Australian Government

Australian Pesticides and Veterinary Medicines Authority

FENTHION

SUPPLEMENTARY RESIDUES AND DIETARY RISK ASSESSMENT OF FENTHION

A component of the reconsideration of the active constituent fenthion, registration of products containing fenthion and approvals of their associated labels.

OCTOBER 2013

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Introduction

Fenthion product registrations and label approvals are being reconsidered by the APVMA due to specific concerns about the environment, human health, human exposure, residues and trade.

In October 2012 the APVMA acted to change the instructions for fenthion use in horticulture by suspending two products and issuing interim instructions for use.

This supplementary residues and dietary exposure assessment examines whether these interim instructions are acceptable in light of new information received by the APVMA in July and August 2013.

This assessment has found that the interim use patterns described in permits PER 13840 and PER 13841 could continue on a time limited basis except for the use of fenthion under the general description of Stone fruit.

Continued use in nectarines and plums with a withholding period of 14 days has been assessed as acceptable in all states, with use in peaches and apricots not supported.

The existing use pattern for cherries grown in WA has been assessed as acceptable. The permits should be amended accordingly to remove the ‘Stone fruit’ use and replace it with these recommendations.

1 BACKGROUND

The Fenthion Residues and Dietary Risk Assessment Report was published for public comment in September 2012. The report proposed suspensions based on unacceptable acute dietary risk for children and the general population from residues associated with uses approved at the time.

During the public consultation period a number of alternative uses were proposed by user groups for the control of fruit flies on stone fruit (apricots, nectarines, peach, plum). For the control of Mediterranean fruit fly the proposals were supported by residue monitoring data and grower spray records. For the control of Queensland fruit fly, the use proposals were supported by OECD Good Laboratory Practice (GLP) compliant residue trials previously submitted by Horticulture Australia Limited.

Based on the information available to the APVMA, a number of the uses proposed by industry were supported for the 2012–13 season. Those uses approved for an interim period under permit PER13840 for the control of Mediterranean fruit fly in 2012-13 are summarised in Table 1 and for the control of Queensland fruit fly in stone fruit under permit PER13841 are summarised in Table 2. The industries involved were requested to provide further residues data to allow more refined assessment of the residues potential of the proposed uses prior to reconsideration of the interim uses for the 2013–14 season.

Table 1 Interim uses of fenthion for the control of Mediterranean fruit fly approved under permit PER13840 for the 2012-13 season.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Citrus	75 mL/100 L (41 g ai/100 L)	14 days	Apply no more than a single application per season in no more than 1000 L/Ha.
Apples	75 mL/100 L (41g ai/100 L)	10 days	Apply a maximum of 2 sprays with at least 14 days between applications.
Pears	90 – 100 mL/100 L (49.5 – 55 g ai/100 L)	7 days	Apply a maximum of 2 sprays with at least 14 days between applications.
Stone fruit (except cherries)	75L/100 L (41g ai/100 L)	7 days	Apply a maximum of 2 sprays with at least 10 days between applications.
Cherries	75L/100 L (41g ai/100 L)	7 days	Apply a maximum of 2 sprays with at least 10 – 14 days between applications.
Persimmons (edible peel)	75 L/100 L (41g ai/100 L)	14 days	Apply a maximum of 2 sprays with at least 10 days between applications.
Grapes	50 mL/100 L (27.5 g ai/100 L)	7 days	Apply a maximum of 2 sprays with at least 7 days between applications.

Table 2. Interim uses of fenthion on stone fruit for the control of Queensland fruit fly approved under permit PER13841 for the 2012-13 season.

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Stone fruit (except cherries)	75mL/100 L (41g ai/100 L)	21 days	Apply a maximum of 3 sprays.

The established Australian residue definition for fenthion *is Sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion* [1]. The Australian residue definition was affirmed by the *Fenthion Residues and Dietary Risk Assessment Report* of 2012 and is the same as that established by Codex and the European Commission. The metabolites were included in the residue definition as they can form a significant proportion of the total residue and they are considered to be toxicologically significant[2].

The currently established fenthion MRLs, based on the above residue definition, for fruits associated with the interim uses are listed in Table 3.

Table 3 Currently established fenthion MRLs, based on the Australian residue definition of *Sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion*[1], for fruits associated with the interim uses approved under permit PER13840.

COMPOUND	FOOD	MRL (mg/kg)
Citrus Fruits		
FC 0001	Citrus fruits	T0.7
Grapes		
FB 0269	Grapes	T0.2
Pome Fruits		
FP 0009	Pome fruits	T0.25
Persimmon		
FT 0307	Persimmon, Japanese	T0.3
Stone Fruits		
FS0240	Apricot	T0.20
FS0013	Cherries	T0.40
FS0245	Nectarine	T0.25
FS0247	Peach	T0.20
FS0014	Plums	T0.25

[1] *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012,* (taking into account amendments up to Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2013 (No. 5)); http://www.comlaw.gov.au/Details/F2013C00638.
Australia New Zealand Food Standards Code - Standard 1.4.2 - Maximum Residue Limits (Australia Only), (Standard 1.4.2 Food Standards as amended, taking into account amendments up to Australia New Zealand Food Standards Code - Standard 1.4.2 - Maximum Residue Limits Amendment Instrument No. APVMA 3, 2013); http://www.comlaw.gov.au/Details/F2013C00616.

[2] JMPR Periodic Reevaluation of Fenthion (1995); http://www.inchem.org/documents/jmpr/jmpmono/v95pr07.htm; accessed 28/08/2013

Summerfruit Australia submitted a Horticulture Australia Limited report of a series of trials undertaken in the 2012-2013 season to GLP standards. The APVMA received the data in August 2013. This report also considers residue surveillance data submitted by the Hills Orchard Improvement Group (HOIG), and additional residues monitoring data submitted by Fruitwest.

Section 2 of this report assesses the use of fenthion for the control of Mediterranean fruit fly on all fruits as permitted in WA. This section considers the Horticulture Australia report in addition to residue surveillance data submitted by the Hills Orchard Improvement Group (HOIG) and by Fruitwest.

Section 3 of this report assesses the use of fenthion on stone fruit, including uses in all states and territories. It considers all the available supervised residue trial data for fenthion on stone fruit and determines potential use patterns for fenthion on stone fruit that would be acceptable from a human health perspective.

2 CONSIDERATION OF FENTHION RESIDUE DATA SUBMITTED IN SUPPORT OF CONTINUED INTERIM USE APPROVAL – MEDITERRANEAN FRUIT FLY USES (PERMIT 13840)

2.1 Consideration

HAL study (HAL/GLP/13/02-1b); Frost, Bill; Determination of fenthion residues in stone fruit following pre-harvest applications of Lebaycid® insecticide, Australia, 2013. Revised 27 August 2013.

The Horticulture Australia Limited (HAL) study reported results of residue trials conducted according to OECD Principles of Good Laboratory Practice (GLP), and undertaken at sites in New South Wales, Queensland and Western Australia. Trials were undertaken on peaches (5 sites), nectarines (4 sites) and plums (1 site). A detailed summary of the trials can be found at Attachment 1. The method achieved a validated Limit of Quantitation (LOQ) of 0.01 mg/kg for each analyte of the residue definition and results between the statistical Limit of Detection (LOD) of 0.005 mg/kg and the LOQ were estimated and reported.

Results are summarised in Table 4.

Table 4. Summary of results of the Horticulture Australia Limited trial conducted according to GLP and reported to the Australian residue definition. Shaded residues are above the currently established MRL.

