Re-evaluation Document REV99-01

Re-evaluation of Organophosphate Pesticides

The purpose of this Announcement is to notify registrants, pesticide regulatory officials and the Canadian public that the organophosphate active ingredients and the end-use products containing them are now subject to re-evaluation under the authority of section 19 of the Pest Control Products Regulations.

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Active Ingredients and Uses

Organophosphate pesticide products, which are mainly insecticides, cover a broad variety of use-site categories, such as forests and woodlands, greenhouse food and non-food crops, livestock, seed treatments, oilseed and fibre crops, stored food and feed, terrestrial feed and food crops, structural uses, outdoor ornamentals and indoor plants, plant scapes and turf.

The 27 active ingredients covered by this announcement are acephate, azinphos-methyl, bensulide, chlorpyrifos, coumaphos, diazinon, dichlorvos, dimethoate, disulfoton, ethion, ethyl parathion, fenitrothion, fenthion, fonofos, malathion, methamidophos, methidathion, naled, oxydemeton-methyl, phorate, phosalone, phosmet, propetamphos, sulfotep, terbufos, tetrachlorvinphos and trichlorfon.

Rationale

Canada has developed a re-evaluation program that uses a modern scientific approach to examining older active ingredients and their end-use products to ensure the ongoing protection of human health and the environment. In order to ensure efficient use of resources in the re-evaluation of organophosphates (and all active ingredients), the Pest Management Regulatory Agency (PMRA) will be making use of the United States (U.S.) Environmental Protection Agency (EPA) reviews to the extent possible.

On August 3, 1996, the U.S. *Food Quality Protection Act* (FQPA) was signed into law. Among other changes, the FQPA sets a stringent health-based safety standard for pesticide residues in all foods by requiring that in establishing or reassessing tolerances, the EPA consider:

- the aggregate non-occupational exposure from the pesticide (dietary exposure, exposure from using pesticides in and around the home, exposure from drinking water);
- the cumulative effects from pesticides with a common mechanism of toxicity;
- whether there is an increased susceptibility to infants and children, or other sensitive subpopulations, from exposure to the pesticide; and
- whether the pesticide produces an effect in humans similar to an effect produced by a naturally occurring estrogen, or other endocrine effects.

The FQPA requires that all tolerances and exemptions from tolerances (approximately 10 000) be reassessed by August 3, 2006.

The PMRA and the EPA have been working together for many years to harmonize the regulation of pesticides between Canada and the U.S. This work includes risk-assessment approaches and methods. In light of the new safety standard established by the FQPA, the PMRA has been working closely with the EPA to ensure that Canada has a full understanding of, and input where appropriate to, the scientific issues raised by the implementation of the FQPA. The PMRA supports the new standard and is incorporating these new approaches into its review processes and methodologies.

The first group for consideration under the FQPA in the U.S. includes most of the major food-use pesticides that are registered in the U.S. The organophosphates, which are also major food-use pesticides in Canada, are considered to be pesticides with a common mechanism of toxicity and are the EPA's initial priority under the FQPA. The proposed risk-management documents that will be published by the EPA for each organophosphate are anticipated to deal with human health assessment, environmental assessment and risk mitigation.

Review Procedure for Organophosphate Pest Control Products Registered in Canada

The starting point for the Canadian re-evaluation of organophosphate pesticides will be the reviews being carried out by the EPA under the FQPA and will encompass all those aspects covered by the EPA. The PMRA will be following in detail the EPA documents as they are published and will reassess this information in the context of the Canadian use situation. This will include a comparison with existing Canadian reviews/approaches and other international reviews and a survey of Canadian use/usage data to try to determine the significance of possible U.S. actions, and the appropriateness to Canada of proposed risk mitigation measures.

There will be a request for registrants of organophosphates to provide certain data or information (for example, updated chemistry on technical grade active ingredients). Registrants will also be asked to describe their activities in terms of intended support for Canadian and U.S. registrations. The specific requirements will be outlined in a letter to each registrant as soon as these requirements are established. This letter will indicate the expected timelines for submission of required information.

The following analysis will be made as part of re-evaluation:

- **Chemistry**:

  The goal will be to obtain sufficient data to consider for registering all unregistered sources of technical active ingredients, to update the chemistry of the registered sources, and to convert all guarantees from minimal to nominal. For unregistered sources, the PMRA will require submission of a new Part 2 chemistry data package. For registered sources, the PMRA will review chemistry data on file and determine if

updated information will be necessary.

- **Toxicology, Occupational Exposure and Food Exposure:**

  The PMRA will be making use of EPA documents that may include:

  - Data Evaluation Reports
  - Hazard Identification Documents
  - Preliminary Risk Assessments
  - Final Risk Assessments
  - Risk Management Proposals
  - Final Risk Management Decision

  The PMRA will carry out assessments for exposure to food residues, occupational and bystander exposure and drinking water exposure that are relevant to formulations registered for use in Canada, and to Canadian conditions of use. As a part of the re-evaluation, formulants in the end-use products will be assessed and registrants informed of changes that will be necessary. The PMRA will implement approaches (increased safety factors for sensitive populations, aggregate exposure and cumulative risk assessment) taken by the EPA for tolerance reassessment under the FQPA where necessary and appropriate. This may necessitate a further assessment of registration status following the initial (aggregate) assessment of an individual organophosphate to consider cumulative risks associated with pesticides having a common mechanism of toxicity.

- **Environmental Assessment**:

  The risk assessment and risk management documents indicated above will also be used in the assessment of environmental impact. The PMRA will carry out environmental exposure assessments that are relevant to the formulations registered for use in Canada, and to the Canadian conditions of use. Where data/information for Canadian research and monitoring on impacts are available (e.g., relevant federal/provincial/territorial environment departments), the PMRA will consider these in its environmental risk assessment.

- **Value Reassessment**:

  A survey is being carried out of the importance of the organophosphate insecticides in Canada and the alternatives that are available. Data has been collected by provincial

governments, extension personnel and users, and is currently being analyzed.

A comparison of the essential uses in Canada and how they compare to those in the U.S. will be carried out. An assessment of the availability and adequacy of alternatives will be presented.

As described in the re-evaluation discussion document, the output of this re-evaluation will be a public consultation document.

Target for Completion of the Re-evaluation of Organophosphates

The progress of these re-evaluations is highly dependent on the availability of EPA reviews. The target for completing the re-evaluation of all organophosphates is December 2000.

Registration of Products Containing Organophosphates

Pending completion of the re-evaluation of organophosphates, no new submissions for major new uses of organophosphates will be considered. In addition, all new products, registration renewals and amended registrations that are granted subsequent to publication of this announcement will expire no later than December 31, 2000. All subsequent new products, registration renewals and amended registrations will be for a period not exceeding one year until this re-evaluation is complete. The future registration status of products containing organophosphates will depend on the outcome of the review.

For further information on this announcement, contact:

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