Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2003-08

Re-evaluation of Fenitrothion

The purpose of this document is to inform the registrant, pesticide regulatory officials, and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of fenitrothion pursuant to Section 19 of the Pest Control Products Regulations. This Proposed Acceptability for Continuing Registration (PACR) document provides a summary of the data and information reviewed, and the rationale for the proposed regulatory decision.

By way of this document, the PMRA is soliciting comments from interested parties on the proposed regulatory decision for fenitrothion. 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 decision. All comments should be forwarded to the Publications Coordinator at the address below.

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Foreword

The re-evaluation of the active ingredient fenitrothion and the associated end-use product, an insecticide developed by Sumitomo Chemical Company, Ltd., for use on various insect pests in forestry and woodlands, has been completed by the Pest Management Regulatory Agency (PMRA).

The PMRA announced in June 1999 that organophosphate active ingredients, including fenitrothion, were subject to re-evaluation under authority of Section 19 of the Pest Control Products (PCP) Regulations.[1]

The PMRA has carried out an assessment of available information and has concluded that the use of fenitrothion and associated end-use product does not entail an unacceptable risk of harm to human health or the environment pursuant to Section 20 of the PCP Regulations, provided that the mitigation measures described in this document are implemented.

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 re-evaluation decision for these products.

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

Table of Contents

1.0 Purpose

The Pest Management Regulatory Agency (PMRA) announced in June 1999 that organophosphate active ingredients, including fenitrothion, were subject to re-evaluation under authority of Section 19 of the Pest Control Products (PCP) Regulations.[2] The purpose of this document is to inform the registrant, pesticide regulatory officials and the Canadian public that the PMRA has completed a review of fenitrothion. The document includes a human health assessment, an environmental assessment and information on the value of fenitrothion to pest management in Canada. By way of this document, the Agency is soliciting comments from interested parties on the proposed regulatory decision for fenitrothion.

2.0 General background on re-evaluation

The PMRA is re-evaluating, under Section 19 of the Regulations pursuant to the *Pest Control Products Act* (PCPA), all pesticides, both active ingredients and formulated end-use products, that were registered prior to 1995 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, outlines the details of the re-evaluation activities. Fenitrothion is under reassessment in the United States (U.S.) as a result of the *Food Quality Protection Act* (FQPA) and therefore is being re-evaluated by the PMRA under Program 3. The following components are addressed and considered in this re-evaluation:

Risk to human health: The initial focus of the re-evaluation of a pest control product in Program 3 is the risk to human health. As indicated in Regulatory Directive DIR2001-03, the reassessment in Program 3 pays particular attention to:

- pest control products with a common mechanism of toxicity,
- aggregate exposure to a pesticide arising from its residues in food and in drinking water, and from non-occupational exposure, such as from treatments in and around homes, and
- susceptibility and exposure of infants and children that may be different from that of adults during critical developmental stages.

The re-evaluation of risks to human health also includes a re-examination of the acceptability of risks resulting from occupational exposure. Once the reassessments of all the individual organophosphates have been completed, a cumulative assessment of all the remaining uses of organophosphates will be conducted.

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[2] Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*

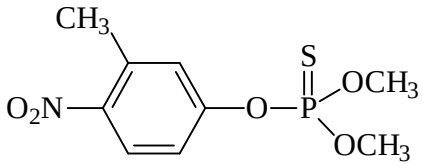
Risk to the environment: The environmental assessments will be tiered, with refined environmental risk assessments taking place only on those active ingredients, products or uses that pass the cumulative health risk assessment or, for unique mechanisms of toxicity, that are acceptable from a human health perspective. At the first tier, based on an identification of hazards to non-target organisms, measures to reduce environmental exposures will be implemented where warranted. These measures may include removing uses that are obsolete, reducing the number of applications, requiring buffer zones to protect sensitive habitats and taking regulatory action against uses that have been determined to be extremely high risk to organisms in the environment. In general, uses that remain after the first tier assessment will be revisited when the results of refined environmental assessments are available.

Value: The PMRA seeks to understand, as early as possible in the process, the current uses of the products and their importance for pest management. The PMRA relies to a great extent on provincial and territorial government input. Registrants and users are also an important source of information. Environment Canada, the Department of Foreign Affairs and International Trade, the Canadian Food Inspection Agency (CFIA) and Agriculture and Agri-Food Canada are also contacted in the process for information specific to their areas of expertise.

The outcome of the re-evaluation of a pesticide, including proposed risk mitigation measures, will be published in a consultation document at the end of the aggregate human health risk assessment and the first tier environmental assessment. In some cases, the PMRA will implement changes in regulatory status of products prior to public consultation, especially where the PMRA considers risk mitigation not effective or practical, or where registrants have opted for voluntary discontinuation of sale of products.

3.0 Re-evaluation of fenitrothion

Fenitrothion



Chemical Name:
O,O-dimethyl O-4-nitro-m-tolyl phosphorothioate

Fenitrothion is one of the 27 organophosphate insecticides subject to re-evaluation in Canada. The re-evaluation of fenitrothion was announced in Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*. Fenitrothion is registered by Sumitomo Chemical Co., Ltd. and is sold as a Restricted Class insecticide, for forestry and woodland use only. Fenitrothion has contact activity on insects. Like other organophosphates, fenitrothion inhibits acetylcholinesterase enzyme, interrupting the transmission of nerve impulses.

In October 1990, the Plant Industry Directorate of Agriculture and Agri-Food Canada, the federal department responsible for administering the *Pest Control Products Act* prior to the formation of the PMRA under Health Canada in April, 1995, initiated a Special Review of fenitrothion, which focussed on the potential risks to the environment and the value of fenitrothion use in Canadian forestry. A Discussion Document (Registration Status of Fenitrothion Insecticide)[3] was released for public consultation in April, 1993, and a Decision Document (Registration Status of Fenitrothion Insecticide)[4] was published in April, 1995 to present the regulatory decision and rationale on the special review and to respond to comments received from the general public regarding the Discussion Document. The outcome of the Special Review was that aerial uses for control of major forest pests (spruce budworm, hemlock looper) were to be phased out by 1998.

