Australian Government

Australian Pesticides and Veterinary Medicines Authority

FENAMIPHOS

PRELIMINARY REVIEW FINDINGS REPORT

Reconsideration of the active constituent fenamiphos, registration of products containing fenamiphos and approvals of their associated labels

FEBRUARY 2013

ISBN: 978-0-9871919-9-1 (electronic)

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FOREWORD

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 (Agvet Code) scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The APVMA can reconsider the approval of an active constituent, the registration of a chemical product or the approval of a label for a container for a chemical product at any time. This is outlined in Part 2, Division 4 of the Agvet Code. A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product containing that chemical or its label.

The reconsideration process includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product.

In undertaking reconsiderations (hereafter referred to as reviews), the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety in the Department of Health and Ageing, the Department of Sustainability, Environment, Water, Population and Communities, and the state departments of agriculture, as well as other expert advisers as appropriate.

The APVMA has a policy of encouraging openness and transparency in its activities and community involvement in decision making. The publication of review reports is part of that process.

The APVMA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements. The APVMA recommends that countries receiving these reports do not use them for registration purposes unless they are also provided with the raw data from the relevant applicant.

The basis for the current reconsideration is whether the APVMA is satisfied that continued use of the active constituent fenamiphos and products containing fenamiphos in accordance with the instructions for their use would not be likely:

- to be an undue hazard to the safety of people exposed to it during its handling
- to have an effect that is harmful to human beings
- to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA also considered whether product labels carry adequate instructions and warning statements.

This document sets out the preliminary review findings relating to fenamiphos-containing products (and their labels) intended for use in agricultural situations; these have been nominated for review by the APVMA. The Preliminary Review Findings and proposed recommendations are based on information collected from a variety of sources. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

The review summary (Volume 1) and the technical reports (Volume 2) for all registrations and approvals relating to fenamiphos are available from the APVMA website www.apvma.gov.au. Please note that the date of each technical report reflects the date the assessment was completed. No new or updated data have been received to alter the results of technical assessments since the start of the review, and those findings remain unchanged.

SUBMISSIONS FROM THE PUBLIC ARE INVITED

This Preliminary Review Findings report:

- outlines the APVMA review process
- advises interested parties how to respond to the review
- summarises the technical assessments from the reviewing agencies
- outlines the proposed regulatory action to be taken in relation to the continued registration of fenamiphos products.

The APVMA invites persons and organisations to submit their comments and suggestions on this Preliminary Review Findings report directly to the APVMA. Comments on this report will be assessed by the APVMA (and partner agencies where required) before the review is finalised and the Final Review Report and Regulatory Decision is published.

Preparing your comments for submission

You may agree or disagree with or comment on as many elements of the preliminary review findings as you wish. When making your comments:

- clearly identify the issue and clearly state your point of view
- give reasons for your comments, supporting them, if possible, with relevant information and indicating the source of the information you have used
- suggest to the APVMA any alternative solution you may have for the issue.

Please try to structure your comments in point form, referring each point to the relevant section in the Preliminary Review Findings. This will help the APVMA assemble and analyse all of the comments it receives.

Finally, tell us whether the APVMA can quote your comments in part or in full.

Please note that, subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Code, all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent unless a request for anonymity accompanies the submission. If no request for anonymity is made, the respondent will be taken to have consented to the disclosure of their identity for the purposes of Information Privacy Principle 11 of the *Privacy Act 1988.*

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and the respondent has provided justification for the material to be classified as confidential or confidential commercial information in accordance with the *Freedom of Information Act 1982* or the Agvet Code, as the case may be.

THE CLOSING DATE FOR SUBMISSIONS IS 31 MAY 2013

Email your submissions to chemicalreview@apvma.gov.au, or send by post (hard copy or on data disc) to:

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EXECUTIVE SUMMARY

Fenamiphos[1] is an organophosphorus insecticide and nematicide widely used in agriculture to control soil-borne pests, particularly nematodes, and sucking insects including aphids and thrips. Fenamiphos can be applied as pre- or post-plant treatment in both food and non-food uses.

In 1994 fenamiphos was nominated for review following reports of possible bird and fish poisonings involving the use of products containing fenamiphos. Additional reports of adverse experiences involved the potential for environmental contamination of groundwater and waterways, particularly due to leaching from the site of application.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) commenced a review of the active constituent fenamiphos, all products containing fenamiphos and all their associated labels in April 2003 because of concerns relating to public health, occupational health and safety (OHS), the environment, and residues in food.

At the date of the publication of this report, there were three active constituent approvals for fenamiphos and 16 registered products containing fenamiphos. All active constituent approvals and registered products are subject to this review.

Preliminary review findings

Toxicological assessment

The Office of Chemical Safety (OCS) undertook the toxicological assessment for the review of fenamiphos. Approvals of the active constituent fenamiphos are being reconsidered because of concerns over its high acute toxicity and potential to cause chronic effects on human health.

The OCS, which considered the toxicological data and information submitted for the review, concluded that use of products containing fenamiphos in accordance with suggested amendments to label instructions would not be likely to have a harmful effect on human health. There were concerns over the potential for risks to worker safety, as assessments conducted in the United States indicated concerns for worker safety when mixing, handling and applying concentrate.

In considering human health issues, no change to the approval status of the active constituent fenamiphos has been proposed. The current Australian Acceptable Daily Intake (ADI) for fenamiphos is 0.0001 mg/kg and is based on the No Observed Effect Level (NOEL) of 0.014 mg/kg bw/d for the inhibition of plasma cholinesterase (ChE) activity in a 2-year dog study and using a 100-fold safety factor. This value is supported by the NOEL of 0.011 mg/kg bw/d for plasma ChE inhibition in a 6-month supplementary dog study. Following a review of all submitted and archived data, the existing ADI for fenamiphos was considered to remain appropriate. Therefore, the current Health Value for fenamiphos in Australian drinking water of 0.0003 mg/mL also remains appropriate.

Furthermore, an Acute Reference Dose (ARfD) of 0.003 mg/kg bw/d for fenamiphos was established by the OCS; before this evaluation no ARfD had been established. The ARfD was derived by applying a 100-fold safety factor to the NOEL of 0.25 mg/kg bw/d for the inhibition of erythrocyte ChE activity.

1 IUPAC name: ethyl 4-(methylthio)-m-tolyl isopropylphosphoramidate

The existing poisons schedule for fenamiphos (Schedule 7) remains appropriate. The review identified a number of additions and amendments to the existing Safety Directions for Australian fenamiphos products.

At the start of the review, there was a single product containing fenamiphos registered for use in the home garden. The registration of the single home garden product is no longer supported on the basis that it does not comply with the criteria established by the APVMA for home garden products. There is no objection on public health grounds to the continued registration of all other existing fenamiphos products.

Occupational health and safety assessment

The OCS undertook the OHS assessment for the review of fenamiphos, which considered all the OHS data and information submitted for the review in light of recommendations made in its toxicological assessment.

Workers preparing and applying the fenamiphos emulsifiable concentrate and granular formulation products may be exposed to the chemical by the dermal and inhalation routes. Based on exposure modelling, this assessment suggests that mixing, loading and applying fenamiphos emulsifiable concentrate products in their currently approved situations is likely to cause toxicologically unacceptable levels of exposure and risk to unprotected operators. However, exposure can be reduced to acceptable levels by using enclosed transfer/mixing systems and personal protective equipment (PPE) including gloves, chemical-resistant clothing and a respirator. If spray application is done using a vehicle equipped with an enclosed cab and air filtration, less extensive PPE is required.

The fenamiphos granular formulation product is of lower acute toxicity than emulsifiable concentrate formulations, and workers are expected to handle relatively small amounts per day. Workers loading and applying fenamiphos granular formulation products by mechanical equipment can be protected adequately by gloves, overalls and a respirator in the absence of engineering controls. If a vehicle equipped with an enclosed cab were used, respiratory PPE would be unnecessary during application.

The continued application of fenamiphos granular formulation products by hand is no longer supported. The available exposure modelling showed that, despite using the most conservative dermal and respiratory PPE, workers applying even small quantities of fenamiphos granules by hand would be exposed to a toxicologically unacceptable extent.

The OCS's risk assessment determined that the estimated level of exposure to fenamiphos residues, when applied to soil or plants, in treated soil is sufficiently low to negate any requirement for PPE. A re-entry period is not required for these situations. A re-entry period of 24 hours for persons undertaking turf care activities is proposed. An exposure study, however, demonstrated negligible potential for toxicologically significant exposure to the public when fenamiphos is applied to turf on golf courses and bowling greens. In addition, a re-entry period is not required for pineapples based on the results of a foliar residue study.

Environmental assessment

The Department of Sustainability, Environment, Water, Populations and Communities (DSEWPaC) undertook the environmental assessment for the review of fenamiphos, which considered all the environmental data and information submitted for the review. The APVMA considered the advice received from DSEWPaC and makes the following recommendations relating to the continued use of products containing fenamiphos**.**

The risk assessment based on current uses on labels considered for this review resulted in a potentially unacceptable risk to birds, aquatic organisms and terrestrial organisms including non-target arthropods and

earthworms for the majority of use patterns for which fenamiphos is currently approved. With current information, mitigation of the risks associated with fenamiphos use is very difficult because:

- fenamiphos has been shown to be highly toxic to organisms in the environment
- while fenamiphos converts relatively rapidly to a major metabolite, this metabolite has been shown to be biologically active and its toxicity to a number of environmental organisms is not remarkably less than the parent compound
- overall removal of fenamiphos and its metabolites from environmental media does not occur quickly. Therefore, the use of time-weighted average exposure concentrations does little to mitigate exposure and potential risk, particularly where repeat applications to crops occur.

Additionally, in soil fenamiphos and its metabolites have been shown to leach to groundwater where conditions favourable for leaching exist. There is no information relating to likely vulnerable leaching sites in fenamiphos use areas to refine this component of the risk assessment.

Based on current information, DSEWPaC concludes that the APVMA cannot be satisfied that the use of fenamiphos in accordance with label instructions would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment. With the exception of two minor use patterns (mushrooms and strawberries), DSEWPaC has recommended cancellation of all current fenamiphos uses.

Residues assessment

The APVMA Residues team undertook the residue assessment for the review of fenamiphos. The team considered all the residue data and information submitted for the review in light of recommendations made by the OCS in its toxicological assessment. There were concerns regarding the safety to human health from a dietary exposure to fenamiphos residues.

No contemporary data from Australian residues trials were submitted to the APVMA. The evaluation of the effect of fenamiphos residues on dietary exposure was undertaken solely on relevant data included in the Joint FAO/WHO Meeting on Pesticides Residues' (JMPR) periodic evaluation of fenamiphos undertaken in 1999. Based on the evaluation, a number of recommendations are made according to the provision of no data, lack of adequate data or exceedance of the ADI and ARfD in the dietary exposure estimates.

The report notes that due to insufficient residues data being available, or inadequate residues data or information in relation to Australian uses being provided, the APVMA cannot ensure that the established maximum residue limits (MRLs) are appropriate. The use patterns for the following commodities are not supported: beetroot, crucifers (including broccoli, brussels sprouts and cauliflower), celery, endive, ginger, lettuce, mushrooms, onions, parsnips, pineapples, strawberries, sugarcane and turnips.

The estimations of the acute (short-term) dietary exposures for bananas, cabbages, carrots, citrus fruit, grapes and melons were acceptable. However, the estimated exposure to residues in potatoes, sweet potatoes and tomatoes was not acceptable and therefore these uses are not supported. The chronic (long-term) dietary exposure of consumers to fenamiphos residues was acceptable, being less than 45% of the ADI for all the above supported commodities.

Use patterns for aloe vera (including planting material), bananas, cabbages, carrot, citrus fruit, grapes and melons are acceptable, and it is proposed that these be supported because of the review.

Citrus peel and grape pomace were identified as likely animal feeds, contributing up to 20% of the livestock diet. The maximum residue likely to occur in citrus peel or pulp was 5 ppm. At this level of feeding, no detectable residues are likely to occur in animal tissues, milk or eggs.

MRL entries in Table 1 of the *MRL Standard* are proposed for bananas, cabbages, carrots, citrus fruit, grapes, dried grapes, melons, watermelons and all animal commodities, including milk and eggs. It is further proposed that MRLs for aloe vera, brassicas (except cabbage), celery, cucurbits, ginger root, leafy vegetables, mushrooms, onions, peanuts, pineapples, and root and tuber vegetables (except carrots), strawberries and sugarcane be deleted. Some changes to Table 4 and Table 5 entries are also proposed.

