Australian Government

Australian Pesticides and Veterinary Medicines Authority

FENTHION

Residues and dietary risk assessment report

SEPTEMBER 2012

ISBN: 978-0-9873591-6-2 (electronic)

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SUMMARY

Fenthion was recommended to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for review in 1994, due to toxicological concerns. Concerns were also raised about the safety to human health from dietary exposure to fenthion residues. Residues data were consequently received in 1999 and additional data generated on behalf of Horticulture Australia Limited (HAL) were received in 2010.
In evaluating the dietary exposure of fenthion residues to consumers, it was necessary to examine the intake of foods that would potentially contain residues of fenthion. The National Estimated Daily Intake and National Estimated Short-Term Intake calculations were undertaken in accordance with the World Health Organization—United Nations Food and Agriculture Organization's recommended guidelines as agreed with Food Standards Australia New Zealand.

Data provided

Residues data were provided for blueberries, citrus fruit, fruiting vegetables (pre- and post-harvest treatment), grapes, olives, persimmons, stone fruit, tropical and sub-tropical fruit inedible peel (for pre- and post-harvest treatment).

Residue data were submitted for blueberries. There are no current registrations or permitted uses for blueberries and no relevant established MRLs. On that basis the data will not be considered further in this report.

There were no residues data provided for apples and pears, deciduous fruits (other than stone fruit), figs, fruit trees (other than olives, citrus and stone fruits), loquats, papaw, pepino and quince.

Evaluation summary

The current residue definition of fenthion and five metabolites is the same as the Codex residue definition and remains appropriate.

Uses that continue to be supported

The following uses of fenthion were supported by appropriate residue data to allow maximum residue limit (MRL) establishment. Acute dietary exposure assessments are acceptable for:

- tropical and sub-tropical fruit (inedible peel) post-harvest uses only
- olives, treatment of nursery stock only.

Uses no longer supported (no residue data and identified acute dietary concerns)

Data were not provided for apples and pears, deciduous fruits (other than stone fruit), figs, fruit trees (other than olives, citrus and stone fruits), loquats, pepino and quince. Acute dietary exposure was estimated using the established MRL and indicated that short term exposure to fenthion residues may exceed the reference health standard. The APVMA cannot be satisfied that these uses of fenthion would not be an undue hazard to the safety of people using anything containing its residues and they must be deleted:

- apples and pears
- deciduous fruits (generally, other than stone fruits),
- figs,
- fruit trees (generally),
- loquats,
- olives (except olive nursery stock),
- pepino
- quince are no longer supported.

Uses no longer supported (insufficient data and acute dietary concerns)

For the following use patterns, available residue data did not match GAP. Assessment of acute dietary risk using the MRL indicate that short term exposure to fenthion residues may exceed the reference health standard. The APVMA cannot be satisfied that these uses of fenthion would not be an undue hazard to the safety of people using anything containing its residues and they must be deleted:

- Citrus fruit

Uses no longer supported (acute dietary concerns)

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

- Egg fruit (pre harvest)
- Fruiting vegetables (including cucurbits), all post harvest uses (except post harvest use on chilli peppers and melons)
- Grapes
- Persimmons (edible peel only)
- Stone fruit
- Tomatoes (pre harvest)

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:

- Capsicums (pre harvest)
- Chilli peppers (post harvest)
- Melons (post harvest)
- Tropical and sub-tropical fruits (inedible peel), including paw paw (pre harvest)

Use in the home garden

Fenthion is approved for use in the home garden on a number of crops grown in these situations. Owing to concerns over acute (short-term) dietary exposure to fenthion residues identified in commercial situations, the following approved home garden uses can no longer be supported:

- peach, plum, nectarine, apricot and other stone fruit
- grapes
- apples, pears, quince
- citrus
- tomatoes, eggplants and other vegetables.

Dietary exposure

The estimated chronic and acute dietary intake of fenthion arising from residues in food is unlikely to exceed the reference health standards if the recommendations of this report are put in place.

Residue related aspects of trade

Use of the product in accordance with the label instructions for the supported uses is unlikely to pose a risk to Australian trade as none of the supported uses are a major export commodity, in accordance with Part 5B of the Ag Requirements Series, Overseas Trade Aspects of Residues in Food Commodities.

1 INTRODUCTION

Fenthion is an organophosphorus insecticide registered in Australia to control fruit flies, fruit moths, mealybugs and thrips in a variety of crops, and for the control of spiders and mosquitos. It is also currently registered for direct application to beef cattle, for flea control in dogs and as a vertebrate poison for the control of birds. Direct application to animals and use as a vertebrate poison are not considered in this report.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) must be satisfied that the use of fenthion 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 would not be likely to have an effect that is harmful to human beings. This report considers the residues data submitted to support the currently approved uses of fenthion in food producing situations, with the exception of direct application to livestock, and the dietary exposure of consumers to fenthion residues.

1.1 Label and maximum treatment regime

The current maximum use patterns for fenthion are presented below.

Lebaycid Insecticide Spray, product no. 32996 (550 g/L fenthion)

CROP	PEST	RATE	CRITICAL COMMENTS
CROP USAGE			
Apples, pears	Fruit fly, codling moth, light brown apple moth	95 or 150 mL/100 L	Apply 3 weeks and 2 weeks before harvest if signs of fly strike are seen.
Citrus	Mediterranean/ Queensland fruit fly	75 or 150 mL/100 L	Apply at 3-weekly intervals from sign of first fly strike.
Deciduous fruit	Fruit fly or Rutherglen bug	75 or 95 mL/100 L	Spray when pests are first seen and then when they re-invade.
Figs, fruit trees, grapes, loquats, papaws and pepinos	Fruit fly, wingless grasshopper and yellow peach moth	75 mL/100 L	Varying withholding periods apply. Repeat spray at 2-weekly intervals as required for pepinos.
Persimmons	Thrips, fruit fly, mealy bug	75 or 90 mL/100 L	Apply as cover spray.
Quince	Fruit fly	150 mL/100 L	Apply 3 weeks and 2 weeks before harvest if signs of fly strike are seen.
Stone fruit	Moths and fruit fly	75 - 95 mL/100 L	Apply 3 weeks and 2 weeks before harvest if signs of fly strike are seen.

CROP	PEST	RATE	CRITICAL COMMENTS
Tropical and sub-tropical fruits (inedible peel), and low-chill stone fruit	Fruit fly	75 mL/100 L	Apply at 6, 4, 3, 2 and 1 weeks before harvest.
Capsicums, egg fruit and tomatoes	Fruit fly and mealybug	75 mL/100 L or 750 mL/ha	Repeat every 14 days.
POST-HARVEST			
Tropical and sub-tropical fruits (inedible peel), fruiting vegetables (including cucurbits) but excluding hollow-fruited capsicums and chilies	Fruit fly	75 mL/100 L	Dip fruit for 1 minute.
Hollow-fruited capsicums and chilies	Fruit fly	75 mL/100 L	Flood spray ONLY with 16 L spray per minute per m^2 over fruit for a minimum of 10 seconds, before drying.

HARVEST WITHHOLDING PERIODS

- apples, pears, citrus, deciduous fruit, figs, grapes, loquats, pepinos, quince, tropical and sub-tropical fruits, eggfruit, tomatoes: 7 days
- papaws, guavas: 14 days
- stone fruit: 3 days
- post-harvest treatment: nil.

