

Veterinary Medicines Authority



Fenitrothion

Review Technical Report April 2024

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the Agricultural and Veterinary Chemicals Code (the Code), which is scheduled to the Agricultural and Veterinary Chemicals Code Act 1994.

The APVMA has legislated powers to reconsider the approval of an active constituent, registration of a chemical product or approval of a label at any time after it has been registered. The Code provides for the suspension and cancellation of approvals and registrations if it appears to the APVMA that the criteria for approval or registration are not, or are no longer, satisfied (s 41 and s 44 of Part 2, Division 5).

About this document

This Technical Report is intended to provide an overview of the assessments that have been conducted by the APVMA and of the specialist advice received from its advisory agencies. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience, thereby encouraging public comment.

This document contains a summary of the assessment reports generated in the course of the chemical review of an active ingredient, including the registered product and approved labels. The document provides a summary of the APVMA's assessment, which may include details of:

- the chemistry of the active constituent
- the toxicology of both the active constituent and product
- · the residues and trade assessment
- occupational exposure aspects
- environmental fate, toxicity, potential exposure and hazard
- · efficacy and target crop or animal safety.

Further information

Further information can be obtained via the contact details provided below. More details on the chemical review process can be found on the APVMA website: apvma.gov.au

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Introduction

Fenitrothion is a broad-spectrum, non-systemic organophosphorus insecticide that was first introduced to Australia in 1959 (British Crop Production Council, 2016). Fenitrothion is used in Australian agriculture for the control of certain insect pests in broadacre and horticultural crops, in stored grain, in grain storage facilities and in poultry houses. Fenitrothion was nominated for review in response to an invitation to the public by the APVMA (then the NRA) in 1994. The APVMA began its reconsideration of fenitrothion active constituent approvals, product registrations and associated label approvals in 1996 because of concerns relating to chemistry, toxicology, occupational health and safety, efficacy, residues, trade, and the environment.

The APVMA took interim regulatory action on fenitrothion products in 2000–01, following publication of component assessment reports (<u>residues</u>, <u>environmental impact</u>, <u>toxicology</u>, <u>chemistry</u> and <u>occupational health and safety</u>) in 1999. These interim actions were to:

- · reduce the label rate for locust and grasshopper control and include buffer zones
- reduce the label rate for control of Sitona weevil in lucerne and include buffer zones
- delete the tobacco use pattern
- limit the number of yearly applications that can be made.

A number of fenitrothion product registrations were voluntarily ceased or cancelled in 2001. These included a range of formulations (liquefied gas, pressurised gas, powder and aerosol) and products intended for home and garden use.

Purpose of review

The scope of the fenitrothion chemical review includes the following aspects of active constituent approvals, product registrations and label approvals for fenitrothion:

- Chemistry:
 - Level of impurities of toxicological concern in fenitrothion active constituents and products.
- Toxicology
 - Consideration of toxicological endpoints, health-based guidance values and poisons scheduling.
- Worker health and safety:
 - Risks to professional workers arising from exposure during handling and application.
 - Risks to professional workers who re-enter treated areas.
 - Determination of appropriate personal protective clothing and engineering control requirements.
 - Establishment of appropriate first aid instructions and safety directions for fenitrothion products.
- Residues and trade:
 - Residues in treated food and animal feeds arising from application in accordance with label instructions.

- Establishment of appropriate maximum residue limits (MRLs) for supported uses of fenitrothion.
- Determination of dietary exposure resulting from the consumption of produce treated with fenitrothion.
- Risks to international trade resulting from the use of fenitrothion on major export commodities.

Environment:

 Risks to terrestrial vertebrates, aquatic species, bees, other non-target arthropods, soil organisms and terrestrial plants resulting from application in accordance with label instructions.

In addition to the above assessments, fenitrothion labels are reviewed for consistency with current APVMA policies and guidelines, including the Agricultural Labelling Code and APVMA Spray Drift Policy July 2019.

Mode of action, product claims and use patterns

Fenitrothion is a group 1B (organophosphorus) insecticide that acts via acetylcholinesterase inhibition and is registered for use in agricultural situations for the control of chewing and sucking insects. It is available in both emulsifiable concentrates (EC) and ultra-low volume (UL) formulations. In Australia, fenitrothion is used in the following situations:

- Cereal grain protection, either alone or in combination with S-methoprene
- Structural protection of grain storage areas and poultry houses
- Control of pests (coleopteran, lepidopteran) in pasture
- Control of Sitona weevil in lucerne
- Control of locusts and grasshoppers in pasture, cereal and horticultural crops

International regulatory status

Fenitrothion has been reviewed by several international regulators, including the US Environmental Protection Agency (USEPA) in 1995, the European Food Safety Authority (EFSA) in 2007, the Joint Meeting on Pesticide Regulators (JMPR) in 2007, the Canadian Pest Management Regulatory Agency (PMRA) in 2004 and the New Zealand Environmental Protection Authority (NZ EPA) in 2013. It is not listed under the Basel, Rotterdam, or Stockholm conventions.

United States

The USEPA issued a <u>re-evaluation decision</u> in 1995, which cancelled most uses other than ant and cockroach baits in child-resistant packaging. By June 2020 the remaining fenitrothion technical active was cancelled.

European Union

The authorisation for the use of fenitrothion was <u>withdrawn in the EU</u> in 2007 based on human health and environmental concerns. Exposure to workers was unacceptable in most outdoor scenarios and there was an

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identified risk to consumers of residues in grapes. Environmental risks to birds, mammals, bees, and aquatic species were also identified.

Canada

The Health Canada Pest Management Regulatory Agency restricted fenitrothion to limited forestry uses in their 2004 reconsideration and it was subsequently voluntarily discontinued.

New Zealand

A reassessment of fenitrothion was completed in July 2013 and its use phased out by July 2016. Overall, the risks to workers, bystanders and the environment ranged from negligible to medium, however as there were no critical uses identified, the benefit of retaining fenitrothion was considered low.

India

The use of fenitrothion was restricted in 2007 to public health applications (e.g. mosquito control) and restricted locust control in desert areas.

Chemistry

Active constituent

The nomenclature and structural formula of the active constituent fenitrothion are provided in Table 1.

Table 1: Nomenclature and structural formula of the active constituent fenitrothion

Parameter	Nomenclature and structure
Common name (ISO):	Fenitrothion
IUPAC name:	O,O-dimethyl O-(3-methyl-4-nitrophenyl) phosphorothioate
CAS registry number:	122-14-5
Molecular formula:	C ₉ H ₁₂ NO ₅ PS
Molecular weight:	277.2 gmol ⁻¹
Structural formula:	H_3C H_3C NO_2

Fenitrothion is a liquid at room temperature (colourless in the case of the pure active ingredient, and yellow-brown in the case of the technical active ingredient). It is practically insoluble in water, while being soluble in aliphatic hydrocarbons, and highly soluble in alcohols, esters, ketones, aromatic hydrocarbons, and chlorinated hydrocarbons. Fenitrothion is relatively more stable to hydrolysis under acidic and neutral conditions (half-life of 180 to 200 days), and less stable under alkaline conditions (half-life of ~100 days). It is rapidly photolysed, with a half-life of approximately 3 days. Further details of the physicochemical properties of fenitrothion are tabulated in Table 2 below (JMPR 2003).

Table 2: Key physicochemical properties of the active constituent fenitrothion

Parameter	Physicochemical property	
Appearance	Colourless, viscous liquid (pure active ingredient, 99% purity)	
	Yellow-brown liquid with a faint characteristic odour (technical active ingredient)	
Melting point	0.3 °C	
Boiling point	140-145 °C (0.1 mm Hg, decomposes)	
Specific gravity	1.328 (25 °C)	

Parameter	Physicochemical property
Solubility in water	19 mg/L (20 °C)
Organic solvent solubility (g/L, 20 °C)	Hexane: 24
	Isopropanol: 138
	Readily soluble in alcohols, esters, ketones, aromatic hydrocarbons and chlorinated hydrocarbons.
Octanol/water partition coefficient (Log K _{ow})	3.43 (20 °C)
Vapour pressure	1.48 × 10 ⁻⁴ Pa (10 °C)
	6.76 × 10 ⁻⁴ Pa (20 °C)
	1.57×10^{-3} Pa (25 °C, interpolated)
	3.39 × 10 ⁻³ Pa (30 °C)
Henry's law constant (calculated)	0.0099 Pa.m³mol⁻¹ (20 °C)
Hydrolysis (DT50, 25 °C)	pH 5: 191–200 days
	pH 7: 180–186 days
	pH 9: 100–101 days
Aqueous photolysis (DT50, 25 °C)	pH 5: 3.3–3.7 days (2 kW xenon lamp, ≥ 290 nm, 10 hours light/14 hours darkness cycle)

There is currently only one active constituent approval for fenitrothion (Table 3).

Table 3: Current active approvals for fenitrothion

Approval number	Holder
44499	Sumitomo Chemical Australia Pty Ltd

The <u>Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022</u> (Agricultural Active Constituents Standard 2022) for fenitrothion, as excerpted in Table 4 below, and the <u>Food and Agriculture Organization of the United Nations (FAO) specification</u> for fenitrothion technical material (TC) (<u>FAO 2010</u>) specify a minimum purity of 930 g/kg, with maximum levels for 2 toxicologically significant impurities of 5 g/kg for S-methyl fenitrothion and 3 g/kg for tetramethyl pyrophosphorothioate (TMPP).

Table 4: Agricultural Active Constituents Standard 2022 for fenitrothion

Identity	Description	Minimum purity	Maximum impurity
Common Name: Fenitrothion Chemical Name: Dimethoxy- (3-methyl-4-nitrophenoxy)- sulfanylidene-λ5-phosphane CAS Number: 122-14-5	The material shall consist of fenitrothion together with related manufacturing impurities and shall be a yellow to brown liquid free from extraneous matter and added modifying agents.	930 g/kg minimum	S-methyl fenitrothion: 5 g/kg maximum Tetramethyl pyrophosphorothioate (TMPP): 3 g/kg maximum

Both S-methyl fenitrothion and tetramethyl pyrophosphorothioate (Figure 1) have higher acute toxicity than fenitrothion itself, as reported by the Joint Meeting on Pesticide Specifications (JMPS) in 2009 (FAO 2010).

Figure 1: Structures of toxicologically significant impurities in fenitrothion

S-methyl fenitrothion (O,S-dimethyl O-(3-methyl-4-nitrophenyl) phosphorothioate), CAS number 3344-14-7

Tetramethyl pyrophosphorothioate (TMPP), CAS number 18764-12-0

The APVMA has considered batch analysis results and certificates of analysis for the currently approved source of fenitrothion active constituent, and confirmed compliance with the manufacturer's own specifications (Declaration of Composition), the <u>Agricultural Active Constituents Standard 2022</u> for fenitrothion and the FAO specification for fenitrothion technical active constituent (TC). The APVMA has also considered real time and accelerated stability information for this active constituent approval, which confirmed that technical fenitrothion is expected to remain in compliance with the Agricultural Active Constituents Standard 2022 for fenitrothion and the FAO specification for fenitrothion TC when stored for at least two years under normal conditions.

Formulated products

There are currently 8 registered chemical products containing fenitrothion, formulated as 3 different formulation types: 4 emulsifiable concentrate (EC) formulations containing 1,000 g/L fenitrothion, one ultra-low volume liquid (UL) product containing 1,230 g/L fenitrothion, and 3 EC formulations containing 600 g/L fenitrothion in combination with 60 g/L (S)-methoprene.

Table 5: Currently registered products containing fenitrothion

Registration number	Holder	Product name		
Emulsifiable concentrat	Emulsifiable concentrate (EC) formulation containing 1,000 g/L fenitrothion			
46127	Babolna Bioenvironmental Centre Ltd	Methograin Fenitrothion 1000 Insecticide		
50775	Sumitomo Chemical Australia Pty Ltd	Sumithion 1000 EC Insecticide		
56170	Kendon Plant Care Pty Ltd	Kendon Fenitrothion 1000 EC Insecticide		
67186	Freezone Public Health Pty Ltd	Freezone Fenitrothion Insecticide		
Ultralow volume liquid (UL) formulation containing 1,230 g/L fenitrothion				
50774	Sumitomo Chemical Australia Pty Ltd	Sumitomo Sumithion ULV Premium Grade Insecticide		
Emulsifiable concentrate (EC) formulation containing 600 g/L fenitrothion and 60 g/L (S)-methoprene				
66520	Sumitomo Chemical Australia Pty Ltd	Grain-Guard Duo Insecticide		
67567	Freezone Public Health Pty Ltd	Freezone Smart Grain Dual Insecticide		
91551	Freezone Public Health Pty Ltd	Titan Dual Grain Treatment		

The APVMA has not established any standards under section 6E of the Agvet Code for chemical products containing the active constituent fenitrothion. The <u>FAO specification</u> for fenitrothion includes specifications for chemical products with EC and UL formulations, with maximum limits specified for both of the toxicologically significant impurities S-methyl fenitrothion and tetramethyl pyrophosphorothioate (TMPP).

It was noted by JMPS in the 2009 evaluation accompanying the FAO specification that levels of S-methyl fenitrothion can increase on storage in both technical fenitrothion and in fenitrothion formulations, particularly at elevated temperatures, or in the presence of other formulation ingredients (notably, anionic surfactants, which are commonly used as emulsifiers in EC formulations) (FAO 2010). Therefore, limits for S-methyl fenitrothion, allowing for possible increases during storage, were included the FAO specifications for fenitrothion EC and UL formulations.

TMPP on the other hand, can be formed during the manufacture of fenitrothion, but is not likely to increase in technical fenitrothion or formulated products during storage. Therefore, while maximum limits for TMPP were included in the FAO specification for fenitrothion EC and UL formulations, it was not necessary to allow for increases in TMPP levels during storage, and the maximum limits were set at 0.3% of the fenitrothion content, i.e.

allowing only for TMPP carried over as an impurity formed during the manufacture of fenitrothion technical active constituent.

It was further noted by JMPS that water is a relevant impurity in EC and UL formulations, as it can contribute to the degradation of fenitrothion, and that pH likewise, is a relevant physicochemical property. Maximum limits for water in EC and UL formulations were recommended, along with a required pH range (to prevent degradation of fenitrothion at low pH or hydrolysis at high pH).

It is therefore recommended APVMA product standards be established under section 6E of the Agvet Code for fenitrothion EC and UL formulations, and for the fenitrothion and S-methoprene combination EC formulation, based on the <u>FAO specifications</u>. It is further recommended that registrants be required to provide batch analyses and stability data for the formulated products to confirm compliance with the relevant FAO specification and the proposed APVMA s6E standard.

Chemistry recommendations

The APVMA is satisfied of the chemistry and manufacturing aspects of the safety and efficacy criteria for fenitrothion active constituent and formulated products, noting the following:

- The APVMA proposes to establish a standard under section 6E of the Agvet Code for fenitrothion EC and UL formulations, harmonised with the FAO specifications as appropriate and incorporating limits for active content, S-methyl fenitrothion, tetramethyl pyrophosphorothioate, water and pH. The specifications proposed to be included in this section 6E standard are included in Table 6 below.
- To confirm compliance with the proposed specifications for fenitrothion chemical products as set out in Table 6, the APVMA would require product holders to provide batch results and stability data within 12 months of the final regulatory decision for the fenitrothion chemical review.

Table 6: The proposed specifications for fenitrothion chemical products

Chemical	Formulation type		
	EC	UL	
Fenitrothion ¹	Above 250 g/L up to 500 g/L: ±5% of the declared content	Above 250 g/L up to 500 g/L: ±5% of the declared content	
	Above 500 g/L: ±25 g/L	Above 500 g/L: ±25 g/L	
(S)-methoprene ¹ (where applicable)	Up to 25 g/L: ±15% of the declared content	N/A	
	Above 25 g/L up to 100 g/L: ±10% of the declared content		
	Above 100 g/L up to 250 g/L: ±6% of the declared content		
	Above 250 g/L up to 500 g/L: $\pm 5\%$ of the declared content		
	Above 500 g/L: ±25 g/L		

Chamical	Formulation type		
Chemical	EC	UL	
S-methyl fenitrothion ²	Max. 2.0% of the fenitrothion content	Max. 2.5% of the fenitrothion content	
Tetramethyl pyrophosphorothioate (TMPP) ²	Max. 0.3% of the fenitrothion content	Max. 0.3% of the fenitrothion content	
Water	Max. 2 g/L	Max. 2 g/L	
pH (CIPAC MT75.3)	3–6	3–6	

¹Allowable ranges of fenitrothion concentrations in products are as specified in the <u>Agricultural and Veterinary Chemicals</u> <u>Code (Allowable Variations in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022</u>.

²Concentration percentages for all impurities in products are relative to the concentration of active in the product.

Toxicology

Evaluation of toxicology

Fenitrothion is an organophosphorus (OP) insecticide. It functions via inhibition of acetylcholinesterase (AChE) activity, which results in an excess of acetylcholine (ACh) in the synaptic cleft, causing hyperstimulation of ACh receptors and impaired transmission of nerve impulses. Symptoms of acute poisoning from OPs include agitation, muscle weakness and/or twitching, pupil constriction, excess salivation, and sweating. Severe poisonings may cause respiratory failure, unconsciousness, confusion, convulsions and/or death.

In 1999, the APVMA (then the NRA) published a detailed assessment of the <u>mammalian toxicology of fenitrothion</u> (APVMA 1999d) and an <u>assessment of the occupational health and safety</u> of the products and associated uses that were registered at that time (APVMA 1999b). The toxicology database for fenitrothion is complete and there is high confidence in the regulatory quality of the information contained therein.

Since the 1999 publications, several reports related to possible adverse effects that may result from exposure to fenitrothion have been published in a variety of scientific publications. These more recent investigations sought to examine endpoints and markers for reproductive and developmental toxicity, to include androgenic, anti-androgenic, oestrogenic, or anti-oestrogenic effects. Other endpoints, such as hepatotoxicity, cognitive deficiencies and ChE inhibition were identified as being characterised previously for fenitrothion and for OP pesticides in general. None of the identified studies report a No Observed Adverse Effect Level (NOAEL) that is more sensitive than those already relied-on for health-based guidance values for fenitrothion. The doses tested in these studies were generally limited, in some cases designed to administer doses already known to cause cholinesterase (ChE) inhibition or toxicity. The new studies build upon the toxicological database, and do not introduce any endpoints that would alter the existing hazard assessment of fenitrothion.

In addition, more recent acute toxicity studies were submitted and evaluated by the APVMA. The results of the assessment of this data indicate that fenitrothion is moderately toxic via the oral route of exposure (Moon 2010a), of low toxicity via the dermal route of exposure (Moon 2010b), is not irritating to the skin of rabbits (Ota 2010a), slightly irritating to rabbit eyes (Ota 2010b) and is not a skin sensitiser in guinea pigs (Kawabe 2010) when tested according to the Buehler method. These results are consistent with existing data on file for fenitrothion.

Health based guidance values

Acceptable daily intake

The <u>acceptable daily intake</u> (ADI) for fenitrothion is 0.002 mg/kg bw/day. It is based on a NOAEL of 0.2 mg/kg bw/d in a 1-year dietary study in dogs (Griggs *et al.*, 1984), using a total uncertainty factor of 100.

Acute reference dose

The <u>acute reference dose</u> (ARfD) of 0.03 mg/kg bw is based on a NOAEL of 0.33 mg/kg bw in a single dose study using human volunteers (Nosál M & Hladká A, 1968) using an uncertainty factor of 10.

Poisons scheduling

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) classifies fenitrothion as Schedule 6, with no cut-offs or exceptions.

There are no proposed changes to the poisoning scheduling of fenitrothion.

Worker health and safety

Previous assessments

In 1999, the APVMA (then the NRA) published an <u>interim occupational health and safety (OHS) assessment</u> for fenitrothion (APVMA 1999b). A Margin of Exposure (MOE) approach was used that involved a calculation of the ratio between estimated exposure and a relevant NOAEL(s) as established in the <u>interim toxicology report</u> (APVMA 1999d).

The APVMA has substantially changed its approach to exposure assessment since the publication of its interim OHS assessment on fenitrothion in 1999. This necessitated a re-evaluation of exposures and risk characterisations associated with the uses of fenitrothion.

Worker exposure assessment

Professional use involves repeated occupational exposure to fenitrothion, principally via the dermal route. Most of the registered uses include limited applications to the treated crops (e.g., 1–3 per season, although some may be higher). Accordingly, the most appropriate point of departure (POD) for occupational risk characterization is 3 mg/kg bw/day. This POD is the no observed adverse effect level (NOAEL) for inhibition of blood cholinesterases in rabbits following dermal exposure to fenitrothion for 21 days (Suetake *et al.*,1991). A margin of exposure (MOE) of 100 was applied to account for inter- and intra-species uncertainties. The point of departure for incidental oral exposure and inhalation exposure is 0.2 mg/kg bw/day, which is the NOAEL from a one-year dietary toxicity study in dogs (Griggs *et al.*, 1984).

For exposure during mixing, loading and application the current assessment has utilised the US EPA Office of Pesticide Programs Occupational Handler Exposure Calculator (US EPA 2020a). For exposure associated with reentry into pesticide treated area, the current assessment has utilised the US EPA Occupational Pesticide Re-entry Exposure Calculator (US EPA 2020b). For exposure associated with the on-farm handling of fenitrothion treated seed grain the current assessment has utilised the US EPA seed treatment calculator (US EPA 2022).

The following assumptions have been used in the exposure modelling (see Table 7):

Table 7: Assumptions used in modelling exposure for professional use of fenitrothion

Parameter	Value(s)/model(s)
POD for risk assessment (dermal exposure)	3 mg/kg bw/day
POD for risk assessment (oral and inhalation exposure)	0.2 mg/kg bw/day
Acceptable margin of exposure (MOE)	100*
Body weight (adult)	80 kg
Body weight (child)	1–2 y = 11 kg
	2–3 y = 15 kg

Parameter	Value(s)/model(s)
Dermal absorption factor	Not required (dermal study for POD)
Inhalation absorption factor	100%
Airblast foliar application (orchard/vineyard)	30 ha/day
Groundboom inter-row application (orchard/vineyard)	30 ha/day
Groundboom field application (typical crops)	50 ha/day
Groundboom field application (broadacre uses)	600 ha/day
Aerial application	Baseline 600 ha/day Upper limit 1,000 ha/day
Backpack application (mixer, loader, applicator)	10 x 15 L refills = 150 L/day
Manually pressurized hand wand application	150 L/day
Mechanically pressurized handgun application	Structural components (e.g. walls, framing, voids, slabs, beams, lumber, etc.) = 4,000 L/day
	Poultry house (whole-house treatment of litter, walls, etc.) = 0.8 ha/day (2 acres)
Exposure modelling	Professional agricultural operators and commercial and on-farm grain protectant uses:
	 A. Mixing, loading and application for agricultural and structural/surface treatment uses: US EPA OPHEC
	Commercial and on-farm seed treatment uses: US EPA Seed treatment exposure calculator
	Agricultural re-entry workers:
	Post-application exposure: US EPA OPREC

^{*} As a NOAEL from an animal study was used to estimate risks, a MOE ≥ 100 was considered acceptable. This value is based on a 10-fold uncertainty factor (UF) for intra-species variability and 10-fold UF for inter-species differences in response.

