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Australian Pesticides and Veterinary Medicines Authority

FENAMIPHOS

Residues and dietary risk assessment report

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EXECUTIVE SUMMARY

Fenamiphos was nominated for review in 1994, mainly due to concerns regarding non-target effects upon the environment and its toxicology. However, there were also concerns regarding the safety to human health from a dietary exposure to fenamiphos residues. Residues data were consequently received and evaluated to determine whether these dietary exposure concerns were justified. In evaluating the dietary exposure of fenamiphos residues to consumers, it was necessary to examine the intake of foods that would potentially contain residues of fenamiphos. To do this, the National Estimated Daily Intake (NEDI) & National Estimated Short-Term Intake (NESTI) calculations were undertaken in accordance with internationally accepted World Health Organization (WHO)/Food and Agriculture Organization (FAO) procedures. As a result, the residues evaluation has resulted in a number of recommendations for amendment of Maximum Residue Limits (MRLs) to cover all on-going food uses of fenamiphos.

A monograph of data submitted to the WHO/FAO Joint Meeting on Pesticide Residues (JMPR) was also submitted to the APVMA in support of the review. Further reference was made to the JMPR periodic evaluation of fenamiphos undertaken in 1999 and subsequently published by the FAO.

No contemporary data from Australian residues trials were submitted to the APVMA. This evaluation of the impact of fenamiphos residues on dietary exposure was undertaken solely on relevant data included in the JMPR report of 1999. No residues data were available to support the ongoing use of fenamiphos on beetroot, broccoli, cauliflower, celery, endive, ginger, lettuce, mushrooms, parsnips, strawberries, sugarcane, swedes and turnips. The continued use of fenamiphos on these commodities is not supported. Data for onions, Brussels sprouts and pineapples were inadequate and therefore these uses cannot be supported. Data were available to assess the use of fenamiphos on bananas, cabbages, carrots, citrus fruit, grapes, melons, potatoes, sweet potato and tomatoes.

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

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

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

1 INTRODUCTION

Fenamiphos is an organophosphorus nematicide and insecticide with activity against nematodes and soil pests, and is registered for use in a variety of field crops and ornamentals, both as a granule and as a spray. In 1994 fenamiphos was nominated for consideration for review, due mainly to environmental and toxicology concerns.

From a residues perspective, there were concerns that the dietary exposure of consumers to fenamiphos residues could exceed acceptable levels. Therefore, interested parties were invited to provide data relevant to this issue to enable an estimate of the dietary exposure to be made. This especially included mention of data for tomatoes, lettuce, strawberries and citrus, as well as animal transfer data for cattle and hens.

1.1 Label and maximum treatment regime

The current registered use patterns for fenamiphos in food crops are presented below for two formulations, a granular product (GR) and a liquid emulsion concentrate (EC):

Table 1: Maximum use patterns for fenamiphos products in Australia

CROP	PEST	MAXIMUM LABEL RATE	CRITICAL COMMENTS
Granular formulations, GR			
Bananas	Nematodes	250 g ai/100m row in 1m band	
Carrots	Nematodes	9 kg ai/ha	Apply up to 7 days before and up to time of seeding
Crucifers	Sugar beet nematode	1.25 g ai/m^2	Apply 7 days within seeding or transplanting
Crucifers	Nematodes	11 kg ai/ha	Apply from 7 days before up to time of seeding or transplanting
Ginger	Nematodes	11 kg ai/ha	Apply 2 treatments per year
Parsnips	Nematodes and sucking insects	9 kg ai/ha	Apply up to 7 days before and up to time of seeding
Pineapples	Nematodes	100 g/100 m row in 1m band	Apply at final bed preparation stage
Potatoes	Nematodes	10 kg ai/ha	Apply pre-planting as a 45 cm band over the row
Strawberries	Crimp nematode	1 kg ai/1000 plants	Apply granules into heart of infested plants within 1 month of planting. Spray irrigate immediately
Sugar cane	Nematodes	4 kg ai/ha planted	Apply in a 30-40 cm band centred on row. Apply at any time from planting to early tillering
Tomato	Root-knot nematode	1.25 g ai/m^2	Apply 7 days within seeding or transplanting
		11 kg ai/ ha	Apply from 7 days before up to time of planting
Liquid formulations, EC			

CROP	PEST	MAXIMUM LABEL RATE	CRITICAL COMMENTS
Aloe vera planting material	Nematodes	400 mL/100 L water	Immerse unpaired pups in dip solution for 30 min, drain and dry
Aloe vera	Nematodes	24 kg ai/ha	Infested established crop: Apply as a conventional spray. The chemical must be washed of plant foliage by overhead sprinkler irrigation within 30 minutes of treatment. Treat for maintenance four months later
Banana planting material	Nematodes	40 g ai/100 L	Immerse material in solution for 10 minutes, drain and dry
Bananas	Nematodes	240 g ai/100 m row	Treat a 0.5 m band each side of centre line
		24 kg ai/ha of wetted area metered into irrigation water	When calculating area wetted, assume at least 1 m^2 is wetted for each metre of single row planted
Citrus	Nematodes	30 kg ai/ha	Apply in spring as an overall treatment. After treatment, irrigate the area with at least 50 mm water
Crucifers	Nematodes and sucking insects	9.6 kg ai/ha	Apply as an overall pre-planting treatment
Cucurbits	Nematodes and sucking insects	9.6 kg ai/ha	Apply as an overall treatment pre-planting or pre-transplanting
Carrots, beetroot, onions, celery, sweet potatoes, lettuce, endive, parsnips	Nematodes and sucking insects	9.6 kg ai/ha	Apply as an overall treatment pre-planting or pre-transplanting
Grapevines	Nematodes	12 kg ai/ha	Apply late September to moist soil across the full width of the inter-vine row. After treatment, irrigate with approximately 30-50 mm water
Mushrooms	Nematodes	26 g ai/20 L water per tonne compost	Apply to compost while it is being turned. DO NOT TREAT BOTH COMPOST AND CASING
Pineapples	Nematodes	2.4 kg ai/ha	During the crop cycle, apply 5 sprays over the plants at 2-3 month intervals beginning 1 month after planting and ending no later than 6 weeks prior to flower induction
Potatoes	Nematodes	5.2 kg ai/ha	At emergence: as soon as sufficient plants have emerged to indicate row position, apply to moist soil and irrigate immediately after application
Strawberries	Nematodes and sucking insects	9.6 kg ai/ha	Apply as an overall treatment pre-planting
Sugar cane	Nematodes	4 kg ai/ha	Apply in a 30-40 cm band centred in the row at any time from planting to tillering
Tomatoes	Nematodes and sucking insects	9.6 kg ai/ha	Apply as an overall treatment pre-planting or pre-transplanting

Harvest Withholding Periods:

Strawberries – 6 weeks
Carrots, beetroot, parsnips, sweet potatoes, potatoes, onions, celery – 12 weeks
Lettuce, endive – 8 weeks
Mushrooms – 6 weeks

Most of the uses are soil-based applications, either pre-planting or at planting/transplanting. With established or semi-permanent crops such as grapes and pineapples, applications may be made during the cropping cycle. The EC formulation is also used for dipping plant material prior to planting, e.g. for bananas and aloe vera.

Fenamiphos and its metabolites are systemic in nature and therefore residues are expected to be present in some commodities as a result of the use.

