RVD2009-16

Re-evaluation Decision

Phenmedipham

(publié aussi en français)

24 September 2009

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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HC Pub: 091019

ISBN: 978-1-100-13611-0 (978-1-100-13612-7)
Catalogue number: H113-28/2009-16E (H113-28/2009-16E-PDF)

Re-evaluation Decision

After a re-evaluation of the herbicide phenmedipham , Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing phenmedipham for sale and use in Canada.

An evaluation of available scientific information found that products containing phenmedipham do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of phenmedipham uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of phenmedipham was first presented in Proposed Re-evaluation Decision PRVD2009-07, *Phenmedipham*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of phenmedipham as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2009-07. To comply with this decision, registrants of products containing phenmedipham will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program,* presents the details of the re-evaluation activities and program structure.

Phenmedipham, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of phenmedipham. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

The USEPA re-evaluated phenmedipham and published its conclusions in a 2005 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2009-07, *Phenmedipham*.

What Is Phenmedipham?

Phenmedipham is an herbicide used to control broad-leaved weeds (for example, lamb's-quarters, wild buckwheat, green foxtail, yellow foxtail, mustard, pigweed, nightshade, Kochia, goosefoot, ragweed, stinkweed) in sugarbeets. Phenmedipham is applied using a groundboom application method.

Health Considerations

Can Approved Uses of Phenmedipham Affect Human Health?

Phenmedipham is unlikely to affect your health when used according to the revised label directions.

People could be exposed to phenmedipham through consumption of food and water, People could be exposed to phenmedipham by consuming food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that phenmedipham was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per

million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Phenmedipham is currently registered in Canada for use on sugarbeets and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for phenmedipham in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Phenmedipham Is Introduced Into the Environment?

Phenmedipham is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target organisms (for example, birds, mammals, insects, aquatic organisms and terrestrial plants) could be exposed to phenmedipham in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of phenmedipham was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of phenmedipham, the PMRA is requiring further risk-reduction measures for product labels.

Environment

- Buffer zones to protect sensitive aquatic and terrestrial habitats

Other Information

Any person may file a notice of objection[3] regarding this decision on phenmedipham within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act.*