Home garden uses

Lebaycid Fruit Fly and Insect Killer, product no. 61308 (80 g/L Fenthion)

CROP	PEST	RATE	CRITICAL COMMENTS
CROP USAGE			
Peach, plum, nectarine, apricot and other stone fruit; grapes; tropical fruit such as avocado, custard apple, kiwifruit, mango, persimmons	Fruit fly	5 mL per 1 L of water	Spray trees and fruit thoroughly 6, 4, 3, 2 and 1 weeks before picking.
Tomatoes			Spray when first fruit changes colour from dark green to light green. Spray again every 2 weeks.
Apples, pears, quince, citrus		10 mL per 1 L of water	Spray trees and fruit thoroughly 6, 3 and 2 weeks before picking.
Stone fruit	Oriental fruit moth	6.25 mL per 1 L of water	Starting late October, spray trees thoroughly every 2 weeks until 2 weeks before picking.
Apples, pears	Codling moth		

CROP	PEST	RATE	CRITICAL COMMENTS
Tomatoes, capsicums, eggplants, other vegetables	Aphids, thrips, bugs, caterpillars, grasshoppers, crickets	5 mL per 1 L of water	Spray plants thoroughly when pests are seen.

WITHHOLDING PERIOD

Do not pick stone fruit for 3 days after spraying.

Do not pick all other edible plants for 7 days after spraying.

1.2 Permits current for the use of fenthion on food crops

Permits current at 1 March 2012

Permit 10455, expires 30 September 2013

Lebaycid Insecticide Spray containing 550 g/L fenthion as its only active constituent.

CROP	INSECT PEST	RATE	CRITICAL COMMENTS
Olive nursery stock: Quarantine treatment for stock exported to Western Australia	Olive lace bug (*froggattia olivinia*)	Apply at 75 mL product per 100 L water	Use commercial wetting agents according to label directions. Apply thoroughly via boom spray or hand-held lance and spray to point of run-off. Retreatment interval: Plants must have a second treatment within 10 to 18 days. This second treatment to be applied either on arrival in Western Australia or immediately pre-import. Product must not be applied to nursery stock bearing fruit.

Permit 11306, expired 30 June 2012

Lebaycid Insecticide Spray plus other registered products containing 550 g/L fenthion as their only active constituent (Permit 11306 also allows the application of various other insecticides).

CROP	PEST	RATE	CRITICAL COMMENTS
Apple	Apple looper (*Phrissogonus laticostata)*	95 mL/100 L	Apply as per label directions for lightbrown apple moth.

WITHHOLDING PERIOD

DO NOT harvest for 7 days after application.

Permit 12483, expires 30 September 2012

Lebaycid Insecticide Spray plus other registered products containing 550 g/L fenthion as their only active constituent.

CROP	PEST	RATE	CRITICAL COMMENTS
Grapevines	Queensland fruit fly (*Bactrocera tryoni*)	Apply at a rate of 75 mL product per 100 L of water	Apply a thorough cover spray 6 and 4 weeks prior to harvest.

WITHHOLDING PERIOD

DO NOT apply later than 7 days before harvest.

Permit 12652, expired 31 March 2012

Lebaycid Insecticide Spray containing 550 g/L fenthion as its only active constituent.

CROP	INSECT PEST	RATE	CRITICAL COMMENTS
Tamarillos; Post-harvest quarantine treatment	Mediterranean fruit fly (*Ceratitis capitata*)	Mix at the rate: 90 mL product per 100 L water	Apply as a dip or flood spray at 500 ppm for 60 seconds. Follow the critical comments on the registered label for post-harvest use.

WITHHOLDING PERIOD

Not required when used as directed.

Permit 12857, expired 31 July 2012

Lebaycid Insecticide Spray plus other registered products containing 550 g/L fenthion as their only active constituent.

CROP	PEST	RATE	CRITICAL COMMENTS
Olives	Lace bug, green vegetable bug, Rutherglen bug, Queensland fruit fly, Mediterranean fruit fly	Apply at a rate of 75 mL product per 100 L water	DO NOT apply repeat applications within 60 days of the last application. Lace bug: Monitor trees carefully in October for any signs of the insect or damage. Healthy trees free from moisture stress are much less susceptible to attack. Good irrigation management and mulching will help protect the trees. The product is most effective if applied 7–10 days after the eggs have hatched, normally in October or November. Thorough coverage, especially to under-leaf surfaces where the insect lives, is essential for good control. Green vegetable bug and Rutherglen bug: Monitor fortnightly when flowers and fruit are present. Action levels: 1–5% fruit infested or damaged for fresh fruit, 10–15% on fruit for oil production. Fruit flies (QFF and Med Fly): Refer to product label critical comments for other orchard fruit crops.

WITHHOLDING PERIOD

Harvest: DO NOT harvest for 14 days after application.

Grazing/stockfeed: DO NOT graze or cut treated areas for stockfeed.

Permit 13159, expires 30 June 2015

Lebaycid Insecticide Spray plus other registered products containing 550 g/L fenthion as their only active constituent.

COMMODITIES	PEST	RATE	CRITICAL COMMENTS
Tropical and sub-tropical fruits (inedible peel)[a] Fruiting vegetables[b] (including cucurbits) but excluding capsicums and chillies	Fruit flies (post-harvest)	Apply at a rate of 75 mL/100 L applied as a dip or flood spray	Dip fruit and completely submerge for 1 minute, or apply as a flood spray at a rate of 16 L spray mixture per minute per m^2 over fruit for a minimum of 10 seconds. Ensure fruit remains wet for at least one minute. Drain and allow to air dry.
Capsicums and chillies	Fruit flies (post-harvest)	Apply at a rate of 75 mL/100 L applied as a flood spray only	DO NOT dip hollow capsicums or chillies as dip may enter cavity. These fruits should only be flood sprayed.

a Includes fruits such as avocado, banana, custard apple, guava, kiwifruit, longan, mango, papaya, passionfruit and sapote.

b Includes melons, cucumbers, gherkins, pumpkins, squash, tomatoes and zucchini.

WITHHOLDING PERIOD

Not required when used as directed.

1.3 Current Australian maximum residue limits and residue definitions

The current fenthion maximum residue limits (MRLs) are listed below.

Table 1 of the MRL Standard

COMPOUND		FOOD	MRL (mg/kg)
Fenthion			
FI	0030	Assorted tropical and sub-tropical fruits—inedible peel	5
MO	0812	Cattle, Edible offal of	1
MM	0812	Cattle meat	1
FC	0001	Citrus fruits	2
PE	0112	Eggs	*0.05
FT	0297	Fig	2
VC	0045	Fruiting vegetables, Cucurbits	3
VO	0050	Fruiting vegetables, other than Cucurbits	5
FB	0269	Grapes	2
FT	0336	Guava	2
ML	0106	Milks	T0.2
FT	0305	Olives	T1
OC	0305	Olive oil, crude	T3
FT	0307	Persimmon, Japanese	2
FP	0009	Pome fruits	2
PO	0111	Poultry, Edible offal of	*0.05
PM	0110	Poultry meat	*0.05
MO	0818	Pig, Edible offal of	0.5
MM	0818	Pig meat	0.5
MO	0822	Sheep, Edible offal of	0.2
MM	0822	Sheep meat	0.2
FS	0012	Stone fruits	5

Table 3 of the MRL Standard

COMPOUND	RESIDUE
Fenthion	Sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion.

Table 4 of the MRL Standard

There are currently no entries for fenthion in Table 4 of the MRL Standard.

Table 5 of the MRL Standard

There are currently no entries for fenthion in Table 5 of the MRL Standard.

1.4 International regulatory status

Fenthion is not registered for use on food producing plants in Canada, the European Union, New Zealand or the USA.

The Australian public health standards for fenthion are similar to those of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) but less conservative than those reported for Canada or the USA, as summarised below. The European Union has no published standards for fenthion as it is not listed in the EU as a plant protection chemical.

	ADI (mg/kg bw/day)	ARfD (mg/kg bw)
Australia	0.002 (2000)	0.007 (2004)
Canada (2003)	0.0001	0.002
EU	-	-
JMPR (2000)	0.007	0.01
US EPA (2001 IRED)	0.00007	0.0007

Fenthion was most recently considered by the JMPR in 1995 (periodic review) and 2000. Codex MRLs are established for cherries, citrus fruits, olives and olive oil (virgin) and rice (husked). The JMPR report noted that an acute (short term) dietary risk assessment would be undertaken at the next JMPR periodic review of residues.