Crop, variety, location year, site number	Nominal Application concentration (g ai/100 L)	Measured tank concentration (g ai/100 L)	No. of applications (interval, days)	Spray volume (L/ha)	PHI (days after last application)	Total Fenthion (mg/kg)	
						As reported	Adjusted[a]
Plums, Black Amber, Perth Hills, WA, 2013, 130526	UTC		-	-	-	<0.03	<0.03
	41	29 34 (35)	2 (11)	1205, 1139	0	0.05	0.05
					7	0.05	0.06
					10	0.05	0.05
					14	0.06	0.06
Nectarines, Artic Snow, Perth Hills, WA, 2013, 130527	UTC		-	-	-	<0.03	<0.03
	41	37 (37) 37	2 (9)	1085, 1097	0	0.30	0.34
					7	0.09	0.10
					10	0.08	0.08
					14	0.04	0.04
Nectarines,	UTC		-	-	-	<0.03	<0.03

Crop, variety, location year, site number	Nominal Application concentration (g ai/100 L)	Measured tank concentration (g ai/100 L)	No. of applications (interval, days)	Spray volume (L/ha)	PHI (days after last application)	Total Fenthion (mg/kg)	
						As reported	Adjusted[a]
Artic Rose, Cobram, Vic, 2013, 130531	41	35 (35) 32	2 (10)	1158, 1159	0	0.21	0.26
					7	0.05	0.07
					10	0.07	0.09
					14	0.07	0.09
Nectarines, Redhaven, Orange, NSW, 2013, 130533	UTC		-	-	-	<0.03	<0.03
	41	25 (25) 29	2 (9)	1372, 1390	0	0.42	0.58
					7	0.26	0.36
					10	0.17	0.23
					14	0.11	0.14
Nectarines, August Red, Stanthorpe, Qld, 2013, 130535	UTC		-	-	-	0.07	0.07
	41	36 (36) 36	2 (10)	924, 1052	0	0.51	0.58
					7	0.19	0.21
					10	0.22	0.24
					14	0.10	0.12
Peaches, Autumn Snow, Perth Hills, WA, 2013, 130528	UTC		-	-	-	0.04	0.04
	41	37 38 (38)	2 (10)	1414, 1265	0	1.01	1.1
					3	1.18	1.29
					7	0.52	0.57
					10	0.33	0.36
					14	0.20	0.22
Peaches, September Snow, Perth Hills, WA, 2013, 130529	UTC		-	-	-	0.06	0.06
	41	40 (40) 40	2 (10)	1079, 1066	0	<0.03	<0.03
					7	0.34	0.35
					10	0.28	0.29
					14	0.08	0.09

Crop, variety, location year, site number	Nominal Application concentration (g ai/100 L)	Measured tank concentration (g ai/100 L)	No. of applications (interval, days)	Spray volume (L/ha)	PHI (days after last application)	Total Fenthion (mg/kg)	
						As reported	Adjusted[a]
Peaches, Tatura 211, Shepparton, Vic, 2013, 130530	UTC		-	-	-	<0.03	<0.03
	41	37 (37) 39	2 (11)	1066, 1031	0	0.78	0.82
					3	0.47	0.49
					7	0.32	0.33
					10	0.24	0.25
					14	0.28	0.29
Peaches, O'Henry, Orange, NSW, 2013, 130532	UTC		-	-	-	<0.03	<0.03
	41	26 35 (35)	2 (11)	1363, 1388	0	1.01	1.17
					8	0.47	0.54
					10	0.27	0.31
					13	0.26	0.30
Peaches, Golden Queen, Stanthorpe, Qld, 2013, 130534	UTC		-	-	-	<0.03	<0.03
	41	38 45 (45)	2 (10)	1367, 924	0	0.64	0.59
					7	0.27	0.25
					10	0.46	0.41
					14	0.40	0.37

[a] *Adjusted for measured spray concentration at the second application. See text*

At most sites the target spray concentration was not attained. Measured spray concentrations at the second (final) application varied between 0.71 and 1.10 of nominal or target spray concentration. Following discussions with the Study Director this was attributed to the use of small spray volumes (100-500 L) in commercial spray equipment without flushing or draining of the spray lines. The data support this, as measured spray concentration could be correlated to the volume of spray solution mixed. The measured spray concentrations were considered more reliable than the nominal concentration and the residues were

all adjusted to the nominal spray concentration and currently approved application concentration of 41 g ai/100L[3].

The Limit of Detection (LOD) of the method was 0.005 mg/kg for each analyte. Residues between the LOD and LOQ were estimated by the laboratory and included in the calculation of the total residue. The half-life of total fenthion residues in nectarines estimated from this study was approximately 7 days and in peaches approximately 9 days.

For nectarines and plums residues exceeded the currently established MRLs at 7 days after the second treatment in 1 of 5 trials. Residues at 10 days after the second application had fallen to just below the currently established MRLs of 0.25 mg/kg.

For peaches, residues exceeded the currently established MRLs 7 days after the second application at 5 of 5 sites. At 4 of the 5 sites residues were above the currently established MRLs of 0.20 mg/kg at the final sampling time 13-14 days after the second fenthion application.

Outcomes of acute dietary exposure estimates are summarised in Table 5, with calculations summarised at Attachments 3 and 4.

Table 5. Acute dietary exposure estimates based on the results of the HAL trial. The shaded estimates are for the currently approved withholding period of 7 days. Calculations are summarised at Attachments 3 and 4[4].

			ACUTE EXPOSURE (% OF ARfD)	
	PHI (days)	RESIDUE (mg/kg)	2-6 YEARS	> 2 YEARS
Nectarine	7	0.36	150	65
	10	0.24	100 (99)	45
	14	0.14	60	25
Plum	7	0.36	130	45
	10	0.24	85	30
	14	0.14	50	15
Apricot	7	0.57	330	45

[3] CCPR 45 (2013) endorsed the use of the proportionality concept for insecticides.

[4] Acute dietary exposure estimates are calculated using methodologies agreed with by Food Standards Australia New Zealand which are consistent with those recommended by the World Health Organisation (2008 (*Dietary Exposure Assessment Of Chemicals In Food*: *Report of a Joint FAO/WHO Consultation* Annapolis, Maryland, USA 2–6 May 2005)). See the APVMA *Fenthion Residues and Dietary Risk Assessment Report* 2012 for further information (http://www.apvma.gov.au/products/review/current/fenthion.php).

			ACUTE EXPOSURE (% OF ARfD)	
	PHI (days)	RESIDUE (mg/kg)	2-6 YEARS	> 2 YEARS
	14	0.37	210	30
Peach	7	0.57	260	90
	14	0.37	170	60

Relationship of residue components to the total fenthion residue

For regulatory purposes, analysis must include all components of the established residue definition for fenthion. Where the data has not been generated to the full residue definition, various assumptions are made in relation to the MRL and dietary exposure estimates. The HAL data demonstrates that parent fenthion often constitutes only a small proportion of the total residue as calculated according to the residue definition (Figure 1). As expected the ratio decreased with increasing time from treatment. From the dataset for nectarines, peaches and plums the ratio of parent fenthion to total fenthion ranged from 0 (0.03 when fenthion was present above the LOD) to 0.8. This ratio can be used to estimate total fenthion residues from results where parent fenthion only was measured. Utilising data from the GLP study at 7 days is considered appropriate for estimating total residues from monitoring data where the time between sampling and treatment is not known. If ratios were used from fruit sampled at longer PHIs total residues may be significantly overestimated. For peaches, if the samples were collected 7 days after treatment, the ratio of parent to total ranged from 0.10 to 0.25 (7 and 8 day observations) with an average (mean) of 0.16. For nectarines, if the samples were collected 7 days after treatment, the ratio of parent to total ranged from 0.21 to 0.41 with an average (mean) of 0.31.

Data from the HOIG surveillance trials did not address the full residue definition but reported a 4-component residue consisting of parent fenthion, fenthion oxon, fenthion sulphone and fenthion sulphoxide. The relationship between the 4-component residue and total fenthion calculated from the HAL data is presented in Figure 2.

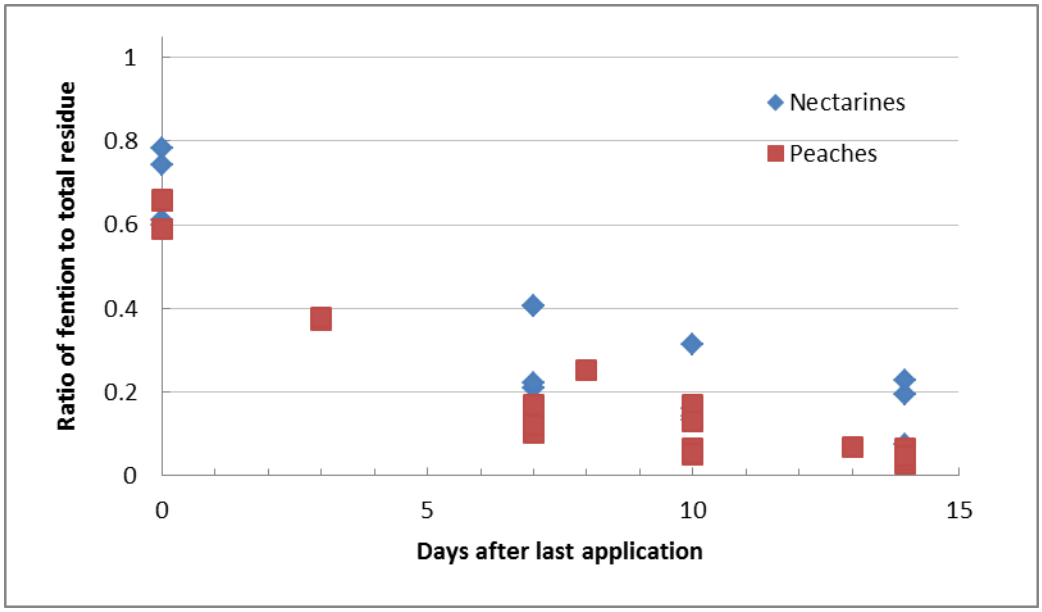

Figure 1. Ratio of parent fenthion to total fenthion residue over time for nectarines and peaches in the HAL trial. Parent fenthion formed a small component of the total residue after the currently established WHP of 7 days. The ratio of parent fenthion to total fenthion declines with time and gives a reasonable relationship for estimating total fenthion from results for parent fenthion.

