Proposed Acceptability for Continuing Registration

PACR2004-34

Re-evaluation of 1,3-dichloropropene

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed the first step in the re-evaluation of 1,3-dichloropropene. The PMRA has determined that 1,3-dichloropropene is acceptable for continued registration provided that the proposed mitigation measures are adopted and the data requirements are addressed.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for 1,3-dichloropropene. This document presents a proposed interim decision for 1,3-dichloropropene, pending assessment of exposure from drinking water based on Canadian specific drinking water monitoring data. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to the Publications Coordinator at the address below.

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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products (EPs), that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, PMRA Re-evaluation Program, presents the re-evaluation activities and program structure.

1,3-dichloropropene has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory 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, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of 1,3-dichloropropene and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration with the implementation of mitigation measures. These conclusions were published in a 1998 RED document for 1,3-dichloropropene. In its re-evaluation of 1,3-dichloropropene, the PMRA based the recommendations for this interim decision on this 1998 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substance Management Policy).

2.0 Re-evaluation of 1,3-dichloropropene

In Canada, 1,3-dichloropropene was first registered in 1975. It is a soil fumigant used to control nematodes and certain soil diseases. It is registered for use on soils to be planted with all food and feed crops; however, it is classified as a non-food use pesticide because it is a pre-plant soil fumigant. Currently registered Canadian products containing 1,3-dichloropropene are listed in Appendix I.

The Canadian registrant has indicated that use of 1,3-dichloropropene in greenhouses or other enclosed areas will no longer be supported in Canada, and the following

re-evaluation decision is proposed for outdoor uses of 1,3-dichloropropene only. Canadian registered outdoor use sites, application rates, application method and formulation type are also registered in the United States. Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for 1,3-dichloropropene is considered to be an adequate basis for the proposed interim Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the USEPA RED for 1,3-dichloropropene.

The federal TSMP and Regulatory Directive <u>DIR99-03</u> were also taken into consideration during the review of 1,3-dichloropropene, and it was concluded that 1,3-dichloropropene is not a TSMP Track 1 substance.

3.0 Proposed regulatory action

Based on the available information, the USEPA concluded that dietary exposure to 1,3-dichloropropene through contaminated groundwater can occur under certain conditions. 1,3-dichloropropene is mobile and persistent, depending on environmental conditions such as temperature, soil type and soil porosity. Regions with colder soil and water temperatures, shallow groundwater and permeable soils may be the most vulnerable to potential 1,3-dichloropropene groundwater contamination. Although using 1,3-dichloropropene in Canada will be prohibited under these most vulnerable conditions by including a groundwater advisory on the label, the PMRA wishes to confirm that the proposed prohibition will adequately protect groundwater in all areas where 1,3-dichloropropene is used. As a result, the PMRA requires the following:

- Drinking water monitoring data for 1,3-dichloropropene and its degradates, in selected Canadian community water systems in areas of use. The registrant must develop and submit a protocol for PMRA approval and implement the water monitoring program starting in 2005. The results of this program will be reviewed by the PMRA. Further regulatory action may be taken in light of the monitoring results.
- Any existing drinking water monitoring data for 1,3-dichloropropene and its degradates. This is required by the end of this 60 day consultation period.

Based on risk mitigation measures recommended in the USEPA RED, Canadian EP labels for 1,3-dichloropropene must be amended to protect workers, bystanders and non-target organisms (see Appendix II). The proposed risk mitigation measures include the following:

- a 90 m no-treatment buffer zone from occupied structures;
- soil sealing requirements;
- restricted re-entry interval increased from 72 hours to 5 days;

- personal protective equipment requirements for handlers;
- a 31 m buffer from any well that is used for potable water; and
- a groundwater advisory prohibiting application in areas overlying karst geology and/or areas where groundwater is less than 15 m from the surface and where the soils have high permeability and infiltration rates (e.g., sandy soil, sandy loam or loamy sand) with a water transmission rate > 0.76 cm/hr (i.e., Hydrologic Soil Group A).

In order to provide users with appropriate guidance and to mitigate exposure, the registrant is required to modify EP labels to add instructions on the following:

- closed-loading requirements;
- application procedure to discontinue the practice of continuously pumping 1,3-dichloropropene when the application rig is lifted out of the ground at row-turns (accomplished by utilizing shut-off valves);
- methods for improving soil sealing methods;
- injection depth (increase to a minimum of 31 cm);
- placement of injection shanks;
- soil conditions and soil moisture requirements ("Feel Method"); and
- soil preparation requirements.

Maximum application rates of 1,3-dichloropropene were reduced by 30–65% in the United States, depending on the crop; the Canadian registrants are required to implement the same reductions, if applicable. Efficacy data will be required to support any reductions in maximum application rates.

