



Proposed Acceptability for Continuing Registration

PACR2005-05

Re-evaluation of 4-Chlorophenoxy-acetic Acid

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated 4-chlorophenoxy-acetic acid (4-CPA). The PMRA has determined that 4-CPA is acceptable for continued registration. The registrant will be required to submit specified confirmatory data. Upon finalization of the re-evaluation decision, the PMRA will provide the registrant of products containing 4-CPA with specific direction on how to address these requirements.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for 4-CPA. 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 Publications 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, 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.

4-CPA 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 4-CPA and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration. These conclusions were published in a 1997 RED document for 4-CPA. The *Report of the FQPA Tolerance Reassessment Progress and Risk Management Decision* was also published in 2003. In its re-evaluation of 4-CPA, the PMRA based its conclusions on the 1997 RED and the 2003 Tolerance Reassessment Decision (TRED) documents, taking into account the Canadian use pattern and 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 4-CPA

Chemical name:

IUPAC: 4-chlorophenoxyacetic acid

CAS: (4-chlorophenoxy)acetic acid

CAS number: 122-88-3

Chemical class: Phenoxy acid

In Canada, 4-CPA was first registered in 1979. According to the current end-use product label, this active ingredient is registered in Canada for domestic use as a plant growth regulator on tomatoes. The Canadian product containing 4-CPA is listed in Appendix I.

Based on a comparison of American and Canadian use patterns, the USEPA assessments described in the RED and TRED documents for 4-CPA are 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 RED and the TRED for 4-CPA.

The federal TSMP and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of 4-CPA, and it was concluded that 4-CPA is not a candidate for Track 1 classification. The 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 RED and TRED documents for 4-CPA addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. These documents addressed uses of 4-CPA that are also registered in Canada. The PMRA has determined that 4-CPA is acceptable for continued registration. The registrant will be required to submit the confirmatory data identified in Section 5.0.

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. The registrant of products containing 4-CPA should not submit the additional data as described in Section 5.0 during this comment period; they will be informed by letter of the specific instructions for addressing data requirements once the re-evaluation decision has been finalized.

4.0 Maximum Residue Limits

There are no dietary concerns regarding use of 4-CPA on food crops reported in the USEPA RED. This document adequately addresses the Canadian dietary exposure. 4-CPA is currently registered in Canada for use on tomatoes. 4-CPA may be used on other crops in other countries. Currently, residues of 4-CPA and metabolites in mung beans must not exceed 0.2 ppm, as specified in Table II, of the Canadian Food and Drug Regulations. Residues of 4-CPA and metabolites in all other commodities (including tomatoes) must not exceed 0.1 ppm, a general maximum residue limit specified in Regulation B.15.002(1) of the Canadian Food and Drug Regulations. However, changes to this general maximum residue limit 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 B15-002(1)]*.

5.0 Additional Data Requirements

The registrant 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); and
- a commitment and schedule to address Canadian requirements listed in the PMRA's data code (DACO) tables for Use-site Category (USC) # 14 that are not addressed through submission of the data outlined above.

The registrant has the option to submit scientifically based rationales to support data waivers.

6.0 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 (*4-Chlorophenoxy-acetic Acid*) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

The USEPA 2003 *Tolerance Reassessment Progress and Risk Management Decision (TRED) for 4-CPA* (OPP-2003-0124-0003) is available on the Office of Pesticide Programs' website at <http://docket.epa.gov/edkpub/index.jsp>.

**Appendix I Products Containing 4-CPA Registered in Canada as of
31 December 2004**

Product Name	Registrant	Registration Number	Guarantee %	Class
Later's Tomato Fruit Set Spray	Nu-Gro IP Inc.	15975	0.005	Domestic