The exposure assessments and risk characterisations for fenitrothion also rely upon a further set of reasonable assumptions, notably that:

- mixing, loading and application is performed by trained, professional operators
- professional operators using fenitrothion wear a long-sleeved shirt, long pants, shoes and socks or an equivalent single layer of clothing as a baseline
- professional operators are capable of accurately measuring, dispensing, and applying products according to
 the directions specified on product labels, and are trained in and are competent and experienced users of
 personal protective equipment (PPE), and relevant application techniques and equipment

- professional operators comply with the PPE specified on product labels and comply with label-specific application rates
- professional operators perform only one type of use or activity per day (e.g. the same operator would not undertake groundboom fenitrothion treatment of horticultural crop(s) and performing grain protectant application of fenitrothion on the same day)
- for ground application, a single operator performs all steps in the use of fenitrothion products that are applied by ground application methods, i.e. a single operator mixes, loads and applies the pesticide during product use
- for aerial application, mixing and loading activities are performed by someone other than the pilot.

The exposure assessments and risk characterisations also assume that there are no concurrent co-exposures to other anticholinesterase substances (the effects of which are likely to be at least additive to those of fenitrothion due to their common mode of action).

Grain protectant treatment for bulk storage

Modelling for the use of fenitrothion as a grain protectant in bulk storage facilities was undertaken using a reverse exposure approach. It was assumed that exposure to fenitrothion during the application process is negligible as specialized equipment is used to treat the grain/seed using nozzles integrated into the auger or using a shielded sprayer on the conveyor belt that transfers the grain into the storage silos. Therefore, the calculation to determine the quantity of fenitrothion that could be handled in a single day was based on unit exposures for open mixing/loading of a liquid in an outdoor environment and assumed that the PPE currently recommended on product labels was worn by individuals performing that task (i.e. single layer of clothing, buttoned to the neck and wrist and elbow-length chemical resistant gloves). The label rate for that use is 6–12 g ac/tonne of grain treated.

Using the above assumptions, a single operator would reach the threshold of acceptable risk at 28.5 kg product handled in a single day. This equates to treating 4,750 tonnes of grain at the low application rate (6 ppm) or 2,375 tonnes of grain at the high application rate (12 ppm). It is expected that a single operator would be unlikely to reach these daily rates and that the use of fenitrothion on grains entering bulk storage, according to existing label directions, remains acceptable.

Seed treatment with fenitrothion is not specifically mentioned on labels; however, treated stored seed grains could conceivably be used as seed. The US EPA seed treatment calculator (<u>US EPA 2022</u>) was used to determine occupational exposure and risk estimates for commercial and on-farm application of fenitrothion to lucerne, barley, canola, corn, flax, lentil, millet, oats, okra, rice, rye, safflower, sorghum, soybean, triticale and wheat at 6 and 12 ppm, assuming operator PPE was used as currently prescribed on registered product labels (i.e. single layer of clothing buttoned to the neck and wrist and elbow-length chemical resistant gloves). Risk estimates were derived for short-term and intermediate term exposure durations, and included the following activities: treating seed, packaging seed, loading, and planting treated seed, and cleaning seed treatment equipment. The exposure estimates yielded acceptable MOEs for all the crops noted above, hence on-farm treatment of seed grains with fenitrothion according to existing label directions remains acceptable.

Surface treatment for bulk stored cereal grains, structural treatments for grain storage and use in poultry sheds

Fenitrothion is used as a structural and surface spray in a limited number of scenarios. The dilution rate for all these uses is 1 L product per 100 L water. As a surface spray for grain storage and associated structural treatments, the diluted solution is applied at a rate of 1 L per 20 m² (or to the point of runoff). In poultry sheds, 1 L of dilute spray treats 7 m².

It is assumed that the product could be applied in these scenarios using a variety of application methods, including backpack sprayers, manually pressurized hand wands or mechanically pressurized handguns. Risk estimates were determined for a single mixer/loader/applicator for each of these application methods, using the default volumes in OPHEC. The results are presented in Table 8 below, which shows that no structural or surface treatments for grain protection are acceptable, nor is the use of fenitrothion in poultry sheds.

Table 8: Risk estimates for the use of fenitrothion as a structural or surface treatment for grain protection and as a structural treatment in poultry sheds

Application method	Scenario	Amount handled/ area treated	MOE¹ with modelled PPE²
Backpack sprayer	Structural/surface ³	150 L	45
Manually pressurized hand wand	Structural/surface ³	150 L	11
Mechanically pressurized handgun	Structural/surface ³	4,000 L	7
Mechanically pressurized handgun	Poultry shed (including litter, walls and roof)	0.8 ha	25

¹ Acceptable MOE>100

Field crops

Ground-based application

Groundboom application

The basic assumptions for groundboom application to field crops is a default area treated per day of 50 hectares, as noted in Table 7. It is however recognised, that modern groundboom equipment can cover a significantly greater area in a single workday, with boom widths approaching 50 m and typical speeds of application of approximately 20 km/hr. It is considered reasonable that a single operator could treat up to 600 ha in one day, or greater than 1,000 ha/day in broadacre scenarios.

² Double layer of clothing, chemical resistant gloves and PF50 (full face) respirator. OPHEC does not include data for exposure mitigation with chemical resistant hat, and there is no engineering control available to mitigate risk for these application methods.

³ Structural treatments include cereal grain storage on farms, produce stores, feed and flour mills, warehouses and processing plants, transport equipment and animal feed bins, and surface treatment includes bulk stored cereal grain (surface application) and stacks of grain bags.

The outcomes for the exposure risk assessment for the use of fenitrothion in field crops and pasture are outlined in Table 9. The field crops that are covered by these risk estimates below include those listed on the registered product labels: horticultural crops including cabbage, lettuce and tomatoes as well as pasture, pasture seed forage and cereal crops (including sorghum, lucerne, soybean, wheat, barley, oats, rice, millet, rye, triticale, and corn).

It is recognised that the implementation of additional risk mitigation measures will decrease individual exposure, translating to a higher margin of exposure. Therefore, Table 9 includes both the minimum PPE and/or engineering control requirements for the various product application rates at the default area treated rate of 50 ha/day, and the maximum daily work rates permitted when fully closed mixing and loading and closed cab application is used.

The use of closed mixing and loading systems (i.e. addition of sealed, lockable valves resulting in closed transfer of the product from its packaging to the spray tank) minimises operational exposure, but it is noted that the APVMA does not currently have evidence that use of this engineering control could be feasibly implemented and managed.

Table 9: Risk estimates for the use of fenitrothion in field crops using groundboom application

Сгор	Application rate (g ac/ha)	Area treated/day (ha)	Minimum PPE and/or engineering controls required in modelled scenario	Mixer/ loader MOE	Applicator MOE	Total MOE ¹
Lucerne	250	50	Single layer, gloves	210	400	137
		450 (max) ²	Closed mixing/loading, closed cab application	230	180	101
Pasture, pasture seed, forage (including	270	50	Single layer, gloves	190	380	126
lucerne), cereal crops, cabbage, lettuce and tomato		400 (max) ²	Closed mixing/loading, closed cab application	240	180	103
Pasture, pasture seed, forage (including lucerne), cereal crops, cabbage, lettuce and tomato	300	50	Single layer, gloves	170	340	113
		350 (max) ²	Closed mixing/loading, closed cab application	240	190	106
Pasture, pasture seed, forage (including	350	50	Double layer, gloves	190	350	123
lucerne), cereal crops, cabbage, lettuce and tomato		300 (max) ²	Closed mixing/loading, closed cab application	240	190	106
Pasture, pasture seed, forage (including lucerne), cereal crops, cabbage, lettuce and tomato	400	50	Double layer, gloves	160	310	105
		250 (max) ²	Closed mixing/loading, closed cab application	260	200	113
Pasture	480	50	Double layer, gloves, half facepiece respirator	150	350	105

Crop	Application rate (g ac/ha)	Area treated/day (ha)	Minimum PPE and/or engineering controls required in modelled scenario	Mixer/ loader MOE	Applicator MOE	Total MOE ¹
		200 (max) ²	Closed mixing/loading, closed cab application	270	210	118
Pasture, pasture seed, cereal crops, grazing sorghum and lucerne	492 (UL)	50	Double layer, gloves, half facepiece respirator	150	340	104
sorgium and laceme		200 (max)	Closed mixing/loading, closed cab application	260	200	113
Pasture	500	50	Double layer, gloves, half facepiece respirator	150	330	103
		200 (max) ²	Closed mixing/loading, closed cab application	260	200	113
Pasture	550	50	Double layer, gloves, closed cab application	120	730	103
		50	Closed mixing and loading, gloves, single layer for application	930	180	150
		200 (max) ²	Closed mixing/loading, closed cab application	230	180	101
Lucerne	650	50	Closed mixing/loading, gloves, single layer for application	790	160	133
		150 (max) ²	Closed mixing/loading, closed cab application	270	210	118
Pasture	700	50	Closed mixing/loading, gloves, single layer for application	730	140	117
		150 (max) ²	Closed mixing/loading, closed cab application	240	190	106
Pasture	800	50	Closed mixing/loading, gloves, single layer for application	640	130	108
		130 (max) ²	Closed mixing/loading, closed cab application	250	190	108
Pasture	1,000	50	Closed mixing/loading, gloves, single layer and half facepiece respirator for application	520	130	104

Crop	Application rate (g ac/ha)	Area treated/day (ha)	Minimum PPE and/or engineering controls required in modelled scenario	Mixer/ loader MOE	Applicator MOE	Total MOE¹
		110 (max) ²	Closed mixing/loading, closed cab application	230	180	101
Pasture	1,200	50	Closed mixing/loading, closed cab application	430	330	186
		90 (max) ²	Closed mixing/loading, closed cab application	240	180	102
Pasture	1,300	50	Closed mixing/loading, closed cab application	390	300	170
		80 (max) ²	Closed mixing/loading, closed cab application	250	190	108

¹ Acceptable MOE>100

Misting application

There is one UL product (1,230 g/L) and multiple EC products (1,000 g/L) that include instructions for ground-based misting application, in addition to air-assisted, electrostatic, and boom spray applications. Exposures from mixing and loading for application by mister is identical to that for groundboom application. While exposures to applicators resulting from misting applications may be slightly higher from those resulting from ground boom applications, overall MOEs are acceptable.

Aerial application

For aerial application, it is assumed that the individual undertaking the mixing/loading activities is someone other than the pilot. Therefore, separate exposure and risk estimates were determined for mixing/loading and application of products containing fenitrothion. Where aerial application is indicated on currently registered product labels, a maximum application rate has been specified. For the 1,000 g/L EC products (APVMA registration numbers 50775, 56170 and 67186), the upper limit for aerial application is 350 g ac/ha. For the UL product (APVMA registration number 50774), aerial application is recommended for rates up to 492 g ac/ha.

The risk estimates presented in Table 10 assume that operators are using closed mixing/loading systems and are wearing gloves, and that pilots are in enclosed cockpits wearing gloves (consistent with the data that supports OPHEC unit exposure values for those activities). Current labels include a restraint for human flaggers in aerial applications whereby they must be protected by engineering controls such as enclosed cabs. It is expected that the use of human flaggers is no longer practiced by aerial applicators, hence the restraint may not be necessary. However, exposure modelling using OPHEC includes estimates of exposure to flaggers, and without engineering controls, the risk is unacceptable. Therefore, if the practice of using human flaggers is undertaken, the restraint must remain on any registered product labels.

² The maximum daily work rate that is supported in scenario modelled.

Table 10: Risk estimates for the use of fenitrothion in field crops using aerial application

Стор	Application rate (g ac/ha)	Area treated/day (ha)	Mixer/loader MOE ¹	Pilot MOE ²
Lucerne	250	600	170	330
		1,000 (max) ³	110	200
Pasture, pasture seed, forage (including lucerne), cereal crops, cabbage, lettuce and tomato	270	600	160	310
		900 (max) ³	110	200
Pasture, pasture seed, forage (including lucerne), cereal	300	600	140	280
crops, cabbage, lettuce and tomato		800 (max) ³	110	210
Pasture, pasture seed, forage (including lucerne), cereal	350	600	120	240
crops, cabbage, lettuce and tomato		700 (max) ³	110	200
Pasture, pasture seed, forage (including lucerne), cereal crops, cabbage, lettuce and tomato	492 (UL)	500 (max) ³	110	200

¹ Acceptable MOE>100, assumes closed mixing/loading systems are used.

Orchard and vineyard crops

Orchard and vineyard uses of fenitrothion are limited to use in apples, cherries, and grapes to control grasshoppers and locusts. The default area treated per day is 30 hectares, and modelling larger areas was not performed.

Groundboom application

As a ground directed spray, exposure modelling was performed for broadcast application using ground boom spraying equipment. Exposure estimates in these scenarios are for a single operator performing mixing, loading and application activities, wearing the recommended PPE on registered product labels (i.e. single layer of clothing buttoned to the neck and wrist and elbow-length chemical resistant gloves).

² Acceptable MOE>100, assumes gloves and enclosed cockpit.

³ The maximum daily work rate that is supported in scenario modelled.

Table 11: Risk estimates for the use of fenitrothion in orchard and vineyard crops using groundboom application	

Crop	Application rate (g ac/ha)	Area treated/day (ha)	Minimum PPE and/or engineering controls required in modelled scenario	Mixer/ loader MOE	Applicator MOE	Total MOE ¹
Apples, cherries and	270	30	Single layer, gloves	320	620	211
grapes	300	30	Single layer, gloves	290	560	191
	400	30	Single layer, gloves	220	430	145
	550	30	Single layer, gloves	160	310	105

¹ Acceptable MOE>100

Airblast application

While it is expected that the application of fenitrothion in these scenarios is a ground directed spray, and that it is not applied to the foliage of these commodities, there is no restraint specified on current label to prevent foliar application to these crops. If airblast application is conducted in the limited orchard and vineyard scenarios above, closed cab application equipment is mandatory to achieve acceptable margins of exposure. The total MOEs for mixer/loaders/applicators using closed cab application remains acceptable.

Misting application

There is one UL product (1,230 g/L) and multiple EC products (1,000 g/L) that include instructions for ground-based misting application, in addition to air-assisted, electrostatic, and boom spray applications. Exposures resulting from mixing and loading for misting applications are identical to those for mixing and loading for airblast. In the limited application scenarios set out above, the total MOEs for mixer/loader/applicators using closed cab application remains acceptable.

Re-entry and re-handling exposure assessments and risk characterisations

Re-entry interval modelling was performed using OPREC with the baseline assumptions in Table 7 and the following additional assumptions about re-entry exposure:

- Re-entry exposure occurs principally via the dermal route with inhalation exposure considered negligible.
- Re-entry exposure assessments and risk characterisations assume that there were no concurrent coexposures to other anticholinesterase products.

While orchard and vineyard use of fenitrothion is expected to be ground application to control grasshoppers and locusts, the product labels do not preclude foliar application. Therefore, post-application exposure and risk assessments were determined for various activities in the relevant crops (i.e. apples, cherries and grapes).

Existing product labels do not include re-entry statements. Unless otherwise specified, a standard re-entry period should be respected. All labels¹ should include at least the following re-entry statement:

Do not enter treated areas until the spray has dried. If prior entry is necessary, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves. Clothing must be laundered after each day's use.

In addition to the general re-entry restraint, the following specific re-entry intervals outlined in Table 12 must be added to the relevant product labels and respected by re-entry workers. As set out in Table 12, the use of fenitrothion on corn at rates greater than or equal to 400 g ac/ha and use of fenitrothion on grapes at rates greater than or equal to 300 g ac/ha have re-entry periods of more than 30 days, which is considered impractical from a risk management perspective. On this basis, these uses of fenitrothion are not supported.

Table 12: Minimum re-entry intervals for post-application activities by crop and application rate

Application rate (g ac/ha)	Crop	Activity	Minimum re-entry interval (days)
250	Lucerne	Scouting	8
		Irrigation (handset)	14
270	Lucerne, barley, forage crops, rice, soybean, wheat	Scouting	9
	nice, soybean, wheat	Irrigation (handset)	14
	Apples, cherries	Scouting, hand pruning, training	4
		Hand harvesting	11
		Fruit thinning	20
	Cabbage	Scouting, harvesting, hand and mechanically assisted	11
		Irrigation (handset)	14
		Hand weeding	22
	Corn	Scouting	9
		Irrigation (handset)	14
		Detasseling, hand harvesting	29
	Lettuce	Hand harvesting	9
		Irrigation (handset)	14

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¹ excluding bulk stored grain uses where re-entry is not relevant

Application rate (g ac/ha)	Crop	Activity	Minimum re-entry interval (days)
	Grapes	Scouting, propagating, hand pruning, hand weeding, bird control, trellis repair	5
		Tying/training, hand harvesting, leaf pulling	30
		Irrigation (handset)	14
	Tomato	Hand harvesting, tying/training	9
		Irrigation (handset)	14
300	Lucerne, barley, forage crops, rice, soybean, wheat	Scouting	10
	nce, soybean, wheat	Irrigation (handset)	15
	Apples, cherries	Scouting, hand pruning, training	4
		Hand harvesting	12
		Fruit thinning	21
	Cabbage	Scouting, harvesting, hand and mechanically assisted	12
		Irrigation (handset)	15
		Hand weeding	23
	Corn	Scouting	10
		Irrigation (handset)	15
		Detasseling, hand harvesting	30
	Lettuce	Hand harvesting	10
		Irrigation (handset)	15
	Grapes	Scouting, propagating, hand pruning, hand weeding, bird control, trellis repair	5
		Tying/training, hand harvesting, leaf pulling	>30 (impractical)
		Irrigation (handset)	15
	Tomato	Hand harvesting, tying/training	10
		Irrigation (handset)	15

Application rate (g ac/ha)	Crop	Activity	Minimum re-entry interval (days)
400	Lucerne, barley, forage crops, rice, soybean, wheat	Scouting	13
	rice, soybean, wheat	Irrigation (handset)	18
	Apples, cherries	Scouting, hand pruning, training	7
		Hand harvesting	15
		Fruit thinning	24
	Cabbage	Thinning plants	1
		Scouting, harvesting, hand and mechanically assisted	15
		Irrigation (handset)	18
		Hand weeding	26
	Corn	Scouting	13
		Irrigation (handset)	18
-		Detasseling, hand harvesting	>30 (impractical)
	Lettuce	Hand harvesting	13
		Irrigation (handset)	18
	Grapes	Scouting, propagating, hand pruning, hand weeding, bird control, trellis repair	8
		Tying/training, hand harvesting, leaf pulling	>30 (impractical)
		Irrigation (handset)	18
	Tomato	Hand harvesting, tying/training	13
		Irrigation (handset)	18
492 (UL)	Lucerne, barley, forage crops,	Scouting	15
	rice, soybean, wheat	Irrigation (handset)	20
	Apples, cherries	Scouting, hand pruning, training	9
		Hand harvesting	17
		Fruit thinning	26

Application rate (g ac/ha)	Crop	Activity	Minimum re-entry interval (days)
	Cabbage	Thinning plants	3
		Scouting, harvesting, hand and mechanically assisted	17
		Irrigation (handset)	20
		Hand weeding	27
	Corn	Scouting	15
		Irrigation (handset)	20
		Detasseling, hand harvesting	>30 (impractical)
	Lettuce	Hand harvesting	15
		Irrigation (handset)	20
	Grapes	Scouting, propagating, hand pruning, hand weeding, bird control, trellis repair	10
		Tying/training, hand harvesting, leaf pulling	>30 (impractical)
		Irrigation (handset)	20
	Tomato	Hand harvesting, tying/training	15
		Irrigation (handset)	20
550	Lucerne, barley, forage crops, rice, soybean, wheat	Scouting	16
	rice, soybeari, wheat	Irrigation (handset)	21
	Apples, cherries	Transplanting	1
		Scouting, hand pruning, training	10
		Hand harvesting	18
	Cabbage	Transplanting	1
		Thinning plants	5
		Scouting, harvesting, hand and mechanically assisted	18
		Irrigation (handset)	21
		Hand weeding	29

Application rate (g ac/ha)	Crop	Activity	Minimum re-entry interval (days)
	Corn	Scouting	16
		Irrigation (handset)	21
		Detasseling, hand harvesting	>30 (impractical)
	Lettuce	Transplanting	1
		Hand harvesting	16
		Irrigation (handset)	21
	Grapes	Transplanting	1
		Scouting, propagating, hand pruning, hand weeding, bird control, trellis repair	11
		Irrigation (handset)	21
		Tying/training, hand harvesting, leaf pulling	>30 (impractical)
	Tomato	Hand harvesting, tying/training	13
650	Lucerne	Scouting	17
		Irrigation (handset)	23
480	Pasture/forage crops	Scouting	15
		Irrigation (handset)	20
700	Pasture/forage crops	Scouting	18
		Irrigation (handset)	23
800	Pasture/forage crops	Scouting	19
		Irrigation (handset)	25
1,000	Pasture/forage crops	Scouting	21
		Irrigation (handset)	27
1,200	Pasture/forage crops	Scouting	23
		Irrigation (handset)	28
1,300	Pasture/forage crops	Scouting	24
		Irrigation (handset)	29

First aid instructions

The existing FAISD Handbook entry for fenitrothion remains adequate and is presented in Table 13:

Table 13 First aid instructions (FAI) for fenitrothion

Status	Substance	Concentration	FAI	Warning Statement
Existing entry	Fenitrothion		m	

The code 'm' above refers to the following first aid instructions in Table 14:

Table 14 Translation of first aid instruction (FAI) code for fenitrothion

Code	Instruction
m	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 13 11 26, New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

Safety directions

The First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals (the FAISD Handbook) currently includes safety directions for 6 different types of products containing fenitrothion. The following are the only product types that remain on the market currently in Australia:

- EC, 1000 g/L
- EC, 600 g/L with S-methoprene, 60 g/L
- UL, 1280 g/L

The remainder of the safety direction entries should be deleted as they represent historical products that are no longer available for use.

A number of fenitrothion use patterns supported from a worker health and safety perspective could not be supported from a residues, trade and/or environment perspective. The safety directions for fenitrothion products have been evaluated based on uses supported by all assessment areas. The safety directions listed in Table 15 should be included on product labels.

Table 15 FAISD Handbook entries - fenitrothion products

Substance	Formulation	Statement codes
Fenitrothion	EC 1,000 g/L or less	130 131 132 133 190 210 211 220 223 279 280 281 282 290 292 294 296 279 284 290 297 300 303 340 342 350 360 361 362 363 364 366

Substance	Formulation	Statement codes
Fenitrothion	EC 600g/L plus S- methoprene 60g/L	130 131 132 133 190 210 211 220 223 279 280 281 282 290 292 294 296 279 284 290 297 300 303 340 342 350 360 361 362 363 364 366
Fenitrothion ULV*	ULV* 1280 g/L or less	130 131 132 133 190 210 211 220 223 279 280 281 282 290 292 294 296 279 284 290 297 300 303 340 342 350 360 361 362 363 364 366

 $^{^{*}}$ ULV is the code currently used for UL formulations in the FAISD Handbook.

The above statement codes translate into the following safety directions in Table 16.

Table 16: FAISD Handbook – fenitrothion products, translation of statement codes to safety directions

Safety directions	Code
Hazards	
Poisonous if absorbed by skin contact, inhaled or swallowed	130 131 132 133
Repeated minor exposure may have a cumulative poisoning effect	190
Precautions	
Avoid contact with eyes and skin	210 211
Do not inhale spray mist	220 223
Mixing or using	
When opening the container, preparing spray, and using the prepared spray, wear cotton overalls buttoned to the neck and wrist and washable hat, elbow-length chemical resistant gloves and face shield. When using in enclosed areas, wear goggles and half-facepiece respirator with combined dust and gas cartridge. If product on skin, immediately wash area with soap and water.	279 280 281 282 290 292 294 296 279 284 290 297 300 303 340 342
After use	
After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash contaminated clothing, gloves, face shield, goggles and respirator and if rubber wash with detergent and warm water	350 360 361 362 363 364 366

Worker health and safety recommendations

The uses of fenitrothion that are not supported from a worker health and safety perspective are listed in Table 17.

