



Proposed Acceptability for Continuing Registration

PACR2004-21

Re-evaluation of Endosulfan – Interim Mitigation Measures

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) is proposing interim mitigation measures for the insecticide endosulfan.

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.

(publié aussi en français)

25 June 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.hc-sc.gc.ca/pmra-arla/

**Information Service:
1 800 267-6315 or (613) 736-3799
Facsimile: (613) 736-3798**



ISBN: 0-662-37506-8 (0-662-37507-6)

Catalogue number: H113-18/2004-21E (H113-18/2004-21E-PDF)

**© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2004**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

| | | |
|------------|--|---|
| 1.0 | Background | 1 |
| 2.0 | Proposed interim measures | 2 |
| 2.1 | Proposed measures pertaining to dietary risk | 2 |
| 2.2 | Proposed measures pertaining to occupational and environmental risks | 2 |
| 2.3 | Removal of unsupported uses | 5 |
| 3.0 | Consultation | 5 |
| | List of abbreviations | 6 |
| Appendix I | Proposed interim measures for endosulfan | 7 |

1.0 Background

The PMRA is re-evaluating pesticide active ingredients and their associated end-uses 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. As indicated in that directive, the PMRA is relying as much as possible on recent foreign reviews, particularly those resulting from reregistration activities by the United States Environmental Protection Agency (USEPA), as the basis for conducting the reviews.

In the United States (U.S.), the USEPA has conducted a re-evaluation of the insecticide endosulfan and, in 2002, published a Reregistration Eligibility Decision (RED) document that outlines a risk management plan for this active ingredient¹. The RED document described measures to mitigate dietary, worker and environmental risks associated with uses of endosulfan in the U.S.

In August 2002, the PMRA announced that the manufacturers of endosulfan for Canada (Bayer CropScience Inc. and Makhteshim-Agan of North America Inc.) had agreed to take the same kind of actions for this active ingredient in Canada as those being implemented in the U.S.² The PMRA also announced at that time that it would be undertaking a re-evaluation of endosulfan for the purpose of determining whether the risk management measures taken in the U.S. would provide adequate safeguards regarding the use of endosulfan products in Canada.

After consideration of the USEPA risk management plan for endosulfan and its relevance to the Canadian situation, the PMRA is proposing to implement certain measures in advance of completing the full re-evaluation, as a precautionary approach to mitigate potential dietary, worker and environmental risks. The proposed measures are described below and in Appendix 1 of this document. The resulting use pattern for endosulfan will serve as the basis for completing the re-evaluation. The outcome of that assessment will be presented in a future document.

The PMRA is proposing that endosulfan products marketed by registrants for the 2005 use season bear labels that reflect the measures outlined in this document.

¹ The USEPA Reregistration Eligibility Decision (RED) for endosulfan (EPA 738-R-02-013, November 2002) is available from the Chemical Status List on the Office of Pesticide Programs webpage at www.epa.gov/pesticides/reregistration

² Re-evaluation Note REV2002-04, *Endosulfan*, 9 August 2002.

2.0 Proposed interim measures

2.1 Proposed measures pertaining to dietary risk

For risks associated with exposure to endosulfan through diet, the USEPA concluded that acute risk estimates from exposure to food exceeded that Agency's level of concern for some population subgroups. To mitigate this risk, the USEPA has proposed deleting endosulfan use on the following commodities that were considered high contributors to exposure: succulent beans, succulent peas, spinach and grapes. Based on this mitigation, the acute risk from food exposure falls below the USEPA's level of concern.

The PMRA is proposing that endosulfan use on succulent beans, succulent peas, spinach and grapes also be discontinued in Canada. It is not anticipated that risks from Canadian dietary exposure to endosulfan will be greater than those calculated by the USEPA for the U.S. for the following reasons.

- The PMRA and the USEPA have harmonized acute and chronic reference doses for endosulfan.
- All agricultural commodities registered for Canadian use (following implementation of the measures proposed in this document) are registered in the U.S.
- In the U.S., endosulfan is registered for use on over 30 additional agricultural commodities that are not registered in Canada.

Removing the use on endosulfan on succulent beans, succulent peas, spinach and grapes in Canada is a precautionary approach taken by the PMRA to address potential dietary risks to the Canadian population.