Proposed review recommendations

The APVMA considered the advice received by the agencies in their respective risk assessments and proposes the following regulatory actions:

a) Affirm active constituent approvals.

b) Cancel all label approvals, as a consequence of the proposed recommendations to:

- delete directions for use on potatoes, sweet potatoes and tomatoes because of an unacceptable potential dietary risk to humans
- delete directions for use on beetroot, crucifers (including broccoli, brussels sprouts and cauliflower), celery, endive, ginger, lettuce, mushrooms, onions, parsnips, pineapples, strawberries, sugarcane and turnips because of a lack of adequate information to assess potential residues[2]
- delete directions for use on all commodities (except mushrooms and strawberries) because of an unacceptable risk to the environment[2].

c) Cancel all product registrations as a consequence of the proposed findings that no currently approved use is likely to be supported.

2 Use patterns will be deleted unless adequate data are submitted in response to these preliminary review findings.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has reviewed the approval of the active constituent fenamiphos, registered products containing fenamiphos and the associated label approvals for products containing fenamiphos. This document summarises the data evaluated and the proposed recommendations from the review.

1.1 Regulatory status of fenamiphos in Australia

Fenamiphos is an organophosphorus (OP) insecticide and nematicide widely used in agriculture to control soil-borne pests and sucking insects. It is a systemic and contact insecticide used primarily for the control of the major genera of nematodes. Fenamiphos also has secondary activity against sucking insects, including aphids and thrips; it is absorbed by the roots of treated plants and translocated to the leaves.

At the start of the review in April 2003, three approved active constituents and four registered products were included in the review. At May 2012 three fenamiphos active constituents were approved and 16 products containing fenamiphos were registered in Australia (see Appendix A). Of the 16 registered products, 15 are 400 g/L emulsifiable or liquid concentrate formulations and one is a 100 g/kg granular formulation. Information on the uses of fenamiphos products can be found in Chapter 2.

1.2 Reasons for fenamiphos review

A review of the active constituent fenamiphos, all products containing fenamiphos and their associated labels began in 2003 because of concerns about toxicology, the environment, residues, and occupational health and safety (OHS). Approvals of the active constituent fenamiphos are being reconsidered because of concerns about a potential risk for acute and chronic toxicity to human health. Products containing fenamiphos and all associated labels are being reviewed because of environmental, toxicological, OHS, and residues concerns.

Fenamiphos was originally nominated as part of the APVMA's Existing Chemical Review Program in 1994. The nomination of fenamiphos for review was related to reports of possible bird and fish poisonings involving the use of products containing fenamiphos. Additional reports of adverse experiences involved the potential for environmental contamination of groundwater and waterways, particularly due to leaching from the site of application.

1.3 Scope of the review

When the extent of the review was determined, the reasons for the nomination of fenamiphos, the information already available on this chemical and the ways for which it is approved for use in Australia were taken into account.

The basis for a reconsideration of the registration and approvals for a chemical is whether the APVMA is satisfied that the requirements prescribed by the Agricultural and Veterinary Chemicals Code (Agvet Code) for continued registration and approval are being met. In the case of fenamiphos, these requirements are that the use of the product in accordance with the instructions for its use would not be likely:

- to be an undue hazard to the safety of people exposed to it during its handling
- to have an effect that is harmful to human beings

- to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA reviewed the toxicological, OHS, environmental, and residue aspects of product containing fenamiphos.

The APVMA also considered whether product labels carried adequate instructions and warning statements. Such instructions should include:

- the circumstances in which the product should be used
- how the product should be used
- times when the product should be used
- frequency of the use of the product
- the withholding period after the use of the product
- disposal of the product and its container
- safe handling of the product
- re-entry into treated areas.

Based on these concerns, it was decided that the active constituent approvals, product registrations and label approvals for fenamiphos be reviewed under the provisions of Part 2, Division 4 of the Agvet Code.

1.4 Regulatory options

There can be three possible outcomes to the reconsideration of the active constituent fenamiphos, registration of products containing fenamiphos and all associated label approvals. Based on the information reviewed, the APVMA may be:

- satisfied that the products and their labels continue to meet the prescribed requirements for registration and approval, and therefore affirms the registrations and approvals
- satisfied that the conditions to which the registration or approval is currently subject to can be varied in such a way that the requirements for continued registration and approval will be complied with, and therefore varies the conditions of registration or approval
- not satisfied that the requirements for continued registration and approval continue to be met, and thus suspends or cancels the registration and/or approval.

2 APPROVED FENAMIPHOS USE PATTERNS

Fenamiphos is used primarily for the control of the major genera of nematodes and sucking insects, including aphids and thrips, in a number of field crops, citrus, grapes, ornamentals, vegetables and turf.

Fenamiphos can be applied as a pre- or post-plant treatment either by broadcast, inter-row, banded or by drench, depending on the application. Products containing fenamiphos are approved for use on 30 crops, with most uses as soil-based applications, pre-planting treatments or at transplanting. With established or semi-permanent crops, such as grapes and pineapples, application can be made during the cropping cycle. Liquid formulations are also used for dipping plant material before planting, for example, aloe vera and bananas. For mushrooms, granular formulations can be applied to either the compost or casing.

At the start of the review, one granular product containing fenamiphos was registered for use in the home garden to control nematodes in soils surrounding tomatoes, herbaceous ornamentals, crucifers and woody ornamentals. This product is no longer registered and there are no products containing fenamiphos registered for use in the home garden.

As of the date of the publication of this report, there were three active constituent approvals for fenamiphos and 16 registered products containing fenamiphos. All active constituent approvals and registered products are subject to this review.

3 SUMMARY OF DATA ASSESSMENTS

3.1 Toxicological assessment

The Office of Chemical Safety (OCS) undertook the toxicological assessment for the review of fenamiphos. The OCS considered all the toxicological data and information submitted for the review. The toxicological findings are summarised below.

Toxicology hazard profile

ABSORPTION, DISTRIBUTION, METABOLISM AND EXCRETION IN MAMMALS	
Rate and extent of oral absorption	Detection in all tissues 0.5 hours after dosing. Based on urinary excretion of radioactivity, oral absorption was complete (> 98%)
Distribution	Highest tissue concentrations found in liver, kidneys and gastrointestinal tract
Potential for accumulation	No evidence of accumulation in fat
Rate and extent of excretion	Majority excreted in urine within 16 hours and completed by 48 hours
Metabolism	Extensive; urinary metabolites include fenamiphos sulfoxide, fenamiphos sulfone and various fenamiphos phenols
Toxicologically significant compounds (animals, plants and environment)	Fenamiphos; fenamiphos sulfoxide; fenamiphos sulfone
ACUTE TOXICITY	(Racemic mixture—no data for enantiomers)
Rat oral LD_{50} (mg/kg bw)	2–19
Worst oral LD_{50} (mg/kg bw) in other species	8 (female mice) ~10 (dogs)
Rat dermal LD_{50} (mg/kg bw)	72 to > 2000 (vehicle dependent)
Worst dermal LD_{50} (mg/kg bw) in other species	179 (female rabbits)
Rat inhalation LC_{50} (mg/m^3)	74 (4-hour aerosol, nose only)
Worst inhalation LC_{50} (mg/m^3) in other species	No data
Skin irritation	Slight (rabbits)
Eye irritation	Moderate (rabbits)
Skin sensitization	Non-skin sensitiser (guinea pigs; maximisation test)
SHORT-TERM TOXICITY	
Target/critical effect	Plasma ChE inhibition
Lowest relevant oral NOEL (mg/kg bw/d)	No data

Lowest relevant dermal NOEL (mg/kg bw/d)	0.5 (15-day rabbit, females)		
Lowest relevant inhalation NOEC (mg/m^3)	0.25 (15-day rat)		
GENOTOXICITY	Non-genotoxic; cytogenic at cytotoxic concentrations		
LONG-TERM TOXICITY AND CARCINOGENICITY			
Target/critical effect	Plasma ChE inhibition		
Lowest relevant NOEL (mg/kg bw/d)	0.011 (6-month oral dog study)		
CARCINOGENICITY	No evidence of carcinogenicity		
REPRODUCTIVE TOXICITY			
Reproduction target/critical effect	No evidence of reproductive toxicity		
Lowest relevant reproductive NOEL (mg/kg bw/d)	3		
DEVELOPMENTAL TOXICITY			
Developmental target/critical effect	No evidence of developmental toxicity at non-maternotoxic doses		
Lowest relevant developmental NOEL (mg/kg bw/d)	0.3 (chain fusion of the sternebrae in one rabbit study)		
DELAYED NEUROTOXICITY	No evidence of delayed neuropathy		
IMMUNOTOXICITY	No data		
DERMAL ABSORPTION	No data		
SUMMARY	NOEL (MG/KG BW/D)	STUDY	SAFETY FACTOR
ADI (0.0001 mg/kg bw/d) [plasma ChE inhibition]	0.01	6-month and 2-year oral studies in dogs	100
ARfD (0.003mg/kg/bw) [red blood cell ChE inhibition]	0.25	Acute oral dosing study in dogs; rat developmental study	100
HEALTH VALUE IN DRINKING WATER	Current: 0.0003 mg/L		

Evaluation of toxicology

The toxicological database for fenamiphos is extensive and consists of unpublished reports generated by industry in addition to a range of published studies. Studies were conducted on products similar to those currently registered in Australia.

Mechanism of mammalian toxicity

Fenamiphos, like other OPs, acts by inhibiting cholinesterase (ChE) enzymes in the blood and central and peripheral nervous systems. This interference causes overstimulation of the nervous system, resulting in rapid twitching and paralysis of muscles, leading to death.

Since it also inhibits acetyl ChE in vertebrates, fenamiphos is highly toxic to mammals, including humans. Poisoning can occur by oral ingestion, dermal absorption or inhalation of spray. The extent of poisoning is directly related to the quantity ingested, absorbed or inhaled. Signs of intoxication are consistent with acetyl ChE inhibition and include salivation, lachrymation, vomiting, diarrhoea and laboured breathing. If intoxication is severe, muscle twitching, loss of reflexes, convulsions and death can eventuate. Fenamiphos is a direct-acting OP and does not require activation to inhibit acetyl ChE activity.

The most sensitive toxicological endpoint for fenamiphos in laboratory animals is the inhibition of red blood cell ChE activity for acute dosing and inhibition of plasma ChE activity for repeated dosing. However, unlike the majority of OPs, fenamiphos was not found to inhibit brain ChE activity (despite the occurrence of overt signs of toxicity) in rats, dogs and rabbits following acute, short-term repeat-dose or subchronic dosing via the dermal, oral or inhalational routes. However, chronic oral toxicity studies conducted in rats and dogs detected some brain ChE inhibition. Collectively, these data suggest that fenamiphos or its metabolites have minimal ability to cross the blood-brain barrier following subchronic or lower durations of exposure in laboratory animals. This was supported by a whole-body autoradiographic study in rats that detected no radioactivity in the brain following acute oral dosing.

Metabolism and toxicokinetics

Studies conducted in rats showed that fenamiphos is almost completely absorbed from the gastrointestinal tract following oral dosing. The majority was excreted via the urine within the first 16 hours of dosing. There was no evidence that fenamiphos or its metabolites accumulate in any tissues. The primary metabolites of fenamiphos were various phenols in different stages of oxidation at the sulfur atom, and their respective sulfate conjugates. There are no unique metabolites generated in plants (or animals) that are of toxicological significance.

Differences in the results of rat metabolism studies largely reflect improvements in techniques rather than any significant discrepancies in the results. In an earlier metabolism study, for example, up to 50% of the administered radioactivity was excreted as CO_2, presumably due to the location of the label in a metabolically labile position. This compared with another metabolism study with the phenyl ring labelled, where minimal radiolabel was excreted as CO_2.

There were no *in vitro* or *in vivo* percutaneous absorption studies submitted or available for evaluation. Therefore the actual level of dermal absorption of fenamiphos in not known. No toxicokinetic studies were submitted for evaluation.

Acute studies

Fenamiphos was highly acutely toxic and its profile of clinical signs was consistent with other OPs. It has high acute oral toxicity and high acute inhalational toxicity in rats. The acute dermal toxicity in rats was low to high depending on the vehicle and sex (LD_{50} 72 to > 2000 mg/kg bw). Fenamiphos has moderate acute oral toxicity in guinea pigs and high acute oral toxicity in mice, rabbits and dogs. Fenamiphos was a slight to moderate eye irritant in rabbits. Fenamiphos was not a skin sensitiser in guinea pigs. Systemic activity occurred in rabbits following ocular administration.

Clinical signs following acute exposure were generally consistent with muscarinic and nicotinic effects, which included salivation, lachrymation, diarrhoea, apathy, laboured breathing, piloerection, muscle tremors, inactivity and rough coats. Signs unique to inhalational exposure included exophthalmos, miosis, corneal opacity, chromodacryorrhea, emaciation and periorbicular red stains. Time of death and the onset/duration of clinical signs varied depending on dose and route. In a few studies, some of the clinical signs observed were more indicative of a central effect (including tremors, dyspnoea and convulsions). However, in light of data indicating the poor ability of fenamiphos (or its metabolites) to cross the blood-brain barrier, it is possible that these signs were elicited by a mechanism not involving the inhibition of brain acetyl ChE activity.

