Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Note REV2004-06

PMRA Re-evaluation Program Workplan (April 2004 to June 2005)

The purpose of this document is to notify registrants, pesticide regulatory officials and the Canadian public of the Pest Management Regulatory Agency's (PMRA) workplan for re-evaluation for 2004–2005.

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The re-evaluation program

The PMRA's approach to re-evaluation is described in Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program.* The approach to re-evaluation, recommended by stakeholders and supported by the Pest Management Advisory Council, is to build on available foreign reviews and expand on the extensive worksharing arrangements with the United States Environmental Protection Agency (USEPA). The four subprograms are as follows:

PROGRAM 1 requires a suitable foreign review that covers the main science areas necessary for Canadian regulatory decisions, addresses the active ingredient itself and its main formulation types registered in Canada, and is relevant to registered Canadian uses.

USEPA Reregistration Eligibility Decision (RED) documents will be the primary source of foreign reviews for Program 1 re-evaluations. PMRA conclusions on the Program 1 re-evaluations will be based on the RED document, with consideration of the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy). The need for further targeted review may be determined following the initial Program 1 re-evaluation.

PROGRAM 2 includes products for which a Canadian regulatory decision requires a detailed in-house re-evaluation covering the full range of assessments of the risks to human health and the environment as well as the consideration of value. In contrast to Program 1, Program 2 has no fully suitable foreign review document on which the PMRA could rely to a substantial degree in its decision making.

PROGRAM 3 focusses on the re-evaluation of pest control products that are scheduled for re-assessment in the United States under the *Food Quality Protection Act* (FQPA). Program 3 addresses the reassessment of pest control products, paying particular attention to pest control products with a common mechanism of toxicity, the aggregate exposures arising from all sources and from all uses as well as the risks to susceptible subgroups in the exposed population, such as children.

PROGRAM 4 is a program of targeted re-evaluations (i.e., special reviews). It comprises reviews initiated to address particular concerns identified for specific pest control products and does not entail a complete re-evaluation of a product's database.

The PMRA priorities for re-evaluation were established based on consideration of a number of factors including the following:

- the extent of use and toxicity profile for food use chemicals (e.g., Program 3; organophosphates and carbamates);
- the potential for cooperative re-evaluation under NAFTA (e.g., wood preservatives)
- Canadian concerns; and
- availability of USEPA reviews (e.g., Program 1).

Many of the priorities for re-evaluation in the United States are identical to those in Canada. For example, the FQPA assessments of food use chemicals such as organophosphates and carbamates are current priorities in the United States.

The PMRA re-evaluation workplan may change in response to emerging issues that require priority action.

The re-evaluation workplan (April 2004 to June 2005)

The PMRA's workplan for completion of re-evaluation reviews and supporting documentation for each of the subprograms in 2004–2005 are found in Tables 1 to 3 hereafter. No new active ingredients are scheduled for completion in Program 4 in 2004–2005.

The supporting documentation for each of the programs may consist of one of the following:

- Risk assessment;
- Re-evaluation Note;
- Proposed Acceptability for Continuing Registration (PACR) document; or
- Re-evaluation Decision Document (RRD).

Table 1

RE-EVALUATION PROGRAM 1

- *Agrobacterium radiobacter*
- Acifluorfen
- Benzylaminopurine
- Metribuzin
- Bronopol
- *Bacillus thuringiensis* berliner ssp *kurstaki*
- *Bacillus thuringiensis* ssp *tenebrionis*
- *Bacillus thuringiensis*, Serotype H-14
- Cedar leaf oil
- Spores of *Colletotrichum gloeosporioides*
- 4-CPA
- Dichlobenil
- Diquat
- Diphenylamine
- Diuron
- Ethoxyquin
- Etridiazole
- Fenbutatin oxide
- Fenvalerate
- Gibberellic acid
- Hexazinone
- Methoprene
- Nuclear Polyhedrosis Virus
- Oxyfluorfen
- Pendimethalin
- Propanil
- Propyzamide
- Prometryne, related triazines
- Sodium bromide
- Sodium cyanide
- Terbacil
- Thiabendazole
- Zinc phosphide

Table 2

RE-EVALUATION PROGRAM 2

- Atrazine (Environmental Assessment)
- CCA
- Creosote
- Pentachlorophenol

Table 3

RE-EVALUATION PROGRAM 3

Organophosphates (OPs)
- Diazinon
- Dichlorvos
- Methamidophos
- Trichlorfon

Carbamates:
- Chlorpropham
- Methomyl
- Triallate

Phenoxy and other herbicides: Agricultural uses
- Dicamba
- 2,4-D acid
- 2,4-D present as amine salts
- 2,4-D present as low volatile esters
- MCPA present as amine salts (diethanolamine, dimethylamine or mixed amines)
- MCPA present as esters
- MCPA acid

Others
- Carbendazim
- Thiophanate-methyl

PMRA re-evaluation progress reports

The PMRA will report on the progress achieved during the 2004/2005 fiscal year.

Information for registrants: Impact on registration of products containing active ingredients subject to re-evaluation

A re-evaluation requires the PMRA to reassess the acceptability of risks to both human health and the environment from all current uses of the active ingredients. Therefore, the use profile must remain static for the duration of the re-evaluation. The PMRA will examine existing submissions that have the potential to increase exposure to the pesticide to determine whether reviews should be completed or whether submissions should be closed. New submissions that have the potential to increase exposure will not be accepted (as of the date of this Re-evaluation Note), with the exception of submissions for emergency registration that meet the criteria set forth in Regulatory Directive DIR2001-05, *Registration of Pesticides for Emergency Use.* New product registration, registration renewals and amended registrations that are granted subsequent to the publication of this Re-evaluation Note will be for a period up to and not exceeding three years for these active ingredients, until the re-evaluation is complete.

Registrants are advised that the registration status of their products may change as a result of re-evaluation. Possible outcomes of re-evaluation could include retaining registration with no changes, implementing mitigation measures or eliminating or phasing-out certain uses or formulations. An active ingredient and its end-use products could also be found to be unacceptable because of the risks posed to the health of Canadians or to the Canadian environment. This information should be taken into consideration by applicants when considering submitting for registration of new products on active ingredients under re-evaluation.