeholders and the public; conclusions were reconsidered in light of new evidence), and the professional qualifications and expertise of the scientists involved (e.g. there was no bias or conflict; the scientists involved were disinterested and independent).

# III. THE HEARING EVIDENCE CONFIRMS THAT THE CLAIMANT'S ARTICLE 1105 CLAIMS ARE UNFOUNDED

- 22. The Tribunal directed the Claimant in this Post-hearing Memorial articulate exactly what it alleged to be a breach of Article 1105 the main focus of its claim and how such alleged breach, if any, related to its claim in damages. As the Claimant in this matter, Chemtura bears the burden of articulating the specific measures by Canada which in its submission constitute a 'breach' of Article 1105. Up to and including the evidentiary hearing, Chemtura instead presented a laundry-list of allegations concerning the PMRA's dealings relating to lindane, which it alleged 'taken together' constituted a breach to Article 1105. In the constituted a breach to Article 1105.
- Given the nature of the Claimant's written pleadings to date, and the <u>simultaneity</u> of filing of Post-hearing Memorials, Canada has no confirmation of the specific measures the Claimant alleges are breach of Article 1105. Canada has therefore divided its comments on facts relating to Article 1105 into two segments, as presented at the hearing: 1) the PMRA's measures relating to the scientific review of lindane, and 2) its measures relating to the Voluntary Withdrawal Agreement. This division reflects the basic factual involvement of the PMRA in matters relating to the withdrawal of lindane in

<sup>&</sup>lt;sup>15</sup> Hearing Transcript, Vol. 6, p. 1399 (Professor Kaufman-Kohler).

<sup>&</sup>lt;sup>16</sup> Claimant's Reply ¶344, Claimant's counsel was unable, when specifically asked by the Tribunal, to point to any specific measure breaching Article 1105, but rather suggested the breach was an overall 'pattern of conduct': Hearing Transcript, Vol. 1, pp. 66, 68.

Canada. These facts must be judged according to the customary MST upheld under Article 1105 of the NAFTA.

#### A. PMRA's scientific review of lindane

- 1) The PMRA's scientific review of lindane was undertaken on the basis of legitimate considerations squarely within PMRA's mandate
- 24. In his opening statement to the Tribunal, counsel for the Claimant suggested that the PMRA defended the use of lindane in international fora, in 1997 but that once a 'trade' issue arose regarding the use of lindane on canola, Canada used this issue as a pretext to pursue the complete elimination of lindane in Canada.<sup>17</sup>
- 25. Counsel appeared to be alleging that Canada's scientific review of lindane in the Special Review was prompted by improper motivations outside of its legal mandate, and that this constituted a breach, or an element of a breach, of Article 1105. The suggestion was that a Special Review of lindane was unwarranted that the very launching of such a review must be a sign PMRA was dealing unfairly with the Claimant.<sup>18</sup>

<sup>&</sup>lt;sup>17</sup> See Hearing Transcript, Vol. 1, pp. 15-19 (Opening Statement) where Claimant's counsel suggested Canada was 'defending' lindane use in 1997-98; but at pp. 25-26, he alleged that the PMRA 'saw this [trade issue] as an opportunity to advance a separate agenda', 'to remove from the market all lindane product.' No explanation was given to explain these mutually contradictory allegations. Counsel later reiterated that Canada was "pursuing an agenda for the phase-out of lindane" without reference to PMRA's justification (Hearing Transcript, Vol. 1, p. 78).

<sup>&</sup>lt;sup>18</sup> Hearing Transcript, Vol. 1, p. 47 (Opening Statement): counsel noted that the PMRA had conducted few Special Reviews in its history. Canada's witnesses had already pointed out that as of 1998, when the Special Review was organized, PMRA had been in existence for only three years, *see* Second Affidavit of Claire Franklin, ¶ 36. John Worgan later noted that the limited number of Special Reviews did not mean the Special Review of lindane was illegitimate; Hearing Transcript, Vol. 3, pp. 583-584 (John Worgan). *See* also Second Affidavit of John Worgan, ¶¶ 18-25, confirming why the Special Review process was selected.

- 26. To support such allegations, counsel relied on a misreading of relevant negotiation documents relating to the Aarhus Protocol. Moreover, counsel strangely suggested that the PMRA, whose core mandate is to review the safety of pesticides, required the cloak of a "trade issue" to justify a complete review of lindane, a pesticide whose use had by the late 1990s raised sustained international concerns. <sup>19</sup>
- 27. None of these allegations substantiate the position that the PMRA acted outside of its legal mandate, let alone so as to constitute a repudiation of its legal mandate.
- 28. The hearing evidence systematically confirmed that PMRA's decision to conduct a Special Review of lindane was prompted by precisely the sort of scientific issues at the core of its mandate. PMRA's decision to conduct the Special Review preceded any alleged 'trade' issues, and would have gone ahead in all events.
- 29. In its written submissions, Canada confirmed that the PMRA agreed in the 1997-98 negotiations of the Aarhus Protocol on Persistent Organic Pollutants to re-evaluate lindane<sup>20</sup>, in light of evidence presented in the negotiations themselves, and in light of recently-released evidence confirming that lindane was among the most prevalent organochlorine pollutants in the Canadian north.<sup>21</sup> Although there were parallel

 $<sup>^{19}</sup>$  Hearing Transcript, Vol. 1, pp. 22-27, 31, 33, 37-39, 44, 66, 78, 79, 80, 82 (Opening Statement).

<sup>&</sup>lt;sup>20</sup> Claimant's counsel incorrectly stated in his opening statement that 'in all negotiations in the international fora, lindane is not being considered for ban or phase-out. It's being considered instead for restricted uses.' Hearing Transcript, Vol. 1, p. 49 (Opening Statement). In fact, the Aarhus Protocol at Annex II restricts lindane to specific existing uses, but only on condition that even these uses are subject to review Canada's Counter Memorial, ¶ 34. The true extent of international bans and restrictions on lindane is set out in the Second Affidavit of John Worgan, ¶¶21-22; First Report of Dr. Lucio Costa, ¶¶40-45; Second Report of Dr. Lucio Costa, ¶¶63-68.

<sup>&</sup>lt;sup>21</sup> Given the evidence of the CACAR concerning lindane Arctic pollution CC-43, it made perfect sense that potential impact on Canada's northern population would be a strong motivating factor for the review. But that does not mean the outcome of the review would be a

substantial concerns about related chemical compounds, the concerns and Canada's action commitments were squarely focussed on lindane itself. <sup>22</sup> The Claimant's repeated attempt to reduce lindane to a 'trade' issue is patently false. <sup>23</sup> Moreover, the timing of Canada's commitment, as of late 1997 (formally signed in June 1998) again belies the Claimant's attempt to suggest that the 'inception' of PMRA attention to lindane was 'trade' Canada's documentary evidence was confirmed at the evidentiary hearing:

• Dr. Claire Franklin, Wendy Sexsmith, John Worgan and Cheryl Chaffey all confirmed that the Special Review was initiated pursuant to Canada's

foregone conclusion, nor did the PMRA restrict itself to this sole issue in conducting the review, as Claimant's counsel appeared to suggest (Hearing Transcript, Vol. 1, p. 49).

<sup>22</sup> PMRA Project Sheet on the Special Review of Lindane, June 1998 (Exhibit WS-91). Claimant's counsel incorrectly alleged in his opening that the problem was with other HCH isomers, not lindane (Hearing Transcript, Vol. 1, pp. 15-16). This has no credibility in light of the clear language of the Aarhus Protocol Annex II, (Exhibit WS-09) and the PMRA's Special Review planning documents and announcement, all of which were focussed squarely on lindane and not simply on 'HCH isomers'. See e.g. PMRA, Special Review Announcement SRA99-01, Special Review of Pest Control Products Containing Lindane, 15 March 1999 (Exhibit WS-32). Annex II of Aarhus "substances scheduled for restriction on use"... referenced "Products in which at least 99% of the HCH isomer is in gamma form (i.e. lindane...), noting that, "All restricted uses of lindane shall be reassessed under the Protocol no later then two years after the date of entry in force." Canadian negotiating documents from the Aarhus Protocol Negotiations note that Lindane is subject to long range atmospheric transport to remote regions. There is monitoring data demonstrating this (e.g. the Canadian CACAR report), and lindane clearly meets the numerical criteria for long-range atmospheric transport established for this protocol. Lindane is persistent in the environment... There is evidence of bioaccumulation.... It is also important to recognize that two new reports (CACAR and AMP) describing the results of Arctic monitoring programs were released in June. Results show that HCH (including the gamma isomer) is the most abundant POP (Persistent Organic Pollutant) in air, seawater, and rivers in the world. The proportion of gamma isomer coming from the use of lindane versus the use of technical HCH is not clearly established." (Claimant's Reply Exhibit 21).

Problems with other HCH isomers had been identified since the 1970s; by the late 1990s, the gamma isomer of HCH, i.e. lindane, was itself become the focus of attention, as the Aarhus negotiations confirm.

<sup>23</sup> Hearing Transcript, Vol. 1, pp. 22-27, 31, 33, 37-39, 44, 46, 78, 80, 82, (Opening Statement).

commitments under the Aarhus Protocol, prompted by domestic and international concerns about the persistence of lindane in the environment and resulting risks to human health. <sup>24</sup>

- Canada did not 'defend' the use of lindane in the Aarhus Protocol negotiations, as the Claimant alleged, and then suddenly develop an animus against the pesticide when a trade issue arose. By the late 1990s, lindane had already come under sustained negative scrutiny in Canada since the 1970s.<sup>25</sup> As of that time, most above-ground uses of lindane were already eliminated. The Claimant had no basis for any legitimate expectation 'Canada would defend the uses internationally', in the sense of advocating lindane use.<sup>26</sup> But despite significant questions being raised about lindane in the Aarhus negotiations, Canada could not legally commit in an international forum to eliminate remaining registered uses of lindane, without first conducting a scientific review. What Canada could and did commit to under Aarhus, as of June 1998, was to conduct a scientific review of remaining registered uses, and take appropriate action based upon the outcome of that review. Canada's commitment was fulfilled through the Special Review of lindane.<sup>27</sup>
- The Claimant's own witnesses agreed that the Special Review was prompted by health and environmental concerns. Paul Thomson noted: "Right. I

<sup>&</sup>lt;sup>24</sup> Hearing Transcript, Vol. 2, p.457, (Cheryl Chaffey); Hearing Transcript, Vol. 4, pp. 817:14-16, 865:2-6 (Wendy Sexsmith); Hearing Transcript, Vol. 3, pp. 564:23-25, 565:1-3 (John Worgan); Hearing Transcript, Vol. 5, p. 1071 (Claire Franklin); *see* also Second Affidavit of John Worgan, ¶ 33-36; Claimant's Reply Exhibits 19 and 21.

<sup>&</sup>lt;sup>25</sup> First Affidavit of Cheryl Chaffey, ¶ 38.

<sup>&</sup>lt;sup>26</sup> Counsel for the Claimant asserted this unfounded expectation in his opening statement. Hearing Transcript, Vol.1, p. 55 (opening Statement).

<sup>&</sup>lt;sup>27</sup> Hearing Transcript, Vol. 3, p. 565 (John Worgan); Hearing Transcript, Vol. 4, pp. 817, 865 (Wendy Sexsmith); Hearing Transcript, Vol. 5, pp. 1070-3 (Claire Franklin).

mean, there certainly were health concerns and environmental concerns, and by no means do I want anyone to have the impression that there are no health concerns or environmental concerns..."<sup>28</sup>

Canada did not plan and conduct a review of lindane 'behind the scenes', to
borrow the conspiratorial language of Claimant's counsel.<sup>29</sup> Its commitments
under Aarhus were part of a public treaty, and the March 15, 1999 Special
Review document publicly announced to all concerned PMRA's re-evaluation
of lindane was proceeding.<sup>30</sup>

# 2) The scientific review of lindane falls within "acceptable scientific parameters"

- 30. The Claimant, at the hearing, adopted a contradictory approach to the relevance of the scientific findings to its claim.
- On one hand, it claimed that the toxicology around lindane was not what this case was about; that the case was about "due process and fair and equitable treatment." It stated: "In terms of where the science was in question and the validity of the science was in question obviously, that's not what your inquiry goes to."<sup>32</sup>

<sup>&</sup>lt;sup>28</sup> Hearing Transcript, Vol. 2, pp. 344-5 (Paul Thomson); Hearing Transcript, Vol. 1, pp. 222-223 (Alfred Ingulli). This hearing evidence supports internal PMRA documents from the relevant period, confirming Chemtura knew well that lindane was a persistent organic pollutant, and that use of lindane as a seed treatment led to environmental contamination: *see* Letter to Health Canada from Wolfgang Biegel, President of CIEL, 24 February 1998 (*See* Exhibit CC-16A); Email from Bill Hallett to Rick Turner, 25 November 1998 (Exhibit CC-44).

Hearing Transcript Vol. 1, p. 37, (Opening Statement).
 See PMRA, Special Review announcement SRA99-01, Special Review of Pest Control Products Containing Lindane, 15 March 1999 (Exhibit WS-32).

<sup>31</sup> Hearing Transcript, Vol. 1, p. 62 (Opening Statement)

<sup>32</sup> Hearing Transcript, Vol. 1, p. 179 (Opening Statement)

- 32. On the other hand, it tried to undermine the scientific findings to show a violation of Article 1105. For example, Mr. Ingulli asserted that the process used by PMRA was not "scientifically rigorous." Claimant's Counsel argued that "If the selection of that additional 10 X was a fair thing to do, fine. Lindane Review Board thought otherwise. The EPA thought otherwise, and the PMRA in the Lindane Review Broad proceedings itself admitted otherwise."
- 33. The following exchange between Judge Brower and Mr. Somers explaining why the Claimant did not call a scientific expert to respond to Dr. Costa is also revealing:

Arbitrator Brower: "Is that because you simply feel whether or not the science is right is irrelevant to your case?" <sup>35</sup>

Mr. Somers: "No. Quite the reverse. We submit that Canada put a witness to editorialize on those three scientists in the Lindane Review Board exactly because they felt they had something to explain away in relation to that Review Board. We are content to take the Review Board scientists' conclusions and many days of hearings and these thousands of pages that our friend took us through on its face. [...] We rely on the Review Board decision itself."<sup>36</sup>

34. As Canada set out above, a NAFTA Chapter 11 Tribunal does not have the authority to review the substance of decisions made by a specialized regulatory agency of the State. In any event, nothing on the record or heard during the hearing would indicate that the PMRA's process or conclusions was outside of "acceptable scientific parameters."

<sup>33</sup> Hearing Transcript, Vol. 1, p. 251 (Alfred Ingulli)

<sup>34</sup> Hearing Transcript, Vol. 1, pp. 62-63 (Opening Statement). Elsewhere, it qualified its arguments again that this case was not about science, by putting forward concepts such as "science... properly done", "science... [that] has all of the integrity that that word is supposed to carry", "science objectively carried out and searchingly performed" Hearing Transcript, Vol. 1, pp 179-180, (Opening Statement).

<sup>&</sup>lt;sup>35</sup> Hearing Transcript, Vol. 1, pp. 180-181 (Judge Brower).

<sup>&</sup>lt;sup>36</sup> Hearing Transcript, Vol. 1, p. 181 (Opening Statement).

35. Canada addresses below the three arguments raised by the Claimant to undermine the science leading to the de-registration of lindane: scientific disagreements between the special review and the board of review, the choice of safety factors and the decision to reply on worker exposure data produced by the Claimant. Canada will also address the Tribunal's question as to the weight to be given to the evidence of Dr. Costa.

# a. Reasonable scientific disagreements do not provide evidence of breach of Article 1105

- 36. As was heard during the hearing, scientists do disagree in good faith.<sup>37</sup> Even provided with the same data, scientists may disagree.<sup>38</sup> The Claimant alleged which is the "right" science when it relied exclusively on the Board of Review findings.<sup>39</sup> This line of argument is misplaced, not only because the Board of Review itself acknowledged that the process and conclusions were generally within acceptable scientific parameters, but more broadly because it misapprehends the nature of scientific enquiries.
- 37. The reality is that a Board of Review, consisting of different scientists, could have reached different results.
- 38. For example, on the issue of safety factors, as Dr. Costa testified, "...the application of these additional uncertainty factors, it's left to the scientists who conduct the Risk Assessment, and it's often very possible that different scientists, as I mentioned earlier, by looking at the same data, may reach different conclusions....And these differences of opinion are within the boundaries of acceptable sciences. Obviously, if you apply a higher safety factor, you are leaning toward a more conservative position,

<sup>&</sup>lt;sup>37</sup> Hearing Transcript, Vol. 5, pp.1111:14-16, 1112:3-5, 1115:22-24 (Dr. Costa); Hearing Transcript, Vol. 3, p. 658:11-18, p. 658:21-25 (John Worgan)

<sup>&</sup>lt;sup>38</sup> Hearing Transcript Vol. 5, pp.1111-1112, 1116-1117, (Dr. Costa); Hearing Transcript, Vol. 3, p. 658:11-18, p. 658:21-25 (John Worgan)

<sup>&</sup>lt;sup>39</sup> Hearing Transcript, Vol. 1, p. 181 (Opening Statement).

and this is what PMRA seemed to have done. They have chosen a more conservative safety factor."<sup>40</sup>

39. Reasonable scientific disagreements simply do not constitute a breach of Article 1105.<sup>41</sup>

# b. The choice of safety factors is PMRA's and in any event was within acceptable scientific parameters

- 40. First, nothing in Chapter 11 constrains Canada from setting the level of protection it deems appropriate under the circumstances (including PMRA's health protection mandate). Certainly, being "conservative" is not a breach of Article 1105. Second, PMRA's choice of safety factor was not unusual. At the hearing, Mr. Ingulli alleged that nothing "would pass registration if everything had a safety factor of a thousand applied to it." This allegation is wrong. As a matter of fact, the Tribunal heard that this factor was not unusual and that other products (including Helix) have met this standard. 43.
- 41. The Claimant argued at the hearing that the PMRA's decision to maintain its safety factor, after considering the Board of Review's suggestion that it was conservative, indicated a predetermined outcome and a failure to reconsider its decision in good faith.<sup>44</sup> This was not the case. In fact, a new group of scientists performed an analysis under the REN<sup>45</sup>, including new data and independently concluded that the additional 10x

<sup>&</sup>lt;sup>40</sup> Hearing Transcript, Vol. 5, pp. 1115-1117 (Dr. Costa)(emphasis added); First Expert Report of Dr. Costa, ¶¶ 4, 113, 116, 158; Second Expert Report of Dr. Costa, ¶¶24, 36.

<sup>&</sup>lt;sup>41</sup> See "Methanex Award", Part III, Chapter A, ¶ 101 (Annex R-235).

<sup>&</sup>lt;sup>42</sup> Hearing Transcript, Vol. 1, p. 209 (Alfred Ingulli).

<sup>&</sup>lt;sup>43</sup> Hearing Transcript, Vol. 1, p. 63:15-18 (Opening Statement); Hearing Transcript Vol. 2, pp.460-461, (Cheryl Chaffey); Hearing Transcript, Vol. 3, p. 621:19-23 (John

Worgan); Hearing Transcript, Vol. 5, pp. 1124:19-22; 1144:25, 1145:1-18 (Dr. Costa).

<sup>&</sup>lt;sup>44</sup> Hearing Transcript, Vol. 1, p. 63 (Opening Statement).

<sup>&</sup>lt;sup>45</sup> For information about the REN, see Canada's Counter-Memorial ¶¶401-450.

uncertainty factor was justified; and that the PMRA in parallel with the REN undertook an extensive policy analysis to consider whether its safety margins were justified (including through public consultations) and reached the conclusion that they were.<sup>46</sup> This process reflects the scientific method in operation: scientists base their decisions on the weight of evidence at a particular juncture, which is a reflection of the constant evolution of science.<sup>47</sup>

- c. It is up to PMRA to decide the adequacy of existing data and in any event it relied on data provided by the Claimant
- 42. At the hearing, Mr. Ingulli asserted that the PMRA should have known that the worker exposure data it was using was not acceptable and that the PMRA had to know that the study it was relying on did not reflect current seed treating practices in Canada and was "outdated". Yet, Mr. Ingulli admitted that this data was provided to the PMRA by Chemtura itself (its 1992 'Dupree' study), after the PMRA had expressly raised concerns about worker exposure data in a one-on-one meeting between the Executive Director of the PMRA, Dr. Franklin, and Mr. Ingulli himself. Moreover, Dr. Franklin confirmed that Mr. Ingulli himself provided this data notwithstanding his efforts to disassociate himself from it. Technical witnesses such as Cheryl Chaffey further

<sup>&</sup>lt;sup>46</sup> Hearing Transcript, Vol. 3, p. 617:5-20 (John Worgan); *see* 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).

<sup>&</sup>lt;sup>47</sup> Hearing Transcript, Vol. 3, p. 658:21-25 (John Worgan).

<sup>&</sup>lt;sup>48</sup> Hearing Transcript, Vol. 1, p. 251-252 (Alfred Ingulli).

<sup>&</sup>lt;sup>49</sup> Hearing Transcript, Vol. 1, pp. 223-4 (Alfred Ingulli).

<sup>&</sup>lt;sup>50</sup> Hearing Transcript, Vol. 5, p. 1044:6-8 (Claire Franklin).

confirmed that the Dupree study data reflected both current practices in Canada, and the conditions of use stated on Chemtura's lindane product label.<sup>51</sup>

- 43. As Dr. Costa noted, theoretically, exposures to any given pesticide may be mitigated through further protective measures although at a certain point this becomes impractical.<sup>52</sup> Indeed, Dr. Goldman pointed out that personal protective equipment is frequently ignored in real-life work environments, given the conditions applicable during actual seed treatment (for example, during the heat of the Dakotas).<sup>53</sup>
- 44. This line of argument, however, is irrelevant to Dr. Costa's opinion on the work of the PMRA. The real question is whether the PMRA reached a scientific decision based on exposure parameters set out in data that PMRA determined was acceptable. In both the Special Review and the *de novo* re-evaluation of lindane under the REN, the PMRA conducted (among other elements of its review) a study of worker exposure risks, based upon particular exposure parameters. In both cases, it relied on the exposure parameters actually communicated to it by the Claimant. In both cases, risks were determined to be unacceptable.<sup>54</sup> As Canada's witnesses have recalled, in the context of re-evaluation, given that the potentially harmful chemical is in current use, the PMRA is to rely on existing data, typically the data submitted by the registrant as part of the product

<sup>51</sup> Hearing Transcript, Vol. 2, p.479:19-21 (Cheryl Chaffey); Hearing Transcript, Vol. 3, p. 592:1-4, p. 593:16-17 (Cheryl Chaffey).

<sup>&</sup>lt;sup>52</sup> Hearing Transcript, Vol. 5, p. 1127, (Dr. Costa).

<sup>&</sup>lt;sup>53</sup> Hearing Transcript, Vol. 5, pp. 1234-1237 (Dr. Goldman).

<sup>&</sup>lt;sup>54</sup> As Dr. Franklin confirmed in testimony, Mr. Ingulli himself encouraged the PMRA to rely on evidence of current exposure patterns in the Dupree study. That study reflected the current labels of lindane products. It also reflects what the PMRA knew to be still-current use patterns in seed treatment facilities. In the course of the *de novo* review of lindane, the Claimant submitted exposure evidence based upon the closed-system practices it argued would remediate the exposure concerns. Even with these stricter exposure parameters in place, lindane use still presented unacceptable worker exposure risk. Hearing Transcript, Vol. 5, p. 1044 (Claire Franklin).

submission. A prior Canadian re-evaluation exercise had bogged down as registrants sought to push back the decision concerning their product, by continual submissions of new data.<sup>55</sup> The PMRA's decision to rely on existing exposure data is precisely the sort of technical, regulatory policy decision by an agency which international Tribunals should not disturb.

## d. The weight to be given to the testimony of Dr. Costa

- 45. In his questions at the end of the hearing, Judge Brower asked the parties to comment on the effect of Canada having produced uncontradicted expert evidence confirming that "in REN, the PMRA got the science right." Canada's response is that this is simply a question of the balance of evidence. The Tribunal can use Dr. Costa's evidence to confirm that PMRA's process was within acceptable scientific parameters. The Claimant clearly had the opportunity to respond to Dr. Costa's evidence, and failed to do so. It also had the chance to challenge that evidence on cross-examination, but failed to undermine Dr. Costa's conclusions in any credible manner. It is of course up to the Tribunal to determine whether it finds Dr. Costa's evidence credible and persuasive. It is for this reason that Canada has submitted together with his reports, ample evidence of Dr. Costa's extensive scientific credentials and experience.
- 46. The Claimant's main attempt at the hearing to undermine the science in this case was through the testimony of Mr. Ingulli (for example his comment that the Special review was not "rigorous"). Ironically, Mr. Ingulli on cross-examination confirmed that he had had no involvement in and had essentially no substantive knowledge of the

<sup>&</sup>lt;sup>55</sup> First Affidavit of John Worgan, ¶¶ 40-42, ¶¶ 67-72.

<sup>&</sup>lt;sup>56</sup> Hearing Transcript, Vol. 6, p.1405 (Judge Brower).

substance of the Special Review. Mr. Ingulli also repeatedly confirmed that he could not speak to technical issues. <sup>57</sup>

## 3) The outcome of the Special Review was not a foregone conclusion

- 47. The Claimant also suggested that the PMRA's scientific process violated Article 1105 because the outcome of the Special Review was a foregone conclusion.<sup>58</sup>
- 48. The question is whether based on the evidence, the Claimant has demonstrated that Canada's scientific review of lindane was fundamentally biased and conducted to a predetermined outcome, leading necessarily to a finding that the process was nothing more than a pretext and that the Claimant did not receive the MST.
- 49. At the hearing, the Special Review was alleged to be a foregone conclusion because of i) Canada's commitment to review lindane under the Aarhus Protocol and / or related international 'pressure' to restrict lindane use, ii) efforts on the part of NAFTA countries to harmonize their pesticides registrations or iii) as support for the VWA. None of these allegations withstood any scrutiny.
- 50. To the contrary, Dr. Costa, and indeed the Board of Review, confirmed that the PMRA reached its conclusions through a scientific process. The PMRA invested hundreds of scientific person-hours into the Special Review; made extensive technical submissions before the Board of Review; invested further substantial scientific resources

<sup>&</sup>lt;sup>57</sup> Hearing Transcript, Vol. 1, p. 203 (Alfred Ingulli).

<sup>&</sup>lt;sup>58</sup> Hearing Transcript, Vol. 1, p. 251:8-12 (Alfred Ingulli).

to conduct the REN and made extensive scientific comments in response to Claimant's comments on the draft REN results.<sup>59</sup>

51. At the hearing, PMRA scientists confirmed that the process of regulatory review – and the Special Review was no exception - is not initiated with a particular outcome in mind. Cheryl Chaffey strongly rejected counsel's suggestion her conclusions were predetermined:

"I can only tell you what I know as scientific evaluator and a scientific assessor, and I could tell you that I received no direction, that there was no preconceived outcome to the re-evaluation of lindane. We conducted our assessment in good faith and that assessment showed unacceptable risk. That was not predetermined. I have no vested interest in terms of whether an assessment comes out acceptable or unacceptable at the end of the day. My only interest is that we conduct our assessment with scientific integrity."