The acute oral toxicity in rats of a number of fenamiphos metabolites (fenamiphos sulfone, fenamiphos sulfoxide, desisopropyl fenamiphos sulfoxide and desisopropyl fenamiphos) was consistent with those seen with the parent compound, including LD_{50} values, time to death and occurrence of clinical signs.

The acute oral toxicities in rats of a number of impurities present in technical material were less than fenamiphos. For those compounds that caused mortalities (4-(methylthio)-meta-cresol (MTMC), MTMC-sulfone, MTMC-sulfoxide, 4-methylmercapto-m-cresol and 3-methyl-4-methylmercaptophenol), clinical signs included ataxia, decreased activity, poor general condition and respiratory disturbances, with only desmethyl fenamiphos causing clinical signs consistent with ChE inhibition.

A 10% granular formulation had high acute oral toxicity in fasted rats and moderate acute oral toxicity in non-fasted rats. It had low acute dermal toxicity and possibly high inhalational toxicity in rats. This formulation was a non-skin irritant and slight eye irritant in rabbits.

In rats, an emulsifiable concentrate formulation containing 40% fenamiphos had high acute oral, dermal and inhalational toxicity. This formulation was a severe skin and eye irritant in rabbits. A 0.7% aqueous dilution of this formulation was still highly acutely toxic via oral and inhalational routes. It was a non-skin and eye irritant in rabbits.

Repeat-dose and chronic toxicity

Dose-related inhibition of plasma and red blood cell ChE activities was the most common manifestation of fenamiphos toxicity in short-term, subchronic, chronic and reproduction studies in mice, rats and dogs. At sufficiently high doses, reduced bodyweight, clinical signs and mortality occurred. There was little indication that repeated exposure of fenamiphos had any effect on haematology, clinical chemistry or urinary parameters, or on organ weights, gross pathology or histopathology.

Carcinogenicity and genotoxicity

Chronic feeding studies in mice, rats and dogs found no evidence that fenamiphos was carcinogenic. *In vitro* genotoxicity assays indicated that fenamiphos was not mutagenic. Some *in vitro* assays (human lymphocytes) indicated that fenamiphos was damaging to genetic material at cytotoxic concentrations, while

others did not. There was no evidence of genotoxicity *in vivo* assays (micronucleus and dominant lethal tests in mice). Collectively, these data indicated that fenamiphos is not considered genotoxic. A 10% granular formulation of fenamiphos was not mutagenic to bacteria.

Reproduction and developmental studies

Multigenerational studies conducted in rats demonstrated no evidence that fenamiphos caused reproductive toxicity. There was no evidence that fenamiphos was teratogenic in rats or rabbits. Chain fusion of the sternebrae occurred in one of two rabbit studies. This, however, was considered secondary to maternotoxicity.

Neurotoxicity

Fenamiphos is neurotoxic in chickens and rats by virtue of its ability to inhibit acetyl ChE activity but there was no evidence that it induced delayed neuropathy in either species after single or repeated oral administration.

Conclusion

The OCS determined that the current Australian Acceptable Daily Intake (ADI) for fenamiphos is 0.0001 mg/kg and is based on the No Observed Effect Level (NOEL) of 0.014 mg/kg bw/d for the inhibition of plasma ChE activity in a 2-year dog study and using a 100-fold safety factor. This value is supported by the NOEL of 0.011 mg/kg bw/d for plasma ChE inhibition in a 6-month supplementary dog study. Following a review of all submitted and archived data, the existing ADI for fenamiphos was considered to remain appropriate. Therefore, the current Health Value for fenamiphos in Australian drinking water of 0.0003 mg/mL also remains appropriate. The present review identified a suitable acute oral dosing study in dogs to allow the setting of an Acute Reference Dose (ARfD) for fenamiphos for the first time. The new ARfD of 0.003 mg/kg bw/d was calculated by applying a 100-fold safety factor to the NOEL of 0.25 mg/kg bw for the inhibition of erythrocyte ChE activity.

No changes to the approval status of fenamiphos have been proposed in this review. Registration of the single product registered for use in the home garden is no longer supported on the basis that it does not comply with criteria established by the APVMA for home garden products. There is no objection on public health grounds to the continued registration of all other existing fenamiphos products.

The existing poisons schedule for fenamiphos (Poison Schedule 7 [Dangerous Poison]) remains appropriate. The review identified a number of additions and amendments to the existing Safety Directions for Australian fenamiphos products.

3.2 Occupational health and safety assessment

The OCS undertook the OHS assessment for the review of fenamiphos, which considered all the OHS data and information submitted for the review.

Workers in agricultural settings can be occupationally exposed to fenamiphos via the dermal and inhalational routes when mixing, loading and applying fenamiphos emulsifiable concentrate and granular formulation products. Fenamiphos acts by inhibiting ChE enzymes in the blood, and central and peripheral nervous systems. Inhibition of plasma ChE activity is the most sensitive toxicological endpoint in acute and short-term studies on experimental animals. For the OHS assessment, the dermal NOEL has been set at 10 mg/kg

bw/d based on a 4-week dermal toxicity study in rats. For inhalation exposure, the most appropriate NOEL is 0.06 mg/kg bw/d, derived from a 3-week inhalation toxicity study in rats in which the No Observed Effect Concentration (NOEC) was 0.25 mg/m^3. The acceptable margin of exposure (MOE) for the dermal and inhalation routes is 100.

Worker exposure during preparation and application

Risk management of exposure during preparation and application of fenamiphos has been facilitated by information provided to the APVMA in response to the review data call-in. This identified the key use patterns of the various products and, in conjunction with the label directions, enabled reasonably precise estimation of the maximum daily work rates achieved by persons using them. No studies that measured the extent of exposure during the preparation and application of fenamiphos-based products were available. Therefore estimates of occupational risks from fenamiphos were prepared by exposure modelling using the Pesticide Handlers Exposure Database and take into account current use patterns.

With fenamiphos, dermal and inhalation NOELs are relatively low, and have dictated the need for high levels of exposure mitigation by personal protective equipment (PPE) and/or engineering controls throughout preparation and application. Based on exposure modelling, persons mixing and loading large quantities of fenamiphos emulsifiable concentrate products for application by spray or irrigation are at risk of unacceptable exposure. Exposure can be reduced to acceptable levels if operations are performed in enclosed mixing/transfer systems while wearing overalls or chemical-resistant clothing, gloves and a respirator.

If not protected by an enclosed cabin, workers applying large quantities of fenamiphos by ground boom spray apparatus can maintain an acceptable MOE only if wearing chemical-resistant clothing, gloves and a full-facepiece respirator. Such PPE would also be required by workers engaged in small-scale application of fenamiphos emulsifiable concentrate products on turf and bananas, and in similar situations using hand wand, handgun and injection lance equipment. If a vehicle equipped with an enclosed cab and air filtration is used, then overalls alone would provide sufficient protection during application.

The 100 g/kg fenamiphos granular formulation product is of lower acute toxicity compared with 400 g/L emulsifiable concentrate products. Workers are expected to handle relatively small amounts of granular-based products per day. Worker exposure during the loading and application of granular formulations by mechanical equipment can be protected adequately with appropriate PPE (gloves, overalls and a respirator) in the absence of engineering controls. If a vehicle equipped with an enclosed cab and air filtration is used, then overalls alone would provide sufficient protection during application. By contrast, exposure modelling implied that workers applying small quantities of fenamiphos granules by hand would be exposed to toxicologically unacceptable levels. The risk cannot be mitigated, even by the most conservative dermal and respiratory PPE. Therefore, manual application of fenamiphos granular formulation products cannot be supported unless a suitable exposure study or additional information can demonstrate the safety of this application method.

Fenamiphos may also be applied to banana and aloe vera planting material by dipping. In the absence of any available exposure studies or models, users need to wear appropriate PPE during dipping operations. Gloves should also be worn when handling treated planting material.

Worker exposure during re-entry

Fenamiphos, when applied to soil and plants, forms relatively persistent chemical residues to which workers may become exposed upon re-entry. However, the estimated level of exposure to fenamiphos residues in

treated soil is sufficiently low to negate any requirement for PPE. Re-entry statements are not required to cover these situations.

A highly relevant exposure study demonstrated negligible potential for toxicologically significant exposure of the public when fenamiphos is applied to turf in situations such as golf courses and bowling greens. However, there is scope for unacceptable exposure of persons undertaking turf care activities if they re-enter treated areas less than 1 day after application. A re-entry period of 24 hours is recommended and, if prior entry is required, dermal PPE comprising overalls and gloves should be worn.

In addition, based on results of a dislodgeable foliar residue study conducted to investigate the extent of worker exposure during application of fenamiphos to pineapples, a re-entry statement is not required for the use of fenamiphos on pineapples.

3.3 Environmental assessment

The Department of Sustainability, Environment, Water, Populations and Communities (DSEWPaC) undertook the environmental assessment for the review of fenamiphos, which considered all the environmental data and information submitted for the review. A summary of the environmental findings follows.

Environmental fate and degradation

Hydrolysis and photolysis

Fenamiphos and its main metabolite, fenamiphos sulfoxide, are found to be hydrolytically stable within environmentally relevant pH and temperature conditions. In aqueous systems and on soil, breakdown of fenamiphos through photolysis is relatively quick (half-life less than 1 day). However, while the parent compound itself may not persist, it is rapidly converted to fenamiphos sulfoxide that appeared to be much more stable to photolysis (half-life up to 96 days with a 12:12 hour light:dark day).

Soil metabolism

In soil, fenamiphos is rapidly oxidised to fenamiphos sulfoxide and then further oxidised to fenamiphos sulfone. While estimated half-lives of the parent compound in soil may be short (less than 1 week), loss of residues as combined fenamiphos and fenamiphos sulfoxide (both biologically active substances) are much shorter. Degradation often appeared biphasic. One study with four soils showed first half-lives from 6.1–17.5 days with second half-lives from 50–78 days. Another study with 16 soils at three temperatures showed degradation half-lives of combined fenamiphos and fenamiphos sulfoxide residues averaging 66.3, 36.0 and 26.2 days at 16^{o}C, 22^{o}C and 28^{o}C respectively.

Aquatic metabolism

Based on a single study, fenamiphos applied in two sediment/water systems disappeared from the media by adsorption to the sediment and through degradation. Fenamiphos half-lives ranged from 3.6–7.9 days in the water column and 9.3–111 days for the whole system. The sediments in both systems were anaerobic and fenamiphos proved to be much more persistent in this media. Fenamiphos sulfoxide was the predominant metabolite in both systems. However, in the sediments, the degradation pathway appeared less significant than in aerobic soils due to the increased persistence of fenamiphos.

Soil mobility

Volatilisation from the soil was shown to be negligible based on one laboratory study.

Laboratory and modelling data showed fenamiphos to be moderately mobile in soil, based on two batch equilibrium studies with 20 soils to consider soil adsorption/desorption of fenamiphos. Fenamiphos has a range of k_{oc} values from 76.2 to 1431.9. For the majority of results (15 of 20 soils), fenamiphos was moderately mobile (k_{oc} between 150–500; the geometric mean k_{oc} was 244.7). In addition, the main soil metabolites were tested for adsorption/desorption characteristics in batch equilibrium studies with six soils considered for each metabolite. Both fenamiphos sulfoxide and fenamiphos sulfone were more mobile than fenamiphos, and fenamiphos sulfoxide was more mobile than fenamiphos sulfone.

Fenamiphos was considered unlikely to leach significantly to groundwater, based on laboratory data and modelling, unlike fenamiphos sulfoxide, which was shown to be a mobile metabolite capable of leaching to groundwater. However, where conditions are suitable for leaching and because of its chemical characteristics, fenamiphos and its major degradates have the potential to leach to groundwater.

Field dissipation

The findings of the leaching potential of fenamiphos were supported by a field dissipation study showing no movement of fenamiphos below 0–15 cm. Fenamiphos sulfoxide was the most mobile and prevalent metabolite, and following a second application was found at the 45–60 cm layer with some detection as low as 75–90 cm. The field dissipation study showed half-lives for fenamiphos (16.8 days) longer than those found in the laboratory, while fenamiphos sulfoxide was again more persistent with field half-lives of 71–77 days. Several groundwater-monitoring studies confirm these findings.

