Consultation on the Eligibility Criteria for Compensable Protection Status for Foreign Test Data

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Canada

Health Canada's Pest Management Regulatory Agency (PMRA) invites stakeholders to comment on the following text to replace the current Appendix 3 – Eligibility Criteria for Compensable Protection Status for Foreign Test Data of the Data Protection Submission Review Process document.

Eligibility Criteria for Compensable Protection Status for Foreign Test Data

In the course of a re-evaluation or special review, the Minister may consider foreign test data used in a foreign review, as per subsection 17.7(2) of the *Pest Control Products Regulations* (PCPR).

Foreign test data will be eligible for compensable protection, and included on the compensable data list established by the Minister under 17.8(1) of the PCPR, if the following criteria are met:

- As per subsection 17.7(2) of the PCPR, the data is considered by the Minister during a re-evaluation or special review decision;

- As per subsection 17.7(2) of the PCPR, the data is relevant to the Canadian re-evaluation or special review, including that it is relevant to the Canadian use pattern;

- As per subsection 17.7(2) of the PCPR, the data has not been previously considered by the Minister to support a regulatory decision; and,

- As per subsection 17.7(3) of the PCPR, the data can be provided by the registrant, upon request. In such cases, PMRA will request that the registrant also provide information demonstrating the data was called-in, or submitted for, and used in that foreign regulatory review, as this will allow PMRA to verify that the data was in fact part of the foreign review and hence eligible for protection.

As per subsection 17.7(2)*(d)* of the PCPR, foreign test data meeting the above criteria will be eligible for 12 years of compensable protection from the initiation date of the Canadian re-evaluation or special review for the active ingredient. Thus, applicants who wish to rely on the data to register a new product or amend a registration during a subsequent application under section 7 of the *Pest Control Products Act* will be required to pay compensation to the applicable registrant and provide PMRA with a Letter of Access, as required by subsection 17.7(1) of the PCPR.

Note: **In the context of an applicant seeking to register a new product containing a registered active ingredient or amend a registration** (that is, not a re-evaluation or special review), foreign test data is only eligible for compensable protection if it is submitted by the applicant in accordance with section 7 of the *Pest Control Products Act*.

How to Get Involved

Written comments will be accepted for up to 45 days from the publication of this document. Please forward your comments to the PMRA Publications Section. Questions or comments can also be directed to the Pest Management Information Service. All contact information is on the cover page of this document.

Comments should include:

- Title of the consultation document on which you are commenting;
- Your full name and organization;
- Your phone number; and,
- Your complete mailing address or email address.

Reporting to Canadians

Health Canada will make the results of this consultation available on the Pesticides and Pest Management portion of Health Canada's website.

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