Currently, one end-use product containing fenitrothion is registered. It is a Restricted Class product for use in forests and woodlands aerially and by ground for Swaine jack pine sawfly and other sawfly species, jack pine budworm and fall cankerworm, and for use by ground only on spruce budworm and hemlock looper.

4.0 Effects having relevance to human health

4.1 Toxicology summary

In laboratory animals fenitrothion has slight to high acute oral toxicity, depending on the test species. Based on limited information, the rhesus monkey appears to be most sensitive to acute fenitrothion exposure, while rats are the next most sensitive species. Acute toxic effects are representative of those associated with cholinesterase inhibition. By the dermal route, fenitrothion has moderate to low acute toxicity. Acute toxicity via inhalation is considered to be low. Fenitrothion is considered to be non-irritating to mildly irritating, to the skin and eyes with acute exposure. Though it has been shown not to be a skin sensitizer, published literature suggests that fenitrothion may be a photoallergen in humans.

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

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

Repeat-dose oral administration of fenitrothion identified inhibition of cholinesterase (plasma, erythrocyte and brain) as the most sensitive endpoint. The species tested showed little discernable difference in sensitivity to this endpoint, though the rat and the monkey showed the lowest no observed adverse effect levels (NOAEL). Duration of exposure appears to have little or no effect on the degree of cholinesterase inhibition. At slightly higher doses a variety of other effects are seen, many typical of cholinergic responses to organophosphate exposure. Data also shows that females are consistently more sensitive to the cholinesterase inhibiting effects of fenitrothion. Repeat dose administration of fenitrothion by the dermal and inhalation routes (in the rabbit and rat, respectively) also identified cholinesterase (plasma, erythrocyte and brain) inhibition as the most sensitive endpoint. It should, however, be noted that the rabbit has been shown to be relatively insensitive to the toxic effects of organophosphates such as fenitrothion, by the dermal route.

Fenitrothion exposure did not result in delayed neurotoxicity, or decreases in neurotoxic esterase (NTE), nor did it cause neuropathology. Neurobehavioural effects associated with fenitrothion exposure are consistent with cholinesterase inhibition.

Fenitrothion is not teratogenic, though fetal variations are seen at and above dose levels which result in maternal toxicity. A multi-generational reproductive study did not elicit adverse effects in offspring at levels below those which resulted in parental toxicity. At higher dose levels parental and reproductive effects included diarrhea, chromorrhinorrhea, tremors and decreases in mating performance and number of implantation sites. Offspring effects consisted of mortality, as well as decreases in body weight gain, lactation index, viability index and mean litter size.

Fenitrothion was not shown to be carcinogenic in chronic mouse or rat studies. The weight of evidence suggests that fenitrothion is not genotoxic, however, positive results were noted in several assays. A potential mammalian metabolite, C-nitroso fenitrothion, has been shown to be strongly mutagenic. Negative results in carcinogenicity studies and in in vivo mammalian genotoxicity studies with fenitrothion provide evidence that, either C-nitroso fenitrothion is not formed, or if formed, it does not result in carcinogenic outcomes. It is not presently known if human dietary factors could result in C-nitroso fenitrothion formation.

The oxygen analogue of fenitrothion, fenitrooxon, results from a minor degradation pathway in mammals, but is an important metabolite as it is the most toxicologically significant metabolite of fenitrothion. Fenitrooxon has been shown to be approximately ten times more acutely toxic than fenitrothion, and is also more potent as a cholinesterase inhibitor.

Human poisoning incidents showed that mortality was reported with fenitrothion ingestion at doses as low as 3000 mg, while doses ranging from 25 000 to 50 000 mg resulted in death in approximately half the cases. Based on this data a rough estimate of the human LD_{50} would be in the range of 350 to 700 mg/kg bw/day, based on a 70 kg body weight. Paralysis was seen with the ingestion of approximately 1500 mg of fenitrothion and higher. Paralysis was accompanied by decreases in plasma cholinesterase activity which often exceeded 80%.

Potentiation has been reported with concurrent exposure to fenitrothion and a number of other organophosphates. Other studies have shown that fenitrothion affects a number of other toxicological endpoints that may not routinely be examined, such as endocrine, immunotoxic and enzymatic effects. With relatively low dose acute exposure, decreases in cytochrome P450 are seen. At higher dose acute exposure and low dose repeat exposure, effects include decreases in cytochrome P450 levels in the liver and testes, mitochondrial respiratory control rate, ATPase activity, plasma testosterone and plaque-forming cells; increases in plasma corticosterone, adrenal weight, and plasma glucose levels; along with changes in hepatic enzymes (aminopyrine N-demethylase activity, aniline hydroxylase). Pre-exposure to fenitrothion has also been shown to result in increased tolerance to later fenitrothion exposure. High dose exposure has shown that fenitrothion exhibits antiandrogenic effects and inhibits androgen-dependent tissue. In a corresponding in vitro study, fenitrothion was shown to be a concentration-dependent, competitive antagonist of the human androgen receptor. It should, however, be noted that these effects were not seen in in vivo studies at dose levels comparable to those used as risk assessment endpoints.

Reference doses have been set on the general toxicological parameters affected in the various studies. These reference doses incorporate various uncertainty factors to account for extrapolating between laboratory animals and humans and for variability within the human population and for data gaps.

4.2 Occupational risk assessment

Occupational risk is estimated by comparing the potential exposure (in mg a.i./kg bw/day) of persons mixing, loading and applying pesticides to the most relevant endpoints from toxicology studies to generate a margin of exposure (MOE). The risk exceeds the PMRAs level of concern if the MOE is less than the desired or target MOE.

For the short-term (1 to 30 days) risk assessment reflecting the current use pattern (exposures < 1 month duration), the most relevant toxicology endpoint for dermal exposure was a NOAEL of 0.3 mg/kg bw/day from a 2-week immunotoxicity study in the rat. The study of lowest observed adverse effect level (LOAEL) (3 mg/kg bw/day) resulted in miosis and decreases in cholinesterase (plasma, erythrocyte, and brain). Standard uncertainty factors of 10 for intraspecies variability and 10 for interspecies extrapolation were applied, for a total target MOE of 100.

