CPDA-CANADA

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RE: Consultation on Revisions to the Agreement for Data Protection under Section 66 of the *Pest Control Products Act*; December 30, 2016 ("the Agreement.")

CPDA-Canada submits the following comments in response to the above-referenced document, which revises the June 23, 2010 version of the Ministerial Agreement that Health Canada's Pest Management Regulatory Agency (PMRA) issued under section 66 of the Pest Control Products Act ("PCPA").[1] CPDA-Canada is an incorporated subsidiary in Canada of the Council of Producers & Distributors of Agrotechnology based in Washington, DC, USA. CPDA has approximately 35 members engaged in the manufacturing, formulating, and distributing of generic agricultural pesticide products, tank-mix adjuvants, and inert ingredients. We represent large and small U.S.-based companies as well as multinational organizations with facilities in Canada and elsewhere around the world.

Among the many important principles and objectives that Parliament enumerated in the preamble to the PCPA is achievement of a balanced federal pesticide regulatory system that is "administered…in a manner that recognizes the various interests and concerns affected and, where consistent with the primary objective of the system, minimizes the negative impact on economic viability and competitiveness."[2] Although CPDA-Canada acknowledges PMRA's significant efforts to meet this statutory objective, we are disappointed that the Agency still refuses to implement an equitable data compensation and regulatory mechanism that balances the interests of companies that develop new pesticides ("innovator companies") fairly with companies that produce generic pesticides ("generic companies").[3] Parliament clearly sought to establish a fair method for generic companies and innovator companies to share the costs and benefits of timely entry of their respective

[1] "Ministerial Agreement for Data Protection under the *Pest Control Products Act;"* June 23, 2010. The proposed revised agreement no longer uses the word "Ministerial."
[2] S.C. 2002, c. 28, *Pest Control Products Act* preamble.
[3] Section 66(1) of the PCPA sets forth the authority of the Minister of Health Canada to determine the terms and conditions of agreements that "applicants" (i.e., generic companies) and "registrants" (i.e., innovator companies) must use to address the compensation that generic companies may have to pay innovator companies if they use or rely on specific innovator data necessary to register their products.

products into the marketplace. Unfortunately, PMRA has failed to implement the regulatory requirements needed to achieve this equitable objective of Parliament and will perpetuate this failure by adopting certain proposed revisions to the Agreement.
Before addressing specific proposed amendments to the Agreement, we will take this opportunity to confirm that CPDA-Canada supports a complete review of the need for a prescriptive Agreement such as this under the PCPA. PMRA plays no role in negotiation and arbitration, and there is no open Agency action while negotiations are undertaken.[4] An Agreement written to simply satisfy the binding arbitration terms of the PCPA is all that should be needed to guide private sector business dealings. In March 2014, PMRA seemed to be moving in the right direction when it announced it was proposing to move away from the inappropriate Final Offer Settlement (FOS) arbitration method to a fairer and more equitable "bounded" binding approach. It is very disappointing to see that PMRA, on the recommendations of a "third party" consultant[5] is assuming there will eventually be "an established level of experience" with FOS, and intends to wait until then to make any changes to the Agreement. However, to the best of our knowledge, there has been no experience with FOS arbitration involving data compensation for pesticide products during the six-plus years the Protection of Proprietary Interests in Pesticide Data (PPIP) policy has been in place. We have repeatedly asked PMRA to confirm whether any arbitration has occurred, but because they are not involved in this phase and would not be provided with a signed Agreement, they are not able to respond. We therefore have no reason to believe there ever will be experience, much less "an established level of experience," with it especially considering certain PMRA-proposed revisions to the Agreement. Surely it is time to make the changes that will ensure a fairer process the registration of newer chemistry generic pesticides.

Final Offer Settlement Arbitration is Not Appropriate

PMRA must first address the fact that the FOS arbitration approach is not working and is not appropriate for data compensation arbitration between competing pesticide manufacturers. This unnecessarily prescriptive approach precludes a fair and equitable determination of data compensation because it can only work when both parties have more complete information, such as could be obtained through discovery during negotiations. The FOS arbitration approach is not a commonly used form of arbitration. It is most often used in major league baseball, where both parties have "perfect" information; a player and team owner/manager know the player's statistics and the argument is over the player's salary and contract. When at an impasse in negotiations, an independent arbitrator dictates the binding settlement by choosing which final offer to award. The premise of this form of arbitration is that the threat of arbitration imposes a cost of disagreement and uncertainty on the two parties, thereby encouraging negotiation.[6] FOS was developed to offset the "chilling" effect on negotiations when it is thought the