2 RESIDUES EVALUATION

2.1 Metabolism

The metabolism of fenthion in plants and animals was evaluated by the JMPR in 1995. No further consideration of fenthion metabolism is required within the scope of this review.

2.2 Analytical methods and storage stability

Analytical methods supplied by Bayer for analysis of fenthion in fruit, vegetable and animal commodities are listed in Chapter 2. Very few of these methods are contemporary. In the recent residue trials conducted by HAL, samples were analysed for residues of fenthion and metabolites fenthion-sulfoxide, fenthion-sulfone, oxon, oxon-sulfoxide and oxon-sulfone by gas chromatography–mass spectrometry (GC-MS). Briefly, samples were homogenised and extracted into organic solvent using sonication. The solvent was evaporated and the aqueous residue partitioned against dichloromethane. The dichloromethane extracts were combined and evaporated before redissolving in acetone. An aliquot was filtered before analysis by GC-MS. The limit of quantitation (LOQ) was 0.01 mg/kg for each analyte. Recoveries from fortified control samples in the HAL trials were acceptable (within 70–110%). Further details of method recoveries can be found with the individual report summaries in the appendices.

Stability of pesticide residues in stored analytical samples

Storage stability of residues has been demonstrated to be satisfactory in a previous evaluation by the 1995 JMPR. In the HAL residue trials submitted, all samples were maintained under freezer conditions before analysis and tested generally within 6 months of collection, with the exception of one trial where the storage interval was up to 9 months. The data are considered to be acceptable.

2.3 Residue definition

There are no proposed changes to the residue definition for fenthion. The present definition of the *sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion* is the same as FAO/WHO Codex Alimentarius Commission (Codex) and reconsideration is not considered necessary at this time.

2.4 Residues in foods and animal feeds

General fruit uses

The Australian good agricultural practice (GAP) for general fruit uses is summarised in the following table.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Deciduous fruit	95 mL/100 L (52 g ai/100 L	7 days	Spray when pests are first seen and repeat when they re-invade.
Fruit trees	75 mL/100 L (41 g ai/100 L)	7 days (stone fruit 3 days)	Apply a full-cover spray if hoppers infest fruit trees.

There were no data presented for deciduous fruits (other than stone fruit) and fruit trees (other than olives, citrus and stone fruits). These general uses are no longer supported, noting that there are acute dietary exposure concerns for various fruit crops as discussed below.

RECOMMENDATION

- The uses of fenthion on deciduous fruits and fruit trees should be deleted.

FC 0001 Citrus fruit

The Australian GAP for citrus fruit is summarised below.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Citrus fruit	75 or 150 mL/100 L (41 or 82 g ai/100 L)	7 days	Apply at 3-weekly intervals from sign of first fly strike.

A fenthion MRL of 2 mg/kg for FC 0001 Citrus fruit is established. Residue data provided for citrus included data for orange and mandarin. The available data for citrus addressing a 7-day withholding period (WHP) and varying pre-harvest interval (PHI) are summarised in Table 1.

Table 1: Residue data for citrus addressing a 7-day WHP

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE	PHI (DAYS)	FENTHION RESIDUE (WHOLE FRUIT) (mg/kg)
Bayer ref. 217, 218	Orange	150 g ai/ha (1 application low-volume aerial)	0	< 0.1, 0.04
			7	< 0.1, 0.06
			14	< 0.1, 0.025
			28	0.02
Bayer ref. 219, 236, 239	Orange	52.5 g ai/ha (1 application low-volume aerial)	0	< 0.01, 0.01, 0.03, 0.09, 0.23, 0.75, 0.98
			3	0.01, 0.02, 0.05, 0.15, 0.18
			7	0.01, 0.15
			14	< 0.01 (2), 0.01, 0.02, 0.04, 0.10, 0.11

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE	PHI (DAYS)	FENTHION RESIDUE (WHOLE FRUIT) (mg/kg)
Bayer ref. 222	Mandarin	375 g ai/ha (1 application low-volume aerial)	0	0.39
			14	0.41
			21	0.26
			28	0.13
			35	0.10
Bayer ref. 220, 221	Mandarin	150 g ai/ha (1 application low-volume aerial)	0	< 0.1, 0.25
			7	< 0.1, 0.22
			14	< 0.1, 0.13
			28	0.08
Bayer ref. 237, 239	Mandarin	52.5 g ai/ha (1 application low-volume aerial)	0	0.02, 0.03, 0.04, 0.04, 0.09
			3	0.02, 0.03, 0.04 (2), 0.08
			7	< 0.01, 0.03
			14	< 0.01, 0.01, 0.02 (2), 0.21

The available trials do not address the current Australian GAP of 41 or 82 g ai/100 L water for high volume application methods. Spray volumes for citrus generally range from 1000 L/ha to 5000 L/ha to give a maximum application rate of 4.1 kg ai/ha (2 kg ai/ha at the lower spray concentration). The highest application rate, on a ground area basis, addressed in the trials was 0.375 kg ai/ha in 20 L/ha of water (aerial application).

Data are not available to support the established fenthion MRL for citrus fruit. Processing data are not available following ground-based application to allow estimation of residues in peel or pulp. Acute dietary exposure estimates based on the established MRL are summarised below.

	MRL (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Oranges	2	900	300	No
Lemons	2	570	55	No
Mandarins	2	750	220	No

RECOMMENDATIONS

Data are not available to support the approved use patterns or to refine acute dietary exposure estimates. Acute dietary exposure based on the established MRL is unacceptable for children and the general population.

- The currently approved uses of fenthion on citrus fruits are no longer supported.
- The current MRL for fenthion on FC 0001 Citrus fruits should be deleted.

FP 0009 Pome fruit

The Australian GAP for pome fruit is summarised below.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Apples, pears	95–150 mL/100 L (52–82 g ai/100 L)	7 days	Apply 3 weeks and 2 weeks before harvest if signs of flystrike are seen.
Loquats	75 mL/100 L (41 g ai/100 L)	7 days	Frequent protective sprays are necessary to prevent fruit loss.
Quince	150 mL/100 L (82 g ai/100 L)	7 days	Apply 3 weeks and 2 weeks before harvest if signs of flystrike are seen.

There were no residues data submitted for apples and pears, loquats and quince. Data are not available to support the established fenthion MRL for pome fruits. Acute dietary exposure estimates based on the established MRL are summarised below.

	MRL (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Apple	2	950	300	No
Pear	2	1000	300	No
Loquats	2	1050	270	No
Quince	2	1900	510	No

RECOMMENDATIONS

Data are not available to support the approved use patterns or to refine acute dietary exposure estimates. Acute dietary exposure based on the established MRL is unacceptable for children and the general population.

- The currently approved uses of fenthion on pome fruits are no longer supported.
- The current MRL for fenthion on FP 0009 Pome fruits should be deleted.

FS 0012 Stone fruit

The Australian GAP for stone fruit is summarised below.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Stone fruit	75–95 mL/100 L (41–52 g ai/100 L)	3 days	Apply every 2–3 weeks during the period of moth activity. Use higher rate for heavy infestations.

Note: Low-chill varieties of stone fruit may have five treatments at 75 mL/100 L at 7-day intervals.

An MRL of 5 mg/kg for fenthion on FS 0012 Stone fruit is currently established. Data addressing the Australian GAP for stone fruit are summarised in Table 2.