## 52. John Worgan stated:

"But our scientists, they work -- the integrity of the regulatory process is very important to them, as it should be, and our decisions are based on science -- the best available science that we can possibly have. They don't go into this with a preconceived notion because that would impact on the integrity of the process. The PMRA, as a regulatory agency, I think, is held in high esteem internationally, and that's one of the reasons why EPA and... other regulatory agencies in Europe want to work with us, because... they see the quality of the work we do. Our scientists -- they have no bias going into this. It is what it is at the end of the day in terms of Risk Assessment. If it comes out acceptable, it's acceptable. If it doesn't ...that's the only way that you can have a system that...has integrity. And our scientists, I believe, take their role very seriously. They want to have the best science possible supporting registration decisions and re-evaluations with an eye to protection of human health and the safety. And

<sup>&</sup>lt;sup>59</sup> Second Affidavit of Dr. Costa, ¶¶26, 28, 38-40; Hearing Transcript, Vol. 1, p. 97 (Opening Statement); Hearing Transcript, Vol. 2, p. 463:8-16 (John Worgan); First Affidavit of Dr. Costa, ¶57; Second Affidavit of John Worgan, ¶93; First Affidavit of Cheryl Chaffey, ¶72. Canada's Counter-Memorial, ¶725, 818, 821.

<sup>&</sup>lt;sup>60</sup> Hearing Transcript, Vol. 2, pp. 501-2 (Cheryl Chaffey).

that's the way you get that, is through the best science available."61

# a. Canada's commitment under Aarhus was to conduct a review, not to achieve a particular outcome

- 53. Canada's commitment under the Aarhus Protocol to review remaining Canadian lindane registrations did not mean that the outcome of the review was predetermined. 62 Many countries made this commitment in response to growing concerns about the safety of lindane use. But the PMRA still had to go through its own scientific process, and follow its own scientific guidelines, to reach its own conclusions about appropriate action.
- 54. One could not be blind to the fact that as of the late 1990s, lindane had already come under sustained negative scrutiny.<sup>63</sup> This did not mean as Wendy Sexsmith noted, that the outcome of the review was a foregone conclusion: "So, the environment was negative. There just is no question about that. That doesn't mean that PMRA as a regulatory organization would go into a scientific review assured that the outcome would be negative."<sup>64</sup> Ms. Sexsmith added:
  - "...the whole purpose of these international POPs Convention was to find a way to deal with [lindane]. Our position was that that could well be the case [ie that a ban was necessary]. But I think it really points out or should point out to everybody that we were not going to take action to ban. This wasn't a preconceived idea that Canada had that they were going to ban this, regardless. We clearly stated that we has to do a review to enable a decision as to whether a ban was acceptable or not..."65

<sup>&</sup>lt;sup>61</sup> Hearing Transcript, Vol. 3, p. 657 (Cheryl Chaffey); *See* also Second Affidavit of John Worgan, ¶¶21-24; First Report of Dr. Lucio Costa, ¶49.

<sup>&</sup>lt;sup>62</sup> Hearing Transcript, Vol. 5, pp. 1070-1073 (Claire Franklin).

<sup>&</sup>lt;sup>63</sup> Canada's Counter-Memorial, ¶¶24-42.

<sup>&</sup>lt;sup>64</sup> Hearing Transcript, Vol. 4, pp. 864-865 (Wendy Sexsmith).

<sup>&</sup>lt;sup>65</sup> Hearing Transcript, Vol. 5, pp. 1073-1074 (Wendy Sexsmith).

55. The Tribunal expressly asked Dr. Franklin what she meant when she noted that the PMRA was under considerable "pressure" to reach its conclusions in the Special Review, wondering whether this meant international pressure. Dr. Franklin confirmed that she meant, rather, the PMRA was putting itself under pressure in an effort to complete its re-evaluation in a timely manner. She expressly rejected any suggestion that the PMRA's outcome was somehow dictated by an international agenda.

# b. The impetus to harmonize was legitimate, but did not trump the science

- The Claimant focussed at the hearing on the PMRA's efforts to harmonize regulatory decision-making with its NAFTA counterparts. Yet as senior PMRA representatives Dr. Franklin and Wendy Sexsmith in the first place confirmed, citing policy documents in the record, the PMRA's mandate included promoting the goals of the NAFTA agreement through such harmonization efforts.<sup>68</sup>
- 57. Second, harmonization did not dictate the outcome of PMRA's scientific review. Dr. Franklin, Wendy Sexsmith, John Worgan and Cheryl Chaffey all emphasized that despite legitimate efforts at harmonization, the PMRA's regulatory decisions in general, and in the Special Review of lindane in particular, are in the end dictated by the science. As John Worgan noted:

"In the case of, you know, lindane, they looked at a number of things. They looked at -- they focused on the science and not on the politics.... They look at the available data. They look at the reviews that had maybe been done by other international regulatory agency, but from a scientific point of view, and we make

<sup>&</sup>lt;sup>66</sup> Hearing Transcript, Vol. 5, pp. 1087-1088 (Claire Franklin).

<sup>&</sup>lt;sup>67</sup> Hearing Transcript, Vol. 5, pp. 1087-1088 (Claire Franklin).

<sup>&</sup>lt;sup>68</sup> Hearing Transcript, Vol. 4, pp. 792-4, 881-2 (Wendy Sexsmith); NAFTA harmonization initiatives included the development of a process for joint review of pest control product submissions and for the re-evaluation of existing pest control product registrations, under the aegis of the NAFTA Technical Working Group on Pesticides.

our own independent scientific decisions on the basis of a scientific assessment and applying our own standards and principle to that... Just because one agency has made a decision, it doesn't mean that necessarily we will arrive at the same decision. You know, in the case of the U.S. EPA, in many cases -- in most cases, I'd say that decisions are essentially harmonized, but they're not entirely harmonized..."<sup>69</sup>

- 58. Ms. Sexsmith responded similarly:
  - Q: Now Ms. Sexsmith, does that mean that in the contest of reviewing any particular pesticide for a re-evaluation, for example, that the outcome of that review is going to be dictated by, for example, getting rid of a trade irritant?
  - A: No. It would be dictated by the results of the scientific review.<sup>70</sup>
    - i. The PMRA and EPA did not agree in advance to reach a particular finding in their respective reviews of lindane
- 59. The Claimant referred on several occasions to a document of October 2, 1998 in support of several different, mutually contradictory allegations that PMRA and EPA colluded to pursue a ban of lindane, irrespective of the science.<sup>71</sup> Its misreading of this document was consistently rejected.
- 60. Given the trans-boundary nature of persistent organic pollution, both countries were seeking coordinated international solutions, recognizing that withdrawal in one country alone would not necessarily resolve the problem. As of October 1998, both Canada and the U.S. had committed under Aarhus to review all of their remaining registered uses of lindane. It made sense for the two countries to co-ordinate their respective reviews. But that did not mean that the US EPA was dictating an outcome for

<sup>&</sup>lt;sup>69</sup> Hearing Transcript, Vol. 3, p 658 (John Worgan).

<sup>&</sup>lt;sup>70</sup> Hearing Transcript, Vol. 4, p. 908:3-8 (Wendy Sexsmith).

<sup>&</sup>lt;sup>71</sup> Claimant's Reply Exhibit 32.

Canada, or vice versa.<sup>72</sup> Dr. Goldman explained the general context of discussions between Canada and the U.S. concerning lindane, reflected in the summary 2 October document.

- 61. Dr. Franklin emphasized that any national regulatory outcome in Canada would depend upon the outcome of the science. The October 2, 1998 document expressly notes that the PMRA was in no position to simply "cancel" lindane registration in the absence of a review. Dr. Goldman similarly put to rest the Claimant's implausible suggestion that the EPA might be dictated in its results by some sort of "pressure" from the PMRA. The US EPA had already as of October 1998 begun a full review of all of its existing lindane regulations. As in the case of Canada's national regulator, the EPA does not initiate a re-evaluation with a particular outcome in mind: the EPA is "not allowed to shoot first and ask questions later." Rather the EPA, just like the PMRA, must undertake a very comprehensive review before reaching a regulatory decision. The initial canada is a regulatory decision.
- As reflected in the October 2, 1998 document, PMRA instead suggested that the two agencies might pursue harmonization initiatives under the aegis of a NAFTA programme, the North American Regional Action Plan, or NARAP.<sup>75</sup> A proposal to engage in a NARAP process is the exact opposite of an agreement to summarily 'ban' a pesticide. The proposal led to a nearly 10-year process, which included extensive public consultation, first to consider whether lindane was indeed a proper candidate for a

<sup>&</sup>lt;sup>72</sup> Hearing Transcript, Vol. 5, pp. 1222-1223 (Lynn Goldman).

<sup>&</sup>lt;sup>73</sup> Hearing Transcript, Vol. 5, pp. 1070-1074, 1082-85 (Claire Franklin).

<sup>&</sup>lt;sup>74</sup> Hearing Transcript, Vol. 5, p. 1225:13-20 (Lynn Goldman).

<sup>&</sup>lt;sup>75</sup> Hearing Transcript, Vol. 5, pp. 1057-1060 (Claire Franklin); Hearing Transcript, Vol. 4, p. 900-901 (Wendy Sexsmith).

NARAP; and thereafter, to develop an appropriate plan of action.<sup>76</sup> The NAFTA parties eventually agreed to a lindane NARAP in November 2006.<sup>77</sup>

- 63. The October 2, 1998 document otherwise reflected the two agencies' recognition of the voluntary lindane arrangement being discussed at the time by canola industry stakeholders, and beyond lindane, addressed efforts to coordinate on the underlying systemic issue differences in seed treatment registrations between Canada and the US.
  - ii. The two agencies' NAFTA-inspired collaboration in the re-evaluation of lindane in the end did not dictate a coordinated result
- 64. The Claimant also suggested that since the PMRA and EPA sought to collaborate in their respective ongoing lindane re-evaluation, the scientific outcome was necessarily suspect. This was simply another example of the Claimant criticizing the harmonization initiative mandated by NAFTA.
- 65. Working together and sharing information in an attempt to harmonize pesticide registrations is part of both agencies' mandate, and indeed promoted good scientific practice<sup>78</sup>. Dr. Franklin clarified that there was nothing untoward in the EPA and PMRA discussing differences in their assessments, as demonstrated in a July 30, 2001 meeting agenda. The two agencies had committed to working together on the re-evaluation of lindane.<sup>79</sup> Dr. Goldman noted that the two agencies recognized working together on

<sup>&</sup>lt;sup>76</sup> See e.g. Draft Decision Document on Lindane, 19 April 2000 (Exhibit WS-81); Annex R-48, 30 November 2006.

<sup>&</sup>lt;sup>77</sup> Hearing Transcript, Vol. 4, p. 516:16-18 (Cheryl Chaffey); First Affidavit of Cheryl Chaffey ¶53; Canada's Counter-Memorial, ¶279, 451, 459.

<sup>&</sup>lt;sup>78</sup> Canada's Counter-Memorial, ¶¶308-314; Canada's Rejoinder, ¶¶43-47.

<sup>&</sup>lt;sup>79</sup> Hearing Transcript, Vol. 2, p. 485:16-18 (Cheryl Chaffey); Hearing Transcript, Vol. 5, pp. 1067-1068 (Claire Franklin).

lindane in this manner would address both countries' commitments under the Long Range Transboundary Air Pollution Convention.<sup>80</sup> This evidence simply confirmed the independent view of Dr. Costa that there was nothing conspiratorial or illegitimate about the EPA and PMRA's interactions on lindane.<sup>81</sup>

- 66. The hearing evidence also confirmed that such collaborative reviews improve scientific decision-making without the collaborating agencies necessarily reaching the same result. <sup>82</sup> Attempts at reaching a harmonised decision are a natural part of the ongoing dialogue between two regulatory authorities collaborating in a review. But that did not mean that scientific differences would necessarily be resolved. Rather, each participating agency puts forward its own scientific opinions, while respecting the other's processes and views. <sup>83</sup>
- 67. Indeed, the hearing evidence confirmed specific persistent differences in the scientific approach between the two agencies, notwithstanding efforts at harmonization.<sup>84</sup> Different data requirements, different approaches to data analysis, different national policies on safety standards, different legislative framework, all mean that differences in registration status can persist over several years indeed, indefinitely notwithstanding the impetus to harmonize under the NAFTA.<sup>85</sup>
- 68. This general finding was also true in the specific case of lindane. As Ms. Chaffey noted in her First Affidavit, one of the main differences in review practice as between the US and Canada is that the US, unlike Canada, applies a lower safety threshold when

<sup>&</sup>lt;sup>80</sup> Hearing Transcript, Vol. 5, p. 1223:2-5 (Lynn Goldman).

<sup>&</sup>lt;sup>81</sup> Second Expert Report of Dr. Costa, ¶¶ 8-19.

<sup>82</sup> Hearing Transcript, Vol. 5, p. 1068:7-13 (Claire Franklin).

<sup>&</sup>lt;sup>83</sup> Hearing Transcript, Vol. 2, pp. 529-530 (Cheryl Chaffey).

<sup>&</sup>lt;sup>84</sup> Hearing Transcript, Vol. 4, p. 911 (Wendy Sexsmith).

<sup>&</sup>lt;sup>85</sup> Hearing Transcript, Vol. 4, pp. 909-910 (Wendy Sexsmith); Hearing Transcript, Vol.5, pp. 1111-1112 (Dr. Costa).

considering worker risk than it does in relation to the general population<sup>86</sup>. Moreover, the US EPA, unlike the PMRA, is legislatively permitted to use proprietary data from one registrant, in considering the eligibility for registration of another registrant's product. Under the PMRA's pre-2006 legislation this was not possible.<sup>87</sup> Both of these factors played out in the review of lindane.

- 69. The PMRA applied a higher safety standard than the US EPA when considering worker exposure concerns, in its review of lindane. The PMRA was also legislatively restricted from using proprietary exposure data of other registrants in its lindane review (although its internal calculations determined this date would in any event make no difference in its result). Applying its own policies and safety standards, the PMRA by October 2001 had determined that agricultural use of lindane led to an unacceptable risk of worker exposure.
- 70. By contrast, the EPA by 2002 had determined that applying a lower safety threshold, and subject to additional mitigation measures, certain existing US registrations could be maintained. These existing US registrations did not include canola. Even taking account of additional mitigation measures, and applying a lower worker safety standard, the US EPA as of 2002 found that the proposed canola use led to unacceptable

<sup>&</sup>lt;sup>86</sup> First Affidavit of Cheryl Chaffey, ¶106.

<sup>&</sup>lt;sup>87</sup> Hearing Transcript, Vol. 2, pp. 481-482 (Cheryl Chaffey).

<sup>&</sup>lt;sup>88</sup> As Cheryl Chaffey noted in her affidavit, the PMRA's restrictions on employing proprietary data of other registrants had been specifically brought to Chemtura's attention at the two-day meeting of 10-11 May 1999, at the outset of the Special Review; (First Affidavit of Cheryl Chaffey, ¶77). The PMRA invited Chemtura to seek agreement from such registrants if they wished PMRA to rely on proprietary data. In any event, in October 2001, the PMRA considered the impact of additional mitigation measures considered in such proprietary studies. They determined based on this calculation that the proposed additional mitigation would make no difference in the outcome of the lindane re-evaluation: worker risk remained too high. Indeed, the Claimant subsequently submitted studies based on 'closed systems' both in the Board of Review proceedings, and during the REN. Worker exposure risk remained in excess of PMRA safety standards notwithstanding such measures; (First Affidavit of Cheryl Chaffey, ¶101).

risk.<sup>89</sup> As for the other remaining registrations, as Dr. Goldman noted, the US EPA as of 2002 spent several years considering additional issues relating to lindane use<sup>90</sup>. By 2006, the US EPA had decided it could not support even these few remaining lindane registrations.<sup>91</sup>

# iii. The VWA had no influence on Canada's scientists

- 71. In the course of the hearing, Claimant's counsel also suggested that the outcome of the Special Review was prejudged, because it was dictated by considerations relating to the Voluntary Withdrawal Agreement. This allegation was rejected by PMRA witnesses, and Claimant provided no evidence to support in allegations.
- Wendy Sexsmith summed up the PMRA's response to such allegation as follows: "... if you're saying that because the Canola Council wanted to get rid of it that it lined up with PMRA's view of wanting to get rid of it, I have to say categorically, no, because we don't have a personal view of products. We're a regulatory organization. We regulate. We ensure health and environmental safety. And it's the science that tells us whether or not it meets those provisions. So, for us to make a conclusion before we've done the work is not something we would do as an organization, so I would just have to

<sup>&</sup>lt;sup>89</sup> Claimant's counsel incorrectly alleged in his opening statement that the EPA 'has a major difference in that it found ultimately that there is no occupational exposure risk of concern.' Hearing Transcript, Vol. 1, p. 83:12-14 (Opening Statement). In making this statement he was ignoring the EPA's specific finding about occupational exposure concern relating to the proposed canola use, despite proposed mitigation measures. Chemtura's own witness Mr. Thomson would only go so far as to say, in his first witness statement, that the 2002 RED indicated that the EPA had no 'major' concern about occupational exposure (First Witness Statement of Paul Thomson, ¶30); U.S. EPA Memorandum, Risk Assessment for Lindane for the 2002 Re-registration Eligibility Decision, 31 July 2002, pp. 36-40 (Exhibit CC-09).

<sup>&</sup>lt;sup>90</sup> First Expert Report of Dr. Goldman, ¶¶41-46; Second Report of Dr. Goldman, ¶¶30-38.

<sup>&</sup>lt;sup>91</sup> 2006 RED Addendum (Exhibit JW-59); Hearing Transcript, Vol. 5, pp. 1185-86 (Lynn Goldman).

say no to your statement... if you're saying PMRA thought this was a foregone conclusion... without a scientific review, I mean, I would have to say no."92

73. Cheryl Chaffey confirmed that neither she nor any of the scientists involved in the review of lindane had any involvement in discussions concerning the Voluntary Withdrawal Agreement. No one told her or any other member of the scientific team involved in the Special Review, what result to reach.<sup>93</sup>

## iv. The Claimant has failed to provide any proof of its allegations that PMRA's scientists were biased

- 74. The Claimant's attempts at the hearing to ground its general allegations of bias or prejudgment in specific examples or evidence related to the PMRA's Special Review process all failed. The Claimant's key allegation in this regard concerned data: either that PMRA refused to receive data in its Special Review or that the PMRA deliberately relied on data it knew was outdated in either case, in order to reach a negative result.<sup>94</sup>
- 75. As Canada's witnesses explained, the PMRA in it review of lindane applied the data policy adopted in its new approached to re-evaluation: a policy designed to promote expeditious reviews based upon existing information, and designed to maximize use of

<sup>&</sup>lt;sup>92</sup> Hearing Transcript, Vol. 4, p. 818 (Wendy Sexsmith). Nor was the Special Review result conceivably dictated as some means of 'punishing' the Claimant, in response to Chemtura's position on the VWA. Again, Wendy Sexsmith's response is instructive:

<sup>&</sup>quot;I mean, if you're saying that because Chemtura was a little reluctant, I guess, at the outset to be part of the canola growers Voluntary Agreement, did that impact in any way on our review process, the answer is no. I mean, one of the things about being a regulatory organization is, you know, essentially, we don't have personal views. We're professionals, and we're trying to meet time lines, trying to make sure we get good information so we can do good science, scientific assessments to make sure we are protecting the public, yet providing benefits to Canadians." Hearing Transcript, Vol. 4, pp. 849-50 (Wendy Sexsmith).

<sup>93</sup> Hearing Transcript, Vol. 2, pp. 499-502 (Cheryl Chaffey).

<sup>&</sup>lt;sup>94</sup> Hearing Transcript, Vol. 1, pp. 46, 49, 51 (Opening Statement).

databases already compiled by other national reviewers<sup>95</sup>. This meant that a data call-in would proceed only after considering such other sources. In the case of lindane, Canada had at its disposal the substantial database compiled by the USEPA in its parallel lindane review, making a data call-in redundant.<sup>96</sup>

- 76. The Claimant otherwise complained PMRA had inappropriately relied on the Claimant's own Dupree study, a point addressed above.
- 77. Other internal PMRA documents from the time of the Special Review, relied upon by the Claimant proved to be only partially cited, or otherwise, unsupportive of its allegations.<sup>97</sup>

 $<sup>^{95}</sup>$  For general information regarding PMRA's data policies, see Canada's Counter-Memorial,  $\P 290\text{-}303$ .

<sup>&</sup>lt;sup>96</sup> Hearing Transcript, Vol. 4, pp. 870-871 (Wendy Sexsmith); Hearing Transcript, Vol. 2, pp. 485-486 (Cheryl Chaffey). *See* also, First Affidavit of Cheryl Chaffey, ¶¶69-71; Memorandum from S. Geertsen to Cheryl Chaffey, 6 December 1999 (Exhibits CC-22A), Memorandum from W. Briggs to Cheryl Chaffey, 23 November 1999 (Exhibit CC-22B), NAFTA Technical Working Group on Pesticides, Executive Meeting, Minutes of 19-20 January, 2000, 19-20 January 2000 (Exhibit CC-22C), and Minutes of meeting of NAFTA Technical Working Group, 19-20 January 2000 (Exhibit CC-22D).

<sup>&</sup>lt;sup>97</sup> Claimant's counsel selectively quoted an email from Wendy Sexsmith of January 1999, which referred to the 'demise of lindane', Hearing Transcript, Vol. 1, pp. 33-34 (Opening Statement); Reply Exhibit 55. As Canada had already pointed out, the document refers exclusively to the planned voluntary withdrawal of lindane use as a canola seed treatment. It in no way refers to the PMRA's scientific review of lindane, which was a separate process (in which Wendy Sexsmith had no substantive role). Counsel cited an internal PMRA email in which a PMRA employee responded to an enquiry about the potential administrative reinstatement of lindane products for canola. This was in connection with the planned VWA update meeting of June 24, 1999. (Minutes of meeting organized by CCC/CCGA to monitor implementation of the VWA and progress on lindane replacements, 24 June 1999 (Exhibit WS-29)). The employee noted that registrants could re-apply, and (as things stood then) the use was approved, so refusal of registration would require a good reason. (Email exchange between Wendy Sexsmith and Roy Lindstone, PMRA, and JoAnne Buth, Canola Council of Canada, re: "lindane", 16 June 1999 (Reply Exhibit 60)). The request relates to the issue of administrative reinstatement that was ultimately resolved in the PMRA's teleconference with registrants of October 22, 1999; Minutes

78. Even if the Tribunal were to find that the PMRA's Special Review of lindane was a 'foregone conclusion', – which Canada denies – its enquiry under Article 1105 would not stop there. Canada's measures must be considered as a whole. As Canada has established, following the Special Review of lindane, the Claimant was granted the opportunity to review the PMRA's scientific decision-making in the Special Review, through a full domestic hearing. Despite the Board of Review's conclusions that the PMRA's process for determining appropriate safety standards, and result, were in generally in accordance with acceptable scientific practice, the PMRA nonetheless undertook a second, de novo review of lindane, with a new scientific team, during which time the Claimant was allowed to submit still further data and comments. The results of this second review were communicated in draft to the Claimant in April 2008. The PMRA thereafter engaged in a year of exchanges with the Claimant to address its comments on the PMRA's conclusions<sup>98</sup>. Considered separately and a fortiori as a whole, nothing in these facts confirms a breach of the contrary international minimum standard of treatment, on any reading of that standard.

# 4) The Special Review was not fundamentally flawed from a procedural point of view

79. In addition to challenging the science underlying PMRA's decision, the Claimant at the hearing also reiterated its allegations that the Special Review of lindane was procedurally flawed, and that this amounted to a breach of Article 1105. Notably, the Claimant alleged that 1) the PMRA failed to inform the Claimant of the process of the

of conference call, Exhibit WS-87. In fact, as Dr. Franklin noted, it was PMRA policy during the course of a re-evaluation to withhold expansions on registrations. This was expressly stated on the face of the Special Review announcement: PMRA, Special Review Announcement SRA99-01, Special Review of Pest Control Products Containing Lindane, 15 March 1999 (Exhibit CC-21). "Pending completion of this Special Review, the PMRA will not consider use expansions."

98 See Canada's Rejoinder, ¶68.

Special Review and 2) the PMRA allegedly failed to disclose the substantive 'focus' of the Special Review.<sup>99</sup>

- 80. Under Article 1105, the Tribunal should consider whether from a procedural point of view, the Claimant was subjected to treatment that breached the high threshold of customary MST, i.e., that the procedural irregularities were such as to amount to a complete lack of due process or gross denial of justice. Moreover, any consideration of the Claimant's procedural treatment would have to consider the treatment as a whole, including actions on the part of the State to remedy any alleged procedural deficiencies.
- 81. The hearing evidence again confirmed the Claimant's complaints to be without foundation. The Claimant admitted that it understood the PMRA's processes, was given an early and extensive opportunity to ask questions about the Speical Review, and was offered the opportunity to raise any concerns about the review at the highest level of the PMRA, well before the PMRA released its Special Review results. The Claimant also admitted it was aware that worker exposure was part of the Special Review from the start, and that PMRA had raised this issue as a particular concern a full year before PMRA issued its results.
- 82. With regard to divulging the process of the Special Review, the Claimant's witness Mr. Ingulli admitted:
  - The Claimant as a sophisticated registrant would be expected to understand PMRA practices.<sup>101</sup>

<sup>&</sup>lt;sup>99</sup> See e.g. Hearing Transcript, Vol. 1, pp. 53-54 (Opening Statement).

<sup>&</sup>lt;sup>100</sup> Canada's Counter Memorial, ¶¶ 676-688; Canada's Rejoinder, ¶¶130-134.

<sup>&</sup>lt;sup>101</sup> Hearing Transcript, Vol. 1, pp. 197-198 (Alfred Ingulli).

- PMRA in any event engaged in a two-day meeting with Chemtura at the outset of the Special Review (May 10-11, 1999)<sup>102</sup>, during which time
   Chemtura's representatives were free to ask PMRA any question they liked.<sup>103</sup>
- The PMRA in October 2000 organised a high-level meeting between Mr.
   Ingulli and Dr. Franklin, the Executive Director of the PMRA, a year before PMRA's results were released, and if PMRA raised an issue at that meeting it would be signalling concern from the highest level of the organization.
- 83. With regard to alleged lack of notice of the 'focus' of the Special Review, the witness evidence confirmed as follows:
  - The Special Review announcement indicated that there were a number of issues arising on health and the environment in connection with lindane. The announcement also indicated that other issues could come up in the course of the review. Mr. Thomson admitted that he was aware of this. Mr. Thomson further agreed in any event that "the evaluation of the exposure to the pesticide is a standard practice of [a PMRA] re-evaluation". 107

<sup>&</sup>lt;sup>102</sup> Regarding the 10-11 May 1999 meeting, *See* Minutes of meeting between PMRA, Chemtura and CIEL (Exhibit CC-23). For a general discussion of the May 10-11 meeting, see Canada's Counter-Memorial, ¶340-344.

<sup>&</sup>lt;sup>103</sup> Hearing Transcript, Vol. 1, pp. 198-200 (Alfred Ingulli); PMRA, Special Review Announcement SRA99-01, Special Review of Pest Control Products Containing Lindane, 15 March 1999 (Exhibit WS-32).

<sup>&</sup>lt;sup>104</sup> Hearing Transcript, Vol. 1, pp. 222-223 (Alfred Ingulli).