1.2 Current Australian MRLs and residue definition

The current fenamiphos MRLs are listed below.

Table 2: ***Table 1 of the current MRL Standard***

COMPOUND	FOOD		MRL (mg/kg)
Fenamiphos			
		Aloe vera	1
	FI 0327	Banana	*0.05
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	*0.05
	VS 0624	Celery	*0.05
	FC 0001	Citrus fruits	*0.05
	MO 0105	Edible offal (mammalian)	*0.05
	PE 0112	Eggs	*0.05
	VC 0045	Fruiting vegetables, Cucurbits	*0.05
	HS 0784	Ginger, root	*0.05
	FB 0269	Grapes	*0.05
	VL 0053	Leafy vegetables [except Lettuce, Head; Lettuce, Leaf]	*0.05
	VL 0482	Lettuce, Head	0.2
	VL 0483	Lettuce, Leaf	0.2
	MM 0095	Meat [mammalian]	*0.05
	ML 0106	Milks	*0.005

COMPOUND	FOOD		MRL (mg/kg)
Fenamiphos			
	VO 0450	Mushrooms	0.1
	VA 0385	Onion, Bulb	*0.05
	SO 0697	Peanut	*0.05
	FI 0353	Pineapple	*0.05
	PO 0111	Poultry, Edible offal of	*0.05
	PM 0110	Poultry meat	*0.05
	VR 0075	Root and tuber vegetables	0.2
	FB 0275	Strawberry	0.2
	GS 0659	Sugar cane	*0.05
	VO 0448	Tomato	0.5

Table 2 continued: *Table 3 of the MRL Standard*

COMPOUND	RESIDUE
Fenamiphos	Sum of fenamiphos, its sulfoxide and sulfone, expressed as fenamiphos

Table 2 continued: *Table 4 of the MRL Standard*

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
Fenamiphos	Primary feed commodities	1

1.3 Toxicological information

The following health standards have been recommended by the Office of Chemical Safety, Department of Health and Ageing (ADI and ARfD lists, as of 19 October 2012)

Table 3: Health Standards recommended by the OCS

COMPOUND	DIETARY STANDARD, mg/kg bw		NO OBSERVABLE EFFECT LEVEL (NOEL), mg/kg bw	SAFETY FACTOR	REFERENCE (OCS, DATE)
Fenamiphos	ADI[1]	0.0001	0.014	100	7/11/2005
	ARfD[2]	0.003	0.25	100	7/11/2005

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

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

1.4 Present estimates of dietary exposure

Chronic exposure

Chronic dietary exposure is estimated by the National Estimated Daily Intake (NEDI) calculation, encompassing all registered/temporary uses of the chemical and the mean daily dietary consumption data derived from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with WHO Guidelines[3] and is a conservative estimate of a life-time dietary exposure to residues of a specific chemical in food.

Acute exposure

Acute dietary exposure is estimated by the National Estimated Short Term Intake (NESTI) calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR[4] with 97.5th percentile food consumption data derived from the 1995 National Nutrition Survey of Australia and subsequent surveys. NESTI calculations are conservative estimates of a single-point acute exposure (24-hour period) to chemical residues in food.

3 Guidelines for predicting dietary intake of pesticide residues, WHO, 1997

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

2 RESIDUES EVALUATION

2.1 Metabolism

The metabolism of fenamiphos in plants and animals has been previously evaluated by the JMPR in 1999. Some details of the JMPR deliberations are given in Appendix 2 of this report. No additional metabolism studies were submitted with this review, and no further consideration of fenamiphos metabolism is required.

2.2 Analytical methods

The JMPR considered the analysis of fenamiphos residues in its 1999 periodic re-evaluation. Gas-liquid chromatography (GLC) methods were identified as the routine type of methods used. Full details can be found in the JMPR report, with methods for both crop and animal tissues. Summaries of the crop and animal tissue methods considerations are included in Appendix 4 of this report.

The stability of residues was raised as an issue by the JMPR.

The Meeting examined studies that determined stability in stored samples of a number of crops including asparagus, banana, cotton seed (seed, meal, hulls and oil), garlic, and grapes (berries, juice, wet and dry pomace and raisins). Samples were fortified and held in frozen storage (≤-5° C) for up to 18 months. Some decrease of total residues (<10%) was observed in garlic and grape pomace after 12 months. At 18 months <10% decrease was found in most commodities and crop fractions except raisins and cotton seed hulls, which had decreased by <20%. The Meeting agreed that a decrease of <20% should not be considered significant, and that residues in the commodities examined were stable when stored frozen for 18 months.

In a study of the storage stability of residues in animal tissues, extracts of cattle fat, kidney, liver and muscle were fortified separately with 1 mg/kg fenamiphos, DIF, FSO, DIFSO, FSO_2 or $DIFSO_2$, and milk with 1 mg/kg fenamiphos, FSO or FSO_2. Tissues and milk were stored at -25° C for up to 2 and 3 months respectively. The results showed that fenamiphos, FSO and FSO_2 were stable in milk for 61 days, but fenamiphos was unstable in fat, liver, kidney and muscle, and was degraded within 83 days. As fenamiphos would have been converted to its sulfoxide and sulfone and the analytical method determines total residues as fenamiphos sulfone, the total fenamiphos residues in tissues are considered to be stable. [5]

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

2.3 Residue definition

The existing definition of the residue is "*sum of fenamiphos, its sulfoxide and sulfone, expressed as fenamiphos*". The analytical methods allow all three compounds to be included in the measured residue, as fenamiphos and the sulfoxide are both oxidized to the sulfone, so the existing residue definition is appropriate on the basis of the metabolism studies reviewed. Therefore, there are no proposed changes to the residue definition for fenamiphos in Australia. The current definition is also in agreement with the Codex definition.

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[5] *DIF = Desisopropyl-fenamiphos; FSO = fenamiphos sulfoxide; DIFSO = Desisopropyl-fenamiphos sulfoxide; FSO_2 = fenamiphos sulfone; $DIFSO_2$ = Desisopropyl-fenamiphos sulfone.*

2.4 Residues in foods and animal feeds

Summaries of residues data from trials conducted in Australia and overseas countries were available in the 1999 JMPR Report. The crops for which trials were reported include carrots, potatoes, onions, Brussels sprouts, cabbages, tomatoes, melons, watermelons, grapefruit, lemons, limes, oranges, bananas and pineapples. All residues data published in the 1999 JMPR report that closely approximate Good Agricultural Practice (GAP) in Australia are presented in Table 12.

There were no data for broccoli, turnip, Swedes, cauliflower, ginger, parsnips, strawberries, sugarcane, beetroot, celery, lettuce, endive and mushrooms, all of which are registered uses in Australia. The continued use of fenamiphos on these crops cannot be supported from a residues perspective.

For mandarins and sweet potatoes, extrapolation from related commodities within a crop group may be possible, to make a determination of appropriate MRLs. There were an insufficient number of trials for onions, Brussels sprouts and pineapples and therefore these uses cannot be supported from a residues perspective.

The relevant data are summarised in Table 4, with an indication of trial numbers and residue ranges for each of the commodities, together with proposed MRLs. For the dietary exposure estimates, residues in the edible portion of the commodity are reported (both the highest residue (HR) and supervised trial mean residue (STMR) values), where available.