Table 2: Residue trials addressing the common GAP for stone fruit

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	PHI (DAYS)	FENTHION RESIDUE (mg/kg)
07-HAL-005(a)GLP; Volume 2; Part b	Peach	41.3 g ai/100 L (1–5 applications)	0	2.24, 3.15
			3	1.02[a], 2.29[b]
			5	1.73
			7	0.57, 0.97, 1.25
			14	0.31
			21	0.16
	Nectarine	41.3 g ai/100 L (1–5 applications)	0	1.18, 2.12, 2.24
			3	0.56[a], 1.07[a], 1.52
			5	1.03
			7	0.19, 0.36, 0.50, 0.86, 0.87
			14	0.09, 0.19
			21	< 0.01, 0.05
	Cherry	41.3 g ai/100 L (1–3 applications)	0	1.74, 2.36, 3.05
			3	0.79
			7	0.32, 0.47[a], 0.61[a], 0.73, 1.16
			14	0.10, 0.27, 0.32
			21	0.08

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	PHI (DAYS)	FENTHION RESIDUE (mg/kg)
Bayer ref. 211, 212, 213, 214	Cherry	25–55 g ai/100 L (1 application)	0	0.03, 4.6, 4.75, 5.05, 5.4
			1	2.4, 4.8
			4	1.4, 1.8
			5	0.02
			7	0.65, 0.66, 0.95 (2), 0.99, 1.25
			8	< 0.01, 0.6, 0.8
			9,10	0.3, 0.5, 0.55, 0.9
			14	0.32, 0.35, 0.5, 0.55, 0.6, 0.65, 0.8, 1.0
			15	< 0.01
			21	< 0.01
Bayer ref. 215	Peach	62.5 g ai/100 L (1 application)	0	4.75
			7	2.1
			14	1.1
			21	0.435
			29	0.225
			35	0.105
Bayer ref. 226, 247	Peach	41 g ai/100 L (5 applications, 7 days apart)	0	1.81, 2.11, 2.9
			1	3.0
			3	1.39, 1.41, 2.3[†]
			4	2.3
			7	0.57, 0.74, 3.8
			14	0.39, 1.46
Bayer ref. 248	Plum	41 g ai/100 L (5 applications, 7 days apart)	0	1.7
			1	2.6
			3	1.1
			4	1.3
			7	1.2

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	PHI (DAYS)	FENTHION RESIDUE (mg/kg)
Bayer ref. 225, 249	Nectarine	41 g ai/100 L (5 applications, 7 days apart)	0	0.51, 0.76, 1.2
			1	1.4
			3	0.33, 0.50, 0.60
			4	0.4
			7	0.21, 0.37, 0.5
			14	0.11, 0.14

a Residues following a single application

b Residues underlined are the significant residues after the withholding period

† A residue of 3.8 mg/kg was recorded at 7 days after last application in this trial, but was not consistent with the residues at shorter WHPs in the same trial. Similarly the residue of 1.46 mg/kg at 14 days after application was not consistent with other residues in the same trial. These observations were not used in the dietary exposure assessment.

Residues observed in stone fruit in the trials addressing GAP (noting that the highest label rate is 52 g ai/100 L, which is within ± 25% of the trial rate) were 0.33, 0.50, 0.56, 0.60, 0.79, 1.02, 1.07, 1.16, 1.3, 1.39, 1.4, 1.41, 1.52, 1.8, 2.29 and 2.3 mg/kg.

Outcomes of the acute dietary exposure estimates for stone fruit are summarised below.

	OBSERVED HR (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Peach	2.3	1030	360	No
Nectarine	1.5	630	270	No
Cherry	1.8	420	70	No
Plum	1.3	470	160	No

HR = High residue

Some trial data were available following a single application of fenthion. Acute exposure estimates for children were also unacceptable for data generated following a single application of fenthion at a 3-day withholding period.

RECOMMENDATIONS

Acute dietary exposure estimates for the currently approved use of fenthion on stone fruit are unacceptable.

- The currently approved uses of fenthion on stone fruits are no longer supported.
- The MRL for fenthion on FS 0012 Stone fruit should be deleted.

FB 0269 Grapes

The Australian GAP for grapes is summarised below.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Grapes	75 mL/100 L (41 g ai/100 L)	7 days	Spray when pest is present.

An MRL of 2 mg/kg for fenthion on FB 0269 Grapes is established. Data addressing the Australian GAP for grapes are summarised in Table 3.

Table 3: Residue data addressing the common GAP for grapes

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	PHI (DAYS)	FENTHION RESIDUE (mg/kg)
07-HAL-005(a)GLP; Volume 3; Part b	Table grapes	41.3 g ai/100 L (1–3 applications)	0	1.95, 2.05, 3.48
			1	2.06
			3	0.95, 2.42
			5	1.16, 1.73
			6–8	0.47, 0.69, 0.77, 1.21
			14	0.19, 0.31
			20	0.07

Residues in table grapes at 6–8 days after the last application at current label rates were 0.47, 0.69, 0.77 and 1.21 mg/kg. The outcome of the acute dietary exposure assessment for grapes is summarised below.

	OBSERVED TOTAL HR (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Grapes	1.21	580	260	No

RECOMMENDATIONS

Acute dietary exposure estimates for the currently approved use of fenthion on grapes are unacceptable.

- The currently approved use of fenthion grapes is no longer supported.
- The MRL for fenthion on FB 0269 Grapes should be deleted.

FT 0297 Figs

The Australian GAP for figs is summarised below.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Figs	75 mL/100 L (41 g ai/100 L)	7 days	Apply a thorough cover spray 6 weeks and 4 weeks prior to harvest.

No data were submitted to support the use on figs. An MRL of 2 mg/kg for fenthion on FT 0297 Fig is established. Acute dietary exposure estimates based on the established MRL are summarised below.

	MRL	ACUTE EXPOSURE (% OF ARfD)		
	(mg/kg)	2-6 YEARS	> 2 YEARS	USE ACCEPTABLE?
Fig	2	520	105	No

RECOMMENDATIONS

Data are not available to support the approved use pattern or to refine acute dietary exposure estimates. Acute dietary exposure based on the established MRL is unacceptable for children and the general population.

- The currently approved uses of fenthion on figs are no longer supported.
- The current MRL for fenthion on FT 0297 Fig should be deleted.

FT 0305 Olives

Fenthion can be used in-field on fruit trees (including olives) at a rate of 41 g ai/100 L as summarised below.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Fruit trees (label)	75 mL/100 L (41 g ai/100 L)	7 days	Apply a full-cover spray if hoppers infest fruit trees.
Olives (permit)	75 mL/100 L (41 g ai/100 L)	14 days	DO NOT apply repeat applications within 60 days of the last application.

Temporary fenthion MRLs of T1 mg/kg for FT 0305 Olives and T3 mg/kg for OC 0305 Olive oil, crude are established. Residue data for fenthion on olives were supplied by Bayer. Additional data were available from the 1995 JMPR and the evaluation for permit 8560. A summary of the available residue data for olives is given in Table 4.

Table 4: Summary of the available residue data for olives

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	PHI (DAYS)	FENTHION RESIDUE (mg/kg)
Bayer ref. 157 (Italy)	Olives	200 g ai/100 L (3–5 applications, 8–38 days apart)	0	1.98, 3.23
			11	1.25, 2.86
			20	1.18, 2.96
			34	0.99, 2.57
			54	0.66, 1.78
Permit 8560 (Australian)	Olives	41 g ai/100 L (4 applications, 14 days apart)	14	5.96
			21	6.71 (6.46)
1995 JMPR (Italy)	Olives	50 g ai/100 L (2 applications)	0	0.86, 0.93, 1.7
			14	0.39, 0.84, 0.92
			28	0.26, 0.36, 0.87
Food additives and Contaminants, 1998, 15, 518–527 (Italy)	Olives	500 g ai/ha (1–3 applications)	0	0.65. 1.54, 1.78
			14	0.18, 0.39
			18	0.67
			28	0.08, 0.14, 0.40
			50	0.15
			60	0.08
			80	0.01
			90	0.02

The following processing factors were determined for olives to crude oil:

PROCESSING FACTORS	REFERENCE
3.2, 3.3, 3.3, 5.2, 5.5	Cavanna S & Molinari GP (1998). Residues of fenthion and trichlorofon in olives and olive oil after olive tree treatments. Food Additives and Contaminants 15(5): 518-527.
1.5, 1.8, 2, 2.2, 2.8, 3.2, 3.6, 5.2, 6, 6.6	JMPR 1995 (various trials; includes Cabras et al. 1993)
Mean = 3.7, Median = 3.3	

The available data for olives do not address the currently approved label withholding period of 7 days for fruit trees.

