Australian Government
Australian Pesticides and Veterinary Medicines Authority

FENAMIPHOS

REVIEW FINDINGS REPORT AND REGULATORY DECISION

JULY 2015

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

The APVMA has legislative powers to reconsider the approval of an active constituent, registration of a chemical product or approval of a label at any time after it has been registered. The reconsideration process is outlined in Sections 29L to 34AC of Part 2, Division 4 of the Agvet Codes.

A reconsideration (or review) 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. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be generated according to scientific principles. The APVMA conducts science and evidence-based risk analysis with respect to matters of concern, analysing all the relevant information and data available.

In undertaking reconsiderations, the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety within the Department of Health, Food Standards Australia New Zealand (FSANZ), the Department of the Environment and the state departments of agriculture, as well as other expert advisers as appropriate.

This document sets out the review findings and regulatory decisions (RF) relating to the active constituent fenamiphos and products containing fenamiphos when used in accordance with label instructions. The RF and regulatory decisions are based on information collected from a variety of sources.

This report, the preliminary review findings report (PRF) published 23 February 2013), public submissions received during the consultation period for the review of fenamiphos, and component assessment reports are available from the APVMA website at www.apvma.gov.au.

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EXECUTIVE SUMMARY

The Australian Pesticides and Veterinary Medicines Authority has completed its review of the active constituent fenamiphos and all products containing fenamiphos. This document summarises the regulatory decisions made by the APVMA and the final review findings. These decisions were made on the basis of the preliminary review findings and technical assessments, as well as the submissions received in response to the publication of the preliminary findings.

Fenamiphos is an organophosphorus (OP) insecticide and nematicide widely used in agriculture to control soil-borne pests, particularly nematodes, and sucking insects including aphids and thrips. The APVMA commenced a review of the active constituent fenamiphos, all products containing fenamiphos and their associated labels in April 2003 because of concerns relating to possible bird and fish poisonings and environmental contamination of groundwater and waterways, leading the APVMA to examine the toxicology, occupational health and safety (OHS), the environmental impacts and residues in food of fenamiphos.

After assessing all the available data, the APVMA published the Preliminary Review Findings report (PRF) for public consultation in 2013. This report concluded that the majority of uses on labels resulted in an unacceptable environmental risk, including risks to birds, aquatic organisms, terrestrial organisms, non-target arthropods and earthworms. In addition, a number of use patterns could no longer be supported on residues grounds due to either a lack of residues data or because they posed an unacceptable dietary risk to humans. Therefore, it was recommended that all product registrations and all associated label approvals be cancelled as no approved uses were likely to be supported.

During the public consultation, the APVMA received 11 submissions from various stakeholders including state and territory governments, holders of product registration and active approvals, user groups and a member of the public. Information contained in these submissions enabled some refinement of the preliminary findings, with a single use on strawberry runners now supported for the granular formulation type, and two uses, on aloe vera planting material and banana planting material, supported for the emulsifiable concentrate formulation type.

FINAL REVIEW OUTCOMES

After consideration of all data by the APVMA, including the advice received from the Commonwealth Departments of Health and the Environment in their respective risk assessments, and submissions received from industry and the public, the APVMA has made the following regulatory decisions in relation to fenamiphos active constituents, fenamiphos product registrations and associated label approvals listed in Appendix A:

a) Affirm active constituent approvals for fenamiphos.

b) Vary relevant particulars of approved labels to allow affirmation.

c) Cancel previous label approvals as the instructions contained on these labels no longer meet the labelling criteria. The labels instructions contain some use patterns that are not supported by the review outcomes.

d) Affirm product registrations with varied labels.

e) Cancel product registrations that cannot be affirmed or varied. The label instructions contain no supported use pattern.

Review of fenamiphos is concluded

These regulatory actions conclude the reconsideration of the active constituent fenamiphos, products containing fenamiphos and their associated label approvals.

Phase out period

The APVMA has determined that the maximum legislative one year phase out period is appropriate for the implementation of the recommended regulatory actions on products containing fenamiphos and their associated labels. During this time, products may continue to be used according to the label instructions.

Maximum Residues Limits for fenamiphos are proposed to be removed from the APVMA MRL Standard after the phase out period has ended.

1 INTRODUCTION

Fenamiphos is an organophosphorus (OP) insecticide and nematicide used in agriculture to control the major genera of nematodes and sucking insects, including aphids and thrips, in a number of field crops, citrus, grapes, ornamentals, vegetables and turf.

In common with all OPs, fenamiphos kills nematodes and insects by interfering with the nervous system via the inhibition of the enzyme, acetylcholinesterase (AChE). Fenamiphos is also toxic to mammals and birds through the inhibition of this same enzyme.

Fenamiphos was originally nominated as part of the APVMA's Existing Chemical Review Program in 1994. The nomination was related to reports of possible bird and fish poisonings, and environmental contamination of groundwater and waterways.

In April 2003, the APVMA commenced a reconsideration of the active constituent fenamiphos, all products containing fenamiphos and their associated labels because of concerns about toxicology, the environment, dietary exposure of the public to residues in food, and occupational health and safety (OHS).

In undertaking the reconsideration, the APVMA conducted toxicological, OHS, environment, and residue assessments. In February 2013, the APVMA published these component assessment reports, which identified unacceptable risks to the environment and to consumers from residues in food. The environmental risk assessment concluded that the majority of the use patterns posed an unacceptable risk to birds, aquatic organisms and terrestrial organisms, including non-target arthropods and earthworms. Sufficient data were provided to demonstrate that fenamiphos and its toxic metabolites, fenamiphos sulfoxide and fenamiphos sulfone, leach into ground water. While the dietary risk assessment supported some use patterns, other use patterns were not supported due to insufficient residues data or exceedance of the short-term dietary safe limit (the acute reference dose—ARfD).

At the same time the APVMA published the component risk assessment reports, the APVMA also released the Preliminary Review Findings (PRF) report. The PRF report summarised the risk assessments undertaken as part of the fenamiphos review and outlined the proposed regulatory actions. Public submissions were invited following the publication of the PRF report and component technical/risk assessment reports to allow interested parties to comment on the PRF report and proposed findings.

Following the technical assessment of information contained in submissions by the Department of Health, and the Department of the Environment and assessment of other information received during the consultation period by the APVMA , the APVMA has made decisions relating to the approvals, continued registration, including changes to registered uses, and cancellation of a product registration and certain label approvals for products containing fenamiphos.

This document summarises the review and the regulatory decisions that are to be implemented as a result of the review.

2 INTERNATIONAL REGULATORY STATUS

Since the publication of the PRF report in 2013, fenamiphos has been the focus of regulatory action in other countries.

United States

The United States Environmental Protection Agency (US EPA) and fenamiphos registrants in the United States of America agreed to a voluntary cancellation and phase out of all existing fenamiphos registrations, with formulation, sale and distribution of new stock prohibited from May 2007. On 1 October 2014, the US EPA extended the deadline for the use of existing stocks of all fenamiphos products until 6 October 2017 as the most cost efficient and effective way of exhausting fenamiphos stocks held by users.

China

The People's Republic of China withdrew the registration certificates and production licences for fenamiphos effective 31 October 2011. The action was taken in response to growing concerns about the safety of agricultural products due to misuse of the chemical. The sales and use of fenamiphos were banned as of 31 October 2013.

New Zealand

The New Zealand Environment Protection Authority (NZ EPA) reassessed the approvals of fenamiphos products and published their final report in June 2013. NZ EPA determined that the risks outweigh the benefits when fenamiphos products are used for plant protection purposes. NZ EPA has implemented a phase in of additional controls over two years, and a time-limited approval of fenamiphos products of 10 years to 2023.

3 PUBLIC SUBMISSIONS

In response to the publication of the PRF report in February 2013, the APVMA received 11 submissions to the review. Submissions were received from state and territory governments, manufacturers, user groups and the general public. These submissions concern various aspects of the review including residues, toxicological, occupational health and safety, and environmental assessments.

The APVMA has carefully considered all submissions. A summary of the submissions and the responses from APVMA and from the Commonwealth Departments of Health and the Environment can be found in Appendix B.

Issues raised in submissions included:

- selection of end points in the toxicology assessment
- toxicity to birds and risk mitigation measures
- disposal of spent dip solution following use on banana planting material
- best practice management practices to mitigate environmental risks
- implementation of buffer zones to manage run-off
- soil incorporation of granules
- extrapolation of data from USA studies
- phase out period for uses no longer supported
- engineering control and personal protective equipment (PPE) to reduce workers exposure
- multiple applications increasing the risk of run-off
- strawberry runners to be considered separately to strawberry fruit production.

Changes to the proposed review outcomes

Strawberries

The APVMA was asked by industry to consider fenamiphos use on strawberry runners separately to fruit-bearing strawberry crops. Advice provided by the APVMA's Residues Assessment section outlined that consideration had been given to the non-food crop nature of strawberry runners and to the time elapsed before fruiting, and concluded that treatment of the strawberry runners would not result in detectable residues in the strawberry fruit crop. This addressed the residues concerns held in the PRF report. The Department of Health and the Department of the Environment supported the use on strawberry fruiting crops in the PRF report. The APVMA has taken all information into consideration and have varied the instructions for use for the granular formulation to allow the use of fenamiphos on strawberry runners to continue.