The impact of these proposed MRLs and residues on dietary exposure is discussed in Section 3 of this report.

Table 4: Summary of trial data and MRL recommendations

COMMODITY/ CROP GROUP	AUSTRALIAN GAP		SUPERVISED TRIAL DATA				RECOMMENDATIONS		
	RATE (FORM.)	WHP	TRIAL NO./YEARS	RATE (FORM.)	WHP (DAYS)	RESIDUES (mg/kg)	MRL (mg/kg)	HR (mg/kg)	STMR (mg/kg)
Carrot	9 kg ai/ha GR 9.6 kg ai/ha EC	12 weeks 12 weeks	9 (1971–1989)	9–11 kg ai/ha EC/GR	65–150	0.01–0.11	0.2	0.11	0.05
Potato	10 kg ai/ha GR	12 weeks	5 (1971–1982)	9–10 kg ai/ha EC/GR	71–118	<0.01–0.17	0.3①	0.17	0.03
Cabbage	11 kg ai/ha GR 9.6 kg ai/ha EC	12 weeks 12 weeks	7 (1971–1973)	9–10 kg ai/ha EC/GR/SC	42–108	<0.01–0.05	0.1	0.05	0.01
Tomato	11 kg ai/ha GR 9.6 kg ai/ha EC	Nil Nil	13 (1971–1996)	9–11 kg ai/ha EC/GR	58–127	<0.02–0.27	0.5	0.27	0.05
Melons	9.6 kg ai/ha EC	Nil	5 (1971–1988)	9–10 kg ai/ha EC/GR	71–112	<0.01–<0.05	*0.05	0.05 (whole fruit) <0.02 (pulp)	0.015 (whole fruit)②
Citrus (Orange, lemon, lime, grapefruit)	30 kg ai/ha EC	Nil	17 (1972–1981)	33.6 kg ai/ha GR/SC	59–190	<0.01–0.56 (whole fruit) <0.01–0.05 (pulp)	0.7③	0.56 (whole fruit) 0.05 (pulp)	0.01 (whole fruit & pulp)
Grapes	12 kg ai/ha EC or 1.2 g ai/m^2	Nil	12 (1987)	1–2 g ai/m^2 EC 12 kg ai/ha EC	73–125	<0.01–<0.05	*0.05	0.05	0.01
Bananas	2.5 g ai/stool G 2.4 g ai/stool EC	Nil Nil	7 (1971–1994)	2.8–5 g ai/stool EC/GR	1–112	<0.01–<0.025	*0.05	0.025	0.015

① The MRL will also be extrapolated to sweet potato.

② Not enough data points to estimate a median value.

③ The group MRL will include mandarins, as well as the citrus crops listed.

2.5 Processing studies

Studies for processing of tomatoes, oranges, apples, grapes and pineapples were reported by the JMPR. The following information has been reproduced from the 1999 JMPR evaluation of fenamiphos in 1999. Only information relevant to tomatoes, oranges and grapes is reproduced below.

Orange trees were treated with Nemacur 15% granular at a rate equivalent to 100 kg ai/ha (Thornton, 1976). Leaves were taken at monthly intervals to determine when peak residues had moved systemically into the upper parts of the trees. When residues had reached plateau levels in the leaves, fruit were harvested and processed. The commercial processing procedure commenced with a pre-rinse wash, scrubbing with soap and water and an after-wash rinse.

Table 5: Residues in processed fractions of oranges and processing factors (Thornton 1976). Taken from JMPR (1999) Table 95.

SAMPLE	RESIDUE, mg/kg	PROCESSING FACTOR
Whole fruit	0.07	-
Peel (unwashed)	0.47	6.71
Pulp (unwashed)	<0.01	0.14
Peel (washed)	0.60	8.57
Pulp (washed)	0.01	0.14
Juice	0.02	0.28
Finisher pulp	0.02	0.28
Peel bits	0.23	3.28
Clear oil	4.48	64
Chopped peel	0.13	1.86
Pressed dry peel	0.40	5.71
Press liquor	0.20	2.85
Molasses	0.49	7

The concentration of residues was greatest in clear oil. Residues were also concentrated in peel and dried peel, both of which are used as cattle feed. Drying peel reduced the total residues by approximately 20%, but the loss of water was greater. Residues in the pulp and juice were negligible.

Whole tomatoes, containing 0.5 mg/kg fenamiphos, were subjected to commercial processing into canned tomatoes, pasteurised juice and ketchup (Morris, 1975). The residues in the processed fractions and the corresponding processing factors are shown in Table 6.

Table 6: Residues and processing factors from a tomato processing trial (Morris, 1975). Taken from JMPR (1999) Table 93.

SAMPLE	Residue, mg/kg	Processing factor
Whole tomatoes	0.50	NA
Pasteurised tomato juice	0.44	0.88
Sterilized tomatoes (canned)	0.36	0.72
Tomato ketchup	0.29	0.58
Tomato juice	0.37	0.74
Tomato pulp solids	0.52	1.04
Dry tomato seeds and fibres	0.79	1.58
Dry tomato peels and cores	1.89	3.78
Dry tomato pulp solids	3.12	6.24
Dry tomato pomace	1.25	2.5

Grape processing studies were conducted in the USA. The results are shown in Table 7 and 8.

The soil around grapevines was treated with three sprays of Nemacur 360 EC at a rate equivalent to 6.72 kg ai/ha (Mobay, 1981d, reports 69745 and 80080), the first at blooming, with 13-14 day intervals. The sprays were incorporated into the soil after application by hand sprayer.

In a processing trial in California (Grace, 1989, report 99611) Nemacur 3 EC was applied twice at a 6-week interval at a rate equivalent to 25.2 kg ai/ha (5 times the normal rate) as band sprays with incorporation. Samples of grapes, grape juice and wet pomace were collected 7 days after the second spray.

Table 7: Effect of processing on residues in Thompson Seedless grapes, California, USA. Taken from JMPR (1999) Table 97.

YEAR	APPLICATION			PHI,	SAMPLE	RESIDUES,	REPORT NO.
	FORM.	kg ai/ha	NO.	DAYS		mg/kg	
1981	360 EC	6.72	3	55	whole fruit	0.07	69745 [1]
				70		0.05	
				80		0.04	
				55	Raisins, sun-dried	0.07	
				70		0.01	
				80		0.02	
				55	raisin trash, sun-	0.77	

YEAR	APPLICATION			PHI,	SAMPLE	RESIDUES,	REPORT NO.
	FORM.	kg ai/ha	NO.	DAYS		mg/kg	
				70	dried	0.11	
				80		0.06	
				55	raisins, oven-dried	0.09	
				70		<0.01	
				80		<0.01	
				55	raisin trash, oven-dried	0.12	
				70		0.12	
				80		0.10	
1981	360 EC	6.72	3	56	whole fruit	0.02	80080 [2]
				73		0.01	
				56	raisins, sun-dried	0.03	
				73		0.01	
				56	raisin trash	0.22	
				73		0.09	
				56	raisins, oven-dried	0.03	
				73		0.02	
				56	raisin trash, oven-dried	0.19	
				73		0.13	
1988	360 EC	25.2	2	7	whole fruit	0.02	99611 [3]
					wet pomace	0.02	
					dry pomace	0.10	
					juice	0.02	

[1] 3 applications (14-day intervals) starting at blooming, by hand sprayer followed by incorporation. Plot size 74.2 m^2.