Where conditions are suitable for leaching, fenamiphos residues (particularly fenamiphos sulfoxide) can leach to groundwater. Soil half-lives as measured in the groundwater studies were generally biphasic. Fenamiphos sulfoxide was more persistent than parent fenamiphos. In three studies, fenamiphos had a first phase half-life of 3.4–14 days and a second phase half-life of 17.3–498 days. By contrast, fenamiphos sulfoxide had a first phase half-life of 6.8–126 days and a second phase half-life of around 151–495 days. In one study, degradation followed first order kinetics with a half-life of 33 days for fenamiphos and fenamiphos sulfoxide, and 42 days for fenamiphos sulfone. The half-life in this study for total residues was 34 days. Residues were more persistent in the subsoil (below 15 cm) than in the top 15 cm of soil.

Bioaccumulation

A single bioaccumulation study with fenamiphos and bluegill sunfish (*Lepomis macrochirus*) indicated fenamiphos to be slightly to moderately concentrating in fish and determined a bioconcentration factor of 110 and depuration half-life of 0.22 days. It was expected that any accumulated compound would depurate from the organism.

Environmental toxicity

Avian toxicity

Fenamiphos and its major metabolites, fenamiphos sulfoxide and fenamiphos sulfone, were very highly toxic to birds based on acute oral studies. While no toxicity data were available to birds for the two main metabolites for short-term dietary exposure or under chronic test conditions, fenamiphos was shown to be very highly toxic to birds when consumed through the diet. Two reproduction studies (mallard duck and

bobwhite quail) showed the main adverse effect being related to 14-day old survivors in both studies, with the lowest NOEC of 1.8 ppm (bobwhite quail).

Aquatic toxicity

Acute testing on fish resulted in relatively consistent LC_{50} values indicative that fenamiphos is very highly toxic to fish. The metabolites were substantially less toxic to fish than fenamiphos. Fenamiphos sulfoxide, considered the most toxic of the tested metabolites, was moderately toxic based on a single test to one species with an LC_{50} of 1200 µg/L. Only one longer term fish study was provided (rainbow trout, early life stage) with exposure to fenamiphos. A NOEC of 3.8 µg/L from this study confirms fenamiphos as being highly toxic to fish.

Very few data were provided for aquatic invertebrates and only one standard study was provided using the parent compound. The results showed fenamiphos to be very highly toxic to *Daphnia magna* (LC_{50} 1.9 µg/L). Fenamiphos sulfoxide and fenamiphos sulfone were also very highly toxic to aquatic invertebrates based on one study each to *D. magna*. Other metabolites tested (fenamiphos sulfoxide phenol, fenamiphos sulfone phenol and fenamiphos phenol sulfonic acid) were much less toxic (slightly to practically non-toxic). Fenamiphos showed very high toxicity towards *D. magna* based on one chronic toxicity study with a NOEC of 0.12 µg/L and EC_{50} of 0.36 µg/L.

Only one study was provided for fenamiphos and its main metabolites to a single algal species. Fenamiphos was moderately toxic while the metabolites were less toxic than the parent compound, with fenamiphos sulfoxide being practically non-toxic and fenamiphos sulfone being slightly toxic.

Fenamiphos and fenamiphos sulfoxide were tested for toxicity to the sediment-dwelling midge *Chironomus riparius*. In the fenamiphos study, a very steep dose–response curve was observed and the NOEC for development was 20 µg/L with the EC_{50} falling between 20–40 µg/L (very highly toxic). Fenamiphos sulfoxide was also considered very highly toxic with a NOEC of 58 µg/L and EC_{50} of 95 µg/L.

A mesocosm study was undertaken where mesocosms were stocked with mature bluegill sunfish (15 males and 15 females per pond). The main initial effect was mortality of the fish at test concentrations greater than 3.5 µg/L resulting in secondary effects on mesocosm structure. The NOEC was 3.5 µg/L.

Terrestrial toxicity

Fenamiphos is very toxic to bees through both the oral and contact exposure routes. Several toxicity studies were performed on a range of non-target terrestrial arthropods with significant effects on adult mortality and reproduction at levels well below field spray rates (less than 1% of field spray rates). Based on soil-dwelling arthropod (Collembola; *Folsomia candida*) results, fenamiphos sulfoxide and fenamiphos sulfone were of a similar order of toxicity as fenamiphos, while fenamiphos sulfoxide phenol and fenamiphos sulfone phenol are less toxic. Fenamiphos demonstrated sub-lethal toxicity to earthworms at very low soil concentrations. In one acute study, the LC_{50} of fenamiphos was 888 mg/kg dw compared to a NOEC of 0.032 mg/kg dw based on worm weights. In a chronic 56-day study, numbers and biomass of offspring were significantly reduced at all application rates (NOEC less than 6 kg ai/ha). In a field study, some earthworm species were negatively affected by fenamiphos applications at 10 and 40 kg ai/ha. Effects were noted up to 3 months after application.

Testing on soil microorganisms indicates no adverse impact on the soil nitrogen cycle up to 133 mg/kg dw soil (highest rate tested) is expected. However, some temporary increase in nitrate production may occur at these levels.

Fenamiphos is not expected to show phytotoxicity based on a single screening level seedling emergence study at application rates up to 15 kg ai/ha on 11 plant species consisting of 6 dicots and 5 monocots.

Environmental risk

For the preliminary risk assessment, a deterministic approach has been used to try to characterise the risk from fenamiphos uses to the environment. Risk quotients, the primary outcome, are established for the different environmental organisms considered environmental assessment, that is, birds and terrestrial organisms and the various trophic levels in the aquatic ecosystem.

The risk quotient is interpreted through comparison with levels of concern (LOCs) to analyse potential risk to non-target organisms and the need to consider further testing/refinement or regulatory action. Implicitly built into these LOCs are assessment factors to increase certainty in the risk assessment. For example, an acute LOC of 0.1 means the (predicted environmental concentration)/(LC_{50}/EC_{50}) has an assessment factor of 10 built into the effects value.

When assessing risk, not every case can be accounted for, so Australia follows an iterative process by considering:

- a ‘worst case’ exposure scenario and, if needed,
- a series of refinements, which account for other factors and results in setting scenarios that are more realistic at each step.

The worst case should identify the sensitive environmental compartment(s) most at risk from exposure to the chemical. If these environmental compartments are not at risk (that is, the risk quotient value is acceptable), then no other assessment is needed.

Exposure estimates are required for food (birds and mammals), soil (soil-dwelling arthropods, earthworms, and soil microorganisms), water (aquatic organisms, from either spray drift or runoff) and sediment (benthic organisms). In addition, exposure to organisms such as bees, other non-target terrestrial arthropods and non-target terrestrial plants are based on the spray rate of the chemical.

Risk evaluation

BIRDS AND MAMMALS

Birds and mammals may be exposed to fenamiphos residues through food and water ingestion but the extent of exposure differs depending on product formulation and use pattern.

The risk characterisation shows an unacceptable risk to birds for all cropping situations (including turf) at all application rates. When applied as the granule formulation, risk quotients are particularly high and modelling showed small birds need only to forage a very small surface area to potentially ingest a lethal dose.

A number of acute avian field studies, conducted in the United States, considered the effects on bird mortality following application of fenamiphos either as a spray or as granules. A number of studies showed treatment-related effects on birds. One study, application of fenamiphos by chemigation in citrus groves, showed 13% higher mortality in the treated plot after significant exposure to fenamiphos compared to control plots. A second study, spray application of 11.2 kg ai/ha to golf courses, had a treatment-related effect of 9% loss (either mortality or emigration) of the avian population. Abnormal behaviours were also observed and recovery rates were high for the birds monitored.

Birds were seen eating 'dosed' invertebrates and subsequently became sick. Residue monitoring indicated that fenamiphos residues were found in all media (soil, water and invertebrates) where tested, and often at levels higher than dietary LC_{50} values. It was also shown that total fenamiphos concentrations were initially high in invertebrates but declined to relatively safe levels within a few days. Most of the treatment-related deaths and behavioural impairments were found on the day of application or the day after application.

Concerning these studies, the United States Environmental Protection Agency (US EPA) noted that the studies had deficiencies that limit or negate their use for evaluating the magnitude of effects to terrestrial and aquatic wildlife from use of fenamiphos. Additionally, it noted that no field exposure reproductive or developmental studies were performed that limited the evaluation to acute effects.

Combined with known incidents to birds from fenamiphos in the field, there appears to be support for concluding that fenamiphos poses a high risk to birds.

NON-TARGET TERRESTRIAL ORGANISMS

An unacceptable risk was identified for bees based on application from both the liquid and granule formulation for all crops (including turf) and at all application rates.

When exposed through the liquid formulation, above-ground terrestrial arthropods all showed risk quotients well above 1 (ranging 28–1000). While LOCs are not established for these organisms, the high-risk quotients are of concern and indicate an unacceptable risk to these organisms. Ecotoxicity data demonstrated adverse effects on both adult mortality and reproduction for a range of arthropods at levels well under application rates prescribed for fenamiphos.

A similar concern exists for ground-dwelling terrestrial arthropods. With the exception of the two lowest application rates (0.4 and 2.4 kg ai/ha) of the liquid formulation, all risk quotients were at least 2, with a highest risk quotient around 20 for both the liquid and granule formulation uses.

Risk quotients for earthworms were calculated using chronic toxicity data as the only available acute toxicity test showed significant effects at the lowest tested rate. Minimum application rates of 9 kg ai/ha or more resulted in an unacceptable risk to earthworms, although application rates lower than these could also result in an unacceptable risk based on the NOECs being undefined in the ecotoxicity tests.

In predicting environmental concentrations, concentrations in soil were estimated to range from 0.33 to 25 mg/kg dw depending on the application rate following a single application. Chronic NOECs for earthworms were less than 0.12 mg/kg dw. This shows that residues in soil may remain at levels higher than the chronic NOEC for a long time following application. This demonstrates that, at overall application rates of fenamiphos to crops, the potential for chronic exposure is high with residues possibly remaining at harmful levels before following applications. This resulted in an unacceptable risk to earthworms.

For non-target terrestrial arthropods, effects are most likely to be acute in nature, particularly where exposed through spray. However, data show that these effects are significant on adult mortality (and reproduction for surviving adults) at levels significantly lower than crop application rates. Furthermore, exposed insects were shown in bird field studies to contain residues at levels in excess of bird dietary LC_{50} values, and birds were observed to feed on affected insects.

Fenamiphos has proven to be very toxic to non-target terrestrial arthropods. However, all studies submitted for this end-point were performed using a microencapsulated formulation that is not sold in Australia.

Consequently, it must be assumed that the current formulation is at least as toxic to non-target terrestrial invertebrates as the formulation used to generate the data.

SOIL MICROORGANISMS

The exposure calculations for soil organisms such as earthworms, soil-dwelling arthropods and soil microorganisms are based on the application rate of the chemical. With regard to these situations, the concentration in soil is predicted based on uniform mixing within the top 10 cm using a soil density of 1500 kg/m^3.

Risks to soil microorganisms were acceptable up to application rates of 15 kg ai/ha (liquid formulation) and 18 kg ai/ha (granule formulation). At rates higher than this, a risk was identified, but this risk could be mitigated, and Q-values for all application rates with both products never exceeded 0.2.

AQUATIC ORGANISMS

Aquatic areas may be exposed through either spray drift or runoff. Risk to aquatic organisms was predicted through exposure modelling with potential exposure resulting from either runoff or spray drift. Generally, the risk to algae and aquatic plants was deemed acceptable through both routes. There was an exception of an unacceptable risk to these organisms from spray drift at the highest application rate to citrus with a buffer zone of 5 or 10 m.

Conversely, the risk to fish, aquatic invertebrates and sediment-dwelling organisms was generally deemed unacceptable (including for turf application).

Runoff

In quantifying exposure from runoff, Australia does not have a defined model. Calculations are based on a simplistic model for runoff (which showed that fenamiphos was a very high hazard to aquatic organisms from runoff). Water concentrations predicted from runoff following a single application ranged from 0.46 to 34.4 µg/L (1% field slope) and 1.38 to 103.3 µg/L (3% slope). A mesocosm study demonstrated a NOEC to aquatic systems of 3.5 µg/L, below the majority of predicted water concentrations based on the predicted modelling following single application. This mesocosm study indicated a half-life in water/sediment systems as high as 111 days. The potential for residues to remain at levels above those known to cause adverse effects is high, particularly with the prospect of continued exposure resulting from repeat applications.

Runoff scenarios, considered with the liquid formulation and based on a NOEC of 3.5 µg/L, resulted in an unacceptable risk to aquatic systems at all application rates for all crops except the lowest application rate at both slopes, and the 2.4 kg ai/ha application rate on a 1% slope. Runoff scenarios, considered with the granular formulation and based on a NOEC of 3.5 µg/L, identified an unacceptable risk to aquatic organisms for all application rates above 4 kg ai/ha at both slopes. This NOEC was based on mortality effects to fish and shows the potential sensitivity of aquatic systems to fenamiphos at very low concentrations.