Banana planting material and Aloe Vera planting material

The APVMA was also asked by industry to consider that the spent dip resulting from the use on banana planting material may be disposed of by licensed waste management companies to an appropriate treatment facility as a possible mitigation measure for environmental risk. This approach would eliminate the environmental concerns associated with the current practice, where the spent dipping solution is applied to

mature banana plantations as per the label instructions. The Department of the Environment noted in their response (Appendix B) that fenamiphos dipping waste disposed of by application to banana plantations poses an unacceptable risk to birds, aquatic organisms and terrestrial organisms at all registered label use rates. The APVMA accepted that the approach proposed by industry to dispose of the dip to a waste treatment facility would mitigate the environmental risk to an acceptable level and the continued use for banana planting material has been supported.

The dip disposal consideration detailed above for banana dipping material is also applicable to aloe vera planting material. Although the aloe vera planting material use pattern uses fenamiphos in a higher concentration, the sole remaining concern was for disposal of the spent dip. By disposing of the spent dip to a waste facility, this concern has been addressed, and the continued use for aloe vera planting material has been supported.

Following advice from the Department of the Environment and continued support from the Department of Health and the APVMA's Residues Assessment section, the instructions for use for the emulsifiable concentrate products that contain these use patterns have been varied to allow the use of fenamiphos to dip banana planting material, and by extension aloe vera planting material, with spent dip disposal to be directed to a waste facility licenced to handle it, in accordance with state and territory legislation.

4 REVIEW OUTCOMES

Supported Uses

Taking into consideration the finding of the February 2013 assessment and assessment of submissions received in response to the PRF report, the following uses of fenamiphos are supported:

Table 4.1: Supported uses and comments

SUPPORTED USES
Aloe vera – Emulsifiable concentrate products only, planting material (not intended for human consumption) for dipping only, with label restraints
Banana - Emulsifiable concentrate products only, planting material for dipping only, with label restraints
Strawberry – Granular products only, **runners only**, with label restraints

Unsupported Uses

The following uses of fenamiphos are not supported and have been deleted:

Table 4.2 : Approved use patterns no longer supported

UNSUPPORTED USES	
Aloe vera	All uses except planting material
Banana	All uses except planting material
Beetroot	All uses
Bulbs	All uses
Carrot	All uses
Chrysanthemum	All uses
Celery	All uses
Citrus	All uses
Crucifer	All uses
Cucurbit	All uses, including melons and watermelon
Duboisia	All uses
Endive	All uses
Ginger	All uses
Grapevines	All uses

UNSUPPORTED USES	
Lettuce	All uses
Mushroom	All uses
Nursery root stock	All uses
Onion	All uses
Ornamentals	All uses, including annual and perennial ornamentals
Parsnip	All uses
Pineapple	All uses
Potato	All uses
Strawberries	Fruiting crop
Sugarcane	All uses
Sweet potato	All uses
Tobacco	All uses
Tomato	All uses
Turf	All uses

All references to unsupported uses have been deleted, or varied to reflect the remaining use(s), as the context dictates.

The varied label components are set out in Appendix A, and covers all label amendments discussed below.

Label Restraints—Granular product

DO NOT apply by hand

DO NOT apply by open cab vehicles

DO NOT treat more than 5% of the total cropping area

DO NOT use in areas that contain highly leachable soils (sandy soils etc)

Label Restraints—Emulsifiable Concentrate products

DO NOT dispose of spent dip on site. Spent dip waste must be transported to a facility that can lawfully receive it.

Withholding Periods

The strawberry withholding period has been varied to ‘STRAWBERRIES (RUNNERS ONLY): NOT REQUIRED WHEN USED AS DIRECTED’.

Banana and Aloe Vera planting material remains ‘NOT REQUIRED WHEN USED AS DIRECTED’.

Protection Statements—Granular product

Dangerous to birds—irrigation according to label directions is vital in order to reduce exposure.

Dangerous to fish and other aquatic invertebrates. Do not contaminate streams, rivers or watercourses with the chemical or used containers.

Protection Statements—Emulsifiable Concentrate products

Dangerous to fish and other aquatic invertebrates. Do not contaminate streams, rivers or watercourses with the chemical or used containers.

Dip Disposal—Emulsifiable Concentrate products

DO NOT dispose of spent dip on site. Spent dip waste must be transported to a facility that can lawfully receive it.

Label Approval Numbers

The APVMA has varied product labels to uniquely identify the labels resulting from this review. The new label approval numbers are [product_number]/0715.

5 REGULATORY DECISIONS

Based on the evaluation of the submitted data and information, with regard to the continued approval of the active constituent fenamiphos, registration of fenamiphos products and label approvals in Australia, and in accordance with section 34, 34A and 34AA of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA has decided to:

1. Affirm active constituent approvals.
2. Vary relevant particulars of approved labels.
3. Affirm product registrations with varied labels.
4. Cancel previous label approvals.
5. Cancel product registrations that cannot be affirmed or varied.

Affirm active constituent approvals

The APVMA is satisfied that the active constituent fenamiphos meets the safety criteria. That is, if the use of the constituent, in accordance with any instructions approved by the APVMA for the constituent or contained in an established standard, is not, or would not be:

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

The APVMA has affirmed the approval of the active constituents listed in Appendix A, Table 1.

Vary label approval, affirm product with varied label and cancel previous label approvals

The APVMA was not satisfied that the approvals or registrations of the chemical products listed in Appendix A, Table 2 met the safety, trade and efficacy criteria, and was not satisfied that the approved labels met the labelling criteria.

However, the APVMA was satisfied that the relevant particulars or conditions of the approval or registration listed in Appendix A, Table 2 could be varied (as described) in such a way as to allow the approval or registration to be affirmed. The APVMA has affirmed the relevant particulars listed in Appendix A, Table 2, with a new label reflecting the review outcomes in Section 4: Review Outcomes. The APVMA has also cancelled the previous label approvals for the affirmed product registrations, as the APVMA was not satisfied that the previous (unvaried) label approvals met the labelling criteria.

Cancel product registration with no supported uses

The APVMA was not satisfied that the approvals or registration of the chemical product listed in Appendix A, Table 3 met the safety, trade and efficacy criteria.

The APVMA was also not satisfied that the relevant particulars or conditions of the approval or registration listed in Appendix A, Table 3 could be varied in such a way as to allow the approval or registration to be

affirmed. The only use on this product label is not supported, and the label cannot be varied. Therefore the APVMA has cancelled the product registration listed in Appendix A, Table 3.

Fenamiphos active constituent/products no longer approved/registered

One active constituent approval (Appendix A, Table 4) and seven fenamiphos products (Appendix A, Table 5) originally included in the review have been voluntarily cancelled or have not renewed their registrations before the finalisation of the fenamiphos review. No action is required on those products that are no longer registered, however the fenamiphos review findings would apply if registrations were renewed.

Phase out periods

The APVMA has determined that the maximum legislative one year phase out period is appropriate for the implementation of the recommended regulatory actions on products containing fenamiphos and their associated labels. During this time, products may continue to be used according to the instructions contained in the APVMA Gazette Notice of 28 July 2015.

6 AMENDMENTS TO STANDARDS

Impurity limits

The active constituent standard for fenamiphos does not list any impurities. However, any detections of sulfoxides, sulphones or oxygen analogues of fenamiphos active constituent are considered to be toxicologically significant impurities at any level, and are required to be quantified and declared to the APVMA in the Declaration of Composition.

Home garden product registration

Given the moderate to high acute oral toxicity of the granular product and the high acute oral and inhalational toxicity and severe skin and eye irritancy of the emulsifiable concentrate product, fenamiphos is inappropriate for home garden use based on criteria established by the APVMA. Therefore, the registration of fenamiphos products as home garden products cannot be supported as an outcome of the review.

Acceptable Daily Intake (ADI)

An ADI of 0.0001 mg/kg bw for fenamiphos, was established by the Office of Chemical Safety in March 1997. This was based on the no-observed-effect-level (NOEL) of 0.014 mg/kg bw for the inhibition of plasma cholinesterase activity in a 2–year dog study and using a 100–fold safety factor. The ADI remains appropriate.

Acute Reference Dose (ARfD)

An ARfD of 0.003 mg/kg bw for fenamiphos was established by the Office of Chemical Safety in November 2005 as part of this review. This was based on the NOEL of 0.25 mg/kg bw/d for the inhibition of erythrocyte cholinesterase activity in an acute dog study and using a 100–fold safety factor.

Poisons scheduling

The existing scheduling for fenamiphos in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) remains appropriate. That is, schedule 6 for products containing 50 g/kg or less granular fenamiphos, and schedule 7 for all other forms and strengths of fenamiphos.

First Aid instructions

The following first aid instructions are to be applied to all fenamiphos products:

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.

Safety directions and personal protective equipment

The OCS has deleted all safety direction entries for the home garden category from the First Aid Instructions and Safety Directions (FAISD) Handbook. This is because the previously registered product containing fenamiphos, for which the home garden safety directions were developed, do not meet APVMA's safety criteria for home garden use.

The safety directions for EC 400 g/L have been amended to EC 450 g/L or less. The safety directions for GR 100 g/kg or less fenamiphos have also been amended to GR 120 g/kg or less. These active constituent ranges have been amended to cover the concentration and actual purity of the active constituent and all non-active constituents of all assessed products.