[2] 3 applications (49- and 36-day intervals) by broadcast spray to soil at 5-10 cm shoots, blooming and post-bloom. Plot size 39.9 m^2.

[3] Two band sprays to soil near vines with incorporation at 42-day interval, 1st spray near maturity and 2nd spray at mature ripe fruit stage; plot size 17.8 m^2, sandy loam soil, pH 6.5-7.5, <1% C. Limit of determination = 0.01 mg/kg. Recoveries from fruit were F 102, 91%, FSO 76, 83% and FSO_2 81, 102% at 0.01 mg/kg; F 82 %, FSO 75%, and FSO_2 95% at 0.02 mg/kg; F 72%, FSO 76%, FSO_2 94% at 0.1 mg/kg. Recoveries from juice were F 99%, FSO 86% and FSO_2 91% at 0.1 mg/kg, from wet pomace F 74, 101%, FSO 75, 84%, FSO_2 83, 90% at 0.05 mg/kg, and from dry pomace F 75% at 0.1 mg/kg.

Table 8: Effect of processing on residues in grapes and mean processing factors for processed fractions. Taken from JMPR (1999) Table 98.

SAMPLE	RESIDUE, mg/kg	PROCESSING FACTOR[1]	REPORT NO.
Whole fruit (PHI 55/56 days)	0.07, 0.02 (average 0.045)		69745, 80080
Raisins	0.07, 0.09, 0.03, 0.03 (average 0.055)	1.22	
Raisin trash	0.77, 0.12, 0.22, 0.19 (average 0.33)	7.33	
Whole fruit (PHI 7 days)	0.02		99611
Wet pomace	0.02	1	
Dry pomace	0.10	5	
Juice	0.02	1	

[1] *(Mean residue in processed fraction) ÷ (mean residue in whole fruit)*

The residues were concentrated in raisins and raisin waste, and in dry pomace after juicing and drying. The residues in juice and wet pomace did not differ from those in the whole fruit. Raisin waste and pomace are used as animal feed.

Other data were also available in the JMPR report for grapefruit. The data from Table 77 of the JMPR report indicate that the mean levels of fenamiphos in the different portions of the grapefruit were 0.35 mg/kg in peel, 0.027 mg/kg in the pulp, and 0.13 mg/kg in the whole fruit, giving processing factors of 2.7 for peel and 0.21 for pulp of the grapefruit. These values are lower than those estimated for oranges.

Relevant processing factors are summarised below in Table 9, together with STMR-P and HR-P values for input into the dietary exposure calculations and livestock burden tables, and for establishing relevant MRLs for processed commodities.

Table 9: Summary of processing factors for relevant fractions

COMMODITY	PF	PF × STMR	STMR-P	PF × HR	HR-P
Orange peel (washed)	8.57	8.57 × 0.01	0.086	8.57 × 0.56	4.8
Orange pulp (washed, wet)	0.14	0.14 × 0.01	0.001	0.14 × 0.56	0.078
Orange juice	0.28	0.28 × 0.01	0.003		
Tomato pulp solids (dry)	6.24	6.24 × 0.05	0.31	6.24 × 0.27	1.68
Tomato juice	0.74	0.74 × 0.05	0.037		
Raisins	1.22	1.22 × 0.01	0.0122	1.22 × 0.05	0.06
Grape pomace (dry)	5	5 × 0.01	0.05	5 × 0.05	0.25
Grape juice	1	1 × 0.01	0.01		

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

In relation to livestock feed commodities, orange pulp/peel, grape pomace and tomato pomace are all considered to be potential feeds for which appropriate MRLs are required. On the basis of the HR-P values tabulated above, an MRL of 5 mg/kg is recommended for citrus pulp (dry); an MRL of 0.5 mg/kg is recommended for grape pomace (dry) and an MRL of 2 is recommended for tomato pomace (dry).

2.6 Animal transfer studies and required animal commodity MRLs

Potential livestock feeds have been identified in Table 10 and predominantly comprise processed fruit by-products. Residues in feeds range from 0.01 to 5 ppm. This translates into a maximum theoretical exposure in animal feed of up to 5 ppm fenamiphos resulting from citrus peel/pulp. However, citrus peel/pulp would be fed at levels no greater than 20% to cattle, sheep, and/or pigs and poultry[6], which indicate a maximum exposure in the total diet of 1 ppm. This is a worst-case estimate, as highest residues are included in the estimate of the dietary burden rather than median residues.

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

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

Table 10: Summary of processing factors for relevant fractions

Cattle—500 kg bw, 20 kg DM/day

FEED GROUP	COMMODITY	% IN DIET	FEED INTAKE, kg	RESIDUE, mg/kg	% DM	LIVESTOCK DIETARY EXPOSURE		
						mg/animal	ppm	mg/kg bw
Fruit waste products	Citrus peel	20	4	5	100	20	1	0.04

Poultry—2 kg bw, 0.15 kg DM/day

FEED GROUP	COMMODITY	% IN DIET	FEED INTAKE, kg	RESIDUE, mg/kg	% DM	LIVESTOCK DIETARY EXPOSURE		
						mg/animal	ppm	mg/kg bw
Fruit waste products	Citrus peel	20	0.03	5	100	0.15	1	0.075

2.7 Fat solubility and potential for bioaccumulation

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

[6] *Stockfeed Guideline Document 1. Primary Feed Commodities As A Proportion of Livestock Diets. Version 1.1 March 2002*

3 DIETARY RISK ASSESSMENT

3.1 Acute dietary exposure assessment

The acute dietary exposure is estimated by the NESTI calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR with 97.5th percentile food consumption data derived from the 1995 National Nutrition Survey of Australia. NESTI calculations are conservative estimates of acute exposure (24-hour period) to chemical residues in food.

The NESTIs for all relevant commodities are summarised in the following table.

Table 11: Estimated Short-term dietary exposures (NESTIs) for relevant food commodities

CODE	FOOD	NESTI (%ARfD)	
		2 YEARS +	2-6 YEARS
MM 0095	Meat (mammalian)	<5	5
PM 0110	Poultry meat	<5	<5
MO 0105	Edible offal (mammalian)	<5	<5
PO 0111	Poultry, edible offal of (1)	<5	<5
ML 0106	Milks	<5	<5
PE 0112	Eggs	<5	<5
FI 0327	Banana	<10	20
VB 0041	Cabbages, head	<20	<30
VR 0577	Carrot	<20	<50
FC 0001	Citrus fruits	–	–
FC 0004	Oranges	<10	<30
FC 0204	Lemons	<10	<40
FC 0203	Grapefruit	<30	<80
	Citrus juice	<5	<10
FB 0269	Grapes	<30	<60
DF 0269	Dried grapes	<5	5
VC 0046	Melons (excluding watermelon)	<20	40
VC 0432	Watermelon	<50	40
VR 0589	Potato	<70	165
VO 0448	Tomato	<90	200

CODE	FOOD	NESTI (%ARfD)	
		2 YEARS +	2-6 YEARS
VR 0508	Sweet potato	<60	280

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

3.2 Chronic dietary exposure assessment

The chronic (lifetime) dietary exposure to fenamiphos is estimated by the NEDI calculation encompassing all registered/temporary uses of the chemical and the mean daily dietary consumption data derived from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with WHO Guidelines[7] and is an estimate of dietary exposure to chemical residues in food. The NEDI for fenamiphos including uses approved at the commencement of the review, is equivalent to 116% of the ADI (NEDI #1). The full calculations are found in Appendix 1.

