



## Re-evaluation Note

REV2004-05

### **Progress Report on the PMRA Re-evaluation Workplan (April 2003–June 2004)**

The Pest Management Regulatory Agency (PMRA) has developed a re-evaluation program that uses a modern scientific approach to re-examine older active ingredients and their uses to determine their continuing acceptability in relation to human health and the environment. Regulatory Directive [DIR2001-03](#), *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Re-evaluation Note [REV2003-08](#), *PMRA Re-evaluation Program Workplan (April 2003–June 2004)* identifies priorities for review in 2003–2004 and stated that the progress of the Re-evaluation Program would be the subject of a future publication.

This Re-evaluation Note documents the progress on the 2003–2004 workplan. Additional active ingredients that were addressed during that time are also listed.

*(publié aussi en français)*

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## Summary

The PMRA has developed a re-evaluation program that uses a modern scientific approach to re-examine older active ingredients and their uses to determine their continuing acceptability in relation to human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the PMRA's plans for the re-evaluation of 401 active ingredients that were registered in Canada prior to 31 December 1995. Re-evaluation Note REV2003-08, *PMRA Re-evaluation Workplan (April 2003–June 2004)*, identifies active ingredients for which the PMRA planned to complete re-evaluation reviews by 30 June 2004 and to publish supporting documentation. This document describes the progress towards completion of that workplan.

## 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 Re-registration Eligibility Decision (RED) documents are 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 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 the 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 reassessment in the United States 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 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.

## Re-evaluation priorities

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 (e.g., Program 4; turf chemicals); and
- availability of USEPA reviews (e.g., Program 1).

Many of the priorities in the United States for re-evaluation are identical to those in Canada (e.g., *Food Quality Protection Act* assessments of food use chemicals such as organophosphates and carbamates).

## The PMRA's re-evaluation workplan (April 2003–June 2004)

Re-evaluation Note REV2003-08, *PMRA Re-evaluation Workplan (April 2003–June 2004)* identifies active ingredients for which the PMRA planned to complete re-evaluation reviews and to publish supporting documentation. The supporting documentation could include the following:

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

## Progress of the re-evaluation program

REV2003-08 also indicated that the PMRA would report on the progress on the workplan. The following tables identify documents that have been published as of 30 June 2004 for each active ingredient on the 2003–2004 workplan. Tables 1 to 4 report on progress on each of the re-evaluation programs (1 to 4). These publications are available on the PMRA website [www.pmra-arla.gc.ca](http://www.pmra-arla.gc.ca). Where reviews are complete but documentation is still in the publications process or companies have not yet been notified, the status is listed as “in progress”.

The re-evaluation of a few active ingredients on the workplan have been carried forward to next year's workplan. The delays in Canada have most often mirrored delays in the United States.

Additional active ingredients that were addressed during 2003–2004 are listed in Table 5. These include additional reviews completed in conjunction with other related active ingredients on the workplan (in some cases these products were registered after 1 January 1995) and active ingredients discontinued by the registrants.

The PMRA will publish re-evaluation workplans and progress reports on an annual basis.

**Table 1 Documentation published for each Program 1 active ingredient identified in 2003–2004 Re-evaluation Workplan (as of 30 June 2004)**

Active ingredient name	Publication in process	Relevant document
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis isomer)		PACR2004-17
1,2-dibromo-2,4-dicyanobutane	✓	
1,3-dichloropropene	✓	
10,10'-oxybis(phenoxarsine)		PACR2004-14
2-(hydroxymethyl)-2-nitro-1,3-propanediol		PACR2004-23
2,2-dibromo-3-nitrilopropionamide		PACR2004-16
2-bromo-4'-hydroxyacetophenone		PACR2004-07
2-hydroxyethyl n-octyl sulfide plus related active compounds		REV2004-02
2-methyl-4-isothiazolin-3-one	✓	
5-chloro-2-methyl-4-isothiazolin-3-one	✓	
Aluminum phosphide	✓	
Ammonia soap salts		PACR2004-04
Ancymidol		PACR2004-01 RRD 2004-15
Bis(trichloromethyl)sulfone		PACR2004-12
Brodifacoum	✓	
Bromacil, present in free form, as dimethylamine salt, or as lithium salt		PACR2004-22
Bromadiolone	✓	
Calcium hypochlorite	✓	
Carbon dioxide	✓	
Chlorophacinone	✓	
Daminozide		PACR2004-24
Difenzoquat, present as methyl sulphate salt		REV2004-03
Diflubenzuron	✓	
Diphacinone, present in free form or as sodium salt	✓	
Disodium cyanodithiomidocarbonate	✓	
Flamprop-m-methyl	✓	
Fosamine ammonium		PACR2004-05
Hexahydro-1,3,5-triethyl-s-triazine		PACR2004-13
Hydramethylnon		PACR2003-11 RRD2004-16
Lithium hypochlorite	✓	
Methyl nonyl ketone		PACR2004-06
Methylene bis(thiocyanate)	✓	
Monolinuron		REV2004-03
Muscalure		PACR2003-12 RRD2004-06
Niclosamide		RRD2004-07
Nuclear polyhedrosis virus of douglas fir tussock moth	✓	

