Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Note REV2002-06

Re-evaluation of Selected Carbamate Pesticides

The purpose of this Re-evaluation Note is to notify registrants, provincial and territorial pesticide regulatory officials, other federal government departments and the Canadian public that the following carbamate active ingredients and their associated end-uses are now subject to re-evaluation under the authority of Section 19 of the Pest Control Products Regulations (PCPR): asulam, bendiocarb, carbaryl, carbofuran, chlorpropham, cycloate, EPTC, formetanate hydrochloride, methomyl, oxamyl, pebulate, propoxur, thiram, triallate, vernolate, zineb and ziram.

(publié aussi en français)

August 29, 2002

This document is published by the Submission Coordination and Documentation Division, Pest Management Regulatory Agency. For further information, please contact:

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ISBN: 0-662-32733-0
Catalogue number: H113-5/2002-6E-IN

Purpose:

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Active ingredients and uses:

As indicated in Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, the Pest Management Regulatory Agency (PMRA) will utilize foreign reviews, particularly those from the United States (U.S.) Environmental Protection Agency (EPA), to the greatest extent possible as a source of information for conducting Canadian re-evaluation assessments. Carbamate active ingredients are currently undergoing tolerance reassessment in the U.S. in accordance with the requirements of the U.S. *Food Quality Protection Act* (FQPA).

The PMRA is announcing at this time the re-evaluation of only those carbamate active ingredients for which EPA reviews under the FQPA have been completed or are anticipated to be completed in the near future. Also included in this Re-evaluation Note are carbamate active ingredients for which regulatory decisions for phase-out of all uses have been made in the U.S. in recent years.

The active ingredients that are subject to this Re-evaluation Note are: asulam, bendiocarb, carbaryl[1], carbofuran, chlorpropham, cycloate, EPTC, formetanate hydrochloride, methomyl, oxamyl, pebulate, propoxur, thiram, triallate, vernolate, zineb and ziram. This group of pesticides is diverse and includes compounds with insecticidal, herbicidal, fungicidal and antimicrobial activity. These active ingredients cover a wide range of use patterns, including food and non-food uses in agricultural, industrial and residential sites. All registered uses and associated end-use products for these active ingredients will be considered during the re-evaluation.

Other carbamate active ingredients are registered in Canada but are not covered by this Re-evaluation Note (see Appendix 1). The initiation of the re-evaluation of carbamate active ingredients not covered by this Re-evaluation Note will be coordinated, as much as possible, with the availability of reviews from the EPA.

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[1] The re-evaluation of the turf uses for carbaryl was announced previously in Re-evaluation Note REV2000-04, *Re-evaluation of Lawn and Turf Uses of Pesticides*. The current Re-evaluation Note, *Re-evaluation of Selected Carbamate Pesticides*, covers the remaining registered uses for carbaryl.

Rationale:

Canada has developed a re-evaluation program that uses a modern scientific approach to examining older active ingredients and their end-uses to determine their continuing acceptability in relation to human health and the environment. The PMRA's re-evaluation program is outlined in Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*. Active ingredients that were registered or found in registered products prior to 1995 and the end uses associated with those active ingredients are subject to the re-evaluation program. All of the active ingredients covered by this Re-evaluation Note were first registered prior to 1995.

Review procedure:

The starting point for the Canadian re-evaluation of the identified carbamate pesticides will be the reviews being carried out by the EPA under the FQPA and will encompass all those aspects covered by the EPA. The PMRA will be following in detail the EPA documents as they are published and will reassess this information in the context of the Canadian use situation. This will include a comparison with existing Canadian reviews and approaches and other international reviews and available information on Canadian use and usage to try to determine the significance of possible U.S. actions and the appropriateness to Canada of proposed U.S. risk-mitigation measures. In some cases, further information and/or data may be requested to supplement available EPA or other international reviews in order to support the Canadian re-evaluation.

The following analysis will be made as part of re-evaluation:

A. Chemistry:

The goal will be to obtain sufficient data to consider for registration all unregistered sources of technical active ingredients currently present in registered products, and to update the chemistry of the registered sources. For unregistered sources, the PMRA will require submission of a new Part 2 chemistry data package. For registered sources, the PMRA will review chemistry data on file and determine if updated information will be necessary.