Spray drift

Exposure by spray drift is only considered through the spray application of the 400 g/L fenamiphos liquid formulation. Spray drift through application of granular formulations is not considered, as per the APVMA's *Operating principles in relation to spray drift*, published in 2008.

Based on the modelling following a single application, predicted concentrations resulting from spray drift of 100 m are generally acceptable (the risk quotient is less than 1 based on the chronic mesocosm NOEC of

3.5 µg/L) except for bananas, perennial ornamentals, aloe vera and citrus (risk quotients of 1.1–2.7, 1.1, 1.4, and 1.7–3.4 respectively). Application rates and/or drift estimates were higher for these crops. Where repeat applications occur, the potential exists for residue levels to remain in the whole system at levels higher than those considered acceptable before subsequent applications.

Spray drift exposure of the liquid formulation from the lowest application rate at 5 and 10 m resulted in acceptable risk quotients (except for aquatic invertebrates at 5 m downwind). Otherwise, all application rates for all crops resulted in an unacceptable risk to fish, aquatic invertebrates and sediment-dwelling organisms at 5 and 10 m downwind, except for sediment organisms following application to sugar cane (4 kg ai/ha) and pineapples (4.8 kg ai/ha) at 10 m downwind. With the exception of application to citrus (30 kg ai/ha), a buffer zone of 100 m downwind resulted in risk that was either acceptable or possibly mitigable being predicted for fish and sediment-dwelling invertebrates. Risk quotients for aquatic invertebrates still exceeded LOCs for all scenarios (except the lowest application rate of 0.4 kg ai/ha, and application to sugar cane at 4 kg ai/ha).

GROUNDWATER

Fenamiphos, particularly its metabolites, have demonstrated mobility in soil based on groundwater monitoring studies. Fenamiphos sulfoxide and fenamiphos sulfone are more mobile than fenamiphos in the soil profile. Both major degradates have been detected in groundwater in the United States, indicating that they are sufficiently persistent to leach in some environments. The available evidence suggests that the persistence of the residues is greater in sub-surface than the topsoil, thereby increasing the potential to migrate to groundwater. No such data exist for Australia and, in its absence, the only conclusion that can be drawn is that the potential exists for contaminating groundwater in areas of fenamiphos use in Australia.

DEGRADATION OF PARENT COMPOUND

Often parent compounds will degrade to less toxic metabolites. In the case of fenamiphos, its main metabolites, fenamiphos sulfoxide and fenamiphos sulfone, will not reduce the risk quotients for many environmental organisms as the limited toxicity data for these metabolites suggest they are of a similar order of toxicity as fenamiphos. Additionally, these metabolites are much more persistent than the parent compound, and the persistence of fenamiphos and its main metabolites is unclear once it is incorporated in soil.

A groundwater study, measuring fenamiphos and its main metabolites in the soil profile to 106 cm in 15 cm increments, provided further insight into the degradation of sub-surface residues. Most of the residues were found in the 0–15 cm layer and the first half-life was around 30 days. However, when residues from 30–106 cm were considered, the half-life was about 130 days.

The main issue is that, while soil incorporation is needed for the product to be efficacious and aids in reducing environmental exposure, for example, to birds or aquatic systems by reducing runoff, the build-up of residues following multiple applications is undesirable, and this cannot be determined without adequate half-life data.

LOWER APPLICATION RATES DUE TO BANDED TREATMENTS

When fenamiphos is applied as a pre-plant treatment, the whole area is treated. In many situations, when applied to established crops, the actual rate of application (averaged over the whole hectare) is reduced compared to the rate in the treatment zone. This may lower PECs and may lead to a more acceptable risk outcome.

However, based on the assessment, banded treatment results in a lower overall application rate per hectare but the application rates are still within the range of those considered for full hectare treatment rates where unacceptable risks to birds, terrestrial organisms and aquatic organisms have already been identified. Therefore, the use of banded treatment rates will not result in sufficient lowering of the risk quotients to conclude an acceptable risk.

CHRONIC EXPOSURE AND MULTIPLE APPLICATIONS

A number of use patterns allow for multiple applications of fenamiphos, although several months are generally required between applications. For example, aloe vera allows fenamiphos to be applied every 4 months and pineapple ratoons may require five sprays over plants at 2–3-month intervals.

Chronic risk to environmental organisms will depend on residues remaining in the environment at the time of subsequent applications, and the biological activity of the residues at expected levels following chronic exposure.

Fenamiphos and fenamiphos sulfoxide are hydrolytically stable within the environmentally relevant pH range. While photolysis may provide a means of rapidly eliminating fenamiphos from soil or water, the substance is predominantly soil incorporated so this is unlikely to be a significant removal mechanism.

In soil, fenamiphos is rapidly oxidised to fenamiphos sulfoxide and then further oxidised to fenamiphos sulfone. While half-lives of the parent compound in soil may be short (generally less than 1 week), loss of residues as combined fenamiphos and fenamiphos sulfoxide are much greater. The available studies displayed biphasic degradation of fenamiphos, with one study showing first half-lives from 6.1–17.5 days with second half-lives from 50–78 days. However, these studies were based on topsoil application, there is the potential for persistence to be significantly increased where fenamiphos is soil incorporated.

Where released to water, fenamiphos may move to sediments where it will degrade slowly. In an aerobic system, the half-life in water was relatively short (less than 8 days), while that for the whole system was much slower (up to 111 days). In an anaerobic soil/supernatant water system, most of fenamiphos was retained in the soil while significant amounts of fenamiphos sulfoxide moved from the soil to the water phase. The degradation of fenamiphos under anaerobic conditions was relatively slow, with a half-life estimated to be around 90 days.

Risk arising from certain use patterns

TURF USE PATTERNS

The current label rate for use of fenamiphos in turf situations, equivalent to 4.4 kg ai/ha, will result in unacceptable risk to birds, bees, aquatic organisms in the event of runoff, and soil-dwelling organisms including earthworms. Based on current information, further mitigation of these risk quotients is not possible. See *Risk evaluation* section below for further information on risks and effects to non-target organisms.

DIPPING SOLUTIONS

Fenamiphos, as a 400 g/L liquid formulation, allows dipping treatment for aloe vera and banana planting material. Treatment rates for aloe vera planting material are 4 mL ai/L dipping solution and 0.4 mL ai/L dipping solution for banana planting material.

While both uses provide directions to allow dipped planting material to drain and dry before planting, neither use provides directions relating to disposal of spent dipping solutions. Undesirable environmental exposure could result.

Advice was received for the method of disposal and volumes of spent dipping solution for banana planting material. Banana planting material is mechanically dipped into a vat containing dipping solution. Following dipping and draining of planting material, unwanted dipping solution is strained of all extraneous materials and used in the adult banana plantations as per label instructions. Rubbish that accumulates in the bottom of dipping vats is placed within the banana row (in the sprayed area) after removal of the product.

This process is sound in terms of controlling environmental exposure of dipping solutions in that exposure is limited to areas where spraying would otherwise occur. However, actual spraying of fenamiphos in banana plantations has been shown to potentially have unacceptable risk to birds, aquatic organisms and terrestrial organisms at all registered label use rates.

TRICKLE OR DRIP IRRIGATION SYSTEMS

It is apparent that some agricultural practices may lower the risk to non-target organisms. For example, where application is through trickle or drip irrigation systems, or as a sub-surface drip, exposure to aquatic areas and non-target plants through spray drift will not occur. Further, risk to birds may be reduced as their exposure would be limited to consumption of soil insects that may contain fenamiphos residues, or from drinking irrigation water if it puddles. Given that application through drip or trickle irrigation systems results in substantially reduced treatment areas on a whole hectare basis, overall exposure would be further reduced.

Despite this, other risks cannot be discounted even when application is through drip or trickle irrigation systems. For example, the chemical and its metabolites remain available in the soil for sub-surface runoff or leaching where the conditions for leaching exist. Further, avian field studies assessed showed treatment-related mortalities to birds where fenamiphos was applied by chemigation in citrus groves, so exposure to birds when applied through the irrigation systems could still pose a risk.

MUSHROOMS

Fenamiphos, as a 400 g/L liquid formulation, may be applied as a spray application to mushrooms grown in compost and in enclosed casings. A number of a different application rates prescribed for treating compost and casing range from 22–26 mg ai/kg compost and 80 mg ai/kg casing, respectively. The label has explicit instructions that both the casing and the compost should not be treated.

The most likely environmental exposure from this use pattern would result from disposing of used compost and casing material. Information provided by the Queensland Department of Agriculture, Fisheries and Forestry stated that spent compost can be marketed as a potting mix or garden soil additive. During the growing cycle, significant degradation of fenamiphos and metabolites would be expected. Elevated temperatures would likely be found in the growing medium, and at the end of the cropping season compost is steam-treated to prevent the spread of pests and diseases.

Following such processes, and further diluting the compost in other soil (for example, when using as a soil additive) should result in soil concentrations unlikely to result in adverse environmental effects and this use pattern is considered acceptable.

STRAWBERRIES

Fenamiphos, as the 100 g/kg granular formulation, is approved for use in strawberries at an application rate of 1 kg product (100 g ai)/1000 plants or 1 g product (0.1 g ai)/plant. Planting density of strawberries is high and, assuming that up to 80,000 plants/ha can be found, an equivalent application rate of 8 kg ai/ha may result.

Fenamiphos granules are applied directly into the heart of infested plants within 1 month of planting and spray irrigated immediately after application to avoid possible phytotoxicity.

While bird exposure is possible, application early on in the growing cycle means flowers and fruits are unlikely to be present to attract birds. Runoff is likely to be limited due to the dense nature of the strawberry plants with application within the plant itself.

The rates prescribed may lead to unacceptable exposure to soil organisms in treated areas. However, as advised by industry, very little fenamiphos is used in strawberries in Australia, with less than 5% of the total growing area likely to be treated with fenamiphos. Given the small extent of application in strawberries (as a proportion of total growing area), extensive untreated areas remain available for soil-dwelling organisms and the risk is considered acceptable.

Conclusion

Risk assessment based on current uses on labels considered for this review resulted in a potentially unacceptable risk to birds, aquatic organisms and terrestrial organisms including non-target arthropods and earthworms for the majority of approved use patterns for fenamiphos. With current information, mitigation of the risks associated with fenamiphos use is very difficult because:

- fenamiphos has been shown to be highly toxic to organisms in the environment
- while fenamiphos converts relatively rapidly to a major metabolite, this metabolite has been shown to be biologically active and toxicity is not remarkably less than the parent compound to a number of environmental organisms
- overall removal of fenamiphos and its metabolites from environmental media does not occur quickly. Therefore, the use of time-weighted average exposure concentrations does little to mitigate exposure and potential risk, particularly where repeat applications to crops occur.

Additionally, fenamiphos and its metabolites have been shown to leach to groundwater where conditions favourable for leaching exist. There is no information relating to likely vulnerable leaching sites in areas where fenamiphos is used to refine this component of the risk assessment.

Based on current information, DSEWPaC concludes that the APVMA cannot be satisfied that the use of fenamiphos in accordance with label instructions would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment. With the exception of two minor use patterns (mushrooms and strawberries), DSEWPaC has recommended cancellation of all current approved fenamiphos uses.

3.4 Residues and trade assessment

The APVMA Residues team undertook the residue assessment for the review of fenamiphos. The team considered all the residue data and information submitted for the review in light of recommendations made

by the OCS in its toxicological assessment. There were concerns regarding the safety to human health from a dietary exposure to fenamiphos residues.

Residues evaluation

Metabolism

The metabolism of fenamiphos in plants and animals has been previously considered by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 1999. In summarising the JMPR evaluation of fenamiphos metabolism, fenamiphos sulfoxide and fenamiphos sulfone are the main resulting metabolites formed after application of fenamiphos to plants. In crops with a substantive period between treatment and harvest, and in animals (rats, goats, cows and hens) various phenols of fenamiphos are formed. The metabolites of fenamiphos in plants and animals are similar and the existing residue definition is appropriate.

Analytical methods

No analytical methods were submitted to the APVMA to support the review of fenamiphos. However the JMPR in 1999 considered the analysis of fenamiphos residues. Gas liquid chromatography methods were identified as the routine methods used to determine fenamiphos residues in food. Methods were identified for both crop and animal commodities, and recoveries were identified.

The JMPR raised an issue of the stability of fenamiphos residues. Fenamiphos residues were stable in crop material, but may be unstable in liver and fatty tissues. The JMPR stated that instability of fenamiphos residues and its metabolites in cattle tissues would not have a marked effect on the overall results of analyses.

The conclusions of the JMPR are accepted and methods of analysis capable of determining fenamiphos and relevant metabolites are readily available.