Table 17: Uses not supported from the viewpoint of worker health and safety

Situation	Basis
Grain structural and surface treatment Poultry shed (including litter, walls and roof	Unacceptable risk to occupational handlers
Corn, application rates ≥ 300 g ac/ha Grapes, application rates ≥ 300 g ac/ha	Impractical re-entry period (>30 days)

The use of fenitrothion on stored cereal grain is supported from a worker health and safety perspective, noting that worker exposure to fenitrothion during the application process is negligible as specialized equipment with nozzles integrated into the auger or using a shielded sprayer on the conveyor belt that transfers the grain into the storage silos is used to treat the grain/seed.

The worker health and safety risks for the use of fenitrothion in field crops and orchard and vineyard crop, other than the situations listed in Table 17, can be mitigated through the implementation of PPE requirements, engineering control requirements, daily work rate restrictions (ha/day) and/or re-entry period requirements, as set out in Table 9 to Table 12. It is noted that closed mixing and loading is required to mitigate the risks to the mixer/loaders or mixer/loaders/applicators in many of the assessed scenarios, and that the APVMA does not currently have evidence that the use of this engineering control could be feasibly implemented and managed by industry. The feasibility of the use of closed mixing/loading systems was not further investigated, as the relevant uses were not supported in the contemporary residues and trade assessment and/or environment assessment below. The first aid instructions listed in Table 13 and the safety directions listed in Table 15 are reflective of use patterns supported by all assessment areas and should be included on all relevant product labels.

Residues and trade

Previous assessments

In 1999, the APVMA (then the NRA) published an <u>interim residues report</u> (APVMA 1999a). The APVMA also published a <u>draft review report</u> in 2004 (APVMA 2004). No new residues data has been submitted to the APVMA following the publication of the 2004 draft review report. This current residues and trade assessment combines the findings of the 1999 interim and 2004 draft review reports and includes a contemporary residues and trade risk assessment for currently approved label use patterns.

Metabolism and residues definition

The metabolism of fenitrothion in plants and animals was evaluated in the 1999 interim report. No additional metabolism studies were submitted following the 1999 interim report, and it is concluded that the current Australian residue definition of parent fenitrothion is appropriate. It is noted that the current Codex residue definition is parent fenitrothion and this was recommended by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in 2004, which concluded that the fenitrothion S-isomer, fenitrooxon and aminofenitrothion were not required for inclusion as they were expected to occur in foods in only small amounts (JMPR 2004).

Analytical methods

Analytical methods for the determination of fenitrothion in plant and animal commodities were evaluated in the 1999 interim report. GLC was the method of choice for the quantitation of fenitrothion and metabolites in the submitted residue trials. Separation of fenitrothion and its polar metabolites can also be achieved using liquid column chromatography. For most substrates, the limit of detection is 0.005 mg/kg; limit of quantitation = 0.02 mg/kg, however lower limits of quantitation of 0.004 mg/kg have been reported with detection at 0.001–0.002 mg/kg.

Residues in food and animal feeds

Use patterns will be supported from a residues and trade perspective in this assessment where there is sufficient relevant residues data for the use pattern(s) to set a Maximum Residue Limit (MRL) for the relevant commodities, where there are no dietary exposure concerns and where an undue risk to international trade is not expected.

Post harvest storage treatment of cereal grains

Registered fenitrothion products may be used as a post-harvest treatment on cereal grains for control of weevils, flour beetles, saw-toothed grain beetles, tropical warehouse moth borers, Indian meal moths and, with the addition of an insect growth regulator, lesser grain borer. Fenitrothion is registered in Queensland, NSW, Victoria, SA and Tasmania as an admixture for cereal grains stored less than 3 months at a treatment rate of 6 ppm. It is also registered in all states as an admixture treatment for cereal grains stored 3–6 months, with a treatment rate of 12 ppm fenitrothion. When treated at 12 ppm, there is a '90 day' storage interval, where the grain must be withheld from use as a human food or animal feed.

In the 1999 interim report, the post-harvest use of fenitrothion on stored cereal grains were supported as data provided showed that the existing fenitrothion MRL of 10 mg/kg for cereal grains was appropriate for post-harvest storage treatments of cereals. Residues in processed commodities such as wheat bran and germ were also found to be below the existing MRLs for those commodities at 20 mg/kg. The Australia Wheat Board 1984 data observed maximum residues in wheat, bran and germ at 5.0 mg/kg (mean 2.9 mg/kg), 22.6 mg/kg (mean 12.8 mg/kg) and 19.8 mg/kg (mean 11.1 mg/kg) respectively. Data from the Flour Millers' Council observed residues in raw bran between <10–23 mg/kg and data on rice from a Japanese processing study showed that when treated at 15 mg/kg residues in polished rice, husked rice and rice bran at 1.02 mg/kg, 9.38 mg/kg and 65 mg/kg respectively.

The 1999 interim report highlighted concerns regarding fenitrothion residues in rice bran. The 2004 draft review report considered additional rice processing data, which were adequate to calculate maximum residue levels in rice bran and in rice hulls. The maximum residue level of 6.3 mg/kg found in the trial was well within the established TMRL of 20 mg/kg for unprocessed rice bran indicating that a rice bran MRL at 20 mg/kg was appropriate. The data also showed that the maximum rice hull residue was 54 mg/kg, at 2 weeks after treatment of 12 ppm fenitrothion. As rice treated under the Australia GAP at 12 ppm should not be processed for a minimum of 90 days (~13 weeks) after treatment, this result is not consistent with label instructions. Residues in hulls at 10–12 weeks after 12 ppm treatment were ~30–42 mg/kg. Residues on hulls processed from rice treated at 6 ppm did not exceed 26 mg/kg. Hence, an MRL at 50 mg/kg level can be established for rice hulls as an animal feed commodity MRL in Table 4 of the MRL standard.

Based on the available data, the existing fenitrothion MRLs for GC 0080 Cereal grains at 10 mg/kg, CM 0654 Wheat bran, unprocessed and Wheat germ at 20 mg/kg remain appropriate for the post-harvest use on stored cereal grains. MRLs for rice bran at 20 mg/kg and hulls at 50 mg/kg are recommended to cover the potential residues from the post-harvest use on stored rice.

The withholding period (WHP) of 90 days for the 12 ppm grain protection use is considered appropriate, but should be expressed as 13 weeks, in accordance with the APVMA Labelling Code.

A WHP is not required for the 6 ppm grain protection use, as fenitrothion residues in stored grain will be below the current MRL at 10 mg/kg (ppm). Most labels do not state a WHP for the 6 ppm grain protection use with the exception of the 3 products containing a co-formulation of 600 g/L fenitrothion and 60 g/L S-methoprene (66520, 67567 and 91551), which have a WHP of one day that was determined as appropriate based on the available one-day data. Product 46127 has a WHP of 'Not required when used as directed'. As it is considered implausible the cereal grain will be treated as it is placed into storage, transported and consumed by either human or animal within 24 hours of treatment, a WHP of 'Not required when use as directed' is considered appropriate and should be applied to all products containing the 6 ppm grain protection use pattern.

The post-harvest uses of fenitrothion for the storage treatment of cereal grains are supported from a residues perspective.

Treatment of grain storage facilities and equipment

The registered structural treatment use involves cereal grain storage on farm, produce stores, feed and flour mills, warehouses and processing plants, transport equipment and animal feed bins. 1 L of products containing 1,000 g/L fenitrothion are added to 100 L of water, which is then applied at 1 L of spray over 20 square metres, or

to the point of runoff, applied at 2 monthly intervals in warm weather and at 3 monthly intervals in winter months (46127) or without specified retreatment intervals (50775, 56170 and 67186).

The grain surface treatment use involves treatment of bulk stored cereal grain and stacks of bags etc. 1 L of products containing 1,000 g/L fenitrothion are added to 100L of water, which is then applied at 1 L of spray over 20 square metres of exposed grain surface, or to the point of runoff on bags. Depending on the product the retreatment interval is either 2 months (46127) or applied at 1-month intervals during summer and 2 or 3 month intervals in winter (50775, 56170, and 67186).

For the structural treatment use, the intention of the use on all labels is for application to structures, as the use name suggests. However, only product 46127 has a critical comment to avoid contamination to the grain. It is recommended that the critical comment 'Precautions should be taken to prevent surface contamination of grain' should be added to the 'Structural treatment' use on all relevant labels.

Structural treatment and grain surface treatment uses may result in lower residues in grain than the 12 ppm grain protection use. However, due to a lack of data to specifically assess these uses, the 13 week withholding period applied to the 12 ppm grain protection use is considered appropriate. It is recommended that the WHP of 'DO NOT use for processing into food for human consumption or stock food within 13 weeks of treatment', present on some labels and silent on others, should be added for all products where this WHP is not clearly stated, including for the 10 ppm grain surface treatment use.

Fenitrothion can be transferred to oilseeds and pulses following structural treatment of grain handling and storage equipment and potentially from storage in structures previously used for treated cereal grains. Storage and supply chains for cereal grains and other grains/seeds are not segregated. The MRLs for oilseeds and pulses at 0.1 mg/kg were established as permanent MRLs in 2014 based on NRS monitoring data in canola, sunflower, chickpea, faba bean, field pea, lentils, lupins, mung bean and soybean seeds for the period of 1 July 2007 to 8 February 2012. It is recommended that the existing MRLs for SO 0088 Oilseeds at 0.1 mg/kg and VD 0070 Pulses at 0.1 mg/kg continue to remain appropriate.

The use patterns for cereal storage facilities and equipment are supported from a residues perspective.

Treatment of broiler poultry houses

The 1999 interim report found that the exposure to chickens from fenitrothion treatment of poultry houses is unlikely to result in residues greater than the existing poultry MRLs and that the use is considered to be of negligible risk from a residues perspective.

The fenitrothion concentration used for treatment of poultry housing and feed-sheds is 10 ppm. Residue trials with poultry, feeding up to 100 ppm, resulted in no poultry products exceeding existing MRLs at *0.05 mg/kg. In addition, current label instructions recommend that if litter is treated, it is covered by fresh untreated litter and that birds are not to be placed in recently treated sheds. In practice, this is at least one to 2 days after treatment, allowing some aeration of treated sheds and some natural breakdown of fenitrothion on treated surfaces. Any uptake by birds would be further reduced by the 10 weeks of growth of the broiler chickens prior to slaughter for human consumption.

Based on the reasoning provided above, the potential uptake of fenitrothion residues by poultry from the use is considered to be low. The use patterns for the treatment of poultry housing, feed sheds and litter are supported from a residues perspective.

Cereal crops (pre-harvest)

The 1999 interim report considered a study conducted in 1996 on sorghum. Sorghum treated at 768 g a.i./ha (~1.4× locust control rate of 550 g ai/ha), with a previous application at least one month before, contained maximum fenitrothion residues in sorghum grain of 4.4 mg/kg at 4 days after last application (DALA) and 0.6 mg/kg at 14 DALA. Residues in sorghum forage were 4.8 mg/kg (dry weight basis) at 14 DALA.

The 2004 draft review report considered a supplementary residues study conducted in 2001 on winter cereals (Litzow 2002), which was also considered in 2003 by JMPR. Four trials were conducted in Australia during 2001 (2× winter wheat, 1× triticale and 1× barley). Each trial received 3 applications of fenitrothion at 550 g ai/ha (1× the maximum locust rate), residues of 0.21, 0.10, 0.08 and <0.06 mg/kg were observed in wheat, triticale and barley grain, at the registered harvest WHP of 14 days. Residues were 4.1, 2.0, 1.2 and 0.41 mg/kg (fresh weight) in wheat, triticale and barley straw at the registered grazing WHP of 14 days.

The 2004 draft review report concluded the available data for sorghum grain, wheat, triticale and barley grain was sufficient to confirm that the current GC 0080 Cereal grains MRL at 10 mg/kg would cover expected residues of fenitrothion in cereal grains in conjunction with the WHP of 14 days. The 2004 draft review report also concluded that the Australian straw data on winter cereals was sufficient to confirm the fenitrothion MRL at 10 mg/kg for cereal straw, fodder (dry) and hay of cereal grains in conjunction with the grazing WHP of 14 days.

It is noted that based on the sorghum, lucerne and pasture forage data, a fenitrothion MRL at 10 mg/kg would also be sufficient to cover potential residues in cereal forage at the 14-day grazing WHP. The use patterns for cereal grains for control of locust pests are supported from a residues perspective (up to 550 g ai/ha). The harvest and grazing WHPs of 14 days are considered appropriate.

Lucerne

The 1999 interim report considered data produced following one treatment of fenitrothion on lucerne at 1120 g ai/ha (~1.7× the Sitona weevil control rate (650 g ai/ha)). Residues of fenitrothion 7 days after treatment were 2 mg/kg for forage (dry weight, based upon 35% dry matter) and 1.1 mg/kg for hay (dry weight). Similarly, residues 14 days after treatment were 1.4 mg/kg for forage and 0.7 mg/kg for hay (both on a dry weight basis).

The lucerne data is sufficient to confirm that the lucerne forage and lucerne fodder MRLs at 5 mg/kg each are appropriate, when the existing grazing intervals of 7 days, or cutting for stockfeed of 14 days, or slaughter interval of 14 days are observed. The 14-day slaughter interval applies in situations where the grazing WHP cannot be observed or where grazing stock have been oversprayed, as instructed on product labels.

The use patterns for lucerne up to 650 g ai/ha are supported from a residues perspective. As the relevant residues data for lucerne was for a single application, label use for lucerne should be restricted to one application per year.

Pastures

The 1999 interim report considered data for fenitrothion use on pastures. In one trial (HR-81-0156) fenitrothion was applied once to pasture at 125 g ai/ha or 375 g ai/ha. When applied at 125 g ai/ha, residues of fenitrothion were 2.88 and 0.52 mg/kg (fresh weight basis) at one and 7 days after application (DAA) respectively. When applied at 375 g ai/ha residues were 6.59, 1.84 and 1.04 mg/kg (fresh weight basis) at 1, 7 and 10 DAA respectively.

The 1977 JMPR reviewed a supervised residue trial conducted in New Zealand, prior to 1974. In this trial fenitrothion was applied once to grass at 1,680 g ai/ha and residues of 74.2, 37.7, 9.0 and 3.25 mg/kg (as received) were measured at a 0, 2, 7 and 14 day WHP respectively.

Six residues studies on grass were provided by the Australian Plague Locust Commission (APLC) in support of an off label permit granted in October 1997 for control of locusts. Fenitrothion was applied at a rate of 210 mL (267 g ai/ha according to the APLC, assumed to be older UL formulation at 1270 g/L) with residues of fenitrothion on grass after a 0-day WHP reported at up to 50 mg/kg. Fenitrothion could not be detected in grass 600 m downwind when applied with winds up to 6 m/s.

Eight other studies with varying application rates between 267–1,680 g ai/ha were also supplied by the APLC. At a zero-day WHP the highest fenitrothion residues were up to 50 mg/kg declining to up to 5 mg/kg at a 7 day WHP (assumed to be reported as fresh weight but not specified).

In February 1998, NSW Agriculture and APLC conducted a residues study to determine if the 14 days WHP from slaughter period was appropriate. The trial assessed the occurrence and depletion of fenitrothion in pasture, soil and animal commodities. The registered UL formulation of fenitrothion was applied to pasture aerially once at a rate of 508 g ai/ha (~1× the locust rate) on which 28 cattle were grazing (oversprayed livestock). A further 38 cattle were allowed to graze the pasture immediately after the treatment was applied. The study duration was 21 days with samplings of pasture at 3 day before treatment (DBT) and 0, 1, 2, 4, 7, 10, 14 and 21 days after treatment (DAT) to establish a residues decline pattern. Soil samples were also taken at the same time points as the pasture samples, at a depth of 25 mm and an area of 100 mm × 100 mm. Animals were slaughtered at 2, 4, 7, 14 or 21 days after overspraying and/or grazing on treated pasture. Some cattle were withdrawn from the treated pasture for 2, 4 or 7 days prior to slaughter, representing grazing durations of between 3–13 days in the treated area. Subcutaneous fat, renal fat, muscle and liver samples were taken for analysis. Results from the decline study in pastures showed that average fenitrothion residues of 81 mg/kg on day 0 had declined to 50% of initial levels within 24 hours and declined to <10% of initial levels (2.5 mg/kg) within 7 days. The residue decline profile was similar in soil, with residues declining within 7 days of treatment. Fenitrothion residues below the limit of determination (0.02 mg/kg) in all muscle or liver samples (16 samples). Residues of fenitrothion were detected in subcutaneous fat and renal fat samples at levels of between 0.020 and 0.064 mg/kg with no obvious decline observed between 2 and 7 days after being withdrawn from the treated pasture (and noting that the 0.064 mg/kg in subcutaneous fat was detected in a control animal).

For the registered locust control rate of 550 g ai/ha, based on the data for pastures, grass, cereals and Lucerne, residues of fenitrothion in pastures are expected below the MRL for AS 0161 Straw, fodder (dry) and hay of cereal grains and other grass-like plants at 10 mg/kg when the following current grazing WHPs are observed:

Pasture and lucerne where stock have not been oversprayed:

DO NOT graze for 7 days after application or withhold stock from slaughter for 14 days after application, whichever is appropriate. DO NOT cut for stockfeed for 14 days after application.

Pasture (including lucerne) where stock have been oversprayed:

DO NOT slaughter for 14 days after application.

These WHPs are considered appropriate for the supported use on pastures for control of locust pests.

The use patterns for pastures for control of spur-throated locust, migratory locust, wingless grasshopper and Australian plague locust on pastures and pasture seed crops are supported from a residues perspective. The registered uses on pasture for control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub at up to 1,300 g ai/ha were not supported by the 1999 interim or 2004 draft review reports. The interim report required Australian data for other grass-like pasture situations and other forage crops where non-locust pests are to be controlled. Since 1999, no Australian data has provided for pasture situations. In the absence of further data, the non-locust uses on pasture should not continue. Therefore, the uses on pasture for control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub should be removed from the approved labels.

Soybean

The 1999 interim report noted that limited residues data was available for soybean forage, and the 2004 draft review report noted no Australian data had been generated in support of the soybean use. Both reports referred to soybean data reviewed by the 1974 JMPR which showed that when fenitrothion is applied at 710 g ai/ha (~1.3× the maximum locust control rate), consisting of 3 applications at 14 day intervals, the maximum residue level encountered at 9–15 days after treatment was 0.01 mg/kg in the harvested grain. There was no residues data available for forage. The 2004 draft review report confirmed that, in the absence of Australian generated data in support of the soybean use, the existing MRL and use should not continue.

Soybean residues data for fenitrothion was considered in the 2004 and 2007 JMPR, but it is noted that these soybean trials have not been submitted in full to the APVMA. In the Japanese trials considered by the 2004 JMPR, young immature green soya beans received 2–3 applications of fenitrothion at 10–13 day intervals at rates of 0.7 kg ai/ha (~1.3× the maximum locust rate), residues in green seeds were 0.002 (n=2), 0.006 and 0.01 mg/kg at 11–14 DALA (n=4). When 4 applications at 1.25 kg ai/ha (~2.3× the maximum locust rate) were applied at 7 day intervals, residues in the green soya bean (in the pod) were <0.01, 0.12 and 0.18 mg/kg at 21-30 DALA (n=3). The remaining applicable Japanese trials received 2–4 applications at 6–47 day intervals with rates of 0.7–1.25 kg ai/ha resulted in residues in soybeans (dry) of 0.001, 0.002 (n=2), 0.004 (4), <0.005 (n=4), <0.01 (n=3), 0.013, 0.022, 0.026 and 0.12 mg/kg at 11–56 DALA (n=15). The highest residue of 0.12 mg/kg was recorded 38 days after the final of 3 applications at 0.75 kg ai/ha (~1.4× the maximum locust rate) with a 12–13-day retreatment interval. The 2007 JMPR considered Brazilian trials conducted on soybeans. The trials involved 2 applications at 10 day intervals at rates of 0.28 or 0.56 kg ai/ha (~0.5–1× the maximum locust control rate), with residues in soybeans (dry) reported as <0.1 mg/kg at 14 DALA (n=6). The analytical method was not validated below 0.1 mg/kg; however, it was reported that no peaks were visible after 3 DALA in the 2 Brazilian trials that included decline data. No forage data was available for JMPR consideration.

The use patterns for soybeans are not supported from a residues perspective. It is recommended that these uses be removed from approved labels as there is not sufficient relevant residues data to enable for a robust assessment of the fenitrothion residue profile in soybeans (particularly in forage).

Fruits and vegetables

Registered fenitrothion products contain a use for locust/ grasshopper control (spur-throated locust, migratory locust, wingless grasshopper, Australian plague locust, yellow winged locust and small plague grasshopper) on the following fruit and vegetables: apples, cabbages, cherries, grapes, lettuce and tomatoes. There are currently 4 products registered with these uses: 50774, 50775, 56170 and 67186. Three of these products are an EC formulation containing 1,000 g ai/L and the other a UL formulation (50774), which contains 1,230 g ai/L of fenitrothion. Treatment rates are ~246–550 g ai/ha. Generally, the labels do not specify the number of applications and the minimum re-treatment interval. The UL product (50774) label states a retreatment interval of not less than 14 days. All approved labels state the WHP associated with these uses is 14 days.

The 1999 interim report recommended the then existing fruit MRLs (apple, cherries, grapes, and fruits except cherries and grapes) and vegetable commodity MRLs (head cabbages, head and leaf lettuce, tomato, and vegetables except head cabbages, head and leaf lettuce, tomato) be deleted, and a fruit MRL of 1 mg/kg and vegetable MRL of 0.5 mg/kg be established. The intention of these MRLs were to cover residues in fruit and vegetables resulting from emergency use situations only, presumably as plague locust situations arose. Consequently, the use patterns for fruits and vegetables remained on the approved labels.

In the 2004 draft review report, no suitable Australian data supporting the fruit and vegetable MRLs was supplied. Without this data, the APVMA could not be satisfied that the existing fruit and vegetable MRLs were acceptable from a dietary exposure and human health perspective. Accordingly, all fruit and vegetable MRLs were recommended for deletion, and the fruit and vegetable use patterns were recommended for removal from approved labels.

No new data has been provided to the APVMA since 2004 and consequently the recommendations of the 2004 draft review report still apply. The fruits and vegetable uses are not supported and all fruit and vegetables MRLs should be deleted. The fenitrothion uses on apples, cabbages, cherries, grapes, lettuce and tomatoes, are not supported, with respect to residues, as there is insufficient data to enable for a robust assessment of the fenitrothion residue profile in these crops.

Animal exposure to fenitrothion

The 1999 interim report considered animal transfer studies in hens, broilers and lactating cattle. Feed levels in the studies ranged from 10 to 100 ppm, and fenitrothion and metabolites were determined in eggs, milk and tissues. The data from the hen and cattle feeding studies showed that following feeding at levels up to 100 ppm for 28 days, fenitrothion residues above the limit of determination of 0.05 mg/kg were not observed in any tissues or eggs or above 0.01 mg/kg in milk and cream. Based on the feeding studies, the 1999 interim report determined that Maximum feeding levels (MFLs) of 100 ppm were required to meet the current MRLs at the LOQ of *0.05 mg/kg for both livestock and poultry.