For the short-term (1 to 30 days) risk assessment reflecting the current use pattern (exposures < 1 month duration), the most relevant toxicology endpoint for inhalation exposure was a LOAEL of 0.45 mg/kg bw/day (0.005 mg/L/day) from a 1-month inhalation study in the rat. The study LOAEL resulted in the inhibition of brain cholinesterase in females. At the next highest dose (0.0165 mg/L/day) brain cholinesterase inhibition was seen in both sexes, and erythrocyte cholinesterase inhibition was seen in females. Standard uncertainty factors of 10 for intraspecies variability and 10 for interspecies extrapolation are applied, as well as an additional 3-fold safety factor to account for the absence of a NOAEL, resulting in a total target MOE of 300.

A dermal absorption value was required in the dermal risk assessment. There were two studies available in the scientific literature. Both studies had limitations. Based on the physical chemical properties of fenitrothion, including low water solubility and high K_{ow}, and the results of the two studies, the default of 100% dermal absorption was reduced to 50%.

4.2.1 Mixer/loader/applicator exposure

For forestry, Christmas tree and tree nursery ground and aerial application, dermal and inhalation exposure estimates for mixer/loader/applicators are based on data from the Pesticide Handlers Exposure Database Version 1.1 (PHED).

PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates. To estimate exposure for each use scenario, appropriate subsets were created from the mixer/loader and applicator database files of PHED. All data were normalized for the amount, in kg, of active ingredient handled. Exposure estimates are presented on the basis of the best-fit measure of central tendency, i.e., summing the measure of central tendency for each body part which is most appropriate to the distribution of data for that body part.

Exposure is calculated as the product of the unit exposure for a given scenario, the application rate and the area treated per day divided by the body weight. Occupational risk is estimated by comparing a calculated margin of exposure to a target MOE incorporating safety factors protective of the most sensitive subpopulation. Since dermal and inhalation studies examined the same endpoint, cholinesterase inhibition, but had different target MOEs, an aggregate risk index (ARI) was calculated. ARIs greater than or equal to 1 do not require risk mitigation.

ARIs for all occupational mixers, loaders and applicators, based on the current label requirements, are below 1. Further mitigation comprising combinations of additional personal protective equipment (PPE) or engineering controls, and lower application rates, is required for all scenarios.

4.2.2 Post-application exposure

Post-application exposure in forests is expected to be minimal because most activities do not involve significant foliar contact.

Potential exposure of Christmas tree plantation and tree nursery workers, who re-enter treated sites to conduct maintenance activities involving significant foliar contact for full 8-hour work days, were assessed considering conservative high-end default estimates of dislodgeable foliar residues and generic agricultural transfer coefficients for staking, topping, training, harvesting, thinning, pruning, scouting and irrigating trees. To mitigate such possible exposures, workers performing tree maintenance duties involving significant foliar contact must wear additional PPE (chemical-resistant gloves and coveralls over long pants and long sleeves) for 1 month following application.

4.3 Residential risk assessment

Fenitrothion is not permitted to be used in residential areas so a residential risk assessment was not conducted.

4.4 Bystander exposure

To minimize the potential for bystander exposure through spray drift, applicators should use good pesticide application practices and 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. Take into consideration wind speed, wind direction, temperature, application equipment and sprayer settings used for application. Post-application bystander exposure is expected to be minimal following pesticide application to forests. Foliar contact would be very low compared to workers in Christmas tree plantations and tree nurseries.

Provincial regulatory bodies responsible for the permitting of Forest and Woodlands Management spray programs are advised to use whatever means necessary and deemed appropriate (e.g., signage, public service announcements, etc.) to minimize bystander exposure during and after application.

4.5 Dietary risk assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet. These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life. For example, assessments take into account children’s greater consumption of fruit, vegetables and juices for their body weight compared to adults.

Acute dietary risk is calculated considering food consumption and residue values in food. A probabilistic statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of fenitrothion residue that might be eaten in a day. A value representing the high end (99.9^{th} percentile) of this distribution is compared to the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake from residues is less than the ARfD, the expected intake is not considered to be of concern.

The chronic dietary risk is calculated by using the average consumption of different foods, and average residue values on those foods, over a 70-year lifetime. This expected intake of residues is compared to the acceptable daily intake (ADI), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, the expected intake is not considered to be of concern.

The acute (single day) dietary reference dose (ARfD) for all populations is 0.003 mg/kg bw, based on a NOAEL of 0.3 mg/kg bw derived from a 2-week immunotoxicity study in the rat. This study has a LOAEL of 3 mg/kg bw/day which resulted in miosis and decreases in cholinesterase (plasma, erythrocyte and brain). A standard 100-fold uncertainty factor is applicable, to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold). The ARfD is considered to be protective of all populations.

ARfD = 0.3 mg/kg bw/day ÷ 100 = 0.003 mg/kg bw

The chronic (lifetime) dietary reference dose or acceptable daily intake value (ADI) for all populations is 0.003 mg/kg bw/day based on a NOAEL of 0.3 mg/kg bw/day from a 2-year chronic rat study. The LOAEL of 0.5 mg/kg bw/day resulted in decreases in erythrocyte cholinesterase during the first two to four months of the study. A standard 100-fold uncertainty factor is applicable, to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold).

ADI = 0.3 mg/kg bw/day ÷ 100 = 0.003 mg/kg bw/day

4.5.1 Dietary exposure

Refined acute and chronic dietary exposure estimates for all population subgroups were generated using the Dietary Exposure Evaluation Model (DEEM®) software and updated consumption data from the United States Department of Agriculture's (USDA) Continuing Survey of Food Intakes by Individuals, CSFII (1994–1998).