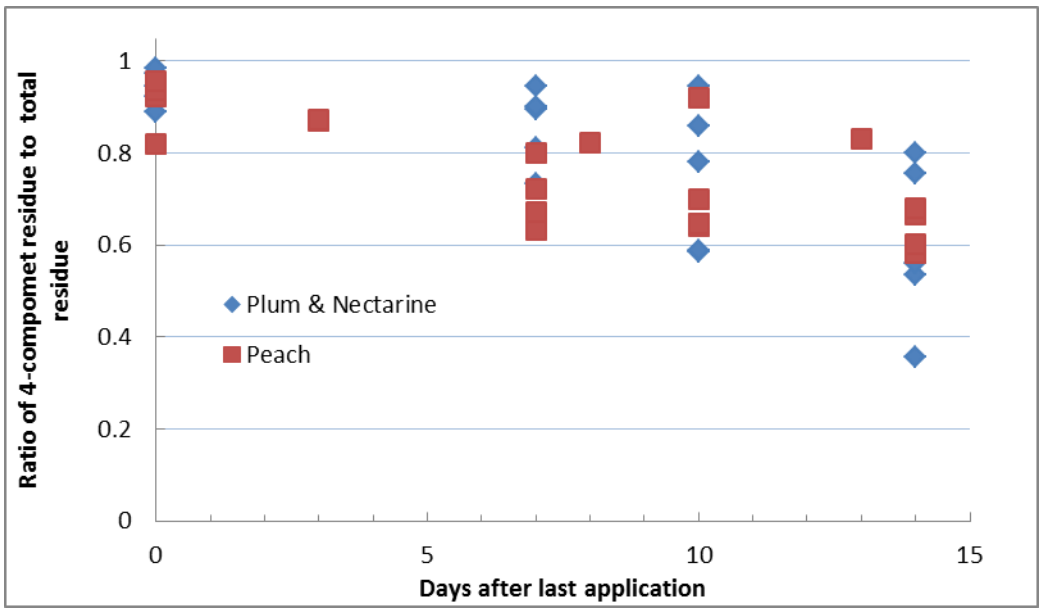

Figure 2. Ratio of the 4-component (parent fenthion, fenthion oxon, fenthion sulphone and fenthion sulphoxide) residue to the total fenthion residue in the HAL trial. The ratio of the 4-component fenthion residue to total fenthion declines with time and gives a reasonable relationship for estimating total fenthion from results for the 4-component fenthion residue.

Hills Orchard Improvement Group Inc: In Orchard Fenthion Trial Results

The Hills Orchard Improvement Group (HOIG) submitted Certificates of Analysis (CoA) and associated spray records for 44 grower-submitted samples, comprising 2 apple, 1 pear, 21 nectarine, 5 plum, 3 apricot, 9 peach, 1 cherry and 2 persimmon samples. The samples were collected following use of fenthion under permit PER13840. In one instance, the spray record and CoA for a nectarine sample did not match, as the CoA was dated January 2012 while the treatment of the orchard occurred in December 2012. That sample has been excluded from further consideration.

Analyses for these samples were not undertaken according to the full residue definition for fenthion. As such, the data is not suitable for regulatory purposes, including for determination of compliance with MRLs.

The data is summarised in Table 6 with further details given at Attachment 2. The analyses included parent fenthion, fenthion oxon, fenthion sulphone and fenthion sulphoxide, but did not include determination of fenthion oxon sulphone and fenthion oxon sulphoxide. It is noted that fenthion oxon sulphone and fenthion oxon sulphoxide are more toxic than other components of the residue definition[2]. Estimates of the ratio of the 4-component residue to the total residue were used to estimate the total residue for samples with detectable (finite) residues. For nectarine and plums (smooth skin) the average (mean) ratio at 7-8 days was estimated to be 0.86, 0.75 at 10-12, and 0.60 at 14-15 days. For apricots and peaches (fuzzy skin) the average (mean) ratio at 7-8 days was estimated to be 0.73, and 0.71 at 9-11 days.

Table 6. Summary of residues data from the HOIG surveillance trial. The estimated total fenthion residue is presented for those samples with finite 4-component residues.

Sample	Number of sprays	Days between applications	PHI – days between last application and sampling	Fruit	Total fenthion (4 components) mg/kg	Ratio of 4-component residue to Total residue[a]	Estimated Total Fenthion (mg/kg)
Pome Fruit							
HOIG032	2	48	15	Apple	<0.05	-	-
HOIG029	2	35	28	Apple	0.06	-	-
HOIG007	2	14	7	Pear	0.17	-	-
Persimmon							
HOIG041	2	48	23	Persimmon	<0.05	-	-
HOIG028	2	16	26	Persimmon	<0.05	-	-
Stone Fruit Nectarine and Plum							

Sample	Number of sprays	Days between applications	PHI – days between last application and sampling	Fruit	Total fenthion (4 components) mg/kg	Ratio of 4-component residue to Total residue[a]	Estimated Total Fenthion (mg/kg)
HOIG002	2	27	7	Nectarine	0.13	0.86	0.15
HOIG037	2	12	7	Nectarine	<0.05		
HOIG044	2	10	8	Nectarine	0.13	0.86	0.15
HOIG001	2	19	8	Nectarine	<0.05		
HOIG024	2	12	9	Nectarine	0.075	0.75	0.10
HOIG003	2	12	9	Nectarine	<0.05		
HOIG026	2	13	9	Nectarine	<0.05		
HOIG035	2	12	10	Nectarine	<0.05		
HOIG036	2	15	10	Nectarine	<0.05		
HOIG039	4	11,12,13	10	Nectarine	<0.05		
HOIG043	2	10	11	Nectarine	0.21	0.75	0.28
HOIG019	2	12	12	Nectarine	0.084	0.75	0.11
HOIG018	2	11	12	Nectarine	0.11	0.75	0.15
HOIG021	2	11	12	Nectarine	0.16	0.75	0.21
HOIG004	2	12	13	Nectarine	0.075	0.60	0.13
HOIG025	2	13	13	Nectarine	<0.05		
HOIG030	1	-	15	Nectarine	0.21	0.60	0.35
HOIG038	2	9	17	Nectarine	<0.05		
HOIG022	1	-	23	Nectarine	<0.05		
HOIG034	1	-		Nectarine	<0.05		
HOIG005	2	20	8	Plum	<0.05		
HOIG027	2	12	9	Plum	0.057	0.75	0.08
HOIG008	2	14	14	Plum	<0.05		
HOIG040	2	11	19	Plum	<0.05		

Sample	Number of sprays	Days between applications	PHI – days between last application and sampling	Fruit	Total fenthion (4 components) mg/kg	Ratio of 4-component residue to Total residue[a]	Estimated Total Fenthion (mg/kg)
HOIG013	2	14	N/A	Plum	<0.05		
Apricot and Peach							
HOIG015	2	15	7	Apricot	<0.05		
HOIG010	2	10	8	Apricot	<0.05		
HOIG017	2	10	11	Apricot	0.066	0.71	0.09
HOIG014	2	10	7	Peach	0.082	0.73	0.11
HOIG023	2	11	7	Peach	<0.05		
HOIG042	2	15	7	Peach	<0.05		
HOIG012	2	10	8	Peach	0.088	0.73	0.12
HOIG031	2	12	8	Peach	0.2	0.73	0.27
HOIG020	2	9	9	Peach	0.14	0.71	*0.20*
HOIG016	2	10	9	Peach	0.18	0.71	0.25
HOIG009	1	-	9	Peach	<0.05		
HOIG033	1	-	10	Peach	0.092	0.71	0.13
Cherry							
HOIG006	2	22	8	Cherry	<0.05	-	-

[a] Estimated from HAL GLP study – see text

As the residue definition was not fully addressed the reported results cannot be used for regulatory purposes, including confirming compliance with MRLs. Based on estimates of total residues for smooth skin stone fruit (nectarines and plums), it is likely that residues in 2 samples exceeded the MRL of T0.25 mg/kg. Those 2 samples were collected 11 and 15 days after treatment, longer that the currently approved withholding period of 7 days. It is noted that estimated residues in at least 1 additional sample (HOIG021; 0.21 mg/kg) were approaching the MRL 5 days after the expiry of the WHP. The half-life of the total residue in nectarines was estimated as 7 days. On that basis the total residue at the currently established withholding period may have been as high as 0.34 mg/kg, exceeding the currently established MRL.