The studies considered for animal feeds adequately covered the possible exposure levels resulting from postharvest treatment of cereal grains and from pastures/forages treated during locust control. Based on the data received, the existing MRLs for eggs and poultry commodities at *0.05 mg/kg were confirmed to be appropriate and therefore remained unamended. The 1999 interim report requested Australian data for lucerne, other grass-like situations, and other forage crops (eg, pasture and sorghum) where non-locust pests are to be controlled, in order to establish appropriate grazing restraints and withholding periods. As there were outstanding data requirements for forage and fodder of cereals, pastures and sorghum for treatments other than locust control, the existing MRLs for milk, meat and edible offal were removed and established as temporary MRLs until appropriate animal feed commodity data was received.

The 2004 draft review report considered a processing study conducted on rice (Ricegrowers Co-operative Ltd, 2002) and a study conducted on winter cereals (Litzow, 2002). The report recommended that the animal commodity MRLs for meat (mammalian), edible offal (mammalian) and milks at T*0.05 mg/kg should be confirmed as permanent and are considered appropriate for the supported uses.

Cereal grains and pulses can form up to 100% of the diet in livestock and poultry. Processed grain fractions can form up to 40% and 20% of the diet in livestock and poultry respectively. Pasture and forage and fodder crops can also form up to 100% of the diet in livestock. Using the MRL for forage at 10 mg/kg as a worst case scenario, the estimated maximum dietary burden is expected to be 40 ppm for beef and dairy cattle, assuming 100% of the diet comprises grass forage at 25% dry matter content. Using the MRLs for cereal grains at 10 mg/kg, the estimated maximum dietary burden is expected to be 10 ppm for poultry or livestock fed a grain diet.

Livestock exposure to fenitrothion from feeding of treated cereals and pastures (for locust control situations), lucerne fodder and forage (for sitona weevil or locust control situations), or other feed substances, including rice hulls and bran, are unlikely to result in detectable residues in animal commodities. Therefore, the current limit of quantification (LOQ) MRLs for meat (mammalian)[in the fat] and edible offal of *0.05 mg/kg are appropriate. The lactating cow feeding study reported a LOQ of 0.01 mg/kg for milk and cream, with no residues of fenitrothion in milk or cream after feeding at 100 ppm, therefore it is recommended that the milks [in the fat] MRL be established as a permanent MRL at *0.01 mg/kg.

Poultry MRLs for eggs, edible offal and meat were confirmed as permanent at *0.05 mg/kg by the 1999 interim report. However, as fenitrothion MRLs in meat (mammalian) and milks are being confirmed in the fat it is also recommended that the poultry meat MRL be changed to in the fat.

Spray drift (RAL)

From the cattle feeding study, after feeding at levels up to 100 ppm for 28 days, fenitrothion residues above the LOQ of 0.05 mg/kg for tissues of 0.01 mg/kg for milk and cream were not observed. A Regulatory Acceptable Level (RAL) of 100 mg/kg will result in residues in meat, edible offal and milk below the current LOQ animal commodity MRLs and therefore should prevent and undue risk to international trade to markets which do not have fenitrothion MRLs established in animal commodities.

Dietary exposure assessment

The chronic dietary exposure to fenitrothion is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/temporary uses of the chemical and the mean daily dietary consumption data derived primarily from the 2011–12 National Nutritional and Physical Activity Survey. The NEDI calculation is made in

accordance with WHO Guidelines and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for fenitrothion is equivalent to <10% of the ADI. It is concluded that the chronic dietary exposure to fenitrothion is acceptable.

The acute dietary exposure is estimated by the National Estimated Short Term Intake (NESTI) calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR with 97.5th percentile food consumption data derived primarily from the 2011–12 National Nutritional and Physical Activity Survey. NESTI calculations are conservative estimates of short-term exposure (24 hour period) to chemical residues in food. Based on the supported uses the highest acute dietary intake was estimated at 27% of the ARfD for children (2–6 years) and 22% of the ARfD for the general population (2+ years). It is concluded that the acute dietary exposure is acceptable.

Trade risk assessment

Cereal grains, oilseeds, pulses and oaten hay are considered major trade commodities, as are the animal commodities associated with the feeding of treated produce to livestock and poultry. Residues in these commodities resulting from the use of fenitrothion may have the potential to unduly prejudice trade.

Comparison of Australian MRLs with Codex and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. Codex CXLs are primarily intended to facilitate international trade and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. The following relevant Codex CXLs and/or international MRLs have been established for the uses and MRLs for fenitrothion which are supported from a residues and trade perspective.

The US has had no registered uses on food commodities since 1987. The only US tolerance is for wheat gluten at 3.0 mg/kg and relates specifically to the postharvest application of the insecticide to stored wheat in Australia (<u>US Electronic Code of Federal Regulations</u>).

Table 18.	Australian and	overseas I	MRLs/tolerances	for fenitrothion
I anic To.	Australian and	UVCISCAS I	WIRLS/ LUICIAIICES	

Commodity	Australia ¹	Codex ²	EU ³	China ⁴	Japan ⁵	Korea ⁶	Taiwan ⁷
Residue definition	Fenitrothion	Fenitrothion	Fenitrothion	Fenitrothion	Fenitrothion	-	-
Barley	_	_	*0.05	_	6	-	0.3
Broad beans				_	0.2	-	_
Buckwheat	_	_	*0.05	_	6	-	_
Cereal grains	10	6	*0.05	5	6 (other cereal grains)	-	0.2 Other cereals and crops (except sorghum)
Edible offal (mammalian)	*0.05	*0.05	*0.01	0.05	0.05	_	-

Commodity	Australia ¹	Codex ²	EU ³	China4	Japan⁵	Korea ⁶	Taiwan ⁷
Eggs	*0.05	*0.05	*0.01	0.05	0.05	0.05	-
Maize/corn	-	_	*0.05	_	0.2		-
Meat (mammalian)	*0.05 (in fat)	*0.05	*0.01	0.05	0.05 in muscle and fat	0.05 (fat)	0.05 (fat)
Milks	*0.01	0.01	*0.01	0.01	0.01	0.002	0.002
Millet	_	_	*0.05	_	_	0.3	_
Oats	_	_	*0.05	_	_	_	_
Oilseeds	0.1	-	*0.02	0.1 (cotton seed only)	7 (sesame seeds)	-	_
					7 (other oilseeds)		
Poultry meat	*0.05	*0.05	*0.01	0.05	0.05 in muscle and 0.4 in fat	0.05	-
Poultry offal	*0.05	_	*0.01	_	0.05	_	-
Pulses	0.1	-	*0.01	_	0.3 Beans, dried, Peas	0.05 (mung bean,	0.05 Dry beans
					0.3 (other pulses)	cowpea, pea)	
Rice	-	-	*0.05	1 and 5 (both listed as Rice)	0.2 (brown rice)	0.2	0.2
Rice bran, unprocessed	20	40	-	-	-	-	_
Rye	-	_	*0.05	_	6	_	-
Sorghum	_	_	*0.05	_	_	_	0.5
Wheat	-	-	*0.05	5 (Wheats and Whole wheat flour)	1		0.5
				1 (Wheat flour)			
Wheat bran, unprocessed	20	25	-	-	-	-	_
Wheat germ	20	_	_	_	_	-	_

¹ Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023 (Cited 28/10/2023)

- ² FAO Codex Alimentarius International Food Standards (Cited 28/10/2023)
- ³ European Commission Pesticide Residue (s) and maximum residue limits (Cited 28/10/2023)
- ⁴ <u>USDA Gain report: National Standard of the People's Republic of China, National Food Safety Standard Maximum Residue Limits for Pesticides in Food, implemented 03-09-2021</u> (Cited 28/10/2023)
- ⁵ <u>Japanese Food Chemical Research Foundation Table of MRLs for Agricultural Chemicals</u> (Cited 28/10/2023)
- ⁶ Food Safety Korea Pesticide MRLs for agricultural commodities (Cited 28/10/2023)
- ⁷ Food and Drug Administration Taiwan Standards for Pesticide Residue Limits in Foods (Cited 28/10/2023)

Potential risk to trade

Export of treated produce containing finite (measurable) residues of fenitrothion may pose a risk to Australian trade in situations where either no residue tolerance (import tolerance) is established in the importing country, or where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

For animal commodities Australian MRLs are established or recommended at the LOQ of *0.05 mg/kg for tissue and eggs and *0.01 mg/kg for milks. Good international MRL coverage exists in all markets at the LOQs noting that the EU has MRLs at *0.01 mg/kg in all animal commodities, Korea has a lower MRL for milks at 0.002 mg/kg and there are no established tolerances in the US. Given that the maximum dietary burdens associated with the uses supported from a residues perspective for livestock and poultry are 40 ppm and 10 ppm respectively and residues were below <0.05 mg/kg in tissues and eggs and <0.01 mg/kg in milk and cream after feeding at 100 ppm, it is likely that residues of fenitrothion in animal commodities would meet the requirements of all overseas markets when the registered withholding periods and export intervals are observed. The potential risk to Australian trade is not considered undue for animal commodities.

The Australian fenitrothion MRL for cereal grains at 10 mg/kg is higher than that established in all other markets. Codex and Japan have cereal grains MRLs at 6 mg/kg and the European Union at *0.05 mg/kg. In China, cereal grains MRLs are established at 5 mg/kg for wheats, rice, upland crops and coarse cereals, noting the MRL for wheat flour and the other rice MRL at 1 mg/kg. In Korea there is limited coverage for cereal grains except for coverage in millet at 0.3 mg/kg and rice at 0.2 mg/kg. The US has had no registered uses on food commodities since 1987. The US wheat gluten tolerance relates specifically to the postharvest application of the insecticide to stored wheat in Australia. The potential risk to trade of cereal grains has existed for many years and has been well managed by industry. The grains industry has well established practices to manage the risks of fenitrothion residues in exported grains and process fractions including the Australian Grains Industry Post Harvest Chemical Usage Recommendations and Outturn Tolerances, which provides specific recommendations for fenitrothion residues in grains for individual export markets and defines an industry outturn target of half the established Australian MRL.

For oilseeds and pulses international MRL coverage is limited; however, as described above the potential risk to trade is not considered undue. The risks have been managed for many years and industry has well established practices for mitigating the risks. It is noted that the Australian Grains Industry Post Harvest Chemical Usage Recommendations and Outturn Tolerances also includes specific recommendations for fenitrothion residues in oilseeds and pulses.

As the potential trade risk associated with fenitrothion residues expected in cereal grains, pulses and oilseeds have been effectively managed by industry, and because international standards for fenitrothion have not significantly changed in recent years, it is currently considered that the trade risk associated with the uses of fenitrothion in cereal grains and grain storage facilities and equipment is not undue. However, as the Australian MRL is higher than those set by Codex or major export destinations, it is recommended that the following trade advice statement should be added to the labels of products containing uses on stored cereal grains (including grain storage facilities and equipment):

EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain or grain storage facilities or equipment using this product.

As the Australian MRL for cereal grains is higher than those set by Codex and major export destinations, the APVMA seeks comments from members of the grain industry on their ability to manage the risk to international trade associated with fenitrothion through this consultation, before a final decision against the trade criteria is made for uses on stored cereal grain.

Residues and trade recommendations

The outcomes of the residues and trade assessment of fenitrothion is summarised in Table 19. This assessment supports the post-harvest uses on cereal grains, the cereal storage facilities and equipment uses, and the uses for poultry housing. The broadacre uses for cereals, pastures and pasture seed crops for control of locust pests at up to 550 g ai/ha, for lucerne for control of sitona weevil at up to 650 g ai/ha are also supported. Sufficient data has been available to support the establishment of permanent MRLs for mammalian offal, meat and milks, rice bran, rice hulls, alfalfa [lucerne] forage and fodder and to recommend other appropriate animal feed MRLs for the supported uses. There was insufficient data to support the continued uses on apples, cherries, cabbages, grapes, lettuce, soybeans, tomatoes. There was insufficient data to support the uses on pasture above 550 g ai/ha, these are essentially the non-locust pest uses on pastures.

Table 19: Summary of residue assessment outcomes for fenitrothion use patterns

Use pattern	Use supported	Outcomes of the residues assessment
Stored cereal grains	Yes	Add WHP statement to all labels 'Not required when used as directed'.
6ppm		Add trade advice statement: EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain or grain storage facilities or equipment using this product.

Use pattern	Use supported	Outcomes of the residues assessment
Stored cereal grain	Yes	Add WHP statement to all labels 'Not required when used as directed'.
6ppm plus addition of S-methoprene		Add trade advice statement: EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain or grain storage facilities or equipment using this product.
Stored cereal grains 12ppm	Yes	Amend WHP statement to 'DO NOT use for processing into food for human consumption or stock food within 13 weeks of treatment'.
		Add trade advice statement: EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain or grain storage facilities or equipment using this product.
Grain storage facilities and equipment	Yes	Add WHP statement to all labels 'DO NOT use for processing into food for human consumption or stock food within 13 weeks of treatment'.
		Add critical comment: 'Precautions should be taken to prevent surface contamination of grain'.
		Add trade advice statement: EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain or grain storage facilities or equipment using this product.
Grain surface treatment	Yes	Add WHP statement to all labels 'DO NOT use for processing into food for human consumption or stock food within 13 weeks of treatment'.
		Add trade advice statement: EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain or grain storage facilities or equipment using this product.
Broiler poultry house litter, walls, roof and feed sheds	Yes	No changes
Locust and grasshopper pests in cereal grains	Yes	Add restraint: 'DO NOT apply more than three application per season to cereals'
Sitona weevil in lucerne fodder and forage	Yes	Add restraint: 'DO NOT apply more than one application per year to lucerne'

Use pattern	Use supported	Outcomes of the residues assessment
Locust and grasshopper pest in pasture and pasture seed crops	Yes	Add restraint: 'DO NOT apply more than three applications per year to pasture or pasture seed crops'
		Amend original term 'Pasture, Pasture Seed Crops, Forage Crops including grazing Sorghum, Lucerne, Soybeans, Cereal Crops' on label to 'Pastures, pasture seed crops, lucerne and cereal crops.'
Non-locust pests in pasture (pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub).	No	No residues data submitted to support control of non-locust pests on pasture.
Locust and grasshopper pests in soybean	No	Insufficient residues data to support the registered use (particularly the 14 day grazing WHP).
Locust and grasshopper pests in apples, cabbages, cherries, grapes, lettuce and tomatoes.	No	Insufficient residues data to support the registered use.

While a number of fenitrothion use patterns could be supported from a residues and trade perspective, only the use of fenitrothion on stored cereal grains is also supported by the environmental and human health risk assessments. As such, the following trade advice statement is recommended on product labels (amended to remove reference to grain storage facilities and equipment)

EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain using this product.

Amendments to the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023

Table 20 to Table 22 include the recommended MRL changes in the <u>Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products)</u> Instrument 2023 (MRL Standard for Residues of Chemical Products), which will be required as an outcome of the review of registered products. It is noted that no changes are required for the existing MRLs for GC 0080 Cereal grains at 10 mg/kg, PE 0112 Eggs at *0.05 mg/kg, SO 0088 Oilseeds at 0.1 mg/kg, PO 0111 Poultry, edible offal at *0.05 mg/kg, VD 0070 Pulses at 0.1 mg/kg, CM 0654 Wheat bran, unprocessed at 20 mg/kg and CF 1210 Wheat germ at 20 mg/kg.

MRLs for registered uses not supported by the APVMA chemical review will be deleted after the completion of any phase out period. As discussed above, the environmental and human health risk assessments have not supported the use of fenitrothion except for uses in stored cereal grains. It is noted that the residues assessment also supported field use in cereal grains, lucerne and pastures, grain storage facilities and equipment, and in poultry

houses. While those uses were not supported by the environmental or human health risk assessments, the same MRL recommendations in Table 1 of the MRL Standard for Residues of Chemical Products for cereal grains and animal commodities are required for the stored grain use.

Although the use of fenitrothion in grain storage facilities and equipment are not expected to be supported due to human health concerns, the MRL recommendations for pulses and oilseeds (retention of the existing MRLs at 0.1 mg/kg) remain appropriate for the supported stored cereal grain use. Exposure of stored pulses and oilseeds to fenitrothion may still occur in structures previously used for treated cereal grains following residue transfer from the cereal grain to the surface of the storage structure, in addition to contact with facilities and equipment directly treated with fenitrothion.

The uses of fenitrothion in pastures and forage crops as well as to grain storage structures, equipment, and broiler poultry houses are not expected to be supported by the APVMA review; however, dietary exposure to livestock and poultry will continue to occur via treated stored cereal grains. With the removal of pasture and forages, the maximum dietary burden for mammalian livestock will reduce from 40 to 10 ppm in the feed (driven by the MRL for cereal grains required for the post-harvest use). The maximum dietary burden for poultry will remain at 10 ppm. Despite the reduction in the animal dietary burden for mammalian livestock, the MRL recommendations made above for animal commodities remains appropriate because finite residues are not expected in mammalian tissues and milk from the higher feeding burden and because the maximum feeding burden for poultry will remain unchanged.

As the field use in cereal crops, lucerne and pasture are not supported by the APVMA chemical review, MRLs in Table 4 of the MRL Standard for Residues of Chemical Products will not be required for cereal and lucerne forage or fodder, or pasture. Therefore, the existing MRLs in Table 4 will be deleted. A MRL for rice hulls at 50 mg/kg will be added to Table 4, which is required for the stored cereal grain use. There is an existing Table 5 entry for fenitrothion when used as a seed dressing, which will also be deleted as it is not associated with a current use.

Table 20: Amendments to Table 1 of the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023

Code		Commodity	MRL (mg/kg)	
			DELETE	ADD
FP	0226	Apple	1	-
VB	0041	Cabbages, head	0.5	-
FS	0013	Cherries	1	-
МО	0105	Edible offal (mammalian)	T*0.05	*0.05
FB	0269	Grapes	1	-
VL	0482	Lettuce, head	0.5	_
VL	0483	Lettuce, leaf	0.5	_
MM	0095	Meat (mammalian) [in the fat]	T*0.05	*0.05

Code		Commodity	MRL (mg/kg)	
			DELETE	ADD
ML	0106	Milks [in the fat]	T*0.05	*0.01
PM	0110	Poultry meat [in the fat] #	*0.05	*0.05
СМ	01206	Rice bran, unprocessed	T20	20
VO	0448	Tomato	0.5	_

^{*}The expression of the MRL for PM 0110 Poultry meat will be changed to Poultry meat [in the fat]

Table 21: Amendments to Table 4 of the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023

Code		Commodity	MRL (mg/kg)		
			DELETE	ADD	
AL	1020	Alfalfa [lucerne] fodder	T5	-	
AL	1021	Alfalfa [lucerne] forage (green)	T5	-	
AL	0157	Legume animal feeds {except Alfalfa [lucerne] fodder; Alfalfa [lucerne] forage }	T10	-	
		Oilseed forage and fodder	T10	_	
		Rice hulls	_	50	
AS	0161	Straw, fodder (dry and hay of cereal grains and other grass-like plants (dry weight basis)	T10	-	

Table 22: Amendments to Table 5 of the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023

Substance	Use
DELETE	
Fenitrothion	For use in seed dressings

Environmental safety

Previous assessments

In 1999, an <u>interim environmental assessment report</u> for fenitrothion was published by the APVMA (then the NRA), which raised concerns about high avian and aquatic invertebrate toxicity. As an outcome of the assessment, various risk management recommendations were implemented to reduce environmental risks including aquatic buffer zones for application to broadacre crops, lucerne, and pasture, and limitations on the quantity applied and frequency of application in certain situations.

Current assessment

Four fenitrothion registrations remain for control of locusts and other insect pests in pasture and certain field, pasture, orchard, vineyard, and vegetable crops. Application rates range from 250 to 1,300 g ac/ha. Three applications possible per season at the rates up to 650 g ac/ha.

Several fenitrothion products are also registered for control of mealworm in poultry houses or various insect pests in stored grain protection (including structural treatments). These are indoor applications and are considered to result in low environmental exposure. Therefore, they have not been quantitatively assessed. However, certain environmental protection statements still apply as indicated in under 'Environment recommendations'.

The environmental risk assessment scenarios considered in the current assessment are summarised in Table 23. Environmental risks were determined according to contemporary methodology outlined in the <u>APVMA Risk Assessment Manual – Environment</u>. Additional data available since the initial 1999 assessment have also been considered.

Table 23: Environmental risk assessment scenarios

Category	Situation	Risk assessment scenario
Animal housing	Poultry houses	Negligible exposure of the environment
Grain protection	Stored grain protection, including structural treatments	Negligible exposure of the environment
Field crops and pasture	Cereals, forage crops, soybeans	3× 550 g ac/ha 14-day retreatment interval
	Lucerne	3× 650 g ac/ha 7-day retreatment interval
	Pasture and pasture seed crops	1× 1,300 g ac/ha

Category	Situation	Risk assessment scenario
Tree and vine crops	Apples, cherries, grapes	3× 550 g ac/ha 14-day retreatment interval
Vegetable crops	Tomatoes, lettuce, cabbage	3× 550 g ac/ha 14-day retreatment interval

Fate and behaviour in the environment

The fate and behaviour of fenitrothion in the environment have been described in the interim 1999 environment assessment report. A few guideline studies have since been generated that inform the key regulatory endpoints for the exposure assessment, which are summarised in Table 24. A full listing of endpoints is provided in Appendix B.

Fenitrothion is non-volatile and has low solubility in water. Its octanol-water partition coefficient indicates a high potential for bioaccumulation. Fenitrothion does not dissociate in water and is susceptible to photochemical degradation under alkaline conditions.

Lewis & Tzilivakis (2017) collated data on the dissipation of fenitrothion on or within various plant matrices using a systematic review approach using several scientific databases. Collated literature was subjected to a quality assessment, for which 14 published articles covering 15 crops across various matrices (leaves, fruits, grass blades, leaf litter) were determined to be acceptable. Mean DT_{50} values for foliar residues ranged from 0.50 to 20 days (geomean 3.2 days); mean DT_{50} values for residues in fruit ranged from 2.2 to 8.3 days (geomean 4.7 days). Fenitrothion is non-systemic and is not known to translocate in plants.

Fenitrothion is non-persistent in soil (geomean DT_{50} 1.1 days) and is moderately mobile (mean Koc 497 mL/g). There is no relationship between soil adsorption and soil organic carbon. However, because the lowest Kf was found for the lowest organic carbon soil (1.3%), this value was considered most appropriate for the runoff assessment. The mean result is used for the food chain assessment (Kf 17 mL/g). Fenitrothion is non-persistent in aquatic systems (geomean DT_{50} 1.6 days) with limited partitioning to sediment (max 28% in sediment; Kf 42 mL/g). Fenitrothion has low volatility and is not subject to long-range transport through the air.