[4] PMRA misrepresents the status of the generic company's product in Article 7 by including "discontinue its application for registration." In fact, there is no policy language in the 2015 Directive that indicates there is an open application during negotiations or arbitration. This clause should be removed as it is non-factual.
[5] Intersol Group, Ltd.
[6] Marburger, D.R. and Scoggins, J.F. (1996). Risk and Final Offer Arbitration Usage Rates: Evidence from Major League Baseball. J. of Labor Research, Vol. XVII, No. 4.

arbitrator will "split the difference" between the offers under conventional arbitration.[7] However, it is the uncertainty concerning the arbitrator's award, combined with the "risk aversion" of the parties that has been hypothesized to make FOS a costly alternative to conventional arbitration.[8]

The Intersol Group Report[9] to PMRA states that the FOS approach "is intended to encourage the parties to seek a negotiated solution and, if that is not possible, to provide the parties with an incentive to move toward a position that the arbitrator regards as reasonable and which is more likely to be selected." This is the "convergence" theory under FOS that the Intersol Group rationalizes, but there is just as much evidence to support the theory that final offers under FOS will *diverge* from those under conventional arbitrations.[10] In fact, the Intersol Group neglected to consider the very real possibility of no negotiations occurring before entering arbitration or negotiations failing to produce final offers. It has also been shown that negotiated settlements under the FOS arbitration approach are skewed against the more risk-averse party,[11] in this case the generic company. PMRA's insistence in using this approach is inconsistent with its assertion when revising the PPIP regulations that:

> "These Regulations will encourage the registration of new innovative pesticides, including registration for use on minor crops, and facilitate timely entry of competitively priced generic pesticides. This will ultimately benefit pesticide users, particularly the agriculture sector."[12] (emphasis added)

PMRA recognizes that the regulations must provide a "legally enforceable and fair process of pesticide data protection"[13] (emphasis added), one that fairly balances the interests of innovator and generic companies, and benefits society. Unfortunately, PMRA remains unreasonably committed to the FOS arbitration approach in which the Arbitral Tribunal must choose either the generic company's "willing-to-pay" final offer or the innovator company's "willing-to-accept" final offer, and completely ignores the fact that PMRA cannot point to a single registered generic pesticide product that was based on an arbitral award under the Agreement since its initial release in 2010. Instead of addressing the fundamental cause of this limitation (a severely biased arbitration approach that eliminates the availability of important lower-priced agricultural products to Canadian growers), the Agency seems insistent on perpetuating the problem by maintaining this inequitable and unworkable form of arbitration.

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[7] Literature Review: Final Offer Arbitration (https://www.dir.ca.gov/CHSWC/BasebalArbFfinal.htm).
[8] Farber, H.S. (1980). An Analysis of Final-Offer Arbitration. J. of Conflict Resolution, Vol. 24.
[9] Intersol Group Ltd., Recommendations: Administering the Data Protection Program for Pesticides in Canada (November 20, 2014).
[10] Supra, note 6.
[11] Id.
[12] Regulations Amending the Pest Control Products Regulations, SOR/2010-119 (June 3, 2010) at p.7.
[13] Regulatory Impact Analysis Statement appended to Archived Regulations Amending the Pest Control Products Regulations; vol. 144, No. 13 (June 23, 2010).

The Financial Risk for Generic Companies is Prohibitive

As mentioned previously, we are not aware of any successful FOS arbitration via the Ministerial Agreement and only know of possibly one successful negotiated settlement for a newer chemistry, and these companies may not have been competitors. A generic company faces too high a financial risk to move to FOS arbitration for at least three reasons:

1. the final offer to accept by the innovator company may exceed the profitability of commercializing the product and this may be chosen by the Arbitral Tribunal;
2. the generic company may never know the innovator company's final offer to accept until the award is made; and
3. as revised, the Agreement may provide the innovator company the right to have all of its share of arbitration costs, and its legal fees and disbursements, reimbursed by the generic company if the generic company ends the arbitration anytime before an award is made and/or it cannot afford to ultimately commercialize the product after an award is made.

Consequently, the generic company cannot possibly enter arbitration given these three risks. In contrast with the generic company's position, the innovator company still faces no financial risk in entering into arbitration. This inequity of financial risk sharing by the parties precludes a "fair" process and effectively prevents market entry of the first few generic companies while data is compensable and commercializing the product can be profitable.