<sup>&</sup>lt;sup>105</sup> Hearing Transcript, Vol. 5, pp. 1048-50 (Claire Franklin); Exhibit CC-21.

<sup>&</sup>lt;sup>106</sup> Hearing Transcript, Vol. 2, p. 280 (Paul Thomson).

<sup>&</sup>lt;sup>107</sup> Pest Control Products Regulations, Section 4 (Exhibit JW-3); Hearing Transcript, Vol. 2 p. 281 (Paul Thomson).

- Mr. Ingulli admitted that as early as May 10-11, 1999 the PMRA indicated to Chemtura that health issues would be addressed in the Special Review in the fall of 1999. He also admitted that health issues would be understood to include exposure to the pesticide during seed treatment. 108
- Dr. Franklin noted that the results of other national authorities (notably the negative finding of the UK Pesticides Safety Directorate, or PSD, on worker exposure) were expressly raised at the meeting of May 11, 1999. 109
  Chemtura's representative Edwin Johnson's own May 11/99 meeting minutes reference the UK PSD's exposure study, and PMRA's interest in obtaining a copy. 110
  The Claimant had been closely engaged in the UK PSD review and would therefore have been aware of their occupational exposure concern as of that time the UK result was publicly announced only a month after the May 1999 meeting. 111
- The Claimant as a sophisticated registrant would also have been aware of international concerns about occupational exposure to lindane, and that the

<sup>&</sup>lt;sup>108</sup> Hearing Transcript, Vol. 1 pp. 205-206 (Alfred Ingulli).

<sup>&</sup>lt;sup>109</sup> Hearing Transcript, Vol. 5, pp. 1051-2 (Claire Franklin); *see* also Hearing Transcript, Vol. 3 pp. 587-8 (John Worgan).

Hearing Transcript, Vol. 2, p. 285 (Paul Thomson); Exhibit C-4.

found the UK study of limited use because of difference in exposure patterns (Hearing Transcript, Vol. 1, p. 53 (Opening Statement)), citing Reply Exhibit 62. As Claire Franklin noted (Hearing Transcript Vol. 5, p. 1054 (Claire Franklin)), this is beside the point: the important issue was that the PMRA would be prompted to consider worker exposure seriously, given a negative finding on this issue by an equivalent national regulator; *see* Ministry of Agriculture, Fisheries and Food (U.K.) News Release: Review of the Pesticide Lindane, 18 June 1999 (Exhibit CC-32). The UK PSD announcement states, "the Government has listened to the concerns raised about lindane and has acted on the scientific findings of the advisory committee on pesticides. We asked the committee to consider all the health and environmental issues raised by lindane. **On the basis of their advice, we plan to take urgent action to ban the use of lindane in the seed treatment process.** We are also seeking further data on environmental impacts." (*our emphasis*).

PMRA would have to take account of the negative findings of equivalent national regulators its own review.

- 84. As Cheryl Chaffey confirmed, the PMRA's Special Review of lindane in fact advanced on all fronts up to October 2001 exposure assessment, toxicology, environmental assessment, carcinogenicity, value. Thus, the notion that worker exposure became the 'focus' of the Special Review at the expense of other issues is simply false. Rather, the PMRA reached a negative conclusion about worker exposure first at which point, it abandoned other aspects of its review as academic. As a cademic.
- 85. The hearing evidence also confirmed that PMRA specifically asked Chemtura to provide worker exposure data, over a year before the Special Review was completed; and that in response, Chemtura encouraged the PMRA to rely on its own Dupree study:
  - At the meeting of October 4, 2000 over a year before the October 2001 release of the Special Review results Dr. Franklin specifically noted to Mr. Ingulli that worker exposure was a PMRA concern in the lindane Special Review. Although Canada would not extrapolate the findings of another national authority due to differences in use patterns, it would take notice of such a review, as any reasonable and sophisticated company would expect. The reference to worker exposure concerns was more than a passing

<sup>112</sup> Claimant's counsel in his opening statement incorrectly alleged that "Industry wasn't aware that this (occupational exposure) would... be a focus of the Special Review." Hearing Transcript, Vol. 1, p.53 (opening statement); First Affidavit of Cheryl Chaffey, ¶¶26, 91-94, 126-130.

<sup>&</sup>lt;sup>113</sup> The PMRA did not <u>also</u> need to know e.g. that lindane was a potential carcinogen, before cancelling the product, as Mr. Ingulli recognized. Hearing Transcript, Vol. 1, pp. 207-208 (Alfred Ingulli).

<sup>&</sup>lt;sup>114</sup> Hearing Transcript, Vol. 5, pp.1040-1042, 1050-1 (Claire Franklin).

<sup>&</sup>lt;sup>115</sup> Hearing Transcript, Vol. 5, pp. 1053-1054 (Claire Franklin).

discussion. Dr. Franklin and Mr. Ingulli also discussed ways in which data was gathered.<sup>116</sup>

- Mr. Ingulli admitted that an issue raised in this context signalled to Chemtura that this was a concern at the highest level within the PMRA.<sup>117</sup> Mr. Ingulli's own notes of the meeting plainly state "Concerns of PMRA: Worker Exposure. Told PMRA that EPA reviewed and accepted seed treat worker exposure study." <sup>118</sup>
- Chemtura's response was indeed to encourage the PMRA to rely on its 1992
   Dupree study in assessing the exposure workers were likely to experience in their review of lindane, sending on a copy of this study only two days after the October 4, 2000 meeting.<sup>119</sup>
- Mr. Ingulli suggested in his testimony that Mr. Dupree had passed on the 1992 study by mistake; that Mr. Dupree had not known that the study was out-of-date. This in itself was an admission against interest by Mr. Ingulli, given that Mr. Dupree was a Chemtura employee and was sending on the study in

<sup>&</sup>lt;sup>116</sup> Hearing Transcript, Vol. 5, p. 1042 (Claire Franklin).

<sup>&</sup>lt;sup>117</sup> Hearing Transcript, Vol. 1, p. 223 (Alfred Ingulli).

Alfred Ingulli handwritten notes from meeting with Dr. Claire Franklin, Executive Director, PMRA.Exhibit, 04 October 2000 (Exhibit CF-12).

Canada) to Janet Taylor, PMRA, 06 October 2000 (Exhibit CF-10). Canada's Counter-Memorial, ¶323, 344, 353. Claimant's counsel in his opening statement, incorrectly alleging the issue had not been raised with Chemtura, also asserted that 'obviously we are in a position to talk about that because they work with seed treaters on a daily basis.' (Hearing Transcript, Vol. 1, p. 53 (Opening Statement)). As counsel would have known when making this statement, the PMRA indeed did consult with Chemtura on the occupational exposure issue, and received the Dupree study from Mr. Ingulli and Mr. Dupree. The Board of Review, on which the Claimant places so much weight, expressly criticized Chemtura for its failure to point out alleged deficiencies in the Dupree study, failure to suggest the labels didn't reflect current practice, and failure to suggest any mitigation measures: *See* Exhibit WS-71, Board of Review decision, pp. 195-196.

Chemtura's name. Mr. Ingulli's testimony was in any event misleading. Dr. Franklin subsequently confirmed that Mr. Ingulli himself had urged the study upon the PMRA, at the October 4, 2000 meeting. <sup>120</sup>

- 86. Moreover, in October 2001, when the PMRA released its draft Special Review results confirming a finding of unacceptable worker exposure risk, Chemtura was offered the opportunity to correct any of the PMRA's errors in analysis, including by stating that Chemtura has relied on the outdated data. Indeed, Chemtura took the same Dupree study and simply applied to it a lower safety standard to suggest that PMRA had reached the wrong result.<sup>121</sup>
- 87. All of the foregoing confirms the fallacy of counsel's claim in opening, that Chemtura was 'not consulted at all' on occupational exposure, and only found out that occupational exposure was an issue 'late in the process.' 122
- 88. As for the Claimant's complaints about the short time-period for comment at the end of the Special Review, between later October 2001 and early December 2001<sup>123</sup>, the critique was misplaced<sup>124</sup>. The comment-period was not intended for registrants to generate entirely new studies (which would in any event be contrary to PMRA policy of relying on existing data in re-evaluations). Rather, the period was primarily to allow

<sup>&</sup>lt;sup>120</sup> Hearing Transcript, Vol. 5, p. 1044 (Claire Franklin).

<sup>121</sup> First Affidavit of Cheryl Chaffey, ¶¶ 101-102; First Affidavit of Wendy Sexsmith, ¶¶99-102; Lindane failed to meet appropriate safety margins even using Chemtura's lower safety threshold: as Cheryl Chaffey noted, Chemtura's calculations were incorrect; Canada's Counter-Memorial, ¶349; First Affidavit of Cheryl Chaffey, ¶ 101; First Affidavit of Wendy Sexsmith, ¶101.

<sup>&</sup>lt;sup>122</sup> Hearing Transcript, Vol. 1, p. 54 (opening statement). *See* also Hearing Transcript, Vol. 2, pp. 280-289 (Paul Thomson), for Mr. Thomson's admissions to the contrary; and Second Affidavit of John Worgan, ¶¶ 6-7 and fn 3.

<sup>&</sup>lt;sup>123</sup> Hearing Transcript, Vol. 1, p. 55 (opening statement).

 $<sup>^{124}</sup>$  For a general discussion of the PMRA's comment period, see Canada's Counter-Memorial,  $\P \mbox{346-355}.$ 

stakeholders the opportunity to bring to the PMRA's attention existing studies that it might have missed; and to correct any errors they saw, such as mistakes in the PMRA's calculations<sup>125</sup>. A period of several weeks was appropriate for this purpose.

- 89. The Claimant also had the opportunity to raise potential mitigation measures during this period, such as restrictions on formulations, or additional protective equipment. It altogether failed to do so, preferring instead to outright reject the PMRA's findings. Mr. Worgan noted that "I recognize that the Board felt that it was too short, but it was still a month and the issues around lindane had been raised for a number of years. Chemtura would have been well aware that there would have been possible mitigation measures that they could have come in to address with us, but essentially what they did is they just rejected the Assessment. They didn't come in and inquire with respect to what were some of the possible mitigation measures". 127
- 90. As Mr. Worgan confirmed in testimony, following the release of the Special Review on lindane, PMRA's typical comment period was subsequently adjusted. It is now in the range of 45-60 days instead of 30 days. This minor variance underlines that the Claimant's complaints relate not to gross procedural unfairness, but to the details of a domestic agency's procedure.

<sup>&</sup>lt;sup>125</sup> First Affidavit of John Worgan, ¶72.

<sup>126</sup> In addition, Mr. Worgan noted that the PMRA *did* consider potential mitigation measures in the Special Review, notwithstanding the Claimant's failure to propose any. These measures were determined to be inadequate to address the risks lindane posed to worker health: Hearing Transcript, Vol. 3, pp. 652-655 (John Worgan). *See* also First Report of Dr. Costa, ¶¶10-11, regarding the PMRA's assessment of mitigation.

<sup>&</sup>lt;sup>127</sup> Hearing Transcript, Vol 3, p. 605 (John Worgan).

<sup>&</sup>lt;sup>128</sup> Hearing Transcript, Vol. 3, p. 599 (John Worgan).

- 91. Taken together, all of this hearing evidence confirmed what had already been evident on the face of Canada's Memorials: the Claimant's alleged "procedural" complaints do not amount to a violation of the customary MST. 129
- 92. Claimant's counsel relied heavily on procedural criticisms put forward by the Board of Review.<sup>130</sup> But as Canada has demonstrated, the Board did not have all relevant evidence before it in this regard the Board's hearing, after all, was intended to focus on the science. And in any event, the Board of Review was not making an inquiry into a potential violation of the customary MST under Article 1105 of the NAFTA.<sup>131</sup> In any event, as Canada will set out in what follows, the very fact that the Board of Review took place is fatal to these claims.
  - 5) The process leading to de-registration including the Board of Review provided the Claimant due process
- 93. The Board of Review procedure confirms that Canada took seriously the Claimant's complaints about the Special Review process<sup>132</sup>. Through this extensive domestic review process, the Claimant was given ample due process to air its complaints, and to propose further evidence for the PMRA's consideration.
- 94. The Board of Review process in itself is powerful and conclusive evidence of the due process Chemtura received in connection with the scientific re-evaluation of lindane, further dismissing any suggestion that Canada violated Article 1105. Canada set out the

<sup>129</sup> Mr. Worgan summed this up: "Were we perfect? No, we weren't perfect. Was it reasonable at the time in light of the risks that had been identified? Yes, we felt it was." Hearing transcript, Vol. 3, p. 654 (John Worgan).

<sup>&</sup>lt;sup>130</sup> Hearing Transcript, Vol. 1, p. 60 (opening statement).

<sup>&</sup>lt;sup>131</sup> Canada's Rejoinder, ¶¶136-144.

<sup>&</sup>lt;sup>132</sup> Canada's Counter-Memorial, ¶¶728-740; Canada's Rejoinder, ¶¶210-213.

evidence of this process in detail in its Counter-Memorial.<sup>133</sup> This evidence is uncontradicted.

- 95. At the hearing, Claimant's counsel attempted to challenge this by alleging that the Board of Review was constituted only after the Claimant had been obliged to launch extensive proceedings against Canada.<sup>134</sup> This is not only irrelevant but testimony at the hearing, supported by the record, confirmed this allegation to be false.
- 96. The Claimant's requests for the constitution of a Board of Review were presented to the Minister of Health in February and March, 2002. The Minister responded to the Claimant by May 2002, confirming that the Claimant's request had been forward to the PMRA for appropriate action.<sup>135</sup>
- 97. Although the Minister's original letter of response did not expressly state the PMRA's role in the Board of Review process, the Claimant did not seek to resolve its doubt in anything like a reasonable manner. Rather, the Claimant waited several weeks before writing to the Minister on June 3, 2002, demanding a clarification; and then within less than 9 business days, before the Minister had reasonable time to reply, launched an application against the Minister of Health in Federal Court, in connection with the PMRA's involvement in the Board of Review process. 136

<sup>&</sup>lt;sup>133</sup> Canada's Counter Memorial, ¶¶371-400; Appendix E.

<sup>134</sup> Hearing Transcript, Vol. 1, p.59 (Opening Statement). Canada's Counter-Memorial, ¶¶373-376. For a full account of the Claimant's Federal Court application, see Appendix E to Canada's Counter-Memorial.

<sup>&</sup>lt;sup>135</sup> Canada's Counter Memorial, ¶373.

<sup>&</sup>lt;sup>136</sup> Exhibit WS-70.

- 98. Dr. Franklin noted that the PMRA was in the course of identifying candidates when the Claimant launched its application in Federal Court against the Minister. While this application was pending, the PMRA suspended its search for candidates.<sup>137</sup>
- 99. Chemtura waited until the matter was heard in Federal Court before confirming that in fact it had no objection to the involvement of the PMRA in identifying appropriate candidates for the Board.<sup>138</sup>
- 100. Once the Claimant's application had been effectively withdrawn, the PMRA proceeded with its original plan to nominate candidates for the Board, consistent with its original plan.
- 101. There was never any question of any employee of the PMRA sitting as a member of the Board of Review.<sup>139</sup> The Minister was simply calling on PMRA's expertise to help identify candidates who would have the technical proficiency to scientifically review PMRA's Special Review of lindane.<sup>140</sup>
- 102. As for the issue of Canada eventually paying costs, Chemtura's application was rolled into a consolidated proceeding encompassing a half-dozen pending Chemtura Federal Court applications. Although Chemtura ultimately agreed to discontinue all of

<sup>&</sup>lt;sup>137</sup> Hearing Transcript, Vol 5, pp. 1086-7 (Claire Franklin).

<sup>&</sup>lt;sup>138</sup> Hearing Transcript Vol. 5, pp 1046-7 (Claire Franklin).

<sup>139</sup> Claimant's counsel incorrectly suggested this was the case in his opening statement: Hearing transcript, Vol. 1, p. 58.

<sup>&</sup>lt;sup>140</sup> Exhibit WS-67.

 $<sup>^{141}</sup>$  Canada's Counter-Memorial, ¶¶206-224; see also Annexes R54, R55-R59, R62, R63, R122.

its proceedings, and notwithstanding their manifest lack of any merit –Chemtura still claimed it should receive its costs.<sup>142</sup>

# 6) The REN was not biased and cured any alleged deficiencies in the Special Review

103. The REN was not undertaken, as the Claimant has suggested, as an admission that the Special Review was fundamentally incorrect.<sup>143</sup> Rather, it demonstrated that the PMRA followed up on the recommendations put forward by the Board of Review.<sup>144</sup> In any event, grave flaws or irregularities us with the Special Review, if proven, could only read to a finding of breach of MST if not remedied. The REN cured all deficiencies of that might have been imputed to the Special Review.

104. In order to undermine the REN process, the Claimant attempted to impugn it as biased. The alleged "evidence" the Claimant presented in this regard was the continuing involvement of John Worgan; or alternatively, a reference to advice given to the PMRA by counsel in connection with the present arbitration.

105. On the first point, the hearing evidence confirmed evidence already presented in Canada's Rejoinder. Mr. Worgan had no substantive role in the lindane REN<sup>145</sup>:

<sup>&</sup>lt;sup>142</sup> Claimant's Memorial, ¶221.

<sup>143</sup> Claimant's counsel reiterated this incoherent critique in his opening statement: Hearing Transcript, Vol. 1, p. 64. On the one hand, the Claimant claimed that REN was tantamount to an admission of guilt by the PMRA; yet if the REN had not taken place, the Claimant would have been the first to complain that the PMRA was not taking the Board's recommendations seriously. As it happened, since the PMRA did in fact consider the Board's recommendations in a complete new review, the Claimant fell back on vague allegations that the REN process was "biased" or "not in good faith".

<sup>144</sup> Regarding the rationale for the REN, *see* First Report of Dr. Costa,  $\P122-125$ . Canada's Counter-Memorial,  $\P735-736$ .

<sup>&</sup>lt;sup>145</sup> Canada's Rejoinder, ¶65.

- Dr. Peter Chan of PMRA confirmed that Mr. Worgan played a very limited role in the conducting the risk assessment in the REN process given his "managerial coordination role as the Director General for the re-evaluation management coordination."<sup>146</sup>
- Dr. Chan confirmed that one of the SMC's primary roles is to ensure that PMRA policy and practices are being applied consistently throughout the Agency. 147
- John Worgan for his part explained that his group, the PMRA's re-evaluation management directorate manages the overall re-evaluation process. This role was distinct from the risk assessments completed by health and environmental directorates and sent to the SMC. He also confirmed that SMC makes its decision on a consensus basis and it would not overturn a decision based on a risk assessment done by a scientific group.<sup>148</sup>
- In the case of lindane, the SMC reviewed the consolidated report for accuracy and consistency. 149

106. In short, there was strictly no evidence of interference on the part of Mr. Worgan or the SMC in the substantive re-evaluation of lindane.

107. Moreover, as Canada had already confirmed, the REN team conducting the scientific review was distinct from the original Special Review team. Scientists such as

<sup>&</sup>lt;sup>146</sup> Hearing Transcript, Vol 3, pp. 545 (Peter Chan). *See* generally Affidavit of Dr.

Peter Chan.

<sup>&</sup>lt;sup>147</sup> Hearing Transcript, Vol 3, pp. 549-550 (Peter Chan).

<sup>&</sup>lt;sup>148</sup> Second Affidavit of John Worgan, ¶¶87-90; Hearing Transcript, Vol 3, pp.641-646 (John Worgan).

<sup>&</sup>lt;sup>149</sup> Hearing Transcript, Vol. 2, p.558 (Peter Chan).

Cheryl Chaffey had minimal involvement in the REN, including no direct involvement in the work of the evaluators. <sup>150</sup>

108. As for the Claimant's alternative allegation that the REN was conducted as a *pro forma* exercise to bolster the PMRA's position in this arbitration, it has no merit. John Worgan confirmed that the primary motivator for launching the REN was the series of recommendations made by the Board of Review, not a recommendation from government lawyers in anticipation of the NAFTA arbitration. John

109. There was no evidence presented at the hearing to suggest that the REN was anything other than a good-faith scientific process. A cursory glance at the REN document itself confirms the REN was an extensive scientific exercise. Mr. Worgan strenuously dismissed the suggestion that the REN's outcome was predetermined:

"We took this very seriously, and, you know, we have a scientific process that has a lot of integrity. We -- in this particular case, we assigned a different group of evaluators than those that had worked on the lindane Assessment. We provided them with absolutely no direction with respect to what the outcome should be, what we were expecting. We had no vested interests, for example, in a particular outcome. The science will lead you where the science goes. It was not a foregone conclusion. We had some additional information on the worker exposure side. We had some additional toxicology that our scientists looked at. We also had -- we undertook a review of some of the other areas that we had not completed previously. We took all of those into account in the decision. That is definitely not a foregone conclusion." 154

<sup>151</sup> Claimant's counsel suggested this at Hearing Transcript, Vol. 1, pp. 64-65.

<sup>&</sup>lt;sup>150</sup> Hearing Transcript, Vol. 2, p. 485 (Cheryl Chaffey).

<sup>&</sup>lt;sup>152</sup> Hearing Transcript, Vol 3, pp. 572-575; *See* JHB, Tab 280; PMRA, Science Management Committee Briefing, Lindane, 31 August 2006 (Exhibit JW-61). *See* also Second Affidavit of John Worgan, ¶¶30-32.

<sup>&</sup>lt;sup>153</sup> PMRA, Re-Evaluation Note REV2008, Draft Lindane Risk Assessment, 14 April 2008 (Exhibit JW-92), Draft Re-Evaluation Note (REN); Second Expert Report of Dr. Costa, ¶25.

<sup>&</sup>lt;sup>154</sup> Hearing Transcript, Vol 3, pp. 650-651 (John Worgan) (our emphasis).

- 110. Dr. Costa independently confirmed that the REN was scientifically acceptable. 155
- 111. As Canada witnesses recalled, the PMRA's commitment to take account of the Board of Review's recommendations did not mean that the PMRA would necessarily achieve a different result from that of the Special Review. The near-universal scientific consensus about lindane confirms there was nothing unusual in the REN result.
  - 7) The PMRA did not deny the Claimant a phase-out period for other lindane uses and in any event there was no breach of MST
- 112. The Claimant has argued that it was treated unfairly in that the PMRA suspended its registrations for non-canola lindane products, based on the Special Review results, without granting it a phase-out period. Canada would note in the first place that Article 1105 does not prescribe minimum phase-out periods, nor does it limit the discretion of regulators to take steps pursuant to their duty to protect public health and the environment. Moreover, nothing heard at the hearing suggests an abuse of discretion that would amount to a breach of MST.
- 113. In any event, the Claimant's allegation that it was unfairly deprived of a phase-out is false.
- 114. Under section 16 of the current Pest Control Product Act Regulations, where (as in the case of lindane) the PMRA has found that continued registration of a product presents unacceptable risk, it may offer to registrants the opportunity to voluntarily withdraw their registration, and in this way be granted a phase-out period. As Ms Sexsmith noted, this phase-out procedure was a standard regulatory practice in the context of re-evaluation of older products:

<sup>&</sup>lt;sup>155</sup> First Report of Dr. Costa, ¶¶122-151, p. 1124 (Dr. Costa).

"Typically for older products that have been on the market for a long time, the whole purpose of re-evaluation is to examine those products and make sure they meet current standards, and in this case lindane did not. And so a reasonable course of action is that it can be allowed to be phased out of the marketplace as opposed to, you know, an urgent kind of action with imminent risk. And this is quite a normal process for regulatory programs all over the world." <sup>156</sup> "So, the point of Section 16 is to provide that opportunity for Registrants. And for the most part, when an unacceptable risk is found, companies are very interested in following up with taking it off the market as opposed to being cancelled or suspended, which is really what the outside world calls 'ban." <sup>157</sup>

- 115. Wendy Sexsmith confirmed that once the Special Review results were released, all registrants (including Chemtura) were offered the opportunity to voluntarily withdraw these registrations under section 16 and in this way benefit from a phase-out period. All but the Claimant accepted this offer. Claimant's counsel in his opening statement conceded that Chemtura unlike the other registrants refused this offer. 159
- 116. Claimant's counsel argued that the PMRA had the discretion to grant Chemtura a phase-out, despite Chemtura's refusal to accept PMRA's offer of phase-out through voluntary withdrawal. Ms. Sexsmith noted that his question made little sense, because a phase-out had in fact been offered to Chemtura, which Chemtura refused. Pursuant to section 16, the Minister had the discretion to offer a phase-out in connection with a voluntary termination of sales. Since Chemtura rejected this offer, voluntary suspension under section 21 of the Regulation applied by default.

<sup>&</sup>lt;sup>156</sup> Hearing Transcript, Vol. 4, p.845 (Wendy Sexsmith).

<sup>&</sup>lt;sup>157</sup> Hearing Transcript, Vol. 4, p.858 (Wendy Sexsmith).

<sup>&</sup>lt;sup>158</sup> Hearing Transcript, Vol. 4, pp.842-859 (Wendy Sexsmith). First Affidavit of Wendy Sexsmith, ¶¶149-58.

<sup>&</sup>lt;sup>159</sup> Hearing Transcript Vol. 1, p. 57 (Opening Statement).

<sup>&</sup>lt;sup>160</sup> Hearing Transcript Vol. 4, pp. 842-846 (Wendy Sexsmith).

For a detailed review of this issue, See First Affidavit of Wendy Sexsmith, ¶¶ 149-158.

117. Unlike section 16, section 21 does not provide for ministerial intervention. The hearing evidence regarding this default process was confused in that counsel referred to "cancellation", whereas section 21 mentions either cancellation <u>or</u> suspension. Where a product is suspended, pursuant to section 22 any product already delivered to vendors can remain in the market until exhaustion. Chemtura's remaining registrations were in fact suspended, and therefore its products in effect remained for sale in the market until they were used up.<sup>162</sup>

118. Moreover, Ms. Sexsmith noted that once notified of the Minister's intention to suspend the registration further to Chemtura's refusal, Chemtura never returned to the PMRA asking for a phase-out period. Instead, Chemtura challenged the entire basis for termination, disagreeing with the substantive result of the PMRA's Special Review.

#### B. PMRA's involvement in VWA

119. The Claimant also alleged that PMRA breached Article 1105 by participating in the development and implementation of a plan of voluntary withdrawal of lindane use on canola (the 'VWA'), and failing to fulfil certain commitments it made. These facts do not disclose any breach of Article 1105. Moreover, the Claimant's allegations are wrong on the facts. The hearing evidence confirmed that, contrary to the Claimant's position, the VWA was an industry-led agreement, driven by their business concerns. The VWA

<sup>&</sup>lt;sup>162</sup> Letter from Janet Taylor, PMRA to Rob Dupree, Chemtura re: suspension of registrations, 11 February 2002 (Exhibit B59).

<sup>&</sup>lt;sup>163</sup> "Nowhere in the correspondence is it in evidence. They said that they disagreed with the reason for termination or that it needed to be terminated, but they didn't provide that." Hearing Transcript, Vol. 4, pp.853-859 (Wendy Sexsmith).

