



Re-evaluation Decision Document

RRD2004-13

Fenitrothion

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of fenitrothion is now complete.

Based on the review of available information, the Pest Management Regulatory Agency (PMRA) has determined that fenitrothion is acceptable for continuing registration, provided that mitigation measures are implemented and additional data requirements are addressed.

This RRD summarizes comments made to the PMRA in response to the Proposed Acceptability for Continuing Registration (PACR) document PACR2003-08, *Re-evaluation of Fenitrothion*, published on 14 July 2003. This document also provides the PMRA's response to the comments and presents the regulatory decisions resulting from the re-evaluation of fenitrothion.

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1.0 Introduction

The re-evaluation of the active ingredient fenitrothion, an insecticide produced by Sumitomo Chemical Company Ltd., and the associated uses on various insect pests in forestry and woodlands, has been completed by the PMRA.

2.0 Background

The PMRA announced in June 1999 that organophosphate active ingredients, including fenitrothion, were subject to re-evaluation¹. The purpose of this RRD is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of fenitrothion is now complete.

On 14 July 2003, the PMRA published PACR2003-08, *Re-evaluation of Fenitrothion*, for consultation on the proposed regulatory decision for fenitrothion. The PMRA received a single response from a federal government department regarding this PACR.

This RRD summarizes the comments received regarding PACR2003-08 and the PMRA's response to the comments (Appendix I). This document also outlines the regulatory decisions resulting from the re-evaluation of fenitrothion.

3.0 Regulatory decision

The PMRA reviewed the comments received and has concluded that no substantial changes are required to the proposed regulatory decision in PACR2003-08. Label statements that were provided in the PACR have been revised and are presented in Appendix II of this document. The PMRA has concluded that the use of fenitrothion and its associated end-use product in accordance with the label, does not entail an unacceptable risk of harm to human health or the environment. Therefore, it is acceptable for continuing registration, provided that the mitigation measures described in Appendix II are implemented and additional data requirements are addressed.

3.1 Conditions of continued use

Based on the assessments for fenitrothion, the end-use product label must be revised as described in Section 8.0 of the PACR and the attached Use Standard (Appendix II). The registrant is required to submit an application to amend their registration in accordance with Appendix II within 90 days of the finalization of this decision, i.e., the date of PMRA's decision letter to the registrant. Product with the existing label can continue to be sold and distributed by the registrant for 18 months after the decision, after which all product sold or distributed by the registrant must bear the new label requirements.

¹ Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*

3.2 Additional data requirements

Section 9.0 of PACR2003-08 outlined the data requirements for continued registration of fenitrothion that the registrant is required to address. The PMRA will send a letter to the registrant outlining the specific requirements for continuing registration.

Appendix I Comments and responses

Comments were received by the PMRA from Environment Canada concerning PACR2003-08, *Re-evaluation of Fenitrothion*, published on 14 July 2003. The PMRA has consolidated and summarized the comments received and provides responses to the comments below.

1.0 Re-evaluation process

1.1 Comment on consultation

“The PACR2003-08 indicated that Environment Canada had been contacted for information pertinent to this review; however, there had not been recent contact.”

Response

PACR2003-08 was based on the special review of fenitrothion that was initiated in 1990 and completed in 1995 (a Discussion Document² and a Decision Document³ were published). No new environmental information or data was reviewed. As part of that special review, a technical review team, consisting of scientific evaluators from Environment Canada, Natural Resources Canada/Canadian Forest Service, and the Department of Fisheries and Oceans, reviewed all available information on both the hazards to the environment and the value of fenitrothion use in Canadian forestry.

1.2 Comment on data used in assessment

“For the environmental assessment, it was difficult to comment on the document, which provided conclusions, without also being provided the data set that was used to draw those conclusions.”

Response

The conclusions in the document are the same as those from the special review (Decision Document E95-01). As indicated in the PACR2003-08, the environmental risk assessment was based on the detailed technical report *Fenitrothion Risk Assessment* (Pauli, B.D., S.B. Holmes, R.J. Sebastien and G.P. Rawn. 1993. Technical Report Series No. 165. Canadian Wildlife Service [Headquarters], Environment Canada, Ottawa. XVI. 75 pp). The authors of the report were the technical review team for the special review of fenitrothion initiated in 1990.