Negotiations Cannot Practically Be Conducted in Good Faith

Because the parties both know that final offers will be submitted to and used by the Arbitral Tribunal once the Agreement is signed and the Tribunal is formed, negotiations cannot practically be conducted in good faith for first market entrants. There is no incentive for the innovator company to provide a final offer to the generic company in a timely manner or at all. In addition, unlike judicial proceedings in Canada, there is no express statutory or regulatory right to discovery during the Agreement arbitration process; and certainly none under negotiations.[14] Thus, discovery can play no role under the Agreement's FOS arbitration, but without discovery during negotiation the final offers presented to the Arbitral Tribunal by both the innovator and generic companies will be skewed high. Although the Agreement encourages the use of agreed-upon procedures for sharing information during arbitration, the lack of discovery during negotiation limits the ability of the generic company to substantiate its final offers during arbitration, particularly in light of the fact it may not even know what the final offer of the innovator company is – the only party with this information.

[14] Under Article 19(1) of the Commercial Arbitration Act (R.S.C., 1985, c 17), "the parties are free to agree on the procedures to be followed by the arbitral tribunal in conducting the proceedings," which presumably would include discovery procedures. If the parties fail to agree on discovery, which is likely, the arbitral tribunal could use its general powers under Article 19(2) to conduct the arbitration "in such manner as it considers appropriate" to allow discovery.

Specific Recommended Revisions to the Agreement

Although we share the goals and objectives of PMRA to establish a fair and equitable process for implementing the data protection provisions of the Pest Control Products Regulations (PCPR),[15] CPDA-Canada has significant concerns about several aspects of the consultation document. Firstly, CPDA-Canada strongly recommends a global change to the Agreement: replace the term "Registrant" with "innovator company" and "Applicant" with "generic company"[16] to clarify that there is no open application, therefore no Applicant, during negotiation and arbitration.

Our specific comments are set forth below, and for ease of reference, the section numbers and headings used in the discussion document are reproduced followed by our comments.

Article 2

The 120-day negotiation phase should be reduced to 30 days to allow the generic company the opportunity to enter into arbitration in a timely manner. In situations where there are a few substantially similar generic products already on the market, negotiations may progress smoothly and quickly. However, in the situation where there is no substantially similar product on the market, it is unlikely that negotiations will proceed quickly or be successful. There is no incentive for an innovator company to negotiate in a timely manner, and in good faith when facing open competition with a first generic company. In fact, it is difficult to perceive of a situation whereby the sole market provider of a product would accept an amount that would not compensate for its consequent loss of market share. Conversely, it is unlikely that a generic company would be able to recoup in the marketplace the costs of an award of this level.

If negotiations are not mutually desired and the innovator company is unwilling to negotiate in good faith, they are effectively keeping the generic product off the market for an additional four months. For example, the innovator company could wait until day 119 to notify the generic company that it will not negotiate, and there are no consequences for doing this. We strongly recommend, therefore, that the 120-day negotiation phase be reduced to 30 days. If negotiations are progressing, the parties can agree to extend the time. The result could be a negotiated agreement and a letter of access (LOA) or a request to go to binding arbitration.

Article 6

Appendix C section 3.3 directs the parties to submit their final offers to the Arbitral Tribunal within five days of the appointment of the Tribunal, but there is no direction to the Tribunal to provide those final offers to both parties. The final offers of the parties that are presented to the Arbitral Tribunal according to Appendix C 3.3 must be provided to both parties and at the same time.

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[15] SOR/2006-124.
[16] Supra, note 3.

Specific recommendation for revision to the proposed text in Article 6 to add a new paragraph as follows:

- Upon receipt of the final offers of the parties, the Arbitral Tribunal shall share the offers with both parties. The generic company shall have 10 days after receiving the final offer to determine whether it will proceed with the arbitration. If the generic company decides to abandon arbitration, both parties share equally the costs accumulated by the Arbitral Tribunal and bear their own individual costs in legal fees and disbursements.

This final willing-to-accept offer by the innovator company is an essential material fact the generic company needs to determine whether to move forward with arbitration, particularly under FOS arbitration. Without an article addressing this, the generic company may never know the innovator company's willing-to-accept final offer, even while in arbitration.