2.2 Proposed measures pertaining to occupational and environmental risks

After consideration of the USEPA risk management plan and its relevance to the Canadian situation, the PMRA is proposing to implement the following measures, as a precautionary approach to reduce occupational and environmental exposure to endosulfan:

- a) Packaging of wettable powder formulation must be in water soluble bags.
- b) Delete the use of the wettable powder formulation on tomatoes, sweet corn, beans and peas.
- c) Require closed cabs for airblast applications to pome fruit and stone fruit.
- d) Use a maximum rate of 0.6 g a.i./L when endosulfan is applied with high pressure handwand equipment.

- e) Establish the following re-entry intervals (REIs) for workers entering areas treated with the emulsifiable concentrate formulation:
- 4 days for Brussels sprouts, broccoli, cabbages and cauliflower;
 - 17 days for sweet corn; and
 - 48 hours for all other crops.
- f) Establish the following REIs for workers entering areas treated with the wettable powder formulation:
- 3 days for cucumbers, melons, pumpkins and squashes;
 - 4 days for celery, lettuce, apples, apricots, cherries, peaches, pears, plums, turnips, rutabagas, and ornamental trees and ornamental shrubs;
 - 5 days for strawberries;
 - 9 days for Brussel sprouts, broccoli, cabbages and cauliflower; and
 - 48 hours for all other crops.
- g) The maximum rate per application must not exceed:
- 2.8 kg a.i./ha for pome fruit, stone fruit, ornamental trees and shrubs; and
 - 1.1 kg a.i./ha for strawberries.
- h) The maximum seasonal application rate must not exceed:
- 1.7 kg a.i./ha for corn;
 - 2.2 kg a.i./ha for melon, cucumber, squash, pumpkin, tomatoes, pepper, eggplant, potatoes, beans, peas and strawberries;
 - 2.8 kg a.i./ha for apples, pears, apricots, peaches, plums and cherries; and 1.1 kg a.i./ha for celery.
- i) The maximum number of applications per season must not exceed:
- 4 for melons, cucumbers, squashes, pumpkins, potatoes and tomatoes;
 - 2 for broccoli, Brussels sprouts, cauliflower, cabbages, beans, peas, lettuce, eggplants, peppers and strawberries; and
 - 1 for corn.
- j) The following personal protective equipment (PPE) is to be used to reduce exposure to workers:
- Workers using high-pressure handwand equipment
Wear coveralls over a long shirt and long pants, chemical-resistant footwear, chemical-resistant gloves and an approved organic vapour respirator during application. In addition to this protective equipment, wear a chemical-resistant apron during mixing/loading, clean-up, repair and all other handling activities.
 - Applicators using airblast equipment on pome and stone fruit crops
Applicators using airblast equipment on pome and stone fruit crops must use enclosed cabs and wear a long-sleeved shirt, long pants shoes plus socks and either an approved organic vapour respirator or an enclosed cab

that provides as much respiratory protection as an organic vapour respirator. When exiting the cab in the treated area, applicator must wear coveralls, chemical-resistant footwear, chemical-resistant headgear and an approved organic vapour respirator. Those PPE must be taken off before re-entering the cab and stored in a chemical-resistant container to prevent contamination of the inside of the cab.

- Early entry to treated areas
If early entry into treated areas is required (i.e., prior to the specified REI), workers must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks and goggles or a face shield.
- All other workers
Wear a long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves and an approved organic vapour respirator during mixing/loading, clean-up, repair, application and all other handling activities. In addition to this protective equipment, wear a chemical-resistant apron during mixing/loading, application of dips, clean-up and repair activities.

- k) To mitigate contamination of aquatic environments:
- Require a 10 metre vegetative buffer strip be maintained between all areas treated with endosulfan and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and estuarine/marine habitats.
 - Require a 30 metre buffer zone between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and estuarine/marine habitats.

[Note: endosulfan products are currently restricted to application with ground equipment].

2.3 Removal of unsupported uses

Certain uses for endosulfan were unsupported by registrants in the U.S. and cancelled in that country prior to publication of the USEPA RED document. The registrants of technical grade endosulfan for Canada (Bayer CropScience Inc. and Makhteshim-Agan of North America Inc.) have withdrawn support for the following similar uses in Canada:

- alfalfa, clover
- field corn
- sunflower
- sugarbeet
- greenhouse ornamentals
- residential uses

These uses of endosulfan will be phased out.

3.0 Consultation

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 measures for endosulfan. Comments received as indicated will be considered before finalizing the interim measures.

