Re-evaluation Note

REV2003-08

PMRA Re-evaluation Program Workplan (April 2003–June 2004)

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 2003/04.

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The re-evaluation program

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

PROGRAM 1 For products to be re-evaluated under Program 1, there must exist a suitable foreign review which covers the main science areas that are necessary for Canadian regulatory decisions, which address the active ingredient itself and its main formulation types registered in Canada, and which is relevant to registered Canadian uses.

USEPA Re-registration 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-specific issues (e.g., the Canadian Toxic Substance 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 consideration of value. In contrast to Program 1, there is no fully suitable foreign review document on which the PMRA could rely to a substantial degree in its decision making.

PROGRAM 3 is focussed on the re-evaluation of pest control products that are scheduled for re-assessment in the US under the *Food Quality Protection Act*. 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, and the risks to susceptible subgroups in the exposed population, such as children.

PROGRAM 4 is a program of targeted re-evaluations or 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 extent of use and toxicity profile for food use chemcals (e.g., Program 3; organophosphates and carbamates)
- the potential for cooperative re-evaluation under NAFTA (e.g., wood preservatives)
- Canadian-specific concerns (e.g., Program 4; turf chemicals) and
- availability of USEPA reviews (e.g., Program 1)

Many of the U.S. priorities for re-evaluation are identical to those in Canada (e.g., FQPA assessments of food use chemicals such as organophosphates and carbamates).

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

The Workplan for re-evaluation (April 2003–June 2004)

The PMRA's workplan for completion of re-evaluation reviews and supporting documentation for each of the subprograms in 2003/04 are found in Tables 1–4 following.

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
- Re-evaluation Decision Document (RRD).

Table 1

RE-EVALUATION PROGRAM 1

- 1-(3-chloroallyl)-3,5,7-triaza-1azoniaadamantane chloride (cis isomer)
- 10,10'-oxybis(phenoxarsine)
- 1,3-dichloropropene
- 2-(hydroxymethyl)-2-nitro-1,3-propanediol
- 2-hydroxethyl n-octyl sulfide
- 2-methyl-4-isothiazolin-3-one
- 2,2-dibromo-3-nitrilopropionamide
- 5-chloro-2-methyl-4-isothiazolin-3-one
- Aluminum phosphide
- Ancymidol
- Bis(trichloromethyl)sulfone
- Brodifacoum
- Bromacil
- Bromadiolone
- Bromohydroxyacetophenone
- Calcium hypochlorite
- Carbon dioxide
- Chlorophacinone
- Daminozide
- Dibromodicyanobutane
- Difenzoquat
- Diflubenzuron
- Diphacinone
- Disodium cyanodithiomidocarbonate
- Flamprop-m-methyl
- Fosamine ammonium
- Hexahydro-1,3,5,-triethyl-s-triazine
- Hydramethylnon
- Lithium hypochlorite
- Methylene bis(thyocyanate)
- Methylnonyl ketone
- Mitin

- Monolinuron
- Muscalure
- Niclosamide
- Nuclear polyhedrosis virus of Douglas fir tussock moth
- O-benzyl-p-chlorophenol
- Oleoresin capsicum (of which principal component is capsaicin)
- Paraquat
- Pheromone: coddling moth
- Pheromone: grape berry moth
- Pindone
- Polybutene
- Putrescent egg solids
- S-(2-hydroxypropyl) methane-thio-sulfonate
- Silica aerogel
- Silicon dioxide salt water fossils
- Sodium dichloro-s-triazinetrione
- Sodium dodecylbenzene sulfonate
- Sodium hypochlorite
- Sodium monofluoroacetate
- Sodium salt of 2-mercaptobenzothiazole
- Soap Salts (Acaricide)
- Soap Salts (Insecticidal)
- Soap Salts (Herbicidal)
- Strychnine
- Sulphur
- Trichlopyr
- Trichloro-s-triazinetrione
- Trifluoro-4-nitro-m-cresol
- Warfarin

Table 2

RE-EVALUATION PROGRAM 2

- Azaconazole
- 2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane)
- 2,2-oxybis(4,4,6)-2,2-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane
- Atrazine
- Barium metaborate monohydrate
- Boracic acid
- Borax, anhydrous
- Borax pentahydrate
- Borax
- CCA

- Chinomethionat
- Oil of Citronella
- Citronella artifical essential oil blend
- Copper-8-quinolinate
- Creosote
- Disodium octaborate tetrahydrate
- Methyl bromide
- Oil of lavender
- Pentachlorophenol
- 2- Thiocyanomethylthiobenzothiazole
- Sulfaquinoxaline
- Zinc borate

Table 3

RE-EVALUATION PROGRAM 3 Organophosphates (Ops)

- Acephate
- Azinphos-methyl
- Bensulide
- Chlorpyrifos
- Coumaphos
- Diazinon
- Endosulfan
- Fenitrothion
- Fenthion
- Malathion

- Methamidophos
- Naled
- Oxydemeton methyl
- Phorate
- Phosalone
- Phosmet
- Terbufos
- Tetrachlorvinphos
- Trichlorfon

Table 4

RE-EVALUATION PROGRAM 4 Turf Special Review

- 2,4-D (Acid)
- 2,4-D (Amine Salts)
- 2,4-D (Volatile Esters)
- 2,4-D (Sodium Salts)
- Dicamba

- MCPA (Potassium Salt or Sodium Salt)
- MCPA (Amine Salts)
- MCPP (Potassium Salt)
- MCPP (Amine Salts)
- MCPP (Acid)

PMRA re-evaluation progress reports

The PMRA will report on the progress achieved during the 2003–2004 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 (i.e., no expansion) for the duration of the re-evaluation. Existing submissions for new uses of products containing these active ingredients, with the exception of those for which reviews have been completed by the PMRA, will be closed. New products, registration renewals and amended registrations that are granted subsequent to the publication of this re-evaluation note will be for a period not exceeding three years, until the re-evaluation is complete.

While the PMRA is engaged in re-evaluating the active ingredients subject to this Re-evaluation Note, no applications will be accepted (as of the date of this Re-evaluation Note) for new uses of products containing these active ingredients, including minor uses, 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*.