Since fenitrothion is not registered for use on food or feed crops in Canada or the U.S., the only potential source of dietary exposure is through imports to Canada from countries other than the U.S.. These imports were assessed with the assumption that residues were present at levels corresponding to their respective Codex MRLs. For commodities which Canada relies almost entirely on imports from outside of the U.S., the assessment was refined by using monitoring data from the Food and Drug Administration (FDA) and the CFIA.

The acute potential daily intake (PDI) was < 11% (99.9th percentile) of the ARfD for all population subgroups. The chronic PDI was < 0.5% of the ADI for all population subgroups.

These acute and chronic dietary risk assessments demonstrated that there were no dietary concerns for any population subgroup in Canada, including infants, children, teenagers, adults and seniors. In addition, no dietary concerns were evident for nursing or pregnant females or based on gender in general.

4.5.2 Residue of concern definition

Currently, there is no formal definition of the Residue of Concern (ROC) for fenitrothion. It is recommended that based on USEPA and Codex reviews, the PMRA define the ROC as the sum of the parent compound fenitrothion (O,O-dimethyl O-4-nitro-*m*-tolyl phosphorothioate) and its oxygen analogue fenitrooxon (O,O-dimethyl O-4-nitro-*m*-tolyl phosphate), expressed as fenitrothion.

4.6 Aggregate risk assessment

There are no residential uses of fenitrothion and no residues are expected to occur in drinking water, so an aggregate risk assessment was not conducted.

5.0 Environmental assessment

The special review of fenitrothion insecticide that was initiated in 1990 was due to environmental concerns over the effects of spraying fenitrothion in forests on songbirds, insect pollinators and aquatic organisms. 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. The following environmental risk assessment is based on a detailed technical report entitled *Fenitrothion Risk Assessment*[5], published in 1993.

[5] Pauli, B. D., S. B. Holmes, R. J. Sebastien and G. P. Rawn, 1993. *Fenitrothion risk assessment.* Technical Report Series No. 165. Canadian Wildlife Service (Headquarters), Environment Canada, Ottawa. xvi 75p.

5.1 Environmental fate

Fenitrothion has low solubility in water (5 mg/L at 10°C). The vapour pressure of fenitrothion is 2.14×10^{-4} mm Hg at 25°C, which indicates that fenitrothion has an intermediate to high volatility under field conditions. Fenitrothion has the potential to volatilize from soil, particularly moist soil. Volatilization from the surface microlayer is the major means of dissipation for fenitrothion spray deposits on natural waters. The octanol/water partition coefficient (log K_{ow}) for fenitrothion is 3.43 at 20°C, which indicates that fenitrothion has a potential for bioaccumulation in the environment.

The half-lives of fenitrothion via hydrolysis are 191–200 d at pH 5, 180–186 d at pH 7, and 100–101 d at pH 9. These results indicate that fenitrothion is hydrolysed at a slow rate under basic conditions and is even more resistant to hydrolysis under neutral and acidic conditions. The major transformation product observed at pH 9 was 3-methyl-4-nitrophenol. The hydrolysis of fenitrothion is not a major route of transformation.

Phototransformation of fenitrothion on soil surfaces (half-life 85 d) and in air is slow. However, the compound can undergo phototransformation quite readily in water (half-life 3.7 d). The major transformation product observed was p-nitro-m-cresol, which transforms through photolytically mediated polymerization.

Aerobic soil transformation studies conducted using a number of soil types indicated that fenitrothion is microbially transformed and is not persistent. A DT_{50} of 36 days was observed in a sandy loam soil from Nebraska. DT_{90}s of 15 and 29 days, respectively, were observed in a sandy loam soil, and an organic soil from Maine. Similarly, its major transformation product 3-methyl-4-nitrophenol is not persistent in forest soils (DT_{50} 6–13 d). Aerobic aquatic transformation studies using sediments have shown that fenitrothion is not persistent (half-lives 10–16 d) under aerobic aquatic conditions and that micro-organisms in natural sediments and water play an important role in the dissipation. Anaerobic aquatic transformation studies have indicated that fenitrothion and its major transformation products aminofenitrothion and 3-methyl-4-nitrophenol are associated with sediments and are not persistent under anaerobic aquatic conditions.

Laboratory studies have indicated that fenitrothion has the potential to be mobile in coarse-textured soils with low organic matter content. Fenitrothion will desorb from all soils and sediment. The major transformation product 3-methyl-4-nitrophenol was observed to be more mobile than the parent compound.

Canadian terrestrial field dissipation studies have shown that fenitrothion is present in low concentrations (<0.005–0.1 µg/g) in forest soil and is not persistent following operational aerial applications to control the spruce budworm *Choristoneura fumiferana*. Fenitrothion and its major transformation products do not leach appreciably in forest soils.

Concentrations of fenitrothion in lotic (flowing) aquatic systems after operational spraying have ranged from 1.3 to 127 µg/L, and usually declined to less than 1.0 µg/L within 24–48 h and to less than 0.5 µg/L within 1–6 d. Fenitrothion is not persistent in stream water (half-life 6–10 h).

Maximum concentrations of fenitrothion in lentic (standing water) systems have usually occurred within 2 hours of the start of operational spraying and have ranged from 0.38 to 2500 µg/L. A large fraction (up to 70%) of the fenitrothion applied to lakes and ponds is rapidly volatilized from the surface layer (half-life <0.5 h). Fenitrothion concentrations at depths of 0.3 and 1 m in acid bog ponds were 0.25–0.5 times the concentrations observed in the surface layer 15 minutes post-spray. However, concentrations observed at the greater depths were not as transitory (half-life about 1 d) as the high residues observed in surface water. Aqueous fenitrothion residues reappeared 1 year after application to an acid bog pond, suggesting that some component of that ecosystem, possibly moss, acted as a reservoir.

Fenitrothion is not persistent in aquatic sediments. After operational spraying, concentrations in sediments were less than 0.5 µg/g and fell below detectable levels 2 d postspray in a small pond in a spruce-fir forest in New Brunswick. Aminofenitrothion, the major transformation product, persisted for less than 4 d.