B. Toxicology, occupational exposure and food exposure:

The PMRA will be making use of EPA documents that may include:

- Data Evaluation Reports
- Hazard Identification Documents
- Preliminary Risk Assessments
- Final Risk Assessments
- Risk Management Proposals
- Final Risk Management Decisions

Where EPA documents or some other suitable foreign review are not available, specific data may be requested from registrants.

The PMRA will carry out assessments for exposure to food residues, occupational and bystander exposure and drinking water exposure that are relevant to formulations registered for use in Canada and to Canadian conditions of use. The PMRA will implement approaches (e.g., increased safety factors for sensitive populations, aggregate exposure and cumulative-risk assessment) taken by the EPA under the FQPA where necessary and appropriate. This may necessitate a further assessment of registration status following the initial (aggregate) assessment of an individual active ingredient to consider cumulative risks associated with pesticides having a common mechanism of toxicity.

C. Environmental assessment:

The risk-assessment and risk-management documents generated by the EPA will also be used in the assessment of environmental impact. Where EPA documents or some other suitable foreign review are not available, specific data may be requested from registrants. The PMRA will carry out environmental exposure assessments that are relevant to the formulations registered for use in Canada, and to the Canadian conditions of use. Where data and information from Canadian research and monitoring on impacts are available (e.g., relevant federal, provincial and territorial environment departments), the PMRA will consider these in its environmental risk assessment.

D. Value reassessment:

The PMRA will review available use and usage information for carbamate pesticides and alternatives to assess the importance of carbamates to pest management. Further use and usage information may be requested from registrants and/or stakeholders (e.g., provinces, grower organizations). A comparison of the essential uses in Canada with those in the U.S. will be carried out. An assessment of the availability and adequacy of alternatives will be presented.

In order to facilitate the re-evaluation, basic manufacturers and registrants of technical carbamate active ingredients covered by this Re-evaluation Note are requested to inform the PMRA of their intention to support their Canadian registrations within 30 days of the date of publication of this Re-evaluation Note.

The PMRA will then identify any specific information or data that would be required from registrants in order to proceed with the Canadian re-evaluation reviews. The specific requirements will be outlined in a letter to each registrant as soon as these requirements are established. This letter will indicate the expected timelines for submission of the required information.

The progress of these re-evaluations is highly dependent on the availability of EPA reviews.

Registration of products containing active ingredients subject to this Re-evaluation Note:

The re-evaluation requires the PMRA to reassess the acceptability of risks to both health and the environment from all current uses of the active ingredients. Therefore, the use profile must remain static (i.e., no use expansion) for the duration of the re-evaluation.

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 actives, 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*. Existing submissions for new uses of products containing these active ingredients that are already with the Agency, with the exception of those for which reviews have been completed and the new use accepted for registration by 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.

The future acceptability of new uses of products containing the carbamate active ingredients under re-evaluation will depend on the outcome of the re-evaluation process. Use expansions for individual active ingredients would be considered on a case-by-case basis following the initial (aggregate) assessment, pending the outcome of an assessment of the cumulative risks (as needed) associated with pesticides having a common mechanism of toxicity.

Appendix 1. Carbamate active ingredients that are were first registered (or found in registered end-use products) in Canada prior to 1995, but are not subject to the current Re-evaluation Note.

The following carbamate active ingredients are subject to the PMRA's re-evaluation program announced in Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, but are not covered by the current Re-evaluation Note:

butylate
desmedipham
disodium ethylene bis dithiocarbamate (nabam)
ferbam
IPBC
mancozeb
maneb
metiram
metam sodium
phenmedipham
pirimicarb
potassium N-methyl dithiocarbamate
potassium dimethyl dithiocarbamate
potassium N-hydroxymethyl-N-methyl dithiocarbamate
propamocarb
sodium dimethyl dithiocarbamate

The initiation of the re-evaluation of these active ingredients by PMRA will be the subject of a separate Re-evaluation Note.