<sup>&</sup>lt;sup>164</sup> The Claimant's response to PMRA's notice of suspension of its remaining lindane products, following the Claimant's refusal to accept a phase-out, was to launch an application against the PMRA in Federal Court on March 14, 2002. Annex R-75. Hearing Transcript, Vol 4, pp. 888-889 (Wendy Sexsmith). The Claimant also requested a Board of Review to challenge the substance of the PMRA's scientific decision.

was proposed by industry to the Claimant on a strictly voluntary basis. PMRA only acted as a facilitator, subject to the condition that the agreement was voluntary and treated all registrants equally. The Claimant freely consented to the VWA and took the benefit of that agreement. The Claimant's attempt to extract improper regulatory concessions from the PMRA in connection with the VWA is not a violation on PMRA's part of Article 1105. Indeed, the hearing evidence confirmed that the Claimant's litany of alleged 'conditions' and 'reasonable expectations' were either misstated or unreasonable. To the extent the PMRA agreed to do anything in connection with the VWA, it substantially lived up to its agreement.

# 1) The VWA was an industry-led agreement and voluntary

- 120. The Claimant has throughout this case alleged that the VWA was PMRA-managed and orchestrated, and that the PMRA somehow 'forced' the Claimant to enter into this agreement. The Claimant has suggested that the PMRA's actions in this regard were improper and a violation of its legal mandate, suggesting this amounted to a breach of Article 1105. 166
- 121. Witnesses overwhelmingly confirmed what had already been evident on the face of the record: the Voluntary Withdrawal Agreement relating to lindane use on canola was an industry-driven agreement, proposed by representative organizations of Canada's over 60,000 canola growers, in light of urgent concerns about the impact of continued lindane use on the canola industry. Tony Zatylny, who at the relevant time was the CCC and CCGA representative, and the chief organizer of the VWA, was unequivocal on the point:

<sup>165</sup> For example, Claimant's counsel alleged in his opening statement that 'the idea of withdrawing lindane was floated to the industry by PMRA' (Hearing Transcript Vol. 1, p. 28). Mr. Zatylny of course rejected this allegation as false.

<sup>&</sup>lt;sup>166</sup> Hearing Transcript, Vol. 1, p.33.

Q. Arbitrator Crawford: Did [the VWA] come from the PMRA?

A. The Witness: It did not.

- Q. Arbitrator Crawford: Would you say that Crompton was effectively compelled to enter into the VWA by the PMRA?
- A. The Witness: I would not say that's the case. This was the initiative of the growers. They were consistent in their response all through this process, that they no longer wanted to use a product. They did not want the health issues raised by nongovernment groups and consumer groups. They did not want issues at the border. It was their solution, and the PMRA was involved to facilitate the Agreement. It was -- it was really the growers' solution. We analyzed the problem. Let's face it; all the lindane used in Canada would amount to \$20 million at the most. The industry was worth \$1.8 billion, 600 million of which was exports to the U.S. When we balance from the growers, when the industry balanced the use of lindane against the health of the industry, there is really no choice, and the solution was was hammered out and agree to by the industry, by the participants, and presented to the PRMA looking for their support." 167
- 122. As Mr. Zatylny's response confirmed the concerns that gave rise to VWA were both trade and environmental/health issues. 168
- 123. The introduction of the US Federal Food Quality Protection Act (FQPA) in 1996 had placed renewed emphasis on the presence of pesticide residues in food or feed. 169
- 124. The Canadian Canola Industry had been aware of the need to resolve differences in pesticides registrations as between the US and Canada, particularly in light of the

<sup>&</sup>lt;sup>167</sup> Hearing Transcript, Vol. 3, p. 725 (Tony Zatylny). Mr. Zatylny's testimony simply confirmed the Claimant's own repeated contemporary written admissions concerning the role of the CCC as set out in the record. For example, an internal Chemtura email of September 22, 1998 stated, "I met with Tony Zatylny of the Canola Council of Canada who has been working on tolerance harmonization between the US and Canada. He has a very negative opinion regarding the future of lindane and has gone as far suggesting a withdrawal to PMRA and EPA". (Exhibit WS-84).

<sup>&</sup>lt;sup>168</sup> Hearing Transcript, Vol. 3, p. 731 (Tony Zatylny).

<sup>&</sup>lt;sup>169</sup> Hearing Transcript, Vol. 3, p. 682 (Tony Zatylny).

FQPA, and since 1997 had been engaged in discussions with the US and Canadian governments in an attempt to resolve this issue at a systemic level.

125. However, when Chemtura's subsidiary Gustafson drew attention to the particular case of lindane in September 1997, this turned lindane into a focal point for the issue – particularly given the negative health and environmental news coming out about lindane at the time.<sup>170</sup>

126. As the Claimant admitted at the hearing, under US law the importation of seed for planting treated with an unregistered pesticide is illegal.<sup>171</sup> The action of Chemtura's subsidiary therefore killed a substantial portion of Canadian grower's export market: following the tip-off, the US EPA could not turn a blind eye to this situation, and called for cessation of imports of treated seed by the end of the same growing season.<sup>172</sup> Growers had a legitimate concern that the US EPA would extend its lindane restrictions from lindane-treated seed, to all canola grown from lindane-treated seed. Under the relevant legislation, the Federal Food, Drug and Cosmetics Act (FFDCA), any residue of a non-registered pesticide in food or feed made that food or feed illegal for sale in the United States, because it would be considered adulterated. <sup>173</sup> The US government had already blocked Canadian agricultural exports on this basis, and had blocked another

M. Barolo, Director, Office of Pesticide Programs, U.S. EPA, 17 September 1997 (Exhibit TZ-02); Letter from Anne Lindsay, Director, Field and External Affairs Division, U.S. EPA to E.L. Moore, Executive Vice President, Gustafson, 12 January 1998 (Exhibit WS-02); Letter from Dale Adolphe, President, CCC to E.L. Moore, Executive Vice President, Gustafson, 27 January 1998 (Exhibit WS-03).

<sup>&</sup>lt;sup>171</sup> Hearing Transcript, Vol. 1, p.21 (Opening Statement).

<sup>&</sup>lt;sup>172</sup> Hearing Transcript, Vol. 1, p.22 (Opening Statement). Claimant's counsel absurdly alleged that an announcement in March 1998 that such imports would be suspended as of June 1998, i.e. by the end of that same planting season 'did not show any urgency' (Hearing Transcript, Vol. 1, p. 24.

<sup>&</sup>lt;sup>173</sup> Hearing Transcript, Vol. 3, pp. 685-686 (Tony Zatylny); Hearing Transcript, Vol. 5, pp. 1204-1205 (Dr. Goldman).

shipment in October 1998. Chemtura admitted that the problem was rooted in the strict terms of US pesticides legislation.<sup>174</sup>

127. The US EPA's January 1998 response to the September 1997 Gustafson letter concerning lindane expressly referenced the residue issue. 175 As Dr. Goldman testified, "the EPA was attempting to provide same flexibility about the enforcement of this importation ban by waiting until June 1st before having the customs department start to halt seeds, that there really was no such agreement by the Federal Food and Drug Administration which is a separate agency." However, since the FDA has enforcement responsibilities, the EPA "could not make such a commitment with regard to FFDCA. Only the FDA could do that." 176 The Claimant repeatedly admitted during the hearing that the presence of residues of an unregistered pesticide on food and feed contravened US law: in order to remedy the problem, a US tolerance or registration for lindane on canola would be required. 177 Yet as of 2005, the US was clearly signalling it had no intention of granting such a tolerance. 178

<sup>&</sup>lt;sup>174</sup> Hearing Transcript, Vol. 1, p. 22 (opening statement).

<sup>175</sup> Letter from Anne Lindsay, Director, Field and External Affairs Division, U.S. EPA to E.L. Moore, Executive Vice President, Gustafson, 12 January 1998 (Exhibit WS-02): "Moreover, even assuming the seed was treated by 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 food commodity. Canola seed treated with registered pesticides cannot 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>&</sup>lt;sup>176</sup> Hearing Transcript, Vol. 5, p.1209 (Dr. Goldman).

Hearing Transcript, Vol. 1, pp. 23-24; Vol. 1, p. 229 (Alfred Ingulli).

<sup>&</sup>lt;sup>178</sup> Second Expert Report of Dr. Goldman, ¶37; Second Expert Report of Dr. Goldman, Tab 39.

- 128. The Canadian Canola industry was also facing a very serious issue of public perception regarding the presence of lindane in canola. Canola was marketed primarily on the basis that it was the healthiest choice as a food oil. News reports that canola was being blocked at the US border given the presence of lindane in the crop could have devastating marketing implications.<sup>179</sup>
- 129. Moreover, in 1997 the Canadian Arctic Contaminants Assessment Report had been released, confirming that lindane and other HCH isomers were the most prevalent organochlorine pollutant in the Canadian North. The World Wildlife Fund was aware that the Canadian canola industry was the single biggest user of lindane in North America. By October 1998 the WWF was threatening to draw attention to this fact. 181
- 130. The Canadian Canola industry was also aware of the fact that the US had launched a lindane Re-registration eligibility decision (RED) review in 1998. The CCC further knew that the PMRA was about to launch its own re-evaluation of lindane based upon is Aarhus Protocol review commitments. Given the increasingly negative findings about lindane, it was far from certain that the outcome of these reviews would be positive.
- 131. The Canadian Canola industry therefore decided that for these many reasons, it would be sensible for them organize a transition away from lindane use, towards

<sup>&</sup>lt;sup>179</sup> Hearing Transcript, Vol. 3, pp. 731-732 (Tony Zatylny).

<sup>&</sup>lt;sup>180</sup> Department of Indian and Northern Affairs Canada, *Canadian Arctic Contaminants Assessment Report* (Ottawa: Government of Canada), 1997 (Exhibit CC-43).

<sup>&</sup>lt;sup>181</sup> Hearing Transcript, Vol. 3, p. 701 (Tony Zatylny); Hearing Transcript, Vol. 1, pp. 236-237 (Alfred Ingulli).

<sup>182</sup> Ignoring this notorious fact, Claimant's counsel counter-factually argued that there was "no particular concern or animosity against lindane in the US". Hearing transcript Vol. 1, p. 27. As Claimant's counsel must also have known when he made this statement, there had been no new registrations of lindane in the US since 1978, and in fact lindane registrations had been progressively withdrawn in the US since the late 1970s.

alternatives. The solution would have to address the most immediate and pressing issue of the potential US border closure, while allowing for a managed transition to lindane replacement products.<sup>183</sup>

- 132. The Canola Council of Canada (CCC) devised a proposed plan of voluntary withdrawal that allowed for a three-year phase-out. During this time registrants would propose lindane replacements. The CCC hoped that a replacement product would be registered within the required timeframe of the VWA.<sup>184</sup>
- 133. Claimant's counsel sought to paint a picture of the PMRA orchestrating the VWA and setting its terms. The CCC testimony (massively supported by the written record) confirmed this as false.<sup>185</sup>
- 134. The Claimant's own witness, Alfred Ingulli, acknowledged that the Canadian Canola industry had raised concerns about the potential closure of the US border to Canadian canola, in light of lindane residues on canola, as early as January 1998, and had been organizing industry meetings to address the issue as of the spring of 1998. His witness statements were notably silent on the CCC's response to the industry crisis, seeking to lay the blame for the agreement on the PMRA.

<sup>183</sup> The Claimant's contemporary internal documents acknowledged that the CCC had several good reasons to pursue a lindane phase-out, not simply related to "trade": "several reasons for the elimination of lindane have been cited...Lindane has also been the subject of a controversy relating to concerns over acceptable and unacceptable use patterns and the resultant effect on the environment...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 (Exhibit WS-15).

184 Hearing Transcript, Vol. 3, pp. 732-734 (Tony Zatylny).

<sup>&</sup>lt;sup>185</sup> For example, Hearing Transcript, Vol. 1, p. 29. By contrast, the Claimant's contemporary documents summed up the situation as follows: "Note that this is not a regulatory action by PMRA, but rather the expressed wish of a grower group" (Exhibit TZ-25).

<sup>&</sup>lt;sup>186</sup> Hearing Transcript, Vol. 1, pp. 234-235.

- 135. Wendy Sexsmith confirmed that it was the CCC that approached the PMRA about the VWA, not the other way around, and that this occurred in the spring/summer of 1998.<sup>187</sup>
- 136. Evidence at the hearing also confirmed that, contrary to the Claimant's allegations, it was the CCC that set the terms for the VWA. For example, Mr. Zatylny confirmed that July 1, 2001 was chosen by the growers associations. It was a compromise date as January 1, 2001 was decided to be too early.<sup>188</sup> His evidence on this point was confirmed by JoAnne Buth.<sup>189</sup>
- 137. Claimant's counsel and certain witnesses (notably Mr. Ingulli) sought to suggest at the hearing that the CCC or CCGA were not reliable representatives of Canadian canola growers. From the perspective of Article 1105, the Claimant's focus on whether or not the CCC was justified in pursuing the VWA is in any event tantamount to an admission that the VWA was not a government measure.
- 138. In any event, hearing evidence confirmed that the Canola Council of Canada and Canadian Canola Growers' Association were grassroots organizations functioning through an extensive network of regional organizations, which could take decisions only by consensus. In other words, the CCC and CCGA could never have pursued the agreement of voluntary withdrawal of lindane on canola, without the support of a broad industry-wide consensus in support of the plan.<sup>190</sup>

<sup>&</sup>lt;sup>187</sup> Hearing Transcript, Vol. 4, pp. 783-784 (Wendy Sexsmith).

<sup>&</sup>lt;sup>188</sup> Hearing Transcript, Vol. 3, p. 714 (Tony Zatylny).

<sup>&</sup>lt;sup>189</sup> Hearing Transcript, Vol. 3, p. 755 (JoAnne Buth).

<sup>190</sup> Tony Zatylny confirmed that the VWA would require agreement and consensus of all growers who are members of the CCGA and CCC. The VWA had unanimous support. A vote was made at the Board of Directors level to go ahead with the VWA after support made clear at "ground roots" level. "So, from a ground roots perspective, they would look at individually

and come together in an organization like the Canadian canola growers to decide on what course of action should be taken. So, from that perspective, each of the provincial organizations essentially had a veto vote. If one Province does not agree with the recommendation of the others, then it's generally a no-go, so it's every -- every organization has equal rights within the Canadian Canola Growers Association and the council to support or reject any action. "So, in this case, a big issue like the lindane Voluntary Withdrawal Agreement would require a huge amount of agreement and consensus building among each of the groups to result in a decision." Hearing Transcript, Vol. 3, p. 668 (Tony Zatylny). Mr. Zatylny responded to related questions from the Claimant's counsel on this issue:

- Q. Okay. And I believe you were starting to talk about decision making and major decisions, so we will get sort of into the Withdrawal Agreement, but a decision like that, a decision for the organization and the industry to move forward with an agreement like that, who is voting on that? How is that decision being made?
- A. The decision would be made by the elected officers, so essentially the Board of Directors of each canola region would either have a public meeting or make the decision within their Board. So both are very common. They sometimes have a plebiscite, which is they will send out a newsletter, a request for a vote, so they actually have quite a number of mechanisms for making a decision. In this case I think it was the board of each provincial organization that ultimately worked through some individual system to come to a conclusion.
- Q. Okay. Was there a vote by the CCC Board of Directors to go ahead with the Withdrawal Agreement?
- A. There was.
- Q. And was there a vote by the Board of Directors of the CCGA?
- A. There was.
- Q. And you're saying there would have been a vote by the provincial organization as well?
- A. Yes.
- Q. And sometimes in the documentation it describes the Withdrawal Agreement as a CCC-driven initiative?
- A. Right.

- 139. The hearing evidence also confirmed that PMRA played the role of facilitator *visà-vis* the VWA. The PMRA was called upon by the CCC because it alone had the regulatory power to process requests for amended labels, grant a grace period for the exhaustion of seeds and regulate replacement products, and consider replacement products. Wendy Sexsmith confirmed that the PMRA's phase-out approach for the end of a product or use's life, in order to deal with disposal of hazardous waste, was carried out under Ministerial discretion in accordance with the PMRA's statutory mandate. As Ms. Sexsmith confirmed, the CCC also asked PMRA to contact the EPA to see if they would agree to hold off border closure based on the VWA. It made sense for PMRA to contact the EPA as "regulatory authority to regulatory authority" to discuss the VWA.
- 140. Ms. Sexsmith reiterated however that the PMRA's involvement remained conditional upon the universal and voluntary nature of this industry agreement. It was also done on the basis that PMRA would treat all stakeholders in the VWA equally. The Claimant acknowledged this same point in its contemporary internal documents. "PMRA will not act without our agreement. Voluntary removal must be by unanimous agreement of all registrants." Indeed, only a concerted agreement would convince the
  - Q. If I take your evidence correctly, CCC and CCGA were for all intents and purposes acting as one?
  - A. In this particular issue, they're aligned. And if you look at the policy statements of the Canola Council of Canada they refer to a policy that they will not support any pesticide registered in Canada for which there is no registration in the U.S. or no tolerance in the U.S. Hearing Transcript, Vol. 3, pp.674-675 (Tony Zatylny).

<sup>&</sup>lt;sup>191</sup> Hearing Transcript, Vol. 3, p. 707 (Tony Zatylny).

<sup>&</sup>lt;sup>192</sup> Hearing Transcript, Vol. 4, pp. 821-22 (Wendy Sexsmith).

<sup>&</sup>lt;sup>193</sup> Exhibit WS-12, Hearing Transcript, Vol. 4, pp. 789-790 (Wendy Sexsmith).

<sup>&</sup>lt;sup>194</sup> Hearing Transcript, Vol. 4, p. 839 (Wendy Sexsmith).

<sup>&</sup>lt;sup>195</sup> E-mail from C.P. Yip, Uniroyal to Al Ingulli and John Lacadie, 20 October 1998 (Exhibit TZ-25).

EPA not to take immediate regulatory action. The PMRA's approach also followed normal principles of regulatory fairness.<sup>196</sup> Ironically, while the Claimant criticized the PMRA for suggesting universal agreement was required, the Claimant expressly made this the first condition in its own October 27, 1999 letter.<sup>197</sup>

- 141. Claimant's counsel seized on PMRA comments on the draft press release of December 1998 regarding the VWA, as alleged evidence of the PMRA seeking to "manage the message" of the VWA from "behind the scenes". Wendy Sexsmith's response confirmed that such allegations lacked any validity, or indeed common sense: the document showed the PMRA correcting comments about the PMRA made in a proposed industry press release. As Ms. Sexsmith noted, the PMRA was "really providing information to include in an external document. And this is something that Governments do all the time." 199
- 142. The hearing evidence also confirmed that reference to the VWA in the ROU was at the request of the canola industry, and was asked for as US acknowledgement of the voluntary withdrawal. Growers saw the ROU as implicit commitment on the part of the

<sup>&</sup>lt;sup>196</sup> Hearing Transcript, Vol 4, pp.784-7 (Wendy Sexsmith).

<sup>&</sup>lt;sup>197</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>198</sup> Hearing Transcript, Vol. 1, pp. 32-33, Reply Exhibit 34. The Claimant used the term 'behind the scenes' (e.g. Hearing Transcript Vol. 1, p. 37) despite that Canada had by the summer of 1998 publicly noted its commitment to conduct a scientific review of lindane pursuant to the Aarhus Protocol, and by March 1999 – six months before the VWA implementation phase – had publicly launched the Special Review, PMRA, Special Review Announcement SRA99-01, Special Review of Pest Control Products Containing Lindane, 15 March 1999 (Exhibit WS-32).

199 Hearing Transcript, Vol. 4, pp. 790-1 (Wendy Sexsmith).

EPA to tolerate a lindane phase-out and not close the border to Canadian canola during this period.<sup>200</sup> As Mr. Zatylny noted:

The Record of Understanding, it was very important that the canola growers were recognized in there. That, in our mind was the commitment made by the EPA that they would accept the Voluntary Withdrawal Agreement. We worked towards harmonization, and that if this thing down the road came off the rails, we could point to that notice in that agreement, that we hoped that it would help prevent any future trade action on canola because we have already shown through our willingness to proceed with the Voluntary Withdrawal Agreement our good intentions to support harmonization. So, that's the assurances we felt we had, and we got that the EPA would live up to their commitments and essentially work with us through the harmonization period.

143. Wendy Sexsmith similarly confirmed that the ROU was a way of the Agencies publicly signalling their recognition of the industry initiative. She confirmed that neither Agency had any way to enforce the ROU nor did they have a vested interest in the VWA. "It was the Canola Council who wanted the VWA. They wanted it clearly for a reason. It was put in place. EPA agreed to it. There was no border action." <sup>202</sup>

144. The hearing evidence also put to rest any doubt that the VWA was in fact voluntary.<sup>203</sup> Again, Mr. Zatylny's evidence was instructive. He noted that CCC and CCGA could not force growers to stop using lindane, and the position of the growers' associations was supported by their membership.<sup>204</sup> Registrants could have backed out at any time, but chose not to.<sup>205</sup> He rejected out of hand Chemtura's allegation that it was

Zatylny).

<sup>&</sup>lt;sup>200</sup> Hearing Transcript, Vol 3, pp. 714-6 (Tony Zatylny).

<sup>&</sup>lt;sup>201</sup> Hearing Transcript, Vol. 4, pp. 898-9 (Wendy Sexsmith); Record of Understanding between the Governments of Canada and the United States of America Regarding Areas of Agricultural Trade, 04 December 1998 (Exhibit WS-18).

<sup>&</sup>lt;sup>202</sup> Hearing Transcript, Vol 4, p. 817 (Wendy Sexsmith).

<sup>&</sup>lt;sup>203</sup> Hearing Transcript, Vol. 3, p. 707: 10-17 (Tony Zatylny).

<sup>&</sup>lt;sup>204</sup> Hearing Transcript, Vol. 3, p. 720: 3-5 (Tony Zatylny).

<sup>&</sup>lt;sup>205</sup> Hearing Transcript, Vol. 3, p. 725: 8-10; p. 727: 23-25; p. 728: 1-8 (Tony

somehow "forced" to enter into the VWA because it "could not say no to the regulator": as Mr. Zatylny noted, registrants regularly pursue the PMRA in court, including at present his own employer.<sup>206</sup>

In summary, hearing evidence conclusively established that the VWA was an 145. industry-led agreement, in which the PMRA played at best a facilitating role, and only on condition that it treated all registrants equally. The VWA was promoted by the CCC based on legitimate industry concerns. The Claimant had the right to refuse to participate in the VWA – there was no coercion on the part of the PMRA or any other party.

146. Chemtura participated willingly in the VWA because it knew that to do so was in its own best interest. The issue was not that the PMRA was going to summarily cancel lindane. The PMRA had no plans and indeed no power to do so at the time. The PMRA at the time was already engaged in its Special Review of lindane and was going to proceed with that re-evaluation, whether or not a VWA was concluded. Mr. Ingulli's attempt to characterize his choice as of October 1999 as between immediate cancellation of Chemtura's products by the PMRA, or a phase-out on Chemtura's terms, ignores the timeline of events.<sup>207</sup> Rather, the real issue for the Claimant was that main end-users of lindane seed treatments were only willing to continue using Chemtura's product within the context of a VWA phase-out. Had Chemtura refused the VWA, the CCC would have counselled growers to stop using lindane to avoid the severe business risks its use occasioned. Adherence to the VWA ensured Chemtura an additional three (ultimately four) years of use of lindane on Canadian canola, rather than an immediate shift away from the pesticide in 1998 by the product's end-users.

Hearing Transcript, Vol. 3, p. 726: 17-22 (Tony Zatylny).
 Hearing Transcript, Vol. 1, pp.258-9 (Alfred Ingulli).

147. Chemtura therefore consented to this industry agreement, and took the benefit of the agreement. There is strictly no basis here for a finding a breach of the customary MST by Canada, even under the incorrect reading of the standard advanced by the Claimant.

# 2) The "expectations" alleged by the Claimant are not supported facts and in any event are not protected by Article 1105

148. The Claimant's other main contention concerning the VWA was that it adhered to this agreement only as of October 1999, and then only on terms different to those agreed by all stakeholders at the meeting of November 24, 1998. Chemtura claims its 'legitimate expectations' were founded on the terms it stated on October 27, 1999, which the PMRA allegedly violated. None of these allegations bears scrutiny, nor do they support any finding of breach of Article 1105 by Canada.

# a. The fact that the Claimant's subjective expectations were not met is not a breach of Article 1105

- 149. As Canada has outlined in its written submissions, the Claimant has failed to demonstrate that the customary MST has expanded to include a doctrine of "legitimate expectations" The Claimant's arguments fail on this basis alone.
- 150. In any event, even under free-standing "fair and equitable treatment" clauses, not bound by customary international law tribunals have recognized enforceable "legitimate expectations" arising out of State undertakings only to the extent such undertakings can be objectively ascertained; that they were made before the investment in question was undertaken; and that the investor relied upon the State undertaking in order to pursue its investment.

<sup>&</sup>lt;sup>208</sup> Canada's Rejoinder, ¶¶192-200.

- 151. The Claimant has in this proceeding sought to elevate its October 27, 1999 letter into a binding agreement with the PMRA, alleging that the PMRA violated the "legitimate expectations" Chemtura attached to this letter.<sup>209</sup> By staking its claim on the October 27, 1999 letter, Chemtura is relying on its own subjective interpretations of an exchange that took place nearly thirty years after its investment in Canada was undertaken. The Claimant's attempt to elevate this into a set of enforceable obligations reflects no known standard.
- 152. The October 27-28, 1999 exchange between Chemtura and the PMRA did not constitute a contract, nor has the Claimant ever alleged this to be the case. It is too late at this stage of its Post-hearing Memorial for the Claimant to raise such new legal arguments.
- 153. In any event, it is well-established that a 'simple breach' of contract does not necessarily amount to a breach of international law. That breach must be amount to a repudiation to rise to the level of a violation of the customary MST.<sup>210</sup> If this analysis applies to contract, it must *a fortiori* apply to arguments based upon mere 'expectations' arising out of an exchange of letters between a State and an investor.

### b. The terms of the VWA were agreed in November 1998

154. The hearing evidence confirmed Canada's position that the VWA was agreed to by all stakeholders (including Chemtura) on November 24, 1998 and not in the October 27, 1999 letter as the Claimant suggests.

<sup>&</sup>lt;sup>209</sup> Hearing Transcript Vol. 1, pp. 36-39 (Opening Statement).

<sup>&</sup>lt;sup>210</sup> See e.g. Azinian, Davitian, Baca v. Mexico (ICSID No. ARB(AF)/97/2) AWARD (18 October 1999) (Annex R-154) ¶87-91; Waste Management Inc. v. Mexico (ICSID No. ARB(AF)00/3) AWARD (30 April 2004) (Annex R-300) ¶¶114-115.

- 155. The Claimant admitted at the hearing there was an agreement in principle regarding the VWA as of the meeting of November 24, 1998.<sup>211</sup> This was termed an agreement 'in principle' because registrants would only need to take steps concerning their lindane product registration in late 1999.<sup>212</sup>
- 156. The agreement was that registrants would cease to generate lindane product for use on canola as of December 31, 1999. To this end, they would by November 1999 submit to PMRA requests for revisions to their lindane product labels, removing the canola use. Stock produced up to December 31, 1999 could be sold and used up to the phase-out deadline of July 1, 2001. During this phase-out period, the PMRA would consider replacement products for potential registration, although the PMRA as of November 1998 made no specific commitments regarding the timing of these reviews, or the number of potential replacement products it would review.
- 157. Both Tony Zatylny and Wendy Sexmith testified to this agreement of November, 1998. Mr. Zatylny's evidence on this point was compelling. Mr. Zatylny described his recollection of the meeting:

<sup>&</sup>lt;sup>211</sup> Claimant's counsel attempted to counter this evidence by citing to documents from *before* the November 24, 1998 meeting, when the VWA was still being discussed between the CCC and registrants (Hearing Transcript Vol. 1, pp. 28-29, p. 31 (Greg Somers), citing e.g. the EPA letter of 23 November 1998); Hearing Transcript, Vol. 1, p. 257 (Alfred Ingulli).