List of abbreviations

| | |
|-------|---|
| a.i. | active ingredient |
| EC | emulsifiable concentrate |
| g | gram |
| ha | hectare |
| kg | kilogram |
| L | litre |
| PHI | pre-harvest interval |
| PMRA | Pest Management Regulatory Agency |
| PPE | personal protective equipment |
| RED | Reregistration Eligibility Document |
| REI | re-entry interval |
| U.S. | United States |
| USC | Use-site Category |
| USEPA | United States Environmental Protection Agency |
| WP | wettable powder |

Appendix I Proposed interim measures for endosulfan

Note: This appendix summarizes the use patterns and new use limitations for endosulfan following implementation of the measures proposed in this document. These uses will serve as the basis for completing the re-evaluation assessments for endosulfan.

| | |
|-----------------------------|---|
| COMMON NAME: | endosulfan |
| CHEMICAL NAME: | 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide |
| FORMULATION TYPE: | EC emulsifiable concentrate WP wettable powder |
| USE-SITE CATEGORIES: | Greenhouse Food Crops (USC 5) Terrestrial Food Crops (USC 14) Structural (USC 20) Ornamentals Outdoor (USC 27) |

Engineering controls for wettable powder formulations:

- All wettable powder formulations are to be packaged in water soluble bags.

Personal Protective Equipment:

- Workers using high-pressure handwand equipment
Wear coveralls over a long shirt and long pants, chemical-resistant footwear, chemical-resistant gloves, and an approved organic vapour respirator during application. In addition to this protective equipment, wear a chemical-resistant apron during mixing/loading, clean-up, repair and all other handling activities.
 - Applicators using airblast equipment on pome and stone fruit crops
Applicators using airblast equipment on pome and stone fruit crops must use enclosed cabs and wear a long-sleeved shirt, long pants, shoes plus socks and either an approved organic vapour respirator or an enclosed cab that provides as much respiratory protection as an organic vapour respirator. When exiting the cab in the treated area, applicator must wear coveralls, chemical-resistant footwear, chemical-resistant headgear and an approved organic vapour respirator. Those PPE must be taken off before re-entering the cab and stored in a chemical-resistant container to prevent contamination of the inside of the cab.
 - Early entry in the treated area
If entry into treated areas is required (i.e., prior to the specified REI), workers must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks and goggles or a face shield.
-

d) All other workers

Wear a long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves and an approved organic vapour respirator during mixing/loading, clean-up, repair, application and all other handling activities. In addition to this protective equipment, wear a chemical-resistant apron during mixing/loading, application of dips, clean-up and repair activities.

To mitigate contamination of aquatic environments:

- a) Require a 10 metre vegetative buffer strip be maintained between all areas treated with endosulfan and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and estuarine/marine habitats.
- b) Require a 30 metre buffer zone between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and estuarine/marine habitats.

[Note: endosulfan products are currently restricted to application with ground equipment].

Uses for endosulfan:

The following are the permitted uses for endosulfan following implementation of the interim measures presented in this document:

| Site | Formulation and rate (g a.i./ha, unless otherwise stated) ¹ | Re-entry interval ^{2, 3} |
|-------------------------------|---|-----------------------------------|
| USC 5 (Greenhouse Food Crops) | | |
| cucumber, tomato | WP and EC formulations: Apply 500–750 g a.i./ha. (Do not exceed 600 g a.i./1000 L of water for application with high pressure handwand equipment.) | WP and EC formulations: 48 hours |
| lettuce, pepper | EC formulation: Apply 600 g a.i./ha. (Do not exceed 600 g a.i./1000 L of water for application with high pressure handwand equipment.) | EC formulation: 48 hours |