The requirement within the safety directions to 'give atropine tablets 0.6 mg if instructed' is now redundant (due to the unavailability of atropine tablets, discussed in APVMA Gazette No. 4, 7 April 2009), and has been deleted from the safety directions.

The following safety directions are to be applied to fenamiphos products, based on their formulation type:

Safety directions for the category 'GR 120 g/kg or less':

GR 120 g/kg OR LESS	
CODES	SAFETY DIRECTIONS
130 131 132 133	Poisonous if absorbed by skin contact or inhaled or swallowed
161 162	Will irritate the eyes
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 221	Do not inhale dust
279 280 285 290 292 294c 297 300 302	When opening the container and preparing the product for use wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves, goggles and half-facepiece respirator with dust cartridge or canister
279 283 290 292b	When using the product wear cotton overalls buttoned to the neck and wrist
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
360 361 363 364 366	After each day's use wash gloves and googles and respirator (and if rubber wash with detergent and warm water) and contaminated clothing

Safety directions for the category 'EC 450 g/kg or less':

EC 450 g/kg OR LESS	
CODES	SAFETY DIRECTIONS
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
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 289e 290 291b 294c 301 303	When opening the container, mixing, loading and if applying by low pressure hand wand wear chemical resistant clothing buttoned to the neck and wrist and washable hat, elbow-length chemical resistant gloves and full facepiece respirator with combined dust and gas cartridge
279 281 (dip) 282 (dip) 290 292 291 or 293a 294c 298 299	When preparing dip and using prepared dip wear cotton overalls buttoned to the neck and wrist and a washable hat, protective waterproof clothing or a PVC apron, elbow-length chemical resistant gloves and impervious footwear and face shield or goggles.
330 331 332	If clothing becomes contaminated with product or wet with spray remove clothing immediately
340 343	If product in eyes, wash it out immediately with water
340 341 342	If product, spray or dip on skin, immediately wash area with soap and water
350	After use and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 363 364 366	After each day's use, wash gloves, goggles and respirator (and if rubber wash with detergent and warm water) and contaminated clothing

The following safety directions should be applied to products that are used for dip only:

EC 450 g/kg OR LESS	
CODES	SAFETY DIRECTIONS
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
161 163	Will irritate nose and throat
210 211	Avoid contact with eyes and skin
220 222	Do not inhale vapour
279 281 (dip) 282 (dip) 290 292 291 or 293a 294c 298 299	When preparing dip and using the prepared dip wear cotton overalls buttoned to the neck and wrist and a washable hat, protective waterproof clothing or PVC apron, elbow-length chemical resistant gloves and impervious footwear and face shield or goggles
330 331 332	If clothing becomes contaminated with product or wet with spray remove clothing immediately
340 343	If product in eyes, wash it out immediately with water
340 341 342	If product or dip on skin, immediately wash area with soap and water
350	After use and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 363 366	After each day's use, wash gloves, goggles and contaminated clothing

Residues definition

The residues definition of fenamiphos remains:

'Sum of fenamiphos, its sulfoxide and sulfone, expressed as fenamiphos'

MRL Standard

The following are amendments to the *MRL Standard* for fenamiphos relating to label uses that will apply once the phase out period for cancelled labels has ended:

Table 1 of the MRL Standard – MRLs in Food Commodities

			MRL (mg/kg)	
COMPOUND	FOOD		CURRENT	AMENDED
Fenamiphos				
		Aloe vera	1	*0.05
	FI 0327	Banana	*0.05	*0.05
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	*0.05	DELETE
	VS 0624	Celery	*0.05	DELETE
	FC 0001	Citrus fruits	*0.05	DELETE
	MO 0105	Edible offal (mammalian)	*0.05	DELETE
	PE 0112	Eggs	*0.05	DELETE
	VC 0045	Fruiting vegetables, Cucurbits	*0.05	DELETE
	HS 0784	Ginger, root	*0.05	DELETE
	FB 0269	Grapes	*0.05	DELETE
	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	DELETE
	ML 0106	Milks	*0.005	DELETE
	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	DELETE
	PM 0110	Poultry meat	*0.05	DELETE
	VR 0075	Root and tuber vegetables	0.2	DELETE
	FB 0275	Strawberry	0.2	*0.05
	GS 0659	Sugar cane	*0.05	DELETE
	VO 0448	Tomato	0.5	DELETE

* MRL set at or about the limit of analytical quantitation.

As strawberry runners, aloe vera planting material and banana planting material are not considered to be significant animal feed commodities for residues assessment purposes, there are no animal feed commodities proposed to be included in Table 4 of the MRL Standard, and the current entry will be deleted.

Table 4 of the MRL Standard – Animal Feed Commodities

		MRL (mg/kg)	
COMPOUND	ANIMAL FEED COMMODITY	CURRENT	AMENDED
Fenamiphos			
	Primary feed commodities	1	**DELETE**

APPENDIX A

Table 1: Active constituent approvals affirmed

APPROVAL NUMBER	ACTIVE CONSTITUENT NAME	APPROVAL HOLDER
51157	Fenamiphos	Amgrow Pty Ltd
55043	Fenamiphos	4 Farmers Australia Pty Ltd
56591	Fenamiphos	Imtrade Australia Pty Ltd
67708	Fenamiphos	Amvac C.V.
70200	Fenamiphos	Amvac C.V.

Table 2: Product registrations affirmed following variation of label approvals

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVALS CANCELLED	LABEL APPROVALS VARIED AND SUBSEQUENTLY CANCELLED	NEW LABEL APPROVAL
33293	**Nemacur 100G Nematicide**	Amgrow Pty Ltd	33293/0198 33293/0803 33293/1209 33293/55718	33293/100185	33293/0715
Label variation 33293/0715. Added label restraints ‘Do not apply by hand', ‘Do not apply to more than 5% of the total cropping area’, ‘Do not use in areas that contain highly leachable soils (sandy soils etc.)’. Deleted all use patterns except for strawberry and vary ‘strawberry’ to ‘strawberry (runner production only)’. Varied Strawberries withholding period to ‘not required when used as directed’. Added protection statements. Updated first aid instructions, safety directions and storage and disposal instructions.					
33295	**Nemacur 400 Nematicide**	Amgrow Pty Ltd	33295/03 33295/0198 33295/0399 33295/1103	33295/1209	33295/0715
Label variation 33295/0715. Added label restraints ‘Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it’. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period ‘not required when used as directed’. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
56946	**Imtrade Assassinator 400 Insecticide**	Imtrade Australia Pty Ltd	56946/0204	56946/51030	56946/0715
Label variation 56946/0715. Added label restraints ‘Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it’. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period ‘not required when used as directed’. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVALS CANCELLED	LABEL APPROVALS VARIED AND SUBSEQUENTLY CANCELLED	NEW LABEL APPROVAL
62234	**Country Fenamiphos 400 Nematicide Liquid**	Accensi Pty Ltd	62234/0707 62234/0709 62234/53392 62234/59913	62234/101311	62234/0715
Label variation 62234/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Added critical comment for aloe vera 'Not to be used on plants for human consumption'. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
62574	**4Farmers Fenamiphos 400 Nematicide and Insecticide**	4 Farmers Australia Pty Ltd	62574/0408 62574/60914	62574/61705	62574/0715
Label variation 62574/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
64407	**AW Sowon Insecticide**	Agri West Pty Limited	64407/1109	64407/100841	64407/0715
Label variation 64407/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
65039	**AC Redback Insecticide**	Axichem Pty Ltd	-	65039/0510	65039/0715
Label variation 65039/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
65405	**Titan Fenamiphos 400 Nematicide Liquid**	Titan Ag Pty Ltd	-	65405/50847	65405/0715
Label variation 65405/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVALS CANCELLED	LABEL APPROVALS VARIED AND SUBSEQUENTLY CANCELLED	NEW LABEL APPROVAL
65756	**Rainbow Fenamiphos 400 Nematicide and Insecticide**	Shandong Rainbow International Co., Ltd	-	65756/51801	65756/0715
Label variation 65756/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
66451	**Mission Fenamiphos 400 Insecticide**	Mission Bell Holdings Pty Ltd	-	66451/53668	66451/0715
Label variation 66451/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
66614	**Genfarm Fenamiphos 400 Nematicide**	Landmark Operations Limited	-	66614/53996	66614/0715
Label variation 66614/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
68795[a]	**Smart Fenamiphos 400 EC Insecticide**	Crop Smart Pty Ltd	-	68795/59099	68795/0715
Label variation 68795/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
69011[a]	**Farmalinx Neptune 400 EC Nematicide and Insecticide**	Farmalinx Pty Ltd	-	69011/59643	69011/0715
Label variation 69011/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVALS CANCELLED	LABEL APPROVALS VARIED AND SUBSEQUENTLY CANCELLED	NEW LABEL APPROVAL
69146[a]	**Sabakem Fenamiphos 400EC Nematicide and Insecticide**	Sabakem Pty Ltd	-	69146/60077	69146/0715
Label variation 69146/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					
70057[a]	**Surefire Neemat Nematicide & Insecticide**	PCT Holdings Pty Ltd	-	70057/62403	70057/0715
Label variation 70057/0715. Added label restraints 'Do not dispose of spent dip on site. Spent dip must be transported to a facility that can lawfully receive it'. Deleted all use patterns except for aloe vera planting material and banana planting material. Affirmed withholding period 'not required when used as directed'. Added protection statements. Added Dip Disposal statement. Updated first aid instructions, safety directions and disposal instructions.					