<sup>&</sup>lt;sup>212</sup> As Wendy Sexsmith noted, "[w]e used the words because, from our perspective, it was an agreement in principle, but we couldn't implement it until the Registrants all came in, and so it was early days yet... It just meant we agree, and, you know, we're waiting to see if it gets implemented which, in fact, it did, ultimately...", Hearing Transcript, Vol. 4, pp. 873-4 (Wendy Sexsmith); *See also* Exhibit 62 Reply. This counters the Claimant's allegations at e.g. Hearing Transcript Vol. 1, pp. 35-36 (Opening Statement). The ROU language was similarly prospective, and in any event reflected the US and Canadian governments taking note of the industry arrangement. PMRA witness Claire Franklin equally noted that the term 'in principle' was used in e.g. the letter of February 9, 1999 consistent with the registrants' own practice.

<sup>&</sup>lt;sup>213</sup> Minutes of meeting organized by CCC/CCGA to monitor implementation of the VWA and progress on lindane replacements, 24 June 1999 (Exhibit CF-15).

"I think it was around 3:00. We had a big board of issues that we were working through and dates and finally there was no more questions, so I asked the Registrants to confirm yes or no: Are they going to support the voluntary withdrawal agreement? Every registrant said yes, they're going to support the voluntary withdrawal agreement. So, we kind of leaned back and said, We have a deal."<sup>214</sup>

158. Canada recalled at the hearing documentary evidence confirming that an agreement was reached. It is not simply that the letter of November 26, 1998 confirmed an agreement had been reached.<sup>215</sup> Within two days of the meeting, a Chemtura representative present at the meeting sent his version of the planned press release, confirming the agreement.<sup>216</sup>

<sup>&</sup>lt;sup>214</sup> Hearing Transcript, Vol. 3, pp.729-30 (Tony Zatylny). Wendy Sexsmith, who was also at the meeting, said the same thing, Hearing Transcript, Vol. 4, p. 873 (Wendy Sexsmith). The Claimant put forward no witness present at the meeting with an alternative recollection.

<sup>&</sup>lt;sup>215</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>&</sup>lt;sup>216</sup> Letter from Bill Hallatt to Tony Zatylny, CCGA/CCC and Louis Caron, Norac Concepts, 26 November 1998 (Annex R-363): the draft press release in Chemtura's version read, "Manufacturers of lindane-based canola seed treatments have agreed to a request by the Canadian Canola growers Association for a voluntary removal of the insecticide lindane from its use in seed treatments." Mr. Ingulli, Chemtura's senior executive, rejected the notion that any agreement could have been reached in November 1998 without his consent, Hearing Transcript, Vol. 1, p. 256 (Alfred Ingulli). Yet the CCC had been in discussion with all stakeholders (including Chemtura) since the spring of 1998 regarding the lindane threat, and by at least September 1998 had had a one-on-one meeting with Chemtura to seek its agreement (Exhibit WS-84). Communications from Chemtura's Canadian subsidiaries in October 1998 plainly confirm that Chemtura was aware a voluntary withdrawal agreement was being organised. See e.g. Letter from Bill Hallatt, Gustafson Partnership (business unit of Chemtura Canada), to PMRA, 28 October 1998 (Exhibit WS-15): "...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...". Chemtura was expressly asked to send representatives to the meeting of November 24, 1998, which was specifically to confirm the terms of the VWA: Fax from Tony Zatylny, VP Crop Production, CCC to multiple recipients, 04 November 1998 (Exhibit WS-83). Chemtura sent at least three: Mr Dupree, Mr. Hallatt, and Mr. Edwin Johnson (Annex R-334). There is no evidence that any of these three refused to give their

159. Internal Chemtura documents confirm that Chemtura misled the CCC and other stakeholders about its subsequent change of position: as an internal Chemtura note of December 21, 1998 plainly stated, 'The position we are taking publicly is, "we have agreed to the voluntary withdrawal of lindane by January 31, 1000, at the request of the Canola growers." <sup>217</sup>

# c. Chemtura's ultimate letter concerning the VWA terms did not disturb those originally agreed

- 160. The hearing evidence also confirmed that the Claimant's insistence the October 1999 exchange was the true "deal" is of little assistance to its case. Chemtura did not obtain any "deal" with PMRA that was materially different than the original VWA.
- 161. None of this evidence casts Chemtura in a particularly good light. Chemtura's own subsidiary Gustafson effectively manufactured the lindane crisis as of late 1997, by seeking to chase lindane products out of the US canola market, to the advantage of its lindane replacement product. Gustafson's tip-off to the US EPA called into question Canadian canola farmers' use of lindane products on their crop, prompting the VWA by late 1998. Chemtura participated in the negotiation of the VWA, recognizing the concerns the CCC was expressing<sup>218</sup>, and publicly stating that it supported the agreement.<sup>219</sup> Yet Chemtura spent nearly a year after November 1998 trying to extract preferential regulatory concessions from the PMRA, in exchange for its continuing

consent to the agreement at the November 24, 1998 meeting. The CCC had every right going out of the November 24, 1998 meeting to believe that an argument had been reached.

<sup>&</sup>lt;sup>217</sup> Memorandum from Rick Turner to Gil Austin, Chub Moore, et al., 21 December 1998 (Exhibit TZ-45) (*our emphasis*).

<sup>&</sup>lt;sup>218</sup> Letter from Bill Hallatt, Gustafson Partnership (business unit of Chemtura Canada), to PMRA, 28 October 1998 (Exhibit WS-15).

<sup>&</sup>lt;sup>219</sup> Memorandum from Rick Turner to Gil Austin, Chub Moore, et al., 21 December 1998 (Exhibit TZ-45).

adherence to the VWA; failing which it repeatedly threatened to scupper the industry agreement, reckless to the consequences to its own clients.

162. Chemtura's allegations demonstrate that it was seeking not "equal" treatment, but preferential treatment by the public regulator. Claimant's counsel stressed that Chemtura was the "most important" player in the lindane market for canola, and that other players were "relatively trivial". The terms of the VWA may have applied to other registrants, but they had "far less at stake". The Claimant apparently believed that this entitled them to a better "deal" at the expense of its competitors. Yet, the PMRA repeatedly confirmed that it would only facilitate an agreement that threated all registrants equally. PMRA's position remained that it would facilitate the VWA only if it treated all registrants equally and remained voluntary.

163. In the end, the terms of the October 27, 1999 letter simply repeated the key provisions of the VWA as established by the CCC in consultation with all registrants. PMRA agreed with the Claimant's October 27, 1999 letter because the terms it stated were substantially those of the original VWA, consented to by all industry: notably, agreement by Chemtura to cease producing lindane product for use on canola as of December 31, 1999, and agreement by Chemtura that any remaining lindane product for canola could only be used up to July 1, 2001. As Dr. Franklin stated in its October 28, 1999 letter, "I would like to thank you for remaining supportive of the November 1998

<sup>&</sup>lt;sup>220</sup> Hearing Transcript, Vol. 1, p. 36.

<sup>&</sup>lt;sup>221</sup> Hearing Transcript, Vol. 1, p. 40.

<sup>&</sup>lt;sup>222</sup> Claimant's witness Alfred Ingulli admitted in any event that the PMRA had no responsibility to maintain Chemtura's market share, nor was the PMRA responsible for the development of new products (Hearing Transcript, Vol. 1, p. 197 (Alfred Ingulli)).

voluntary agreement and look forward to receiving the request in writing to remove the canola/rapeseed seed treatments from the labels of the products." <sup>223</sup>

- 164. Otherwise, the October 27, 1999 letter referenced actions that PMRA had already undertaken notably, the scientific review of lindane, in collaboration with the US EPA, and with stated a target-date for completion of the end of 2000.
- 165. The only newly true element added through the October 1999 exchanges, was confirmation of what might occur if the conditions prompting the VWA were reversed. Specifically, the PMRA agreed that if US EPA granted a registration or a tolerance for lindane use on canola, it would fast-track the administrative reinstatement of lindane use on canola pending the results of the Special Review of lindane. As Wendy Sexsmith noted, the PMRA had no problem committing to this because the withdrawal was taking place because of industry concerns, and if those concerns no longer held true, the PMRA was not going to gratuitously block a return to the status quo ante. However, if the PMRA's Special Review indicated health or environmental concerns, it would not have been able to reinstate because the conditions had changed.<sup>224</sup>
- 166. This arrangement therefore remained contingent upon a positive outcome for the PMRA's own Special Review, which by October 1999 was underway. As noted in the third point in the Claimant's 27 October 1999 letter, if the Special Review was negative, there would be no reinstatement.<sup>225</sup> The fourth point envisaged a scenario in which the

<sup>&</sup>lt;sup>223</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). Chemtura sent these on November 1, 1999 (Exhibit WS-46, Exhibit WS-46B, and Exhibit WS-49).

<sup>&</sup>lt;sup>224</sup> Hearing Transcript, Vol. 4, pp. 839-841 (Wendy Sexsmith).

<sup>&</sup>lt;sup>225</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).

US EPA might grant a lindane tolerance or registration for use on canola, but the Special Review had not yet been completed. In that case, the lindane use might be reinstated for canola in Canada – but only so long as the PMRA did not ultimately reach a negative outcome in the Special Review.<sup>226</sup>

167. As Canada has pointed out, this clarification regarding the process for potential reinstatement of lindane registrations on canola was communicated to all four registrants by the PMRA in a teleconference of October 22, 1999, in which Chemtura participated.<sup>227</sup> Thus, the PMRA was at best adding a clarification to the original VWA terms – and doing so on the basis that this clarification was to the benefit of all four lindane product registrants.

### 3) The PMRA did not violate any alleged conditions of the VWA

168. The hearing evidence in this matter in any event confirmed that the Claimant's interpretation of these alleged 'conditions' was incorrect and unreasonable. To the extent the PMRA agreed to do anything in connection with the VWA, it substantially lived up to its agreement. In any event, even if the PMRA had not fulfilled all of its commitments under the VWA this does not amount to a breach of Article 1105. The PMRA sought to uphold the agreement and substantially fulfilled any undertakings. Its actions cannot amount to a breach of customary international law.

### a. The deadline for last use was July 1, 2001

169. The Claimant alleged based on its October 27, 1999 letter that the PMRA had agreed to allow lindane use as a seed treatment on canola past July 1, 2001, even though

<sup>&</sup>lt;sup>226</sup> This understanding of the October 27, 1999 letter was confirmed at the hearing by both Wendy Sexsmith and Claire Franklin (Hearing transcript, Vol. 4, pp. 839-41 (Wendy Sexsmith); Vol. 5, pp. 1063-4 (Claire Franklin).

<sup>&</sup>lt;sup>227</sup> Minutes of conference call, 22 October 1999 (Exhibit WS-87).

sales of lindane product had to cease as of that date.<sup>228</sup> Claimant's counsel cited the language of the October 27, 1999 letter which plainly states, "All stocks of Uniroyal's products containing lindane for use on canola *are allowed to be used up to and including July 1, 2001*" (our emphasis). On the face of the Claimant's own letter, its allegation that July 1, 2001 was not the agreed cut-off for "use" of its lindane product, is false.

170. Counsel attempted to avoid the plain meaning of the letter by suggesting "use" meant "applied to the canola seed," with no time-limit on when such treated seed might be planted.<sup>229</sup> This late-proposed interpretation was directly counter to the core purpose of the VWA, to ensure lindane was out of the Canadian canola industry by a specific date. The language of Chemtura's letter was virtually identical to that of November 26, 1998, confirming the VWA: "All commercial stocks of products containing lindane for use on canola and lindane treated canola seed cannot be used after July 1, 2001<sup>230</sup>."

171. Claimant's counsel acknowledged that according to the VWA, the prohibition on 'use' of lindane after July 1, 2001 indeed meant that lindane-treated seeds could not be planted after that date, but suggested that such terms did not apply to the Claimant because it had much more at stake. The Claimant's argument is further belied by the fact that in its October 26, 1999 letter, Chemtura had written "All stocks of products containing lindane for use on 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>231</sup>. In

<sup>&</sup>lt;sup>228</sup> Hearing Transcript, Vol. 1, p. 39.

Hearing Transcript, Vol. 1, p. 40 (Opening Statement).

<sup>&</sup>lt;sup>230</sup> Exhibit WS-17

<sup>&</sup>lt;sup>231</sup> Exhibit WS-40, Whereas the October 27, 1999 letter read instead, "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.

its revised letter of the next day, October 27, 1999, the Claimant dropped this language, acknowledging the VWA cut-off date.

- 172. Mr. Ingulli himself admitted in testimony that July 1, 2001 was the last date for use of lindane.<sup>232</sup> As Canada pointed out in opening, the Claimant's alleged understanding of the July 1, 2001 is repeatedly contradicted by its own contemporary internal documents: writing on June 28, 1999, the Claimant's, Mr. Dupree reported on the recent meeting of VWA shareholders, confirming that "...stocks of carryover product and seed have till July 1, 2001 to be used up."<sup>233</sup>
- 173. Even if the Claimant sincerely believed its late-proposed interpretation of "use" in relation to July 1, 2001, that reading is clearly subjective and unreasonable, given the repeated confirmations to the contrary. On its face, Chemtura's October 27, 1999 letter reiterates one of the key terms of the VWA. But allowing the "use" of lindane up to July 1, 2001, the PMRA was in 'breach' of no condition whatsoever.
- 174. The Claimant otherwise alleged that PMRA had threatened purchasers of lindane products with fines if they used lindane product after July 1, 2001, causing a reduction in Chemtura's sales for the 2001 season.<sup>234</sup> This again would amount to a "breach" of its expectations. In the first place, given that the cut-off date for use of lindane was in effect July 1, 2001 the PMRA would have been entirely justified in reminding growers of that date. Moreover, growers had no right to plant lindane-treated canola after July 1, 2001, so Chemtura cannot reasonably complain that it lost sales for a period when its product was

<sup>&</sup>lt;sup>232</sup> Hearing Transcript, Vol. 1, p. 241 (Alfred Ingulli).

<sup>&</sup>lt;sup>233</sup> Annex R-331 (our emphasis).

<sup>&</sup>lt;sup>234</sup> Hearing Transcript Vol. 1, pp. 40-41 (Opening Statement). The 'Fast Fax' document counsel relied on was not a PMRA-generated document.

no longer authorized. In any event, the hearing evidence confirmed that Chemtura's allegations of PMRA "threats" were without any merit:

- Mr. Ingulli admitted that according to Chemtura's own internal reports from 2001, the PMRA was making no such threats;<sup>235</sup>
- Mr. Ingulli admitted that when he made his comments about reduced sales in the 2001 season, he had not accounted for the significant drop in canola acreage in 2001 due to the drop in worldwide commodity prices, and drought.<sup>236</sup>
- Mr. Ingulli also admitted that based on contemporary Chemtura documents
  which he was unable to contradict, Chemtura had in any event pre-booked
  sales for the 2001 season, and therefore was not going to lose any sales in this
  season.<sup>237</sup>
- JoAnne Buth confirmed that the CCC received virtually no notice of any concerns on the part of seed treaters or growers, regarding alleged PMRA "fines" after July 1, 2001. <sup>238</sup>
- Canola industry requests that the PMRA allow leftover treated seed be used in the 2002 planting season confirm *a contrario* stakeholders' assumption that, under the terms of the VWA, use of lindane as a seed treatment on canola was only allowed until July 1, 2001, i.e. the effective end of the 2001 planting

<sup>&</sup>lt;sup>235</sup> Hearing Transcript, Vol. 1, pp. 241-242 (Alfred Ingulli).

<sup>&</sup>lt;sup>236</sup> Hearing Transcript, Vol. 1, pp.242-244 (Alfred Ingulli).

<sup>&</sup>lt;sup>237</sup> Hearing Transcript, Vol. 1, pp. 246-247 (Alfred Ingulli).

<sup>&</sup>lt;sup>238</sup> Hearing Transcript, Vol. 3, p.759 (Joanne Buth).

season.<sup>239</sup> The PMRA ultimately permitted leftover treated seed to be planted and used up in 2002, after extensive consultation with stakeholders, rendering the issue of leftover treated seed moot.<sup>240</sup>

- 175. Faced with evidence that PMRA had made none of the threats Chemtura had alleged, Mr. Ingulli retreated to the position that it was ultimately an issue of "perception" on the part of the seed treatment purchasers, irrespective of what PMRA was actually saying.<sup>241</sup>
- 176. Mr. Ingulli's comment was in effect an admission that the PMRA did not take any "measures" that could conceivably be viewed as a violation of Article 1105 in connection with the July 1, 2001 date.
  - b. The PMRA made only limited undertakings regarding replacement products
    - The Document the Claimant Relies on to Establish the Terms of the "Agreement" Does Not mention Replacement Products
- 177. Throughout the hearing, the Claimant's position was that its agreement to withdraw lindane was pursuant to the terms laid out in the letters exchanged between Mr. Ingulli and Dr. Franklin on October 27 and 28, 1999.<sup>242</sup> As acknowledged by both Mr.

<sup>&</sup>lt;sup>239</sup> Hearing Transcript, Vol. 1, p. 43 (Opening Statement).

<sup>&</sup>lt;sup>240</sup> Counter-Memorial ¶¶274-275.

<sup>&</sup>lt;sup>241</sup> Hearing Transcript, Vol. 1, p.242 (Alfred Ingulli).

<sup>&</sup>lt;sup>242</sup> Mr. Ingulli was clear about this in his testimony, stating that "[t]here was no final agreement until I put my signature to it in October of 1999, and that agreement was acknowledged in writing by Dr. Franklin in a letter to me." Hearing Transcript, Vol. 1, p. 257:14 (Alfred Ingulli).

Ingulli and Mr. Kibbee during their testimony, this correspondence does not mention replacement products at all.<sup>243</sup>

178. To get around that omission, the Claimant argued that the commitment to review replacement products was contained in the November 26, 1998 letter from the CCC,<sup>244</sup> which it otherwise claims is not the source of the terms of the Voluntary Withdrawal Agreement.<sup>245</sup> This position is inconsistent with the rest of the Claimant's case. Moreover, Wendy Sexsmith pointed out in her testimony that the passage referred to in the November 1998 letter contained only a general commitment to work with registrants, rather than a specific one to review products for each lindane registrant from each category listed.<sup>246</sup>

# ii. The PMRA's Commitment Regarding Replacement Products was Clarified in February and June 1999

179. In a February 23, 1999 letter to the CCC, the PMRA committed to review three replacement products: Gaucho Helix, and Premiere Z. Mr. Kibbee acknowledged this at the hearing. JoAnne Buth has also confirmed that it was the canola growers' understanding that the commitment to expedite replacement products extended to products that were in the queue. Gaucho CS FL was not in the queue in 1999 – in fact, it was not submitted for review by the PMRA until over a year after the February 23 letter, in March 2000.

<sup>&</sup>lt;sup>243</sup> Hearing Transcript, Vol. 1, p. 259:13 (Alfred Ingulli); Hearing Transcript, Vol. 2, p.364:3 (John Kibbee).

<sup>&</sup>lt;sup>244</sup> Hearing Transcript, Vol. 2, pp. 382-383 (John Kibbee).

<sup>&</sup>lt;sup>245</sup> Hearing Transcript, Vol. 1, pp. 255-257 (Alfred Ingulli).

<sup>&</sup>lt;sup>246</sup> Hearing Transcript, Vol. 4, p. 806:19 (Wendy Sexsmith).

<sup>&</sup>lt;sup>247</sup> Hearing Transcript, Vol. 2, pp. 352-355 (John Kibbee).

<sup>&</sup>lt;sup>248</sup> Hearing Transcript, Vol. 3, pp. 742-743 (JoAnne Buth).

# iii. The PMRA fulfilled its Commitment through the Registration of Gaucho 75ST and Gaucho 480FL

180. The evidence clearly shows that the limited commitment that the PMRA *did* make to review lindane replacement products was fulfilled by the expedited registration of Gaucho 75ST and Gaucho 480FL.<sup>249</sup> Mr. Kibbee recognized that internal Chemtura correspondence in July of 1999 refers to the registration of "Gaucho" as fulfilling the PMRA's commitment to expedite replacement products.<sup>250</sup> Mr. Kibbee further confirmed that, since the all-in-one product, Gaucho CS FL, was not submitted to the PMRA for review until 8 months after the date of this correspondence, these e-mails necessarily refer to the insecticide-only Gauchos (that is, 75ST and 480FL).<sup>251</sup> In other words Chemtura itself understood the PMRA commitment to have been met by the registration of these products. Chemtura's demands for expedited registration of Gaucho CSFL was an after-the-fact effort to extract further concessions from PMRA.

181. Furthermore, as also acknowledged by Mr. Kibbee during his testimony, when seeking concessions in October 1999, Mr. Ingulli only asked for commitments related to Gaucho 75ST and Gaucho 480FL. Not only did he not challenge Dr. Franklin's statement that the PMRA had met its commitment concerning replacement products through the temporary registration of those two products, but he did not mention replacement products at all in subsequent correspondence, including the letter that he

<sup>&</sup>lt;sup>249</sup> Ms. Chalifour has attested to the fact that the PMRA gave these two products an expedited review. Hearing Transcript, Vol. 4, p. 936:24 (Suzanne Chalifour).

<sup>&</sup>lt;sup>250</sup> Hearing Transcript, Vol. 2, p. 359:7 (John Kibbee).

<sup>&</sup>lt;sup>251</sup> Hearing Transcript, Vol. 2, pp.357-364 (John Kibbee).

testified contained the "deal".<sup>252</sup> Mr. Ingulli himself acknowledged that the letter he said was the basis of the "deal" with PMRA said nothing at all about replacement products.<sup>253</sup>

#### iv. The PMRA did not Favour Helix

- 182. There is no indication that PMRA favoured Helix to the detriment of Gaucho CS FL during the registration process. Nor has the Claimant given any convincing explanation for what reason PMRA would have for such a preference: when asked by the Tribunal, Mr. Kibbee admitted that he could only speculate: none of his speculation is supported by any evidence, either documentary or oral.<sup>254</sup>
- 183. In fact, Mr. Kibbee's oral evidence supports Ms. Chalifour's written testimony that many of the regulatory stages he described as "advantages" to Helix, were also available to the Claimant. For example, the Claimant was allowed to add a tank mix to the Gaucho CS FL label partway through the application.<sup>255</sup>
- 184. In his written testimony, Mr. Kibbee also complained about the fact that Syngenta was permitted to amend its Helix label, despite the fact that this product was registered temporarily.<sup>256</sup> However, in oral testimony, Mr. Kibbee confirmed that Gustafson received similar treatment for of Gaucho 480FL. While Mr. Kibbee suggested that he was "not sure the same policy would apply" for an amendment to include new pests (as in the case of Gaucho 480FL) compared to an amendment to include new use sites (as in the

<sup>&</sup>lt;sup>252</sup> Hearing Transcript, Vol. 2, p.362:20 (John Kibbee).

<sup>&</sup>lt;sup>253</sup> Hearing Transcript, Vol. 1, p. 259 (Alfred Ingulli).

<sup>&</sup>lt;sup>254</sup> Hearing Transcript, Vol. 2, p. 388:20 (John Kibbee).

<sup>&</sup>lt;sup>255</sup> Hearing Transcript, Vol. 3, pp. 376-378 (John Kibbee).

<sup>&</sup>lt;sup>256</sup> First Witness Statement of John Kibbee, ¶ 49.

case of Helix),<sup>257</sup> he advanced no explanation for why there might be a different policy, nor why this policy might grant Helix any advantage "denied" to Gaucho.

- 185. During the hearing, Ms. Chalifour also explained that Helix's initial registration on a temporary basis was not evidence of special treatment: there were around 200 outstanding temporary registrations when the new Pest Control Products Act came into force in 2006.<sup>258</sup>
- 186. Finally, on the basis that they were replacement products, PMRA considered both Gaucho products and Helix for expedited review, pursuant to the voluntary withdrawal of lindane. Mr. Kibbee confirmed at the hearing that contemporary documents show that Chemtura itself considered Helix to be a "replacement product" and that this designation had not been contested by Chemtura.<sup>259</sup>

# v. Gaucho CSFL was registered following standard PMRA process

187. The hearing evidence also confirmed that the registration process for Gaucho CSFL followed standard PMRA procedure. To the extent it was delayed, this was substantially due to Chemtura's own failure to provide the data required for the review. From the perspective of Article 1105, the Claimant's complaints of an alleged "delay" to the Gaucho CSFL application are in any event inaccurate. The "delay" in reviewing Gaucho was one calculated in relation to the PMRA's own internal, non-binding performance standards. Article 1105 does not hold government agencies to a standard of perfection, nor a *fortiori* does it elevate an agency's own good-faith targets (which it might not establish at all) into a rigid standard of liability.

<sup>&</sup>lt;sup>257</sup> Hearing Transcript, Vol. 3, pp.379-381 (John Kibbee).

<sup>&</sup>lt;sup>258</sup> Hearing Transcript, Vol. 4, p. 1008 (Suzanne Chalifour).

 $<sup>^{259}</sup>$  John Kibbee testimony, pp. 364-367. His testimony in this regard contradicted his witness statement: John Kibbee first Witness Statement, ¶ 28

188. In any event, Ms. Chalifour explained, and Mr. Kibbee confirmed, that the Claimant's failure to provide all required data, and its decision to initially rely on data waivers that were ultimately not accepted by the PMRA, led to extra screen and preliminary review loops, which added to the length of review time. When one considers the amount of time that was added for these extra reviews, and the amount of time that the application was with the registrant waiting for a response, the PMRA was very close to meeting its performance standards for the Gaucho CS FL application. <sup>261</sup>

189. Furthermore, Ms. Chalifour has explained that, while the registration of Gaucho CS FL did not involve the review of new active ingredients, it was a new formulation, and not merely, an existing product with a minor change. Ms. Chalifour has also explained that there was an unusual amount of correspondence and clarification required in the course of the Gaucho CS FL registration process, all of which added time to the submission review. Section 263

8 267, two tables confirming the dates of application and of registration of various lindane replacement products (including Gaucho CS FL) in Canada and the U.S. What the Canadian table shows is that in some cases (as with Gaucho 75 ST and 480 FL) PMRA did better then its performance standards, sometimes (as with Gaucho CS FL) it was past its target. That PMRA missed its own internal target in the case of CS FL, in circumstances of substantial registrant delay, and in light of resource constraints at the

<sup>&</sup>lt;sup>260</sup> Hearing Transcript, Vol. 4, pp. 951-954 (Suzanne Chalifour); Hearing Transcript, Vol. 2, pp. 369-376 (John Kibbee).

<sup>&</sup>lt;sup>261</sup> Hearing Transcript, Vol. 4, pp.1021-1022 (Suzanne Chalifour).

<sup>&</sup>lt;sup>262</sup> Hearing Transcript, Vol. 4, p. 940 (Suzanne Chalifour).

<sup>&</sup>lt;sup>263</sup> Hearing Transcript, Vol. 4, pp. 1007, 1014-1015 (Suzanne Chalifour).