| Site | Formulation and rate (g a.i./ha, unless otherwise stated) ¹ | Re-entry interval ^{2,3} |
|---|--|--|
| USC 14 (Terrestrial Food Crops) | | |
| apple, pear (eastern Canada) | WP formulation: Apply 500–750 g a.i./1000 L of water. For white apple leafhopper and potato leafhopper, apply 1300 g a.i./ha. Do not exceed 2800 g a.i./ha per season. | WP formulation: 4 days |
| apple, pear (western Canada) | WP formulation: Apply 375–500 g a.i./1000 L of water. For white apple leafhopper and potato leafhopper, apply 1300 g a.i./ha. Do not exceed 2800 g a.i./ha per season. | WP formulation: 4 days |
| apricot, cherry, plum, peach | Do not exceed 2800 g a.i./ha per season. <u>Foliar treatment</u> WP formulation: Apply 375–750 g a.i./1000 L of water. <u>Trunk/limb treatment</u> WP and EC formulations: Apply 700–750 g a.i./1000 L of water to bark on trunk and scaffold limbs. Do not exceed 600 g a.i./1000 L for application with high pressure handwand equipment. | WP formulation: 4 days EC formulation: 48 hours |
| peach (pre-plant treatment) | EC formulation: Dip roots and crown in a solution of 500 g a.i./100 L water prior to planting. | EC formulation: 48 hours |
| bean (do not apply to succulent beans) | EC formulation: Apply 600–1000 g a.i./ha/application. Do not exceed 2 applications per season. | EC formulation: 48 hours |
| broccoli, Brussels sprout, cabbage, cauliflower | WP and EC formulations: Apply 500–875 g a.i./ha/application. Do not exceed 2 applications per season. | WP formulation: 9 days EC formulation: 4 days |
| lettuce (field, head) | WP and EC formulations: Apply 800–875 g a.i./ha/application. Do not exceed 2 applications per season. | WP formulation: 4 days EC formulation: 48 hours |
| celery | WP and EC formulations: Apply 800–875 g a.i./ha/application. Do not exceed 1100 g a.i./ha per season. | WP formulation: 4 days EC formulation: 48 hours |
| corn (sweet) | EC formulation: Apply 1100–1700 g a.i./ha/application. Do not apply more than once per season. | EC formulation: 17 days |

| Site | Formulation and rate (g a.i./ha, unless otherwise stated) ¹ | Re-entry interval ^{2,3} |
|---|--|--|
| cucumber, squash, melon, pumpkin | WP and EC formulation: Apply 500–600 g a.i./ha/application. Do not exceed 2200 g a.i./ha/season. Do not exceed 4 applications per season. | WP formulation: 3 days EC formulation: 48 hours |
| eggplant, pepper | WP and EC formulations: Apply 500–1200 g a.i./ha/application. Do not exceed 2200 g a.i./ha per season. Do not exceed 2 applications per season. | WP formulation: 48 hours EC formulation: 48 hours |
| tomato | EC formulation: Apply 600–1200 g a.i./ha/application. Do not exceed 2200 g a.i./ha per season. Do not exceed 4 applications per season. | EC formulation: 48 hours |
| pea (canning, seed) (do not apply to succulent pea crops) | EC formulation: Apply 600–800 g a.i./ha/application. Do not exceed 2 applications per season. | EC formulation: 48 hours |
| potato | WP and EC formulations: Apply 500–875 g a.i./ha/application. Do not exceed 2200 g a.i./ha per season. Do not exceed 4 applications per season. | WP formulation: 48 hours EC formulation: 48 hours |
| rutabaga, turnip | WP and EC formulations: Apply 800–875 g a.i./ha/application. Do not apply more than 2 applications per season. | WP formulation: 4 days EC formulation: 48 hrs. |
| strawberry | WP and EC formulations: Apply 1000–1100 g a.i./ha/application. Do not exceed 2200 g a.i./ha per season. Do not apply more than 2 applications per season. | WP formulation: 5 days EC formulation: 48 hours |
| USC 20 (Structural) | | |
| food processing plant (outdoor areas) | WP formulation: Apply 250 g a.i./22.5 kg bait. | N/A |

| Site | Formulation and rate (g a.i./ha, unless otherwise stated) ¹ | Re-entry interval ^{2, 3} |
|------------------------------|---|--|
| USC 27 (Ornamentals Outdoor) | | |
| ornamental trees and shrubs | WP and EC formulations: Apply 500–750 g a.i./1000 L of water. Do not exceed 600 g a.i./1000 L for application with high pressure handwand equipment. Do not exceed 2800 g a.i./ha. | WP formulation: 4 days EC formulation: 48 hours |

¹ Rate range for a given site represents a summary of all registered rates for endosulfan products, regardless of formulation type. Registered rates for specific products may differ, but fall within the specified range.

² Do not enter or allow worker entry into treated areas during the REI.

³ Where proposed REI is longer than existing pre-harvest interval (PHI), the PHI will be increased to match the REI.