3.3 Dietary exposure conclusions

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

[7] *Guidelines for predicting dietary intake of pesticide residues, WHO, 1997.*

4 RESIDUE RELATED ASPECTS OF TRADE

As an outcome of these decisions it is not likely that residues observed in traded produce will be higher than those observed under the currently approved use patterns. The APVMA remains satisfied that the use of fenamiphos according to approved use patterns does not pose an undue risk to trade between Australia and places outside of Australia.

5 RECOMMENDATIONS

This assessment of the residues data associated with current approved uses of fenamiphos on crops was undertaken under the Existing Chemical Review Program to determine the present acceptability of the dietary exposure of consumers to fenamiphos residues, especially from a short-term intake perspective.

Uses no longer supported (acute dietary concerns)

For the following use patterns, available residues data indicate that short-term exposure to fenamiphos residues may exceed the reference health standard. The APVMA cannot be satisfied that these uses of fenamiphos would not be an undue hazard to the safety of people using anything containing its residues, and they must be deleted.

- Potatoes, sweet potatoes and tomatoes.

Uses no longer supported (insufficient data)

For certain use patterns, the available residue data were insufficient for a robust assessment of acute dietary exposure and for establishment of appropriate MRLs. However, the available residue data indicate that acute dietary exposure is likely to be acceptable. Immediate action is not proposed for these uses but the APVMA is likely to remove these uses when the review is finalised if sufficient data to set an MRL are not made available by that time. These uses are summarised below.

- Beetroot, crucifers (broccoli, Brussels sprouts, cauliflower), celery, endive, ginger, lettuce, mushrooms, onions, parsnips, pineapples, strawberries, sugarcane, swedes and turnips.

Use patterns that remain acceptable from a residues (human health) perspective

The residues assessment found that certain uses could be supported, based on the data assessed to date. Label and permit uses for commodities that may continue beyond interim action are summarised below.

- Aloe vera (including plant material), bananas, cabbages, carrot, citrus fruit, grapes and melons.

The above recommendations are summarised in Table 12 below.

Table 12: Status of all uses of fenamiphos following review of residues data

CROP	PEST	RESIDUE STATUS	WHP (DAYS)
Aloe vera planting material	Nematodes	Supported	Nil
Aloe vera	Nematodes	Supported	Nil
Banana planting material	Nematodes	Supported	Nil
Bananas	Nematodes	Supported	Nil
Beetroot, onions, celery, lettuce, endive, parsnips	Nematodes and sucking insects	Not supported	NA

CROP	PEST	RESIDUE STATUS	WHP (DAYS)
Cabbage	Sugar beet nematode, nematodes, sucking insects	Supported	Nil
Carrots	Nematodes	Supported	84
Citrus	Nematodes	Supported	Nil
Crucifers	Sugar beet nematode, nematodes, sucking insects	Not supported (except cabbage)	NA
Cucurbits	Nematodes and sucking insects	Not supported (except melons)	Nil
Ginger	Nematodes	Not supported	NA
Grapevines	Nematodes	Supported	Nil
Melons	Nematodes and sucking insects	Supported	Nil
Mushrooms	Nematodes	Not supported	NA
Parsnips	Nematodes and sucking insects	Not supported	NA
Pineapples	Nematodes	Not supported	NA
Potatoes	Nematodes	Not supported	NA
Strawberries	Crimp nematode	Not supported	NA
Sugar cane	Nematodes	Not supported	NA
Sweet potato	Nematodes and sucking insects	Not supported	NA
Tomato	Nematodes, sucking insects, root-knot nematode	Not supported	NA

The following amendments to the *MRL Standard* are recommended as an outcome of the above changes:

Table 13: *Table 1 of the proposed MRL Standard*

COMPOUND	FOOD		MRL (mg/kg)	
			CURRENT	NEW
Fenamiphos				
		Aloe vera	1	Delete
	FI 0327	Banana	*0.05	*0.05
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	*0.05	Delete
	VB 0041	Cabbage, head	–	0.1
	VR 0577	Carrot	–	0.2
	VS 0624	Celery	*0.05	Delete

COMPOUND	FOOD		MRL (mg/kg)	
			CURRENT	NEW
	FC 0001	Citrus fruits	*0.05	0.7
	DF 0269	Dried grapes	-	0.1
	MO 0105	Edible offal (mammalian)	*0.05	*0.01
	PE 0112	Eggs	*0.05	*0.01
	VC 0045	Fruiting vegetables, Cucurbits	*0.05	Delete
	HS 0784	Ginger, root	*0.05	Delete
	FB 0269	Grapes	*0.05	*0.05
	VL 0053	Leafy vegetables [except Lettuce, Head; Lettuce, Leaf]	*0.05	Delete
	VL 0482	Lettuce, Head	0.2	Delete
	VL 0483	Lettuce, Leaf	0.2	Delete
	MM 0095	Meat [mammalian]	*0.05	*0.01
	ML 0106	Milks	*0.005	*0.005
	VC 0046	Melons, excluding watermelon	–	*0.05
	VO 0450	Mushrooms	0.1	Delete
	VA 0385	Onion, Bulb	*0.05	Delete
	SO 0697	Peanut	*0.05	Delete
	FI 0353	Pineapple	*0.05	Delete
	PO 0111	Poultry, Edible offal of	*0.05	*0.01
	PM 0110	Poultry meat	*0.05	*0.01
	VR 0075	Root and tuber vegetables	0.2	Delete
	FB 0275	Strawberry	0.2	Delete
	GS 0659	Sugar cane	*0.05	Delete
	VO 0448	Tomato	0.5	Delete
	VC 0432	Watermelon	-	*0.05

Table 13 continued: *Table 4 of the proposed MRL Standard*

COMPOUND	ANIMAL FEED COMMODITY		MRL (mg/kg)	
			CURRENT	NEW
Fenamiphos				

COMPOUND	ANIMAL FEED COMMODITY		MRL (mg/kg)	
			CURRENT	NEW
		Primary feed commodities	1	Delete
	AB 0001	Citrus pulp, dry	–	5
	AB 0269	Grape pomace, dry	–	0.5

Table 13 continued: *Table 5 of the proposed MRL Standard*

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

The current residue definition of ***sum of fenamiphos, its sulfoxide and sulfone, expressed as fenamiphos*** remains relevant, and analytical methods are capable of determining fenamiphos residues in the supported commodities.

APPENDIX 1: NESTI AND NEDI FOR FENAMIPHOS

Appendix 1 can be found online at:
www.apvma.gov.au/products/review/docs/fenamiphos_residues_appendix_1.xls

APPENDIX 2: METABOLISM

The metabolism of fenamiphos has been considered by the JMPR[8] in its report of 1999. Summaries are provided below.

Animal metabolism

In summary, the primary processes of metabolism in rats, goats, cows and hens involve oxidation of the methylthio sulfur, cleavage of the isopropyl group leaving a primary amine, cleavage of the phosphate ester group and conjugation of the resulting phenols leading to ease of elimination. Evidence of cleavage of the isopropyl group was found only in the goat and hen studies, where desisopropyl-fenamiphos sulfoxide was identified as an additional metabolite.