For fuzzy skinned stone fruit (apricots and peaches), it is likely that residues in 2 samples exceeded the MRL of T0.20 mg/kg. Those 2 samples were collected 8 and 9 days after final treatment, longer than the currently

approved withholding period of 7 days. Residues in an additional sample collected 9 days after treatment were estimated to be at the MRL of T0.20 mg/kg. It is likely that at the currently approved WHP of 7 days this sample would have also had residues above the MRL.

Residue surveillance data are only available for 1 cherry sample collected during the 2012–2013 season. The analyses were not undertaken according to the residue definition, however no residues were observed above the limit of reporting.

Results from 3 pome fruit samples were reported. Two of these samples contained residues above the limit of reporting. No data on the metabolite profile on pome are currently available to estimate total residues. The highest residue of parent fenthion observed was 0.17 mg/kg from a pear collected 7 days after treatment. While the residue of parent was below the MRL for the total residue of T0.25, it is not known if this sample actually complied with the MRL as the metabolites were not included in the analysis.

Results from 2 persimmon samples were reported. The samples did not contain residues above the limit of reporting.

Fruitwest Residue Monitoring Data

Residue monitoring data for the period 7 November 2012 to 22 July 2013 has been supplied by Fruitwest and are summarised in Table 7. These samples were collected from growers not participating in the HOIG surveillance trials.

Table 7. Residue monitoring data for the 2012-2013 season submitted by Fruitwest. These samples were collected from growers not participating in the HOIG surveillance trials.

	NUMBER OF SAMPLES	NUMBER OF RESIDUES >LOR	FENTHION (parent, mg/kg)
Citrus fruit	32	0	
Grapes	26	0	
Pome fruit	49		
Apple	37	1	0.06
Nashi pear	2	0	
Pear	10	0	
Stone fruit	36		
Apricot	2	0	
Nectarine	9	0	
Peach	7	1	0.19
Plum	18	0	

(LOR = level of reporting)

Only parent fenthion has been reported for these samples and the analytical method did not address the complete residue definition. As other components of the fenthion residue can comprise a significant proportion of the total, the results do not necessarily confirm compliance with the MRLs. The data are not suitable for regulatory purposes.

No residues of fenthion (parent only) were observed in citrus or grapes. In pome fruit, 1 sample had reportable levels of parent fenthion and the residue of 0.06 was below the MRL of T0.25 for total fenthion. No data on the metabolite profile on pome are currently available to estimate total residues.

A ratio of parent to total fenthion was derived from the HAL data for peaches at 7 days after treatment. Based on that ratio of 0.16, the estimated total fenthion residue is (0.19/0.16) 1.2 mg/kg. In the HAL data residues of parent fenthion as high as 0.19 mg/kg in peaches were not seen at PHIs longer than 7 days. It is highly likely that the residues of fenthion in the peach sample with 0.19 mg/kg of parent exceeded the MRL of T0.20 mg/kg.

2.2 Summary

Stone Fruit (not including cherries)

The GLP study supplied by Horticulture Australia Limited was conducted according to the interim use for Mediterranean fruit fly that is currently approved under permit PER13840. The study included 10 residue decline trials on stone fruit. The study was undertaken using commercial application equipment and analyses were undertaken according to the established residue definition. The study was considered fully reliable and can be used for regulatory purposes.

For smooth skin stone fruit (nectarines and plums) the final sampling time was 14 days after the second fenthion application. Dietary exposure estimates were unacceptable for children at the currently approved withholding period of 7 days. The dietary exposure estimate for children was acceptable at 14 days.

For fuzzy skin stone fruit (peaches), the final sampling time was 14 days after the second fenthion application. Dietary exposure estimates were unacceptable for children at the currently approved withholding period of 7 days. The dietary exposure estimate for children was also unacceptable at the final sampling point of 14 days.

The results from the residue surveillance and residue monitoring studies are consistent with the results of the GLP residues study. The analyses were not undertaken according to the residue definition for fenthion. When residues were corrected to estimate the total fenthion residue it is considered that up to 4 fuzzy skin stone fruit samples and up to 3 smooth skin stone fruit exceed the currently established MRLs. Samples in these studies having residues that were estimated to exceed the established MRLs were harvested, where recorded, 8, 9, 11 and 15 days after the final treatment with fenthion.

On the basis of the results of the GLP study and the residue surveillance and monitoring results, the currently approved interim use of fenthion on stone fruit (apricots, nectarines, peaches, plums) of 2 applications at least 10 days apart of 41 g fenthion/100L with a 7 day withholding period is no longer supported. The APVMA is not satisfied that the use *would not be likely to have an effect that is harmful to human beings* and the use must be deleted from the interim permit.

Cherries

Residue surveillance data are only available for 1 cherry sample collected during the 2012–2013 season. The analyses were not undertaken according to the residue definition. The available data do not indicate that the currently established fenthion TMRL for cherries of T0.40 mg/kg is likely to be exceeded following treatment according to the interim use. It is recommended that the interim use of 2 applications at least 10 days apart of 41 g fenthion/100L with a 7 day withholding period on cherries be continued. It is noted that further GLP data will be required prior to review finalisation to allow a robust dietary exposure estimate and establishment of appropriate MRLs.

Citrus fruit

Results of 32 samples from the residue monitoring program were provided by Fruitwest. The analyses were not undertaken according to the residue definition. No residues were observed above the limit of reporting of 0.05 mg/kg. The available data do not indicate that the currently established fenthion TMRL for citrus of T0.7 mg/kg is likely to be exceeded following treatment according to the interim use. It is recommended that the interim use of a single application of 41 g fenthion/100L with a 14 day withholding period on citrus be continued. It is noted that further GLP data will be required prior to review finalisation to allow a robust dietary exposure estimate and establishment of appropriate MRLs.

Grapes

Results of 26 samples from the residue monitoring program were provided by Fruitwest. The analyses were not undertaken according to the residue definition. No residues were observed above the limit of reporting. The available data do not indicate that the currently established fenthion TMRL for grapes of T0.2 mg/kg is likely to be exceeded following treatment according to the interim use. It is recommended that the interim use of 2 applications at least 7 days apart of 27.5 g fenthion/100L with a 7 day withholding period be continued. It is noted that further GLP data will be required prior to review finalisation to allow a robust dietary exposure estimate and establishment of appropriate MRLs.

Pome fruit

Results of 52 samples from the residue monitoring and surveillance program were provided. The analyses were not undertaken according to the residue definition. Three samples contained finite residues. No data on the metabolite profile on pome are currently available to estimate total residues. The highest residue of parent observed was 0.17 mg/kg from a pear collected 7 days after treatment. While the residue of parent was below the MRL for the total residue, it is not known if this sample actually complied with the MRL.

The available data do not indicate that the currently established fenthion TMRL for pome of T0.25 mg/kg is likely to be exceeded following treatment according to the interim use. It is recommended that the interim use of 2 applications at least 14 days apart of 41 g fenthion/100L (apples) or 55 g fenthion/100L (pears) with a 10 day (apples) or 7 day (pears) withholding period be continued. It is noted that further GLP data will be required prior to review finalisation to allow a robust dietary exposure estimate and establishment of appropriate MRLs.

Persimmons

Results of 2 samples were available from the residue surveillance program. The analyses were not undertaken according to the residue definition. No residues were observed above the limit of reporting of 0.05 mg/kg. The available data do not indicate that the currently established fenthion TMRL for persimmon of T0.3 mg/kg is likely to be exceeded following treatment according to the interim use. It is recommended that the interim use of 2 applications at least 10 days apart of 41 g fenthion/100L with a 14 day withholding period be continued. It is noted that further GLP or surveillance data will be required prior to review finalisation to allow a robust dietary exposure estimate and establishment of appropriate MRLs.

2.3 Recommendations: Mediterranean fruitfly uses

1. The APVMA is not satisfied that the following uses would not be likely to have an effect that is harmful to human beings and the use must be deleted from the interim permit:

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Stone fruit (except cherries)[5]	75L/100 L (41g ai/100 L)	7 days	Apply a maximum of 2 sprays with at least 10 days between applications.