Numerous Canadian field studies have indicated that fenitrothion can persist in conifer foliage and possibly accumulate for periods of more than 1 year at concentrations of approximately 1 µg/g.

5.2 Environmental toxicology

Fenitrothion is highly toxic to the honey bee (*Apis mellifera)* in acute contact toxicity tests. The LD_{50}s ranged from 0.018 to 0.176 µg/bee. Fenitrothion also has a high toxicity to other native pollinators. The LD_{50}s for *Andrena erythronii, Megachile rotundata,* and *Bombus terricola* are 0.10, 0.40, and 0.76 µg/bee respectively.

The acute oral LD_{50} of fenitrothion to various bird species ranged from 20.3 mg a.i./kg bw for the zebra finch (*Poephila guttata*) to 1662 mg a.i./kg bw for the mallard (*Anas platyrhynchos*) which would classify it as highly to slightly toxic, respectively. The metabolite fenitrooxon is much more toxic than the parent compound; acute oral LD_{50}s for ring-necked pheasant and mallard are 10.6 and 12.5 mg a.i./kg bw, respectively, compared with 55.6 and >259–1662 mg a.i./kg for the parent compound.

The subacute dietary toxicity for fenitrothion ranged from 50 mg a.i./kg diet for the white-throated sparrow (*Zonotrichia albicollis*) to 2482 mg a.i./kg diet for the mallard (*Anas platyrhynchos*) which would classify it as very highly toxic to slightly toxic respectively. There is a general inverse relationship between avian weight and acute sensitivity to fenitrothion with smaller species being more sensitive.

In the laboratory, the threshold for sublethal effects on reproduction following chronic (18–19 weeks) exposures of fenitrothion in the diet of Northern bobwhites *(Colinus virginianus)* and mallards (*Anas platyrhynchos)* was between 10 and 30 mg/kg diet. Residues in this range have been detected in food items of birds following operational applications of fenitrothion, but little information is available on the persistence of these residues.

The acute toxicity 48-h static LC_{50} of fenitrothion for *Daphnia magna* is 8.6 µg/L, with a no observed effect concentration (NOEC) of <2.0 µg/L. The 48-h flow-through LC_{50} of Sumithion 8E to *D. magna* is 2.3 µg/L, with a NOEC of 1.0 µg/L. These acute toxicities indicate that Sumithion and its active ingredient fenitrothion are very highly toxic to aquatic invertebrates.

Laboratory studies have shown that fenitrothion can be toxic to frog eggs and tadpoles, with the toxicity depending upon the duration of exposure. Acute LC_{50}s for tadpoles of the green frog *Rana clamitans* are 9.9 mg/L after 24 h, 4.9 mg/L after 96 h, and below 4 mg/L after 160 h (with this exposure duration, there was 100% mortality at 4 mg/L).

Technical fenitrothion is moderately toxic to various species of fish. The acute toxicity 96-h LC_{50} ranges from 1000 to 5000 µg a.i./L. At less than acute toxic concentrations, fenitrothion can induce sublethal effects in fish, such as reduction in feeding activity (1000 µg a.i./L), swimming inhibition (480–750 µg a.i./L), and a decrease in reaction distance to prey (5.5 µg a.i./L).

The 96-h EC_{50} of fenitrothion for *Selenastrum capricornutum* was 1300 µg/L. Although it is difficult to extrapolate to other algae species, the limited data suggest that operational applications to control spruce budworm are not expected to be a risk to algae inhabiting small ponds.

5.3 Concentrations in drinking water

The potential for the contamination of drinking water with fenitrothion is expected to be minimal because of the current very limited use pattern in Canada. Fenitrothion is at present only registered to control minor forest pests in Canada. The special review decision in April of 1995 phased out the aerial uses against major forest pests such as the hemlock looper and spruce budworm by 1998. Following this decision, there has been no reported use of fenitrothion for the remaining registered uses, i.e., control of minor forest pests.

5.4 Terrestrial risk assessment

The potential impact of fenitrothion on forest pollinators and pollination is a concern. Impacts on plant populations are likely to be difficult to measure, because many flowering forest plants are long-lived perennials that, besides sexual reproduction, have well-developed clonal growth. In the absence of studies addressing sublethal effects on pollinators, 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.

The available data support the following general observations concerning forest birds. Brain cholinesterase (ChE) data collected following operational applications indicate that songbird impacts will occur following fenitrothion treatments. A proportion of the bird population will receive a significant exposure to the insecticide; some of the exposed birds may die, and others will suffer from sublethal effects. These conclusions are supported by sporadic findings of dead or incapacitated songbirds following large-scale operational forest sprays. Current understanding of the biological relationships between ChE inhibition and sublethal impacts does not allow prediction of the outcome of sublethal ChE depression, but present application rates appear to be able to adversely affect reproductive success. An estimate of the total mortality resulting from any application cannot be made, and possible influences of the insecticide on the long-term status of bird populations in the spray areas cannot be assessed. ChE monitoring data reveal that high exposures may occur frequently. With present application technology, there is no known means of diminishing or preventing these exposures. Because of the range of effects seen following fenitrothion applications, and because the ChE data indicate that these effects may occur frequently, concerns are raised for forest songbird populations in fenitrothion treatment areas.

Nesting waterfowl may breed in small ponds that are sensitive to fenitrothion and that also tend to receive direct applications of the compound, when without buffer zones. The data suggest that success of breeding waterfowl may be hampered by an insecticide-induced depletion of their prey resource.

5.5 Aquatic risk assessment

The invertebrates inhabiting small ponds could be potentially at risk from forest spraying with fenitrothion. Mean surface water concentrations of fenitrothion in small ponds (<0.5 ha) directly oversprayed with fenitrothion at an application rate of 210 g a.i./ha ranged from 20 to 1500 µg/L. These concentrations are 10–200 times greater than the 96-h LC_{50}s for some aquatic invertebrates. It must be recognized, however, that maximum surface water concentrations are rapidly attenuated as a result of dilution, transformation, and volatilization and are not directly comparable with concentrations of fenitrothion used to develop laboratory toxicity values. Therefore, the toxicities measured by conventional procedures (i.e., 24- to 96-h LC_{50}s) may not accurately predict the effects of the short-pulse exposures to fenitrothion that organisms receive in the field.