² Discussion Document D93-01 (2 April 1993), *Registration Status of Fenitrothion Insecticide*

³ Decision Document E95-01 (13 April 1995), *Registration Status of Fenitrothion Insecticide*

2.0 Environmental effects

2.1 Comment on potential environmental effects

“It appears that this review has not resulted in a label expansion, which would have been of substantive concern; however, it seems that the uncertainties with regard to potential effects have increased since the last review, particularly in the area of endocrine effects, which are known in mammals, but have not been investigated in wildlife. Those coupled with the known songbird and pollinator effects, which are not mitigatable, would seem to suggest a more precautionary approach should be taken. The statement in the PACR2003-08 that ‘. a complete understanding of the impact of spraying with fenitrothion on the forest ecosystem due to effects on forest pollinators is not possible at this time’ would seem in itself to warrant such a precautionary approach.”

Response

The decision in the fenitrothion special review, which concluded in 1995 (Decision Document E95-01), was that given

- the smaller area of use,
- the lower application rate,
- the later timing of application and
- the lack of alternatives for some forest pests,

the aerial application of fenitrothion for the control of minor forest pests and for minor uses, such as in seed orchards, was acceptable provided that treatment blocks were < 500 ha and buffer zones were observed to protect all specified aquatic habitats. Given the smaller areas of use, all ground applications of fenitrothion in forestry were also considered to be acceptable. The current re-evaluation of fenitrothion has concluded that the risks are acceptable if the proposed mitigative measures are observed. Uncertainties regarding endocrine effects in wildlife were a consideration in this decision.

2.2 Comment on calculations of surface water concentrations

“Environment Canada has also calculated the surface water concentrations, which have been measured in small ponds to be 600 times the aquatic invertebrate LC₅₀, not 200 times as stated.”

Response

Mean surface water concentrations of fenitrothion in small ponds directly oversprayed with fenitrothion ranged from 20 to 1500 µg/L. The concentration of 1500 µg/L is 174 times greater than the LC₅₀ for *Daphnia magna* (8.6 µg/L), which was used to set buffer zones.

3.0 Value

3.1 Comment on cost benefit analysis and availability of alternatives

“PACR2003-08 did not present any quantitative cost benefit analyses for the continued use of fenitrothion. It is noted that there are registered alternatives.”

Response

The PMRA’s decisions are guided by a risk management decision-making framework according to which health and environmental risks and value of a product must be acceptable for it to be registered. To maintain the registration of fenitrothion, it is sufficient that the risks and value have been determined to be acceptable; under the current *Pest Control Products Act*, there is no requirement to consider the availability of more preferable alternatives.

A list of alternatives to fenitrothion was presented in the PACR2003-08. A more comprehensive list of alternatives is presented in Table 3.1.1, with uses separated into ground and aerial applications. It is apparent that there is a paucity of products registered for use on forestry sawfly defoliators, especially those to be applied by air.

Table 3.1.1 Registered alternatives to fenitrothion (as of 2 October 2003)