It is proposed that Canadian 1,3-dichloropropene EPs be registered as "Restricted Class" products to ensure that 1,3-dichloropropene is used only by certified applicators who have received training on the proper use of soil fumigants and have obtained an appropriate provincial permit. Statements pertaining to the restricted classification required on 1,3-dichloropropene EP labels are listed in Appendix II.

A submission to request label revisions is required within 90 days of finalization of the re-evaluation decision.

4.0 Additional data requirements

In addition to the water monitoring data mentioned above, the registrant is required to submit the following within 24 months of finalization of the re-evaluation decision:

- a submission to register a source of the technical grade of active ingredient (TGAI), which includes data indicating the level of the microcontaminant 1,2-dichloropropane. Please refer to PMRA Regulatory Directive DIR98-04, Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product;
- all data (as they relate to the Canadian use pattern) submitted to the USEPA in response to the data call-in prior to reregistration in the United States and USEPA Data Evaluation Reports (DERs);
- all data (as they relate to the Canadian use pattern) that were required by the USEPA as a condition of reregistration of 1,3-dichloropropene, including the run-off study conducted by Dow AgroSciences; and
- a commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above. These requirements are outlined in PMRA's data code (DACO) tables for use-site categories (USCs) # 4, 14 and 27. The registrants are required to address the following sections of DACO tables:
 - for the TGAI: DACOs 2 through 9, inclusive;
 - for the EP: DACOs 5 through 9, inclusive.

The above data and additional data may be required sooner if expansion of current uses of 1,3-dichloropropene is requested.

5.0 Proposed re-evaluation decision

The USEPA published a RED document for 1,3-dichloropropene addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed all outdoor uses of 1,3-dichloropropene that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that 1,3-dichloropropene is acceptable for continued registration for all currently registered Canadian outdoor uses provided that the mitigation measures specified in Section 3.0 are adopted and provided that data requirements related to these uses and specified in Section 4.0 are addressed. This is an interim decision pending the results of the required drinking water monitoring data.

The Canadian registrant has informed the PMRA of their intention to discontinue the greenhouse use of 1,3-dichloropropene in Canada; therefore, the use of 1,3-dichloropropene in greenhouses or other enclosed areas was not re-evaluated. The

registrants are required to delete any statement on EP labels pertaining to greenhouse use or use in any indoor/enclosed areas as per Appendix II.

It should be noted that for EPs that contain more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

6.0 Supporting documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at www.hc-sc.gc.ca/pmra-arla. PMRA documents are also available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or 1 (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document (1,3-Dichloropropene) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

Appendix I Canadian 1,3-dichloropropene products currently registered (as of 31 December 2003)

Product name	Class	Guarantee	Registrant	Registration number
Telone TM II	Commercial	94%	Dow AgroSciences Canada	15893
Telone TM C-17 ¹	Commercial	78.3%	Dow AgroSciences Canada	16324
Vorlex® Plus ^{2 3}	Commercial	40%	Agrevo Canada Inc.	18353

¹ This product also contains 16.5% chloropicrin

² This product will be discontinued on 31 August 2004 and will expire on 31 August 2007

³ This product also contains 20% methyl isothiocyanate

Appendix II Use standard for commercial class products containing 1,3-dichloropropene

NOTE:

The information in this appendix summarizes the acceptable uses, limitations and minimum personal protective equipment (PPE) for the commercial class products containing 1,3-dichloropropene resulting from this re-evaluation. This use standard does not identify all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary PPE that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this use standard.

COMMON NAME: 1,3-dichloropropene

CHEMICAL NAMES: (IUPAC) (EZ)-1,3-dichloropropene

(CAS) 1,3-dichloro-1-propene

FORMULATION TYPE: Liquid

SITE CATEGORIES: Forests and Woodlots, USC # 4

Terrestrial Food Crops, USC # 14 Ornamentals Outdoor, USC # 27

GENERAL LIMITATIONS:

The word "RESTRICTED" must appear on the Principal Panel of the label.

The following must appear prominently at the top of the Secondary Panel of the label:

"NOTICE TO USER: This control product is to be used only in accordance with the directions on this label. It is an offence under the *Pest Control Products Act* to use a control product under unsafe conditions."

"NATURE OF RESTRICTION: Only to be used by individuals holding an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the application occurs; contact local pesticide authorities about use permits that may be required."

Labels must be modified to include the following statement on the Principal Panel of the label:

"Not for use in greenhouses or other enclosed areas."

USE RESTRICTIONS:

1) Workers Performing Direct-contact Tasks

"Direct-contact tasks are tasks performed outdoors or in well-ventilated areas and include:

- any activity closer than 2 m from an unshielded pressurized hose containing this product;
- equipment calibration, clean-up and repair;
- product sampling;
- removal of a containment tarp or plastic film;
- rinsate disposal;
- preparation of containers for aeration;
- fumigant transfer;
- on-farm bulk tank cleaning and maintenance; and
- clean-up of minor spills.