Agency placing multiple demands on reviewers, cannot amount to a breach of customary Minimum Standard of Treatment.

# vi. Helix received a joint review because it applied and was eligible for this NAFTA programme

- 191. The Claimant at the hearing also argued that the PMRA had granted Helix an unfair advantage over Gaucho CSFL, because the Helix registration was dealt with under the NAFTA Joint Review initiative, and Gaucho CSFL was not. Hearing evidence confirmed this complaint was without substance.
- 192. Helix was dealt with under the Joint Review procedure because it applied for the process, and was eligible.<sup>264</sup> The Joint Review Process was a NAFTA process to promote harmonization.<sup>265</sup> As of 1998, the programme (created in 1996) was in its early days. It was up to the registrants to volunteer for the process, and to submit applications that fulfilled the conditions of the programme.<sup>266</sup> PMRA and EPA dealt with these applications on essentially a first come first serve basis. Syngenta applied for Helix.<sup>267</sup> This had nothing to do with the VWA Helix would have been treated under the Joint Review process in any event. Helix also fit within certain policy objectives entirely unrelated to the VWA: notably it acted as a replacement to a class of pesticides, organophosphates, to which certain pests were developing a resistance.<sup>268</sup>

<sup>&</sup>lt;sup>264</sup> Hearing Transcript, Vol. 4, pp. 883-885 (Wendy Sexsmith)

<sup>&</sup>lt;sup>265</sup> Hearing Transcript, Vol. 5, p. 1077 (Claire Franklin); Hearing Transcript, Vol. 4, pp. 8810882 (Wendy Sexsmith).

<sup>&</sup>lt;sup>266</sup> Hearing Transcript, Vol. 4, pp. 883-885 (Wendy Sexsmith).

<sup>&</sup>lt;sup>267</sup> Hearing Transcript, Vol. 4, pp. 883-885 (Wendy Sexsmith).

<sup>&</sup>lt;sup>268</sup> Hearing Transcript, Vol. 2, pp. 470-471 (Cheryl Chaffey); Hearing Transcript, Vol. 4, p. 881 (Wendy Sexsmith).

- 193. By contrast, Chemtura made no attempt to apply for Gaucho to be reviewed under the Joint Review Programme. In any event, it was objectively ineligible.<sup>269</sup> At the time, the Joint Review programme was open only to new pesticides not yet registered in any formulation.<sup>270</sup> The pesticide in Gaucho, Imidacloprid, had already participated in an early version of Joint Review in connection with a Bayer product, and had therefore already taken the benefit of the programme.<sup>271</sup>
- 194. It was also not clear in 1998 that participating in a Joint Review was an advantage.<sup>272</sup> Companies were concerned that if the registration process with one company was complex, a co-ordinated review between two countries would only increase this complexity. Indeed, in the case of Helix, the review took several hundred days longer than the target period for this particular Joint Review, and twice as long as the ideal Joint Review "target" timeline of one year.<sup>273</sup>
- 195. Moreover, the Joint Review process did not lead to any reduction of standards, making this review any "easier" for Helix than it would otherwise have been. Helix was among other things required to submit an entirely new worker experience study in order to gain registration, and the PMRA applied to this study a safety factor of 1000 which the Claimant described at the hearing as unreasonably conservative. <sup>274</sup> In the end, the US and Canada did <u>not</u> achieve symmetrical registrations of Helix: Canada refused to register certain uses of Helix that were allowed in the U.S. <sup>275</sup>

<sup>&</sup>lt;sup>269</sup> Hearing Transcript, Vol. 4, pp. 919-921 (Wendy Sexsmith)

<sup>&</sup>lt;sup>270</sup> Hearing Transcript, Vol. 4, p. 933 (Wendy Sexsmith).

<sup>&</sup>lt;sup>271</sup> Hearing Transcript, Vol. 5, p. 1078 (Claire Franklin).

<sup>&</sup>lt;sup>272</sup> Hearing Transcript, Vol. 4, pp. 883-885 (Wendy Sexsmith).

<sup>&</sup>lt;sup>273</sup> Hearing Transcript, Vol. 5, p. 1078 (Claire Franklin); see Appendix A, table of Canadian registrations.

<sup>&</sup>lt;sup>274</sup> Hearing Transcript, Vol. 2, p. 461 (Cheryl Chaffey).

<sup>&</sup>lt;sup>275</sup> Hearing Transcript, Vol. 4, pp. 915-917 (Wendy Sexsmith).

- c. The delay in completion of the Special Review of lindane was due to circumstances beyond PMRA's control
- 196. The Claimant further alleges another condition of its October 27, 1999 letter was that a scientific review of lindane would be conducted by the PMRA, in collaboration with the EPA, and that this review would be completed by the end of 2000. The Claimant suggests that both the delay in completion of the Special Review, and its result, was in breach of this condition.
- 197. In the first place, the PMRA's Special Review of lindane was not simply a "condition" of the October 27, 1999 letter. As of that time, the PMRA had already committed to, publicly announced and undertaken its Special Review of lindane.<sup>276</sup> The Special Review would have gone ahead irrespective of the VWA.
- 198. Secondly, the Claimant at the hearing appeared to be arguing that its 'reasonable expectation' was that the Special Review outcome would be positive, and that any other result would violate a condition of its October 27, 1999 letter. Claimant's counsel alleged that the Claimant was "confident that its product would pass on scientific review". He suggested that they were expecting lindane to be 'exonerated' by late 2000 and returned to the market. The Claimant also seemed to suggest that the fact that the Special Review did not reach a positive outcome necessarily means that it was conducted in a scientifically deficient manner.
- 199. If this is the Claimant's argument, it is patently unreasonable. The Claimant could not predict an outcome. The PMRA had given no assurance of a positive outcome.

<sup>&</sup>lt;sup>276</sup> See e.g. PMRA, Special Review Announcement SRA99-01, Special Review of Pest Control Products Containing Lindane. 15 March 1999 (Exhibit WS 32).

<sup>&</sup>lt;sup>277</sup> Hearing Transcript, Vol. 1, p. 37 (Opening Statement).

<sup>&</sup>lt;sup>278</sup> Hearing Transcript, Vol. 1, p. 45 (Opening Statement).

Moreover, the Claimant's expectation of a positive result was particularly unreasonable in circumstances where lindane had come under increasingly negative scientific scrutiny. The Claimant's alleged "expectation" in a positive outcome was indeed disavowed at the relevant time by the Claimant's own witness Mr. Ingulli.<sup>279</sup>

200. As for the timing of the Special Review, Chemtura's fixation on the end of 2000 as a 'firm deadline' is again unreasonable and counter-factual. As Canada's witnesses recalled at the hearing, the PMRA had as of October 1999 repeatedly noted that the end of 2000 was a "target date" for completion of the review.<sup>280</sup> The work being referenced was a complex scientific review, whose parameters was broad, and was being conducted in collaboration with another national agency. Even apart from PMRA's confirmation late 2000 was a "target", a sophisticated registrant such as Chemtura could not reasonably have understood the date to be set in stone. As Dr. Franklin noted, "there are circumstances beyond which one doesn't always have control" so the PMRA could never guarantee or make a commitment to a firm date. The PMRA could only provide a target date within a timeframe, which is what it did.<sup>281</sup>

201. The Tribunal asked at the end of the hearing, assuming that the October 27, 1999 was not a contract, how much can one expect from undertakings by an administrative

<sup>&</sup>lt;sup>279</sup> As Mr. Ingulli stated in an e-mail of 1999, "...PMRA has initiated a lindane special review to be completed by the end of 2000. This could spell and end to lindane regardless of what we decide to do. If I had to guess, lindane will probably be gone." Second Expert Report of Dr. Goldman, Tab 58.

<sup>&</sup>lt;sup>280</sup> Hearing Transcript, Vol. 5, pp. 1091-95 (Claire Franklin); PMRA, Special Review Announcement SRA99-01, Special Review of Pest Control Products Containing Lindane, 15 March 1999 (Exhibit WS-32); 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), 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>&</sup>lt;sup>281</sup> Hearing Transcript, Vol. 5, pp.1093-95 (Claire Franklin).

agency which is part of governmental system which has many influences, distractions, priorities, and intervening concerns? And what if the failure of performance of what was set out in that agreement was beyond the control of the PMRA? The answer is that government agencies cannot be held to a standard of perfection. As replied in the questions, governments need the latitude to react when subjected to conflicting demands on their time. It is unreasonable to expect otherwise.

202. The Claimant's unreasonable expectation is underscored when one considers that the PMRA was delayed because it was waiting for information from the US EPA – and yet the Claimant itself agreed that one of its alleged 'conditions' regarding the review was that PMRA would collaborate with the EPA.<sup>282</sup> As Canada recalled in its opening statement at the hearing, the Claimant had acknowledged this in its contemporary comments:

As I read and recall the withdrawl agreement PMRA had committed to review of lindane by December 2000. EPA was stated to have their review completed by October. Which December has not yet expired I do not know how PMRA can complete their review because they were relying on EPA assessment as part of their Special Review process.<sup>283</sup>

203. Moreover, the US EPA's own delay in turn resulted from lags on Chemtura's part in delivering required data. Again, Dr. Franklin referred to this issue:

"I think I would have to agree that it is not a reasonable expectation because there is frequently additional information or other issues that arise once the review is started that are beyond the control of the people doing the review. I believe for one thing that one of the studies that were to be submitted was actually from the company was late. I think these were some of the data the U.S. had requested. And if memory serves me right, they were late on submitting the carcinogenicity study well beyond 2000, so that obviously would be sufficiently

60).

<sup>&</sup>lt;sup>282</sup> Counter-Memorial, ¶ 336, footnote 380.

<sup>&</sup>lt;sup>283</sup> Email from Rick Turner to C.P. Yip et al., 14 December 2000 (Exhibit CC-

important end point that one could not complete a review without having that information." <sup>284</sup>

204. Dr. Franklin's latter point relates to evidence from the First Affidavit of Cheryl Chaffey. Ms. Chaffey noted that Chemtura submitted the new mouse cancer study on May 17, 2001, a supplementary (range finding) study in June 2001 and an additional pathology report dated July 21, 2001 to EPA. The EPA reviewed those studies by August 30, 2001 and provided them to the PMRA. This information was required by the PMRA to conclude its toxicological evaluation. Thus, the delay was due to the late delivery of data by Chemtura itself. 286

205. As Dr. Franklin noted, in any event, the PMRA was trying to act in good faith to meet its own target deadline.<sup>287</sup> As of July 30, 2001, PMRA was under internal pressure to move forward with the review because it had "in good faith made a commitment to do things." Recalling that governments are not to be held to a standard of perfection under Article 1105, the Claimant's allegations again are inapposite.

# d. The conditions for administrative reinstatement of lindane use on canola were never realized

206. The Claimant also reiterated at the hearing its allegation that pursuant to the October 27, 1999 letter, PMRA undertook to reinstate Chemtura's lindane registration on canola, whatever the outcome of the Special Review.<sup>288</sup>

207. As was confirmed at the hearing, the PMRA made no such undertaking; any expectation on Chemtura's part that such an undertaking would be made by a public

<sup>&</sup>lt;sup>284</sup> Hearing Transcript, Vol. 5, p.1103 (Claire Franklin).

<sup>&</sup>lt;sup>285</sup> First Affidavit of Cheryl Chaffey, ¶83.

<sup>&</sup>lt;sup>286</sup> Hearing Transcript, Vol. 2, pp.519-20 (Cheryl Chaffey).

<sup>&</sup>lt;sup>287</sup> Hearing Transcript, Vol. 5, pp.1087-8 (Claire Franklin).

<sup>&</sup>lt;sup>288</sup> Hearing Transcript, Vol. 1, pp. 37-38 (Opening Statement).

regulator would be unreasonable; and in any event, the basic conditions for even a temporary reinstatement of the Claimant's lindane registration on canola never materialized.

208. Dr. Franklin confirmed that if EPA issued a tolerance before the PMRA had completed its review, then the PMRA would be in a position to reinstate. But if PMRA had reviewed the product and found adverse effects in the Special Review, that would not have been possible. The PMRA recognized that registrants had agreed to withdraw their canola labels based on threat that canola products treated with lindane might be blocked at the US border. If PMRA had determined that there were no serious health effects and the trade issue had been resolved, then the PMRA was prepared to reinstate it. Reversal of the voluntary suspension was contingent on the status of the re-evaluation. The condition was requested by registrants, rather than growers, but is evidence that PMRA had no bias against lindane in advance of the Special Review.<sup>289</sup>

Executive Vice President, Uniroyal Chemical (predecessor-in-title of Chemtura Canada), 15 October 1999 (Exhibit WS-36). Dr. Franklin's evidence is supported by several contemporary documents, which confirm the common understanding of the parties. The October 22, 1999 minutes of meeting note "If EPA and PMRA review is unfavourable the product would be gone." Exhibit WS-87. 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 reiterated it will be a 30-day administrative process to meet this end." Exhibit WS-43. Rhône-Poulenc wrote on November 1, 1999, "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." Exhibit WS-44. IPCO wrote on November 1, 1999, "If in the meantime, lindane is cleared by the special review and tolerances are established for residues in oil and meal in the USA, IPCO expects to be able to re-instate the registration as and administrative action sheet, current label and fees." Exhibit WS-45.

- 209. Wendy Sexsmith similarily confirmed that the administrative reinstatement would take effect, if at all, only pending the completion of the Special Review.<sup>290</sup> Ms. Sexsmith added that "we didn't have any objection to that particular statement or set of statements [in the October 27, 1999 letter], and it would apply equally not only to Chemtura, but to all of the four registrants... we would note that those conditions were never achieved in that the Special Review in Canada was negative, the re-registration decision in the U.S. was negative. There was no tolerance granted in the U.S."<sup>291</sup>
- 210. Canada's evidence was further confirmed by Mr. Ingulli who admitted that the conditions were of reinstatement set out in his October 27, 1999 letter, and that the administrative reinstatement of lindane use on canola in all events remained subject to the results of the PMRA's Special Review.<sup>292</sup>
  - e. The PMRA never undertook to maintain all other lindane registrations irrespective of the results of the Special Review
- 211. Claimant's allegation concerning PMRA's alleged undertaking in the October 27, 1999 to maintain non-canola lindane registrations, irrespective of the results of the Special Review.<sup>293</sup> This is not credible. If this was Claimant's belief, it confirms the unreasonableness of its alleged 'expectations' arising out of the October 27, 1999 letter. The comment referring to canola merely reflected the VWA's focus on canola uses for lindane.<sup>294</sup> The PMRA had already stated in its Special Review announcement of March 15, 1999 that all remaining registrations of lindane would be subject to the results of the

<sup>&</sup>lt;sup>290</sup> Hearing Transcript, Vol. 4, p.840 (Wendy Sexsmith).

<sup>&</sup>lt;sup>291</sup> Hearing Transcript, Vol. 4, p.839 (Wendy Sexsmith).

<sup>&</sup>lt;sup>292</sup> Hearing Transcript, Vol. 1, pp. 247-248(Alfred Ingulli).

<sup>&</sup>lt;sup>293</sup> Hearing Transcript, Vol. 1, p.56 (Greg Somers).

<sup>&</sup>lt;sup>294</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).

Special Review<sup>295</sup>. The Claimant is in effect arguing that the PMRA undertook to the Claimant to maintain registrations of products even if the PMRA's ongoing review determined these registrations presented unacceptable risk to the public. This cannot be. As Canada's witnesses confirmed at the hearing, the PMRA has an obligation to regulate in favour of the safety of public health and the environment.<sup>296</sup> The case of lindane was no different.

#### IV. Article 1103

212. At the hearing, the Tribunal asked for clarification regarding the objections to the Claimant's Article 1103 arguments raised in Canada's Counter-Memorial at paragraphs 852-858. While Canada did not repeat it in its Rejoinder, Canada maintains its jurisdictional objection that it did not consent to arbitrate the Investor's Article 1103 allegations.

213. According to NAFTA Article 1122(1) Canada's consent to arbitration in these proceedings is limited to claims brought "in accordance with the procedures set out in this Agreement". The procedures for the submission of a claim to arbitration include the requirement that the Claimant file a proper Notice of Intent and Notice of Arbitration<sup>297</sup>

<sup>&</sup>lt;sup>295</sup> Lindane Special Review Announcement, 15 March 1999 (Exhibit WS-32).

<sup>&</sup>lt;sup>296</sup> Hearing Transcript, Vol. 3, p 579 (John Worgan).

Canada's consent to arbitration only <u>IF</u> all the 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. *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). 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." *United Parcel Service v. Canada* (UNCITRAL), Award on Merits and Dissenting Opinion, 24 May 2007, ¶120 (Annex R-297); *ADF Group Inc. v. United States* (ICSID No. ARB(AF)/00/1) Award, 9 January 2003, ¶185 #Chem cite#.

setting out the basis for its claim.<sup>298</sup> These requirements are intended to provide the disputing NAFTA Party proper notice of the claim it is facing. Indeed, other Tribunals have rejected the introduction of new claims not properly brought at the commencement of the arbitration.<sup>299</sup>

214. In this case, the Claimant filed three Notices of Intent and two Notices of Arbitration. The first Notice of Intent (November 16, 2001) contained no reference to an Article 1103 claim. The second Notice of Intent (April 4, 2002) identified the breach of Article 1103 as arising from more favourable treatment accorded to competing products such as Helix and Syngenta. The first Notice of Arbitration (October 17, 2002) simply refers to discrimination against Crompton "to the advantage of MFN formulators". A third Notice of Intent in September 19, 2002 simply repeats the claims as stated in the second Notice of Intent. Finally, the second Notice of Arbitration in February 10, 2005 specifies that the Article 1103 breach arises from more favourable treatment that was accorded to other registrants and other companies.

215. It is therefore clear that the Article 1103 claim that was brought against Canada related to more favourable treatment granted to other companies and registrants as compared to Chemtura. In other words, a MFN claim based on differences in *actual* treatment. However, in its written submissions, the Investor sought to bring a completely new claim under Article 1103 based on allegedly different language in Canada's post-NAFTA BITs and not on differences in treatment between companies. Despite the many opportunities the Claimant had to identify and notify Canada of its claims, this was never

<sup>&</sup>lt;sup>298</sup> Article1119 (c) requires a claimant to specify the issues and the factual basis for its claim.

<sup>&</sup>lt;sup>299</sup> Merrill & Ring Forestry L.P. v. Canada (UNCITRAL) Tribunal Decision on Motion to Add a New Party, 31 January 2008, ¶¶27-30; Methanex Corp. (Can) v. United States, (UNCITRAL) Part II, Ch. F, Final Award of the Tribunal on Jurisdiction and Merits, 3 August, 2005, ¶¶20-21

a claim identified by the Claimant.<sup>300</sup> The issue is not one of prejudice suffered by Canada, but one of jurisdiction and disregard of the applicable NAFTA procedures. Therefore Chemtura's Article 1103 claim should be dismissed without further consideration.

### V. Article 1110

# A. The Hearing Evidence Failed to Substantiate Chemtura's Article 1110 Expropriation Claim

216. Neither the oral nor the documentary evidence presented during this hearing substantiate Chemtura's Article 1110 expropriation claim. To the contrary, there was plenty of evidence which demonstrated that the PMRA's decision to de-register lindane did <u>not</u> amount to an expropriation of Chemtura's investment.

# B. The Hearing Evidence Confirmed that Chemtura was not Substantially Deprived of its Investment

217. The evidence presented at the hearing confirmed Canada's position that Chemtura was not substantially deprived of its investment as a result of the PMRA's decision to deregister lindane. Indeed, the evidence of Chemtura's Mr. Thomson was revealing: when asked on cross examination what percentage of Chemtura's total sales was taken up with the sale of lindane, Mr. Thomson admitted that "[i]t wouldn't be more than 5%". 301

<sup>&</sup>lt;sup>300</sup> This case is therefore unlike the situation in *ADF Group Inc. v. United States* (ICSID No. ARB(AF)/00/1) Award, 9 January 2003 ¶127-133 (Annex R-143) where the Tribunal allowed a similar Article 1103 claim not identified in the Notice of Intent or Notice of Arbitration. Moreover, in that case, the Tribunal found it appropriate not to reject the claim because the investor had no reason to expect that the Article 1103 argument might be relevant until after the FTC Note of Interpretation which was issued after the commencement of the arbitration. This was not the situation here.

<sup>&</sup>lt;sup>301</sup> Hearing Transcript Vol. 2, p. 325 (Paul Thomson).

218. There was no evidence at the hearing that Chemtura suffered anything more than diminished profits on a small portion of its investment as a result of the PMRA's decision to de-register lindane. Certainly, there was nothing presented at the hearing that resembled the degree of interference required to establish a substantial deprivation.

# C. The Hearing Evidence Confirmed that the PMRA's Decision to De-Register Lindane was a Valid Exercise of Canada's Police Power

- 219. In both its Counter Memorial and its Rejoinder, Canada explained in considerable detail how the police powers doctrine could apply in a case such as this one where regulatory conduct is the subject of an expropriation claim.<sup>302</sup> The adoption of a product ban for reasons of health and safety falls within the police powers doctrine. Moreover, the hearing evidence confirmed that the conduct was not arbitrary, not discriminatory, not excessive and based on good faith. The relevant evidence has already been referred to in the context of Article 1105, in particular:
  - There was nothing arbitrary in the way the Claimant was treated in the science-based decision-making process that led to the ban on lindane. The Claimant received significant due process throughout.<sup>303</sup>
  - Chemtura was not discriminated against on the basis of nationality. In fact, the PMRA treated all of the lindane producers equally.<sup>304</sup>
  - There was nothing in the PMRA's scientific review or its treatment of Chemtura that was so "out of bounds" or so "excessive" as to compel an inference that Canada was trying to use regulation as a pretext or to hide an expropriation.<sup>305</sup>

<sup>&</sup>lt;sup>302</sup> Canada's Counter-Memorial, ¶¶ 565-629; Canada's Rejoinder, ¶¶ 275-297.

<sup>&</sup>lt;sup>303</sup> Hearing Transcript Vol. 3, pp. 549, (Peter Chan); Hearing Transcript Vol. 3, pp. 564-567, (John Worgan).

<sup>&</sup>lt;sup>304</sup> Hearing Transcript Vol. 2, pp. 378 &380, (John Kibbee); Hearing Transcript Vol. 4, p. 787, (Wendy Sexsmith); Hearing Transcript Vol. 4, p. 1008, (Suzanne Chalifour).

<sup>&</sup>lt;sup>305</sup> Hearing Transcript Vol. 3, pp.605-606, 621, (John Worgan); Hearing Transcript Vol. 5, pp. 1115-1117, 1142-1146, (Dr. Costa); Hearing Transcript Vol. 2, p. 461, (Cheryl Chaffey).

- Chemtura has provided no evidence at the hearing of a lack of good faith on Canada's part. The PMRA acted within its mandate in furtherance of its mission to protect the health and safety of Canadians.<sup>306</sup>
- 220. In sum, the evidence presented at the hearing confirmed that, to the extent there was a substantial deprivation of the investment (which was clearly not the case) the PMRA's conduct and in particular its decision to de-register lindane represented a valid exercise of Canada's police power.

# D. The Hearing Evidence Confirmed that Chemtura Entered into the VWA Voluntarily – Canada Did Not Compel Chemtura to Do So

- 221. Canada's last argument against expropriation is that, because Chemtura consented to the VWA, it cannot now claim that its investment with respect to lindane use on canola was expropriated. Chemtura is precluded from establishing that claim because an expropriation necessarily includes an act of state compulsion which was clearly absent with respect to the VWA.<sup>307</sup>
- 222. Indeed, the evidence presented during the hearing confirmed what Canada has already set out in Tony Zatylny's second affidavit ( $\P\P$  11-21) and Wendy Sexsmith's second affidavit ( $\P\P$  35-42) regarding the fact that Chemtura willingly entered into and took the benefit of the VWA.<sup>308</sup>
- 223. In particular, the Tribunal asked Mr. Zatylny, the CCC's president at the time of the VWA, the following question: "Would you say that Crompton was effectively compelled to enter into the VWA by the PMRA?" Mr. Zatylny responded this way:

<sup>&</sup>lt;sup>306</sup> Hearing Transcript Vol. 3, pp.616-620, 650-651, (John Worgan); Hearing Transcript Vol. 2, pp. 500, 523, (Cheryl Chaffey); Hearing Transcript Vol. 5, p. 1088, (Claire Franklin); Hearing Transcript Vol. 4, pp. 817-818, (Wendy Sexsmith);

<sup>&</sup>lt;sup>307</sup> See Counter Memorial, ¶¶ 651-652.

 $<sup>^{308}</sup>$  See also the documents referenced in ¶¶ 87-89 of the Rejoinder.

I would not say that's the case. This was the initiative of the growers. They were consistent in their response all through this process, that they no longer wanted to use a product. They did not want the health issues raised by nongovernment groups and consumer groups. They did not want issues at the border. It was their solution, and the PMRA was involved to facilitate the Agreement. It was--it was really the growers' solution. We analyzed the problem. Let's face it, all the lindane used in Canada would amount to \$20 million at the most. The industry was worth \$1.8 billion, 600 million of which was exports to the U.S. When we balance from the growers, when the industry balanced the use of lindane against the health of the industry, there is really no choice, and the solution was--was hammered out and agreed to by the industry, by the participants, and presented to the PMRA looking for their support. (Emphasis added)

224. In short, the evidence at the hearing substantiated Canada's position that Chemtura was not compelled by Canada or any other party to enter into the VWA but in fact willingly entered into it. Consequently, the principle enunciated in the *Tradex*<sup>310</sup> case applies here to preclude Chemtura from establishing its expropriation claim with respect to lindane use on canola.

### VI. DAMAGES

A. Oral Testimony Has Confirmed Canada's Position That Claimant's Damages Analysis is Defective and Unreliable

225. Testimony at the hearing confirmed the criticisms that Canada set out in its Counter-Memorial and Rejoinder with respect to damages<sup>311</sup>, including the following:

 a) LECG's damages assessment is explicitly conditioned on Chemtura's ability to access the US market, and Canada is not responsible for the failure of Chemtura to obtain a tolerance and registration in the US for lindane-use on canola;

<sup>&</sup>lt;sup>309</sup> Hearing Transcript Vol. 3, p.725 (Tony Zatylny); Hearing Transcript Vol. 4, p.786 (Wendy Sexsmith).

<sup>&</sup>lt;sup>310</sup> Tradex Hellas S.A. v. Republic of Albania (ICSID No. ARB/94/2) Award (29 April 1999) (Annex R-288). See also Canada's Counter Memorial at ¶¶ 651-659.

<sup>&</sup>lt;sup>311</sup> See Canada's Counter Memorial, pp. 319-344; See Canada's Rejoinder, pp.115-134.

- b) By ignoring both domestic and international regulatory risk, LECG has produced an inaccurate and invalid damages assessment;
- c) LECG has failed to identify and assess any specific losses that may be linked to specific alleged breaches; and
- d) There are no damages arising from Canada's actions with respect to non-canola.