As fenitrothion does not persist for very long in ponds, the threat to amphibians may stem from a reduction in their invertebrate food resource, rather than from a direct effect. Field data from New Brunswick suggest that fenitrothion may have detrimental impacts on the long-term viability of frog populations, although the influence on frog densities of other habitat quality parameters measured at the study sites could not be factored out.

Based on comparisons of fenitrothion concentrations detected in lotic water with concentrations required for acute toxic effects to fish, the hazard associated with direct effects of fenitrothion on fish in streams is low. The hazard due to indirect effects resulting from aerial spraying with fenitrothion on fish inhabiting lotic ecosystems is also expected to be low because of the transitory effects that have been observed on benthic invertebrates inhabiting these systems.

Observed concentrations in small ponds exceed the acute toxicity endpoints for *D. magna* which indicates a risk to aquatic invertebrates. Recent studies have demonstrated mortality of invertebrates and trout in bioassays conducted using water collected from a small pond oversprayed with fenitrothion during an operational application. Because such ponds provide substantial areas of good quality fish habitat, particularly for brook trout *Salvelinus fontinalis*, there is cause for concern that the unprotected aquatic fauna in small ponds are at risk.

5.6 Environmental assessment conclusions

The decision document issued on April 13, 1995, which resulted from the special review of fenitrothion concluded that “given the smaller area of use (compared to the broad-scale aerial application for the control of spruce budworm and hemlock looper), the lower application rate, the later timing of application and the lack of alternatives, the aerial application of fenitrothion for minor pests such as Swaine jack pine sawfly, jack pine budworm and fall cankerworm, and for minor uses such as seed orchards, is acceptable.” Given the smaller areas of use, all ground applications of fenitrothion in forestry were also considered to be acceptable.

5.7 Environmental risk mitigation

Buffer zones are required around all specified aquatic habitats for all aerial applications. No direct applications of fenitrothion are to take place within 190 m upwind if applied by fixed wing aircraft or 110 m upwind if applied by helicopter of these specified aquatic habitats. As a minimum, specified aquatic habitats include all rivers designated as double-sided and all lentic (standing) 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 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, should also be considered specified aquatic habitats, where possible.

6.0 Value

Fenitrothion is registered in Canada to control lepidopteran and hymenopteran defoliators of conifers in forests and woodlands (see Table 6.1). The use of fenitrothion has declined over the years and provincial governments have not been using the product in recent spray programs. However, it should be noted that 1) there are few registered non-organophosphate insecticide alternatives to fenitrothion (Table 6.1) that are as effective or economical as fenitrothion, 2) few species of sawfly (Hymenoptera), which are emerging pests, have any registered controls other than fenitrothion, 3) the pests registered to be controlled by fenitrothion occur in cyclical outbreaks (e.g., spruce budworm populations peak every 35–40 years), and 4) the value of forests are high.

In the U.S., fenitrothion is only registered for the control of ants and cockroaches in and around homes, restaurants, warehouses, stores and other sites via containerized baits.

Table 6.1 Registered alternatives to fenitrothion (as of June 3, 2002)

SITE	PEST	REGISTERED ALTERNATIVES IN CANADA[1]
Christmas tree plantations (pests not listed on label but are assumed to include those listed)	fall cankerworm	MI: Bt
	eastern hemlock looper, western hemlock looper	SP: permethrin (high value crop) Other: tebufenozide
	jack pine budworm	MI: Bt Other: tebufenozide
	spruce budworm	OP: dimethoate, trichlorfon MI: Bt CA: carbaryl, methomyl Other: tebufenozide SP: permethrin (high value crop)
	sawflies	CA: carbaryl SP: permethrin (high value crop) MI: Lecontvirus (redheaded pine sawfly larvae only) Other: azadirachtin (limited to balsam fir sawfly, yellowheaded spruce sawfly and pine false webworm)
Forest lands, forest plantings, tree (woodland)	fall cankerworm	MI: Bt
	eastern hemlock looper	MI: Bt Other: tebufenozide
	western hemlock looper	Other: tebufenozide
	jack pine budworm	MI: Bt Other: tebufenozide
	spruce budworm	MI: Bt Other: tebufenozide
	sawflies	MI: Lecontvirus (redheaded pine sawfly larvae only) Other: azadirachtin (limited to balsam fir sawfly, yellowheaded spruce sawfly and pine false webworm)

SITE	PEST	REGISTERED ALTERNATIVES IN CANADA[1]
Tree (nursery; pests not listed on label but are assumed to include those listed)	fall cankerworm	MI: Bt
	eastern hemlock looper	MI: Bt Other: tebufenozide
	western hemlock looper	Other: tebufenozide
	jack pine budworm	MI: Bt Other: tebufenozide
	sawflies	SP: permethrin (high value crop) MI: Lecontvirus (redheaded pine sawfly larvae only) Other: azadirachtin (limited to balsam fir sawfly, yellowheaded spruce sawfly and pine false webworm)
	spruce budworm	SP: permethrin (high value crop) MI: Bt Other: tebufenozide

1 OP = organophosphate, CA = carbamate, SP = synthetic pyrethroid, MI = microbial insecticide

7.0 Other assessment considerations

The PMRA has taken into account the federal Toxic Substances Management Policy (TSMP)[6] and has followed its Regulatory Directive DIR99-03[7] during the review of fenitrothion. The following has been considered:

- The half-life values in soil (16.4 days) and water (6 days) are below the TSMP Track-1 criterion for persistence ($\geq$182 days).
- The half-life value in sediment (< 2 days) is below the TSMP Track-1 criterion for persistence ($\geq$365 days).
- No data were available for the persistence of fenitrothion in air.
- The Log K_{ow} for fenitrothion (3.43) falls below the TSMP Track-1 criterion for bioaccumulation (Log K_{ow} $\geq$5.0).
- The toxicity of fenitrothion is described in Chapters 4 and 5.2.

