Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

# Proposed Acceptability for Continuing Registration

**PACR2004-37**

## Re-evaluation of Triclopyr

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 a re-evaluation of triclopyr. The PMRA has determined that triclopyr is acceptable for continued registration provided that the proposed mitigation measures are adopted. Additional data requirements are identified. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing triclopyr with specific direction on how to address these measures and requirements.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for triclopyr. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to the Publications Coordinator at the address below.

*(publié aussi en français)*

**22 September 2004**

**This document is published by the Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency. For further information, please contact:**

**Publications Coordinator**
**Pest Management Regulatory Agency**
**Health Canada**
**2720 Riverside Drive**
**A.L. 6605C**
**Ottawa, Ontario**
**K1A 0K9**

**Internet:** pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
**Information Service:**
**1 800 267-6315 or (613) 736-3799**
**Facsimile: (613) 736-3798**

ISBN: 0-662-38207-2  (0-662-38208-0)
Catalogue number: H113-18/2004-37E (H113-18/2004-37E-PDF)

## 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 details of the re-evaluation activities and program structure.

Triclopyr 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 triclopyr 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 triclopyr. In its re-evaluation of triclopyr, the PMRA based its conclusions on this 1998 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

## 2.0 Re-evaluation of triclopyr

Active substance: [(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid

Common name: Triclopyr

Chemical names
IUPAC: 3,5,6-trichloro-2-pyridyloxyacetic acid
CAS: [(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid

CAS number: 55335-06-3

In Canada, triclopyr was first registered in 1989. According to current EP labels, it is registered in Canada as a herbicide for use on pastures, rangelands, non-crop areas (including rights-of-way, electrical power lines, communication lines, pipelines, roadsides, railroads, fence rows as well as around farm buildings, military bases, industrial, manufacturing and storage sites), woodland management sites (≤500 ha), forest management areas (>500 ha) and lowbush blueberry site preparation areas. Currently registered Canadian products containing triclopyr are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for triclopyr is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the USEPA RED for triclopyr.

The federal TSMP and Regulatory Directive DIR99-03 were taken into consideration during the review of triclopyr, and it was concluded that triclopyr is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

## 3.0 Proposed re-evaluation decision

The USEPA published a RED document for triclopyr addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of triclopyr that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that triclopyr is acceptable for continued registration provided that the mitigation measures specified in Section 4.0 are adopted. Additional data requirements are identified in Section 6.0.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision.

## 4.0 Proposed regulatory actions

Based on the USEPA RED and the Canadian use pattern, Canadian EP labels should be amended as follows to further protect workers and the environment.

- Under the section entitled “Precautions”, the following statements must be included:
    - “Do not enter or allow worker entry into treated areas within 12 hours of application.”
    - “Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”
    - “Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.”
- The section entitled “Environmental Hazards” must include the following statement:
    - “The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g., sandy soil) and/or where the depth to the water table is shallow.”
- The use directions must include the following:
    - “Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and parks is minimal.”
    - “Do not use in residential areas. Residential areas are defined as sites where bystanders including children may be potentially exposed during or after spraying. This includes around homes, schools, parks, playgrounds, playing fields, public buildings or any other areas where the general public, including children, could be exposed.”
    - a maximum rate of 1.12 kg a.e./ha[1] and only one application per growing season for use on ranges, pastures and sites where cattle can be grazed. **Note**—registrants have the option of supporting a different maximum rate by submitting a rationale and/or supporting data;

[1] a.e. = acid equivalent

    - a 14-day preharvest interval for grass hay; and
    - a restriction against grazing lactating dairy cattle until the next growing season.
- Based on findings by the USEPA the following statement must be added to the label for Garlon 3A Integrated Formulation Product, Manufacturing Concentrate (PCP # 25842):
    - "POTENTIAL SKIN SENSITIZER"

The label amendments presented above do not include all label requirements for individual EPs, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

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

## 5.0 Maximum residue limits of triclopyr in food

Triclopyr is currently registered for feed crops (pasture and rangeland) in Canada. There are currently maximum residue limits (MRLs) specified for triclopyr and the metabolite TCP (3,5,6-trichloro-2-pyridinol) at 0.5 ppm for the liver and kidney of cattle, goats, hogs, horses and sheep in Table II, Division 15 of the Canadian Food and Drug Regulations (FDR). Triclopyr may be used on agricultural crops in other countries, and it is noted that the United States has established tolerances for residues of triclopyr on various commodities. Currently, any residues of triclopyr on food imported into Canada must not exceed 0.1 ppm, a general MRL specified in subsection B.15.002(1) of the FDR. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002 (1)]*.

## 6.0 Additional data requirements

The technical registrant of triclopyr is required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to the Canadian use pattern) submitted to the USEPA in response to the data call-in prior to the 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 triclopyr; these should include the additional confirmatory data required by the USEPA to characterize the fate of TCP in the aquatic environment; and

- a commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above. These are outlined in the PMRA's data code (DACO) tables for use-site categories (USCs) # 4, 13, 14, and 16. The registrant is required to address the following sections of the 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 triclopyr is requested.

## 7.0 Supporting documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. 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 (*Triclopyr*) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

# Appendix I Products containing triclopyr registered in Canada as of 31 May 2004

| Product name | Registrant | Registration number | Guarantee* | Class |
|---|---|---|---|---|
| Triclopyr BEE Technical Herbicide | Dow Agrosciences Canada Inc. | 21052 | 69% | Technical |
| Garlon 4 Herbicide | Dow Agrosciences Canada Inc. | 21053 | 480 g a.e./L | Commercial |
| Release Silvicultural Herbicide | Dow Agrosciences Canada Inc. | 22093 | 480 g a.e./L | Commercial and Restricted |
| Fencerow Herbicide Agricultural | Dow Agrosciences Canada Inc. | 22203 | 480 g a.e./L | Commercial |
| Garlon Manufacturing Concentrate | Dow Agrosciences Canada Inc. | 23447 | 480 g a.e./L | Manufacturing Concentrate |
| Garlon 3A Integrated Formulation Product | Dow Agrosciences Canada Inc. | 25842 | 360 g a.e./L | Manufacturing Concentrate |
| Remedy EC Herbicide Agricultural | Dow Agrosciences Canada Inc. | 26420 | 480 g a.e./L | Commercial |

* a.e. = acid equivalent