The currently approved permit is for a 14-day withholding period with reapplication at intervals no shorter than 60 days. Residues data resulting from the permit use were 0.18, 0.39 (2), 0.84 and 0.92 mg/kg. Outcomes of the acute dietary exposure assessment for olives based on the permit use are summarised below. The HR in oil was calculated using the olive HR × the median processing factor (0.92 × 3.3).

	OBSERVED TOTAL HR (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Olives	0.92	140	30	No
Olive oil, crude	3	150	25	No

The use of fenthion on olive nursery stock is approved by permit (10455) as summarised below.

CROP	INSECT PEST	RATE	CRITICAL COMMENTS
Olive nursery stock: Quarantine treatment for stock exported to Western Australia	Olive lace bug (*froggattia olivinia*)	Apply at 75 mL product per 100 L water	Use commercial wetting agents according to label directions. Apply thoroughly via boom spray or hand-held lance and spray to point of run-off. Retreatment interval: Plants must have a second treatment within 10 to 18 days. This second treatment to be applied either on arrival in Western Australia or immediately pre-import. Product must not be applied to nursery stock bearing fruit.

Residues are not expected to arise in olives or olive oil as a result of this use. A fenthion MRL of *0.01 mg/kg for FT 0305 Olives is appropriate for this use.

RECOMMENDATIONS

Data are not available to support the approved (label, as fruit) use pattern or to refine acute dietary exposure estimates. The acute dietary exposure estimate for the in-field permit use, based on a limited data set, is unacceptable for children.

- The currently approved label and permit uses of fenthion in-field on olives are not supported.
- The currently approved use on nursery stock continues to be supported.
- The MRLs of T1 mg/kg for fenthion on FT 0305 Olives and T3 mg/kg for fenthion on OC 0305 Olive oil, crude should be deleted.
- A fenthion MRL of *0.01 mg/kg for FT 0305 Olives should be established.

FT 0307 Persimmon, Japanese

The Australian GAP for persimmons is summarised below.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Persimmons	75–90 mL/100 L (41–49.5 g ai/100 L)	7 days	Apply as a cover spray as required.

A fenthion MRL of 2 mg/kg for FT 0307 Persimmon, Japanese is established. Data addressing the Australian GAP for persimmons are summarised in Table 5.

Table 5: Residue data addressing the common GAP for persimmons

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	PHI (DAYS)	FENTHION RESIDUE (mg/kg)
07-HAL-005(a)GLP; Volume 4; Part b	Persimmon	41.3 g ai/100 L (1–3 applications)	0	1.88, 2.37
			3	1.65
			5	1.21
			7–8	0.37, 0.68, 0.84
			11	0.31
			14	0.17
			21	0.06
NSW Agriculture and Fisheries Report, 1989	Persimmon	41 g ai/100 L (4–5 sprays)	0	†2.28
			1	†0.46
			3	†0.36
			5	†0.24
			7	†0.36
			14	†0.06

† Trial determined fenthion residues only—metabolites not included.

Residues of fenthion in persimmons in the trials addressing GAP (noting that the highest label rate is 49.5 g ai/100 L) were 0.36, 0.37, 0.68 and 0.84 mg/kg. Outcomes of the acute dietary exposure estimates for persimmons are summarised below.

	OBSERVED TOTAL HR (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Persimmon	0.84	230	50	No

RECOMMENDATIONS

Acute dietary exposure estimates for the currently approved use of fenthion on Persimmon are unacceptable.

- The currently approved use of fenthion on persimmons (edible peel) is no longer supported.
- The MRL for fenthion on FT 0307 Persimmon, Japanese should be deleted.

FI 0030 Assorted tropical and sub-tropical fruits—inedible peel

Tropical and sub-tropical fruits (inedible peel) may receive pre- and post-harvest treatments with fenthion. The currently approved Australian GAP for each treatment is summarised below.

Pre-harvest

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Tropical and sub-tropical fruits (inedible peel)	75 mL/100 L	7 days (except guava and papaws 14 days)	Tropical and sub-tropical fruits (inedible peel) include avocado, banana, breadfruit, custard apple, durian, feijoa, guava, jackfruit, kiwifruit, lychee, longan, mango, mangosteen, papaw, passionfruit, persimmon, pineapple, pomegranate, rambutan, sapodilla, sapote, tamarind. Thorough spray coverage of fruit is essential. Apply at 6, 4, 3, 2, and 1 week before the expected start of harvest.

Post-harvest

CROP	RATE	WITHHOLDING PERIOD	CRITICAL USE COMMENTS
Tropical and sub-tropical fruit (inedible peel)	75 mL/100 L (41 g ai/100 L)	Nil	Dip fruit and completely submerge for 1 minute. Drain and allow to air dry *or* Apply as a flood spray of 16 L spray mixture per minute per m^2 over fruit for a minimum of 10 seconds, then ensure fruit remains wet for at least 1 minute.
Tamarillo (post-harvest quarantine treatment under permit)	90 ml/100 L (50 g ai/100 L)	Nil	Apply as a dip or flood spray for 60 seconds. Follow the critical comments on the registered label for post-harvest use.

Note: Tamarillos were previously classified by Codex as having edible peel. However, tamarillos are considered to have inedible peel as per Codex-CX/PR11/43/6-February 2011, which proposes to place Tamarillo under subgroup 006B 'Miscellaneous fruits—inedible smooth peel—large'.

A fenthion MRL of 5 mg/kg for on FI 0030 Assorted tropical and sub-tropical fruits—inedible peel is established.

Data for the pre-harvest treatment of avocado, custard apple, kiwifruit and mango were previously provided to the APVMA. However, analyses did not include metabolites and were for the parent compound only. The data did not address the residue definition, which includes five metabolites. Furthermore, there were no data that examined the distribution of residues between the pulp and the peel. The data are summarised in Table 6.

Table 6: Residue data addressing the common pre-harvest GAP for tropical and sub-tropical fruit (inedible peel)

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	PHI (DAYS)	FENTHION RESIDUE (PARENT ONLY/WHOLE FRUIT) (mg/kg)
NSW Agriculture and Fisheries Report, 1989	Avocado	41 g ai/100 L (4–5 sprays)	0	0.31
			1	0.25
			3	0.04
			5	0.01
			7	0.01
			14	< 0.01
	Custard apple	41 g ai/100 L (4–5 sprays)	0	1.16
			1	0.67
			3	0.43
			4	0.50

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	PHI (DAYS)	FENTHION RESIDUE (PARENT ONLY/WHOLE FRUIT) (mg/kg)
			7	0.15
			14	0.07
	Kiwifruit	41 g ai/100 L (4–5 sprays)	0	5.51
			1	4.60
			3	2.61
			5	1.96
			7	1.51
			16	0.56
	Mango	41 g ai/100 L (4–5 sprays)	0	0.61
			1	0.45
			3	0.36
			5	0.36
			7	0.30

Residues data are not available that address the residue definition for fenthion to allow the recommendation of an appropriate MRL or to allow the estimation of acute dietary exposure resulting from the currently approved use. Continued use pre-harvest use of fenthion on FI 0030 Assorted tropical and sub-tropical fruits—inedible peel cannot be supported.

Data on the post-harvest treatment of tropical and sub-tropical fruits (inedible peel) have been provided for the review. These data are summarised in Table 7.