SITE	PEST	REGISTERED ALTERNATIVES IN CANADA ^a	
		GROUND APPLICATION ^b	AERIAL APPLICATION ^b
Christmas tree plantations (pests not listed on label but are assumed to include those listed)	fall cankerworm	11: <i>Bacillus thuringiensis</i> (Bt)	11: Bt
	eastern hemlock looper, western hemlock looper	3: permethrin 11: Bt 18: tebufenozide	11: Bt 18: tebufenozide
	jack pine budworm	11: Bt 18: tebufenozide	11: Bt 18: tebufenozide
	spruce budworm	1A: carbaryl, methomyl 1B: dimethoate, trichlorfon 3: permethrin 11: Bt 18: tebufenozide	11: Bt 18: tebufenozide
	sawflies	1A: carbaryl (pine sawflies only) 1B: acephate (limited to redheaded pine sawfly, European pine sawfly and yellowheaded spruce sawfly), dimethoate (limited to redheaded pine sawfly and blackheaded pine sawfly) 3: permethrin	1B: trichlorfon (yellowheaded spruce sawfly in forest plantations or young regeneration situations only)
Forest lands, forest plantings, tree (woodland)	fall cankerworm	11: Bt	11: Bt
	eastern hemlock looper, western hemlock looper, jack pine budworm, spruce budworm	11: Bt 18: tebufenozide	11: Bt 18: tebufenozide
	sawflies	1A: carbaryl (pine sawflies only) 1B: acephate (limited to redheaded pine sawfly, European pine sawfly and yellowheaded spruce sawfly), dimethoate (limited to redheaded pine sawfly and blackheaded pine sawfly)	1B: trichlorfon (yellowheaded spruce sawfly in forest plantations or young regeneration situations only)
Tree (nursery; pests not listed on label but are assumed to include those listed)	fall cankerworm	11: Bt	11: Bt
	eastern hemlock looper, western hemlock looper, jack pine budworm	11: Bt 18: tebufenozide	11: Bt 18: tebufenozide
	sawflies	1A: carbaryl (pine sawflies only) 1B: acephate (limited to redheaded pine sawfly, European pine sawfly and yellowheaded spruce sawfly), dimethoate (limited to redheaded pine sawfly and blackheaded pine sawfly) 3: permethrin	1B: trichlorfon (yellowheaded spruce sawfly in forest plantations or young regeneration situations only)
	spruce budworm	3: permethrin 11: Bt 18: tebufenozide	11: Bt 18: tebufenozide

^a Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*

^b 1A = acetylcholinesterase inhibitors (carbamates);
1B = acetylcholinesterase inhibitors (organophosphates);
3 = sodium channel modulators (diphenylethanes or synthetic pyrethroids or pyrethrins);
11 = microbial disruptors of insect mid-gut membranes (Bt microbials);
18 = ecydone agonist (benzoic acid hydrazide or botanical).

NOTE: Carbaryl, methomyl, acephate, dimethoate and trichlorfon are presently under re-evaluation.

4.0 Regulatory decision

4.1 Comment on decision on aerial application in forests

“It is understood that there will be no aerial application to forests (> 500 ha) and woodlands aerial spraying will be confined to 500 ha or less. It should be indicated that the total spray program should be 500 ha or less and that the restriction does not simply apply to block sizes. Environment Canada wishes to reinforce their concern regarding large-scale aerial application of this chemical for any pest species.”

Response

The decisions on the area allowed to be treated for aerial applications were agreed upon during the special review of fenitrothion by Environment Canada, the Department of Fisheries and Oceans, Natural Resources Canada as well as Agriculture and Agri-Food Canada. The decision was to restrict block sizes for aerial applications to < 500 ha, not to restrict the total spray program to < 500 ha. The current re-evaluation of fenitrothion supports this decision.

5.0 Labelling

5.1 Comment on buffer zone labelling

“The aquatic buffer zones that are proposed are appropriate from our perspective for small lentic water bodies; however, small lotic systems may still be at risk. It is recognized that it is difficult to identify small lotic systems; however, it is suggested that current GPS systems and ground truthing of blocks prior to aerial spraying make this possible, particularly in areas that are 500 hectares or less. It is also recommended that wind speed limitations should be provided to make those buffer zones effective.”

Response

The words “and lotic” will be added to the label text to ensure the protection of small lotic (running) waterbodies as well as small lentic (standing) water bodies. The statement “Do not apply when wind speed is greater than 16 km/h at flying height at the site of application.” will also be added to the label to make the buffer zones effective.

5.2 Comment on environmental precautions

“The Environmental Precautions in the PACR2003-08 Use Standard indicate that applications may adversely affect birds in rangeland treatment areas - that probably should be forest areas.”

Response

The wording will be changed to read “forest areas”.

5.3 Comment on disposal statement

“It is recommended that the label contain specific directions on container decontamination and disposal, as well as environmental decontamination in the case of spills.”