Plant metabolism

In summary, the conclusions from the JMPR plant metabolism studies were that fenamiphos sulfoxide and fenamiphos sulfone are the main metabolites formed after the application of fenamiphos by various methods. In crops with a substantial period from treatment to harvest fenamiphos sulfoxide phenol and fenamiphos sulfone phenol are also formed, as is apparent by the change in the extraction characteristics of the radioactivity with time.

Overall, the metabolites of fenamiphos in plants and animals are similar and the existing definition of the residue as "sum of fenamiphos, its sulfoxide and sulfone, expressed as fenamiphos" is appropriate.

[8] *Pesticide Residues in Food – 1999. Volume 121/1. Evaluations 1999 Part I - Residues*

APPENDIX 3: MAGNITUDE OF RESIDUES IN CROPS, LIVESTOCK AND PROCESSED COMMODITIES

No trial data were submitted to the APVMA for consideration. The Fenamiphos Monograph prepared by Bayer Germany to the JMPR periodic review of fenamiphos, was submitted to support the review of Fenamiphos in Australia. This contained very little contemporary Australian data for commodities approved on current labels. The JMPR Report contained a full data set of all data submitted to it, including companies other than Bayer. Details and results of data generated in Australia and included in the JMPR 1999 Residues Report are shown in Tables 14 and 15.

Table 14: Summary of Australian and overseas residues data relevant to Australian registrations

COMMODITY/ CROP GROUP	AUSTRALIAN GAP		DATA FROM SUPERVISED RESIDUES TRIALS				
	RATE (FORM.)	WHP	TRIAL/YEAR	RATE (FORM.)	WHP	RESIDUE (mg/kg)	COMMENTS
Carrot	9 kg ai/ha GR	12 weeks	Australia, 1971	8.96 kg ai/ha EC	93 days	0.08	'baby carrot'
	9.6 kg ai/ha EC	12 weeks	Australia, 1972	8.96 kg ai/ha EC	107 days	0.05	'baby carrot'
			Australia, 1986	11 kg ai/ha GR	84 days	0.02	
			Spain, 1981	10 kg ai/ha GR	136 days	0.06	
			Spain, 1981	10 kg ai/ha GR	136 days	0.06	
			Spain, 1981	9.6 kg ai/ha EC	136 days	0.01	
			Spain, 1981	9.6 kg ai/ha EC	136 days	0.11	
			Italy, 1989	10 kg ai/ha GR	150 days	<0.02	
			Italy, 1989	10 kg ai/ha GR	65 days	0.05	
Potato	10 kg ai/ha GR	12 weeks	Australia, 1971	9 kg ai/ha EC	96 days	<0.05	
			Spain, 1975	10 kg ai/ha GR	118 days	0.07	
			Spain, 1977	10 kg ai/ha GR	97 days	0.17	
			Spain, 1982	10 kg ai/ha GR	71 days	<0.01	
			Spain, 1982	10 kg ai/ha GR	71 days	<0.01	
Onions	9.6 kg ai/ha EC	12 weeks	Australia, 1971	9.7 kg ai/ha EC	151 days	<0.01	
Cabbage (crucifers)	11 kg ai/ha GR	12 weeks	Australia, 1971	8.9 kg ai/ha GR	106 days	<0.01	

COMMODITY/ CROP GROUP	AUSTRALIAN GAP		DATA FROM SUPERVISED RESIDUES TRIALS				
	RATE (FORM.)	WHP	TRIAL/YEAR	RATE (FORM.)	WHP	RESIDUE (mg/kg)	COMMENTS
	9.6 kg ai/ha EC	12 weeks	Australia, 1971	8.9 kg ai/ha EC	106 days	<0.01	
			Australia, 1971	8.9 kg ai/ha EC	42 days	<0.01	
			USA, 1973	10 kg ai/ha GR	65 days	<0.02	
			USA, 1973	10 kg ai/ha GR	108 days	0.05	
			USA, 1973	10 kg ai/ha SC	79 days	<0.01	
			USA, 1973	10 kg ai/ha SC	108 days	0.02	
Brussels sprouts (crucifers)	11 kg ai/ha GR	12 weeks	USA, 1973	10 kg ai/ha	107 days	0.02	
	9.6 kg ai/ha EC	12 weeks					
Tomato	11 kg ai/ha GR	Nil	Australia, 1971	11 kg ai/ha GR	78 days	<0.05	Field trials
	9.6 kg ai/ha EC	Nil	Australia, 1971	8.9 kg ai/ha EC	81 days	<0.05	
			Australia, 1971	11 kg ai/ha EC	81 days	<0.05	
			Australia, 1971	8.7 kg ai/ha EC	127 days	0.15	
			Australia, 1971	8.7 kg ai/ha EC	127 days	<0.05	
			Brazil, 1989	10 kg ai/ha GR	94 days	<0.1	
			South Africa, 1976	10 kg ai/ha GR	58 days	<0.05	
			South Africa, 1976	10 kg ai/ha EC	58 days	<0.05	
			Spain, 1984	10 kg ai/ha EC	62 days	0.27	Glasshouse trials
			Spain, 1988	10 kg ai/ha EC	60 days	<0.02	

COMMODITY/ CROP GROUP	AUSTRALIAN GAP		DATA FROM SUPERVISED RESIDUES TRIALS				
	RATE (FORM.)	WHP	TRIAL/YEAR	RATE (FORM.)	WHP	RESIDUE (mg/kg)	COMMENTS
			Spain, 1988	10 kg ai/ha GR	60 days	<0.02	
			Spain, 1988	10 kg ai/ha GR	66 days	<0.02	
			Spain, 1988	10 kg ai/ha EC	66 days	<0.02	
Melons (Cucurbits)	9.6 kg ai/ha EC	Nil	Australia, 1971	8.9 kg ai/ha EC	112 days	<0.01	
			Australia, 1971	8.9 kg ai/ha EC	77 days	<0.01	
			Guatemala, 1987	10 kg ai/ha GR	85 days	<0.05	
			Guatemala, 1987	10 kg ai/ha GR	71 days	<0.05	
Watermelon (Cucurbits)	9.6 kg ai/ha EC	Nil	Italy, 1988	10 kg ai/ha GR	99 days	<0.02	
Grapefruit (Citrus)	30 kg ai/ha EC	Nil	USA, 1972	33.6 kg ai/ha GR	184 days	<0.01	
			USA, 1972	33.6 kg ai/ha GR	184 days	<0.01	
			USA, 1972	33.6 kg ai/ha SC	184 days	<0.01	
			USA, 1972	33.6 kg ai/ha SC	186 days	0.56	
			USA, 1981	33.6 kg ai/ha GR	60 days	0.02	
			USA, 1981	33.6 kg ai/ha GR	169 days	0.01	
			USA, 1981	33.6 kg ai/ha GR	184 days	0.29	
			USA, 1981	33.6 kg ai/ha SC	126 days	0.09	
			USA, 1981	33.6 kg ai/ha SC	59 days	0.02	
			USA, 1981	33.6 kg ai/ha SC	184 days	0.26	