Table 24: Key regulatory endpoints for exposure assessment

Compartment	Value	Reference
Animal food items	Foliage: DT ₅₀ 3.2 d	Bahaffi et al. 2005, Gilmour et al. 1999, Hu et al. 2009, Likas & Tsiropoulos 2007, Sundaram 1986, Willis & McDowell 1987, Zongmao & Haibin 1997
	Fruit: DT ₅₀ 4.7 d	Bahaffi et al. 2005, Cabras & Angioni 2000, Cabras et al. 1997, Fernández-Cruz et al. 2004, Ishii 2004, Malhat et al. 2017, Passarella et al. 2009
	Other: DT ₅₀ 10 d	Default

Compartment	Value	Reference
Soil	DT ₅₀ 1.1 d	Cranor & Daly 1989, Yeomans & Swales 2001
(Runoff assessment) (Food chain assessment)	Kf 4.9 mL/g, 1/n 0.95 Kf 17 mL/g	Spillner & Neuberger 1979
Water	DT ₅₀ 1.6 d	Swales 2001
Sediment	DT ₅₀ 1.6 d	Swales 2001
	Kp 42 mL/g	Spillner & Neuberger 1979
Air	DT ₅₀ 0.23 d	Nishiyama et al. 2000

Effects on non-target species

The effects of fenitrothion on non-target species have been described in the interim 1999 environment assessment report. A few guideline studies have since been generated and literature published that inform the key regulatory endpoints for the effects assessment, which are summarised in Table 25. A full listing of endpoints is provided in Appendix B.

Fenitrothion has moderate toxicity to mammals (LD_{50} 330 mg ac/kg bw, *Rattus norvegicus*) and high toxicity to birds (geomean LD_{50} 45 mg ac/kg bw, three sensitive species) following a single oral dose. Fenitrothion also has high toxicity to birds following short-term dietary exposure (lowest LDD_{50} 68 mg ac/kg bw/d, *Colinus virginianus*). Therefore, the following protection statement is required on fenitrothion product labels where there is potential for exposure (followed by an appropriate risk management statement).²

Toxic to birds.

For acute toxicity to birds, the geomean $LD_{50}/10$ (4.5 mg ac/kg bw) is lower than the lowest LD_{50} value (23 mg ac/kg bw); therefore, the higher tier RAL can be used for risk assessment (EFSA 2009, 2023).

Following dietary exposure in reproductive toxicity tests, reduced pup body weights in litters of both generations, viability and lactation indices of mammals were observed at doses as low as 7.4 mg ac/kg bw/d (NOEL 2.3 mg ac/kg bw/d, *Rattus norvegicus*), reduced egg production was observed in birds at doses as low as 3.1 mg ac/kg bw/d (NOEL 2.3 mg ac/kg bw/d, *Colinus virginianus*), and reduced adult body weight was observed at doses as low as 9.2 mg ac/kg bw/d (NOEL 6.0 mg ac/kg bw/d, *Anas platyrhynchos*).

A field study investigating bird mortality and activity following application of 485 or 825 g ac/ha to savannah recovered 6 dead/debilitated birds on the lower dose plot and 10 birds on the higher dose plot. Mortality on the low dose plot was estimated to be 2% of larger birds and 7% of smaller birds, while it was 6% and 7%, respectively, on

² Not required for stored grain protection

the high dose plot. Bird numbers on fenitrothion treated plots declined by 30–47%, a much greater reduction than estimated to be due to mortality. A general decrease occurred with all bird species monitored. Population reductions appeared to mainly reflect bird movement in response to a reduction in grasshopper prey.

The APVMA is also aware of literature investigating cholinesterase activity and residues in tissues. However, there is currently no clear method for linking these types of observations to field effects. Therefore, such studies have not been considered in depth here nor used to set endpoints for use in risk assessment.

Fenitrothion has moderate toxicity to fish (lowest LC $_{50}$ 1.3 mg ac/L, *Oncorhynchus mykiss*) and algae (E $_{r}$ C $_{50}$ 2.7 mg ac/L, *Pseudorkirchneriella subcapitata*), and high toxicity to aquatic invertebrates (lowest LC $_{50}$ 0.0081 mg ac/L, *Chironomus riparius*). The major metabolites NMC and AM-FNT are less toxic than the parent substance fenitrothion. Based on the available data, the following protection statement is required on fenitrothion product labels.

Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.

Following long-term exposure to fenitrothion, reduced growth of fish in the early life stages was observed at concentrations as low as 0.17 mg ac/L (NOEC 0.088 mg ac/L, *Oncorhynchus mykiss*) and reduced survival and fecundity of aquatic invertebrates was observed at concentrations as low as 0.00023 mg ac/L (NOEC 0.000087 mg ac/L, *Daphnia magna*).

Fenitrothion shows a low potential to bioaccumulate in fish. Under flow-through conditions at a nominal concentration of 0.05 mg/l, the steady state BCF was reached within approximately one day of exposure (Ohshima *et al.* 1988). The average BCFs for the parent compound over the exposure period for whole fish, fillet and viscera were 29, 19 and 36, respectively. Fenitrothion readily depurates from fish tissues with an estimated CT₉₅ of less than one day. It is concluded that fenitrothion will not persist in fish. In fish tissues, fenitrothion, DM-FNT, NMC and the AAMC related metabolites together accounted for 85–96% of the radioactive residue (Ohshima & Mikami 1990). These metabolites also depurate readily from fish tissues with a CT₉₅ of less than 7 days.

A field study investigating impact on invertebrates in temporary ponds following application of 500 g ac/ha to a cultivated savannah measured initial concentrations of 80 μ g ac/L in the pond water (DT₅₀ 34 hours). Fenitrothion significantly reduced population densities of backswimmers of the genus *Anisops* (Hemiptera, Notonectidae) and in addition caused an extensive kill of other species of insects. Both insecticide applications were also followed by reductions of zooplankton densities, especially Cladocera. Recovery proceeded at fixed rates, which were different for each taxon. *Anisops* spp. recovered from the treatments in 0.5 to 3 weeks, most likely through aerial migration. Cladocerans returned to normal densities in 3.5 to 6 weeks.

The RAL established for the aquatic risk assessment is based on an SSD (BurrliOz v2.0) of acute aquatic invertebrate data. The SSD (see Figure 2) showed the lower limit HC $_5$ derived from the curve (0.18 μ g ac/L) to be less than 1/3 of the median HC $_5$ (0.57 μ g ac/L). Additionally, the lower tail the toxicity data are, overall, positioned on the left side of the SSD curve. As a result of these considerations an assessment factor of 6 was applied to the median HC $_5$ resulting in a RAL of 0.095 μ g ac/L.

Fenitrothion has high toxicity to adult bees by contact exposure (LD₅₀ 0.16 μ g ac/bee, *Apis mellifera*) and oral exposure (LD₅₀ 0.20 μ g ac/bee, *Apis mellifera*). Therefore, the following hazard statement is advised for fenitrothion product labels that have outdoor uses (followed by an appropriate risk management statement).³

Toxic to bees.

For the spray drift assessment, the RAL is 27 g ac/ha based on the contact LD $_{50}$ 0.16 µg ac/bee and a conversion factor of LOC 0.4/ExpE 2.4 * 1,000 as per APVMA's spray drift risk assessment manual (SDRAM).

There are no contemporary data on the toxicity of fenitrothion to predatory and parasitic arthropods. Fenitrothion products are not considered to be compatible with integrated pest management programs utilising beneficial arthropods. Therefore, the following protection statement is advised for fenitrothion agricultural product labels.⁴

Toxic to beneficial arthropods. Not compatible with integrated pest management (IPM) programs utilising beneficial arthropods. Minimise spray drift to reduce harmful effects on beneficial arthropods in non-crop areas.

In an Australian field study using fenitrothion for plague locust control, effects on non-target invertebrates were investigated during Australian plague locust control operations on a Mitchell grass plain in south-western Queensland following application at 267 g ac/ha. Significant differences in invertebrate community compositions between the treated and control sites were evident for up to 39 days (yellow pan traps) and over 79 days (pitfall traps) with invertebrate assemblages among all sites again being similar when sampled 189 days post spray. The response pattern of the sprayed sites was driven mostly by decreases in the abundance of Orthoptera, Formicidae and Collembola.

Fenitrothion is moderately toxic to soil macro-organisms such as earthworms (LC_{50corr} 116 mg ac/kg dry soil, *Eisenia fetida*), the metabolite NMC is also moderately toxic (LC_{50corr} 18 mg/kg dry soil, *Eisenia fetida*). Fenitrothion did not influence soil processes such as nitrogen transformation at the highest test concentration (NOEC 10 mg ac/kg dry soil).

Field studies are available that investigated the effect of fenitrothion, applied once as a granular formulation at 2.24 kg ac/ha, on soil dwelling organisms. No effect on the abundance of earthworms (*Allolobophora caliginosa*) was reported. Effects on individual species of collembola and acari cannot be excluded, though where an effect could not be excluded in most cases recovery was observed within 30 weeks.

The toxicity of a 40% WP formulation to 6 species of non-target terrestrial plants has been tested following postemergent exposure in a screening test. All ER₂₅ values are >1,000 g ac/ha. Fenitrothion does not show any fungicidal activity against 7 test diseases (Oguri 2001).

Normal agricultural practice was not expected to lead to significant exposure of sewage treatment works to fenitrothion. The activated sludge test indicates that no adverse effect on microbial activity in sewage treatment works is expected at concentrations of 1,000 mg ac/L (L'Haridon 2002).

³ Not required for poultry houses or stored grain protection

⁴ Not required for poultry houses or stored grain protection

Table 25: Regulatory acceptable levels for non-target species

Group	Exposure	Endpoint	AF	RAL	Reference
Mammals	Acute	LD ₅₀ 330 mg ac/kg bw	10	33 mg ac/kg bw	Kadota et al. 1972
	Chronic	NOEL 2.3 mg ac/kg bw/d	1	2.3 mg ac/kg bw/d	Hoberman 1990
Birds	Acute	LD ₅₀ 45 mg ac/kg bw	10	4.5 mg ac/kg bw	Fletcher 1971, Grimes & Jaber 1988a, Kadota et al. 1974
	Chronic	NOEL 2.3 mg ac/kg bw/d	1	2.3 mg ac/kg bw/d	Beavers et al. 1991
Aquatic species	Acute	HC ₅ 0.57 μg ac/L	6	0.095 μg ac/L	Burke 2011, Burke & Flenley 2011, Burke & Scholey 2011a, Forbis 1987, Lahr et al. 2001, Matsumoto et al. 2009, Shigehisa & Shiraishi 1998, Yokoyama et al. 2009
Adult bees	Acute contact	LD ₅₀ 0.16 μg ac/bee	2.5	0.064 µg ac/bee	Hoberg 2001
	Acute oral	LD ₅₀ 0.20 μg ac/bee	2.5	0.080 µg ac/bee	Hoberg 2001
Soil macro- organisms	Acute	LC _{50corr} 116 mg ac/kg ds	10	12 mg ac/kg ds	Ellgehausen et al. 1985
Soil micro-organisms	Chronic	NOEC 10 mg ac/kg ds	1	10 mg ac/kg ds	Mikami et al. 1984
Terrestrial plants	Post- emergent	ER ₂₅ >1000 g ac/ha	2	500 g ac/ha	Mito 2001

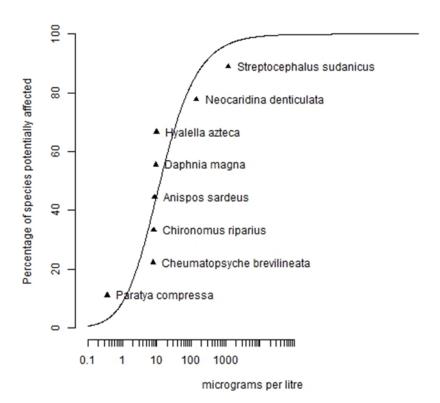


Figure 2: Acute aquatic invertebrate species sensitivity distribution

Risks to non-target species

Terrestrial vertebrates

For outdoor uses of fenitrothion, risks to terrestrial vertebrates following dietary exposure to contaminated food items were determined by the APVMA as indicated in Appendix C. No outcomes were identified as acceptable for birds (Table 26). The maximum seasonal rate supported for each use pattern is below the lowest label rate for any situation in any of the currently registered fenitrothion products.

The log Pow 3.3 for fenitrothion indicates a potential for bioaccumulation. As bioaccumulation processes are often slow, a chronic assessment is appropriate. The food chain assessment for fish-eating species assumes that the RAL for aquatic species is not exceeded on the basis that only use situations with acceptable risks to aquatic species will be approved. Provided water concentrations do not exceed the aquatic RAL, any accumulated residues in fish will not reach levels harmful to predators (Table 25). A maximum seasonal rate of 924 g ac/ha was determined to be acceptable to earthworm-eating mammals. After considering potential exposure rates over a 10-hectare area (see Table D1 in Appendix D), any accumulated residues in earthworms will not reach levels harmful to predators.

Table 26: Summary of risk assessment outcomes for terrestrial vertebrates

Use pattern	Situation	Application rate and frequency	Wild mammal assessment	Bird assessment	Max seasonal rate supported
Field crops and pasture	Cereals	3× 550 g ac/ha 14d interval	Acceptable risk	Not supported	78 g ac/ha
	Soybeans, forage crops	3× 550 g ac/ha 14d interval	Not acceptable at BBCH 40–49	Not supported	81 g ac/ha
	Lucerne	3× 650 g ac/ha 7d interval	Not acceptable at BBCH 40–49	Not supported	81 g ac/ha
	Pasture, pasture seed crops	1× 1,300 g ac/ha	Not supported	Not supported	148 g ac/ha
Tree and vine crops	Apples, cherries	3× 550 g ac/ha 14d interval	Not acceptable up to BBCH 19	Not supported	96 g ac/ha
	Grapes	3× 550 g ac/ha 14d interval	Not acceptable up to BBCH 19	Not supported	156 g ac/ha
Vegetable crops	Tomatoes	3× 550 g ac/ha 14d interval	Not acceptable at BBCH 10–49 or during fruiting	Not supported	78 g ac/ha
	Lettuce, cabbage	3× 550 g ac/ha 14d interval	Not acceptable at BBCH 40–49	Not supported	50 g ac/ha

Table 27: Food chain assessment for terrestrial vertebrates (maximum acceptable threshold)

Exposure	Indicator species	Group	Shortcut value	PECmedia (mg/kg or mg/L)	DDD (mg/kg/d)	RAL (mg/kg/d)	RQ
Chronic	Earthworm-eating species	Mammals	1.28	1.2	2.3	2.3	1.0
		Birds	1.05	1.2	1.9	2.3	0.82
	Fish-eating species	Mammals	0.142	0.000095	0.00039	2.3	<0.01
		Birds	0.159	0.000095	0.00044	2.3	<0.01

Shortcut values from EFSA (2009)

 $\mathsf{PEC}_{\mathsf{medium}}\;\mathsf{is} \colon$

PEC_{soil} = predicted environmental concentration in soil (mg/kg) = 924 g ac/ha (maximum acceptable seasonal rate to achieve RQ 1.0) /750

PEC_{water} = aquatic RAL (from Table 23)

 $PEC_{food} = PEC_{medium} * BCF$, where:

BCF_{earthworm} is 1.5 based on [0.84 + 0.012 * 10^(log Pow 3.3)] / Kf 17 (from Table X)

BCF_{fish} is 29 (Oshima et al. 1988)

DDD = daily dietary dose (mg/kg bw/d) = shortcut value * PEC_{food}

RAL = regulatory acceptable level (from Table 23)

RQ = risk quotient = PEC / RAL, where acceptable RQ ≤1

Aquatic species

For outdoor uses of fenitrothion, runoff risks to aquatic species were determined by the APVMA as indicated in Appendix D. Risks were determined to be acceptable with some restraints required in certain situations. The summary of the runoff assessment outcomes for each use pattern is reported in Table 28. In addition, because the assessment assumes a runoff event occurs 3 days after application, the following restraint is required for fenitrothion product labels that have outdoor uses.⁵

DO NOT apply if heavy rains or storms are forecast within 3 days.

DO NOT irrigate to the point of runoff for at least 3 days after application.

As indicated in Table 25, the RAL for the spray drift assessment is 0.095 μ g ac/L for the protection of natural aquatic areas. Risks of spray drift are assessed separately in the <u>Spray drift</u> section, as needed.

Table 28: Fenitrothion – summary of runoff risk assessment outcomes

Use pattern	Situation	Application rate and frequency	Runoff assessment outcome
Field crops and pasture	Cereals	3× 550 g ac/ha 14d interval	Acceptable risk
	Forage crops	3× 550 g ac/ha 14d interval	Restrictions required: Victoria: DO NOT apply from September to May South Australia: DO NOT apply from September to May Western Australia: DO NOT apply from December to February

⁵ Not required for poultry houses or stored grain protection

Use pattern	Situation	Application rate and frequency	Runoff assessment outcome
	Soybeans	3× 550 g ac/ha	Restrictions required:
		14d interval	Victoria: DO NOT apply from December to February
			Burdekin: DO NOT apply in October
			Mackay/Whitsunday: DO NOT apply from August to December
	Lucerne	3× 650 g ac/ha	Restrictions required:
		7d interval	DO NOT apply in Victoria
			South Australia: DO NOT apply from September to May
		Western Australia: DO NOT apply from September to May	
	Pasture,	1× 1,300 g ac/ha	Restrictions required:
	pasture seed crops		Victoria: DO NOT apply from September to May
	'		South Australia: DO NOT apply from September to May
		Western Australia: DO NOT apply from December to February	
Tree & vine crops	Apples, cherries	3× 550 g ac/ha 14d interval	Acceptable risk
	Grapes	3× 550 g ac/ha	Restrictions required:
		14d interval	Mackay/Whitsunday: DO NOT apply from October to November unless there is pasture inter-row
Vegetable	Tomatoes	3× 550 g ac/ha	Restrictions required:
crops		14d interval	Mackay/Whitsunday: DO NOT apply from August to December
	Lettuce,	3× 550 g ac/ha	Restrictions required:
	cabbage	14d interval	Victoria: DO NOT apply from December to February
			Burdekin: DO NOT apply in October
			Mackay/Whitsunday: DO NOT apply from August to December

Bees

Risks to bees are assessed using a tiered approach. A screening level risk assessment assumes the worst-case scenario of a direct overspray of blooming plants that are frequented by bees in order to identify those substances and associated uses that do not pose a risk. Acceptable risks to foraging bees could not be concluded at the

lowest application rate of 250 g ac/ha (Table 29). No higher tier information is available and therefore the following protection statement is advised for all outdoor uses of fenitrothion products. ⁶

Toxic to bees. DO NOT apply to crops from the onset of flowering until flowering is complete. DO NOT allow spray drift to flowering weeds or flowering crops in the vicinity of the treatment area. Before spraying, notify beekeepers to move hives to a safe location with an untreated source of nectar and pollen, if there is potential for managed hives to be affected by the spray or spray drift.

As indicated in Table 23, the RAL for the spray drift assessment is 27 g ac/ha for the protection of pollinator areas. Risks of spray drift are assessed separately in the Spray drift section, as needed.

Table 29: Screening level assessment of risks to bees

Life stage	Exposure	Rate (g/ha)	Predicted total dose (µg/bee)	RAL (µg/bee)	RQ
Highest single ra	ate				
Adults	Acute contact	1 300	3.1	0.064	49
	Acute oral	1 300	37	0.080	465
Lowest single ra	te				
Adults	Acute contact	250	0.60	0.064	9.4
	Acute oral	250	7.2	0.080	89

Predicted total dose calculated using USEPA BeeREX tool for adult worker bee foraging for nectar and larval drone within the hive

RAL = regulatory acceptable level (from Table 25)

RQ = risk quotient = PEC / RAL, where acceptable RQ ≤1

Other non-target arthropod species

In the absence of contemporary toxicity data, fenitrothion products are not considered to be compatible with integrated pest management programs utilising beneficial arthropods. Therefore, the following protection statement is advised for outdoor uses of fenitrothion products. ⁷

Toxic to beneficial arthropods. Not compatible with integrated pest management (IPM) programs utilising beneficial arthropods. Minimise spray drift to reduce harmful effects on beneficial arthropods in non-crop areas.

⁶ Not required for poultry houses or stored grain protection

⁷ Not required for poultry houses or stored grain protection

Soil organisms

Risks to soil organisms are assessed using a tiered approach. A screening level risk assessment assumes the worst-case scenario of a direct overspray of soil without interception in order to identify those substances and associated uses that do not pose a risk to soil organisms. Acceptable risks of fenitrothion to soil organisms could be concluded at the screening level at the maximum single and seasonal rate of 1,300 g ac/ha (pasture) (Table 30). Available field studies suggests that there are no long-term effects on soil organisms. Therefore, no protection statements are required for soil organisms on fenitrothion product labels.

Table 30: Screening level assessment of risks to soil organisms

Group	Exposure	Rate (g/ha)	PEC (mg/kg dry soil)	RAL (mg/kg dry soil)	RQ
Macro-organisms	Acute	1 300	1.7	12	0.14
Micro-organisms	Chronic	1 300	1.7	10	0.17

Maximum single and seasonal rate based on 1× 1300 g ac/ha in pasture situations

PEC = predicted environmental concentration in top 5-cm soil (mg ac/kg dry soil) = rate (g ac/ha)/750

RAL = regulatory acceptable level (from Table 25)

RQ = risk quotient = PEC / RAL, where acceptable RQ ≤1

Terrestrial plants

As indicated in Table 25, the RAL for the spray drift assessment is 500 g ac/ha for the protection of vegetation areas. Risks of spray drift are assessed in the <u>Spray drift</u> section, as needed.

Recommendations

Uses supported from the viewpoint of environmental safety are listed in Table 31 with the required protection statements and restraints. Uses that are not supported from the viewpoint of environmental safety are listed in Table 32.

Table 31: Supported uses from the viewpoint of environmental safety

Situation	Protection statements and restraints
All supported situations	Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
Stored grain protection, including structural treatments	(No additional protection statements or restraints are required).
Poultry houses	Toxic to birds. Remove birds from fowl houses before spraying. Avoid spraying drinking water and feed troughs.

Table 32: Uses not supported from the viewpoint of environmental safety

Situation	Basis
Pasture and pasture seed crops	Unacceptable risk to birds and wild mammals
Cereals, soybeans, forage crops, lucerne	Unacceptable risk to birds
Apples, cherries, grapes	-
Tomatoes, lettuce, cabbage	

Efficacy and target safety

Efficacy

The label variations recommended in this Technical Report are within the currently approved use patterns. However, it is noted that fenitrothion/S-methoprene combination products do not include a defined protection period. Based on previous assessments, the APVMA is satisfied that the protection period stemming from use of these dual active products should be 'up to 9 months' based on previous assessments of fenitrothion products where tank mixes with S-methoprene are recommended.

The use of the products, when used according to label directions, is expected to meet the efficacy criteria as described in the Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014 based on previous assessments and a demonstrated history of effective use.

Target crop safety

The label variations recommended in this Technical Report are within existing use patterns. Based on the previous satisfaction that the uses would be safe to target crops and that the APVMA has not received any adverse experience reports in relation to in-crop damage or off target damage from fenitrothion products, the APVMA is satisfied that the products will meet the safety criteria as they relate to target crop safety when used according to the proposed labels.

Spray drift

The APVMA's approach to spray drift management set out in the <u>APVMA Spray Drift Policy July 2019</u> specifies consideration of spray drift in bystander areas, livestock areas, natural aquatic areas, pollinator areas and vegetation areas. The regulatory acceptable levels (RALs) for each area are summarised in Table 33, which is the maximum amount of spray drift exposure that is not expected to cause undue harm to sensitive areas.

Table 33: Regulatory acceptable levels of fenitrothion resulting from spray drift

Area considered	Regulatory acceptable level
Natural aquatic areas	0.095 μg ac/L
Pollinator areas	27 g ac/ha
Vegetation areas	500 g ac/ha
Bystander areas	7.74 g ac/ha
Livestock areas	100 mg/kg

The APVMA has only considered spray drift implications for uses of fenitrothion that are supported by worker health and safety, residues, trade and environmental risk assessments. These uses include post-harvest cereal grain protection from stored cereal pests.