2. Based on currently available information the following interim uses of fenthion for the control of medfly are not likely to have an effect that is harmful to human beings and are supported from a residues perspective, subject to the continued implementation of residue monitoring programs:

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Citrus	75 mL/100 L (41 g ai/100 L)	14 days	Apply no more than a single application per season in no more than 1000 L/Ha.
Apples	75 mL/100 L (41g ai/100 L)	10 days	Apply a maximum of 2 sprays with at least 14 days between applications.
Pears	90 – 100 mL/100 L (49.5 – 55 g ai/100 L)	7 days	Apply a maximum of 2 sprays with at least 14 days between applications.
Cherries	75L/100 L (41g ai/100 L)	7 days	Apply a maximum of 2 sprays with at least 10 – 14 days between applications.
Persimmons (edible peel)	75 L/100 L (41g ai/100 L)	14 days	Apply a maximum of 2 sprays with at least 10 days between applications.
Grapes	50 mL/100 L (27.5 g ai/100 L)	7 days	Apply a maximum of 2 sprays with at least 7 days between applications.

[5] Further discussion of nectarines and plums is included in section 3 of this report.

3 CONSIDERATION OF ACCEPTABLE FENTHION USES ON STONE FRUIT FOR FRUIT FLY CONTROL (PER 13841)

This section considers all the residues data available for the use of fenthion on stone fruit to arrive at recommendations for acceptable use patterns.

The data considered in the *Fenthion Residues and Dietary Risk Assessment Report* (September 2012)[6] are summarised below:

TRIAL AND STUDY REFERENCE	COMMODITY	SPRAY CONCENTRATION (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, 2.29
			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, 1.07, 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, 0.61, 0.73, 1.16
			14	0.10, 0.27, 0.32
			21	0.08

[6] http://www.apvma.gov.au/products/review/current/fenthion.php

TRIAL AND STUDY REFERENCE	COMMODITY	SPRAY CONCENTRATION (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	SPRAY CONCENTRATION (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

The level of residue observed in the Bayer trial (ref. 215) following a single application at 62.5 g fenthion/100L and variability in the other Bayer trials (ref. 226 & 247) are noted. The single application study was undertaken in South Africa in 1986 with a water rate of 3000L/Ha. While proportionality could be applied on the basis of application concentration the water rate is higher than commonly used in Australia. Although water rates generally scale with canopy size there is considered to be too much uncertainty associated with this data to apply the proportionality principle. The multiple application studies were undertaken in Australia in 1991 and 1997 and some of the residues at 7 and 14 days were not consistent with the rest of the dataset. Sampling was not undertaken at 21 days. At the time of approval of the interim uses on peaches in 2012 the trial at 62.5 g fenthion/100L and residues of 1.46 mg/kg (ref. 226) and 3.8 mg/kg (ref.247) were excluded from consideration. Similarly they are excluded from consideration here.

This section also considered the data submitted to the APVMA by Summerfruit Australia in August 2013 *Horticulture Australia Limited (HAL/GLP/13/02-b); Frost, Bill; Determination of fenthion residues in stone fruit following pre-harvest applications of Lebaycid® insecticide, Australia, 2013. Revised 27 August 2013* as discussed in Sections 2.1 and 2.2 of this report and summarised in Table 6 in Section 2.2.

The reliable data for nectarines and plums available to the APVMA is presented in Figure 3 and for peaches in Figure 4. This data includes the data considered in the *Fenthion Residues and Dietary Risk Assessment Report* (September 2012) and the additional data submitted by Summerfruit Australia in August 2013.

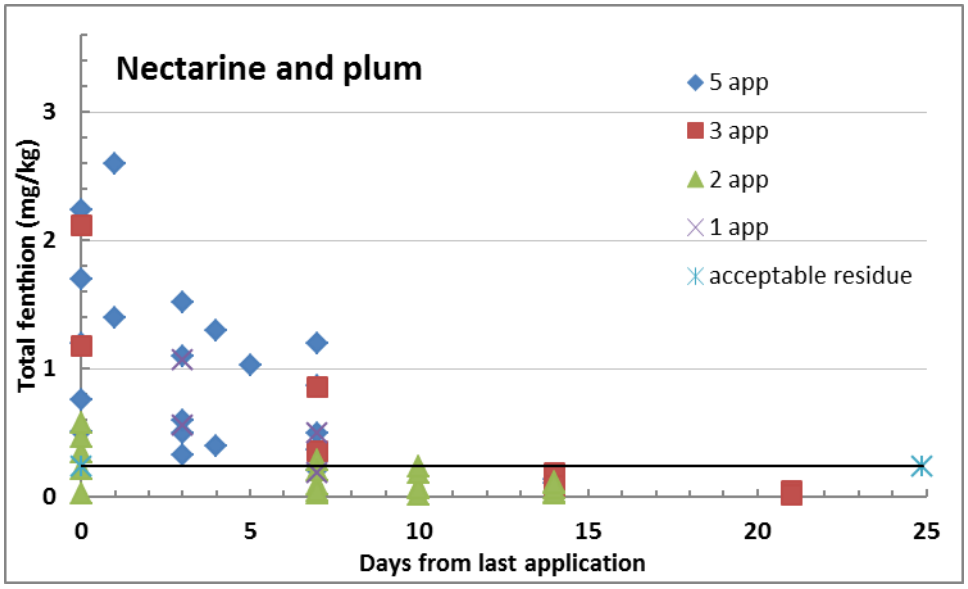

Figure 3. Total fenthion residues over time for various application (app) regimes on nectarine and plum. The acceptable residue is the highest acceptable residue to attain an estimate of acute dietary exposure of less than the health standard (ARfD) for children.

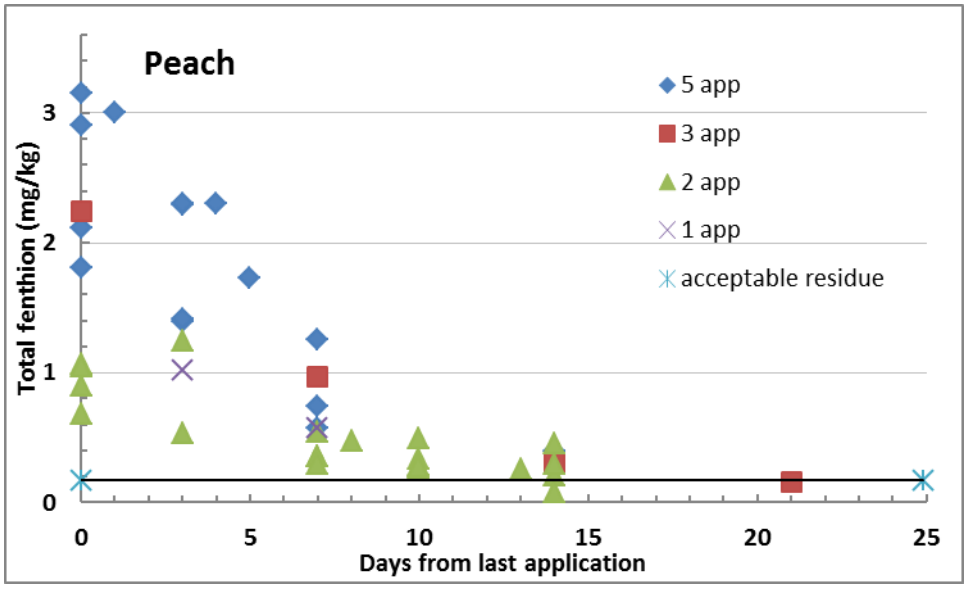

Figure 4. Total fenthion residues over time for various application (app) regimes on peach. The acceptable residue is the highest acceptable residue to attain an estimate of acute dietary exposure of less than the health standard (ARfD) for children.

From Figure 3 it can been seen that the residues in nectarines and plums are above acceptable levels until approximately 10 days after application. From Figure 4 it can be seen that residues in peach samples are above acceptable levels until 21 days after application (one sample). Outcomes of acute dietary exposure

estimates at and after these PHIs are summarised in Table 8, with calculations summarised at Attachments 5 and 6.

Table 8. Acute dietary exposure estimates based on the results of the supervised trials. The shaded estimates are for the currently approved withholding period of 21 days for Queensland fruit fly control. Calculations are summarised at Attachments 5 and 6[7]. Residues observed in peach are extrapolated to apricot.