COMMODITY/ CROP GROUP	AUSTRALIAN GAP		DATA FROM SUPERVISED RESIDUES TRIALS				
	RATE (FORM.)	WHP	TRIAL/YEAR	RATE (FORM.)	WHP	RESIDUE (mg/kg)	COMMENTS
Lemons (Citrus)	30 kg ai/ha EC	Nil	USA, 1972	33.6 kg ai/ha SC	184 days	0.01	
			USA, 1976	33.6 kg ai/ha GR	190 days	0.18	
			USA, 1976	33.6 kg ai/ha SC	190 days	0.44	
Limes (Citrus)	30 kg ai/ha EC	Nil	Tahiti, 1972	33.6 kg ai/ha GR	147 days	<0.01	
			Tahiti, 1972	33.6 kg ai/ha SC	147 days	<0.01	
Oranges (Citrus)	30 kg ai/ha EC	Nil	USA, 1972	33.6 kg ai/ha GR	182 days	<0.01	
			USA, 1972	33.6 kg ai/ha SC	184 days	<0.01	
Grapes	12 kg ai/ha EC	Nil	South Africa, 1987	1 g ai/m^2 EC	97 days	<0.05	
	Or 1.2 g ai/m^2			2 g ai/m^2 EC	97 days	<0.05	
			South Africa, 1987	1 g ai/m^2 EC	97 days	<0.05	
				2 g ai/m^2 EC	97 days	<0.05	
			Chile, 1987	12 kg ai/ha EC	73 days	0.02	
			Chile, 1987	12 kg ai/ha EC	80 days	0.02	
			Chile, 1987	12 kg ai/ha EC	117 days	<0.01	
			Chile, 1987	12 kg ai/ha EC	125 days	<0.01	
			Chile, 1987	12 kg ai/ha EC	103 days	<0.01	
			Chile, 1987	12 kg ai/ha EC	110 days	<0.01	
			Chile, 1987	12 kg ai/ha EC	103 days	<0.01	

COMMODITY/ CROP GROUP	AUSTRALIAN GAP		DATA FROM SUPERVISED RESIDUES TRIALS				
	RATE (FORM.)	WHP	TRIAL/YEAR	RATE (FORM.)	WHP	RESIDUE (mg/kg)	COMMENTS
			Chile, 1987	12 kg ai/ha EC	110 days	<0.01	
Bananas	2.5 g ai/stool G	Nil	Australia, 1972	2.8 g ai/stool GR	21 days	<0.01	
	2.4 g ai/stool EC	Nil	Australia, 1972	2.8 g ai/stool GR	112 days	<0.01	
			Australia, 1971	4.5 g ai/stool EC	28 days	<0.01	
			Windward Islands, 1970	2.8 g ai/stool GR	1 day	<0.025	
			Canary Islands, 1994	5 g ai/stool EC	15 days	<0.02	
			Canary Islands, 1994	5 g ai/stool EC	14 days	<0.02	
			Canary Islands, 1994	5 g ai/stool EC	90 days	<0.02	
Pineapples	5 × 2.4 kg ai/ha	Nil	Australia, 1974	5 × 2.2 kg ai/ha EC	330 days	<0.01 (whole fruit)	
	+ 2 × 4.8 kg ai/ha EC		Australia, 1974	5 × 4.5 kg ai/ha EC	330 days	<0.01 (whole fruit)	
			Hawaii, 1976	6 × 5.6 kg ai/ha SC	237 days	<0.01 (pulp)	
			Hawaii, 1976	6 × 2.8 kg ai/ha SC	237 days	<0.01 (pulp)	
			Hawaii, 1976	4 × 5.6 kg ai/ha SC	237 days	<0.01 (pulp)	
			Hawaii, 1976	4 × 5.6 kg ai/ha SC	256 days	<0.01 (pulp)	

Table 15: Fenamiphos residues in crops from data generated in Australia and reported by the JMPR, along with treatment details

CROP	YEAR	APPLICATIONS				PHI,	SAMPLE	RESIDUES,	GAP
		FORM.	kg ai/ha	NO.	TIMING	days		mg/kg	(Y/N)
Carrot	1972	400 EC	8.96	1	21D pre-sowing	107	'Baby' carrot	0.05	Y
						117		0.04	Y
						136		0.02	Y
	1971	400 EC	8.96	1	7D pre-sowing	93	'Baby' carrot	0.08	Y
						103		0.07	Y
						122		0.04	Y
	1971	400 EC	13.44	1	7D pre-sowing	93	'Baby' carrot	0.13	N
						103		0.1	N
						122		0.09	N
	1986	10 GR	11	1	At sowing	84	Root (early maturity)	0.02	Y
	1986	10 GR	22	1	At sowing	84	Root (early maturity)	0.05	N
Potatoes	1971,	400 EC	4.47	1	1D pre-planting	96	Tuber	<0.05	N
	1971,	400 EC	8.96	1	1D pre-planting	96	Tuber	<0.05	Y
Onion	1971,	43.6% EC	9.7	1	5D pre-sowing	151	mature bulb	<0.01	Y
Cabbage	1971	5 GR	8.9	1	1D pre-transplant	106	mature head	<0.01	Y
	1971	5 GR	17.9	1	1D pre-transplant	106	mature head	<0.01	N
	1971	400 EC	8.9	1	1D pre-transplant	106	mature head	<0.01	Y
	1971	400 EC	17.9	1	1D pre-transplant	106	mature head	<0.01	N
	1971	400 EC	4.48	1	At planting	42	head	<0.01	N
	1971	400 EC	8.9	1	At planting	42	head	<0.01	Y

CROP	YEAR	APPLICATIONS				PHI,	SAMPLE	RESIDUES,	GAP
		FORM.	kg ai/ha	NO.	TIMING	days		mg/kg	(Y/N)
	1971	400 EC	17.9	1	At planting	42	head	0.04	N
Tomatoes	1971	5 GR	11.2	1	3D post-transplant	78	Whole fruit	<0.05	N
	1971	400 EC	8.9	1	1D pre-transplant	81	Whole fruit	<0.05	Y
	1971	400 EC	11.2	1	1D pre-transplant	81	Whole fruit	<0.05	Y
	1971	400 EC	13.4	1	1D pre-transplant	81	Whole fruit	<0.05	N
	1971	400 EC	8.7	1	21D pre-transplant	127	Whole fruit	0.15	Y
	1971	400 EC	8.7	1	21Dpre-transplant	127	Whole fruit	<0.05	Y
Melons	1971	400 EC	8.9	1	35D pre-sowing	112	mature fruit	<0.01	Y
	1971	400 EC	8.9	1	4D pre-sowing	77	mature fruit	<0.01	Y
Lemon	1980	436 g/l	40	1	Unknown	8	fruit	<0.02	Y
Orange	1980	436 g/l	40	1	Mature fruit stage	8	fruit	<0.02	Y
Bananas	1971	400 EC	4.48	1	Flood irrigation	28	whole fruit	<0.01	N
	1971	400 EC	8.96	1	Flood irrigation	28	whole fruit	<0.01	N
	1972	5 GR	2.8 g ai/stool	2	15 cm band width 231 days apart	21	whole fruit	<0.01	Y
	1972	5 GR	2.8 g ai/stool	2	15 cm band width 231 days apart	112	whole fruit	<0.01	Y
Pineapples	1974	43.6%	1.1	5	1, 92, 192, 271 and 377D after planting	330	whole fruit	<0.01	N
	1974	43.6%	2.2	5	1, 92, 192, 271 and 377D after planting	330	whole fruit	<0.01	Y
	1974	43.6%	4.5	5	1, 92, 192, 271 and 377D after planting	330	whole fruit	<0.01	N