Article 7

Although PMRA appears to address the uncertainty of section 66 in the Ministerial Agreement language in the new Agreement by allowing a generic company to withdraw from an arbitration under certain conditions,[17] it also creates significant new financial barriers to generic company registrations. Allowing the Arbitral Tribunal the option of assessing the generic company significant costs for leaving the arbitration process before an award is made or for abandoning registration is prohibitive.[18] The generic company should not be held responsible to pay either the innovator company's legal fees and disbursements or its share of arbitration costs. This potential application of punitive measures on the generic company was vague and non-comprehensive in the Ministerial Agreement, but is now explicit and comprehensive in the Agreement. Again, the FOS arbitration approach and new stipulations of the Agreement place the generic company at a significant disadvantage. Once negotiations have failed, the generic company will have to enter into, and possibly complete arbitration in order to discover what the ultimate cost for registering its product might be, probably without ever having been provided the innovator company's final offer-to-accept. The punitive provisions of the proposed Agreement will only assure that generic registrations of newer chemistries will not occur until those chemistries are no longer subject to data compensation because of the uncertainty of the process and seemingly inevitable financial risk to the generic company of even entering arbitration, whether they ultimately register the product or not.

In PMRA's Response to the Intersol Group Report,[19] the Agency accepted the Intersol Group's recommendations in section 3.3.2 regarding the punitive measures, by noting

[17] Appendix C, sections 3.5, 10, and 11.
[18] Appendix C, section 10.2.
[19] Health Canada's Pest Management Regulatory Agency's Response to the Intersol Group Report. 30 December 2016. Section 3.3.2: "Binding Nature of Arbitral Awards; 1. The PMRA should modify the requirements of the data protection program to clarify that the payment of arbitral awards is conditional upon applicants opting to pursue registration. 2. Provide arbitral tribunals with the power to determine the

"although stakeholders (generic and innovator registrants) have divergent views on this recommendation, PMRA considers that this proposed approach balances appropriately the needs of both the generic and innovator registrants." (emphasis added). We fail to find any possible justification for this statement and PMRA offers no rationale. We do not see how creating additional and inevitable financial risk for the generic company can be considered to "balance" the needs of both parties. It certainly does not balance the financial risk to both parties.

Specific recommendations for revision to the proposed text in Article 7 include:

- Add to the first sentence of the article "to be paid upon receipt by the generic company of the LOA."
- Remove from the second paragraph "or discontinue its application for registration of the applicable pest control product" and "but any costs awarded by the Arbitral Tribunal in favour of the Registrant will be binding and enforceable against Applicant."

Appendix B

Section 17.9(1) of the PCPR requires the innovator company and the generic company to enter into negotiations upon delivery of the Agreement. The specifics of how the negotiation process works are set forth in the main body and Appendix B of the Agreement. As currently drafted, Appendix B suggests that the parties are to "attempt to obtain a negotiated settlement" by undertaking five specified activities. Moreover, the parties must "undertake to communicate and exchange information during the negotiation process and make serious efforts to obtain a negotiated settlement in accordance with Article 3." In practice, the innovator companies do not provide to the generic companies the information they need to develop a fair and appropriate offer to pay, and there is no recourse for the generic company if the innovator company does not do so.

The situation is further complicated by the fact that this is a final offer regime, which requires the Arbitral Tribunal to choose one offer or the other. The offers must be prepared by the parties at the outset of the arbitration process, but the two participants are far from being equally informed. Instead, only the innovator company knows the real costs of the data that are being valued by the Arbitral Tribunal. Again, there is no obligation on the innovator company to share that information during the negotiation phase and no repercussions if it fails to do so. CPDA-Canada therefore strongly recommends that PMRA revise Appendix B:

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allocation of arbitration and the parties' costs between the registrant and applicant in the event that the applicant subsequently chooses to discontinue their application. 3. Require applicants to notify the arbitral tribunal and registrant no later than 30 days from the date an arbitral award is rendered if they intend to seek registration of their product and pay the arbitral award. In the event that the applicant provides no indication of its registration intentions or indicates they will not be registering their product, the applicant will be subject to the arbitral tribunal's decision regarding the allocation of costs under point two, above."

- Paragraph 4:
  Retain the text of the five enumerated settlement roles under item 4 and the text of item 5.
  Add the following provisions under item 4 to require discovery during negotiation:
  - 4.1 The parties agree to exchange all information and documents relevant to any matter in issue in the negotiation, including but not limited to the historical invoices, quantification and calculation of eligible data costs, inflation adjustments, interest adjustments, financial/investment risk premiums and cost sharing. The innovator company also agrees to permit the generic company to have access to the studies on the basis that information obtained from such review will remain confidential to the parties.
  - 4.2 Where a party fails to disclose and provide a document relevant to any matter in issue in the negotiation, (a) the party may not use the document at the arbitration, except with leave of the Arbitral Tribunal and (b) the Arbitral Tribunal may draw an adverse inference against the party who failed to disclose the information or document.
  - 4.3 Nothing in paragraph 4.2 restricts a party from applying to the court to seek any remedy available under the Federal Court Rules.
- Paragraph 9: Change "may" to "shall."
- Paragraph 14: Change "120 days" to "30 days."