Post-harvest application of fenitrothion to cereal grain uses specialized equipment that includes nozzles integrated into the auger or a shielded sprayer on the conveyor belt that transfers the grain into the storage silos. In accordance with the APVMA Spray Drift Policy July 2019, mandatory downwind buffer zones are not required for post-harvest treatment of agricultural produce, including grain protection uses. Therefore, no spray drift restraints are required for uses of fenitrothion supported by the worker health and safety, residues, trade and environment risk assessments.



Appendix

Appendix A – summary of assessment outcomes

Table 34: Fenitrothion uses supported by all risk assessments

Crop/host	Pest	Rate	Amended instructions for use*		
Post-harvest uses					
Stored cereal grains including malting barley	Stored grain insect pests (excluding Sitophilus spp.)	6 g ac/L	Withholding period: Not required when used as directed.		
		(6 g ac/tonne) 6ppm: 3 months protection	Protection statement: Very toxic to aquatic		
		Fenitrothion and S- methoprene combination product	life. DO NOT contaminate wetlands or watercourses with this product or used containers.		
combina			Trade advice statement: EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain using this product.		
Stored Cereal (uninfested	Stored grain insect pests (excluding lesser grain borer)	6 g ac/L (6 g ac/tonne) 6ppm: 3 months protection	Withholding period: Not required when used as directed.		
wheat, barley, oats, rice, sorghum and millet)			Protection : Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.		
			Trade advice statement: EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain using this product.		

Crop/host	Pest	Rate	Amended instructions for use*
		12 g ac/L 12 g ac/tonne grain 12ppm: 6 months protection	Withholding period: DO NOT use for processing into food for human consumption or stock food within 13 weeks of treatment. Protection statement: Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
			Trade advice statement: EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain using this product.
Tank mix with insect growth	Stored grain insect pests (excluding Sitophilus spp.)	6 g ac/L (6 g ac/tonne) 6ppm: up to 9 months protection when applied with IGR grain protectant at label	Withholding period: Not required when used as directed.
regulator for treatment of stored cereal			Protection statement: Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
		rates e.g. Methograin IGR Grain Protectant	Trade advice statement: EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain using this product.

^{*}All instructions for use on labels of agricultural chemical products should also align with requirements set out in the Agricultural Labelling Code.

Table 35: Fenitrothion uses that are not supported due to safety and/or trade concerns

Crop/host	Pest	Rate	Assessment outcome
Post-harvest uses			
Grain storage facilities and equipment	Stored grain insect pests (except lesser grain borer and/or sawtoothed grain beetle)	10 g ac/L, 1 L dilute spray treats 20 m ²	Not supported – safety (worker health and safety concerns)
Surface treatment bulk stored cereal grain, stacks of bags etc.	Stored grain insect pests (except lesser grain borer and/or sawtoothed grain beetle)	10 g ac/L, 1 L dilute spray treats 20 m ²	Not supported – safety (worker health and safety concerns)

Crop/host	Pest	Rate	Assessment outcome	
Broiler poultry house litter, walls, roof and feed sheds	Lesser mealworm (litter beetle), darkling beetle (black beetle)	10 g ac/L, 10 L dilute spray treats 70m ²	Not supported – safety (worker health and safety concerns)	
Field crops				
Pasture, pasture seed crops, forage crops including grazing	Australian plague locust, spur-throated locust, migratory locust	246–550 g ac/ha (EC: 270–550 g ac/ha; UL: 246–492 g ac/ha)	Not supported – safety (environment) concerns	
sorghum, lucerne, cereal crops	Wingless grasshopper	300-308 g ac/ha (EC: 300 g ac/ha; UL: 308 g ac/ha)	Not supported – safety (environment) concerns	
	Yellow-winged locust	246–394 g ac/ha (UL only)	Not supported – safety (environment) concerns	
	Small plague grasshopper	246–369 g ac/ha (UL only)	Not supported – safety (environment) concerns	
Lucerne	Sitona weevil	250–650 g ac/ha	Not supported – safety (environment) concerns	
			Closed mixing/loading required to mitigate worker health and safety concerns above 550 g ac/ha	
Pasture	Pasture cockchafer	480–700 g ac/ha	Not supported – safety (environment and residues) and trade concerns	
			Closed mixing/loading required to mitigate worker health and safety concerns above 550 g ac/ha	
	Corbie, winter corbie	800–1,300 g ac/ha	Not supported – safety (environment and residues) and trade concerns	
			Closed mixing/loading required to mitigate worker health and safety concerns	
	Underground grass grub	500–1,000 g ac/ha	Not supported – safety (environment and residues) and trade concerns	
			Closed mixing/loading required to mitigate worker health and safety concerns above 550 g ac/ha	
	Oxycanus grub	1,200–1,300 g ac/ha	Not supported – safety (environment and residues) and trade concerns	
			Closed mixing/loading required to mitigate worker health and safety concerns	

Crop/host	Pest	Rate	Assessment outcome	
Apples,	Australian plague locust,	246–550 g ac/ha	Not supported – safety (environment	
cabbages, cherries, grapes, lettuce,	spur-throated locust, migratory locust	(EC: 270–400 g ac/ha, UL: 246–492 g ac/ha)	and residues) and trade concerns	
tomatoes, soybean	Wingless grasshopper	300–308 g ac/ha	Not supported – safety (environment	
		(EC: 300 g ac/ha; UL: 308 g ac/ha)	and residues) and trade concerns	
	Small plague	246–369 g ac/ha	Not supported – safety (environment	
	grasshopper	(UL only)	and residues) and trade concerns	

Appendix B – listing of environmental endpoints

Table B1: Physical and chemical properties

Substance	Study	Result			Reference
Fenitrothion	Vapour pressure	6.8 × 10 ⁻⁴ Pa at 20°C 1.6 × 10 ⁻³ Pa at 25°C			Schetter 2000
	Henry's law constant	9.9 x 10 ⁻³ Pa m ³ mol ⁻¹			Okada 2001
	Solubility in water	19 mg/L at 20°C			Concha 2000
	Partition coefficient	log P _{ow} 3.3			Shepler & Schick 2002
	Dissociation constant	No dissociable moieties			
	UV-VIS absorption (max)	solution acidic neutral basic basic	λ _{max} 268 nm 267 nm 264 nm 393 nm		Yoshida 2000

Table B2: Dissipation in animal food items

Substance	Matrix	Result	Reference
Fenitrothion	Leaves	White spruce: DT ₅₀ 20 d	Sundaram 1986
		Spruce: DT_{50} 7.9 d Maize: DT_{50} 3.0 d Bermuda grass: DT_{50} 2.6 d Apple: DT_{50} 1.6 d	Willis & McDowell 1987
		Cabbage: DT ₅₀ 6.6 d	Hu et al. 2009
		Parsley: DT ₅₀ 4.1 d Rocket: DT ₅₀ 4.0 d	Bahaffi et al. 2005
	Grape:DT ₅₀ 2.5 d		Likas & Tsiropoulos 2007
Pasture: DT ₅₀ 1.5 d			Gilmour et al. 1999

Substance	Matrix	Result	Reference
		Tea: DT ₅₀ 0.50 d	Zongmao & Haibin 1997
		Geomean DT ₅₀ 3.2 d	
	Fruit	Persimmon: DT ₅₀ 8.3 d	Fernández-Cruz et al. 2004
		Apricot: DT ₅₀ 6.9 d	Cabras et al. 1997
		Pear: DT ₅₀ 6.7 d	Passarella et al. 2009
		Fig: DT ₅₀ 5.6 d	Bahaffi et al. 2005
		Grape: DT ₅₀ 2.9 d	
		Rice: DT ₅₀ 4.5 d	Ishii 2004
		Grape: DT ₅₀ 3.8 d	Cabras & Angioni 2000
		Tomato: DT ₅₀ 2.2 d	Malhat et al. 2017
		Geomean DT ₅₀ 4.7 d	

Table B3: Fate and behaviour in soil

Study	Substance	Result	Reference
Soil photolysis	Fenitrothion	DT ₅₀ 85 d (irradiated) DT ₅₀ 182 d (dark control) 4.3% mineralisation after 30 d	Dykes & Carpenter 1988
		6.8% bound residues after 30 d No major photoproducts	
Aerobic laboratory soil	Fenitrothion	Sandy loam: DT ₅₀ 2.4 d	Cranor & Daly 1989
		Sandy loam: DT ₅₀ 0.62 d	Yeomans & Swales 2001
		Sandy loam: DT ₅₀ 1.4 d	
		Clay loam: DT ₅₀ 0.74 d	
		Clay loam: DT ₅₀ 0.85 d	_
		Geomean DT ₅₀ 1.1 d	

Study	Substance	Result	Reference
		23–54% mineralisation after 90–122 d 26–70% bound residues after 90–122 d Max 44% NMC	
	NMC	Sandy loam: DT ₅₀ 3.3 d	Cranor & Daly 1989, Kodaka et al. 2000
		Sandy loam: DT_{50} 2.8 d Sandy loam: DT_{50} 3.1 d Clay loam: DT_{50} 3.3 d Clay loam: DT_{50} 3.0 d	Yeomans & Swales 2001
Anaerobic laboratory soil	Fenitrothion	Sandy loam DT ₅₀ 0.80 d 0.1% mineralisation after 122 d 79% bound residues after 122 d Max 14% NMC, DT ₅₀ 1.2 d	Cranor & Daly 1990, Kodaka et al. 2000
		Max 11% AM-FNT, DT_{50} 16 d Max 10% AA-FNT, DT_{50} 50 d	
Adsorption/ desorption	Fenitrothion	Soil %OC Kf Koc 1/n Sand 1.3 4.9 384 0.86 Sandy loam 3.1 32 1022 0.94 Silty clay 3.9 13 330 1.04 Silty clay 7.1 18 252 0.97 Sediment 42 830 1966 1.10 Mean Kf 17 mL/g, Koc 497 mL/g, 1/n 0.95	Spillner & Neuberger 1979
	NMC	Soil %OC Kf Koc 1/n Sandy loam 0.8 2.4 303 0.81 Clay loam 2.7 7.6 281 0.76 Silty clay loam 2.9 7.8 270 0.71 Mean Kf 5.9 mL/g, Koc 285 mL/g, 1/n 0.76	Lewis 2001

Table B4: Fate and behaviour in water and sediment

Study	Substance	Result	Reference	
Hydrolysis	Fenitrothion	pH 5, 25°C: DT ₅₀ 196 d, max 10% DM-FNT pH 7, 25°C: DT ₅₀ 183 d, no major degradates	Ito et al. 1988	
		pH 9, 25°C: DT ₅₀ 101 d, max 15% NMC		
Aqueous photolysis	Fenitrothion	DT ₅₀ 3.5 d (irradiated)	Katagi et al. 1988	
		DT ₅₀ 106 d (dark control)	1900	
		42% mineralisation after 30 d		
		Max 10% CA-FNT		
		Quantum yield 8.0 x 10 ⁻⁴ at 313 nm	Takahashi 1981	
		DT ₅₀ 0.76 d at 40°N in spring		
Ready biodegradability	Fenitrothion	Not readily biodegradable	Gruetzner 2000	
Degradation in	Fenitrothion	Millstream Pond: water DT ₅₀ 0.88 d	Swales 2001	
water/sediment		Emperor Lake: water DT ₅₀ 1.3 d		
		Geomean DT ₅₀ 1.1 d	_	
		Millstream Pond: sediment DT ₅₀ 1.1 d	_	
		Millstream Pond: system DT ₅₀ 1.6 d		
		Emperor Lake: system DT ₅₀ 1.6 d		
		Geomean DT ₅₀ 1.6 d	_	
		14-15% mineralisation after 59 d		
		71-76% bound residue after 59 d		
	Max 28% fenitrothion in sediment			
		Max 33% NMC (24% in water, 13% in sediment)		
		Max 19% AM-FNT (18% in water, 4.7% in sediment)		
		Max 17% DM-AM-FNT (17% in water, nd in sediment)		

Table B5: Fate and behaviour in air

Study	Substance	Result	Reference
Photochemical oxidative degradation	Fenitrothion	DT ₅₀ 0.23 d	Nishiyama et al. 2000

Table B6: Laboratory studies on terrestrial vertebrates

Test substance	Group	Exposure	Species	Toxicity value	Reference
Fenitrothion	Mammals	Acute	Rattus norvegicus	LD ₅₀ 330 mg ac/kg bw	Kadota et al. 1972
				LD ₅₀ >300 mg ac/kg bw	Moon 2010
		Chronic	Rattus norvegicus	NOEL 2.3 mg ac/kg bw/d	Hoberman 1990
	Birds	Acute	Colinus virginianus	LD ₅₀ 23 mg ac/kg bw	Grimes & Jaber 1988a
			Phasianus colcicus	LD ₅₀ 35 mg ac/kg bw	Fletcher 1971
			Coturnix japonica	LD ₅₀ 115 mg ac/kg bw	Kadota et al. 1974
			Anas platyrhynchos	LD ₅₀ >244 mg ac/kg bw	Grimes & Jaber 1988b
			Geomean LD ₅₀ 45 mg ac	/kg bw (3 species)	-
		Dietary	Colinus virginianus	LDD ₅₀ 68 mg ac/kg bw/d	Grimes & Jaber 1988c
			Anas platyrhynchos	LDD ₅₀ 601 mg ac/kg bw/d	Grimes & Jaber 1988d
		Chronic	Colinus virginianus	NOEL 2.3 mg ac/kg bw/d	Beavers et al. 1991
			Anas platyrhynchos	NOEL 6.0 mg ac/kg bw/d	Beavers et al. 1989

 Table B7:
 Field studies on terrestrial vertebrates

Test substance	Crop	Exposure	Effect	Reference
Fenitrothion	Semi-arid thornbush savannah	1x 485 or 825 g ac/ha	Up to 7% bird mortality observed in both low and high dose plots with 30-47% reduction in numbers, mainly due to movement in response to a reduction in grasshopper prey	Mullié & Keith 1993

Table B8: Laboratory studies on aquatic species

Substance	Group	Exposure	Species	Toxicity value	Reference
Fenitrothion	Fish	Acute	Oncorhynchus mykiss	LC ₅₀ 1.3 mg ac/L	Swigert 1987a
			Pseudorasbora parva	LC ₅₀ 2.3 mg ac/L	Kagoshima et al. 1974
			Lepomis macrochirus	LC ₅₀ 2.5 mg ac/L	Swigert 1987b
			Cyprinus carpio	LC ₅₀ 4.1 mg ac/L	Kagoshima et al. 1974
		Chronic	Oncorhynchus mykiss	NOEC 0.088 mg ac/L	Cohle 1988
	Invertebrates	Acute	Paratya compressa	LC ₅₀ 0.00036 mg ac/L	Shigehisa & Shiraishi 1998
			Cheumatopsyche brevilineata	EC ₅₀ 0.0078 mg ac/L	Yokoyama et al. 2009
			Chironomus riparius	LC ₅₀ 0.0081 mg ac/L	Burke & Flenley 2011
			Anisops sardeus	LC ₅₀ 0.0086 mg ac/L	Lahr et al. 2001
			Daphnia magna	EC ₅₀ 0.0086 mg ac/L	Forbis 1987
				EC ₅₀ 0.010 mg ac/L	Matsumoto et al. 2009
			Geomean EC ₅₀ 0.0093 mg a	c/L	
			Hyalella azteca	LC ₅₀ 0.0097 mg ac/L	Burke & Scholey 2011a
			Neocaridina denticulata	LC ₅₀ 0.14 mg ac/L	Burke 2011
			Streptocephalus sudanicus	EC ₅₀ 1.2 mg ac/L	Lahr et al. 2001
		Chronic	Daphnia magna	NOEC 0.000087 mg ac/L	Burgess 1988
	Algae Chronic Pseudokirchneriella subcapitata			E _r C ₅₀ 2.7 mg ac/L	Burke & Scholey 2011b
NMC	Invertebrates	Acute	Daphnia magna	EC ₅₀ 18 mg/L	Putt 2001

Substance	Group	Exposure	Species	Toxicity value	Reference
AM-FNT	Invertebrates	Acute	Daphnia magna	EC ₅₀ 5.9 mg/L	Gries 2002

Table B9: Field studies on aquatic species

Test substance	Crop	Exposure	Effect	Reference
EC 500 g/L	Cultivated savannah	1x 500 g ac/ha	Reduced populations of backswimmers (<i>Anisops</i> spp.), other insects, and zooplankton (especially Cladocera) in natural temporary ponds	Lahr et al. 2000

Table B10: Effects on bees

Test substance	Species	Life stage	Exposure	Toxicity value	Reference
Fenitrothion	Apis mellifera	Adult	Acute contact	LD ₅₀ 0.16 μg ac/bee	Hoberg 2001
			Acute oral	LD ₅₀ 0.20 μg ac/bee	Hoberg 2001

Table B11: Field studies on other non-target arthropod species

Test substance	Crop	Exposure	Effect	Reference
Fenitrothion	Mitchell grass plain	1× 267 g ac/ha	Significant impact on invertebrate community composition for over 79 days with recovery by 189 DAT	Walker et al. 2016

Table B12: Laboratory studies on soil organisms

Substance	Group	Exposure	Species/process	Toxicity value	Reference
Fenitrothion	Macro-organisms	Acute	Eisenia fetida	LC _{50corr} 116 mg ac/kg dry soil	Ellgehausen et al. 1985
	Micro-organisms	Chronic	Respiration	NOEC 10 mg ac/kg dry soil	Mikami et al. 1984
			Nitrification	NOEC 10 mg ac/kg dry soil	Mikami et al. 1984
NMC	Macro-organisms	Acute	Eisenia fetida	LC _{50corr} 18 mg/kg dry soil	Teixeira 2001

Table B13: Field studies on soil organisms

Test substance	Crop	Exposure	Effect	Reference
GR formulation	Pasture	2.24 kg ac/ha	No deleterious effects on populations of the earthworm <i>Allolobophora caliginosa</i>	Martin 1976
			No overall effect on abundance of arthropods, collembola or acari was detected. For individual species that exhibited reduced abundance, recovery was observed within 30 weeks in majority of cases.	Martin 1978

Table B14: Effects on non-target terrestrial plants (post-emergent exposure)

Test substance	Species	ER ₂₅	ER ₅₀	Reference
WP 40%	Ambrosia trifida	>1,000 g ac/ha	>1,000 g ac/ha	Mito 2001
	Chenopodium album	>1,000 g ac/ha	>1,000 g ac/ha	
	Digitaria saguinalis	>1,000 g ac/ha	>1,000 g ac/ha	
	Setaria faberi	>1,000 g ac/ha	>1,000 g ac/ha	
	Sorghum halepense	>1,000 g ac/ha	>1,000 g ac/ha	
	Xanthium strumarium	>1,000 g ac/ha	>1,000 g ac/ha	

Appendix C – terrestrial vertebrate assessments

Risks to terrestrial vertebrates following dietary exposure to contaminated food items are assessed using a tiered approach. Long-term exposure of mammals was determined to be higher risk than acute exposure, while acute exposure of birds was determined to be higher than long-term exposure. Therefore, the assessment in this Appendix focuses only on the long-term risks to wild mammals and acute risks to birds.

The acute assessment assumes 100% of food items are obtained from the treatment area on the last day of application, while the chronic assessment assumes 50% of food items are obtained from the treatment area for the first 21 days after the last application (PT 0.5).

The use patterns were divided up into groups which consist of crop species that have similar growing patterns (Table C1). It is assumed that the exposure of a 'generic focal species' within each group will be the same as they relate to feeding habits and other ecological needs. A 'generic focal species' is not a real species; however, it is considered to be representative of all those species potentially at risk. The APVMA utilises the EFSA (2009) generic focal species which are considered protective of species that occur in Australia. Interception of the spray by the crop is taken into account by calculating the residue level on the several food types, depending on the growth stage of the crop. This consideration is reflected in the EFSA (2009) shortcut values.

Long-term risks to wild mammals are summarised in Table C2; acute risks to birds are summarised in Table C3.