[a] products that have been registered since the Preliminary Review Findings report.

Table 3: Fenamiphos product registrations that have been cancelled

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
62093	Barmac Electricur Turf Nematicide	Amgrow Pty Ltd	62093/0309 62093/100182

Table 4: Fenamiphos active constituent approvals included in the review that have been discontinued before the review has been completed

APPROVAL NUMBER	APPROVAL HOLDER
44171	Bayer CropScience Pty Ltd

Table 5: Fenamiphos product registrations included in the review that have been discontinued before the review was 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	33296/1197 33296/1005
57185	Chipco Nemacur Turf Nematicide Liquid	Bayer CropScience Pty Ltd	57185/0303
59067	Pacific Fenamiphos 400 Nematicide and Insecticide	Pacific Agriscience Pty Ltd	59067/1004 59067/51662
60659	Nomad 400 Nematicide and Insecticide	Cheminova Pty Ltd	66007/1207
62639	RACS Fenamiphos 400 Nematicide and Insecticide	Rural Agricultural Chemical Suppliers Pty Ltd	62639/0108
66007	Apparent Fenamiphos 400 Nematicide and Insecticide	Apparent Pty Ltd	66007/52470

Granular formulation label variation includes:

- **Vary** statement of claims from ‘various crops’ to ‘strawberry runners’
- **Add** restraints ‘DO NOT apply by hand’, ‘DO NOT apply by open cab vehicles’, ‘DO NOT treat more than 5% of the total cropping area’, ‘DO NOT use in areas that contain highly leachable soils (sandy soils etc)’
- **Delete** all directions for use, except for strawberries
- **Vary** the directions of use for ‘strawberries’ to ‘strawberries (runners only)’
- **Vary** the general instructions for use to delete references to use patterns that have been deleted
- **Delete** all withholding periods
- **Add** a new withholding period ‘STRAWBERRIES (RUNNERS ONLY): NOT REQUIRED WHEN USED AS DIRECTED’
- **Add** protection statements ‘Dangerous to birds—irrigation according to label directions is vital in order to reduce exposure’. ‘Dangerous to fish and other aquatic invertebrates. Do not contaminate streams, rivers or waterways with the chemical or used containers.’
- **Vary** storage and disposal instructions ‘Store in a locked room or place away from children, animals, food, feedstuffs, seed and fertilisers. Store in the closed, original container in a dry, cool, well-ventilated area. Do not store for prolonged periods in direct sunlight. Triple rinse containers before disposal. Dispose of rinsate or any undiluted chemical according to state/territory legislative requirements. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, bury the empty packaging 500 mm below the surface in a disposal pit specifically marked and set up

for this purpose, clear of waterways, desirable vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.'

- **Vary** safety directions 'Poisonous if absorbed by skin contact or inhaled or swallowed. Will irritate the eyes. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin. Do not inhale dust. When opening the container and preparing the product for use wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves, goggles and half facepiece respirator with dust cartridge or canister. When using the product wear cotton overalls buttoned to the neck and wrist. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use wash gloves and goggles and respirator (and if rubber wash with detergent and warm water) and contaminated clothing.'
- **Update** first aid instructions '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.'

Emulsifiable concentrate formulation label variation includes:

- **Vary** statement of claims from 'various crops' to 'aloe vera planting material and banana planting material'
- **Add** restraints 'DO NOT dispose of spent dip on site. Spent dip waste must be transported to a facility that can lawfully receive it'
- **Delete** all directions for use, except for aloe vera planting material and banana planting material
- **Vary** the general instructions for use to delete references to use patterns that have been deleted
- **Delete** all withholding periods except: NOT REQUIRED WHEN USED AS DIRECTED'
- **Add** protection statements 'Dangerous to fish and other aquatic invertebrates. Do not contaminate streams, rivers or waterways with the chemical or used containers.'
- **Vary** storage and disposal instructions 'Store in a locked room or place away from children, animals, food, feedstuffs, seed and fertilisers. Store in the closed, original container in a dry, cool, well-ventilated area. Do not store for prolonged periods in direct sunlight. Triple-rinse containers before disposal. Add rinsings to dip tank. Do not dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, bury the empty packaging 500 mm below the surface in a disposal pit specifically marked and set up for this purpose, clear of waterways, desirable vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.

  Dip Disposal—Do not dispose of spent dip on site. Spent dip waste must be transported to a facility that can lawfully receive it.'
- **Vary** safety directions 'Poisonous if absorbed by skin contact or inhaled or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Will damage eyes and skin. Will irritate the nose and throat. Avoid contact with eyes and skin. Do not inhale vapour. When preparing dip and using the prepared dip wear cotton overalls buttoned to the neck and wrist and a washable hat,

protective waterproof clothing or a PVC apron, elbow-length chemical resistant gloves and impervious footwear and face shield or goggles. If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product in eyes, wash it out immediately with water. If product or dip on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, goggles and contaminated clothing.'

- **Update** first aid instructions '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.'

APPENDIX B: SUMMARY OF PUBLIC SUBMISSIONS

SUBMITTER	AREAS OF CONCERN	ISSUES RAISED
Amvac Chemical Corporation	Residues	**Issue 1:** *The APVMA's dietary intake calculations were questioned, and it has been proposed that National Estimated Short-Term Intake (NESTI) be recalculated using highest residue (HR) values.* **Response 1:** NESTI calculations were already conducted using HR values rather than the MRL therefore generating a more refined intake estimate. The APVMA's Residues Assessments team has confirmed the NESTI calculations for potato, sweet potato and tomato as provided in the 2013 residues assessment report. It has also confirmed that the NESTIs for 2–6 year olds for fenamiphos in potato, sweet potato and tomato exceed the ARfD (165, 280 and 200%, respectively) when using the HR values from the available residue data sets. **Issue 2:** *The short-term dietary exposure estimations for potatoes, sweet potatoes and tomatoes should indicate acceptable risk.* **Response 2:** Given the large exceedance of the ARfD by 2–6 year olds consuming potato, sweet potato and tomato, the APVMA cannot support the ongoing use of fenamiphos on these commodities. **Issue 3:** *The available residue data in pineapple and onion are considered sufficient to support continued use of fenamiphos in these commodities.* **Response 3:** One trial in onions at Good Agricultural Practice (GAP) was submitted and evaluated as part of the review. In this trial, a single application of fenamiphos was made at 9.6 kg ai/ha at five days prior to sowing. Onions collected at harvest had fenamiphos residues below the limit of quantification (LOQ) (0.01 mg/kg). Sampling occurred 151 days after application, noting that the label carries a 12 week (84 day) withholding period for onions. Given that only a single trial was made available, the APVMA does not consider that this is an adequate data set to support the continued use of fenamiphos on onions. Regardless, fenamiphos use on onions is also unsupported due to unacceptable environmental risks. The rationale for the non-support of fenamiphos use in pineapple is provided under the submission by Growcom, on behalf of the pineapple industry.
	Environment	**Issue 1:** *Effective soil incorporation of the granular products through irrigation/watering should mitigate the main risk for birds.* **Response 1:** The environmental risk assessment undertaken by the Department of the Environment took into account soil incorporation practices but still identified an unacceptable risk to birds. The assessment assumed that 85% of granules would be incorporated into the soil, with 15% potentially remaining on the surface. This is a standard first tier assumption, and information on the accuracy of this assumption was

SUBMITTER	AREAS OF CONCERN	ISSUES RAISED

sought from industry during the development of the draft environmental risk assessment in 2008. The Department was advised by industry at that time that:

> In some cases, 100% incorporation will be achieved as the granule is physically placed in planting furrows and covered with soil.
>
> In other cases, 85% primary incorporation sounds close to correct, for example, where a rotary hoe or planter is used to achieve primary incorporation, however secondary incorporation by irrigation (most crops are irrigated immediately after planting to ensure good soil to root or seed contact, and to ensure that desiccation of the seedling does not take place). This secondary incorporation would ensure an incorporation level higher than 85%. There are no measured/scientific data to support this assumption.

Without further information, the Department is unable to refine the granule incorporation estimation further.

Issue 2: *Runoff should not be an issue with soil incorporation.*

Response 2: This issue was also raised by Tasmanian Farmers and Graziers Association, please also refer to the above response to Amvac's submission.

Soil incorporation does not mitigate fully against runoff. The Department of the Environment has assessed the study by Lin (1992)[1] and considered Amvac's preliminary assessment with respect to runoff. The Department of the Environment has also assessed the outcomes of its extended screening runoff model against application rates, soils, slopes, rainfall and delay between application and rainfall described in Lin's report and demonstrated a good agreement between the measured and modelled outcomes. Therefore, runoff continues to be an issue with soil incorporation of granular fenamiphos products.

Issue 3: *A 10–metre buffer zone on the label may provide additional measures to prevent runoff.*

Response 3: The use of vegetative buffer/filter strips as a risk mitigation tool to manage runoff is not straightforward. While removal efficacy in vegetative filter strips in field trials can exceed 90% it is generally below 50% and is highly variable (removal efficacy of 0– 99%). A simple width-based 'one size fits all' runoff mitigation factor does not adequately address this high variability (Roepke, undated[2]).