Active ingredient name	Publication in process	Relevant document
O-benzyl-p-chlorophenol	✓	
Oleoresin capsicum / capsaicin		PACR2004-08
Paraquat	✓	
Pheromone: codling moth		RRD2004-02
Pheromone: grape berry moth		RRD2004-03
Pindone, present in free form or as sodium salt	✓	
Polymerized butenes		PACR2004-03
Putrescent whole egg solids		PACR2004-02
S-(2-hydroxypropyl)thiomethane sulfonate		REV2003-04
Silica aerogel		PACR2004-09
Silicon dioxide from salt water fossils		PACR2004-09
Soap		PACR2004-04
Soap [herbicidal]		PACR2004-04
Sodium dichloro-s-triazinetrione		PACR2004-25
Sodium dodecylbenzenesulfonate		REV2003-04
Sodium hypochlorite	✓	
Sodium monofluoroacetate		PACR2004-20
Sodium salt of 2-mercaptobenzothiazole		PACR2004-15
Mitin		PACR2004-19
Strychnine, present as alkaloid or as sulphate	✓	
Sulphur		PACR2004-10
Trichloro-s-triazinetrione		PACR2004-25
Triclopyr	✓	
Trifluoro-4-nitro-m-cresol		PACR2004-11
Warfarin, present in free form or as sodium salt	✓	

**Table 2 Documentation published for each Program 2 active ingredient identified in 2003–2004 Re-evaluation Workplan (as of 30 June 2004)**

Active ingredient name	Publication in process	Relevant document
2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane)	✓	
2,2-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane)	✓	
CCA component: arsenic pentoxide		REV2004-01
Atrazine plus related active triazines		PACR2003-13 RRD2004-12
Azaconazole		REV2004-02
Barium metaborate monohydrate		PACR2004-18
Boracic acid	✓	
Borax	✓	
Borax pentahydrate [antisapstain uses]		RRD2004-08
Borax pentahydrate [non-antisapstain uses]	✓	
Borax, anhydrous	✓	
Chinomethionat	✓	
CCA component: chromic acid		REV2004-01
Copper 8-quinolinolate		RRD2004-08
Creosote		REV2003-09
CCA component: cupric oxide		REV2004-01
Disodium octaborate tetrahydrate [antisapstain uses]		RRD2004-08
Disodium octaborate tetrahydrate [non-antisapstain uses]	✓	
Methyl bromide		RRD2004-01
Oil of citronella	✓	
Artificial essential oil blend	✓	
Oil of lavender		REV2004-02
Pentachlorophenol plus related active chlorophenols*		
Sulfaquinoxaline, present as sodium salt	✓	



Active ingredient name	Publication in process	Relevant document
2-(thiocyanomethylthio)benzothiazole or TCMTB		RRD2004-08
Zinc borate	✓	

\* Review delayed

**Table 3 Documentation published for each Program 3 active ingredient identified in 2003–2004 Re-evaluation Workplan (as of 30 June 2004)**

Active ingredient name	Publication in process	Relevant document
Acephate	✓	
Azinphos-methyl		PACR2003-07 RRD2004-05
Bensulide	✓	PACR2003-06
Chlorpyrifos [part 2]	✓	PACR2003-03
Coumaphos	✓	PACR2003-04
Diazinon [non-turf uses]	✓	
Endosulfan		PACR2004-21
Fenitrothion		PACR2003-08 RRD2004-13
Fenthion		PACR2003-05 RRD2004-10
Malathion [part 2: mosquito control]		REV2003-03
Methamidophos*		
Naled [part 2]	✓	
Oxydemeton-methyl		REV2004-03
Phorate		PACR2003-01 RRD2004-11
Phosalone	✓	
Phosmet	✓	
Terbufos		PACR2003-02 RRD2004-04
Tetrachlorvinphos		PACR2003-09 RRD2004-14
Trichlorfon*		

\* Review delayed

**Table 4 Documentation published for each Program 4 active ingredient identified in 2003–2004 Re-evaluation Workplan (turf special reviews) (as of 30 June 2004)**

Active ingredient name—review of turf uses only	Publication in process	Relevant document
Dicamba	✓	
2,4-D acid	✓	
2,4-D, present as amine salts	✓	
2,4-D, present as low volatile esters	✓	
2,4-D, present as sodium salts	✓	
MCPA, present as acid	✓	
MCPA, present as amine salts	✓	
Mecoprop (d-isomer), present as amine salts		RRD2004-09
Mecoprop (d-isomer), present as potassium salt		RRD2004-09
Mecoprop (d-isomer), present as acid		RRD2004-09

**Table 5 Additional active ingredients not on the 2003–2004 workplan**

Active ingredient name	Publication in process	Relevant document
Mecoprop acid [Non-turf uses]		RRD2004-09
Mecoprop (d-isomer) amine salts [non-turf uses]		RRD2004-09
Mecoprop potassium salt [non-turf uses]		RRD2004-09
Other citronella-based active ingredients [three registered after 1995]	✓	
Magnesium phosphide [registered after 1995]	✓	
Silicon dioxide freshwater fossils [registered after 1995]		PACR2004-09
Pesticidal soap [registered after 1995]		PACR2004-04
Sodium metaborate tetrahydrate		REV2004-02
N-[a-(1-nitroethyl)benzyl]ethylenediamine, present as potassium salt		REV2003-04
Mixture of three compounds: BCD + DDH + DDM	✓	
Poly[hydroxyethylene(dimethyliminio)ethylene(dimethyliminio)methylene dichloride]	✓	
Bendiocarb		REV2004-03
Methyl isothiocyanate	✓	
Flurecol-methyl		REV2004-03
Pebulate		REV2004-03
Butylate		REV2004-03