Table C1: Seasonal exposure estimates for fenitrothion in animal food items

Use pattern	EFSA 2009	Situation	Application rate and frequency	Seasonal expo	sure rate (g/ha)	
pattern	crop group		and nequency	Foliage (DT ₅₀ 3.2 d)	Fruit (DT ₅₀ 4.7 d)	Other items (DT ₅₀ 10 d)
Field crops and pasture	Cereals	Cereals	3× 550 g ac/ha 14d interval	578	n/a	837
	Pulses	Soybeans	3× 550 g ac/ha 14d interval	578	n/a	837
	Legume forage	Forage crops	3× 550 g ac/ha 14d interval	578	n/a	837
		Lucerne	3× 650 g ac/ha 7d interval	824	n/a	964
	Grassland	Pasture, pasture seed crops	1× 1300 g ac/ha	1300	n/a	1300
Tree and vine crops	Orchards	Apples, cherries	3× 550 g ac/ha 14d interval	578	629	837

Use pattern	EFSA 2009			Seasonal exposure rate (g/ha)			
pattern	attern crop group and no		and frequency	Foliage (DT ₅₀ 3.2 d)	Fruit (DT ₅₀ 4.7 d)	Other items (DT ₅₀ 10 d)	
	Vineyards	Grapes	3× 550 g ac/ha 14d interval	578	629	837	
Vegetable crops	Fruiting vegetables	Tomatoes	3× 550 g ac/ha 14d interval	578	629	837	
	Leafy vegetables	Lettuce, cabbage	3× 550 g ac/ha 14d interval	578	n/a	837	

Seasonal exposure rates based on indicated application rate, frequency, and $\ensuremath{\text{DT}_{50}}$

Table C2: Long-term risks of fenitrothion to wild mammals (RAL 2.3 mg/kg bw/d)

Generic focal species	Crop stage	Shortcut value	Exposure rate (g/ha)	DDD (mg/kg bw/d)	RQ
Large herbivore	Early (shoots)	22.3	578	1.4	0.61
Small omnivore	BBCH 10-29	7.8	837	1.7	0.75
	BBCH 30-39	3.9	837	0.86	0.37
	BBCH ≥40	2.3	837	0.41	0.22
Small herbivore	BBCH ≥40	21.7	578	1.4	0.59
Small insectivore	BBCH 10-19	4.2	837	0.93	0.40
	BBCH ≥20	1.9	837	0.42	0.18
Small insectivore	BBCH 10-19	4.2	837	0.93	0.40
	BBCH ≥20	1.9	837	0.42	0.18
Small herbivore	BBCH 40-49	72.3	578	4.5	2.0
	BBCH ≥50	21.7	578	1.4	0.59
	Large herbivore Small omnivore Small herbivore Small insectivore	Large herbivore Early (shoots) Small omnivore BBCH 10–29 BBCH 30–39 BBCH ≥40 Small herbivore BBCH ≥40 Small insectivore BBCH 10–19 BBCH ≥20 Small insectivore BBCH 10–19 BBCH ≥20 Small herbivore BBCH 40–49	Large herbivore Early (shoots) 22.3 Small omnivore BBCH 10-29 7.8 BBCH 30-39 3.9 BBCH ≥40 2.3 Small herbivore BBCH ≥40 21.7 Small insectivore BBCH 10-19 4.2 BBCH ≥20 1.9 Small herbivore BBCH 10-19 4.2 BBCH ≥20 1.9	Large herbivore Early (shoots) 22.3 578 Small omnivore BBCH 10–29 7.8 837 BBCH 30–39 3.9 837 BBCH ≥40 2.3 837 Small herbivore BBCH ≥40 21.7 578 Small insectivore BBCH 10–19 4.2 837 BBCH ≥20 1.9 837 Small insectivore BBCH 10–19 4.2 837 BBCH ≥20 1.9 837 Small herbivore BBCH 40–49 72.3 578	Large herbivore Early (shoots) 22.3 578 1.4 Small omnivore BBCH 10–29 7.8 837 1.7 BBCH 30–39 3.9 837 0.86 BBCH ≥40 2.3 837 0.41 Small herbivore BBCH ≥40 21.7 578 1.4 Small insectivore BBCH 10–19 4.2 837 0.93 BBCH ≥20 1.9 837 0.42 Small insectivore BBCH 10–19 4.2 837 0.93 BBCH ≥20 1.9 837 0.42 Small herbivore BBCH 40–49 72.3 578 4.5

Crop group	Generic focal species	Crop stage	Shortcut value	Exposure rate (g/ha)	DDD (mg/kg bw/d)	RQ
	Large herbivore	BBCH 10-49	14.3	578	0.90	0.39
		BBCH ≥50	4.3	578	0.27	0.12
	Small omnivore	BBCH 10-49	7.8	837	1.7	0.75
		BBCH 50-80	2.3	837	0.41	0.22
		BBCH 81–99	6.6	837	1.5	0.63
Forage crops, luce	rne					
Legume forage	Small insectivore	BBCH 10-19	4.2	964	1.1	0.46
		BBCH ≥20	1.9	964	0.48	0.21
	Small herbivore	BBCH 40-49	72.3	578	4.5	2.0
		BBCH ≥50	21.7	824	1.9	0.85
	Large herbivore	BBCH 21–49	14.3	824	1.3	0.56
	Small omnivore	BBCH 10-49	7.8	964	2.0	0.86
		BBCH ≥50	2.3	964	0.58	0.25
Pasture, pasture s	eed crops					
Grassland	Small omnivore	Early or late season	6.6	1 300	2.3	0.98
	Large herbivore	All season	17.3	1 300	2.4	1.1
	Small herbivore	All season	72.3	1 300	10	4.4
	Small insectivore	Late season	1.9	1 300	0.65	0.28
Apples, cherries						
Orchards	Large herbivore	BBCH <10	11.1	578	0.70	0.30
		BBCH 10-19	6.7	578	0.42	0.18
		BBCH 20-39	5.5	578	0.35	0.15
		BBCH ≥40	3.3	578	0.21	0.09
	Small insectivore	BBCH 10-19	4.2	837	0.93	0.40
		BBCH ≥20	1.9	837	0.42	0.18

Crop group	Generic focal species	Crop stage	Shortcut value	Exposure rate (g/ha)	DDD (mg/kg bw/d)	RQ
	Small herbivore	BBCH <10	72.3	578	4.5	2.0
		BBCH 10-19	43.4	578	2.7	1.2
		BBCH 20-39	36.1	578	2.3	0.99
		BBCH ≥40	21.7	578	1.4	0.59
	Small omnivore	BBCH <10	7.8	837	1.7	0.75
		BBCH 10-19	4.7	837	1.0	0.45
		BBCH 20-39	3.9	837	0.86	0.37
		BBCH ≥40	2.3	837	0.41	0.22
	Frugivore	BBCH 71–79	22.7	629	2.2	0.96
Grapes						
Vineyards	Large herbivore	BBCH <10	11.1	578	0.70	0.30
		BBCH 10-19	6.7	578	0.42	0.18
		BBCH 20-39	5.5	578	0.35	0.15
		BBCH ≥40	3.3	578	0.21	0.09
	Small insectivore	BBCH 10-19	4.2	837	0.93	0.40
		BBCH ≥20	1.9	837	0.42	0.18
	Small herbivore	BBCH <10	72.3	578	4.5	2.0
		BBCH 10-19	43.4	578	2.7	1.2
		BBCH 20-39	36.1	578	2.3	0.99
		BBCH ≥40	21.7	578	1.4	0.59
	Small omnivore	BBCH <10	7.8	837	1.7	0.75
		BBCH 10-19	4.7	837	1.0	0.45
		BBCH 20-39	3.9	837	0.86	0.37
		BBCH ≥40	2.3	837	0.41	0.22
Tomatoes						
Fruiting vegetables	Small insectivore	BBCH 10-19	4.2	837	0.93	0.40
		BBCH ≥20	1.9	837	0.42	0.18

Crop group	Generic focal species	Crop stage	Shortcut value	Exposure rate (g/ha)	DDD (mg/kg bw/d)	RQ
	Small herbivore	BBCH 10-49	72.3	578	4.5	2.0
		BBCH ≥50	21.7	578	1.4	0.59
	Small omnivore	BBCH 10-49	7.8	837	1.7	0.75
		BBCH ≥50	2.3	837	0.51	0.22
	Frugivore	BBCH 71–89	25.2	629	2.4	1.1
Lettuce, cabbage						_
Leafy vegetables	Small insectivore	BBCH 10-19	4.2	837	0.93	0.40
		BBCH ≥20	1.9	837	0.42	0.18
	Small herbivore	BBCH 40-49	72.3	578	4.5	2.0
		BBCH ≥50	21.7	578	1.4	0.59
	Large herbivore	All season	14.3	578	0.90	0.39
	Small omnivore	BBCH 10-49	7.8	837	1.7	0.75
		BBCH ≥50	2.3	837	0.51	0.22

Crop groups as indicated in Table C1; generic focal species and shortcut values for indicated crop groups from EFSA (2009)

Seasonal exposure rates selected from Table A1 for the indicated crop groups represent worst-case scenario (if acceptable) or best-case scenario (if not acceptable)

DDD = daily dietary dose (mg/kg bw/d) = shortcut value * rate (kg ac/ha) * PT 0.5 * TWA 0.22 (herbivores) or 0.31 (frugivores) or 0.53 (other)

RAL = regulatory acceptable level = NOEL 2.3 mg/kg bw/d (Hoberman 1990)

RQ = risk quotient = DDD/RAL, where acceptable RQ \leq 1

Table C3: Acute risks of fenitrothion to birds (RAL 4.5 mg/kg bw/d)

Crop group	Generic focal species	Crop stage	Shortcut value	Exposure rate (g/ha)	DDD (mg/kg bw/d)	RQ
Cereals						
Cereals	Large herbivore	BBCH 10-29	30.5	578	18	3.9
	Small omnivore	BBCH 10-29	24.0	837	20	4.5
		BBCH 30-39	12.0	837	10	2.2
		BBCH ≥40	7.2	837	6.0	1.3
	Small insectivore	BBCH 71-89	57.6	837	48	11
	Small granivore/insectivore	Late season	27.0	837	23	5.0
Soybeans						
Pulses	Small granivore	BBCH 10-49	24.7	837	21	4.6
		BBCH ≥50	7.4	837	6.2	1.4
	Small omnivore	BBCH 10-49	24.0	837	20	4.5
		BBCH ≥50	7.2	837	6.0	1.3
	Medium herbivore/granivore	BBCH 10-19	55.6	837	47	10
	Small insectivore	BBCH 10-19	26.8	837	22	5.0
		BBCH ≥50	25.2	837	21	4.7
Forage crops, luc	erne					
Legume forage	Small granivore	BBCH 10-49	24.7	837	21	4.6
		BBCH ≥50	7.4	837	6.2	1.4
	Small omnivore	BBCH 10-49	24.0	837	20	4.5
		BBCH ≥50	7.2	837	6.0	1.3
	Medium herbivore/granivore	BBCH 21-49	55.6	837	47	10
	Small insectivore	BBCH 10-19	26.8	837	22	5.0
		BBCH ≥20	25.2	837	21	4.7

Crop group	Generic focal species	Crop stage	Shortcut value	Exposure rate (g/ha)	DDD (mg/kg bw/d)	RQ
Pasture, pasture s	seed crops					
Grassland	Small granivore	New sown	20.4	1300	27	5.9
	Large herbivore	Growing shoots	30.5	1300	40	8.8
	Small insectivore	Growing shoots	26.8	1300	35	7.7
	Small granivore	Late season	24.7	1300	32	7.1
Apples, cherries						
Orchards	Small insectivore	Spring/summer	46.8	837	39	8.7
	Small insectivore/worm feeder	BBCH <10	7.4	837	6.2	1.4
		BBCH 10-19	5.9	837	4.9	1.1
		BBCH 20-39	4.4	837	3.7	0.82
		BBCH ≥40	2.2	837	1.8	0.41
	Small granivore	BBCH <10	27.4	837	23	5.1
		BBCH 10-19	21.9	837	18	4.1
		BBCH 20-39	16.4	837	14	3.1
		BBCH ≥40	8.2	837	6.9	1.5
Grapes						
Vineyards	Small insectivore	BBCH 10-19	27.4	837	23	5.1
		BBCH ≥20	25.7	837	22	4.8
	Small granivore	BBCH 10-19	14.8	837	12	2.8
		BBCH 20-39	12.4	837	10	2.3
		BBCH ≥40	7.4	837	6.2	1.4
	Small omnivore	BBCH 10-19	14.4	837	12	2.7
		BBCH 20-39	12.0	837	10	2.2
		BBCH ≥40	7.2	837	6.0	1.3
	Frugivore	Ripening	28.9	629	18	4.0

Crop group	Generic focal species	Crop stage	Shortcut value	Exposure rate (g/ha)	DDD (mg/kg bw/d)	RQ
Tomatoes						
Fruiting vegetables	Small granivore	BBCH 10-49	24.7	837	21	4.6
		BBCH ≥50	7.4	837	6.2	1.4
	Small omnivore	BBCH 10-49	24	837	20	4.5
		BBCH ≥50	7.2	837	6.0	1.3
	Small insectivore	BBCH 10-19	26.8	837	22	5.0
		BBCH ≥20	25.2	837	21	4.7
	Frugivore (e.g. crow)	BBCH 71-89	57.4	629	36	8.0
	Frugivore (e.g. starling)	BBCH 71–89	49.4	629	31	6.9
Lettuce, cabbage						
Leafy vegetables	Small granivore	BBCH 10-49	27.4	837	23	5.1
		BBCH ≥50	8.2	837	6.9	1.5
	Small omnivore	BBCH 10-49	24.0	837	20	4.5
		BBCH ≥50	7.2	837	6.0	1.3
	Medium herbivore/granivore	BBCH 10-19	90.6	837	76	17
	Small insectivore	BBCH 10-19	26.8	837	22	5.0
		BBCH ≥20	25.2	837	21	4.7

Crop groups as indicated in Table A1; generic focal species and shortcut values for indicated crop groups from EFSA (2009)

Seasonal exposure rates selected from Table C1 for the indicated crop groups represent worst-case scenario (if acceptable) or best-case scenario (if not acceptable)

DDD = daily dietary dose (mg/kg bw/d) = shortcut value * rate (kg ac/ha)

RAL = regulatory acceptable level = LD50 4.5 mg/kg bw/d (Fletcher 1971, Grimes & Jaber 1988a, Kadota et al. 1974) and assessment factor of 10

RQ = risk quotient = DDD/RAL, where acceptable RQ ≤1

Appendix D - runoff assessments

Assessment scenarios

Runoff has been modelled following the methodology described in Appendix B, aquatic species of the APVMA <u>Risk Assessment Manual, Environment</u>. To perform the appropriate high tier calculations, the runoff assessment has been undertaken using the PERAMA⁸ software. All runoff calculations assume that 50% of residues intercepted by the foliage are washed off due a rainfall event and contribute to the total soil residue subject to runoff.

Table D1: Soil exposure rates assessed for the runoff assessments of fenitrothion

Use pattern	Situation	Application rate and frequency	Foliar interception fraction	Fraction field treated	Fraction of 10 ha treated	Seasonal rate over 10 ha (g/ha)
Field crops and pasture	Cereals	3× 550 g ac/ha 14d interval	0	1	1	550
	Forage crops, soybeans	3× 550 g ac/ha 14d interval	0.35	1	1	454
	Lucerne	3× 650 g ac/ha 7d interval	0.35	1	1	543
	Pasture, pasture seed crops	1× 1,300 g ac/ha	0.90	1	1	715
Tree and vine crops	Apples, cherries	3× 550 g ac/ha 14d interval	0.50	1	1	413
	Grapes	3× 550 g ac/ha 14d interval	0.40	1	1	440
Vegetable crops	Tomatoes	3× 550 g ac/ha 14d interval	0.50	1	1	413
	Lettuce, cabbage	3× 550 g ac/ha 14d interval	0.25	1	1	481

⁸ © Australian Environment Agency Pty Ltd 2023

Risk assessment scenarios as described in section 2; foliar interception values are based on EFSA (2020) defaults for similar situations; exposure rates based on indicated application rate, frequency, soil DT_{50} 1.1 days, foliar interception (with 50% wash-off) and fractions of field & 10 ha treated.

Tier 1 assessments

The Tier 1 (screening level) is a worst-case scenario where slope is fixed at 8%, which is considered protective of 95% of agricultural activities in Australia. The rainfall value is set at 8 mm, which results in the maximum receiving water concentration using the standard water body of 1 ha and 15 cm initial depth when the clay dominated Queensland soil profile is used; the catchment is 10 ha. Further, for this worst-case scenario, a fallow/bare soil runoff profile is assessed. Acceptable risks could not be concluded for any of the scenarios assessed.

Tier 2 assessments

A regional assessment (Tier 2) was undertaken as either a state based or tropical/subtropical based assessment depending on the cropping situation and production areas. At this level of assessment, the 90th percentile slope value is applied. The rainfall value used is determined as that required to result in the maximum water concentration using the standard water body (1 ha surface area, 15 cm deep). At this level of assessment, the rainfall value is determined to be that resulting in the maximum water body concentration and reflects the soil profile applied in the modelling, not the actual rainfall pattern of the region being assessed. Acceptable risks could not be concluded for any of the scenarios assessed.

Tier 3 assessments

This highest tier of assessment applies long term rainfall data for representative weather stations in the different regions, which has been obtained from the Bureau of Meteorology. Further, the receiving water characteristics are based on long term stream flow monitoring data and this tier therefore allows assessments to be undertaken on both spatial and temporal scales.

The high tier assessment approach for runoff has been used for a number of years and through this experience, scope for additional refinements have become apparent. There are two areas where significant improvement has been made.

The first relates to fraction of catchment treated at a given time. The current approach in the APVMA manual assumes for in-stream analysis that 20% of a catchment is treated at a given time, and all treated area contributes to runoff. This has been shown to potentially underestimate exposure for some situations such as cereals and pasture, and overestimate exposure for cropping situations where growing occurs over smaller areas such as horticultural crops.

The updated MCAS-S data on a 1 km² scale have been assessed for major land uses and proportions of catchments grown to a particular land use have now been assessed. These values, while stated in MCAS-S as being 'catchment' are probably more appropriate to be considered a basin level so may underestimate exposure in smaller catchments. However, overall, the results are considered applicable as a general indication of the dominance of a particular land use within a catchment scale assessment.

In order to identify a fraction of catchment for a particular land use, catchments where ≥90% of the land use in a region was found were used for the analysis. The fraction of catchment was then taken as the 90th percentile

value from this range of catchments. This value was lower than the highest catchment but tended to be higher than the majority of catchments. Nonetheless, it is considered sufficiently conservative to include situations where higher contributions in sub-catchment areas are found and these data are not available.

The second area for improvement relates to the time over which the rainfall event is assumed to occur (currently 1 h for the 25th percentile rainfall value and 2 h for the 75th percentile rainfall value). The 25th and 75th rainfall values are based on daily rainfall (24 h) data from different weather stations within the growing regions. These results have now been compared to a 1 in 10 year rainfall intensity for a 24 hour duration to better allocate a duration of the rainfall event being assessed. The rainfall intensity values are obtained from the intensity frequency distribution data available from BOM.

The coordinates for the town/weather station assessed are used. As an example, in Cairns, the 25th percentile rainfall value in January is 16 mm, and the 1 in 10 year 24 h rainfall intensity is 16.1 mm/h. Therefore, the use of a 1 h duration for this is appropriate. However, in Richmond, Tasmania, the 25th percentile rainfall value in summer is 11.7 mm, and the 1 in 10 year 24 h rainfall intensity is 2.98 mm/h. Therefore, with this intensity, the 25th percentile rain event will occur over a duration of 3.9 hours. This method, while increasing realism, still does not address temporal rainfall trends in the different areas because the BOM value is an annual result irrespective of the time of year the result was obtained. However, this methodology is considered a significant improvement to the modelling in PERAMA.

Regions showing acceptable risk without timing restrictions are summarised in Table D2; regions showing unacceptable risks at any time are summarised in Table D3; regions showing acceptable risks with timing restrictions are summarised in Table D4.

Table D2: Tier 3 scenarios showing acceptable runoff risks of fenitrothion to aquatic species without timing restrictions

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
Cereals									
Queensland and NT	0.86	0.16	87	Winter	25	13	1.0	0.003	98
					75	29	2.3	0.012	>99
NSW and ACT	0.82	0.27	147	Summer	25	16	2.1	0.001	>99
					75	31	3.5	0.006	>99
Victoria	0.51	0.64	353	Autumn	25	18	3.5	0.001	96
					75	31	5.5	0.004	>99
Tasmania	1.1	0.01	3.9	Winter	25	12	1.9	0.002	>99
					75	23	3.0	0.009	>99

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
South Australia	1.1	0.64	354	Summer	25	20	5.0	0.003	90
					75	36	8.5	0.010	>99
Western Australia	1.1	0.66	362	Summer	25	20	3.5	0.001	>99
					75	39	5.9	0.004	98
Forage crops									
Queensland and NT	0.48	0.20	91	Winter	25	13	1.0	0.003	96
					75	29	2.3	0.008	>99
NSW and ACT	2.5	0.53	241	Summer	25	17	1.3	0.010	93
					75	42	2.8	0.038	98
Tasmania	3.6	0.35	159	Winter	25	11	1.3	0.013	96
					75	20	2.6	0.036	>99
Lucerne									
Queensland and NT	0.48	0.20	109	Winter	25	13	1.0	0.001	96
					75	29	2.3	0.004	>99
NSW and ACT	2.5	0.53	288	Summer	25	17	1.3	0.010	92
					75	42	2.8	0.038	97
Tasmania	3.6	0.35	190	Winter	25	11	1.3	0.013	95
					75	20	2.6	0.037	>99
Pasture and pasture s	seed crop	s							
Queensland and NT	0.48	0.20	143	Winter	25	13	1.0	0.001	96
					75	29	2.3	0.004	>99
NSW and ACT	2.5	0.53	379	Summer	25	17	1.3	0.004	93
					75	42	2.8	0.022	97
Tasmania	3.6	0.35	250	Winter	25	11	1.3	0.004	98
					75	20	2.6	0.018	>99

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
Apples, cherries									
Queensland and NT	1.8	0.03	14	Winter	25	13	1.0	0.006	>99
					75	29	2.3	0.023	>99
NSW and ACT	1.8	0.08	31	Summer	25	17	1.3	0.003	>99
					75	42	2.8	0.017	>99
Victoria	1.2	0.09	38	Autumn	25	18	1.3	0.002	97
					75	32	2.9	0.007	>99
Tasmania	5.4	0.07	28	Winter	25	11	1.3	0.007	>99
					75	21	2.6	0.039	>99
South Australia	2.3	0.10	40	Summer	25	19	1.3	0.004	92
					75	34	3.0	0.014	>99
Western Australia	1.6	0.02	8.3	Summer	25	19	1.3	0.001	>99
					75	28	2.9	0.001	>99
Grapes									
NSW and ACT	1.8	0.08	33	Summer	25	17	1.3	0.003	>99
					75	42	2.8	0.016	>99
Victoria	1.2	0.09	40	Autumn	25	18	1.3	0.002	97
					75	32	2.9	0.007	>99
Tasmania	5.4	0.07	29	Winter	25	11	1.3	0.007	>99
					75	21	2.6	0.036	>99
South Australia	1.2	0.10	43	Summer	25	19	1.3	0.004	95
					75	34	3.0	0.013	>99
Western Australia	1.6	0.02	8.8	Summer	25	19	1.3	0.001	>99
					75	28	2.9	0.001	>99
Wet Tropics	3.0	0.06	2.5	Oct	25	12	0.6	0.009	98
					75	31	1.4	0.038	>99

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
Burdekin	0.80	0.13	58	Oct	25	13	0.8	0.002	96
					75	36	2.1	0.011	>99
Mackay/Whitsunday	2.0	0.28	123	Oct	25	14	0.7	0.003	96
(pasture inter-row)					75	23	1.1	0.012	>99
Fitzroy	1.9	0.01	3.1	Apr	25	14	0.8	0.008	98
					75	43	1.9	0.032	97
Mary/Burnett	1.6	0.09	40	Oct	25	14	1.0	0.006	>99
					75	35	2.5	0.021	98
SE Queensland	1.7	0.05	20	Dec	25	13	1.3	0.006	98
					75	33	3.2	0.021	96
Northern NSW	3.4	0.04	18	Oct	25	13	1.0	0.011	>99
					75	28	2.2	0.040	99
Tomatoes									
NSW and ACT	1.8	0.08	37	Summer	25	17	1.3	0.006	>99
					75	42	2.8	0.024	>99
Victoria	1.2	0.09	44	Summer	25	20	1.4	0.005	90
					75	34	3.4	0.012	>99
Tasmania	5.4	0.07	32	Winter	25	11	1.3	0.021	>99
					75	23	2.6	0.064	>99
South Australia	1.2	0.10	47	Summer	25	19	1.3	0.004	91
					75	34	3.0	0.011	>99
Western Australia	1.6	0.02	9.6	Summer	25	19	1.3	0.001	>99
					75	34	2.9	0.006	>99
Wet Tropics	3.0	0.06	27	Nov	25	14	0.6	0.020	97
					75	39	1.8	0.063	>99

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
Burdekin	0.80	0.13	63	Oct	25	13	0.8	0.004	90
					75	36	2.1	0.014	>99
Fitzroy	1.9	0.01	3.4	Apr	25	14	8.0	0.013	97
					75	43	1.9	0.041	96
Mary/Burnett	1.6	0.09	44	Oct	25	14	1.0	0.011	98
					75	35	2.5	0.028	96
SE Queensland	1.7	0.05	22	Dec	25	13	1.3	0.010	97
					75	32	3.2	0.029	94
Northern NSW	3.4	0.04	20	Oct	25	13	1.0	0.021	99
					75	28	2.2	0.056	98
Soybeans, lettuce an	d cabbage)							
NSW and ACT	1.8	0.08	37	Summer	25	17	1.3	0.007	99
					75	42	2.8	0.028	>99
Tasmania	5.4	0.07	32	Winter	25	12	1.3	0.024	>99
					75	23	2.6	0.075	>99
South Australia	1.2	0.10	47	Summer	25	19	1.3	0.005	89
					75	34	3.0	0.013	>99
Western Australia	1.6	0.02	9.6	Summer	25	19	1.3	0.001	>99
					75	34	2.9	0.008	>99
Wet Tropics	3.0	0.06	27	Oct	25	12	0.6	0.020	96
					75	31	1.4	0.061	99
Fitzroy	1.9	0.01	3.4	Apr	25	14	0.8	0.015	96
					75	43	1.9	0.048	96
Mary/Burnett	1.6	0.09	44	Oct	25	14	1.0	0.012	97
					75	35	2.5	0.033	94

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
SE Queensland	1.7	0.05	22	Dec	25	13	1.3	0.012	96
					75	32	3.2	0.034	93
Northern NSW	3.4	0.04	20	Oct	25	13	1.0	0.025	98
					75	28	2.2	0.065	98

Only worst-case scenarios are presented for each region; seasonal 10 ha exposure rates from Table B1 have been readjusted to account for the fractions of a full catchment treated; risks are considered acceptable where ≥90% of receiving waters are protected.