	PHI (days)	HIGH RESIDUE (mg/kg)	ACUTE EXPOSURE (% OF ARfD)		IS USE ACCPETABLE?
			2-6 YEARS	> 2 YEARS	
Nectarine	10	0.24	100 (99)	45	No (see text)
	14	0.19	80	35	Yes
	21	0.05	20	10	Yes
Plum	10	0.24	85	30	No (see text)
	14	0.19	70	25	Yes
	21	0.05	20	5	Yes
Apricot	14	0.37	210	30	No (see text)
	21	0.16	90	15	No (see text)
Peach	14	0.37	170	60	No (see text)
	21	0.16	70	25	No (see text)

Dietary exposure estimates for nectarine and plum are less than the ARfD at 10 days (n=5), 14 days (n=9) and 21 days (n=2). However, the estimate at a PHI of 10 days rounds to 100% of the ARfD. The estimate is based on data from only 5 trials and it is not considered to be sufficiently robust for the acute dietary exposure to be assessed as acceptable. The likely MRL exceedences at PHIs of 10+ days in the 2012–2013 Western Australian surveillance data are also noted. The estimate at 14 days is based on 3 or 5 applications at varying intervals with a sample size of 9. The estimated acute dietary exposure for children at the 14 day PHI is 80% of the ARfD for nectarine and 70% for plum and is considered acceptable. As the dataset at 14 days only includes data for 2 samples following 5 applications and as there are no data for 5 applications at a PHI of 10 days it is recommended that any use approval for a 14 day WHP is limited to 3 applications of 41 g fenthion/100L with applications occurring at least 10 days apart.

[7] Acute dietary exposure estimates are calculated using methodologies agreed with by Food Standards Australia New Zealand which are consistent with those recommended by the World Health Organisation (2008 (DIETARY EXPOSURE ASSESSMENT OF CHEMICALS IN FOOD Report of a Joint FAO/WHO Consultation Annapolis, Maryland, USA 2–6 May 2005)). See the APVMA *Fenthion Residues and Dietary Risk Assessment Report* 2012 for further information (http://www.apvma.gov.au/products/review/current/fenthion.php).

Acute dietary exposure estimates for peach and apricot are not acceptable at a PHI of 14 days. Only one trial in the dataset that is considered to be fully reliable included sampling of peach 21 days after the last of 3 applications. While the dietary exposure estimate is less that the acute reference dose for the results from the single trial, it is not a robust assessment. An interim use was granted in 2012 on the basis of the data available at that time.

Noting that:

- No new residue data has been provided addressing a 21 day PHI for peach or apricot
- For the data available in 2012, residues in 2 of 2 samples exceeded the currently established MRL 14 days after the final application.
- Data for 5 new trials in peach following 2 applications are available. Residues for 4 of the 5 trials at 14 days exceeded the currently established MRL.

On this basis it is considered that the results from a single trial do not provide an adequate estimation of the high residue from the population of residues that are likely to result from the application fenthion to apricot and peach following a 21 day PHI. The APVMA cannot continue to have confidence in the acute dietary exposure assessment based on this single observation. It is recommended that the currently approved interim use of fenthion on peach and apricot be withdrawn and the associated fenthion MRLs for peach and apricot be deleted from the APVMA MRL Standard as the APVMA cannot be satisfied that the use *would not be likely to have an effect that is harmful to human beings.*

Further, it is noted that no data are available at longer intervals following application of fenthion to apricot and peach that may allow the APVMA to be satisfied that such a use *would not be likely to have an effect that is harmful to human beings*.

3.1 Recommendations for use of fenthion on stone fruit (except cherries)

1. The APVMA is not satisfied that the following use would not be likely to have an effect that is harmful to human beings and the use must be deleted from the interim permit:

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Stone fruit (except cherries)	75mL/100 L (41g ai/100 L)	21 days	Apply a maximum of 3 sprays.

2. Based on currently available information the following interim uses of fenthion for the control of fruit flies are not likely to have an effect that is harmful to human beings and are supported from a residues perspective:

CROP	RATE	WITHHOLDING PERIOD	CRITICAL COMMENTS
Nectarine and Plum only	75mL/100 L (41g ai/100 L)	14 days	Apply a maximum of 3 sprays at intervals of no less than 10 days.

3. The following changes should be made to Table 1 of the APVMA MRL Standard :

COMPOUND	FOOD	MRL (mg/kg)
Fenthion		
DELETE		
FS0240	Apricot	T0.20
FS0247	Peach	T0.20

4 Glossary

ADI	Acceptable Daily Intake (for humans)
ai	active ingredient
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
bw	bodyweight
Codex	FAO/WHO Codex Alimentarius Commission
DAFA	days after first application
DALA	days after last application
g	gram
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
ha	hectare
HAL	Horticulture Australia Limited
HPLC	high pressure liquid chromatography *or* high performance liquid chromatography
HR	high residue (used in dietary intake calculations)
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOD	limit of detection (the lowest level at which residues can be detected)
LOQ	limit of quantitation (the level at which residues can be reliably measured)
LOR	level of reporting (the lowest level at which reisdues can be reliably reported as present)

m	metre
mg	milligram
mL	millilitre
MRL	maximum residue limit
NEDI	National Estimated Daily Intake
NESTI	National Estimated Short-Term Intake
NSW	New South Wales
PHI	post-harvest interval
Qld	Queensland
UTC	untreated control
Vic.	Victoria

5 APPENDICES

5.1 Attachment 1: DPS no. 9811 - HAL/GLP/13/02-1b; Frost, Bill; Determination of fenthion residues in stone fruit following pre-harvest applications of Lebaycid® Insecticide, Australia, 2013. Revised 27 August 2013

A GLP residue study was conducted on peaches (5 sites), nectarines (4 sites) and plums (1 site) during the 2012/2013 season. The trial sites were located in Western Australia, New South Wales and Queensland. In all trials, two applications of Lebaycid® Insecticide (550 g/L fenthion) were made at nominal concentrations of 75 mL/100 L (41.3 g ai/100 L) at 17 and 7 days before commercial harvest. Treatments were applied by commercial air-blast orchard sprayers, in total volumes ranging from 924 to 1414 L/ha. Samples of whole fruit were collected for analysis at 0, 3 (2 trials), 7-8, 10 and 13-14 days after the last application. At least 2 kg of fruit was sampled from at least 4 individual trees of each treatment for each sample. In addition to the fruit samples, the fenthion spray solution was also sampled prior to the application. Samples were stored frozen until analysis which was completed within approximately 7 months of the first sampling.

Each sample of stone fruit from the trials was cut in half and the stone removed and weighed and discarded. The remaining pulp and skin was blended in a commercial food processor. Fenthion, its oxygen analogue and their sulphoxides and sulphones were extracted from the blended and homogenised samples with acetonitrile. Magnesium sulphate and sodium chloride and other selected salts were added to the extract creating a partition between the acetonitrile and water layers. Fenthion, its oxygen analogue and their sulphoxides and sulphones were found in the acetonitrile layer, from which an aliquot was taken and cleaned up by the addition of primary secondary amine and magnesium sulphate. An aliquot of the extract was taken and evaporated to dryness before re-dissolving in toluene. Fenthion, its oxygen analogue and their sulphoxides and sulphones were determined by Gas Chromatography coupled with a tandem mass spectrometer (GC/MS/MS) using external standards. The LOQ for the method was 0.01 mg/kg for each of fenthion, its oxygen analogue and their sulphoxides and sulphones. The LOD was 0.005 mg/kg for each analyte. Mean recoveries of fenthion and its metabolites from fortified control samples of stone fruit were within acceptable limits as summarised below. Residues between the LOD and LOQ were estimated by the laboratory and included in the calculation of the total residue.

Substrate	Fortification level (mg/kg)	n	Mean recovery ±RSD (%)					
			fenthion	Fenthion sulphone	Fenthion sulphoxide	Fenthion oxon	Fenthion oxon sulphoxide	Fenthion oxon sulphone
Stone fruit*	0.01	6	104 ± 5.4	108 ± 7.6	104 ± 14	105 ± 7.7	93 ± 16	107 ± 11
Stone fruit*	0.1	6	97 ± 22	98 ± 9.7	101 ± 14	92 ± 5.9	100 ± 16	103 ± 17
Stone fruit*	1	7	97 ± 16	93 ± 8.1	95 ± 12	94 ± 11	89 ± 18	90 ± 15

*Peaches, nectarines, plums

Residues found in untreated and treated samples are summarised below:

Crop, variety, location year, site number	Nominal Application concentration (g ai/100 L)	Measured tank concentration (g ai/100 L)	No. of applications, (interval, days)	Spray volume (L/ha)	PHI (days after last application)	Fenthion (mg/kg)	Fenthion sulphone (mg/kg)	Fenthion sulphoxide (mg/kg)	Fenthion oxon (mg/kg)	Fenthion oxon sulphone (mg/kg)	Fenthion oxon sulphoxide (mg/kg)	Flesh factor	Max total fenthion whole fruit residue (mg/kg)	Detected total fenthion whole fruit residue (mg/kg)
Plums, Black Amber, Perth Hills, WA, 2013, 130526	UTC		-	-	-	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.9633	<0.030	<LOD
	41.25	29.36 34.27 (35.27)	2 (11)	1205, 1139	0	<0.005	<0.005	0.023	<0.005	<0.005	<0.005	0.9569	<0.048	0.024
					7	<0.005	<0.005	0.028	<0.005	<0.005	<0.005	0.9474	<0.052	0.028
					10	<0.005	<0.005	0.021	<0.005	<0.005	<0.005	0.9606	<0.046	0.021
					14	<0.005	<0.005	0.022	<0.005	<0.005	0.016	0.9548	<0.057	0.038