No data were submitted to the APVMA regarding animal feeding studies. However, the JMPR in its 1999 report examined data before it and reported:

Alfalfa pellets containing fenamiphos sulfoxide were fed to dairy cattle for 28 days at levels equivalent to 2, 6 and 20 ppm in the diet (Wargo, 1978). The feed levels equated to 44, 151 and 493 mg/kg bw/day for an average feed intake of 15 kg/animal/day and the average body weight of each group. The cows were milked in the morning and evening and samples of milk from the cows in each group for each day were composited for analysis. On day 29 the animals were killed and samples of liver, kidney, muscle (flank and loin), and fat (omental, subcutaneous and renal) were extracted for analysis less than 24 hours after death. The residues were <0.001 mg/kg in all milk samples taken from the highest dose group. Residues in the liver were ≤0.01 mg/kg in the 6 ppm group and <0.01 to 0.012 mg/kg in the 20 ppm group (levels of 0.011-0.012 mg/kg were found in 1 of the 3 animals). In the kidneys, composite fat and muscle taken from the 20 ppm group, residues were all <0.01 mg/kg.

Groups of 4 laying hens were fed for 14 consecutive days with [U-phenyl-^{14}C]fenamiphos at 0, 0.06, 0.18 and 0.65 ppm incorporated into the feed each morning (Gronberg et al., 1973). The feed concentrations corresponded to average intakes of 3.42, 10.18 and 37.96 μg fenamiphos/kg bw/day. Eggs were collected each morning and the hens were killed after 14 days for the analysis of blood, brain, skin, muscle, heart, liver, gizzard, kidney and fat.

The radioactive residues in eggs reached maximum levels after 7 days feeding in all groups. The limit of detection in eggs was reported as 0.003 mg/kg. Residues in the tissues of the high-dose group are shown in Table 15.

Table 16: Total radioactive residues in hen tissues and blood after feeding at 0.65 ppm (Taken from JMPR (1999) Table 90, based on data in Gronberg et al., 1973)

SAMPLE	TRR, μg/kg AS FENAMIPHOS
Brain	*2.58*
Heart	*5.32*
Liver	*4.51*
Kidney	*4.70*
Muscle	*2.76*
Fat	*2.96*
Gizzard	*4.22*
Skin	*2.46*
Whole blood	*3.90*

In a subsequent trial (Bell et al., 1974), groups of four laying hens were fed for 14 consecutive days with [U-phenyl-^{14}C]fenamiphos at 2, 4 and 100 ppm in the feed, corresponding to average concentrations of 0.12, 0.28 and 0.76 mg fenamiphos/kg bw/day. Eggs were collected each morning and samples of brain, liver, kidney, fat, gizzard, heart, and white and dark muscle were collected at death.

The total radioactivity in eggs reached maximum levels after 6 days feeding in all groups, similar to the 7 days found in the Gronberg study. The maximum residues in the tissues were below the minimum quantifiable limits (7-20 µg/kg) in the 2 and 4 ppm groups. At the 10 ppm feeding level, residues of 47, 27 and 18 µg/kg were present in the gizzard, kidneys and liver respectively.

APPENDIX 4: ANALYTICAL METHODS

No analytical methods were submitted to the APVMA to support the review of fenamiphos. However, the JMPR have reviewed the analytical methodology available for the determination of fenamiphos residues in food. The JMPR identified the main methods used which involved GLC with a range of detectors, including ion-trap, flame-photometric and flame ionisation. Methods were identified for both crop and animal commodities, and recoveries were identified. Full details are included in the JMPR report and so only a summary is reproduced here.

> *The basic procedure involves homogenization of the sample, filtering, and partitioning the solution with methyl chloride or other organic solvents. The organic extract is evaporated to dryness, and the residue is redissolved in acetone and oxidised with KMnO4 solution. The oxidised residues are partitioned again into methyl chloride, which is evaporated before dissolution in acetone for quantification by GLC with an FPD in the phosphorus mode. Total residues of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone are quantified in a single sulfone peak. The limits of determination in various crops are reported as 0.01-0.1 mg/kg*
>
> *Analyses of animal tissues involve quantification of total residues including Fenamiphos sulfoxide, sulfone and sulfoxide phenol (FSO, FSO_2, and FSOP). The metabolites desisopropyl fenamiphos and its sulfoxide and sulfone (DIF, DIFSO and $DIFSO_2$) are quantified in an additional peak containing the methylated residues. The work-up procedures for animal tissues and milk are similar to those for crops, but CH_3CN is used in the partitioning steps before oxidation. Reported limits of quantification in milk and tissues are 0.005 and 0.01 mg/kg respectively.*

Fenamiphos residues were found to be stable in crop material, but the JMPR identified that residues may be unstable in liver and fatty tissues. The Meetings deliberations of this issue are as follows:

> *In the first part of the analytical method described above for the determination of fenamiphos and its metabolites in animal tissues and milk (Sandie et al., 1978), both fenamiphos and FSO are oxidized to FSO_2, which is quantified as part of the total fenamiphos residue. Any degradation of fenamiphos and FSO to FSO_2 in the original extracts would not affect the total level of FSO_2 determined.*
>
> *In the second part of the method, the total fenamiphos residues are determined by converting the oxidized fenamiphos, des-isopropyl-fenamiphos and DIFSO to sulfone phenols and determining the methylated phenols. Since DIF and DIFSO are both oxidized to $DIFSO_2$ before hydrolysis and methylation the observed degradation of DIF to DIFSO would not affect the total amount of methylated phenols.*
>
> *DIFSO and $DIFSO_2$ are degraded to the corresponding phenols, but neither DIFSO nor $DIFSO_2$ was detected in the liver or kidney in the most recent goat metabolism study (Weber and Ecker, 1990), and $DIFSO_2$ was present in flank muscle but not detected in loin or round muscle. DIFSO and $DIFSO_2$ would therefore not be expected to be present at significant concentrations in the tissues of cattle, and their instability would not have a marked effect on the overall results of the analyses.*

ABBREVIATIONS

µg	microgram	bw	bodyweight
g	gram	ha	hectare
kg	kilogram	L	Litre
mg	milligram	mL	millilitre
		ppm	parts per million

ADI	Acceptable Daily Intake (for humans)	GAP	Good Agricultural Practice
ai	active ingredient	GLC	Gas-liquid chromatography
ARfD	Acute Reference Dose	GR	Granular
CXL	Codex Alimentarius Maximum Residue Limit	HR	Highest residue
DIF	Desisopropyl-fenamiphos	JMPR	WHO/FAO Joint Meeting on Pesticide Residues
DIFSO	Desisopropyl-fenamiphos sulfoxide	MRL	Maximum Residue Limit
$DIFSO_2$	Desisopropyl-fenamiphos sulfone	NEDI	National Estimated Daily Intake
DM	Dry matter	NESTI	National Estimated Short Term Intake
EC	Emulsifiable Concentrate	NOEL	No Observable Effect Level
FAO	Food and Agriculture Organization	STMR	Supervised trial median residue
FSO	fenamiphos sulfoxide	WHO	World Health Organization
FSO_2	fenamiphos sulfone	WHP	Withholding Period

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