Table 7: Residue data addressing the common post-harvest GAP for tropical and sub-tropical fruit (inedible peel)

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	DAT* (DAYS)	FENTHION RESIDUE (mg/kg)	
				WHOLE FRUIT	PULP
07-HAL-005(b)GLP; Volume 3; Part b	Avocado	41.25 g ai/100 L dip	0	0.88, 0.97, 1.05, 1.29	0.03 (2), 0.05, 0.07
	Custard apple	41.25 g ai/100 L dip	0	1.58, 2.71	0.02, 0.06
	Mango	41.25 g ai/100 L dip	0	1.30, 1.51	0.07, 0.09
	Papaya	41.25 g ai/100 L dip	0	–	0.03, 0.05

From permit 2934	Tamarillo	500 ppm dip (= 50 g ai/100 L)	0	†0.09, 0.07
			2	†0.06, 0.05
			4	†0.06, 0.07
			8	†0.07, 0.06

† Pin-pricked tamarillos.

*DAT = Days after treatment

Outcomes of the acute dietary exposure assessment based on the edible portion residues in the post-harvest trials are summarised below.

	OBSERVED TOTAL HR (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Avocado	0.07 (pulp)	50	10	Yes
Custard apple	0.06 (pulp)	60	15	Yes
Mango	0.09 (pulp)	30	15	Yes
Papaya	0.05 (pulp)	60	15	Yes
Tamarillo	0.09	25	5	Yes

Acute dietary exposure estimates for the post-harvest use of fenthion on FI 0030 Assorted tropical and sub-tropical fruits—inedible peel are acceptable. The currently established MRL of 5 mg/kg for fenthion on FI 0030 Assorted tropical and sub-tropical fruits—inedible peel remains appropriate for the post-harvest use.

It is noted that Tamarillo is currently classified as FT (edible peel) by Codex. However, in Australia it is considered to have inedible peel. Codex are proposing to place Tamarillo in a new 'Miscellaneous fruits, inedible smooth peel, large' sub-group of *Assorted tropical and sub-tropical fruits—inedible peel* (as per Codex CX/PR11/43/6, February 2011).

RECOMMENDATIONS

- The currently approved pre-harvest treatment of tropical and sub-tropical fruits—inedible peel is not supported as data are not available to confirm MRLs or to allow estimation of acute dietary exposure as a result of the use.
- The currently approved uses for post-harvest dipping of tropical and sub-tropical fruits—inedible peel continue to be supported.
- The currently established MRL for fenthion on FI 0030 Assorted tropical and sub-tropical fruits—inedible peel remains appropriate.
- The MRL for FT 0336 Guava should be deleted as it will be covered by the FI 0030 Assorted tropical and sub-tropical fruits—inedible peel MRL.

VC 0045 Fruiting vegetables, Cucurbits

Cucurbits may receive a post-harvest treatment with fenthion. The currently approved Australian GAP is summarised below.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Fruiting vegetables (including cucurbits)	75 mL/100 L (41 g ai/100 L)	Nil	Dip fruit and completely submerge for 1 minute. Drain and allow to air dry *or* Apply as a flood spray of 16 L spray mixture per minute per m^2 over fruit for a minimum of 10 seconds, then ensure fruit remains wet for at least 1 minute.

A fenthion MRL of 3 mg/kg for VC 0045 Fruiting vegetables, Cucurbits is established. Data covering the post-harvest treatment of rockmelon, cucumber and zucchini have been provided for review. It is noted that the rockmelon trials determined residues only in the edible portion and not in the whole fruit. The available data are summarised in Table 8.

Table 8: Residue data addressing the post-harvest GAP for cucurbits

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	DAT (DAYS)	FENTHION RESIDUE (mg/kg)
09-HAL-017GLP	Cucumber	42 g ai/100 L dip	0	1.35, 2.67, 3.40, 5.12
			3	1.79, 1.97
			5	0.98, 1.15
			7	0.22, 0.40
	Zucchini	42 g ai/100 L dip	0	0.73, 1.96, 2.10, 2.17, 3.24
			3	0.83, 1.09
			5	0.34, 0.44
			7	0.17, 0.23
07-HAL-005(b)GLP;Volume 4; Part b	Rockmelon	41 g ai/100 L dip	0	0.02, 0.04, 0.06 (residues in pulp only)

Outcomes of the acute dietary exposure assessments for cucurbits are summarised below.

	OBSERVED TOTAL HR (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Cucumber	5.12	1200	420	No

Zucchini	3.24	990	280	No
Melon, except watermelon	0.06 (pulp)	50	20	No

Acute dietary exposure estimates are unacceptable for cucumbers and zucchini and, by extrapolation, cucurbits other than melons. On the basis of the available data, the use on melons is acceptable; however, three trials are not adequate for a robust acute dietary exposure assessment. Additionally, the data for rockmelon are inappropriate for confirmation of MRLs as residues were not determined on a whole-fruit basis.

RECOMMENDATIONS

- The current approved post-harvest uses of fenthion on cucurbits is no longer supported:
  - for cucurbits generally (other than melons) based on unacceptable acute dietary exposure estimates for children and the general population for cucumber and zucchini
  - for melons, as the data set is not suitable for robust dietary exposure estimates or for MRL establishment.
- The current MRL for fenthion on VC 0045 Fruiting vegetables, cucurbits should be deleted.

VO 0050 Fruiting vegetables, other than Cucurbits

Other fruiting vegetables may receive pre- and post-harvest treatments with fenthion. The currently approved Australian GAP is summarised below.

Pre-harvest

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Capsicums, eggfruit and tomatoes	75 mL/100 L or 750 mL/ha (41 g ai/100 L or 410 g ai/ha)	7 days	Repeat every 14 days.
Pepino	75 mL/100 L (41 g ai/100 L)	7 days	Repeat spray at 2-weekly intervals.

Post-harvest

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Fruiting vegetables excluding hollow-fruited capsicums or chilies	75 mL/100 L (41 g ai/100 L)	Nil	Dip fruit and completely submerge for 1 minute. Drain and allow to air dry *or* Apply as a flood spray of 16 L spray mixture per minute per m^2 over fruit for a minimum of 10 seconds, then ensure fruit remains wet for at least 1 minute.
Hollow-fruited capsicums or chilies			Flood spray only.

A fenthion MRL of 5 mg/kg for VO 0050 Fruiting vegetables other than Cucurbits is established. Available residue data addressing the pre-harvest GAP for other fruiting vegetables are summarised in Table 9. Residue data addressing the post-harvest GAP are summarised in Table 10.

Table 9: Residue data addressing the pre-harvest GAP for other fruiting vegetables

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	PHI (DAYS)	FENTHION RESIDUE (mg/kg)
07-HAL-005(a)GLP; Volume 9; Part b	Tomato	41.3 g ai/100 L (3 applications)	0	1.09, 1.65
			3	0.59, 1.28
			7	0.53, 0.76, 0.95
			14–15	0.18, 0.51
	Eggplant	41.3 g ai/100 L (3 applications)	1	1.12, 1.69
			3–4	0.74, 1.13
			5–6	0.28, 0.35
			7	0.23, 0.36
	Capsicum	41.3 g ai/100 L (3 applications)	0	0.28, 0.35, 0.64, 1.03
			3	0.24, 0.37, 0.41, 0.57
			7	0.05, 0.09, 0.13, 0.24
			14	0.02, 0.03, 0.04, 0.07

Table 10: Residue data addressing the post-harvest GAP for other fruiting vegetables

TRIAL AND STUDY REFERENCE	COMMODITY	APPLICATION RATE (g ai/100 L)	DAT (DAYS)	FENTHION RESIDUE (mg/kg)
09-HAL-017GLP	Capsicum	42 g ai/100 L dip	0	1.06, 1.09, 1.79, 2.06, 2.29, 6.01
			3	1.53, 2.47
			5	0.50, 1.40
			7	0.33, 0.36
	Eggplant	42 g ai/100 L dip	0	1.30, 3.97
			3	2.16
			5	0.99
			7	0.29
Australian Journal of Experimental Agriculture (1987)	Tomato	40 g ai/100 L dip	0	†1.2, †1.3
			3	†0.83, †1.1

27:465–469	7	†0.58, †1.1

† Trial determined fenthion residues only–metabolites not included.

