Notice of Intent NOI2022-01

Enhanced Transparency of the Pesticide Regulatory Process

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Purpose

The purpose of this notice is to inform stakeholders of Health Canada's Pest Management Regulatory Agency's (PMRA) intention to disclose the names of applicants and registrants for certain pest control product regulatory activities set out in Appendix I, while an application is under review and a decision is pending.

Background

On 4 August 2021 the Ministers of Health, Agriculture and Agri-Food and Environment and Climate Change announced that the Government of Canada would be investing $42 million in Health Canada's PMRA to further strengthen its human and environmental health and safety oversight and protection, and improve transparency of the pesticide review process.

Several strategies are in process of being implemented by the PMRA to make more information available to the public and enhance transparency of the pesticide regulatory process. This proposal focuses on disclosing the name of applicants and registrants at the time that the review process is initiated.

Current approach

Currently an applicant's name is kept confidential while an application is under review and a decision is pending. Once a regulatory decision is issued by the PMRA and the application is closed, the name of the applicant is added to the Pesticide Product Information Database (PPID), which is publicly available online. Exceptions to the current process include when the application is withdrawn or denied; in this case, the name of the applicant is kept confidential. In addition, pre-market consultation documents (Proposed Registration Decisions, Proposed Maximum Residue Limits) and Registration Decision Documents do not currently specify the name of the applicant.

Proposed approach

It is the PMRA's intent to disclose the names of applicants after administrative screening of a complete application package, once the application enters the review stream. This includes the names of any individuals who are applicants. This information would be included in:

a. The Register (via the Pesticide Product Information Database (PPID));
b. Consultation documents posted on Health Canada's website (in other words, Proposed Registration Decision (PRD) and Proposed Maximum Residue Limit (PMRL)); and subsequently
c. Registration Decision documents.

This proposal will apply:

- To the types of regulatory activities set out in Appendix I.
- Regardless of the outcome of the application (in other words, Registered, Withdrawn, or Denied).

- To consultation documents posted on Health Canada's website (Proposed Registration Decisions (PRD), Proposed Maximum Residue Limits (PMRL)) as well as Registration Decision Documents.
- To Re-evaluations and Special Reviews, where the PMRA intends to disclose the names of registrants whose products are subject to a re-evaluation or special review in the PPID upon initiation of those post-market processes.

This proposed name disclosure will be considered following consultation with stakeholders, analysis of all comments and once modifications to internal systems are ready for implementation. Disclosure of the applicant name would only apply to future applications.

This approach is consistent with transparency measures implemented for applications for approval of prescription drugs, vaccines and medical devices by Health Canada, in addition to aligning with transparency measures implemented by the United States Environmental Protection Agency (USEPA) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) for applications pending a regulatory decision.

Next steps

The PMRA will consider written comments addressing this item in this notice up to 30 days from the date of publication of this document.

Please direct all comments to:
Publications Section
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Appendix I Types of regulatory activities released in the pesticide product information database

Category A – New Active Ingredients, Major New Uses, Maximum Residue Limits on unregistered active ingredients.

Category B – New or Amendments to Existing Registrations plus Emergency Registrations

Category C – Precedent Based Registrations and Amendments plus Minor Use Registrations

Category D – IMEP, URMULE, Master Copies, Private Labels, Renewals, Discontinuations

Category H – Notices of Objection and Review Panels

Category L – Data Protection Applications and Registrations

Category N and R – Re-Evaluations and Special Reviews