It has been determined that fenitrothion does not meet the TSMP Track-1 criteria because it does not meet the criteria for persistence or bioaccumulation. Therefore, use of fenitrothion is not expected to result in the entry of TSMP Track-1 substances into the environment.

6 The federal Toxic Substances Management Policy is available through Environment Canada's Web site at: www.ec.gc.ca/toxics

7 The PMRA's Strategy for Implementing the Toxic Substances Management Policy, DIR99-03, is 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 pminfoserv@hc-sc.gc.ca or through our Web site at www.hc-sc.gc.ca/pmra-arla

8.0 Proposed regulatory action

The PMRA has determined that the aggregate risks for fenitrothion are acceptable provided that the mitigation measures proposed below are adopted. As indicated earlier in the document, these proposed actions represent an interim decision until a final full reassessment of the cumulative risk from all organophosphate pesticides is completed. The acceptable uses for the fenitrothion product, together with proposed mitigation measures and use limitations, are presented in Appendix I.

There are few registered non-organophosphorus insecticide alternatives to fenitrothion that are as effective or economical as fenitrothion. Also there are species of sawfly (Hymenoptera) which are emerging as cyclical pests that have no registered controls other than fenitrothion.

All uses of fenitrothion will be Restricted Uses with the following Nature of Restriction:

> This product is to be used only in the manner authorized; contact local pesticide regulatory authorities regarding appropriate use permits that may be required.

Further details for label statements are listed in the Appendix II Use Standard for Fenitrothion.

8.1 Proposals pertaining to toxicology

Based on the toxicological assessments, the label text of products containing fenitrothion should include the following text:

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, uncoordination, 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 exposed, plasma and red blood cell cholinesterase tests may indicate 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.

8.2 Proposals pertaining to exposure

The PMRA has determined that the human health risks for fenitrothion are acceptable provided that the mitigation measures proposed below are adopted.

General Mitigation for all M/L/A scenarios:

- lower the maximum application rate to 210 g/a.i./ha
- do not mix/load/apply for more than 30 days
- wear chemical-resistant gloves, chemical-resistant headgear and chemical-resistant coveralls (except while applying using a closed cab/cockpit)

For protection of M/L (aerial application only):

- use closed mixing and loading system

For protection of applicators (aerial only):

- wear cotton coveralls

For protection of workers conducting re-entry activities that involve significant foliar contact:

- chemical-resistant gloves and coveralls for one month following application

Human flaggers:

- no human flaggers allowed

For protection of bystanders:

- Use good pesticide application practices and apply only when the potential for drift to 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.

8.3 Proposals pertaining to environment

In order to mitigate risks to aquatic organisms, buffer zones are required around all specified aquatic habitats for aerial applications (details contained in Section 5.7).

9.0 Additional data requirements

9.1 Chemistry

A product specification form as per Regulatory Directive DIR98-04 is required.

9.2 Toxicology

A developmental neurotoxicity study is required, and a subchronic dermal study in the rat is required as the available dermal studies were not conducted in a suitable animal model.

9.3 Human exposure

Although not required for the current fenitrothion re-evaluation (provided that the mitigation measures outlined in this document are implemented), the following data would be required to refine the risk assessment, thus possibly reducing or removing some restrictions and(or) personal protective equipment requirements.

- Dislodgeable foliar residue (DFR) study on conifer tree foliage. No DFR studies were available so a conservative default value (20% of the application rate with a 10% dissipation per day) was used.

- Dermal absorption study. An appropriate dermal absorption study could be used to refine the 50% value that was used in this assessment.

9.4 Dietary exposure

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to recommend new maximum residue limits (MRLs) at the limit of quantification for any raw agricultural commodities not approved for continued treatment in Canada. Additional MRLs for import purposes will be considered if sufficient data are provided by interested parties to allow a reassessment of those residues. The USEPA undertakes similar action in such circumstances.

In the case of fenitrothion, there are currently no specific MRLs. Consequently, any residues on imported commodities must not exceed 0.1 ppm, a default value specified by the Food and Drugs Regulations subsection B.15.002(1). As there are no products with food uses proposed for continuing registration, the PMRA will recommend that MRLs are established at the limit of quantification for all raw agricultural commodities (i.e. 0.017 ppm for plant commodities, 0.002 ppm for milk, and 0.05 ppm for meat) unless a petition to consider different MRLs for import purposes is received.

Parties interested in supporting an MRL to allow additional imports of specific commodities treated with fenitrothion should contact the PMRA during the consultation period to discuss the submission of appropriate data. If no petitions are received, proposed amendments to the Food and Drugs Regulations reflecting these MRLs will be published in the Canada Gazette.

10.0 Proposed re-evaluation decision

The PMRA has carried out an assessment of available information and has found it sufficient, pursuant to Section 20 of the PCP Regulations, to allow a determination of the safety, merit and value of fenitrothion and the associated end-use product. The Agency has concluded that the use of fenitrothion and associated end-use product does not entail an unacceptable risk of harm to human health or the environment pursuant to Section 20, provided that the mitigation measures described in this document are implemented. Further measures may be necessary/proposed pending the the outcome of the cumulative risk assessment for all organophosphates, which share a common mechanism of toxicity.

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 re-evaluation decision for these products.