No trials to determine residues after combined pre- and post-harvest treatment were available. It is also noted that the available data for the post-harvest treatment of tomatoes have limited value as residues were determined as parent only.

Outcomes of the acute dietary exposure assessments for pre-harvest uses are summarised below.

	OBSERVED TOTAL HR (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Tomato (pre-harvest)	0.95	300	120	No
Eggplant (pre-harvest)	0.36	140	90	No
Capsicum (pre-harvest)	0.24	†30	15	No (see text)

† Only four pre-harvest capsicum trials are available—if the HR of 0.95 mg/kg for the tomato trials is used the exposure is 130% of the ARfD for children.

Acute dietary exposure estimates are unacceptable for pre-harvest uses of fenthion on tomato and eggplant. For capsicum, although the acute dietary exposure estimates are acceptable based on the available data, adequate data are not available for a robust assessment. The use on capsicum cannot be supported without additional data to confirm the acute dietary exposure assessment and to allow MRL establishment. No data are available for pre-harvest treatment of pepinos. This use is no longer supported, given that pre-harvest uses on tomatoes, capsicums and eggplant are also not supported.

Outcomes of the acute dietary exposure assessments for post-harvest uses are summarised below.

	OBSERVED TOTAL HR (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		USE ACCEPTABLE?
		2-6 YEARS	> 2 YEARS	
Tomato (post-harvest)	1.3	415	170	No
Capsicum (post-harvest)	6.01	810	360	No
Chilies (post-harvest, capsicum data)	6.01	20	50	No (see text)
Eggplant (post-harvest)	3.97	1500	950	No

Acute dietary exposure estimates for the post-harvest use of fenthion are unacceptable for tomatoes, capsicum and eggplant. For chilies, the use is acceptable on the basis of the capsicum residue data. However, residues data for capsicums may underestimate the residue on smaller chili peppers and the use cannot be supported in the absence of specific data for chili.

RECOMMENDATIONS

- The currently approved pre- and post-harvest uses on other fruiting vegetables are no longer supported owing to unacceptable estimates of acute dietary exposure.
- The MRL for fenthion on VO 0050 Fruiting vegetables other than Cucurbits should be deleted.

Use in the home garden

Fenthion is approved for use in the home garden on a number of crops grown in these situations. Owing to concerns over acute (short-term) dietary exposure to fenthion residues identified in commercial situations, the following approved home garden uses can no longer be supported:

- peach, plum, nectarine, apricot and other stone fruit
- grapes
- apples, pears, quince
- citrus
- tomatoes, eggplants and other vegetables

2.5 Animal transfer studies and required animal commodity MRLs

The direct treatment of livestock with fenthion will not be considered as part of the review of the horticultural uses of fenthion. It is also noted that the pig and sheep MRLs appear to be related to direct treatments for these animals, which are no longer current[1].

Of the horticultural crops that continue to be supported, none are considered to be significant animal feeds.

In an animal transfer study, various levels of fenthion were fed to cattle, ranging from 25 ppm to 100 ppm, and also from 0.075 mg/kg bw/day to 0.75 mg/kg bw/day. Detectable residues did not occur in the tissues and milk for treatment at 0.225 mg/kg bw/day, which for a 500 kg animal eating 20 kg dry matter is considered to be equivalent to 5.6 ppm in the total feed an animal consumes. The following animal commodity MRLs would be appropriate in relation to the supported horticultural uses:

MO 0105	Edible offal (mammalian)	*0.05 mg/kg
MM 0095	Meat [mammalian]	*0.05 mg/kg
ML 0106	Milks	*0.01 mg/kg

[1] There are no current registrations of fenthion as a veterinary treatment for pigs or sheep. Previous use patterns for pasture (circa 1981) are not currently approved

No changes are required to the current poultry commodity MRLs, each established at *0.05 mg/kg.

RECOMMENDATIONS

- The horticultural uses of fenthion do not require any changes to the animal commodity MRLs, which were established to cover direct treatments of livestock.
- MRLs of *0.05, *0.05, *0.01 mg/kg for MO 0105 Edible offal (mammalian), MM 0095 Meat [mammalian] and ML 0106 Milks respectively would be appropriate in relation to the supported horticultural uses.
- The poultry commodity MRLs each at *0.05 mg/kg remain appropriate in relation to the supported horticultural uses.

3 DIETARY RISK ASSESSMENT

The following health standards have been recommended by the Office of Chemical Safety, Department of Health and Ageing and were reported in the Preliminary Review Findings of the APVMA review of fenthion in 2005.

COMPOUND	DIETARY STANDARD, mg/kg bw		NOEL mg/kg bw	SAFETY FACTOR	REFERENCE
Fenthion	ADI[2]	0.002	0.02	10	OCS, 30/4/2004
	ARfD[3]	0.007	0.07	10	OCS, 19/10/2000

NOEL = No Observable Effect Level

The ADI for fenthion was recommended by the Advisory Committee on Pesticides and Health in 1997. At its 20th meeting the committee affirmed the fenthion ADI of 0.002 mg/kg bw/d based on a NOEL for plasma cholinesterase (ChE) inhibition of 0.02 mg/kg bw/d in a human study, supported by a monkey study.

The ARfD for fenthion was also recommended at the 20th meeting of the Advisory Committee on Pesticides and Health. The ARfD is based on a NOEL of 0.07 mg/kg bw for red blood cells (RBC) ChE inhibition in a human study and applying a 10-fold safety factor.

3.1 Chronic dietary exposure assessment

The chronic dietary exposure to fenthion is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered and temporary uses of the chemical and the mean daily dietary consumption data derived from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with World Health Organization Guidelines[4] and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for fenthion will be equivalent to 17% of the ADI following the implementation of the recommendations of this review.

It is concluded that the chronic dietary exposure of fenthion is acceptable.

3.2 Acute dietary exposure assessment

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

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

2 <http://www.health.gov.au/internet/main/publishing.nsf/Content/ocs-adi-list.htm>

3 <http://www.health.gov.au/internet/main/publishing.nsf/Content/ocs-arfd-list.htm>

4 World Health Organization (1997). Guidelines for predicting dietary intake of pesticide residues (revised). Geneva: Programme of Food Safety and Food Aid, WHO. <http://www.who.int/foodsafety/publications/chem/en/pesticide_en.pdf>

COMMODITY	RESIDUE FOR ACUTE DIETARY EXPOSURE ASSESSMENT (mg/kg)	% OF ACUTE REFERENCE DOSE		OUTCOME
		2-6 YEARS	2+ YEARS	
FB 0269 Grapes	1.21	580	260	Not supported
FC 0003 Mandarin	2	750	220	Not supported
FC 0004 Orange	2	900	300	Not supported
FC 0204 Lemon	2	570	55	Not supported
FI 0326 Avocado	0.07	50	10	Supported
FI 0332 Custard apple	0.06	60	15	Supported
FI 0345 Mango	0.09	30	15	Supported
FI 0350 Papaya	0.05	60	15	Supported
FP 0226 Apple	2	950	300	Not supported
FP 0230 Pear	2	1000	300	Not supported
FP 0228 Loquat	2	1050	270	Not supported
FP 0231 Quince	2	1900	510	Not supported
FS 0013 Cherries	1.8	420	70	Not supported
FS 0245 Nectarine	1.52	630	270	Not supported
FS 0247 Peach	2.29	1030	360	Not supported
FS 0014 Plum	1.3	470	155	Not supported
FT 0297 Fig	2	520	100	Not supported
FT 0305 Olives	0.92	140	30	Not supported
OC 0305 Olive oil, crude	3	150	25	Not supported
FT 0305 Olives (use on nursery stock)	0.01	< 5	< 1	Supported
FT 0307 Persimmon, Japanese	0.84	230	50	Not supported
FT 0312 Tamarillo	0.09	25	5	Supported
VC 0424 Cucumber	5.12	1200	420	Not supported
VC 0046 Melons, except watermelons	0.06	50	20	Not supported (insufficient data)