Issue 4: *In relation to recommendation 3 of the Environmental Assessment report, which specifies the requirement of a full suite of ecoxtoxicity data for M01 metabolite, toxicity should not be an issue for birds, bees or earthworms when granular product is*

[1] Lin J, 1992. Field Measurement of Fenamiphos Runoff from Bare Soil Simulating Tobacco and Row Crop Uses in Georgia Soil. Milnes Inc. Agriculture Division, Kansas, Study Number NE222401, APVMA Data No. 9877.13 July 1992.

[2] Roepke B, undated. Modelling run-off mitigation efficiency of vegetated filter strips (VFS) within the FOCUSsw framework using VFSMOD-W. http://abe.ufl.edu/carpena/files/pdf/software/vfsmod/EMW5_8.pdf

SUBMITTER	AREAS OF CONCERN	ISSUES RAISED
		incorporated in soil. Therefore, the avian tests for the M01 metabolite should not be required, and limitations to granular formulations only would indicate bee, aphid, mite and earthworm toxicity tests should not be required. **Response 4:** As discussed in Response 1, the risk assessment undertaken on the granular product, which assumed soil incorporation of 85% of the product, demonstrated unacceptable risk to birds, bees, aquatic invertebrates, terrestrial arthropods and earthworms in all cases. In the absence of the ecotoxicity data, if further refinement of the environmental assessment is required, it will be assumed that the M01 metabolite is toxicologically equivalent to the parent compound based on the results of acute toxicity tests with both compounds. Any further refinement of the risk assessment to earthworms will focus significantly on likely exposure based on the timing of application and the use patterns being defenced. As noted in EPHC (20089), current requirements for chronic earthworm tests are triggered by exposure considerations such as repeat application or persistence of a chemical, so where use patterns only consist of single application in a season, the need for chronic earthworm toxicity data is reduced. **Issue 5:** *Higher tier field data are already available that clearly indicate that any impact that fenamiphos may have on earthworm populations in treated areas are temporary and a full recovery will occur within a season. These data account for the impact of fenamiphos and its main soil metabolite M01. Running additional lower tier tests should therefore not be required.* **Response 5:** The Department of the Environment agrees with the comment. Any further refinement of the risk assessment to earthworms will focus significantly on likely exposure based on the timing of application and the use patterns being defended. As noted in the Environmental Risk Assessment Guidance Manual by the National Environmental Protection and Heritage Council (2009), current requirements for chronic earthworm tests are triggered by exposure considerations such as repeat application or persistence of a chemical, so where uses patterns only consists of single applications in a season, the need for chronic earthworm toxicity is reduced. **Issue 6:** *Amvac indicated that it does not intend to repeat the existing mesocosm study.* **Response 6:** In the absence of further information, the Department of the Environment will continue to rely on the current no observable effect concentration (NOEC) of 3.5 µg/L in the aquatic risk assessment.
	Human Health	**Issue 1:** *The use of plasma cholinesterase (ChE) inhibition as the basis for the Australian ADI for fenamiphos had been questioned and it was recommended that the ADI be based on red blood cell (RBC) ChE inhibition and be brought in line with the ADI established by the EU and JMPR.* **Response 1:** Australia has a long-standing policy of establishing ADIs for cholinesterase-inhibiting compounds such as OPs, based on the inhibition of plasma

SUBMITTER	AREAS OF CONCERN	ISSUES RAISED
		butyrylcholinesterase activity. This is a somewhat more conservative approach than that taken by other jurisdictions such as the EU, and by international bodies such as the World Health Organisation (WHO) that base their ADIs for OPs on the inhibition of erythrocyte acetylcholinesterase activity. In contrast, the establishment of ARfDs for OPs by Australia is based on the inhibition of erythrocyte acetylcholinesterase activity, consistent with other jurisdictions. The dietary risk assessment undertaken by the APVMA identified concerns in relation to the exposure of children to fenamiphos residues in potatoes, sweet potatoes and tomatoes where short-term intakes exceeded the Australian ARfD, which is based on the inhibition of erythrocyte acetylcholinesterase activity. When potatoes, sweet potatoes and tomatoes were excluded from the chronic intake calculations, there was no exceedance of the Australian ADI for fenamiphos, which is based on the inhibition of plasma butyrylcholinesterase activity. On this basis, the difference between Australia and other jurisdictions in relation to the basis of the ADI for fenamiphos has no bearing on the outcome on the acute dietary risk assessment of fenamiphos. **Issue 2:** *In response to the toxicology assessment report, which states there has been no percutaneous studies available for evaluation, Amvac advised that data reviewed and cited in the EU review describes the result of an in vitro study with human skin and using a microencapsulated formulation of fenamiphos.* **Response 2:** The study referred to by Amvac was not submitted to the APVMA for evaluation. Without an assessment of the full study, the dermal absorption factor used in the OHS assessment cannot be refined. **Issue 3:** *The toxicology report indicates that there were no data on immunotoxicity.* **Response 3:** The APVMA has no immunotoxicity concerns in relation to fenamiphos and does not specifically require this information at present.
	OHS	**Issue 1:** *The OHS assessment was thought to be overly conservative because the ADI is based on the plasma ChE inhibition instead of RBC ChE inhibition and older reference values from the PHED Surrogate Exposure Guide (1998) were used.* **Response 1:** As discussed above, Australia has a long-standing policy on establishing ADIs for OPs based on the inhibition of plasma butyrylcholinesterase activity. OCS does not currently use the latest US EPA exposure reference values, as the underlying surrogate data is currently being validated for its suitability as a replacement for PHED data. **Issue 2:** *The optional use of engineering control (closed loading system) would reduce the potential for inhalation exposure significantly, making the need for a half facepiece respirator not necessary.*

SUBMITTER	AREAS OF CONCERN	ISSUES RAISED
		Response 2: This scenario cannot be modelled in PHED and as such, additional reductions in exposure conferred by closed mixing and loading cannot be estimated. **Issue 3:** *Granular product being dispensed from a shaker-type applicator should lead to acceptable worker exposure risks.* **Response 3:** The OCS does not have surrogate exposure data for this type of application, and acknowledges that dermal exposure via the hands is likely to be lower from granules poured from a container as opposed to being handled directly (as modelled by OCS in PHED). However, inhalational exposure is also an issue, which is not expected to be reduced by this type of application method.
Australian Banana Growers Council Inc.	Environment	**Issue 1:** *The APVMA should reconsider the proposed deletion of the banana planting material dipping treatment. The banana industry believes that current practice of disposing of the spent dip as per current label instructions within the plantation would pose minimal environmental risk as the quantities are relatively small. Nevertheless, should this practice be considered unacceptable the industry believes that alternative options for spent dip disposal are available and could be pursued on an as needs basis, for example, collection and disposal of spent dip solutions at a waste treatment facility.* *ABGC has already had discussions with a hazardous waste management company to confirm that collection and disposal of spent dip solutions could be accommodated with current hazardous waste management systems.* **Response 1:** There is currently no label requirements relating to disposal of spent dip. The current practice in the banana industry had been discussed in the Environmental Assessment Report (section 10.3.4), where spent dip is strained to remove extraneous materials and used in adult banana plantations as per label instructions. However, spraying of fenamiphos in banana plantations poses unacceptable risk to birds, aquatic organisms and terrestrial organisms at all registered label use rates and therefore can no longer be supported. There do not appear to be any current label requirements relating to disposal of spent dip. The proposal for collection and disposal of spent dip solutions at a waste treatment facility may address the concern above regarding spraying of spent dipping solutions. Such disposal method are required to comply with state and territory's environmental protection regulations. New label directions regarding dip disposal are to be added in conjunction with this use to specify the new waste disposal requirement.
Australian Sweet Potato Growers Inc.	Residues	**Issue 1:** *Australian Sweet Potato Growers Inc. (ASPG) has questioned the APVMA's proposal to not support continued use of fenamiphos in sweet potatoes on the grounds of unacceptable acute dietary risk. ASPG does not believe that residues of up to 0.2mg/kg of fenamiphos in sweet potatoes are likely and has supplied monitoring data provided by several major growers. This data is residue screening data from samples analysed over a number of years for a large number of pesticides and has been generated by growers as a requirement for selling produce to the major supermarket*

SUBMITTER	AREAS OF CONCERN	ISSUES RAISED
		chains. ASPG has also noted that the sweet potato is a slower growing crop than potatoes and that dietary consumption is significantly lower than that of potato, further reducing the residue risk. **Response 1:** The APVMA's decision not to support the continued use of fenamiphos in sweet potatoes is based on unacceptable environmental risks and unacceptable acute dietary risks in children. The APVMA appreciates the effort in providing monitoring data to address residue concerns. However, the residue monitoring data is not suitable for regulatory purposes without confirmation of the residue definition addressed. Furthermore, these data do not address the significant environmental concerns with the ongoing use of fenamiphos.
CANEGROWERS	Residues	**Issue 1:** *CANEGROWERS have questioned the residue assessment, stating that the lack of residue data should not be a barrier to continued use as they consider it unlikely that any residues would be detectable in raw or refined sugar after processing.* **Response 1:** The APVMA's decision not to support the continued use of fenamiphos in sugarcane is based predominantly on unacceptable environmental risks to birds, aquatic organisms from runoff, bees, terrestrial arthropods and earthworms. In relation to the APVMA's residue assessment, no residue or processing data has been provided for sugarcane, and therefore the APVMA's dietary risk cannot be further refined.
	Environment	**Issue 1:** *Cane is generally a five year crop cycle. The use of fenamiphos is minor with Bundaberg region being the main area for application. The total area of application in Bundaberg is on average less than 1000 hectares per year. In context, this is approximately 5% of the total area of cane to be harvested in 2013 (20,000 ha). Fenamiphos is applied to plant cane which is on average 12–15% of the total area of a cane farm.* **Response 1:** Assuming only 15% of a farm is treated at a given time, it would still result in an unacceptable risk for birds, bees, terrestrial arthropods and earthworms. However, this information could be used to consider restricting the use of fenamiphos to the Bundaberg (Mary-Burnett) region where runoff may be minimal due to the majority of the region being relatively flat. **Issue 2:** *Bundaberg Canegrowers have established an Irrigation Planning and Management Program that monitors drainage and supports irrigation through an interactive irrigation and weather information centre for the Bundaberg Sugarcane Industry. This program, in combination with other practices and the limited use of fenamiphos would reduce the risk to the environment.*