Residue definition

The existing definition of the residues is *sum of fenamiphos, its sulfoxide and sulfone, expressed as fenamiphos*. The analytical methods allow all three compounds to be included in the measured residues, as fenamiphos and the sulfoxide are both oxidised to the sulfone. Therefore, the existing residue definition remains appropriate, which is in agreement with the FAO/WHO Codex Alimentarius Commission's (Codex) definition.

Residues in food and animal feeds

Residues data from crop trials conducted in Australia and overseas were available in the 1999 JMPR report. Relevant data that closely approximate good agricultural practice (GAP) in Australia are summarised in Table 3.1. The commodities for which trials were reported included carrots, potatoes, onions, brussels sprouts, cabbages, tomatoes, melons, watermelons, grapefruit, lemons, limes, oranges, bananas and pineapples.

Table 3.1: Residues of fenamiphos in food and animal feeds, including MRL recommendations

COMMODITY	AUSTRALIAN GAP		SUPERVISED TRIAL DATA				PROPOSED MRL (mg/kg)
	APPLICATION RATE (FORM.)	WHP	APPLICATION RATE (FORM.)	WHP (DAYS)	HR (mg/kg)	STMR (mg/kg)	
Carrot	9 kg ai/ha (GR) 9.6 kg ai/ha (EC)	12 weeks 12 weeks	9–11 kg ai/ha (EC/GR)	65–150	0.11	0.05	0.2
Potato	10 kg ai/ha (GR)	12 weeks	9–10 kg ai/ha (EC/GR)	71–118	0.17	0.03	0.3[a]
Cabbage	11 kg ai/ha (GR) 9.6 kg ai/ha (EC)	12 weeks 12 weeks	9–10 kg ai/ha (EC/GR/SC)	42–108	0.05	0.01	0.1
Tomato	11 kg ai/ha (GR) 9.6 kg ai/ha (EC)	Nil Nil	9–11 kg ai/ha (EC/GR)	58–127	0.27	0.05	0.5
Melons	9.6 kg ai/ha (EC)	Nil	9–10 kg ai/ha (EC/GR)	71–112	0.05 (whole fruit) < 0.02 (pulp)	0.015 (whole fruit)[b]	*0.05
Citrus (Orange, lemon, lime, grapefruit)	30 kg ai/ha (EC)	Nil	33.6 kg ai/ha (EC/GR)	59–190	0.56 (whole fruit) 0.05 (pulp)	0.01 (whole fruit & pulp)	0.7[c]
Grapes	12 kg ai/ha (EC) or 1.2 g ai/m^2	Nil	1–2 g ai/m^2 (EC) 12 kg ai/ha (EC)	73–125	0.05	0.01	*0.05
Bananas	2.5 g ai/stool (GR) 2.4 g ai/stool (EC)	Nil Nil	2.8–5 g ai/stool (EC/GR)	1–112	0.025	0.015	*0.05

EC emulsifiable concentrate GR granular formulation SC suspension concentrate

(a) MRL will also be extrapolated to sweet potato.

(b) Not enough data points to estimate a median value.

(c) Group MRL will include mandarins, as well as the citrus crops listed.

No data were presented to support continued use of fenamiphos in broccoli, turnip, swedes, cauliflower, ginger, parsnips, strawberries, sugarcane, beetroot, celery, lettuce, endive and mushrooms. For mandarins and sweet potatoes, extrapolation from related commodities within a crop group may be possible, to make a determination of appropriate maximum residue limits (MRLs). There were insufficient numbers of trials for onions, brussels sprouts and pineapples, and therefore these uses cannot be supported.

Effect of processing on residues

Studies for the processing of tomatoes, organs and grapes were reported in the JMPR.

ORANGES

Orange trees were treated with Nemacur 15% granular at the equivalent rate of 100 g ai/ha. Leaves were taken at monthly intervals to determine when peak residues had moved systemically into the upper parts of the trees. When fenamiphos residues had reached a plateau in the leaves, fruit were harvested and commercially processed. Residues concentration was greatest in clear oil. However, they were also concentrated in peel and dry peel, both of which are used as animal feed. Residues in pulp and juice were negligible.

TOMATOES

Whole tomatoes containing 0.5 mg/kg fenamiphos were subjected to commercial processing into canned tomatoes, pasteurised juice and ketchup. Residues were greatest in dry pulp solids. Residues were also concentrated in dry tomato peels and cores, and dry tomato pomace, all of which are used as animal feed. Residues in pasteurised juice, canned tomatoes and ketchup were detected and the concentrations were lower than that for whole tomatoes.

GRAPES

In a processing trial in California, Nemacur 3 EC was applied twice at a 6-week interval at a rate equivalent to 25.2 kg ai/ha (5 times the normal rate) as band sprays with incorporation. Samples of grapes, grape juice and wet pomace were collected 7 days after the second spray. The residues were concentrated in raisins and raisin waste, and in dry pomace after juicing and drying. The residues in juice and wet pomace did not differ from those in the whole fruit. Raisin waste and pomace are used as animal feed.

The processing factor for raisins is 1.22, and therefore residues in dried grapes will not be adequately accommodated by the MRL of *0.05 mg/kg recommended for grapes. Therefore an MRL of 0.1 mg/kg is recommended for dried grapes.

LIVESTOCK FEED COMMODITIES

Orange peel and pulp, grape pomace and tomato pomace are all considered potential for which appropriate MRLs are required. Based on the highest residue level detected (incorporating processing or edible portion factors), an MRL of 5 mg/kg is recommended for citrus pulp (dry); an MRL of 0.5 mg/kg is recommended for grape pomace (dry) and an MRL of 2 is recommended for tomato pomace (dry).

Animal transfer studies and required animal commodity MRLs

Potential livestock feeds predominantly comprise processed by-products. Residues in feed range from 0.01–5 ppm, translating to a maximum theoretical exposure in animal feed of up to 5 ppm fenamiphos resulting from citrus peel or pulp. However, citrus peel or pulp would be fed at levels no greater than 20% to livestock. This indicates a maximum exposure in the total diet of 1 ppm.

The data examined by the JMPR indicated that there were no detectable residues in the tissues of milk of cattle fed 6 ppm fenamiphos in the diet, and that there were no detectable residues in the tissues and eggs of chicken fed 2 and 4 ppm fenamiphos.

The risk of residues occurring in the tissues and milk of cattle, sheep or pigs, or the eggs of chickens is very low. The data support the reduction of the present MRLs for all animal commodities except milk to *0.01 mg/kg.

Fat solubility and potential for bioaccumulation

Fenamiphos is not known to bioaccumulate in animal tissues or crops. The log P_{ow} of fenamiphos is 3.3; however, the residues as defined by the JMPR were determined as not being fat-soluble.

Dietary risk assessment

OCS has recommended the following health standards (Table 3.2) in the toxicological assessment.

Table 3.2: Health standards for fenamiphos

COMPOUND	DIETARY STANDARD, mg/kg bw		NOEL, mg/kg BW	SAFETY FACTOR	REFERENCE (OCS, DATE)
Fenamiphos	ADI[3]	0.0001	0.014	100	7/11/2005
	ARfD[4]	0.003	0.25	100	7/11/2005

Acute dietary exposure

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[5] with 97.5th percentile food consumption data derived from the 1995 National Nutrition Survey of Australia and subsequent surveys. NESTI calculations are conservative estimates of a single-point acute exposure (24-hour period) to chemical residues in food. The NESTIs for all relevant commodities are summarised in Table 3.3.

The acute dietary intake estimates for potatoes, tomatoes and sweet potatoes for 2–6 year olds exceeded the ARfD for fenamiphos, giving values of 165%, 200% and 280% respectively. It is concluded that the acute dietary exposures for potatoes, tomatoes and sweet potato are not acceptable. The estimates for all other commodities for both the 2 year old and 2–6 year old age groups were satisfactory.

3 www.health.gov.au/internet/main/publishing.nsf/content/E8F4D2F95D616584CA2573D700770C2A/$File/ADI-Dec12.pdf

4 www.health.gov.au/internet/main/publishing.nsf/content/CC3EFF3468126E3ECA2573D70077C069/$File/ARfD-Dec12.pdf

5 Pesticides Residues in Food 2003, Report 2003, FAO Plant Production and Protection Paper 176

Table 3.3: Estimated short-term dietary exposures (NESTIs) for relevant food commodities

CODE	FOOD	NESTI (% ARfD)	
		2 YEARS +	2-6 YEARS
MM 0095	Meat (mammalian)	< 5	5
PM 0110	Poultry meat	< 5	5
MO 0105	Edible offal (mammalian)	< 5	< 1
PO 0111	Poultry, edible offal of (1)	< 5	< 5
ML 0106	Milks	< 5	< 5
PE 0112	Eggs	< 1	< 5
FI 0327	Banana	5	20
VB 0041	Cabbages, head	20	20
VR 0577	Carrot	20	50
FC 0001	Citrus fruits	–	–
FC 0004	Oranges	10	25
FC 0204	Lemons	10	35
FC 0203	Grapefruit	20	80
	Citrus juice	< 5	5
FB 0269	Grapes	10	25
DF 0269	Dried grapes	10	< 5
VC 0046	Melons (excluding watermelon)	15	40
VC 0432	Watermelon	40	40
VR 0589	Potato	60	165
VO 0448	Tomato	80	200
VR 0508	Sweet potato	60	280

Chronic dietary exposure

The chronic (lifetime) dietary exposure to fenamiphos 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 from the 1995 National Nutrition Survey of Australia. The NEDI calculation is

made in accordance with World Health Organization Guidelines[6] and is an estimate of dietary exposure to chemical residues in food. The NEDI for fenamiphos, is equivalent to 116% of the ADI (NEDI #1).

Dietary exposure conclusions

The continued use of fenamiphos on potatoes, tomatoes and sweet potato cannot be supported from an acute dietary exposure perspective, as all these commodities exceed the ARfD. Therefore, the chronic exposure calculations will exclude these and the NEDI is then determined to be equivalent to 45% of the ADI (NEDI #2). Following both the short-term and chronic dietary exposure calculations, the continued use of fenamiphos in bananas, cabbages, carrots, citrus fruit, grapes and melons is supported.

Residue related aspects of trade

Based on the conclusions in the previous paragraph, the APVMA has assessed that it is not likely that residues observed in traded product will be higher than those observed under the current use patterns. The APVMA remains satisfied that the use of fenamiphos according to approved use patterns does not pose an undue risk to trade between Australia and places outside of Australia

Conclusion

The APVMA has assessed the impact of fenamiphos residues on dietary exposure, which was undertaken solely on relevant data included in the JMPR report of 1999. No residues data were available to support the ongoing use of fenamiphos on beetroot, broccoli, cauliflower, celery, endive, ginger, lettuce, mushrooms, parsnips, swedes, strawberries, sugarcane and turnips. Data for crucifers (brussels sprouts**),** onions, and pineapples were inadequate and therefore these uses cannot be supported. Data were available that supported the ongoing use of fenamiphos on aloe vera (including plant material), bananas, cabbages, carrots, citrus fruit, grapes and melons. Amendments to the MRL Standard have been proposed.

Short-term (acute) dietary exposure estimations for bananas, cabbages, carrots, citrus fruit, grapes and melons were acceptable. However, the estimated exposure to residues in potatoes, sweet potatoes and tomatoes was not acceptable and therefore these uses are not supported.

When treated commodities are fed to animals, no detectable residues are likely to occur in animal tissues, milk or eggs. Amendments to Table 4 of the MRL Standard will need to be made for fruit processing wastes identified in the review for minor animal feeds of dried citrus pulp and dried grape pomace.

The current residue definition of fenamiphos remains relevant and analytical methods are capable of determining fenamiphos residues in the supported commodities.

The potential for undue prejudice of trade is possible for export of citrus to Hong Kong and Malaysia as they are likely to defer to Codex standards. Codex has not established MRLs for citrus. However, there is little potential for trade to be an issue with all other supported commodities.

6 *Guidelines for predicting dietary intake of pesticide residues*, WHO, 1997.

3.5 INTERNATIONAL REGULATORY STATUS

United States

The US EPA published an Interim Reregistration Eligibility Decision document for fenamiphos in May 2002. The document identifies risk mitigation measures needed to reduce risk, as well as data needed to better characterise risks. The sole registrant of fenamiphos in the United States requested voluntary cancellation and phase-out of all existing fenamiphos registrations rather than committing to develop additional data.

Fenamiphos residues in food do not pose dietary (acute and chronic) risk concerns; however, exposure to shallow water tables (less than 50 feet deep) and extremely vulnerable soils do pose risk concerns.

Although fenamiphos is not used in residential settings, golf course uses could lead to exposure to golfers from residues on treated courses. The US EPA felt that the watering-in of fenamiphos following its application according to label directions adequately protects golfers from exposure.

The US EPA's Risk Assessment showed that acute and chronic risks exceed the agency's LOC for terrestrial, aquatic and endangered species.

