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Re-evaluation Decision

Aliphatic Alcohols

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Re-evaluation Decision

After a re-evaluation of the aliphatic alcohols, 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 aliphatic alcohols for sale and use in Canada.

An evaluation of available scientific information found that products containing aliphatic alcohols 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 aliphatic alcohol uses, new risk-reduction measures must be included on the labels of all products.

The regulatory approach for the re-evaluation of aliphatic alcohols was first presented in Proposed Re-evaluation Decision PRVD2009-03, *Aliphatic Alcohols*, a consultation document. This Re-evaluation Decision describes this stage of PMRA's regulatory process for the re-evaluation of aliphatic alcohols 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 PRVD2009-03. To comply with this decision, registrants of products containing aliphatic alcohols will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

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.

Aliphatic alcohols, 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 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 re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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 aliphatic alcohols. 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 aliphatic alcohols and published its conclusions in a 2007 Reregistration Eligibility Decision.

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 PRVD2009-03, Aliphatic Alcohols.

What Are Aliphatic Alcohols?

Aliphatic alcohols are plant growth regulators that are used to control tobacco suckers in tobacco plants. They act by physically burning the young sucker growth at each leaf axil touched by the spray solution. The aliphatic alcohols dissolve the layer of waxy cuticle on the epidermis, causing dehydration (burning).

Health Considerations

Can Approved Uses of Aliphatic Alcohols Affect Human Health?

Aliphatic Alcohols are unlikely to affect your health when used according to the revised label directions.

People could be exposed to aliphatic alcohols by inhaling smoke of treated tobacco and/or by consuming water from run-off in treated areas, while 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 aliphatic alcohols were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

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.

Aliphatic alcohols are currently registered in Canada for use on tobacco and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for aliphatic alcohols 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 Aliphatic Alcohols Are Introduced Into the Environment?

Aliphatic alcohols are unlikely to affect non-target organisms when used according to the label directions.

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 aliphatic alcohols was acceptable. The same conclusion applies to the Canadian situation. Furthermore, the PMRA will require both aquatic and terrestrial buffer zones to protect aquatic organisms and terrestrial plants from spray drift.

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 aliphatic alcohols, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Protective equipment to protect mixer/loader/applicators
- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Buffer zones to protect non-target, sensitive terrestrial and aquatic habitats

Other Information

Any person may file a notice of objection¹ regarding this decision on aliphatic alcohols 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, www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd), or contact the PMRA's Pest Management Information Service.

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