COMMODITY	RESIDUE FOR ACUTE DIETARY EXPOSURE ASSESSMENT (mg/kg)	% OF ACUTE REFERENCE DOSE		OUTCOME
		2-6 YEARS	2+ YEARS	
VC 0432 Watermelon	0.06	50	50	Not supported (insufficient data)
VC 0431 Zucchini	3.24	990	280	Not supported
VO 0440 Eggplant (pre-harvest)	0.36	140	90	Not supported
VO 0440 Eggplant (post-harvest)	3.97	1500	950	Not supported
VO 0445 Peppers, sweet (pre-harvest)	0.24	30	15	Not supported (insufficient data)
VO 0445 Peppers, sweet (post-harvest)	6.01	810	360	Not supported
VO 0444 Peppers, chilli (post-harvest)	6.01	20	50	Not supported (insufficient data)
VO 0448 Tomato (pre-harvest)	0.95	300	120	Not supported
VO 0448 Tomato (post-harvest)	1.3	415	170	Not supported

4 RESIDUE-RELATED ASPECTS OF TRADE

None of the commodities for which uses have been supported is considered to be a major export commodity. Uses on citrus, pome fruit and stone fruit have not been supported. The risk to trade as a result of the remaining supported uses is low, given also that the uses have been in place for a number of years.

The overall risk to export trade in animal commodities as a result of the horticultural uses of fenthion is considered to be low as detectable residues are not expected to occur.

5 CONCLUSIONS

Uses no longer supported (acute dietary concerns)

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

USE PATTERN	LABEL USE	PERMIT USE
Eggfruit (pre-harvest use)	✓	-
Fruiting vegetables, all pre-harvest uses (except pre-harvest use on capsicum) and all post-harvest uses (except post-harvest use on chili peppers and melons)	✓	✓
Grapes	✓	✓
Persimmons (edible peel only)	✓	-
Stone fruit	✓	-

Uses no longer supported (no residue data and identified acute dietary concerns)

For the following use patterns, residue data were requested but were not provided to the APVMA. Acute dietary exposure was estimated using the established MRL and indicated that short term exposure to fenthion residues may exceed the reference health standard. The APVMA cannot be satisfied that these uses of fenthion would not be an undue hazard to the safety of people using anything containing its residues and they must be deleted.

USE PATTERN	LABEL USE	PERMIT USE
Apples and pears	✓	✓ (Apples only)
Deciduous fruits	✓	-
Figs	✓	-
Fruit trees	✓	-
Loquats	✓	-
Olives (except olive nursery stock)	-	✓
Pepino	✓	-
Quince	✓	-

Uses no longer supported (insufficient data and acute dietary concerns)

For the following use patterns, available residue data did not match GAP. Assessment of acute dietary risk using the MRL indicate that short term exposure to fenthion residues may exceed the reference health standard. The APVMA cannot be satisfied that these uses of fenthion would not be an undue hazard to the safety of people using anything containing its residues and they must be deleted:

USE PATTERN	LABEL USE	PERMIT USE
Citrus fruits	✓	-

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.

USE PATTERN	LABEL USE	PERMIT USE
Capsicums, pre-harvest use	✓	-
Chili peppers, post-harvest use	✓	✓
Melons, post-harvest	✓	✓
Tropical and sub-tropical fruits (inedible peel), pre-harvest uses including papaw	✓	-

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.

USE PATTERN	LABEL USE	PERMIT USE
Olives (treatment of nursery stock)	-	✓
Tropical and sub-tropical fruit (inedible peel), all post-harvest uses (including tamarillo under permit)	✓	✓

Home garden use

Fenthion is approved for use in the home garden on a number of crops grown in these situations. Owing to concerns over acute (short-term) dietary exposure to fenthion residues identified in commercial situations the following approved home garden uses can no longer be supported:

- peach, plum, nectarine, apricot and other stone fruit
- grapes

- apples, pears, quince
- citrus
- tomatoes, eggplants and other vegetables.

5.1 Amendments to the APVMA MRL Standard

The following amendments to Table 1, Table 4 and Table 5 of the MRL Standard are recommended.

Amendments to Table 1 of the MRL Standard

COMPOUND		FOOD	MRL (mg/kg)
Fenthion			
DELETE			
FC	0001	Citrus fruits	2
FT	0297	Fig	2
VC	0045	Fruiting vegetables, Cucurbits	3
VO	0050	Fruiting vegetables, other than Cucurbits	5
FB	0269	Grapes	2
FT	0336	Guava	2
FT	0305	Olives	T1
OC	0305	Olive oil, crude	T3
FT	0307	Persimmon, Japanese	2
FP	0009	Pome fruits	2
FS	0012	Stone fruits	5
ADD			
MO	0105	Edible offal (Mammalian)	*0.05
MM	0095	Meat [mammalian]	*0.05
ML	0106	Milks	*0.01
FT	0305	Olives	*0.01

Following implementation of these changes, entries in Table 1 of the MRL Standard for fenthion will be as follows:

Table 1 of the MRL Standard

COMPOUND		FOOD	MRL (mg/kg)
Fenthion			
FI	0030	Assorted tropical and sub-tropical fruits—inedible peel	5
MO	0105	Edible offal (Mammalian)	*0.05
PE	0112	Eggs	*0.05
MM	0095	Meat [mammalian]	*0.05
ML	0106	Milks	*0.01
FT	0305	Olives	*0.01
PO	0111	Poultry, Edible offal of	*0.05
PM	0110	Poultry meat	*0.05

5.2 Dietary exposure

The estimated dietary intake of fenthion arising from residues in food is unlikely to exceed the health standards if the recommendations of this review are put in place.

5.3 Residue related aspects of trade

Use of the product in accordance with the label instructions for the supported uses is unlikely to risk Australian trade as none of the supported uses is a major export commodity.

6 APPENDICES:

6.1 Appendix 1: Dietary exposure calculations

Appendix 1 can be found online at:
http://www.apvma.gov.au/products/review/docs/fenthion_part2_residues_report_appendix_1.xls

6.2 Appendix 2: Technical summary of residues data

Appendix 2 can be found online at:
http://www.apvma.gov.au/products/review/docs/fenthion_part2_residues_report_appendix_2.pdf

ABBREVIATIONS

ADI	Acceptable Daily Intake (for humans)
AGAL	Australian Government Analytical Laboratories (now National Measurement Institute)
ai	active ingredient
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
Bw	Bodyweight
ChE	cholinesterase
Codex	FAO/WHO Codex Alimentarius Commission
DALA	days after last application
DAT	days after treatment
g	gram(g)
GAP	good agricultural practice
GC–MS	gas chromatography–mass spectrometry
GC–MS/MS	gas chromatography–tandem mass spectrometry
GC–NPD	gas chromatography–nitrogen phosphorus detector
GLP	good laboratory practice
GPC	gel permeation chromatography
ha	hectare
HAL	Horticulture Australia Limited
HPLC	high pressure liquid chromatography *or* high performance liquid chromatography
HR	high residue
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOQ	limit of quantitation (the level at which residues can be quantified)
m	metre
mg	milligram
mL	millilitre
MRL	maximum residue limit
NEDI	National Estimated Daily Intake
NESTI	National Estimated Short-Term Intake

NOEL	No Observable Effect Level
NSW	New South Wales
OCS	Office of Chemical Safety in the Australian Government Department of Health and Ageing
PHI	pre-harvest interval
ppm	parts per million
Qld	Queensland
SA	South Australia
SIM	selected ion monitoring
Tas.	Tasmania
UTC	untreated control
Vic.	Victoria
WHP	Withholding period