Response

The Use Standard in PACR2003-08 listed the proposed changes to uses and conditions of use of fenitrothion resulting from re-evaluation only. It was noted that this did not identify all label requirements for such products. Registrants were referred to the PMRA Registration Handbook (www.hc-sc.gc.ca/pmra-arla/) for further guidance on label requirements for pest control products. This statement on the Use Standard has since been updated for better clarity (Appendix II).

Appendix II Use standard for RESTRICTED class products containing fenitrothion

Note: The information in this appendix summarizes the acceptable uses, limitations and minimum Personal Protective Equipment (PPE) for restricted class products containing fenitrothion, 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: fenitrothion

CHEMICAL NAME: *O,O*-dimethyl *O*-4-nitro-*m*-tolyl phosphorothioate

FORMULATION TYPE: (EC) emulsifiable concentrate

USE SITE CATEGORIES: USC# 04, Forests and Woodlots

NOTE: All uses of fenitrothion fall under the RESTRICTED classification.

NATURE OF RESTRICTION: This product is to be used only in the manner authorized; contact local pesticide regulatory authorities about use permits that may be required.

NOTE: Consult federal and provincial forestry regulatory officials for specific recommendations regarding:

1. Timing of application with regard to the development of the insect pest.
2. Mixing an application of this product in the spray equipment.

Federal or provincial forestry or regulatory officials may recommend inclusion of a water-soluble dye for purposes of monitoring spray deposit.

LIMITATIONS:

Refer to Acceptable Uses for Fenitrothion.

For aerial applications, only closed mixing loading systems are to be used.

TOXICOLOGICAL INFORMATION:

Fenitrothion is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, muscle cramps and diarrhea in more serious poisonings. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If a person is exposed, plasma and red blood cell cholinesterase tests may indicate the degree of exposure (baseline data are useful). Atropine,

only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician.

PRECAUTIONARY STATEMENTS:

KEEP OUT OF REACH OF CHILDREN

Fatal or poisonous if swallowed. Fatal or harmful if absorbed through the skin. Harmful if inhaled. May irritate eyes, nose, throat and skin. DO NOT get in eyes or on skin and avoid contact with clothing. Avoid breathing spray mist.

When handling the product, and during mixing, loading, clean-up and repairs, the following PPE must be worn: chemical resistant coveralls over long-sleeved shirt, long pants, chemical resistant gloves and protective eyewear.

When applying the product (without using a closed cab or cockpit), the following PPE must be worn: chemical resistant coveralls over long-sleeved shirt, long pants, chemical resistant gloves and a chemical resistant hood.

When applying the product using a closed cab or cockpit, the following PPE must be worn: cotton coveralls over long-sleeved shirt and long pants.

Wash face and hands thoroughly with soap and water after handling and before eating, drinking, smoking or using toilet. Remove contaminated clothes and laundry before re-use. Take a shower immediately after work. Store and wash all protective clothing separately from household laundry. Follow the manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions for washables, use detergent and hot water.

Do not mix, load, apply or handle the product for more than 30 consecutive days.

Workers conducting re-entry activities that involve significant foliar contact within one month of application must wear chemical resistant gloves and cotton coveralls.

Bystanders should be protected by using good pesticide application practices and by applying 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. Take into consideration wind speed, wind direction, temperature, application equipment and sprayer settings used for application.

ENVIRONMENTAL PRECAUTIONS:

Undiluted product may be toxic to wildlife. Exercise caution in handling the contents of the container, and in disposing of the container to prevent exposure of wildlife to the undiluted product. Do not contaminate water by cleaning of equipment or disposal of wastes. Consult the provincial regulatory agency for information on the cleanup of spills. Observe buffer zones specified under Acceptable Uses for Fenitrothion.

This pesticide is toxic to birds. Applications may adversely affect birds in forest treatment areas. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

ACCEPTABLE USES FOR FENITROTHION:**RESTRICTED USES:**

NATURE OF RESTRICTION: This product is to be used only in the manner authorized; contact local pesticide regulatory authorities about use permits that may be required.

DO NOT apply more than 2 applications per season.

A minimum interval of 4 days between applications is required.

DO NOT apply during periods of dead calm or when winds are gusty.

Airblast application: **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application: **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the ASAE very fine to fine classification.