# **B.** LECG's Damages Assessment Lacks Causation (Canola)

- 1) The Hearing Evidence Confirmed that Claimant's Damage Analysis is Conditioned on Access to the US Market
- 226. Both Claimant and Respondent agree that the Canadian canola growers would not use lindane products unless there was a tolerance and registration for lindane use in the US, without which Canadian canola could not be guaranteed entry into the US.<sup>312</sup> When asked whether or not the Canadian canola growers would have been interested in using lindane-treated seed if they were not able to export their product to the American market, Mr. Zatylny testified, "No, they would not be interested in using the product."<sup>313</sup>
- 227. In fact, it was contrary to CCC policy to use a product that was not registered for use in the US. As Ms. Buth explained in her testimony: "we remind Registrants on a regular basis that the Canola Council of Canada policy is that we do not support a

<sup>&</sup>lt;sup>312</sup> Hearing Transcript, Vol. 6, pp. 1271-1273, (Manuel Abdala); First Expert Report of LECG, ¶¶44-46. Second Affidavit of Tony Zatylny, ¶¶5-10. Even if the idea of separating out lindane treated canola from non-lindane treated canola was an option for the growers (which it was not), LECG did not assess the viability of such an alternative, nor the costs of setting up such a system. Hearing Transcript, Vol. 6, pp. 1276-1280, (Manuel Abdala).

<sup>&</sup>lt;sup>313</sup> Hearing Transcript, Vol. 3, p. 722, (Tony Zatylny). Furthermore, it is far from clear whether the canola growers would have continued to use lindane even if it was approved for use in the US and Canada. Mr. Zatylny testified that one of the main drivers of the VWA was the concern about health and environmental concerns of the growers: canola was being marketed as a "healthy" oil and the CCC was concerned about, amoung other things, being associated with a pesticide increasingly found in breast milk. Hearing Transcript, Vol. 3, p. 731 (Tony Zatylny); First Affidavit of Tony Zatylny, ¶10; Second Affidavit of Tony Zatylny, ¶¶22-28.

registration in Canada unless there is a simultaneous registration on canola in the US."<sup>314</sup> This is done to avoid the type of situation that arose in the case of canola.<sup>315</sup>

- 228. LECG was unequivocal in conditioning its damages analysis on the ability of Canadian canola growers to export lindane-treated canola to the US.<sup>316</sup> Accordingly, Claimant's entire claim for damages is dependant on whether the United States would issue a tolerance and registration for lindane use on canola. This is a fundamental flaw in causation because Canada cannot be held liable for the actions or non-actions of a foreign government agency.
- 229. In its attempt to invent a causal link between Canada's actions and Claimant's failure to obtain a tolerance in the United States, Claimant argues that because of Canada's alleged breach of the "October 1999 agreement" commitments and failure to complete a proper scientific assessment by the end of 2000, it discontinued its efforts to obtain a tolerance.<sup>317</sup> Claimant's counsel instructed LECG to assume that if Chemtura had not discontinued its efforts, it would have attained a tolerance by 2003, and a full registration by 2007.<sup>318</sup>
- 230. The oral and written evidence has exposed this instruction as fundamentally defective. Chemtura did not stop its efforts to obtain a tolerance in the United States until early 2006 when it became concerned that the EPA would make a negative finding about lindane. The substantial efforts Chemtura did make between 2002 and 2006 were stymied by factors that had nothing to do with Canada, but everything to do with

<sup>&</sup>lt;sup>314</sup> Hearing Transcript, Vol. 3, p. 753, (Joanne Buth).

<sup>&</sup>lt;sup>315</sup> Hearing Transcript, Vol. 3, p. 753, (Joanne Buth).

<sup>&</sup>lt;sup>316</sup> Hearing Transcript, Vol. 6, pp. 1271-1273, (Mr. Abdala); First Expert Report of LECG, ¶¶44-46.

<sup>&</sup>lt;sup>317</sup> First Witness Statement of Paul Thompson, ¶41.

<sup>&</sup>lt;sup>318</sup> First Expert Report of LECG, Tab 4, page 2, point 3; First Witness Statement of Paul Thompson, ¶¶41-42.

Chemtura's own tardiness and the EPA's own requirements and decision-making process.

# 2) Canada is Not Responsible for Chemtura's Failure to Obtain a Tolerance in the US

231. Contemporaneous documentary evidence and testimony prove that the reasons for Chemtura's failure to obtain a tolerance in the US are as follows: (a) the EPA set requirements for a tolerance that Chemtura had to meet; (b) Chemtura pursued all EPA requirements but suffered delays in submitting the requested studies; and (c) various decisions taken by EPA during its comprehensive review of lindane. Canada bears no responsibility for any of these factors.

### a. EPA Requirements

232. Mr. Johnson confirmed his written testimony that in order to import lindane treated canola seed into the US, both a tolerance and registration were necessary.<sup>319</sup> In order to attain a tolerance and registration for lindane-use on canola, Chemtura had to meet the requirements of the 2002 EPA RED. These requirements included a plant metabolism study, a seed leaching study and an anaerobic aquatic metabolism study.<sup>320</sup> Mr. Johnson and Mr. Thomson confirmed that the EPA told Chemtura that these studies were a precondition for a tolerance and registration.<sup>321</sup>

<sup>&</sup>lt;sup>319</sup> Hearing Transcript, Vol. 2, p. 400, 406, (Edwin Johnson); First Witness Statement of Edwin Johnson, ¶18.

<sup>&</sup>lt;sup>320</sup> First Expert Report of Dr. Goldman, Exhibit 16, pp. 1-2. The RED's requirements also applied to the re-registration of non-canola registrations.

<sup>&</sup>lt;sup>321</sup> Hearing Transcript, Vol. 2, p. 300, (Paul Thomson); Hearing Transcript, Vol. 2, pp. 408, 413, 417, 422, (Edwin Johnson).

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233. Mr. Aidala's opinion that the EPA could have issued a tolerance without these requirements, which he explicitly classified as "hypothetical," <sup>322</sup> ignores reality. For example, the EPA explicitly rejected the request to waive the requirement of the plant metabolism study, <sup>323</sup> and Mr. Johnson and Mr. Thompson confirmed that the EPA told Chemtura on several occasions that it must do the study before any new tolerances could be issued. <sup>324</sup> While Mr. Johnson was of the opinion that it "wasn't a crucial study," <sup>325</sup> he admitted that the EPA did not share this view and his proposal for a waiver "didn't get very far." <sup>326</sup> Mr. Aidala also admitted that one of the reasons why Chemtura did not get a tolerance between 2002 and 2006 was because the EPA insisted on the plant metabolism study. <sup>327</sup>

<sup>322</sup> Hearing Transcript, Vol. 5, p. 1161 (James Aidala) ("Q. Now, given that Chemtura did not submit the required plant metabolism study until 2005, and given that the EPA was still reviewing the plant metabolism study as of early 2006, February 2006, the key assumptions underlying your opinion that a tolerance decision would have been issued in early 2003 are not present, are they? A. They were not present in realtime, and *that's why it's a hypothetical situation...*" [emphasis added]); p. 1162 ("...the record would indicate that again, *under the hypothetical*, that they get the data in." [emphasis added]); p. 1181 (Claimant's counsel referring to the "hypothetical" in James Aidala's First Expert Statement).

<sup>&</sup>lt;sup>323</sup> First Expert Report of Dr. Goldman, Exhibit 9 ("EPA rejected our previous comments regarding the need for a new plant metabolism study.")

<sup>&</sup>lt;sup>324</sup> First Expert Report of Dr. Goldman, Exhibits 3, 28, 43, 44, 33, 34; Hearing Transcript, Vol. 2, p. 408, 413, 417, 420, (Edwin Johnson); Hearing Transcript, Vol. 2, p. 300, 309 (Paul Thompson).

<sup>&</sup>lt;sup>325</sup> Hearing Transcript, Vol.2, p. 446, (Edwin Johnson).

<sup>&</sup>lt;sup>326</sup> Hearing Transcript, Vol. 2, p. 446, (Edwin Johnson).

<sup>&</sup>lt;sup>327</sup> Hearing Transcript, Vol. 2, p. 1164, (James Aidala) ("Q. And as the documents say and as Mr. Johnson and Mr. Thomson said, they knew that the EPA would not [issue a tolerance between 2002 and 2006] because the plant metabolism study was still outstanding; is that right? A. It appears that that was their understanding that EPA – they weren't going to get a positive – you know, they weren't going to get a decision from EPA at that time, that's correct.").

234. Canada cannot be held responsible for the decision of a foreign government agency to set certain requirements before it would permit the entry of a particular product from Canada. Canada is equally blameless for any resulting delays associated therewith.

# b. Chemtura Pursued all Requirements but Suffered Delays

- 235. Contemporaneous documentary evidence between July 2002 (the date of the RED) and August 2006 (the date of the Addendum to the RED), and testimony from Claimant's witnesses prove that the Claimant was actively pursuing a tolerance for lindane use on canola during this period, but was unable to fulfill the EPA's requirements in a timely fashion.
- 236. The exhibits to Dr. Goldman's Second Expert Report document Claimant's substantial efforts to conduct the requisite studies.<sup>328</sup> At the hearing, Dr. Goldman testified that from her reading of these documents, it was clear to her that the Claimant was:

aggressively attempting to maintain their registrations and to secure a registration for canola all the way through the beginning of 2006...I see that they were continuing to perform studies, continuing to submit studies, continuing to pay consultants to do work for them on this, continuing to meet with the EPA.<sup>329</sup>

237. Testimony from Claimant witnesses Mr. Johnson and Mr. Aidala confirms exactly what Dr. Goldman observed: Chemtura was making substantial efforts to secure a tolerance for canola through early 2006.<sup>330</sup> These efforts included working on the

<sup>&</sup>lt;sup>328</sup> Second Expert Report of Dr. Goldman, Exhibits 22-60; Hearing Transcript, Vol. 2, pp. 413-415, (Edwin Johnson).

<sup>&</sup>lt;sup>329</sup> Hearing Transcript, Vol. 5, pp. 1232-1233, (Dr. Goldman).

<sup>&</sup>lt;sup>330</sup> Hearing Transcript, Vol. 2, pp. 420-433, 440, (Edwin Johnson); Hearing Transcript, Vol. 5, p. 1164 (James Aidala).

requisite studies between 2002-2005, constant lobbying of the EPA, and submitting extensive comments on the HCH Study published in February, 2006.<sup>331</sup>

- 238. Documentary evidence and testimony confirms that the reason Chemtura was not able to get a tolerance between 2002 and 2006 was because it took them three years to complete the EPA's requisite studies. For example, Chemtura was having technical problems with the anaerobic aquatic metabolism study, and these problems were present as late as 2005.<sup>332</sup> The plant metabolism study also took Chemtura a substantial amount of time to complete.<sup>333</sup> Ultimately, none of the three studies were submitted until 2005, and the EPA was still reviewing the studies as of February 2006.<sup>334</sup>
- 239. Again, Canada is blameless for Chemtura's own delays in submitting the requisite studies to the EPA.

# c. EPA's Decision-Making Process and Concerns with Lindane

- 240. Chemtura's inability to get a tolerance in the US was also caused by various decisions the EPA made during its comprehensive review of lindane.
- 241. First, in addition to the requisite studies, Mr. Johnson confirmed during the hearing that the EPA indicated in the 2002 RED, and in subsequent discussions with

<sup>&</sup>lt;sup>331</sup> Hearing Transcript, Vol. 2, pp. 440-44, (Edwin Johnson).

<sup>&</sup>lt;sup>332</sup> Second Expert Report of Dr. Goldman, Exhibits 33, 35, 36, 37, 40; Hearing Transcript, Vol. 2, pp. 422-424 (Edwin Johnson).

<sup>&</sup>lt;sup>333</sup> Hearing Transcript, Vol. 2, p. 300, (Paul Thomson); Hearing Transcript, Vol. 2, p. 412, (Edwin Johnson); Hearing Transcript, Vol. 5, p. 1162 (James Aidala) ("that kind of study normally takes some time but not as long as it did."); Second Expert Report of Dr. Goldman, Exhibit 44.

<sup>&</sup>lt;sup>334</sup> Hearing Transcript, Vol. 2, pp. 422-425 (Edwin Johnson); Second Expert Report of Dr. Goldman, Exhibits 33, 35, 36, 37, 40; First Expert Report of Dr. Goldman, Exhibit 16, pp. 1-2; Hearing Transcript, Vol. 2, p. 424 (Edwin Johnson).

Chemtura, that it would not issue any new tolerances until it determined whether pharmaceutical uses of lindane had to be included in the aggregate risk cup.<sup>335</sup> The EPA did not make a decision on this issue until February 2006.<sup>336</sup> This lengthy decision-making process at the EPA was despite the fact that Chemtura had expended great efforts to lobby the EPA on this issue.<sup>337</sup>

- 242. Second, the EPA rebuffed Chemtura's efforts to get a time-limited import tolerance. Contrary to Mr. Johnson's written testimony that Chemtura did not "actively pursue" a time-limited import tolerance, <sup>338</sup> he testified orally that the Claimant in fact had been lobbying the EPA to issue one for years without success: "we were constantly calling on the EPA trying to get them to move. We called them regularly, sent memos over to the managers at [the] EPA..." Despite all of Chemtura's efforts, the EPA responded by "didn't say anything, or they said not now." <sup>340</sup>
- 243. Third, the EPA said in 2001 that it would not issue a tolerance until it had completed a comprehensive risk assessment of lindane. As conceded by Claimant's

<sup>335</sup> Hearing Transcript, Vol. 2, p. 429, 431, 433 (Edwin Johnson) ("Q: So it was in February 2006 that the EPA determined internally that it was not going to include pharma uses in its risk cup? A: Yes, that's what it says in the E-mail. Q: And that's four years after the issue was flagged in the RED? A: Yes Q: And again, the EPA said explicitly that no new tolerances would be granted until that FQPA issue was determined; is that right? A: I'm trying to think of whether they actually said it that way or not. I guess you could imply that from what they said."). *See also* Second Expert Report of Dr. Goldman, Tabs 3, 38, 42, 43, 44.

<sup>&</sup>lt;sup>336</sup> Hearing Transcript, Vol. 2, p. 433 (Edwin Johnson); Second Expert Report of Dr. Goldman, Exhibit 42.

<sup>&</sup>lt;sup>337</sup> Hearing Transcript, Vol. 2, pp. 428-433 (Edwin Johnson); Second Expert Report of Dr. Goldman, Tab 38.

<sup>&</sup>lt;sup>338</sup> First Witness Statement of Edwin Johnson, ¶28.

<sup>&</sup>lt;sup>339</sup> Hearing Transcript, Vol. 2, p. 446 (Edwin Johnson).

<sup>&</sup>lt;sup>340</sup> Hearing Transcript, Vol. 2, p. 447 (Edwin Johnson).

<sup>&</sup>lt;sup>341</sup> Hearing transcript, Vol. 2, pp. 403-404 (Edwin Johnson); *See also* Second Expert Report of Dr. Goldman, Tab 25 ("Unfortunately, until the Agency has completed a

witnesses during the hearing, the comprehensive risk assessment included the 2002 RED, but it was still ongoing with the HCH Study issued in February 2006.<sup>342</sup> The HCH Study raised new and difficult hurdles that Chemtura would have to overcome before a canola tolerance would be issued, including, among other things, serious concerns about lindane in breast milk.<sup>343</sup>

244. Chemtura assembled a group of "well-renowned scientists" and lawyers to make voluminous submissions on the various concerns raised by the EPA in the HCH Study.<sup>344</sup> Mr. Johnson conceded that the EPA apparently did not find Chemtura's arguments to be very compelling, and "totally ignored" and "didn't buy" Chemtura's submissions on lindane in breast milk.<sup>345</sup> The EPA published its Addendum to the RED in July, 2006, which was not a favourable decision for lindane.<sup>346</sup>

comprehensive risk assessment for lindane, we will not be able to make a decision on your client's petition.").

<sup>&</sup>lt;sup>342</sup> First Expert Report of Dr. Goldman, Exhibit 16, p. 2 ("As a result of the Agency's *continuing review* of lindane, the Agency initiated the preparation of this document. This document presents EPA's *revised assessment of risks* related to the continued registration of the insecticide lindane, also known as gamma HCH." [emphasis added]). Claimant's witnesses, Mr. Thompson, Mr. Aidala and Mr. Johnson all admitted this in testimony. See Hearing Transcript, Vol. 2, p.303 (Paul Thompson) ("Q. "[the HCH study] is part of the…ongoing narrative that started with the 2002 RED; is that right? A. Correct"); Hearing Transcript, Vol. 2, p.438 (Edwin Johnson) ("Q. …So, the comprehensive risk assessment was not finished yet in February 2006? A. That's what it says."); Hearing Transcript, Vol. 5, p.1171 (James Aidala) (described the HCH study as "part of the continuing [a]ssessment of the risks of lindane and HCH-related isomers.").

<sup>&</sup>lt;sup>343</sup> Hearing Transcript, Vol. 2, pp. 442-443, (Edwin Johnson); First Expert Report of Dr. Goldman, Tab 16.

<sup>344</sup> Hearing Transcript, Vol. 2, p. 440-441, (Edwin Johnson)

<sup>&</sup>lt;sup>345</sup> Hearing Transcript, Vol. 2, pp. 441-442, (Edwin Johnson). ("Q. And what was the EPA's response to this obviously compelling case that Chemtura and your...team of scientists and lawyers submitted? A...From what I saw in [the RED Addendum] wasn't compelling to them.")

<sup>&</sup>lt;sup>346</sup> In fact, this unfavourable decision was anticipated by Chemtura. An internal Chemtura email from June, 2006 reads: "EPA WILL make a decision on lindane before the end

- 245. The EPA sets its own priorities, undertakes its own review of issues on its own schedule and determines for itself whether to accept or deny the submissions of pesticide registrants. Canada cannot be held responsible for the decision-making process of the EPA during its comprehensive review of lindane.
  - 3) Even if Canada Had Acted Differently, Damages are Too Remote and Speculative to Recover
    - a. It is Too Speculative To Assume Chemtura Would Have Been Granted a Tolerance Between 2002 and 2006
- 246. Even if Canada's actions did affect Claimant's pursuit of a tolerance for lindane use on canola, damages are too remote and speculative to recover.
- 247. Mr. Johnson admitted in his oral testimony that, given the EPA requirements, no tolerance was possible between 2002 and 2006:
  - Q: So, in other words, given the three studies, the Plant Metabolism Study, the Anaerobic Aquatic Metabolism Study, the Seed Leaching Study, and this FQPA issue, no tolerances were actually possible between 2002 and 2006; is that right?
  - A: Yes, it is for full tolerances...<sup>347</sup>
- 248. Mr. Johnson's admission contradicts given to LECG that its damages analysis should assume a US tolerance by 2003.<sup>348</sup> LECG admitted during the hearing that its

of August because of the FQPA deadline. It will not likely be a favorable decision. Therefore, if you intend to offer a phase-out, you need to show your hand before EPA shows their hand." (Second Expert Report of Dr. Goldman, Tab 51); Mr. Thomson agreed in testimony that Chemtura's concern was concerned that the EPA's decision on the tolerance in August 2006 would not be favourable, Hearing Transcript, Vol. 2, p. 312 (Paul Thomson); Hearing Transcript, Vol. 2, p. 441-442, (Edwin Johnson).

<sup>&</sup>lt;sup>347</sup> Hearing Transcript, Vol. 2, p. 433, (Edwin Johnson).

<sup>&</sup>lt;sup>348</sup> First LECG Report, Exhibit 4.

damage analysis has not accounted for the scenario that no tolerance was possible between 2002 and 2006.<sup>349</sup>

- 249. It is entirely speculative to assume what the EPA would or would not have done if Canada had acted differently. The EPA is an independent regulatory body with its own processes and policies in place. The scientific regulatory process is not *pro forma* and, as Chemtura discovered, there is no guarantee that an application for a tolerance or registration would result in the issuance of a tolerance.<sup>350</sup>
- 250. Part of this uncertainty is because new issues and concerns could arise during the EPA's comprehensive review process. The EPA's release of the HCH Study in February, 2006 is evidence of this. As well, public consultations play a considerable role in the EPA's risk assessment which can, as it did with lindane, have a major impact on the EPA's tolerance assessment.<sup>351</sup>
- 251. Given the reality of what happened between 2002 and 2006 EPA's insistence on completion of requisite studies, EPA's rejection of a time-limited tolerance request, EPA's lengthy deliberation on the FQPA risk cup issue, EPA's scepticism of Chemtura's submissions on the HCH study any alternative reality promoted by Claimant must be based on real evidence, not "hypothetical" speculation. Claimant has only the latter.
  - b. It is Too Speculative to Assume A Time-Limited Import Tolerance Would Have Been Granted

<sup>&</sup>lt;sup>349</sup> Hearing Transcript, Vol. 2, pp. 1368-1269, 1299-1300, 1340, (Manuel Abdala).

<sup>&</sup>lt;sup>351</sup> See Hearing Transcript, Vol. 2, pp. 333-334, (Paul Thomson); Hearing Transcript, Vol. 2, p. 341 (Edwin Johnson).

- 252. Testimony has also proven that it is highly speculative to assume that the EPA would have granted Chemtura a time-limited import tolerance. Dr. Goldman testified that time-limited import tolerances were rarely granted, and only done so in an "extraordinary situation" in the context of "very unusual events."<sup>352</sup> The EPA was wary of issuing such tolerances as it required a rapid Special Review of the data, and in her five years as Assistant Administrator of OPPTS, this type of tolerance was issued only once.<sup>353</sup>
- 253. This uncertainty was confirmed by Mr. Johnson in his testimony. The most Claimant's witnesses could say is that they were hoping an "action-forcing event" that might convince the EPA to grant this rare type of tolerance.<sup>354</sup> In response to Claimant's counsel's invitation to "do a little bit of speculation" as to whether or not the EPA would have granted Chemtura a time-limited tolerance in the face of "something to force their action", Mr. Johnson testified "...I don't know that they would have, but they well could have."<sup>355</sup> Mr. Johnson could only speculate whether or not the EPA would have made such a decision.<sup>356</sup>
- 254. Further, Mr. Aidala confirmed in his testimony that the data requirements for a time limited import tolerance were the same as those for a regular tolerance.<sup>357</sup> Mr.

<sup>&</sup>lt;sup>352</sup> Hearing Transcript, Vol. 5, p. 1193, 1240-1241 (Dr. Goldman).

<sup>353</sup> Hearing Transcript, Vol. 5, pp. 1240-1241 (Dr. Goldman).

<sup>&</sup>lt;sup>354</sup> Hearing Transcript, Vol. 2, p. 412-413, 421, 434 (Edwin Johnson).

<sup>355</sup> Hearing Transcript, Vol. 2, p. 450 (Edwin Johnson).

<sup>&</sup>lt;sup>356</sup> In fact contemporaneous documents prove that, at the time, Chemtura knew that the chances such a tolerance were remote. (Second Expert Report of Dr. Goldman, Tab 51). Dr. Goldman also refers to this situation in her testimony, saying that if the "crisis or precipitating event" that might have caused EPA to consider a time-limited import tolerance existed after the border issue arose, but that it "was not a road taken at the time". Hearing Transcript, Vol. 5, p. 1193, (Dr. Goldman).

 $<sup>^{357}</sup>$  Hearing Transcript, Vol. 5, pp. 1166-1167, (James Aidala). This would include the plant metabolism study. *See* Second Expert Report of James Aidala, ¶6 referring to

Aidala's hypothesis that there was a way for the EPA to have granted an import tolerance is undermined by reality: despite constant pressure on the EPA to issue one, "they never got a time-limited tolerance." His opinion that such a tolerance was still possible despite the fact that the EPA refused consistent requests by Chemtura is not credible.

## c. It is Too Speculative to Assume a Tolerance Would Have Been Granted After 2006

255. Mr. Thompson's written testimony is that, for the purposes of calculating damages, 2022 was the reasonable end date, and this was the basis for LECG's damages calculation per Claimant's counsel instructions.<sup>359</sup> This has been discredited. Any damages claim based on the US granting a tolerance to Chemtura after 2006 is too remote and speculative to recover.

256. The HCH Study and 2006 Addendum to the RED flagged further concerns about, among other things, lindane's detection in breast milk. Mr. Johnson testified that the breast milk concerns would have required Chemtura or another entity to submit even more data to the EPA for review.<sup>360</sup> Both he and Mr. Aidala confirmed that they had "no idea" how long such a study or studies would have taken to satisfy the EPA, and could not predict whether the results of such studies would reveal an acceptable level of exposure to lindane in breast milk.<sup>361</sup> Both Mr. Aidala and Mr. Johnson testified that they could not confirm when and if the EPA ever would have granted a tolerance for lindane use on canola:

requisite "residue chemistry" studies, which include plant metabolism. See Hearing Transcript, Vol. 5, p. 1165 (James Aidala).

<sup>358</sup> Hearing Transcript, Vol. 5, p. 1182, (James Aidala)

<sup>&</sup>lt;sup>359</sup> First Witness Statement of Paul Thomson, ¶42; LECG First Report, ¶69.

<sup>&</sup>lt;sup>360</sup> Hearing Transcript, Vol. 2, pp. 443-444, (Edwin Johnson).

<sup>&</sup>lt;sup>361</sup> Hearing Transcript, Vol. 2, p. 443, (Edwin Johnson); Hearing Transcript, Vol. 5, pp. 1174-1175, (James Aidala).

Mr. Johnson:

Q: You can't say for sure if and when the EPA would have ever granted a tolerance for lindane use on canola in the United States; is that right?

A: Yes, that's right.<sup>362</sup>

Mr. Aidala:

Q: ...you cannot say with certainty if and when the EPA would have ever issued a tolerance for lindane use on canola in the United States, can you?

A: Not with absolute certainty, no.363

257. Given the explicit testimony of Claimant's own witnesses that they are uncertain as to whether the EPA would have ever granted a tolerance in the USA, LECG's damages calculations based on a 2022 end date is equally uncertain and cannot be relied upon by the Tribunal.

#### C. LECG's Damages Analysis Fails to Properly Take into Account Risk

- 258. The LECG damages assessment fails to take into account the reality that lindane registrations were at risk in Canada, the US, and worldwide.<sup>364</sup>
- 259. During the hearing, Mr. Abdala conceded that the LECG damages assessment was based purely on the but-for scenario given to them by Claimant's counsel.<sup>365</sup> The but-for scenario ignores the risk that a registration or tolerance may not be granted in the US, or may not continue in Canada. Mr. Abdala admitted that as a result of the but-for

<sup>&</sup>lt;sup>362</sup> Hearing Transcript, Vol. 2, p. 444, (Edwin Johnson).

<sup>&</sup>lt;sup>363</sup> Hearing Transcript, Vol. 5, p. 1179, (James Aidala).

<sup>&</sup>lt;sup>364</sup> Second Expert Report of Navigant, Section III(A)(B)(i)-(iv).