SUBMITTER	AREAS OF CONCERN	ISSUES RAISED
		Response 2: The Department of the Environment commends this approach. As the environmental risk assessments are undertaken within a national framework, the Department is not in a position to consider farm specific issues. Without further information, it has to be assumed that such voluntary practices are not adopted as standard practice throughout the region. **Issue 3:** *Neither of the two avian species used in ecotoxicity studies (mallard duck and bobwhite quail) occurs in Australian sugarcane areas. The use of fenamiphos in sugarcane blocks is limited and birds do not generally feed in cane blocks as there are very few weeds and weed seeds and refuge areas for birds to use. Therefore, fenamiphos exposure would be extremely limited to birds. CANEGROWERS questions which bird species could acquire significant levels of fenamiphos from a sugar field given the management practices within the industry as well as relevance of the findings to species occurring in sugarcane fields.* **Response 3:** Australian specific bird toxicity data are rarely available, therefore ecotoxicity data are often derived from standard test species, including the mallard duck and bobwhite quail. This approach is consistent with international guidelines for testing of chemicals. It should be noted that the local Pacific Black Duck is closely related and may interbreed with the mallard duck, therefore the use of mallard duck test results is relevant for this assessment. At the time of the diuron review, the Department of the Environment attempted to seek information on bird species frequenting sugarcane plantations from industry but no information could be obtained. The Department of the Environment therefore undertook a preliminary review to determine if there was the likelihood of birds being found within sugarcane plantations, and if such birds were likely to breed within these plantations. The review indicated that there could be several ground dwelling bird species that could choose to nest in cane fields. For example, the Pheasant Coucal is often found in sugarcane plantations near wetlands. Of greater value in refining the avian risk assessment may be information pertaining to the likely limited exposure, particularly noting that fenamiphos is only applied to plant cane (12–15% of on-farm area) and that overall fenamiphos is only likely to be used on 5% of the sugarcane area in the Bundaberg region. **Issue 4:** *Sugarcane seldom flower and do not rely on bees or insects for pollination. Therefore, fenamiphos' risk to bees (terrestrial non-target arthropods) should not be considered as a risk in sugarcane. Furthermore, the use pattern for sugarcane and application would not directly affect bees.* **Response 4:** While the APVMA acknowledge the argument that sugarcane do not rely on insects for pollination, there are no information to indicate the absence of bees and non-target arthropods in areas treated with fenamiphos. Additionally, the environmental assessment identified unacceptable risk for a number of organisms other than bees and terrestrial arthropods.

SUBMITTER	AREAS OF CONCERN	ISSUES RAISED
		Issue 5: *Risk to aquatic organisms through spray-drift or run-off is minimised in sugarcane due to the farming systems and practices used. Best Management Practices (BMP) can manage the potential risk to the environment from fenamiphos.* **Response 5:** This approach is commendable. However, the Department of the Environment is not in a position to consider farm specific issues. Without further information, it has to be assumed that such voluntary practices are not adopted as a standard practice throughout the region.
	OHS	**Issue 1:** *Workers' exposure to fenamiphos during preparation and application 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.* **Response 1:** The OHS review concluded that most use patterns assessed for EC and granular products were acceptable, with the use of appropriate PPE for worker protection. The exception was application by hand where the risk could not be mitigated with PPE. According to the information provided by CANEGROWERS, hand application is not a relevant method of application in sugarcane, with granular products applied by granule applicator attached to a tractor. Therefore, the OHS findings are not a reason for discontinuing use of fenamiphos in sugarcane.
Growcom on behalf of the Pineapple Industry	Residues	**Issue 1:** *The continued use of fenamiphos is required for control of root knot nematode, as it is currently the only available chemical for control of this pest. Growcom has noted that the acute dietary intake for fenamiphos in pineapple is below the ARfD, and with removal of uses for tomatoes, potatoes and sweet potatoes, the chronic intake of fenamiphos would be less than the ADI.* **Response 1:** The APVMA notes the comments received from Growcom on behalf of the pineapple industry and acknowledges that the acute and chronic dietary intakes of fenamiphos residues in pineapples are acceptable.
	Environment	**Issue 1:** *Industry is already planning to undertake water quality trials for the diuron review which may be able to incorporate fenamiphos testing to address the issues of high water solubility and toxicity of the two main fenamiphos metabolites.* **Response 1:** The Department of the Environment appreciates the industry effort to undertake water quality trials as part of the diuron review outcomes and note their willingness to include fenamiphos in this testing regime. Water issues from runoff were one aspect of concern from use in pineapples, but there were many other areas of concern also. The assessment had also identified unacceptable risk to birds, aquatic organisms, bees, terrestrial arthropods and earthworms for the lowest application rate in pineapples.

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Hon John McVeigh MP on behalf of QDAFF	Environment	**Issue 1:** *Fenamiphos is very highly toxic to birds, fish, aquatic invertebrates, earthworms and bees. Importantly, the metabolites of fenamiphos are also very highly toxic to some of these species. The evidence for the toxicity to birds is well supported by the scientific literature and agrees with the risk assessment for the post planting and turf uses. It is noted that further data on the toxicity of the metabolites of fenamiphos to a range of indicator organisms will be required before the APVMA could be satisfied that the uses according to label instruction do not present an unacceptable environmental risk.* *The Queensland Department of Agriculture, Fisheries and Forestry (DAFF) provides a diagnostic service for pesticide poisonings of wildlife. Samples are received from other Queensland Government departments and where pesticide analyses are valuable in animal disease investigations. Since 2001, 13 samples of various bird tissues and food sources comprising 7 separate incidents have involved fenamiphos. The species involved were kookaburras, ducks, brolgas and crows: with some birds unidentified. It is however unclear whether the incidents relate to use according to label instructions or from illegal baiting of birds. In a recent incident involving brolgas, the evidence suggests that corn kernels were treated with fenamiphos (bait) as there is no registered use on corn and the property in question and surrounding properties did not grow corn.* **Response 1:** The Department of the Environment thank Qld DAFF for this information and requests the details of the pesticide poisoning incidents for inclusion in any revision of the fenamiphos assessment. **Issue 2:** *In considering the risk to bees, it is requested that consideration be given to the hardness and the amount of fines produced from the formulation during application. Potentially, the application of fenamiphos granules could be analogous to the risks posed by abraded treated seed coatings.* **Response 2:** The methodology relating to exposure and subsequent risks from abraded seed coatings during planting operations is still not finalised, therefore the methodology is not available for assessing the risk from hardness and amount of fines. However, the Department of the Environment accepts that the risk to bees is adequately mitigated through the current proposed regulatory actions where all use patterns, except strawberry runners, are to be deleted due to unacceptable environmental risks, which include risks to birds, aquatic and terrestrial organisms. **Issue 3:** *Some of the pre-plant uses of fenamiphos such as the pineapple use pattern include instructions for incorporation to 10–15 cm by using rotary tillage equipment. Other use patterns for tree and vine crops, such as for citrus and grapes, is for injection at 150–200 kPa which suggests that the residues will not be on the surface. The report does not directly comment on incorporation and injection as risk mitigation strategy for birds and therefore we request consideration of these aspects. However, it is noted that rotary tillage will increase the availability of soil borne organisms and may encourage greater bird feeding in treated areas.*

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Response 3: The use patterns for citrus and grapevines do not describe injection into the soil explicitly. For citrus, the current label instruction states to apply 'as an overall treatment at 150–200 kPa to the root zone'. Similarly for grapevines, label instruction states to apply 'using a boom spray at about 200 kPa'. These do not directly refer to soil injection but, in fact, refer to the use of boom spray.

Injection is referred to on the label, but only in the cases of applying in trickle irrigation systems where the product is injected into the system.

Issue 4: *The persistence and potential multiple applications of fenamiphos raises valid concerns about residue accumulation particularly in light of the resultant run-off potential of fenamiphos and metabolites. However, in some of the crops on which it is registered it is only seldom used. It is also considered unlikely that further soil half-life data would be submitted to the APVMA to clarify the risk. In that context, it would appear to be a better outcome to limit the uses to an acceptable number, if one exists.*

Response 4: While the Department of the Environment agrees with the comment, risk quotients in the environmental assessment report are based ONLY on a single application initially and risk quotients remained unacceptable in most situations even at one application.

Arguments pertaining to limited use and frequency in different crops may allow further refinement of exposure. However, this information needs to be provided to the APVMA and to date has only been received for a limited number of situations.