Crop, variety, location year, site number	Nominal Application concentration (g ai/100 L)	Measured tank concentration (g ai/100 L)	No. of applications, (interval, days)	Spray volume (L/ha)	PHI (days after last application)	Fenthion (mg/kg)	Fenthion sulphone (mg/kg)	Fenthion sulphoxide (mg/kg)	Fenthion oxon (mg/kg)	Fenthion oxon sulphone (mg/kg)	Fenthion oxon sulphoxide (mg/kg)	Flesh factor	Max total fenthion whole fruit residue (mg/kg)	Detected total fenthion whole fruit residue (mg/kg)
Nectarines, Artic Snow, Perth Hills, WA, 2013, 130527	UTC		-	-	-	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.8122	<0.025	<LOD
	41.25	36.58 (37.04) 36.71	2 (9)	1085, 1097	0	0.27	<0.005	0.065	<0.005	<0.005	0.006	0.834	<0.30	0.28
					7	0.04	0.007	0.033	<0.005	<0.005	0.016	0.8086	<0.088	0.08
					10	0.013	0.007	0.027	<0.005	<0.005	0.031	0.8456	<0.076	0.068
					14	<0.005	<0.005	0.008	<0.005	<0.005	0.014	0.822	<0.035	0.018
Peaches, Autumn Snow, Perth Hills, WA, 2013, 130528	UTC		-	-	-	<0.005	<0.005	0.005	<0.005	<0.005	0.013	0.9507	<0.037	0.017
	41.25	37.22 37.67 (38.03)	2 (10)	1414, 1265	0	0.7	0.031	0.14	<0.005	0.011	0.17	0.9453	<1.0	1
					3	0.46	0.042	0.58	<0.005	0.01	0.11	0.9473	<1.2	1.2
					7	0.056	0.046	0.24	<0.005	0.01	0.17	0.954	<0.52	0.52
					10	0.017	0.029	0.17	<0.005	0.008	0.1	0.9546	<0.33	0.32
					14	0.006	0.016	0.1	<0.005	0.007	0.073	0.9528	<0.21	0.2

Crop, variety, location year, site number	Nominal Application concentration (g ai/100 L)	Measured tank concentration (g ai/100 L)	No. of applications, (interval, days)	Spray volume (L/ha)	PHI (days after last application)	Fenthion (mg/kg)	Fenthion sulphone (mg/kg)	Fenthion sulphoxide (mg/kg)	Fenthion oxon (mg/kg)	Fenthion oxon sulphone (mg/kg)	Fenthion oxon sulphoxide (mg/kg)	Flesh factor	Max total fenthion whole fruit residue (mg/kg)	Detected total fenthion whole fruit residue (mg/kg)
Peaches, September Snow, Perth Hills, WA, 2013, 130529	UTC		-	-	-	<0.005	<0.005	0.03	<0.005	<0.005	0.008	0.9408	<0.057	0.037
	41.25	40.00 (40.11) 40.09	2 (10)	1079, 1066	0	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.9476	<0.029	<LOD
					7	0.042	0.033	0.16	<0.005	0.009	0.093	0.9514	<0.34	0.33
					10	0.019	0.028	0.14	<0.005	0.009	0.082	0.9566	<0.28	0.27
					14	0.005	0.01	0.032	<0.005	<0.005	0.028	0.9631	<0.084	0.075
Peaches, Tatura 211, Sheppart on, Vic, 2013, 130530	UTC		-	-	-	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.9205	<0.028	<LOD
	41.25	37.26 (37.48) 39.49	2 (11)	1066, 1031	0	0.59	0.02	0.23	<0.005	0.006	0.035	0.8661	<0.78	0.78
					3	0.2	0.02	0.24	<0.005	0.007	0.045	0.8767	<0.47	0.47
					7	0.06	0.039	0.16	<0.005	0.009	0.076	0.8765	<0.31	0.31
					10	0.014	0.03	0.13	<0.005	0.01	0.074	0.8821	<0.24	0.24
					14	0.011	0.032	0.16	<0.005	0.011	0.071	0.9145	<0.28	0.27

Crop, variety, location year, site number	Nominal Application concentration (g ai/100 L)	Measured tank concentration (g ai/100 L)	No. of applications, (interval, days)	Spray volume (L/ha)	PHI (days after last application)	Fenthion (mg/kg)	Fenthion sulphone (mg/kg)	Fenthion sulphoxide (mg/kg)	Fenthion oxon (mg/kg)	Fenthion oxon sulphone (mg/kg)	Fenthion oxon sulphoxide (mg/kg)	Flesh factor	Max total fenthion whole fruit residue (mg/kg)	Detected total fenthion whole fruit residue (mg/kg)
Nectarines, Artic Rose, Cobram, Vic, 2013, 130531	UTC		-	-	-	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.9453	<0.029	<LOD
	41.25	34.97 (35.38) 32.19	2 (10)	1158, 1159	0	0.13	0.006	0.053	<0.005	<0.005	0.02	0.931	<0.21	0.2
					7	0.01	0.006	0.019	<0.005	<0.005	0.011	0.9389	<0.055	0.045
					10	0.009	0.008	0.02	<0.005	<0.005	0.024	0.944	<0.069	0.059
					14	0.005	0.009	0.022	<0.005	<0.005	0.029	0.9449	<0.073	0.064
Peaches, O'Henry, Orange, NSW, 2013, 130532	UTC		-	-	-	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.9485	<0.029	<LOD
	41.25	26.16 35.46 (35.30)	2 (11)	1363, 1388	0	0.69	0.019	0.29	<0.005	<0.005	0.027	0.9567	<1.0	0.99
					8	0.12	0.031	0.24	<0.005	<0.005	0.067	0.9615	<0.47	0.46
					10	0.046	0.023	0.18	<0.005	<0.005	0.009	0.9591	<0.27	0.26
					13	0.018	0.028	0.17	<0.005	<0.005	0.031	0.9638	<0.26	0.25

Crop, variety, location year, site number	Nominal Application concentration (g ai/100 L)	Measured tank concentration (g ai/100 L)	No. of applications, (interval, days)	Spray volume (L/ha)	PHI (days after last application)	Fenthion (mg/kg)	Fenthion sulphone (mg/kg)	Fenthion sulphoxide (mg/kg)	Fenthion oxon (mg/kg)	Fenthion oxon sulphone (mg/kg)	Fenthion oxon sulphoxide (mg/kg)	Flesh factor	Max total fenthion whole fruit residue (mg/kg)	Detected total fenthion whole fruit residue (mg/kg)
Nectarines, Redhaven, Orange, NSW, 2013, 130533	UTC		-	-	-	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.8763	<0.027	<LOD
	41.25	25.36 (24.81) 29.23	2 (9)	1372, 1390	0	0.28	0.021	0.13	<0.005	<0.005	0.026	0.8738	<0.42	0.41
					7	0.064	0.026	0.17	<0.005	<0.005	0.016	0.8674	<0.26	0.25
					10	0.025	0.021	0.1	<0.005	<0.005	0.033	0.8541	<0.17	0.16
					14	0.022	0.012	0.056	<0.005	<0.005	0.018	0.8577	<0.10	0.1
Peaches, Golden Queen, Stanthorpe, Qld, 2013, 130534	UTC		-	-	-	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.9094	<0.028	<LOD
	41.25	38.61 45.27 (45.32)	2 (10)	1367, 924	0	0.4	0.027	0.2	<0.005	<0.005	0.038	0.9334	<0.64	0.63
					7	0.05	0.025	0.16	<0.005	<0.005	0.047	0.8985	<0.27	0.26
					10	0.064	0.054	0.23	<0.005	0.009	0.12	0.9078	<0.45	0.45
					14	0.021	0.061	0.22	<0.005	0.012	0.12	0.8822	<0.40	0.4
Nectarine	UTC		-	-	-	<0.005	0.007	0.022	<0.005	<0.005	0.037	0.8731	<0.073	0.06

