RVD2009-17

Re-evaluation Decision

Desmedipham

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Re-evaluation Decision

After a re-evaluation of the herbicide desmedipham, 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 desmedipham for sale and use in Canada.

An evaluation of available scientific information found that products containing desmedipham 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 desmedipham 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 desmedipham was first presented in Proposed Re-evaluation Decision PRVD2009-06, *Desmedipham*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of desmedipham as well as summarizes the Agency's decision and the reasons for it. Comments received during the consultation process resulted in a minor change to the proposed regulatory decision as described in PRVD2009-06. Appendix I summarizes the comments and provides the PMRA's response and Appendix II outlines the revised label statements.

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.

Desmedipham, 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 desmedipham. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated desmedipham and published its conclusions in a 1996 RED and a 2005 Tolerance Reassessment Eligibility Decision (TRED).

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in PRVD2009-06.

What Is Desmedipham?

Desmedipham 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. Desmedipham is applied using a groundboom application method.

Health Considerations

Can Approved Uses of Desmedipham Affect Human Health?

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

People could be exposed to desmedipham through consumption of 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 desmedipham 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 or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Desmedipham 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 desmedipham 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 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 Desmedipham Is Introduced Into the Environment?

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

Terrestrial and aquatic species could be exposed to desmedipham 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. In this screening level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some potential risks of concern.

The USEPA concluded that the reregistration of desmedipham 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 desmedipham, the PMRA is requiring further risk-reduction measures for product labels.

Environment

- Buffer zones to protect sensitive aquatic and terrestrial habitats

Appendix II lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on desmedipham 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*.

Appendix I Comments and Responses

Comment on the requirement of an advisory label statement regarding desmedipham's toxicity to birds

In PRVD2009-06, *Desmedipham*, it is proposed that all desmedipham end-use product labels be amended to include the statement "Toxic to birds". This advisory statement is not required for the safe use of desmedipham end-use products in Canada.

Response

The proposed requirement of the statement "Toxic to birds" was based on risks of concern for avian species reported in the 1996 USEPA RED. The USEPA's risk assessment is a screening-level assessment only and further, is considered very conservative for the Canadian situation (i.e. the application rates assumed in the risk assessment are approximately 2× the maximum Canadian application rates) and is therefore, expected to overestimate risks to avian species in Canada. Based on this, the statement "Toxic to birds" is not required on Canadian end-use products containing desmedipham.

Appendix II Revised Label Amendments for Products Containing Desmedipham

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in the "**DIRECTIONS FOR USE"** section:

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Sugarbeet (reduced rate applications)	1	1	0	0	1
	Sugarbeet (full rate applications)	1	1	1	0	1

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

II) The following statements must be included in the "**ENVIRONMENTAL HAZARDS"** section:

TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.