Risk mitigation strategies agreed to by the registrant and the US EPA included a reduction in the manufacture of fenamiphos products over a 5-year phase-out period. The formulation, sale and distribution of new and existing stock was prohibited from May 2007. It was also agreed that use of all stock existing in the marketplace could continue until depleted.

European Union

The Netherlands, being the designated Rapporteur Member State, submitted the draft assessment report on fenamiphos to the European Food Safety Association in November 2003. Following a quality check on the report, a peer review was initiated. A final discussion of the outcome of the consultation of experts took place with representatives from the Member States, which lead to the conclusion regarding the peer review of the pesticide risk assessment of fenamiphos in January 2006.[7]

Fenamiphos, as a capsule suspension formulation, can be used as nematicide and insecticide. There were only two representative uses as nematicide as proposed by the applicant, comprising application at 10 kg fenamiphos/ha by drip irrigation and 6 kg fenamiphos/ha by 'chisel application' (spray application followed by incorporation into the soil) in bell peppers and tobacco, respectively.

The review constituted the revaluation of the ADI (0.0008 mg/kg bw/day), ARfD (0.0025 mg/kg bw) and the adverse operator effect level (0.0008 mg/kg bw/day).

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. Additional intake from water and products of animal origin were not expected to give rise to intake problems. Estimates of acute dietary exposure of adults and toddlers revealed that the ARfD would not be exceeded.

Several acceptable exposure scenarios for operators, workers and bystanders were identified.

7 EFSA Scientific Report (2006) 62, 1–81. Conclusion on the peer review of fenamiphos, 13 January 2006.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment. A number of critical areas of environmental concern were identified, including the high potential for groundwater contamination by the metabolites of fenamiphos (and high acute toxicity of some of these metabolites), and high potential risk to non-target organisms identified based on FOCUS step 2 surface water predicted environmental concentration values for both representative uses.

Particular conditions proposed to manage the risks identified that use of fenamiphos on bell peppers should be restricted to greenhouses with permanent structures and a waiting period before replanting or sowing of 8 months is advised for uses in the field.

Member States must pay particular attention to the protection of aquatic organisms, soil non-target organisms and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures and monitoring programs should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.

Joint FAO/WHO Meeting on Pesticide Residues

The JMPR evaluated the toxicology of fenamiphos in 1974, 1985, 1987, 1997 and 2002. An ADI of 0.0006 mg/kg bw/d was set in 1974, but this was reduced to a temporary ADI of 0.0003 mg/kg bw/d in 1985, due to concerns regarding foetotoxicity in rabbits. Following consideration of results of an oncogenicity study conducted in rats, and additional data from a rabbit developmental study, the JMPR established an ADI of 0.0005 mg/kg bw/d in 1987. Fenamiphos was re-evaluated by the JMPR in 1997; an ADI of 0.0008 mg/kg bw/d was set by applying a 100-fold safety factor to the NOEL of 0.083 mg/kg bw/d for inhibition of brain acetyl ChE activity and anaemia in a 1-year dog study. The available data did not allow the establishment of an ARfD different from the ADI and therefore the JMPR requested data on the acute effects in dogs (the most sensitive test species) to help establish an ARfD for fenamiphos. At its 2002 meeting, the JMPR established an ARfD of 0.003 mg/kg bw, based on the NOAEL of 0.25 mg/kg bw for inhibition of erythrocyte acetyl ChE activity in a single-dose dog study and using a 100-fold safety factor. This was supported by an acute neurotoxicity study in rats, for which the NOAEL was 0.37 mg/kg bw for cholinergic signs.

4 PROPOSED REVIEW FINDINGS

Based on the evaluation of the submitted data and information, the following recommendations are made with regard to the continued approval of the active constituent fenamiphos, registration of fenamiphos products and label approvals in Australia.

4.1 Affirm approvals of the active constituent

The APVMA is satisfied that, provided the conditions to which an approval is currently subject are complied with, the continued use of, or any other dealings with, the active constituent fenamiphos would not:

- be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
- be likely to have an effect that is harmful to human beings
- have an unintended effect that is harmful to animals, plants and things, or to the environment.

The APVMA recommends that currently approval active constituents listed in Table A.1 be affirmed.

4.2 Proposed cancellation of all label approvals as an outcome of the review findings

The APVMA proposes to find that it is not satisfied that the labels of the products in Table A.2 contain adequate instructions in relation to the criteria set out in 14(3)(g) of the Agvet Code, as well as those referred to in Regulations 11 and 12 of the Agvet Code Regulations.

The labels contain use patterns that are not supported. The APVMA recommends they be deleted (Table 4.1).

Table 4.1: Approved use patterns that are not supported and are to be deleted

CROP	PEST	PRODUCT RATE	COMMENTS
Aloe vera	Soil-borne plant parasitic nematodes	400 g/L EC	Not supported: unacceptable environmental risk
Aloe vera planting material	Soil-borne plant parasitic nematodes	400 g/L EC	Not supported: unacceptable environmental risk
Banana	Soil-borne plant parasitic nematodes	100 g/kg GR 400 g/L EC	Not supported: unacceptable environmental risk (Hand application) Not supported: unacceptable toxicological risk
Banana planting material	Soil-borne plant parasitic nematodes	400 g/L EC	Not supported: unacceptable environmental risk
Beetroot	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data

CROP	PEST	PRODUCT RATE	COMMENTS
Bulbs	Plant parasitic nematodes	100 g/kg GR	Not supported: unacceptable environmental risk
Carrot	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	100 g/kg GR 400 g/L EC	Not supported: unacceptable environmental risk
Chrysanthemum	Leaf nematode	400 g/L EC	Not supported: unacceptable environmental risk
Celery	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data
Citrus	Soil-borne plant parasitic nematodes	400 g/L EC	Not supported: unacceptable environmental risk
Crucifer	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	100 g/kg GR 400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data (except cabbage)
Cucurbit	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data (except melons)
Duboisia	Root-knot nematode	100 g/kg GR	Not supported: unacceptable environmental risk
Endive	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data
Ginger	Soil-borne plant parasitic nematodes	100 g/kg GR	Not supported: unacceptable environmental risk Not supported: lack of residues data
Grapes	Soil-borne plant parasitic nematodes	400 g/L EC	Not supported: unacceptable environmental risk
Lettuce	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data
Melons (including watermelon)	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk
Mushroom	Soil-borne plant parasitic nematodes	400 g/L EC	Not supported: lack of residues data

CROP	PEST	PRODUCT RATE	COMMENTS
Nursery root stock	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk
Onion	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data
Ornamentals (annual, perennial and woody)	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	100 g/kg GR 400 g/L EC	Not supported: unacceptable environmental risk
Parsnip	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	100 g/kg GR 400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data
Pineapple	Soil-borne plant parasitic nematodes	100 g/kg GR 400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data
Potato	Soil-borne plant parasitic nematodes	100 g/kg GR 400 g/L EC	Not supported: unacceptable environmental risk Not supported: short-term dietary risk
Strawberries	Crimp nematode	100 g/kg GR	Not supported: lack of residues data
	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk (except 100 g/kg GR) Not supported: lack of residues data
Sugar cane	Soil-borne plant parasitic nematodes	100 g/kg GR 400 g/L EC	Not supported: unacceptable environmental risk Not supported: lack of residues data
Sweet potato	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk Not supported: short-term dietary risk
Tobacco	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	400 g/L EC	Not supported: unacceptable environmental risk
Tomato	Soil-borne plant parasitic nematodes and sucking insects (aphids and thrips)	100 g/kg GR	Not supported: unacceptable environmental risk Not supported: short-term dietary risk
Turf	Soil-borne plant parasitic nematodes	400 g/L EC	Not supported: unacceptable environmental risk

Accordingly, the APVMA proposes to find that it is not satisfied that the relevant particulars or conditions of label approval can be varied in such a way that the prescribed requirements for continued approval will be

complied with. Therefore, the APVMA proposes that label approvals for products listed in Table A.2 be cancelled in accordance with Section 40 of the Agvet Code.

4.3 Proposed registration cancellation as an outcome of the review findings

As a consequence of the proposed findings of the review and as prescribed in Section 44(3) of the Agvet Code, if the APVMA cancels the only approved label, or all the approved labels, for containers for a chemical product, it may also cancel, as the case may be, the registration of the product.

As described above, the APVMA is not satisfied that label approvals can be varied in such a way that the prescribed requirements for continued approval will be complied with. The APVMA proposes that the registrations for products listed in Table A.2 be cancelled under Section 44 of the Agvet Code.

4.4 Withdrawn fenamiphos products

An active constituent (Table 4.2) and two fenamiphos products (Table 4.3) have been voluntarily cancelled since the start of the review (once cancellation of registration is formally effected, reconsideration is no longer required).

Table 4.2: Fenamiphos active constituents included in the review that have been withdrawn before the review being completed

APPROVAL NUMBER	APPROVAL HOLDER
44171	Bayer CropScience Pty Ltd

Table 4.3: Fenamiphos products included in the review that have been withdrawn before the review being completed

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
33291	Bayer Nemacur Granular Nematicide	Bayer CropScience Pty Ltd	33291/0103
33296	Nemacur Turf Nematicide Liquid	Bayer CropScience Pty Ltd	33291/1197

4.5 Further data requirements

Assessments undertaken for certain component evaluations, particularly environment and residues, identified a basis for which a potential risk may exist (that is, unacceptable risk to the environment). Insufficient and/or inadequate data were provided or available to the APVMA to refine its assessment of fenamiphos. However, further data that are relevant to the use of fenamiphos in Australia may allow the APVMA to identify potential label changes that mitigate such risk.

To allow the APVMA to adequately quantify identified risks, the APVMA may exercise its data call-in powers (Section 33 of the Agvet Code); this will be considered on a case-by-case basis. The requirement for additional data will be to determine the validity of concerns identified in the modelled risk assessment by

providing representative and measured exposure data, which may allow for adequate determination of the risk of continued use of fenamiphos in Australia.

Environmental exposure and ecotoxicity data requirements

Additional data and information are required to refine the assessments of environmental exposure and environmental effects. Based on the current information, exposure remains unacceptable for most situations for birds, aquatic organisms (primarily resulting from exposure through run-off), non-target terrestrial arthropods exposed through spray application and soil-dwelling organisms (including earthworms) exposed through soil residues. With current information, it is difficult to mitigate the risks associated with the modelled exposures.

Additional information has been identified to allow refinement of the assessments of environmental exposure and environmental effects for fenamiphos that feed into the risk characterisation. Refer to the environmental assessment report for information on specific data requirements.

Residues data requirements

Insufficient data, or inadequate data or information relating to Australian uses, were provided or available to support the continued use of fenamiphos on a number of commodities (refer to residues assessment component report for further information). Additional residues data are required for the APVMA to confirm that it is satisfied that the continued use of fenamiphos would not be a hazard to the safety of people exposed to it during its handling or people using anything containing its residues.

5 AMENDMENTS TO STANDARDS

5.1 Public health standards

Arising from the OCS's toxicological assessment of data submitted to the review of fenamiphos and the consideration of the expanded toxicological database, the following advice is provided by the OCS.

Approval status

No change is recommended to the approval status of fenamiphos.

Impurity limits

Fenamiphos does not contain any impurities of toxicological concern.

Product registration

Given the moderate to high acute oral toxicity of the granular-based product containing 50 g/kg fenamiphos and that only a small amount of granules would be lethal to a child if ingested, this product is inappropriate for home garden use based on criteria established by the APVMA. Therefore its registration as a home garden product can no longer be supported.

There is no objection on public health grounds to the continued registration of all other existing fenamiphos products.

Acceptable Daily Intake

The present review reaffirmed that the current ADI for fenamiphos of 0.0001 mg/kg, based on the NOEL of 0.014 mg/kg bw/d for the inhibition of plasma ChE activity in a 2-year dog study and using a 100-fold safety factor, remains appropriate.

Acute Reference Dose

An ARfD of 0.003 mg/kg bw/d for fenamiphos was established by the OCS; before this review no ARfD had been established. A safety factor of 100 was applied to the NOEL of 0.25 mg/kg bw/d, based on red blood cell ChE inhibition at 0.5 mg/kg bw from an acute dog study.

Health Value for Australian drinking water (Water Quality Guidelines)

The current National Health and Medical Research Council health-based guideline value for Australian drinking water for fenamiphos of 0.0003 mg/L is supported.

Poisons scheduling

The existing Schedule 7 listing in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP, then the Standard for the Uniform Scheduling of Drugs and Poisons) for fenamiphos remains appropriate.