Appendix C

- Paragraph 3.3: Add a new sentence to the paragraph stating "the final offers submitted to the Arbitral Tribunal will be shared with the parties upon receipt."
- Paragraph 10.2: Delete all new text regarding costs allocation under Escrow.
- Paragraphs 11.1 and 11.2: Delete all proposed new text and retain original text.

Appendix D

- Paragraph 4: Add new subparagraph 4.3:
  - 4.3 In the event that a party has failed to disclose or provide a document relevant to any matter in issue during direct or mediated negotiation under this Agreement, the parties are permitted to introduce as evidence in a court proceeding or in the arbitration under the PCPR of such non-disclosure.

Appendix E

Delete this entire Appendix. CPDA-Canada believes it provides no real value to the Arbitral Tribunal or the parties. If PMRA retains Appendix E, CPDA-Canada insists that the original text on Cost Sharing remain in the new Agreement. PMRA has provided no rationale for the proposed deletion of this text and there is no reference in the Intersol Group Report regarding this. If Appendix E is deleted then delete Article 11.

Summary of Recommendations

CPDA-Canada has followed PMRA's claims and efforts to implement the PCPA through a pesticide regulatory program that fairly balances the interests of all affected parties. However, we are disappointed that our previous suggestions on behalf of the generic pesticide industry have, for the most part, been ignored. PMRA's changes to the regulations in the 2015 Directive and the proposed revisions to the Agreement fall far short of the PCPA and Health Canada's goal of establishing a fair and equitable data compensation process that facilitates the timely entrance of safer, efficacious generic pesticide products on the market to benefit Canadian producers.

If PMRA will not revamp entire the Agreement with a fairer and more equitable arbitration mechanism, CPDA strongly recommends that the Agency:

1. replace FOS arbitration with unbounded binding arbitration and eliminate Appendix E;
2. include right of discovery and information sharing during negotiations;
3. abandon the changes proposed in Article 7 regarding the reimbursement of the innovator company's share of arbitration costs, disbursements and legal fees if arbitration is abandoned prior to an award being made (i.e., the generic company can withdraw from the arbitration without any form of penalty);
4. require that all Arbitral Tribunal costs are split equally between the parties and each party's unique costs are paid only by that party; and
5. require that the innovator company provide the LOA to receive the binding award from the generic company; if the LOA is not provided, the registration may proceed without the LOA and no award is paid by the generic company.

These five recommendations implemented *in toto* will significantly improve PMRA's data compensation mechanism as outlined in the Agreement. If any one or more of them are not implemented, the system is not improved and cannot and will not be considered equitable by a generic company.

Conclusion

The FOS approach mandated in the Agreement continues to present a significant impediment to striking a fair balance between the interests of the innovator company and the generic company. We have provided compelling evidence here and previously to PMRA to indicate there has been no level of experience with the FOS method in the six years the Ministerial Agreement has been in force. It is unlikely there will be such experience going forward. PMRA's attempts to "tweak" a biased, poorly designed data compensation system that highly favors the innovator company has so far not expedited the entrance of newer chemistry generic products into the Canadian market for producers. Moreover, there is no fair market competition supported by PMRA's data compensation approach, and we believe strongly that the prescriptive FOS method of arbitration all but ensures fair competition cannot occur.

PMRA is required to develop an effective "Agreement" under the PCPA, but it should be based solely on binding arbitration, under provisions of the Canadian Arbitration Act.

PMRA should develop a new Agreement that lays out timelines of 30 days for negotiation and 120 days for arbitration, with the stipulation that the award is paid upon receipt of the LOA by the generic company. No "final offers" need be made and negotiations can continue in the background during arbitration as evidence is presented to the Arbitral Tribunal. The arbitration award would be the responsibility of the arbitrator(s) based on evidence provided. Each party has an investment in the process. If the innovator company does not provide the LOA after the award is final, the generic company product can be registered without the LOA and without paying the award. Everything else in the current Ministerial Agreement and new Agreement is solely protective of the innovators market until data are no longer compensable.

We would ask that PMRA arrange for a stakeholder meeting to discuss the issues raised here and the comments received on the Consultation Document.

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