CPDA-CANADA

December 17, 2018

Pest Management Regulatory Agency Publications Section
Pest Management Regulatory Agency (PMRA)
Health Canada
2720 Riverside Drive
Ottawa, Ontario
Address Locator: 6607D
K1A 0K9

E-mail: PMRA.publications@hc-sc.gc.ca

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 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.

We would like to reiterate to PMRA that our previous comments regarding the Agreement are still relevant and desirable to members of CPDA-Canada but would also like to acknowledge and commend PMRA for certain small but welcomed changes, which will be mentioned when the specific changes to the various Articles are listed.

Specific Recommended Revisions to the Agreement

Article 3: Conduct of Negotiation

CPDA-Canada comments are relating to the conduct of a negotiation but fall within the changes made to Appendix D.

Appendix D

The involvement and action of both parties to settle data compensation in a professional and timely manner is crucial to any Applicant's ability to innovate and participate in the various Canadian markets. In the previous version of the agreement, there was no incentive of the Registrant to participate or respond to an Applicant's request for data

[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."

compensation negotiations. While it is still not included in this section of the Agreement, CPDA-Canada would like to commend PMRA adding statements in Appendix D regarding the consequences of poor conduct of either parties to come to the table in a good faith effort of negotiating a data compensation settlement that is satisfactory to both parties.

Article 5: Arbitration

CPDA-Canada would like to commend PMRA for included a definitive timeframe in which an Applicant can provide all parties with a notice of arbitration once negotiations fail. Previously, there was no process or timeline for an Applicant to notify the Registrant that they wanted to enter into arbitration, leaving the Registrant wondering if and when an Applicant would move towards arbitration. This provides clarity to the Agreement.

Article 6: Arbitration Period

In the past, if an Applicant was uncomfortable with the final offer made by the Registrant, they would not pursue arbitration because there was no process by which an Applicant could opt out at anytime during the arbitration. Article 6(b) allows an Applicant to opt out any time during the arbitration.

CPDA-Canada does not agree with the ability of the Arbitral Tribunal to extend the arbitration process. This process is lengthy and expensive. Allowing the Arbitral Tribunal to extend the process adds more time and cost to it, which neither parties want. If PMRA insists on retaining this new part of Article 6, CPDA-Canada will insist that the Arbitral Tribunal get an extension agreed upon in writing by both parties and that there be a time limitation of up to 30 days prior to executing the extension.

Article 7: Enforcement of Arbitral Award

CPDA-Canada appreciates the clarification of when an Arbitral Awards are binding and when they are not binding. Having said that, Section 7.2(a) is inconsistent with the new 2-step registration process. This section states “a) during the arbitration period the Applicant notifies the Registrant and the Arbitral Tribunal in writing, that it will discontinue its application for registration…” Since the negotiation and arbitration processes occur after the first step of the registration process, which involves only establishing equivalency, and before the second step, which is the application for registration, this section should remove “that it will discontinue its application for registration of the applicable pest control product or” part of 7.2(a).

Article 8: Conduct of Arbitration
Appendix C

In Section 2.2 of this Appendix, this discussion of the number of arbiters is described as 1 arbiter or 3 arbiters depending on the request and agreement of the two parties. If there is no agreement, the default is 1 arbiter. CPDA-Canada sees that there is an advantage to having 3 arbiters but feels this may also cause issues with cost and scheduling as there are more participants, which will be more expensive, and it may be

more difficult scheduling 3 people given the 120-day timeline for the arbitration process. Instead, CPDA-Canada would like to suggest PMRA adopt a sliding scale. Based on the highest last offer at the end of negotiations, if the potential value of the award is less than or equal to $1,000,000, 1 arbiter shall be appointed. However, if the potential value of the award is greater than $1,000,000, 3 arbiters shall be appointed. Both parties, by mutual agreement, can decide to have the arbitration process handled by either 1 or 3 arbiters regardless of the potential value of the award.

Article 10: Delivery of Letter of Access

CPDA-Canada would like to commend PMRA on the language included in the Agreement that removes limitations in the Letter of Authorization. If parties are going to the time and expense of the negotiation and/or arbitration processes, and because an Applicant is paying for the data to support their label and registration, there should be no limitations of use or market access.

Article 11: Compensation Principles

Appendix E

While CPDA-Canada doesn't agree with everything in the 2014 Intersol Group, Ltd. report, the changes made to Appendix E are not supported by this report. The following points are concerns for CPDA-Canda.

- Appendix E gives the Arbitral Tribunal the power to assign fees (e.g., legal etc…) that one party incurs during the arbitration to the other party. This is not fair and/or equitable. The parties typically agree that communal costs should be shared 50/50, while company specific costs is the responsibility of that company and not the other company.

- The language in "Financial/Investment Risk Premium" is not strong enough. Risk premiums should not be considered in the cost of data compensation. The Registrant will submit data to support a registration without thought to other entrants. They accept the risk of registration by submitting the data and Applicants should not be held responsible for a Registrant's decisions. As a result, CPDA-Canada would like to see "…Claims for an additional adjustment to the cost of compensable data to reflect financial risks borne by Registrants to successfully obtain or maintain a registration should generally be discouraged." changed to "…Claims for an additional adjustment to the cost of compensable data to reflect financial risks borne by Registrants to successfully obtain or maintain a registration should ~~generally be discouraged~~ not be considered."

- The previous version of Appendix E provided language on an equitable (not equal) compensation principles. It takes into account multiple registrant compensation of the same studies. The current changes have removed the "Cost Sharing" section of Appendix E, which CPDA-Canada feels is an important

part of calculating data compensation. We would strongly encourage PMRA to retain the following section.

> "Cost Sharing
> Compensation should be based on an equitable sharing of costs between a data owner and follow-on applicants, to the extent possible. Where data compensation for the same data has already been paid by another generic previously, an award in a subsequent process could be based on the determined cost of data divided by the number of applicable parties (e.g., the data owner, the generic that paid compensation in the first process, and the applicant in the subsequent process).
>
> Arbitration decisions may include provisions regarding future adjustment to the compensation amounts paid in the event that another party subsequently provides compensation for the same data. Since the data subject to compensation may vary over time, it would be important to identify data compensation awarded by specific study in order for this approach to be practicable."

If PMRA is concerned with the language around future adjustments, CPDA-Canada would agree to removing that language but keeping the rest of the Cost Sharing language in Appendix E.

CPDA-Canada appreciates this opportunity to make comments to an important part of the registration process. Please contact me at 202-386-7407 or ghalvorson@cpda.com should you have any questions regarding these comments.

Sincerely,

Gary Halvorson
President
Council of Producers & Distributors of Agrotechnology
Founding Director
Council of Producers & Distributors of Agrotechnology Canada
17300 Rhode Island Avenue NW
Suite 812
Washington, DC 20036
ghalvorson@cpda.com
Office 202 386 7407
Cell 612 759 4358