



CPDA-CANADA

February 28, 2017

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

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

RE: Consultation on the Eligibility Criteria for Compensable Protection Status for Foreign Test Data; December 30, 2016

CPDA-Canada submits these comments in response to the above-referenced document, which revises certain sections of the Pest Control Products Regulations (PCPR).¹ CPDA-Canada is an incorporated subsidiary in Canada of the Council of Producers & Distributors of Agrotechnology based in Washington, DC, USA. CPDA members are engaged in the manufacturing, formulating, and distributing of generic agricultural pesticide products, tank-mix adjuvants, and inert ingredients in the U.S., Canada, and around the world.

CPDA-Canada appreciates PMRA's continuing efforts to improve the pesticide data compensation process, consistent with the Agency's articulated goal of providing a "legally enforceable and fair process of pesticide data protection,"² and supports the Agency's proposed revision of the eligibility criteria³ for foreign test data. This important clarification of the compensation status of the foreign data PMRA considers during re-evaluations, special reviews, and the registration of generic products is appropriate and needed.

However, as outlined in other comments⁴ submitted to PMRA, the Agency needs to make changes to the negotiation and arbitration component of the current data compensation process in order to strike a fair balance between the competing views of innovator and generic companies. Unless the Agency does so, the helpful clarifications of this current proposed action will remain irrelevant to achieving a "fair" and "equitable" data compensation process for timely registration of generic products based on newer chemistries.

Susan Ferenc, DVM, Ph.D.
President

¹ SOR/2006-124.

² Regulatory Impact Analysis Statement appended to Archived Regulations Amending the Pest Control Products Regulations: Vol. 143, No. 46 (November 14, 2009).

³ PCPR § 17.7(2), Appendix 3.

⁴ CPDA-Canada's February 28, 2017 comments on the Revisions to the Agreement for Data Protection under Section 66 of the Pest Control Products Act; December 30, 2016.