Crop, variety, location year, site number	Nominal Application concentration (g ai/100 L)	Measured tank concentration (g ai/100 L)	No. of applications, (interval, days)	Spray volume (L/ha)	PHI (days after last application)	Fenthion (mg/kg)	Fenthion sulphone (mg/kg)	Fenthion sulphoxide (mg/kg)	Fenthion oxon (mg/kg)	Fenthion oxon sulphone (mg/kg)	Fenthion oxon sulphoxide (mg/kg)	Flesh factor	Max total fenthion whole fruit residue (mg/kg)	Detected total fenthion whole fruit residue (mg/kg)
s, August Red, Stanthorpe, Qld, 2013, 130535	41.25	36.26 (36.24) 36.17	2 (10)	924, 1052	0	0.43	0.009	0.13	<0.005	<0.005	<0.005	0.8581	<0.51	0.49
					7	0.082	0.013	0.086	<0.005	<0.005	0.015	0.8802	<0.19	0.18
					10	0.073	0.017	0.11	<0.005	<0.005	0.025	0.8859	<0.22	0.21
					14	0.024	0.011	0.045	<0.005	<0.005	0.022	0.8854	<0.10	0.093

Total fenthion = fenthion + (fenthion sulphone x 1.115) + (fenthion sulphoxide x 1.057) + (fenthion oxon x 0.9423) + (fenthion oxon sulphone x 1.056) + (fenthion oxon sulphoxide x 0.9997)

Concentrations of fenthion in the spray solutions taken after agitation and immediately before each treatment are summarised below:

Sample number	Sample timing	Fenthion (mg/L)
130533-1	-0 DAFA	253.6 (248.1)
130533-2	-0 DALA	292.3
130532-1	-0 DAFA	261.6
130532-2	-0 DALA	354.6 (353.0)
130530-1	-0 DAFA	372.6 (374.8)
130530-2	-0 DALA	394.9
130531-1	-0 DAFA	349.7 (353.8)
130531-2	-0 DALA	321.9
130534-1	-0 DAFA	386.1
130534-2	-0 DALA	452.7 (453.2)
130535-1	-0 DAFA	362.6 (362.4)
130535-2	-0 DALA	361.7
130526-1	-0 DAFA	293.6
130526-2	-0 DALA	342.7 (352.7)
130527-1	-0 DAFA	365.8 (370.4)
130527-2	-0 DALA	367.1
130528-1	-0 DAFA	372.2
130528-2	-0 DALA	376.7 (380.3)
130529-1	-0 DAFA	400.0 (401.1)
130529-2	-0 DALA	400.9

LOD = 5 mg/L, LOQ = 10 mg/L
DAFA = days after first application, DALA = days after last application
Results in parentheses are duplicate analyses

5.2 Attachment 2: Hills Orchard Improvement Group Inc In Orchard Fenthion Trial Results

Certificates of analysis from Agrifood Technology were provided for 44 grower nominated samples, comprising 2 apple, 1 pear, 21 nectarine, 5 plum, 3 apricot, 9 peach, 1 cherry and 2 persimmon samples by the Hills Orchard Improvement Group. Spray records were provided for each sample. Second party sample collectors were generally utilised with sample collection usually occurring from packed lines at the markets. Sample collection generally occurred on the day of harvest or on the following day. Individual sample weights were not reported to the APVMA however protocols required samples of between 1 kg and 2 kg. Samples were shipped on-ice by overnight courier to the laboratory. Verification of the match between spray record and certificate of analysis was not possible. The certificate of analysis for 1 nectarine sample declared as treated on 15 and 23 December 2012 with testing on 12 Jan 2013 was dated 24 January 2012. Results for this sample have been excluded from further consideration.

The certificates provided indicated that the analysis was for parent fenthion, fenthion oxon, fenthion sulphone and fenthion sulphoxide. Analyses for fenthion oxon sulphone and fenthion oxon sulphoxide, also components of the residue definition, were not undertaken. Results for parent fenthion were not provided where the analysis was for the 4-component residue. Information on method performance and validation were not supplied.

Table 9. Results from HOIG field surveillance trials. Data differs from summary in HOIG submission as it has been corrected to reflect dates and results from spray diaries, sample submission sheets and certificates of analysis. Certificates of analysis were not available for all measured components of the residue for all samples.

Sample	Number of sprays	Days between applications	PHI – days between last application and sampling	Fruit	Total fenthion (4 components) mg/kg	Fenthion (parent) (mg/kg)	Fenthion oxone (mg/kg)	Fenthion sulphone (mg/kg)	Fenthion sulphoxide (mg/kg)
Pome Fruit									
HOIG032	2	48	15	Apple	<0.05	N/A[a]	<0.05	<0.05	<0.05
HOIG029	2	35	28	Apple	N/A[b]	0.06	N/A	N/A	N/A
HOIG007	2	14	7	Pear	0.17	N/A	<0.05	<0.05	0.13
Persimmon									
HOIG041	2	48	23	Persimmon	<0.05	N/A	<0.05	<0.05	<0.05
HOIG028	2	16	26	Persimmon	<0.05	N/A	<0.05	<0.05	<0.05
Stone Fruit									
Nectarine and									

Sample	Number of sprays	Days between applications	PHI – days between last application and sampling	Fruit	Total fenthion (4 components) mg/kg	Fenthion (parent) (mg/kg)	Fenthion oxone (mg/kg)	Fenthion sulphone (mg/kg)	Fenthion sulphoxide (mg/kg)
Plum									
HOIG002	2	27	7	Nectarine	0.13	N/A	N/A	N/A	N/A
HOIG037	2	12	7	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG044	2	10	8	Nectarine	0.13	N/A	<0.05	<0.05	0.073
HOIG001	2	19	8	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG024	2	12	9	Nectarine	0.075	N/A	<0.05	<0.05	<0.05
HOIG003	2	12	9	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG026	2	13	9	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG035	2	12	10	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG036	2	15	10	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG039	4	11,12,13	10	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG043	2	10	11	Nectarine	0.21	N/A	<0.05	0.071	0.1
HOIG019	2	12	12	Nectarine	0.084	N/A	<0.05	<0.05	0.064
HOIG018	2	11	12	Nectarine	0.11	N/A	<0.05	<0.05	0.062
HOIG021	2	11	12	Nectarine	0.16	N/A	<0.05	<0.05	0.099
HOIG004	2	12	13	Nectarine	0.075	N/A	N/A	N/A	N/A
HOIG025	2	13	13	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG030	1	-	15	Nectarine	0.21	N/A	<0.05	<0.05	0.1
HOIG011*	2	8	16	Nectarine	<0.05	N/A	N/A	N/A	N/A
HOIG038	2	9	17	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG022	1	-	23	Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG034	1	-		Nectarine	<0.05	N/A	<0.05	<0.05	<0.05
HOIG005	2	20	8	Plum	<0.05	N/A	<0.05	<0.05	<0.05
HOIG027	2	12	9	Plum	0.057	N/A	<0.05	<0.05	0.05

Sample	Number of sprays	Days between applications	PHI – days between last application and sampling	Fruit	Total fenthion (4 components) mg/kg	Fenthion (parent) (mg/kg)	Fenthion oxone (mg/kg)	Fenthion sulphone (mg/kg)	Fenthion sulphoxide (mg/kg)
HOIG008	2	14	14	Plum	<0.05	N/A	<0.05	<0.05	<0.05
HOIG040	2	11	19	Plum	<0.05	N/A	<0.05	<0.05	<0.05
HOIG013	2	14	N/A	Plum	<0.05	N/A	<0.05	<0.05	<0.05
Apricot and Peach									
HOIG015	2	15	7	Apricot	<0.05	N/A	<0.05	<0.05	<0.05
HOIG010	2	10	8	Apricot	<0.05	N/A	<0.05	<0.05	<0.05
HOIG017	2	10	11	Apricot	0.066	N/A	<0.05	<0.05	<0.05
HOIG014	2	10	7	Peach	0.082	N/A	N/A	N/A	N/A
HOIG023	2	11	7	Peach	<0.05	N/A	N/A	N/A	N/A
HOIG042	2	15	7	Peach	<0.05	N/A	<0.05	<0.05	<0.05
HOIG012	2	10	8	Peach	0.088	N/A	<0.05	<0.05	0.064
HOIG031	2	12	8	Peach	0.2	N/A	N/A	N/A	N/A
HOIG020	2	9	9	Peach	0.14	N/A	<0.05	<0.05	0.095
HOIG016	2	10	9	Peach	0.18	N/A	<0.05	<0.05	0.12
HOIG009	1	-	9	Peach	<0.05	N/A	<0.05	<0.05	<0.05
HOIG033	1	-	10	Peach	0.092	N/A	N/A	N/A	N/A
Cherry									
HOIG006	2	22	8	Cherry	<0.05	N/A	<0.05	<0.05	<0.05

[a]N/A is not available

[b]Only parent fenthion reported

* Certificate of analysis predates sample collection – not included in further consideration

5.3 Attachments 3 to 6: Dietary exposure calculations

Attachments 3 to 6 can be found online at http://www.apvma.gov.au/products/review/current/fenthion.php or on request from the APVMA.