Issue 5: *The report states, 'in predicting environmental concentrations, concentrations in soil were estimated to range from 0.33–25 mg/kg dw depending on the application rate following a single application'. The report also states 'the concentration in soil is predicted based on uniform mixing within the top 10 cm using a soil density of 1500 kg/m3'. It is questioned whether soil injection at 150–200 kPa places the residues at depths greater than 10 cm. It is requested that advice be provided on incorporation to 15 cm and injection as risk mitigation strategies for earthworms.*

Response 5: As noted above, the 400 g/L product label does not directly discuss soil injection as a method of application except for trickle irrigation. The spray pressure relates to that used for general boom spraying, not vertical injection into the soil horizon. Australian methodology uses a 10 cm soil depth, however, for more mobile chemicals, a depth of 15 cm can be considered (EPHC, 2009[3]). Mixing to a depth of 15 cm can readily be modelled and may be appropriate in the event of soil incorporation through irrigation/rainfall noting fenamiphos is relatively mobile.

Increasing soil depth by an additional 5 cm means the chemical will be distributed through an additional 500 m^3 on a per hectare basis, or an additional 750,000 kg (wet weight) of soil. This results in predicted soil concentrations decreasing by almost 45%

[3] EPHC (2009) Environmental Risk Assessment Guidance Manual for Agricultural and Veterinary Chemicals. http://www.scew.gov.au/sites/www.scew.gov.au/files/resources/bffdc9e9-7004-4de9-b94f-b758140dbc8c/files/cmgt-nchem-eragm-agricultural-and-veterinary-chemicals-200902.pdf

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		from the predicted soil concentrations calculated in the report with a range of 0.19–13.9 mg/kg dw soil. Unfortunately, this does not allow any further risk mitigation for earthworms. The chronic no observed effect concentration (NOEC) for fenamiphos was <0.12 mg/kg dw, so even at the lowest application rate modelled of 0.4 kg ac/ha, the risk quotient remains >1.6. **Issue 6:** *The report states, 'in quantifying exposure from runoff, Australia does not have a defined model'. Whilst this is accepted as correct, it is questioned why the fenamiphos review has not adopted the same modelling as the diuron review. The diuron review methodology has produced extremely complicated use instructions for some crops such as sugarcane and pineapples and it remains a question whether this is an optimal solution. Nevertheless, consistency in modelling is seen as highly desirable as it enhances the predictability and fairness of review outcomes.* **Response 6:** The diuron review represented an initial approach to refining aquatic exposure from runoff based on regional specific environmental characteristics (soils, long term stream flow data and long term rainfall data). This methodology was developed in response to the outcomes of the diuron review and post-dates the environmental assessment for fenamiphos undertaken in 2008. **Issue 7:** *Despite the commentary above on some of the assumptions used in the assessment, there are risks that cannot be readily mitigated such as the leaching and run-off potential. Although the likelihood of contaminating groundwater is much less if there is limited use within a catchment, the logic of the acceptability of the strawberry use appears to be that the amount of area treated is low compared with the total crop area.* *It is difficult to appreciate why birds would be less attracted to strawberries than some other crops such as leafy vegetables, root vegetables, crucifers and pineapples that also do not have flowers or fruit at the time of application. Based on the report, it appears that the risk is to birds consuming treated soil borne species. This is reflected in the types of birds reported in the literature as having being affected by fenamiphos applications. It is queried whether the types of birds attracted to fruit and flowers are the birds at risk.* **Response 7:** Section 8.5.4.3 of the Environmental Assessment Report only relates to use of the granular formulation where granules were applied directly to the heart of infested plants, which possibly results in lower exposure through not being readily available on the soil surface. The Department of the Environment does not have the necessary information on the specific types of birds attracted to fruit and flowers of the different cropping situations in which fenamiphos is registered for use. Hence, two standard indicator species and standard modelling were used to predict residues in birds' diets (primarily grains and insects) when applied as a foliar spray, or through direct ingestion of granules. **Issue 8:** *It is agreed that run off of fenamiphos in strawberries will be lessened when the residues are below the plastic. However, the discussion appears to be about the granular product. It is unclear if the discussion is relevant to the liquid formulations. It is noted that*

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		100 g/kg GR product is the only use supported on environmental grounds for strawberries. **Response 8:** Application under plastic sheeting is not discussed in the report for either the 400 g/L or 100 g/kg granular products since it is not mentioned on the product labels. The runoff assessment has been performed based on surface application. The discussion in Section 8.5.4.3 of the Environmental Assessment Report relates to the granular product. Runoff and corresponding risk quotients from use in strawberries using the liquid formulation are discussed in Section 8.5.1. **Issue 9:** *Whilst under the Agvet Code, review only applies to active approvals, registrations and their labels, it is requested that permits are also considered in this process in a similar manner to the dimethoate and fenthion reviews. Specifically, there is a permit, (PER12968) relevant to strawberry runner production that is worthy of consideration in the context of the acceptability of the environmental risks of fenamiphos in strawberries.* *The permit is for use of the EC formulation for leaf and bud nematodes in strawberry runners. Leaf and bud nematodes are a different type of pest to the majority of other pests on the labels because the label uses are generally for soil borne nematodes whilst the permit is for a crown nematode. This difference means that the use pattern under permit is to treat to the point of runoff and generally does not involve soil treatment. This should substantially lessen the risk to earthworms, birds and reduce run off potential. However, it is understood that runner producers tend to treat soil just prior to planting under label, with further applications under permit onto the crop at a later juncture.* **Response 9:** The use under PER12698 is for a different pest and application rate than those registered on current fenamiphos labels. Further detail is discussed in a response to the environmental issue raised by Queensland Strawberry Growers Association (below). **Issue 10:** *It is presumed that as the granular product is an acceptable environmental risk to strawberries generally that this also applies to strawberry runners but clarification of this point is requested as the production system for the runner is quite different. For instance, the plastic sheeting is not used in runner production and the instruction to add to the heart of the plant is less clear in its meaning for plants with lots of long runners.* **Response 10:** The product labels for fenamiphos assessed for the review do not distinguish between strawberry runner production or any other form of strawberry farming. Further, application under plastic sheeting is not discussed on either the 400 g/L or 100 g/kg granular product labels. **Issue 11:** *Consideration is also requested that the impact of pre-fumigation on the environmental risks from fenamiphos. Some industries or sectors of industries routinely use soil fumigants such as chloropicrin to sterilise the soil. The subsequent application of fenamiphos during the cycle of crops is unlikely to be a risk to birds as the soil borne*

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organisms have already been killed during fumigation such that there is no reason for birds to forage in the crop for ground dwelling organisms.

Response 11: The Department of the Environment advised that no information has been provided on which industries routinely use pre-fumigation. Pre-fumigation is not a label requirement for any of the registered uses of fenamiphos. Furthermore, as the environmental risk assessments were undertaken within a national framework, farm-specific issues cannot be taken into consideration.

Issue 12: *Some industries such as strawberries are moving towards protected cropping systems, which should limit the exposure to birds and potentially reduce run-off. It is requested that consideration be given to the use of protected cropping systems as a risk mitigation strategy.*

Response 12: Consideration can only be given to areas where data or information is received. To date, the APVMA has not received any information on any aspect of protected cropping systems including the type of crop subjected to such systems and the methods used that will allow further refinement of exposure calculations.

Issue 13: *The banana industry has indicated its strong desire to continue with the plant material dip. It is understood that the industry is considering methods for chemically treating spent dip waste. However, the chemical properties of fenamiphos and metabolites will make its degradation to compounds of low environmental significance particularly challenging. The industry is reliant on this use for producing 'pest free' planting material.*

Ultimately, the industry may have to move to other technologies such as tissue culture, which are likely to be significantly more expensive. However, it is requested that consideration is given to allowing use with the waste taken by waste disposal contractors. Waste contractors are not necessarily going to be available in all areas, nor would the costs of such disposal necessarily be able to be borne by the industry. However, it would allow an additional option for some growers and potentially offer a transitional arrangement as the industry seeks other solutions to obtaining 'pest free' planting material.

Response 13: This issue was also raised by the Australian Banana Growers Council. Please see response to the submission from the Australian Banana Growers Council above.