List of abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
CA	carbamate
CFIA	Canadian Food Inspection Agency
ChE	cholinesterase
d	day(s)
DFR	dislodgeable foliar residue
DT_{50}	dissipation time to 50%
FDA	Food and Drugs Administration (U.S.)
K_{ow}	octanol/water partition coefficient
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
MI	microbial insecticide
min	minute(s)
MOE	margin of exposure
MRL	maximum residue level
NOAEL	no observed adverse effect level
NTE	neurotoxic esterase
OP	organophosphate
PACR	Proposed Acceptability for Continuing Registration
PCP	pest control product
PCPA	*Pest Control Products Act*
PHED	Pesticide Handlers' Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ROC	residue of concern
SF	safety factor
SP	synthetic pyrethroid
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
y	year(s)
µg	microgram

Appendix I Toxicology endpoints for risk assessment for fenitrothion

EXPOSURE SCENARIO	DOSE (mg/kg bw/day)	ENDPOINT	STUDY	UF/SF or MOE[c]
Acute Dietary	NOAEL = 0.3	Miosis, cholinesterase inhibition (plasma, erythrocyte and brain)	2-Week Immunotoxicity —Rat	100
	ARfD = 0.003 mg/kg bw			
Chronic Dietary	NOAEL = 0.3	Cholinesterase inhibition (erythrocyte)	2-Year Chronic —Rat	100
	ADI = 0.003 mg/kg bw/day			
Short-Term[a] Dermal[b]	Oral NOAEL = 0.3	Miosis, cholinesterase inhibition (plasma, erythrocyte and brain)	2-Week Immunotoxicity —Rat	100
Short-Term[a] Inhalation	LOAEL = 0.005	Brain cholinesterase inhibition (♀)	1-Month Inhalation —Rat	300

[a] Duration of exposure is 1–30 days

[b] Since an oral NOAEL was selected, a dermal absorption factor of 50% should be used in route-to-route extrapolation

[c] UF/SF refers to total of uncertainty and(or) safety factors for dietary assessments, MOE refers to desired margin of exposure for occupational or residential assessments

Appendix II Use standard for the RESTRICTED Class product containing fenitrothion

(Note: The information in this appendix summarizes the acceptable uses, limitations and precautions for the restricted class product containing fenitrothion, but does not identify all label requirements for such products. Registrants are referred to the PMRA Registration Handbook for further guidance on label requirements for pest control products.)

COMMON NAME: fenitrothion

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

FORMULATION TYPE: EC emulsifiable concentrate

USE SITE CATEGORIES: Forests and woodlots 04

NOTE: All uses of fenitrothion fall under 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 your spray equipment.

Federal or provincial forestry or regulatory officials may recommend inclusion of 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, uncoordination, 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 exposed, plasma and red blood cell cholinesterase tests may indicate 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:

SAFETY PRECAUTIONS: It is necessary to distinguish between the higher order of operator exposure to the concentrated insecticide prior to dilution and spraying, and the much lower exposure of third party or bystanders to the diluted spray resulting from drift spraying operations. Precautionary measures relevant to the concentrated product and operational personnel who are likely to be exposed to it during handling and loading are outlined under the heading PRODUCT PRECAUTIONS.

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

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

Triton X114 is an eye irritant. Wear suitable goggles when working with this material.

PRODUCT PRECAUTIONS: KEEP OUT OF REACH OF CHILDREN. This product is harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin or clothing. Do not breathe vapours or spray mist. If spilled on skin, wash immediately with soap and water. If clothing becomes contaminated, remove it and wash clothing before re-use. Persons in contact with product are cautioned to wash hands, arms and face frequently with soap and water throughout the operation, after handling and certainly before eating or smoking. Do not allow children or pets to come into contact with treated areas until sprays have dried. Combustible. Keep away from heat, sparks or open flame. Keep container closed when not in use. Keep product out of reach of children. Do not contaminate food or feed. Keep unauthorized and unprotected persons out of loading, mixing and application zones. Do not mix, load, apply or handle the product for more that 30 consecutive days.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Aerial applicators must wear: cotton coveralls over long-sleeved shirt and long pants, shoes and socks. All other applicators, mixers, loaders and other handlers must wear: chemical-resistant coveralls and chemical-resistant gloves over long-sleeved shirt and long pants, shoes plus socks and chemical-resistant headgear for overhead exposure. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS: Users should:
* Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
* Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
* Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

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 equipment or disposing of waste. Consult the provincial regulatory agency for information on the cleanup of spills. Do not apply when weather conditions favour drift or run-off from areas treated. Do not apply directly to aquatic systems, or to areas where surface water is present or to intertidal areas below the mean high water mark.

Buffer zones are required around all specified aquatic habitats for all aerial applications. No direct applications of fenitrothion are to take place within 190 m upwind if applied by fixed wing aircraft or 110 m upwind if applied by helicopter of these specified aquatic habitats. As a minimum, specified aquatic habitats include all rivers designated as double-sided and all lentic (standing) 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 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, should also be considered specified aquatic habitats, where possible. This pesticide is toxic to birds. Applications may adversely affect birds in rangeland 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.

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 a.i./ha or two applications 4–6 days apart of 140–210 g a.i./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 a.i./ha for any one application or a total of 420 g a.i./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 a.i./ha or two applications 4–6 days apart of 140–210 g a.i./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 sawfly, apply at the peak of emergence of the second instar. **LIMITATIONS:** 1) Use no more than 210 g a.i./ha for any one application or a total of 420 g a.i./ha applied in two treatments. 2) Buffer zone are required around all specified aquatic systems. No direct applications of fenitrothion are to take place within 190 m upwind if applied by fixed wing aircraft or 110 m upwind if applied by helicopter of these specified aquatic systems as defined under Environmental Precautions.

SITE	PESTS	RATE (g a.i./ha)	APPLICATION
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 a.i./ha or two applications 4–6 days apart of 140–210 g a.i./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 sawfly, apply at the peak of emergence of the second instar. **LIMITATIONS:** 1) Use no more than 210 g a.i./ha for any one application or a total of 420 g a.i./ha applied in two treatments. 2) All aerial application of fenitrothion must be conducted using light (up to 5670 kg) fixed wing aircraft or rotary-wing aircraft, or aircraft (e.g., helicopter) must be equipped with electronic guidance systems (e.g., Global Positioning System). 3) Buffer zone are required around all specified aquatic systems. No direct applications of fenitrothion are to take place within 190 m upwind if applied by fixed wing aircraft or 110 m upwind if applied by helicopter of these specified aquatic systems as defined under Environmental Precautions.
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 a.i./ha or two applications 4–6 days apart of 140–210 g a.i./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.