SITE	PESTS	RATE (g a.i./ha)	APPLICATION
Use Site Category 04, Forests and Woodlots			
FORESTS (>500 ha)	eastern hemlock looper, spruce budworm, western hemlock looper	140–210	GROUND APPLICATION: Apply as a low-volume or ultra-low volume spray or as an emulsion in sufficient water for good coverage. Make a single application of 210 g ai/ha or two applications 4–6 days apart of 140–210 g ai/ha. For hemlock looper, apply before the fourth instar. For spruce budworm, apply as soon as insects are noted, and repeat about one week later, just before the peak of the fourth instar. When used as described for spruce budworm, spruce budmoth may also be controlled. LIMITATIONS: Use no more than 210 g ai/ha for any one application or a total of 420 g ai/ha applied in two treatments.
	fall cankerworm, jack pine budworm, sawflies	140–210	GROUND APPLICATION: Apply as a low-volume or ultra-low volume spray or as an emulsion in sufficient water for good coverage. Make a single application of 210 g ai/ha or two applications 4–6 days apart of 140–210 g ai/ha. For jack pine budworm, apply between the third and sixth instars. For sawflies or fall cankerworm, apply as soon as larvae appear. For swain jack pine sawflies, apply at the peak of emergence of the second instar. LIMITATIONS: Use no more than 210 g ai/ha for any one application or a total of 420 g ai/ha applied in two treatments.
WOODLANDS (≤500 ha) Includes: woodlots, tree nurseries, Christmas tree plantations and minor uses such as in seed orchards	fall cankerworm, jack pine budworm, sawflies	140–210	AERIAL APPLICATION: Apply as a low-volume or ultra-low volume spray or as an emulsion in sufficient water for good coverage. Make a single application of 210 g ai/ha or two applications 4–6 days apart of 140–210 g ai/ha. For jack pine budworm, apply between the third and sixth instars. For sawflies or fall cankerworm, apply as soon as larvae appear. For swain jack pine sawflies, apply at the peak of emergence of the second instar. LIMITATIONS: Use no more than 210 g ai/ha for any one application or a total of 420 g ai/ha applied in two treatments. All aerial application of fenitrothion must be conducted using light (up to 5670 kg) fixed-winged aircraft or rotary-wing aircraft, or aircraft (e.g., helicopter) equipped with electronic guidance systems (e.g., Global Positioning System).
WOODLANDS (≤500 ha) Includes: woodlots, tree nurseries and Christmas tree plantations	eastern hemlock looper, fall cankerworm, sawflies, spruce budworm, western hemlock looper	140–210	GROUND APPLICATION: Apply as a low-volume or ultra-low volume spray or as an emulsion in sufficient water for good coverage. Make a single application of 210 g ai/ha or two applications 4–6 days apart of 140–210 g ai/ha. For hemlock looper, apply before the fourth instar. For jack pine budworm, apply between the third and sixth instars. For sawflies or fall cankerworm, apply as soon as larvae appear. For swain jack pine sawfly, apply at the peak of emergence of the second instar. For spruce budworm, apply as soon as insects are noted and repeat about one week later, just before the peak of the fourth instar. When used as described for spruce budworm, spruce budmoth may also be controlled.

Buffer zones

The buffer zones specified in the table below are required between the downwind point of direct application and the closest edge of sensitive aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands), and estuarine/marine habitats.

For aerial application to forests, sensitive aquatic habitats include all rivers designated as double-sided, as well as all lentic (standing) and lotic (running) water bodies, including impoundments, beaver ponds and bog ponds, that appear on the most recent 1:50,000 topographic map of the area to be treated, or as identified by more up-to-date data (e.g., GPS systems) in the particular jurisdiction and approved by provincial regulatory authorities. Lentic and lotic water bodies that do not appear on a 1:50,000 topographic map of the treatment area, or a more up-to-date data system, but are visible from the air during pretreatment reconnaissance flights, must also be considered sensitive aquatic habitats.

Method of application	Buffer zone (metres) required for the protection of aquatic habitat
Airblast	10
Fixed wing aircraft	380
Helicopter	230