Issue 14: *It is difficult to reconcile the report's environmental conclusion of 'cancellation of all current approved fenamiphos uses' when the report argues the environmental acceptability of the mushroom and strawberry use patterns. Overall, it is evident that there are no uses that are acceptable against all criteria.*

Response 14: The conclusion quoted is the overall report conclusion, taking into account both the environmental conclusions, which support the use in mushrooms and

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		strawberries, and the residues conclusions, which do not support use in mushrooms and strawberries.
Member of public	Environment	**Issue 1:** A member of public supports the proposed cancellation of fenamiphos use in the turf industry, quoting that he has been made aware of numerous incidents of wildlife deaths in golf courses. **Response 1:** Noted.
Queensland Strawberry Growers Association Inc.	Residues	**Issue 1:** *Queensland Strawberry Growers Inc. has proposed that use in strawberries be restricted to runner productions, stating that continued use in this specialised area of strawberry farming is required to control bud and leaf nematodes. The respondent has noted that use of fenamiphos in runner production is allowed under permit number 12698 and has proposed a Table 5 entry to cover the use, as residues would not be expected in fruit.* **Response 1:** The APVMA's Pesticide Residues Section advised that the use of fenamiphos in strawberries for runner production only is expected to be a nil residue situation and supports continued use of fenamiphos in non-fruit bearing strawberry crops for runner production. It is proposed that a Table 1 entry be established at the limit of quantitation (LOQ) (*0.05 mg/kg) for fenamiphos in strawberries should this be acceptable in relation to other assessment criteria.
	Environment	**Issue 1:** *In the Fenamiphos Preliminary Review Findings it is indicated that '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'. This conclusion was based upon an application rate of 1 kg product (100 g ai)/1000 plants or 1 g product (0.1 g ai)/plant and the high planting density of up to 80,000 plants/ha.* *The use approved under PER12698 differs from that assessed in the PRF to the extent that the industry believes that the above assessment is in fact an over estimate of potential environmental exposure from use in strawberry runners.* **Response 1:** The assessments undertaken within the Chemical Review Program assess currently registered use patterns and do not take into account off-label uses and rates such as those issued under permit. The use pattern considered acceptable with respect to strawberries was only for the granular product where granules are applied to the heart of infested plants at a rate of 1 g/plant. While the department of the Environment assumed a high planting density of up to 80,000 plants/ha, actual application was only assumed to occur to 5% of the crop based on information provided by industry at the time, hence a maximum per hectare

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		rate of 0.4 kg/ha for this particular use (see Table 2 of the Environmental Assessment Report for Fenamiphos). The Department of the Environment does not have equivalent information relating to use of the 400EC formulation, which still has a 'per hectare' rate of 24 L product/ha (8 kg ac/ha) and can be applied as an overall treatment by boom spray. **Issue 2:** *The use approved in strawberry runner production is targeted at obtaining thorough coverage of the foliage to control potentially invasive nematode infestations. As a result the EC formulation is required. The use approved in strawberry runner production involves a treatment regime of 100 mL/100 L or 8 mL/10 m row. Advice from strawberry runner producers is that water volumes of 500–600 L/ha are applied, i.e., 500–600 mL/ ha of fenamiphos EC or 200–240 g ai/ha. Amounts significantly lower than the 8 kg ai/ha upon which the assessment detailed in the PRF is based.* **Response 2:** The use approved in strawberry runner production, targeted at obtaining thorough coverage of foliage is approved under permit, not on currently registered product labels. While the permit states the crop as 'Strawberry runner production crops only (non-fruiting), the product labels for fenamiphos assessed for the review do not distinguish between strawberry runner production or any other form of strawberry farming'. The label rates registered with the 400 EC formulation include an over the top rate of 24 L/ha (8 kg active constituent per hectare), 16 mL product/10 m row applied on a 60 cm band pre-transplanting; or 16 mL/10 m row when injected into an irrigation system. These rates are significantly higher than those advised by the Queensland Strawberry Growers Association, but as they are the rates registered on label at the time of the review and are legally able to be used, they are the ones that have been assessed. The use under PER12698 (now PER14598) is for a different pest (leaf and bud nematodes) and application rate than the rates and pests registered on current fenamiphos labels. If this submission is in fact seeking registration of this use with an associated reduction of the use rates to those currently used under PER 12698, then such an application would need to made through the normal registration channels in the APVMA.
Tasmanian Farmers & Graziers Association (TFGA)	Regulatory	**Issue 1:** *The TFGA notes from the PRF that all label approvals are to be cancelled and believes there needs to be a process whereby farmers have a phase out period to adjust and find a suitable alternative to fenamiphos.* **Response 1:** Upon cancellation of a product or its label, up to a one-year 'phase out' period can apply. **Issue 2:** *The TFGA proposes that including additional information in safety data sheets (SDS) may be able to minimise the dietary risk to humans from fenamiphos use in potatoes, sweet potatoes and tomatoes.*

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		Response 2: Material Safety Data Sheets (MSDS or SDS) are a requirement under the Work Health and Safety Regulations, which are the responsibility of the work health and safety authorities in each State and Territory. The MSDS document provides information on the properties of hazardous chemicals and how they can affect health and safety in the workplace, which is useful information for both workers, and medical personnel in the case of poisoning. The MSDS does not however cover dietary risk to humans. In addition, the MSDS is not a document that the APVMA has jurisdiction over. The APVMA approved product label, attached to the product itself, is the only legal instrument that controls the safety of consumers by controlling the uses and rates of use. Therefore, the label must contain the necessary information to protect consumer health. If the use is likely to pose a dietary risk to humans, then the only recourse is to remove that risk.
	Environment	**Issue 1:** *To minimise the risk to birds and mammals to ingest fenamiphos granules when applying the chemical it can be incorporated into the soil, which won't see it staying on the surface and in view of birds or mammals.* **Response 1:** This issue was also raised by Amvac Chemical Corporation, please refer to the above response to Amvac's submission. **Issue 2:** *In regards to runoff issues, incorporating appropriate buffer zones from the water course is an appropriate strategy to assist with this issue. It is proven that riparian vegetation acts as a filter to trap sediment, nutrients and other contaminants, reducing their movement into water courses*. **Response 2:** This issue was also raised by Amvac Chemical Corporation, please also refer to the above response to Amvac's submission. The Department of the Environment is aware of arguments for use of vegetative buffer strips in mitigating runoff risk and has considered the use of such tools in assessments in the past. However, the Department has concluded current information does not allow us to include this tool in our screening level model for our assessments. With respect to use of vegetative filter/buffer strips it needs to be recognised that application of these as a mitigation tool is not straightforward. Removal efficacy in vegetative filter strips in field trials has been shown to often exceed 90% and is mostly >50%, however, the variability of 0–99% raises concern. A simple width based 'one size fits all' runoff mitigation factor does not seem to adequately capture this variability (Roepke, undated).[4]

[4] Roepke B, undated. Modelling run-off mitigation efficiency of vegetated filter strips (VFS) within the FOCUSsw Framework using VFSMOD-W. http://abe.ufl.edu/carpena/files/pdf/software/vfsmod/EMW5_8.pdf

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		Significant effort has been made in assessing the use of these as risk mitigation tools in Europe (FOCUS, 2007)[5], and information is available on important factors such as location and sizing of buffer zones, trapping efficiency, infiltration etc. The level of work in this area, and commitment in Australia for different cropping systems is not at all clear, if it exists at all in certain industries. This makes it very difficult to apply vegetative filter strips as a mitigation tool at this stage.
Titan Ag	Environment	**Issue 1:** *Many of the data that formed the basis for environmental risk assessment were generated from studies conducted in the USA and that the use patterns and label directions in the USA may not have the consistency of users in Australian agricultural and horticultural situations. It is not reasonable to extrapolate findings of USA studies to the Australian environment. It also emphasised that Australian agriculture, horticulture and turf culture systems are very different to those in the USA.* **Response 1:** The Department of the Environment advised that it is standard practice to report monitoring results for chemicals where available, but these results were not the sole factor supporting the recommendations of the environmental assessment report. To support the assessment, a suite of environmental fate and ecotoxicity data were provided. These were performed to standard test guidelines, and in the case of ecotoxicity data, using standard indicator species. Environmental fate data were generated in North America or Europe, and this too is standard and generally acceptable practice. Neither the Department of the Environment nor the APVMA is responsible for generating data to support the registration of a chemical product. In undertaking our assessments, we rely on data generated and supplied by registrants and also data available in the public domain. If Australian industry wish to generate Australian specific test data then that is their prerogative, however, an insistence on such data would significantly restrict access of new chemistry to industry and farmers as the cost of generation of data is likely to be prohibitive.
The Vegetable Growers Association of Victoria	Regulatory	**Issue 1:** *It is requested that the review of fenamiphos be conducted on a sound scientific basis and not based on an emotional response to environmental concerns only.* **Response 1:** The environmental risks identified during the fenamiphos review resulted from expert scientific advice provided to the APVMA by the Commonwealth Department of the Environment. The environmental risk assessment prepared by the Department of the Environment is based on the most up-to-date scientific data and highlights the following issues: • Run-off into waterways and into ground water;

[5] FOCUS (2007). Landscape and Mitigation Factors in Aquatic Ecological Risk Assessment. Volume 2: Detailed Technical Reviews. Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. SANCO/10422/2005, version 2.0, September 2007.

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		• Toxicity to birds and non-target soil organisms; • Persistence in the soil; and • The lack of ecotoxicity data on a breakdown products of fenamiphos in soil. While most of these issues would need to be addressed by product registrants (through the generation of additional environmental toxicity studies), growers could also contribute to the review by considering farm management practices for controlling run-off into waterways and groundwater.

ABBREVIATIONS AND ACRONYMS

AChE	Acetyl cholinesterase
ADI	Acceptable Daily Intake
Agvet Code	Agricultural and Veterinary Chemicals Code, Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
AOEL	Acceptable Operator Exposure Level
EC	Emulsifiable concentrate formulation
EU	European Union
FAISD	First Aid Instructions and Safety Directions
GR	Granular formulation
HG	Home garden
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	Limit of Quantification
MRL	Maximum Residue Limit
NESTI	National Estimated Short-Term Intake
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
OCS	Office of Chemical Safety, Australian Government Department of Health
OHS	Occupational health and safety
OP	Organophosphorus
PPE	Personal protective equipment
PVC	Polyvinyl chloride
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
US EPA	United States Environmental Protection Agency