Table D3: Regions showing unacceptable runoff risks of fenitrothion to aquatic species at any time

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
Lucerne									
Victoria	1.7	0.63	286	Winter	25	17	1.2	0.007	88
					75	30	2.1	0.016	98

Only best-case scenarios are presented for each region; seasonal 10 ha exposure rates from Table B1 have been readjusted to account for the fractions of a full catchment treated; risks are considered acceptable where ≥90% of receiving waters are protected.

Table D4: Regions showing acceptable runoff risks of fenitrothion with timing restrictions

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)		Runoff (%)	Waters protected (%)
Forage crops									
Victoria	1.7	0.63	286	Autumn	25	18	1.3	0.007	74
					75	32	2.9	0.017	93
				Winter	25	17	1.2	0.007	90
					75	30	2.1	0.016	99
				Spring	25	17	1.3	0.007	82
					75	28	2.6	0.015	95

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)		Stream flow (%)	Rainfall (mm/d)		Runoff (%)	Waters protected (%)
				Summer	25	20	1.4	0.008	59
					75	34	3.4	0.019	89
South Australia	1.3	0.63	286	Autumn	25	19	1.4	0.005	79
					75	31	3.0	0.012	95
				Winter	25	18	1.3	0.004	92
					75	26	2.7	0.009	99
				Spring	25	19	1.3	0.005	85
					75	28	2.7	0.010	97
				Summer	25	19	1.3	0.005	64
					75	34	3.0	0.013	93
Western Australia	1.4	0.35	159	Autumn	25	19	1.3	0.001	89
					75	27	3.2	0.004	>99
				Winter	25	19	1.4	0.001	96
					75	27	3.0	0.003	>99
				Spring	25	18	1.3	0.001	91
					75	22	2.6	0.002	>99
				Summer	25	19	1.3	0.001	80
					75	28	2.9	0.004	97
Lucerne									
South Australia	1.3	0.63	342	Autumn	25	19	1.4	0.005	77
					75	31	3.0	0.012	94
				Winter	25	18	1.3	0.004	91
					75	26	2.7	0.009	99
				Spring	25	19	1.3	0.005	83
				-	75	28	2.7	0.010	96

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)		Stream flow (%)	Rainfall (mm/d)		Runoff (%)	Waters protected (%)
				Summer	25	19	1.3	0.005	62
					75	34	3.0	0.013	90
Western Australia	1.4	0.35	190	Autumn	25	19	1.3	0.001	87
					75	27	3.2	0.004	>99
				Winter	25	19	1.4	0.001	95
					75	27	3.0	0.004	>99
				Spring	25	18	1.3	0.001	89
					75	22	2.6	0.002	>99
				Summer	25	19	1.3	0.001	77
					75	28	2.9	0.004	96
Pasture and pasture	seed crop)S							
Victoria	1.7	0.63	450	Autumn	25	18	1.3	0.003	73
					75	32	2.9	0.010	91
				Winter	25	17	1.2	0.003	89
					75	30	2.1	0.009	98
				Spring	25	17	1.3	0.003	82
					75	28	2.6	0.008	94
				Summer	25	20	1.4	0.004	58
					75	34	3.4	0.010	85
South Australia	1.3	0.63	450	Autumn	25	19	1.4	0.002	79
					75	31	3.0	0.006	94
				Winter	25	18	1.3	0.002	92
					75	26	2.7	0.005	99
				Spring	25	19	1.3	0.002	84
				-	75	28	2.7	0.005	96

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
				Summer	25	19	1.3	0.002	63
					75	34	3.0	0.007	89
Western Australia	1.4	0.35	250	Autumn	25	19	1.3	0.001	90
					75	27	3.2	0.002	>99
				Winter	25	19	1.4	0.001	96
					75	27	3.0	0.002	>99
				Spring	25	18	1.3	0.001	92
					75	22	2.6	0.001	>99
				Summer	25	19	1.3	0.001	82
					75	28	2.9	0.002	97
Tomatoes									
Mackay/Whitsunday	2.0	0.28	134	Jan	25	14	0.7	0.014	96
					75	58	2.8	0.050	>99
				Feb	25	16	0.8	0.016	98
					75	51	2.4	0.048	>99
				Mar	25	16	0.8	0.017	>99
					75	49	2.4	0.047	>99
				Apr	25	13	0.6	0.012	97
					75	39	1.9	0.041	>99
				May	25	12	0.6	0.010	93
					75	24	1.1	0.026	98
				Jun	25	14	0.7	0.013	91
					75	33	1.6	0.036	99
				Jul	25	12	0.6	0.010	90
					75	31	1.5	0.034	>99

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
				Aug	25	11	0.5	0.009	85
					75	30	1.4	0.033	93
				Sep	25	12	0.6	0.011	84
					75	32	1.5	0.035	93
				Oct	25	14	0.7	0.014	72
					75	23	1.1	0.025	94
				Nov	25	12	0.6	0.011	71
					75	38	1.8	0.040	>99
				Dec	25	14	0.7	0.014	84
					75	40	1.9	0.041	99
Lettuce and cabbage									
Victoria	1.2	0.09	44	Autumn	25	18	1.3	0.006	93
					75	32	2.9	0.013	>99
				Winter	25	17	1.2	0.005	97
					75	30	2.1	0.012	>99
				Spring	25	17	1.3	0.005	96
					75	28	2.6	0.011	>99
				Summer	25	20	1.4	0.006	88
					75	34	3.4	0.014	>99
Burdekin	0.80	0.13	63	Jan	25	16	1.0	0.007	>99
					75	50	2.9	0.020	>99
				Feb	25	16	0.9	0.007	>99
					75	53	3.2	0.021	>99
				Mar	25	15	0.9	0.006	>99
					75	50	3.0	0.020	>99

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)		Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
				Apr	25	14	0.8	0.006	>99
					75	39	2.3	0.017	>99
				May	25	12	0.7	0.005	>99
					75	28	1.7	0.013	>99
				Jun	25	13	0.8	0.005	>99
					75	28	1.7	0.014	>99
				Jul	25	13	0.7	0.005	>99
					75	29	1.7	0.014	>99
				Aug	25	13	0.8	0.005	>99
					75	29	1.7	0.014	>99
				Sep	25	15	0.9	0.006	96
					75	34	2.0	0.016	>99
				Oct	25	13	0.8	0.005	88
					75	36	2.1	0.017	>99
				Nov	25	14	0.8	0.006	>99
					75	33	2.0	0.015	>99
				Dec	25	14	0.9	0.006	>99
					75	42	2.5	0.018	>99
Mackay/Whitsunday	2.0	0.28	134	Jan	25	14	0.7	0.016	95
					75	58	2.8	0.059	>99
				Feb	25	16	8.0	0.019	98
					75	51	2.4	0.056	>99
				Mar	25	16	0.8	0.020	99
					75	49	2.4	0.055	>99
				Apr	25	13	0.6	0.015	96
				_	75	39	1.9	0.048	>99

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)	Timing	Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
				May	25	12	0.6	0.012	92
					75	24	1.1	0.031	98
				Jun	25	14	0.7	0.015	90
					75	33	1.6	0.042	99
				Jul	25	12	0.6	0.012	89
					75	31	1.5	0.040	99
				Aug	25	11	0.5	0.011	83
					75	30	1.4	0.039	92
				Sep	25	12	0.6	0.013	82
				·	75	32	1.5	0.041	92
				Oct	25	14	0.7	0.016	69
					75	23	1.1	0.030	91
				Nov	25	12	0.6	0.013	69
					75	38	1.8	0.047	>99
				Dec	25	14	0.7	0.016	82
				200	75	40	1.9	0.048	99
Grapes									
Mackay/Whitsunday	2.0	0.28	123	Jan	25	14	0.7	0.008	98
(bare soil inter-row)	2.0	0.20	120	oan	75	58	2.8	0.041	>99
				Feb	25	16	0.8	0.010	>99
				rep	75	51	2.4	0.038	>99
				Mar	0.5	40	0.0	0.040	- 00
				Mar	25 75	16 49	0.8 2.4	0.010 0.037	>99 >99
				Apr	25 75	13 39	0.6 1.9	0.007	99 >99
				_	7.5	33	1.3	0.01	- 33

Region	Slope (%)	Fraction catchment treated	Catchment exposure (g/ha)		Stream flow (%)	Rainfall (mm/d)	Rain duration (h)	Runoff (%)	Waters protected (%)
				May	25	12	0.6	0.005	96
					75	24	1.1	0.019	99
				Jun	25	14	0.7	0.007	95
					75	33	1.6	0.027	>99
				Jul	25	12	0.6	0.005	95
					75	31	1.5	0.025	>99
				Aug	25	11	0.5	0.004	92
					75	30	1.4	0.024	95
				Sep	25	12	0.6	0.006	91
					75	32	1.5	0.026	95
				Oct	25	14	0.7	0.008	82
					75	23	1.1	0.018	>99
				Nov	25	12	0.6	0.006	83
					75	38	1.8	0.031	>99
				Dec	25	14	0.7	0.008	91
					75	40	1.9	0.032	>99

Seasonal 10 ha exposure rates from Table D1 have been readjusted to account for the fractions of a full catchment treated; risks are considered acceptable where $\geq 90\%$ of receiving waters are protected.

Appendix E - PBT and pop assessments

The Stockholm Convention provides scientifically based criteria for potential POPs (persistent organic pollutants) and a process that ultimately may lead to elimination of a POP substance globally. POPs are persistent, bioaccumulative, and toxic (PBT) and also have potential for long-range transport.

Persistence criterion

The criteria for persistence in Annex D of the convention are expressed as single-media criteria as follows:

- Evidence that the half-life of the chemical in water is greater than 2 months (60 days), or that its half-life in soil is greater than 6 months (180 days), or that its half-life in sediment is greater than 6 months (180 days); or
- Evidence that the chemical is otherwise sufficiently persistent to justify its consideration within the scope of the Convention.

The half-lives for fenitrothion in water and sediment and soil do not exceed 60 and 180 days, respectively. In 2 water/sediment systems, the geomean DT₅₀ values were 1.1 days in water and 1.1 days in sediment (Swales 2001). The half-life of fenitrothion in soil did not exceed 180 days. The geomean DT₅₀ in 5 aerobic laboratory soils was determined to be 1.1 days (Cranor & Daly 1989, Yeomans & Swales 2001). It can thus be concluded that fenitrothion does not meet the persistence criterion.

Bioaccumulation criterion

As noted above, the criteria for bioaccumulation in Annex D of the Stockholm Convention are given as follows:

- Evidence that the bioconcentration factor or bioaccumulation factor in aquatic species for the chemical is greater than 5000 or, in the absence of such data, that the log Pow is greater than 5;
- Evidence that a chemical presents other reasons for concern, such as high bioaccumulation in other species, high toxicity or ecotoxicity; or
- Monitoring data in biota indicating that the bioaccumulation potential of the chemical is sufficient to justify its
 consideration within the scope of the Convention.

Fenitrothion is considered not bioaccumulative based on a whole fish BCF of 29 (Ohshima et al. 1988).

Toxicity criterion

For persistent and bioaccumulative substances, exposure may be anticipated to cover the whole life of an organism as well as multiple generations. Consequently, chronic ecotoxicity data, preferably covering impacts on reproduction, are used to establish the toxicity within the PBT context.

As noted, the Stockholm Convention on POPs provides scientifically based criteria for potential POPs and a process that ultimately may lead to elimination of a POP substance globally. The criteria for toxicity in Annex D of the POPs convention do not consist of numerical values, but are given as follows:

- Evidence of adverse effects to human health or to the environment that justifies consideration of the chemical within the scope of this Convention; or
- Toxicity or ecotoxicity data that indicate the potential for damage to human health or to the environment.

The lowest aquatic long-term effect value is below 10 μ g/L (lowest NOEC is 0.087 μ g/L, Burgess 1988). That study was performed for 21 days under flow-through conditions. When considering fenitrothion rapidly dissipates from aquatic systems (water/sediment DT₅₀ 1.6 days), the aquatic toxicity value corresponds to an initial concentration of 0.79 μ g ac/L⁹, which is still below the 10 μ g/L threshold. Therefore, fenitrothion is considered to meet the toxicity criterion.

Potential for long-range environmental transport

The criteria for long-range transport in Annex D of the Stockholm convention are expressed as follows:

- Measured levels of the chemical in locations distant from the sources of its release that are of potential concern;
- Monitoring data showing that long-range environmental transport, with the potential for transfer to a receiving environment, (via air, water or migratory species); or
- Environmental fate properties and/or model results that demonstrate that the chemical has a potential for such transportation, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For a chemical that migrates significantly through the air, its half-life in air should be greater than two days.

Fenitrothion is non-volatile and has a modelled atmospheric half-life of <2 days (Nishiyama et al. 2000); therefore, it is unlikely to travel long distances through the air. There is no evidence to suggest fenitrothion is being transported long distances in the environment.

Conclusion

Fenitrothion does not fulfil the PBT criteria (not PBT) and has low potential for long-range transport. Therefore, fenitrothion does not meet the criteria for POPs in Annex D of the Stockholm convention.

⁹ Initial concentration = mean measured endpoint / (1 - EXP (21 exposure days * (-ln(2)/DT50 1.6 days))) * (21 exposure days * ln(2)/DT₅₀ 1.6 days)

Acronyms and abbreviations

Shortened term	Full term
AA-FNT	acetylaminofenitrothion
AAMC	4-acetylamino-3-methylphenol
ac	active constituent
ADI	Acceptable daily intake (for humans)
AF	assessment factor
AM-FNT	aminofenitrothion
APVMA	Australian Pesticide and Veterinary Medicines Authority
ARfD	Acute reference dose
ввсн	Biologische Bundesanstalt, Bundessortenamt and Chemical Industry
BCF	bioconcentration factor
ВОМ	Bureau of Meteorology
bw	body weight
CA-FNT	carboxyfenitrothion
CIPAC	Collaborative International Pesticides Analytical Council
cm	centimetre(s)
CT _X	time required for X% clearance
d	day(s)
DAF	Dermal Absorption Factor
DAT	days after treatment
DDD	daily dietary dose
DM-AM-FNT	O-(4-amino-3-methylphenyl) O-hydrogen O-methyl phosphorothioate
DM-FNT	desmethylfenitrothion
ds	dry soil
DT _X	period required for X% percent dissipation
EC _X	concentration causing X% effect (ErC _X is used for growth rate; EbC _X is used for biomass)

Shortened term	Full term
EFSA	European Food Safety Authority
ER _X	rate causing X% effect
ExpE	exposure estimate
FAO	Food and Agriculture Organization of the United Nations
FNT	fenitrothion
g	gram(s)
GR	granular formulation
ha	hectare(s)
HC _X	hazardous concentration for X% of the species
IPM	integrated pest management
Kd or Kf	(Freundlich) adsorption constant
kg	Kilogram(s)
Koc or Kfoc	(Freundlich) organic carbon partition coefficient
Кр	sediment sorption coefficient
L	Litre(s)
LC _x	lethal concentration to X% of the tested population (LC_{Xcorr} is a corrected value to account for bioavailability in the test system)
LD _X	lethal dose to X% of the tested population
LOAEL	Lowest Observed Adverse Effect Level
LOC	level of concern
m	metre(s)
max	maximum
MCAS-S	multi-criteria analysis shell for spatial decision support
mg	milligram(s)
mL	millilitre(s)
MRL	Maximum Residue Limit
nd	not detected

nm nanometre(NEDI National Es	
NEDI National Es	<u>·</u>
	timated Daily Intake
NESTI National Es	timated Short Term Intake
NMC 3-methyl-4-	nitrophenol
NOAEL No Observe	d Adverse Effect Level
	d effect concentration (NOEC $_{corr}$ is a corrected value to account for ty in the test system)
NOEL no observed	d effect level
OC organic carl	oon
OECD Organisatio	n for Economic Co-operation and Development
Pa pascal(s)	
PBT persistent –	bioaccumulative – toxic
PEC predicted er	nvironmental concentration
PERAMA Pesticide E	nvironmental Risk Assessment Model for Australia
PHED Pesticide H	andler Exposure Database
POP persistent o	rganic pollutant
Pow octanol-wat	er partition coefficient
PPE Personal Pr	otective Equipment
ppm parts per m	illion
PT proportion of	of an animal's daily diet obtained in habitat treated with pesticide
RAL regulatory a	cceptable level
RQ risk quotien	t
SDRAM spray drift r	isk assessment manual
SSD species ser	sitivity distribution
TMPP Tetramethy	pyrophosphorothioate
TWA time-weight	ed average
μg microgram(s	s)

Shortened term	Full term
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VIS	visible
WHO	World Health Organisation
WP	wettable powder

Glossary

Term	Description
acute exposure	Contact between a pesticide and a target occurring over a short time (e.g., less than a day)
acute toxicity	Adverse effects of finite duration occurring within a short time (up to 14 d) after administration of a single dose (or exposure to a given concentration) of a test substance or after multiple doses (exposures), usually within 24 h of a starting point (which may be exposure to the toxicant, or loss of reserve capacity, or developmental change, etc.)
adsorption constant	A measure of the tendency of a chemical to bind to soils
adverse effect	Change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or subpopulation that results in impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences
agricultural crop	Any terrestrial plant species grown commercially for food, fibre, foliage, fuel or medicinal production, with the exception of plants that are not part of a crop under management at the time of pesticide application (eg blackberries or volunteer grain plants that have escaped from a cropped area and become weeds in another area)
aquatic	Relating to water, as distinct from land or air
assessment factor	Reductive factor by which an observed or estimated endpoint of a pesticide is divided to arrive at a regulatory acceptable level
bioaccumulation	Progressive increase in the amount of a substance in an organism or part of an organism that occurs because the rate of intake exceeds the organism's ability to remove the substance from the body
bioconcentration	Uptake of a pesticide residue from an environmental matrix, usually through partitioning across body surfaces to a concentration in the organism that is usually higher than in the environmental matrix
bioconcentration factor	Ratio between the concentration of pesticide in an organism or tissue and the concentration in the environmental matrix (usually water) at apparent equilibrium during the uptake phase
bound residue	Residue associated with one or more classes of endogenous macromolecules that cannot be disassociated by extraction or digestion without alteration
catchment	Landform that collects precipitation and retains it in an impoundment or drains it through a single outlet
chronic exposure	Continued or intermittent long-term contact between an agent and a target
chronic toxicity	Adverse effects following chronic exposure
concentration	Amount of a material, agent (e.g., pesticide) dissolved or contained in unit quantity in a given medium or system
degradate	Chemical that is formed when a substance breaks down

Term	Description
dose	Total amount of a pesticide or agent administered to, taken up or absorbed by an organism, system, or (sub-) population
dissipation	Loss of pesticide residues from an environmental compartment due to degradation and transfer to another environmental compartment
dissociation constant	The ratio of concentration of dissociated ions to the concentration of original acid
effect assessment	Combination of analysis and inference of possible consequences of the exposure to a pesticide based on knowledge of the dose–effect relationship associated with that agent in a specific target organism, system, or (sub-) population
emulsifiable concentrate	A liquid, homogenous preparation to be applied as an emulsion after dilution in water
endpoint	Measurable ecological or toxicological characteristic or parameter of the test system that is chosen as the most relevant assessment criterion
environmental fate	Destiny of a pesticide or chemical after release to the environment involving considerations such as transport through air, soil, or water, bioconcentration, degradation, etc.
environmental risk	Probability that an adverse effect on humans an environmental system/receptor will be observed for a given exposure to a pesticide based on the probability of that exposure and the sensitivity of the system/receptor
exposure	Concentration or amount of a particular substance that is taken in by an individual, population or ecosystem in a specific frequency over a certain amount of time
exposure assessment	Evaluation of the exposure of an organism, system, or (sub-) population to a pesticide or agent (and its derivatives)
Freundlich isotherm	Empirical relationship describing the adsorption of a solute from a liquid or gaseous phase to a solid in which the quantity of material adsorbed per unit mass of adsorbent is expressed as a function of the equilibrium concentration of the sorbate
granular formulation	A free-flowing solid preparation of a defined granule size range ready for use
half-life	The time taken for the reactant concentration to fall to one-half its initial value
hazard	Inherent property of a pesticide having the potential to cause adverse effects when an organism, system, or (sub-) population is exposed to that agent or situation
Henry's law constant	A gas law that states the amount of gas absorbed by a given volume of liquid at a given temperature is directly proportional to the partial pressure of that gas in equilibrium with that liquid. As such it provides an indication of the preference of a chemical for air relative to water i.e. its volatility
hydrolysis	Chemical decomposition induced by water
in vitro	outside the living body and in an artificial environment
indicator species	Species whose presence shows the occurrence of defined environmental conditions

Term	Description
integrated pest managment	Use of pest and environmental information in conjunction with available pest control technologies to prevent unacceptable levels of pest damage by the most economical means and with the least possible hazard to persons, property, and the environment
larva	Recently hatched insect, fish, or other organism that has different physical characteristics than those seen in the adult, requiring metamorphosis to reach the adult body structure
metabolite	Substance formed as a consequence of metabolism in an organism
mineralisation	Conversion of an element from an organic form to an inorganic form. Mineralisation of pesticides most commonly refers to the microbial degradation to carbon dioxide as a terminal metabolite
no observed effect level	Greatest concentration or amount of a substance, found by experiment or observation, which causes no detectable adverse alteration of morphology, functional capacity, growth, development, or life span of the target organism under defined conditions of exposure
non-target species	Organisms that are not the intended targets of a particular use of a pesticide
organophosphorus	Generic term for pesticides containing phosphorus but commonly used to refer to insecticides consisting of acetylcholinesterase inhibiting esters of phosphate or thiophosphate
partition coefficient	log Pow is the logarithm (base-10) of the partition coefficient between n-octanol and water
persistence	Residence time of a chemical species (pesticide and/or metabolites) subjected to degradation or physical removal in a soil, crop, animal, or other defined environmental compartment
photolysis	Chemical decomposition induced by light or other radiant energy
regulatory acceptable level	Criterion or standard that is considered safe or without appreciable risk
runoff	Portion of the wet precipitation on the land that ultimately reaches streams and, eventually, the sea
solubility in water	The mass of a given substance (the solute) that can dissolve in a given volume of water
terrestrial	Relating to land, as distinct from water or air
vapour pressure	The pressure at which a liquid is in equilibrium with its vapour at a given temperature. It is a measure of the tendency of a material to vaporise. The higher the vapour pressure the greater the potential
volatile	Any substance which evaporates quickly
watercourse	A river, creek or other natural watercourse (whether modified or not) in which water is contained or flows (whether permanently or from time to time); and includes:
	 a dam or reservoir that collects water flowing in a watercourse a lake or 'wetland' through which water flows a channel into which the water of a watercourse has been diverted part of a watercourse

Term	Description				
	an estuary through which water flows.				
wetland	An area of land where water covers the soil—all year or just at certain times of the year. They include:				
	 swamps, marshes billabongs, lakes, lagoons saltmarshes, mudflats mangroves, coral reefs bogs, fens, and peatlands. 				
	A 'wetland' may be natural or artificial and its water may be static or flowing, fresh, brackish or saline.				
wettable powder	A powder preparation to be applied as a suspension after dispersion in water				

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