First Aid Instructions

At the start of the review, there was a legislative requirement that stipulated that users must retain atropine sulfate tablets on site as a first aid measure. However, this First Aid Instruction, First Aid Instruction 'h' (and 'x'), which related to the treatment of OP poisoning with atropine following oral, dermal and inhalational exposures, have now been deleted from the First Aid Instructions and Safety Directions (FAISD) Handbook, because of lack of availability of atropine in prescribed tablet form. It has been replaced with the following instruction, as per the existing FAISD Handbook:

CODE	FIRST AID INSTRUCTION
m	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (phone Australia 131 126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

Therefore, First Aid Instruction 'h' should be removed from all commercial fenamiphos product labels and replaced with statement 'm'. No warning statements or general safety precautions are required for fenamiphos products.

Safety directions and personal protective equipment

Based on the consideration of the toxicological and OHS assessments, the following changes to the hazard-based safety directions and PPE have been recommended:

As all fenamiphos products are in Schedule 7 (Dangerous Poison) of the SUSMP, with the exception of the home-garden product (HG), the statement 'Very dangerous' duplicates the signal heading already contained on the product label, so it can be deleted.

Amendment to existing entry for granular-based formulations

The OCS has recommended the deletion of the HG granular formulations (GRs) entry and the consolidation of the Safety Directions for the other fenamiphos granular products into a single category of 'GR 120 g/kg or less'.

The current OHS exposure-based risk assessment has indicated that product users should wear dermal PPE and a half-facepiece respirator when loading fenamiphos granular products and applying them to soil by open cab solid broadcast spreader or similar equipment. If a vehicle equipped with an enclosed cab and appropriate air filters are used, overalls alone would confer sufficient protection during application.

However, even a high level of dermal and respiratory PPE (gloves, chemical-resistant clothing and a half-facepiece respirator) is insufficient to protect workers if the granules are dispensed by hand. Labels of fenamiphos granular products should bear a restraint against manual application.

On this basis, the following amended Safety Directions for GRs are appropriate:

GR 120 g/kg OR LESS	
CODES	SAFETY DIRECTIONS
120 130 131 132 133	Product is poisonous if absorbed by skin contact or inhaled or swallowed
161 162	Will irritate the eyes

GR 120 g/kg OR LESS	
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 221	Do not inhale dust
279 280 287b 283 [open cab] 290 292 294 300 302	When opening the container, loading and using the product (open cab) wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves and half-facepiece respirator with dust cartridge or canister
279 282 [closed cab fitted with charcoal filters] 290 292b	When using the prepared spray (closed cab fitted with charcoal filters) wear cotton overalls buttoned to the neck and wrist (or equivalent clothing)
340 342	If product on skin, immediately wash area with soap and water
340 343	If product in eyes, wash it out immediately with water
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 364 366	After each day's use wash gloves and respirator if rubber wash with detergent and warm water and contaminated clothing

Amendment to existing entry for emulsifiable concentrate-based formulations

The current OHS exposure-based risk assessment has indicated that workers mixing, loading and applying fenamiphos emulsifiable concentrate products by hand or ground boom spray apparatus from an open cab vehicle can be protected adequately if the operator uses an enclosed mixing/loading system and wears gloves, chemical resistant clothing and a full facepiece respirator throughout the entire mixing/loading/ application cycle.

If spray operators use a vehicle equipped with a closed cab and appropriate air filters, overalls would be the only PPE required during application. However, they should also have access to gloves, chemical-resistant clothing and a respirator to protect them if equipment maintenance is required during application. This should be located outside the cab but shielded from contamination (that is, in a waterproof container). Suitable wash equipment also needs to be available to minimise any subsequent contamination of the cab when it is re-entered.

When treating planting material by dipping, workers should wear overalls, impervious footwear, elbow-length PVC gloves and protective waterproof clothing or a PVC/rubber apron. Gloves should also be worn when handling treated plant material.

On this basis, the following amended Safety Directions for emulsifiable concentrate (EC) formulations are appropriate:

EC 450 g/L OR LESS	
130 131 132 133	Poisonous if absorbed by skin contact or inhaled or swallowed
190	Repeated minor exposure may have a cumulative poisoning effect
207 211	Will damage eyes and skin

EC 450 g/L OR LESS	
161 163	Will irritate nose and throat
210 211	Avoid contact with eyes and skin
220 222 223	Do not inhale vapour or spray mist
279 280 287 287b 282 [open cab] 290 291b 294 301 303	When opening the container, mixing, loading and using the prepared spray (open cab) wear chemical resistant clothing buttoned to the neck and wrist and washable hat, elbow-length PVC gloves and full-facepiece respirator with combined dust and gas cartridge
279 282 [closed cab fitted with charcoal filters] 290 292b	When using the prepared spray (closed cab fitted with charcoal filters) wear cotton overalls buttoned to the neck and wrist (or equivalent clothing)
279 [applying by dip] 290 292 291 or 293a 294 298	When applying by dip wear cotton overalls buttoned to the neck and wrist and washable hat, protective waterproof clothing or PVC apron, elbow-length PVC gloves and impervious footwear
330 331 332	If clothing becomes contaminated with product or wet with spray remove clothing immediately
340 341 342	If product, spray or dip on skin, immediately wash area with soap and water
340 343	If product in eyes, wash it out immediately with water
350	After use and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 364 366	After each day's use, wash gloves and respirator and if rubber wash with detergent and warm water and contaminated clothing

Re-entry intervals

For turf use patterns the following re-entry statement is recommended on the product label:

> Do not allow entry into treated areas for 24 hours after application, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical-resistant gloves. Clothing must be laundered after use.

5.2 MRL Standard

Arising from the assessment of data submitted for the review of fenamiphos, the following changes to the MRL Standard are to be made:

Table 1 of the APVMA's MRL Standard: Maximum residue limits of agricultural and veterinary chemicals and associated substances in food commodities

COMPOUND	FOOD		MRL (mg/kg)	
			CURRENT	PROPOSED
Fenamiphos				
		Aloe vera	1	DELETE
	FI 0327	Banana	*0.05	*0.05
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	*0.05	DELETE
	VB 0041	Cabbage, head	ADD	0.1
	VR 0577	Carrot	ADD	0.2
	VS 0624	Celery	*0.05	DELETE
	FC 0001	Citrus fruits	*0.05	0.7
	DF 0269	Dried grapes	ADD	0.1
	MO 0105	Edible offal (mammalian)	*0.05	*0.01
	PE 0112	Eggs	*0.05	*0.01
	VC 0045	Fruiting vegetables, Cucurbits	*0.05	DELETE
	HS 0784	Ginger, root	*0.05	DELETE
	FB 0269	Grapes	*0.05	*0.05
	VL 0053	Leafy vegetables [except Lettuce, Head; Lettuce, Leaf]	*0.05	DELETE
	VL 0482	Lettuce, Head	0.2	DELETE
	VL 0483	Lettuce, Leaf	0.2	DELETE
	MM 0095	Meat [mammalian]	*0.05	*0.01
	ML 0106	Milks	*0.005	*0.005
	VC 0046	Melons, excluding watermelon	ADD	*0.05
	VO 0450	Mushrooms	0.1	DELETE
	VA 0385	Onion, Bulb	*0.05	DELETE
	SO 0697	Peanut	*0.05	DELETE
	FI 0353	Pineapple	*0.05	DELETE
	PO 0111	Poultry, Edible offal of	*0.05	*0.01
	PM 0110	Poultry meat	*0.05	*0.01
	VR 0075	Root and tuber vegetables	0.2	DELETE
	FB 0275	Strawberry	0.2	DELETE
	GS 0659	Sugar cane	*0.05	DELETE
	VO 0448	Tomato	0.5	DELETE
	VC 0432	Watermelon	ADD	*0.05

Table 4 of the APVMA's MRL Standard: Maximum residue limits for pesticides in animal feed commodities

COMPOUND	ANIMAL FEED COMMODITY		MRL (mg/kg)
Fenamiphos			
DELETE		Primary feed commodities	1
ADD	AB 0001	Citrus pulp, dry	5
	AB 0269	Grape pomace, dry	0.5

Table 5 of the APVMA's MRL Standard: Uses of substances where maximum residue limits are not necessary

COMPOUND	USE
Fenamiphos	
ADD	Aloe vera planting material for the control of soil-borne plant parasitic nematodes
	Banana planting material for the control of soil-borne plant parasitic nematodes

APPENDIX: FENAMIPHOS ACTIVE CONSTITUENT APPROVALS AND PRODUCT REGISTRATIONS

Table A.1: Active constituent approvals included in the review

APPROVAL NUMBER	ACTIVE CONSTITUENT NAME	APPROVAL HOLDER
44171[a]	Fenamiphos	Bayer CropScience Pty Ltd
51157	Fenamiphos	Barmac Industries Pty Ltd
55043	Fenamiphos	4 Farmers Pty Ltd
56591	Fenamiphos	Imtrade Australia Pty Ltd

a Active constituent is no longer approved.

Table A.2: Product registrations and associated label approvals included in the review

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	PRODUCT TYPE	LABEL APPROVAL NUMBER
33291[a]	Bayer Nemacur Granular Nematicide	Bayer CropScience Pty Ltd	Granular	33291/0103
33293	Nemacur 100g Nematicide	Barmac Industries Pty Ltd	Granular	33293/0198 33293/0803 33293/1209
33295	Nemacur 400 Nematicide Liquid	Barmac Industries Pty Ltd	Liquid concentrate	33295/03 33295/0198 33295/0399 33295/1103 33295/1209
33296[a]	Nemacur Turf Nematicide Liquid	Bayer CropScience Pty Ltd	Liquid concentrate	33291/1197 33291/1005
56946	Imtrade Assassinator 400 Insecticide	Imtrade Australia Pty Ltd	Emulsifiable concentrate	56946/0204 56946/51030
59067	Pacific Fenamiphos 400 Nematicide And Insecticide	Pacific Agriscience Pty Ltd	Emulsifiable concentrate	59067/1004 59067/51662
60659	Nomad 400 Nematicide and Insecticide	Ospray Pty Ltd	Emulsifiable concentrate	60659/1207
62093	Barmac Electricur Turf Nematicide	Barmac Industries Pty Ltd	Emulsifiable concentrate	62093/0309
62234	Country Fenamiphos 400 Nematicide Liquid	Accensi Pty Ltd	Emulsifiable concentrate	62234/0707 62234/0709
62574	4farmers Fenamiphos 400 Nematicide and Insecticide	4 Farmers Pty Ltd	Emulsifiable concentrate	62574/0408
62639	Racs Fenamiphos 400 Nematicide and Insecticide	Rural Agricultural Chemical Suppliers Pty Ltd	Emulsifiable concentrate	62639/0108

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	PRODUCT TYPE	LABEL APPROVAL NUMBER
64407	AW Sowon Insecticide	Agri West Pty Limited	Emulsifiable concentrate	64407/1109
65039	AI Redback Insecticide	Axichem Pty Ltd	Emulsifiable concentrate	65039/0510
65405	Titan Fenamiphos 400 Nematicide Liquid	Titan Ag Pty Ltd	Emulsifiable concentrate	65405/50847
65756	Rainbow Fenamiphos 400 Nematicide and Insecticide	Shandong Rainbow International Co., Ltd	Emulsifiable concentrate	65756/51801
66007	Apparent Fenamiphos 400 Nematicide and Insecticide	Apparent Pty Ltd	Emulsifiable concentrate	66007/52470
66451	Mission Fenamiphos 400 Insecticide	Mission Bell Holdings Pty Ltd	Emulsifiable concentrate	66451/53668
66614	Genfarm Fenamiphos 400 Insecticide	Landmark Operations Limited	Emulsifiable concentrate	66614/53996

a Products are no longer registered.

ABBREVIATIONS AND ACRONYMS

ADI	Acceptable Daily Intake
Agvet Code	Agricultural and Veterinary Chemicals Code, Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*
ai	active ingredient
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
ChE	cholinesterase
Codex	FAO/WHO Codex Alimentarius Commission
DSEWPaC	Australian Government Department of Sustainability, Environment, Water, Population and Communities
EC	emulsifiable concentrate (or liquid concentrate) formulation
EC_{50}	median effective concentration
EU	European Union
FAISD	First Aid Instructions and Safety Directions
GAP	good agricultural practice
GR	granular formulation
HG	home garden
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
k_{oc}	soil–water partition coefficient
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOC	level of concern
MOE	margin of exposure
MRL	maximum residue limit
NEDI	National Estimated Daily Intake
NESTI	National Estimated Short-Term Intake
NOEC	No Observed Effect Concentration

ADI	Acceptable Daily Intake
NOEL	No Observed Effect Level
OCS	Office of Chemical Safety, Australian Government Department of Health and Ageing
OHS	occupational health and safety
OP	organophosphorus pesticide
PPE	personal protective equipment
PVC	polyvinyl chloride
SC	suspension concentrate
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (formerly the Standard for the Uniform Scheduling of Drugs and Poisons)
US EPA	United States Environmental Protection Agency