Workers performing direct-contact tasks must wear the following:

- coveralls over normal work clothing;
- chemical-resistant apron;
- chemical-resistant gloves;
- chemical-resistant footwear and socks;
- chemical-resistant headgear for overhead exposure; and
- a full-face respirator with either a NIOSH/MSHA-approved cartridge to remove organic vapours with a prefilter approved for pesticides or NIOSH/MSHA-approved canister for pesticides."

2) Workers in Enclosed Cabs

"Workers in enclosed cabs (with closed windows and filtered air) must wear the following:

- coveralls:
- shoes and socks; and
- a full-face respirator with either a NIOSH/MSHA-approved cartridge to remove organic vapours with a prefilter approved for pesticides or NIOSH/MSHA-approved canister for pesticides.

A respirator is NOT required if occupants are within an enclosed cab equipped with a vapour-adsorptive filter (activated charcoal); however, the protective equipment specified in the "Direct Contact" task section above (respirator, chemical-resistant gloves and footwear) must be available in the cab, and must be worn if the worker leaves the cab to perform any direct-contact activity, and then re-enters the cab."

3) Applicators Outside an Enclosed Cab

"Applicators applying product (or sealing the soil following application of product), who are not inside a closed-cab tractor with air filtration, must wear the following:

- coveralls over normal work clothing;
- chemical-resistant gloves;
- chemical-resistant footwear and socks;
- chemical-resistant headgear for overhead exposure; and
- a full-face respirator with either a NIOSH/MSHA-approved cartridge to remove organic vapours with a prefilter approved for pesticides or a NIOSH/MSHA-approved canister for pesticides."

4) Workers in Treated Areas Within 5 Days After Application

"Only the following tasks are permitted within 5 days after the application is complete:

- assessing/adjusting the soil seal;
- assessing pest control or application efficacy; and
- sampling air or soil for this product.

ALL other tasks are prohibited within the 5 day interval."

"Unless in a closed-cab tractor, all workers performing the above tasks within 5 days after application must wear the following:

- coveralls over normal work clothing;
- chemical-resistant gloves;
- chemical-resistant footwear and socks; and
- a full-face respirator with either a NIOSH/MSHA-approved cartridge to remove organic vapours with a prefilter approved for pesticides or a NIOSH/MSHA-approved canister for pesticides."

5) Handlers Exposed to High Concentrations

"Handlers exposed to high airborne concentrations of this product, such as clean-up following large spills and exposure to this product in poorly ventilated areas, must wear the following:

- chemical-resistant suit;
- chemical-resistant gloves;
- chemical-resistant footwear plus socks;
- chemical-resistant headgear; and
- a full face respirator with either a NIOSH/MSHA-approved cartridge to remove organic vapours with a prefilter approved for pesticides or a NIOSH/MSHA-approved canister for pesticides."

PERSONAL PROTECTIVE EQUIPMENT:

"Where chemical-resistant materials are required, leather, canvas and cotton materials offer no protection and must not be worn when contact with this product is possible."

RESPIRATOR REQUIREMENTS:

"When a respirator is required for use with this product, the following criteria must be met:

- a full-face respirator must be worn;
- the respirator must fit properly; and
- the cartridges or canisters must be changed daily, or sooner if odour of the product is detected."

SAFETY RECOMMENDATIONS:

- "Never use the mouth to siphon product from containers or to blow out clogged lines, nozzles, etc.
- Users should:
 - wash hands before eating, drinking, smoking or using the toilet;
 - remove clothing if pesticide comes in contact with skin through soaked clothing or spills. Then wash contaminated skin thoroughly and put on clean clothing.
 - remove protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.
 - aerate clothing thoroughly, then wash separately from household laundry in detergent and hot water before re-use.
 - dispose of clothing or shoes if heavily contaminated."

"DO NOT enter the treated area within 5 days after treatment (except to perform the tasks described in the "Workers in Treated Areas Within 5 Days After Application" section above, and wearing the proper protective equipment)."

ENVIRONMENTAL HAZARDS:

"1,3-dichloropropene is known to move through soil and under certain conditions has the potential to reach groundwater as a result of agricultural use. DO NOT apply in areas overlying karst geology. DO NOT apply in areas where groundwater is less than 15 m from the surface and where the soils have high permeability and infiltration rates (e.g., sandy soil, sandy loam or loamy sand) with a water transmission rate > 0.76 cm/hr (i.e., Hydrologic Soil Group A)."

"DO NOT apply within 31 m of any well that is used for potable water."

"Toxic to aquatic organisms. Do not apply to aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands) or estuarine habitats."

"Do not contaminate water by cleaning equipment or disposing of water."

DIRECTIONS FOR USE:

"DO NOT apply within 90 m of an occupied structure."

"Row treatment maximum application rate must not exceed broadcast treatment maximum application rate."

"After application and sealing, leave the soil undisturbed for 7 to 14 days."

"Under optimum soil and weather conditions, allow one week of aeration for each 100 L of [product] applied per hectare."