<sup>&</sup>lt;sup>365</sup> Hearing Transcript, Vol. 6, pp. 1340-1342, (Manuel Abdala).

scenario, its assessment did not take into account "regulatory risks or uncertainty as to the approval in either Canada or the US." 366

- 260. This is exactly the criticism Navigant made in its written reports. Mr. Kaczamarek recognized that "LECG has essentially been instructed to assume there is zero risk to the EPA granting a tolerance and registration for lindane."<sup>367</sup>
- 261. Mr. Abdala admitted this in testimony:

"so, we have not attempted to conduct any valuations dated back in the year 2000 and see what the value or situation would be there under the assumption that there would be still regulatory risks or uncertainty as to the approved in either Canada or U.S.<sup>368</sup>

262. Mr. Abdala also conceded in testimony that LECG did not incorporate a risk factor to reflect the international context, including the possibility of a general ban of lindane worldwide.<sup>369</sup> In fact, LECG has extrapolated beyond the but-for scenario and ignored international events that introduce risk into the assessment, such as the NARAP and the Stockholm Convention.<sup>370</sup> As Mr. Kaczmarek explained:

What I think LECG has done with respect to calculating their but-for assessment is they're going beyond just but-for the acts, and they are attaching to those acts a series of other events that they're suggesting would not have happened, such as the Stockholm Convention or the NARAP and so forth in order to make it fit into

<sup>&</sup>lt;sup>366</sup> Hearing Transcript, Vol. 6, pp. 1299-1300, (Manuel Abdala); Mr. Kaczamarek argues that the analysis "should have, at the very least, incorporated an adjustment to account for the probability that a United States registration for lindane use on canola would have been unsuccessful." For further discussion on the inherent valuation problem for businesses that rely on regulatory approval and are facing increasingly tight regulation internationally, *See* Hearing Transcript, Vol. 6, pp. 1384-1386 (Manuel Abdala); Second Expert Report of Navigant, ¶ 54.

<sup>&</sup>lt;sup>367</sup> Second Expert Report of Navigant, ¶ 7.

<sup>&</sup>lt;sup>368</sup> Hearing Transcript, Vol. 6, pp. 1299-1300, (Manuel Abdala).

<sup>&</sup>lt;sup>369</sup> Hearing Transcript, Vol. 6, pp. 1300-1301, (Manuel Abdala).

<sup>&</sup>lt;sup>370</sup> Hearing Transcript, Vol. 6, pp. 1370, 1379, (Manuel Abdala).

the hypothetical.<sup>371</sup>

- 263. Mr. Abdala also testified that LECG did not provide adequate evidence to support its assumption that canola exports would go to Mexico<sup>372</sup>, Japan<sup>373</sup>, China<sup>374</sup>, or any other country<sup>375</sup> in the future. These exports, which account for approximately 33% percent of the Claimant's damages,<sup>376</sup> are, as LECG conceded, entirely without support.
- 264. Finally, LECG has inappropriately applied the ex-post approach to assessing damages. Because the ex-post approach does not discount the damages projection to take into account risk, a higher degree of market certainty is required to justify using it.<sup>377</sup> As Mr. Kaczamarek explained, by using the ex-post methodology:
  - ...you're removing the discounting associated with those cash flows. Instead, you're adding interest, so you're implying that what you're doing is adding a higher degree of confidence to the measurement of those cash flows and implementing an ex post approach.<sup>378</sup>
- 265. The kind of information that would ordinarily be used in an ex-post assessment is not present in this case:

...we don't really have any experience to judge in the sort of post VWA environment where lindane products are competing against non-lindane based products, so we can't observe the competition at all. We can't see how one product might differentiate itself from another, we can't see what the pricing strategies are, we can't see what the costs maybe would be for lindane if there are lower volumes being purchased for particular market shares. There is just no competitive market experience to assess in my view, and with the absence of

<sup>&</sup>lt;sup>371</sup> Hearing Transcript, Vol. 6, p. 1379 (Brent Kaczamarek).

<sup>&</sup>lt;sup>372</sup> Hearing Transcript, Vol. 6, pp. 1324-1327, (Manuel Abdala).

<sup>&</sup>lt;sup>373</sup> Hearing Transcript, Vol. 6, pp. 1329-1330, (Manuel Abdala).

<sup>&</sup>lt;sup>374</sup> Hearing Transcript, Vol. 6, pp. 1331-1332, (Manuel Abdala).

<sup>&</sup>lt;sup>375</sup> Hearing Transcript, Vol. 6, pp. 1332-1333, (Manuel Abdala).

<sup>&</sup>lt;sup>376</sup> Hearing Transcript, Vol. 6, pp. 1324-1331, (Manuel Abdala).

Hearing Transcript, Vol. 6, p. 1361, (Brent Kaczamarek); Second Expert

Report of Navigant, ¶ 70; First Expert Report of Navigant, ¶¶29-30, 96-97.

<sup>&</sup>lt;sup>378</sup> Hearing Transcript, Vol. 6, p. 1361 (Brent Kaczamarek).

that, I think that the only reasonable thing to do is make ex ante forecasts of maybe what would happen rather than suggest that we know precisely how the market would have evolved post VWA.<sup>379</sup>

266. The only information LECG took into account relates to the amount of canola acreage, the size of the market and applicable interest rate, and this is not enough on which to base an ex-post analysis.<sup>380</sup> Mr. Kaczamarek testified that:

you have to have a sufficient amount of information, not just the acreage in which canola is planted, but other things such as market share, prices and so forth, costs, on how to implement those in order to justify removing the discounting associated with them and adding an interest component on top of it.<sup>381</sup>

- 267. In other words, by using the ex-post approach inappropriately, LECG has artificially inflated its damages assessment.<sup>382</sup>
- 268. Because the information required to calculate damages based on an ex-post approach is absent, Mr. Kaczamarek has argued that the only appropriate way to assess damages in this case is to use the ex-ante approach for the entire calculation:

[I]n a properly structured but-for scenario as of 1 July 1001, there was merely a possible, but unquantifiable market at some unknown future date for lindane-based canola pesticides... Given the presence of these significant market uncertainties, an ex-ante approach is the most appropriate approach to consider

<sup>&</sup>lt;sup>379</sup> Hearing Transcript, Vol. 6, pp.1378-1379, (Brent Kaczamarek).

<sup>&</sup>lt;sup>380</sup> Hearing Transcript, Vol. 6, pp.1344 (Manuel Abdala), 1361-1363, 1378, (Brent Kaczamarek); Second Expert Report of Navigant, ¶70.

<sup>&</sup>lt;sup>381</sup> Hearing Transcript, Vol. 6, p.1361, (Brent Kaczamarek).

<sup>&</sup>lt;sup>382</sup> LECG has also chosen the incorrect discount rate and, in doing so, has artificially increased its damages calculation. LECG has chosen the WAAC of an average company in the agrochemical industry as the discount rate. This is not appropriate as Chemtura may not be an average company in the industry, but more importantly, the investment at issue is not Chemtura Canada, but the Claimant's equity ownership of Chemtura Canada. The appropriate discount rate is therefore the cost of equity, as cost of equity accurately reflects the form of investment the Investor has in this case. Hearing Transcript, Vol. 6, pp.1374-1377, (Brent Kaczamarek); Second Expert Report of Navigant, ¶93.

because an ex-post approach does not consider the risks of achieving the market share sales, and profits that LECG projects in its damages model.<sup>383</sup>

269. Setting aside the methodological differences, Mr. Kaczamarek concludes that even if an ex-ante approach is used, it "cannot account for all the uncertainties that would have existed in a properly structured but for scenario." The result is that on an ex-ante basis, an assessment of the value of the Claimant's lindane for canola product line is entirely speculative. Even if the PMRA had reached the conclusion that lindane was approved for use, the trade irritant issue would still have remained and there is no way to know when and if the EPA would have ever granted Claimant a tolerance in the USA. Mr. Kaczamarek described such a scenario as follows:

Q: And so how would a reasonable businessman at that moment in time see the business?

A: Well, obviously I think with great uncertainty. There was no market to sell the product. I think a reasonable businessman would be gravely concerned that the customer base and the trade groups associated with the customer base are saying that...it no longer wants the product due to the healthy image concerns for canola. Standing there at that point in time back at the end of the VWA, as I've stated in my Second report, you have an uncertain future market at the some uncertain future date for an unknown amount of time. That's about as uncertain as one can get regarding a business.<sup>385</sup>

## D. Claimant has Failed to Provide Damages Calculations for Individual Breaches

<sup>&</sup>lt;sup>383</sup> Second Expert Report of Navigant, ¶65.

<sup>&</sup>lt;sup>384</sup> Second Expert Report of Navigant, ¶65.

 $<sup>^{385}</sup>$  Hearing Transcript, Vol. 6, p. 1380-1381, (Brent Kaczamarek); Second Expert Report of Navigant,  $\P$  77-79.

- 270. A damages claim based on an alleged individual breach fails because the Claimant has not provided a calculation of losses for any of the alleged individual breaches.
- 271. Mr. Abdala agreed in testimony that LECG has not calculated damages for anything short of what it was asked to assume in the but-for scenario: "we have not attempted to set damages individually for each breach…because we took all the breaches as a bundle."<sup>386</sup> The Claimant has therefore not linked a specific loss to a specific breach, and any damages claim based on individual breaches fails on this basis alone.
- 272. More specifically, there is no damages calculation for a breach to any of the individual alleged commitments made in the VWA, or any commitment in the alleged "October 1999 agreement." For example, there has been no damages calculation by LECG for the impact of the alleged misunderstanding of the July 1<sup>st</sup> deadline: "we have taken the bundle of all the claims in this case and computed damages for those and did not attempt to compute separate damages." <sup>387</sup>
- 273. Similarly, there was no calculation done by LECG for any alleged delay in registering its all-in-one replacement products: "we have not attempted to assess how much more Gaucho CS would have sold in the absence of lindane replacement[s] so as to be able to identify...a separate single category of that claim." Navigant confirmed this: "as I think LECG ..testified..there wasn't any calculation put into the record as to possible losses for the late introduction of Gaucho CS." 389

<sup>&</sup>lt;sup>386</sup> Hearing Transcript, Vol. 6, pp.1340-1342, 1391 (Manuel Abdala).

<sup>&</sup>lt;sup>387</sup> Hearing Transcript, Vol. 6, p.1392, (Manuel Abdala).

<sup>&</sup>lt;sup>388</sup> Hearing Transcript, Vol. 6, pp.1393-1394, (Manuel Abdala).

<sup>&</sup>lt;sup>389</sup> Hearing Transcript, Vol. 6, p.1389, (Brent Kaczamarek); Hearing Transcript, Vol. 6, p. 1391 (Manuel Abdala).

#### E. In any event, the alleged individual breaches did not cause any damages

274. Any damages claim based on alleged individual breaches fails not only because the Claimant does not link a specific loss to a specific breach, but because in actual fact there was no damage to assess. The individual alleged breaches caused no losses.

# 1. The Voluntary Withdrawal Agreement caused no damage

275. All documentary evidence suggests that it was the growers, not the PMRA, that initiated the VWA.<sup>390</sup> This is supported by the testimony of both Mr. Zatylny and Ms. Buth of the CCC.<sup>391</sup> There is no causation for this alleged loss as the VWA was not "forced" on the Claimant by the PMRA.

276. Even if Canada had forced the Claimant to agree to the VWA, which it did not, the VWA did not cause any damages to Chemtura. The VWA actually worked to extend the life of lindane sales in Canada, as it allowed the growers to continue to use lindane during the phase-out period until July 1, 2001, and ensured that the US border would not be closed during this period so the growers could continue with their sales to the US.<sup>392</sup> This phase-out also provided the necessary time for replacement products to get to market, which Chemtura benefitted from.

<sup>&</sup>lt;sup>390</sup> Canada's Rejoinder, ¶¶ 70-79; Canada's Counter Memorial, ¶¶ 74-77, 82-97; E-mail from C.P. Yip, Uniroyal to Al Ingulli and John Lacadie, 20 October 1998 (Exhibits TZ-25); E-mail from Bill Hallatt to Rick Turner et al., 19 October 1998 (Exhibit TZ-34); E-mail from Bill Hallatt to Rick Turner, Kim Turner, et al., 20 October 1998 (Exhibit TZ-38); E-mail from Rob Dupree to C.P. Yip and Tom Geise, 20 October 1998 (Exhibit TZ-40).

<sup>&</sup>lt;sup>391</sup> Hearing Transcript, Vol. 3, pp. 725, 730-731, (Tony Zatylny); Hearing Transcript, Vol. 3, p.740, (JoAnne Buth).

<sup>&</sup>lt;sup>392</sup> Record of Understanding between the Governments of Canada and the United States of America Regarding Areas of Agricultural Trade, 04 December 1998 (Exhibit WS-18); First Affidavit of Tony Zatylny, ¶¶53-54; Hearing Transcript, Vol. 3, pp. 714-716 (Tony Zatylny).

277. Furthermore, the LECG assessment failed to take into account the benefit of the VWA. As Mr. Kaczamarek explained:

As of (October 1998, the business) was worthless. Then, with the implementation of the VWA...now there was some certainty to the business for a particular defined period of time. So now it has some amount of value.<sup>393</sup>

- 278. If the VWA had never been negotiated, Canadian Canola growers would have faced the serious risk of their products being stopped at the U.S. border. This threat flowed from both the EPA ban on lindane treated canola seed and the U.S. FFDCA restriction against residues of unregistered pesticides on canola grown from lindane treated seeds.<sup>394</sup> As Mr. Zatylny explained to the Tribunal at the hearing: "...ultimately, I believe that had the [VWA] fallen through, there would have been enormous pressure from the US growers to shut down the border until lindane was gone or it [was] registered in the US."<sup>395</sup>
- 279. The growers had made it very clear they were not going to risk using a product if it meant they did not have access to the US market. Therefore, without a VWA, the industry would have been forced to move away from lindane "cold turkey"<sup>396</sup> as the registrants would have had no phase-out period for lindane use on canola.<sup>397</sup> Furthermore, there would have been no readily available replacement products.

<sup>&</sup>lt;sup>393</sup> Hearing Transcript, Vol. 6, pp. 1366, (Brent Kaczamarek).

<sup>&</sup>lt;sup>394</sup> Hearing Transcript, Vol. 3, p. 727 (Tony Zatylny); Letter from Lynn Goldman, Assistant Administrator, EPA to Tony Zatylny, CCC, 23 November 1998 (Exhibit TZ-12). *See also* First Affidavit of Tony Zatylny, ¶¶ 44-45; Second Affidavit of Tony Zatylny, ¶¶ 5-10.

<sup>&</sup>lt;sup>395</sup> Hearing Transcript, Vol. 3, p. 727 (Tony Zatylny).

<sup>&</sup>lt;sup>396</sup> Second Affidavit of Tony Zatylny, ¶ 31.

<sup>&</sup>lt;sup>397</sup> Evidence suggests that growers could have stopped using lindane altogether and would have turned to a fungicide only treatment and foliar spray. *See* E-mail from Bill

280. Regardless, even if the VWA had never occurred, by October 2001, the PMRA would have released its findings that no remaining lindane registrations could be supported for agricultural use.

# 2. Any alleged misunderstanding of the July 1<sup>st</sup> deadline caused no damage

- 281. Canada was clear about the meaning of the July 1<sup>st</sup> deadline in the VWA, <sup>398</sup> but even if it was not, there are no damages that flow from the alleged breach.
- 282. There is no evidence to suggest that the growers stopped using lindane products as a result of any misunderstanding with respect to the deadline.<sup>399</sup> Ms. Buth testified that even if there had been any misunderstanding, it did not result in any real fear on the part of the growers that using the product would result in fines: "there wasn't a lot of fear out there, and I didn't receive a lot of phone calls from growers about, you know what would happen to them."<sup>400</sup>
- 283. Moreover, Chemtura sold out of its lindane inventory by 2001 because it forward-sold its product back in 1999.<sup>401</sup> The evidence proves that Chemtura did not lose any

Hallatt to Rick Turner et al., 19 October 1998 (Exhibit TZ-34). Also, Ms. Buth has noted that canola growers had the option of moving to other crops (First Affidavit of Joanne Buth, ¶ 72).

<sup>&</sup>lt;sup>398</sup> Canada's Rejoinder, ¶221.

<sup>&</sup>lt;sup>399</sup> Canada's Rejoinder, ¶ 315.

<sup>&</sup>lt;sup>400</sup> Hearing Transcript, Vol. 3, pp. 758-761, (JoAnne Buth). Moreover, Chemtura itself recognized there was no threat of fines unless there was an intention to actually stockpile. Hearing Transcript, Vol. 1, p. 240-241 (Alfred Ingulli). *See also*, Second Affidavit of Joanne Buth, ¶19.

<sup>&</sup>lt;sup>401</sup> Annex 339: ("We are completely sold out of our inventory primarily as a result of getting our key distributors to commit to the 2001 season back in 1999....If the acreage reduction scenario holds true, this will have turned out to be a wise decision.") Mr. Ingulli had no basis to dispute this. See Hearing Transcript, Vol. 1, p. 246-247, (Alfred Ingulli).

lindane product sales in 2001.<sup>402</sup> But in any event, the PMRA extended the phase-out period to allow existing stocks of lindane to be used up from 2001 to 2002.<sup>403</sup> As a result, there are no damages that flow from any alleged misunderstanding about the deadline.

# 3. Any alleged delay in registering Gaucho CSFL caused no damage

- 284. The VWA does not make any commitment to expedite certain lindane replacement products. However, even if it did, the Claimant's argument that Gaucho CSFL's registration had been delayed caused no damages.
- 285. Both parties in this arbitration recognize that Gaucho CSFL was a substandard product compared to both Helix (Syngenta) and Prosper (Gustafson).<sup>405</sup> This is further supported by a third party study of the products.<sup>406</sup>
- 286. Evidence and testimony confirmed that Gaucho CSFL was outperformed by Helix in 2001-2006. Prosper, after it was introduced on the market in late 2003, gained 22% of

<sup>&</sup>lt;sup>402</sup> Hearing Transcript, Vol. 1, p. 247, (Alfred Ingulli) "Q. So, in fact, this document is confirming that Chemtura didn't lose any lindane product sales at all in that 2001 season because those sales were forward-booked, weren't they?" A. "That's what the document says.").

<sup>&</sup>lt;sup>403</sup> Canada's Counter-Memorial, ¶¶ 228-233.

<sup>&</sup>lt;sup>404</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).

Hearing Transcript, Vol. 6, pp. 1386, (Brent Kaczamarek); Hearing Transcript, Vol. 6, pp. 1391, 1393-1394, (Mr. Abdala). See also Second Expert Report of LECG, Table IV.
 See Stratus Agri-Marketing Inc. "Brand Usage and Image Study: Canola Seed Treatments in Western Canada" 2004; (Second Expert Report of LECG Tab 12, pp. 20, 30, 40, 50).

the market by 2006, while Gaucho CSFL held only 3.8% of the market by that time. 407 Both Prosper and Gaucho CSFL were Gustafson products and the introduction of Prosper appeared to overtake Gaucho CSFL sales. 408

287. Based on the evidence of both LECG and Navigant, it is highly speculative to assume that any change in the timelines for Gaucho CSFL would not have increased its ability to attain a foothold in the market.<sup>409</sup> Mr. Abdala testified that "obviously we realize the actual performance of Gaucho CS was not too good as compared to other substitutes,"<sup>410</sup> a sentiment shared by canola farmers.<sup>411</sup> Similarly, Mr. Kaczamarek explained:

It seems doubtful whether an earlier introduction [of Gaucho CSFL] would have allowed it to perform any better than it actually did perform because eventually Gustafson saw fit to cannibalize the Gaucho of sales, if you will, by the introduction of an alternative product.<sup>412</sup>

#### 4. The Special Review caused no Damage (Canola)

288. The Claimant has made several allegations with respect to the Special Review: it was unfair and biased; it should have been done more quickly; and that the result should

<sup>&</sup>lt;sup>407</sup> Second Expert Report of LECG, Table IV; Hearing Transcript, Vol. 6, pp. 1314, (Manuel Abdala); Hearing Transcript, Vol. 6, pp. 1386-1387, (Brent Kaczamarek).

<sup>&</sup>lt;sup>408</sup> Hearing Transcript, Vol. 6, pp. 1387-1388, (Brent Kaczamarek).

Hearing Transcript, Vol. 6, pp. 1386-1388, (Brent Kaczamarek); Hearing Transcript, Vol. 6, pp. 1393-1394, (Manuel Abdala). Furthermore, Syngenta was an aggressive marketer of their products, and the evidence suggests that they were more effective at marketing their products than Chemtura. Hearing Transcript, Vol. 3, pp. 763-765, (JoAnne Buth); Canada's Rejoinder, ¶316. This adds to the highly speculative nature of any assumption that Gaucho CSFL would have been able to compete successfully with Helix in the market place.

<sup>&</sup>lt;sup>410</sup> Hearing Transcript, Vol. 6, p. 1394, (Manuel Abdala).

<sup>&</sup>lt;sup>411</sup> Hearing Transcript, Vol. 3, p. 756, (JoAnne Buth);

<sup>&</sup>lt;sup>412</sup> Hearing Transcript, Vol. 6, pp. 1387-1388, (Brent Kaczamarek).

have been positive for Chemtura.<sup>413</sup> No damages flow from any of these alleged breaches.

289. As has already been agreed to by both parties, the actions of the PMRA alone did not impact the decision of the growers to use lindane. That decision was made on the basis of whether or not the growers could be assured stable and secure access to the US market. Therefore, even if the Special Review had been positive and completed earlier, the growers would not have used it as the border would have remained closed. This point was conceded by LECG in its reports, and confirmed by Mr. Abdala in oral testimony: "until the trade irritant issue was taken off the table, sales could not resume of lindane products."

290. The same is true of the allegation that PMRA improperly suspended Claimant's lindane product registrations. As Mr. Kaczamarek testified:

Improperly suspending the Claimant's lindane product registrations, again with respect to at least the canola products, with the trade irritant issue open, there still is no damage with respect to that. The trade irritant is really controlling in terms of whether or not sales could proceed or not proceed.<sup>417</sup>

291. As a result, no damages were caused by any of these alleged breaches.<sup>418</sup>

<sup>&</sup>lt;sup>413</sup> Claimant's Memorial, Part III, IV, c.

 $<sup>^{414}</sup>$  First Expert Report of LECG,  $\P\P$  46, 70.

<sup>&</sup>lt;sup>415</sup> Hearing Transcript, Vol. 3, p. 722, (Tony Zatylny); First Expert Report of LECG, ¶ 44, fn 20.

<sup>&</sup>lt;sup>416</sup>Hearing Transcript, Vol. 6, p. 1390, (Manuel Abdala). LECG agrees that an earlier Special Review was irrelevant as the damages assessment relies on sales as of early 2003, the date they assume by which time the US EPA would have granted a tolerance. Hearing Transcript, Vol. 6, p. 1393, (Manuel Abdala).

<sup>&</sup>lt;sup>417</sup> Hearing Transcript, Vol. 6, pp. 1389-1390, (Brent Kaczmarek).

<sup>&</sup>lt;sup>418</sup> Hearing Transcript, Vol. 6, pp. 1380, (Brent Kaczmarek).

- 292. The argument that PMRA action during the Special Review caused the Claimant to abandon its attempts to pursue a tolerance or registration in the US and therefore Canada is responsible for damages fails as well. As argued above, there lacks a sufficient causal link between PMRA action and the EPA's refusal to grant a tolerance or registration for lindane use on canola to Chemtura.
- 293. Finally, Dr. Costa testified that even if the PMRA had used a lower uncertainty factor during the Special Review, the conclusion of the PMRA would still have been the same.<sup>419</sup> Therefore, there are no damages for this alleged breach.

#### b. There are No Damages for Non-Canola

- 294. Even if the Tribunal decides that the Special Review's negative conclusion on lindane constitutes a breach, a damages claim based on the non-canola line of products fails because, as Mr. Kaczamarek testified, LECG did not assess what losses would be incurred in a scenario where growers stopped using lindane for canola but where non-canola sales would continue.<sup>420</sup> Mr. Abdala conceded that "you are not going to find a single number for each of the breach[es] because we took all the breaches as a bundle".<sup>421</sup>
- 295. Further, as Mr. Kaczamarek testified: "the amount of volume of sales for those products was so small relative to canola that we highly questioned whether or not the business would even be feasible to continue marketing a lindane-based product for those

<sup>&</sup>lt;sup>419</sup> Hearing Transcript, Vol. 5, p. 1147, (Dr. Costa) ("Q: Do I understand you correctly that if ...PMRA had chosen three, the outcome of the Special Review in terms of acceptability of the risk would not have changed?" A: "Yes, because if you look at the margin of exposure values in the 2008 RED, you see that a large percent of them, about half of them, were still below the target, below 300.").

<sup>&</sup>lt;sup>420</sup> Hearing Transcript, Vol. 6, p. 1381, (Brent Kaczmarek).

<sup>&</sup>lt;sup>421</sup> Hearing Transcript, Vol. 6, pp. 1341-1342, (Mr. Abdala).

crops.."<sup>422</sup> Lindane may have become more expensive on a per seed basis if Chemtura Canada was to purchase significantly lower volumes of lindane for use only on non-canola crops. The overhead of marketing and packaging the product may have been too high for the remaining volumes to generate a profit.<sup>423</sup>

296. As a result, Mr. Kaczamarek "considered it speculative to know whether or not that business could survive economically for non-canola." Moreover, the Claimant "didn't provide any additional evidence which would allow us to substantiate whether the business would be viable."

297. Moreover, alussuming a PMRA breach with respect to the outcome of the Special Review, it is entirely speculative to assume that the registration for non-canola products would continue in the US past 2006. The requirements of the 2002 RED not only applied to new tolerances, but existing registrations as well.<sup>426</sup> As discussed above, despite diligent and extended efforts to meet the requirements of the 2002 RED, the EPA did not come to a favourable decision on lindane.

298. Finally, even if Chemtura withdrew its existing registrations in the US due to PMRA action, the EPA's decision against lindane would have occurred regardless. The EPA clearly had major concerns with lindane, as evidenced by the HCH study, and decided in August 2006 with the issuance of the Addendum to the RED that lindane's time was up. Ultimately, the EPA decided that "withdrawn or not withdrawn, there was

<sup>&</sup>lt;sup>422</sup> Hearing Transcript, Vol. 6, p. 1381, (Brent Kaczmarek).

<sup>&</sup>lt;sup>423</sup> Second Expert Report of Navigant, ¶ 80.

<sup>&</sup>lt;sup>424</sup> Hearing Transcript, Vol. 6, p. 1381, (Brent Kaczmarek).

<sup>425</sup> Hearing Transcript, Vol. 6, p. 1382, (Brent Kaczmarek). *See also* First Affidavit of Paul Thompson, ¶¶ 35, 36; Hearing Transcript, Vol. 2, p. 292, (Paul Thomson).

426 U.S. EPA, Re-registration Eligibility Decision for Lindane, 31 July 2002, pp. 1-3 (Annex R-34).

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no benefit[] for those seed treatments that they were looking at."<sup>427</sup> As a result, there are no damages for the non-canola line not only between 2002 and 2006, but post-2006 as well.

<sup>&</sup>lt;sup>427</sup> Hearing Transcript, Vol. 2, p. 340, (Paul Thomson).

### 2) REQUEST FOR RELIEF

299. For the foregoing reasons, and for the reasons set out in its Counter-Memorial and Rejoinder, Canada respectfully requests that this Tribunal render an award:

- Dismissing the claims of Chemtura in their entirety; and
- 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 23rd DAY OF OCTOBER 2009.

Sylvie Tabet

Christophe Douaire de Bondy

Stephen Kurelek

Céline Lévesque

Yasmin Shaker

Mark Luz

Christina Beharry

On behalf of the Respondent, Canada

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## **Comprehensive List of Annexes to the Post-Hearing Memorial**

Annex No.	Description	Short Form
R-366	Registration Timeline for Replacement Products - Canada	"Canada Replacement Product Chart"
R-367	Registration Timeline for Replacement Products – United States	"US Replacement Product Chart"