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FENTHION -
PRELIMINARY REVIEW FINDINGS PART 2
HILLS ORCHARD IMPROVEMENT GROUP Inc.
COMMENTS AND SUGGESTIONS

EXECUTIVE SUMMARY

On the evidence presented in the Preliminary Review Findings report the Hills Orchard Improvement Group Inc. (HOIG) submits there is no new information to support the immediate removal of fenthion from registration as a pesticide for use on pome and stonefruit. HOIG makes no comment on permits for uses of fenthion other than for pome and stonefruit. If new evidence established the requirement to ban fenthion immediately on pome and stonefruit then HOIG would support that decision.

HOIG recommends that if fenthion permits are suspended as proposed the APVMA should allow a two-year phase-out period for fenthion, as it did upon the deregistration of Dichlorvos 1140 and Parathion Methyl, to allow industry to transition to alternatives now in development.

In the event that the APVMA refuses to allow a phase-out period, HOIG urges the APVMA to adopt the recommendation of the Senate Regional and Rural Affairs and Transport Committee regarding a transition period.

The *"Implications of the restriction on the use of fenthion on Australia's horticultural industry" (July 2014)* report at Recommendation 4 says: The committee recommends that the maximum twelve month transition period allowed under the *Agricultural and Veterinary Chemicals Code Act 1994* be initiated by the APVMA, that fenthion be permitted for sale during the first half of that period, and that the APVMA allow fenthion to be used during the full transition period, subject to appropriate 'conditions of use'.

Occupational Health and Safety
Fenthion is used for field and post-harvest treatment of various fruits, vegetables, and ornamentals, for mosquito control in water and septic tanks, for pest control in commercial and domestic areas and as an ectoparasiticide in cattle. Fenthion is also used for quarantine control of Queensland fruit fly and other fruit flies through post-harvest treatments (dipping, flood sprays and non-recirculating low volume sprays).

The Office of Chemical Safety recommends that the APVMA should be satisfied that fenthion will not present an undue risk to human health via occupational exposure when used on:

- vegetables and **fruits by boomspray and closed cab airblast** (our emphasis);
- mosquito larvae in water when using high-pressure spray equipment and on adult mosquitoes and larvae in septic tanks and commercial areas for the control of control of spiders and ants;
- produce for quarantine treatment;
- treatment of cracks and crevices for crawling insects as a 1% dust formulation; and
- on cattle as a spot-on ectoparasiticide when applied with a Spot-On Gun or Dial-a-dose cup.

Environmental review
The Department of Environment and Heritage has prepared three environmental review reports on fenthion. The 2002, 2009 and 2014 reports rely largely on the same research material. There were two new studies considered in the 2009 report and three in 2014, with the majority of additional information being revised or updated guidance manuals or regulations of other regulatory agencies.

While the draft environmental assessment 2002 considered fenthion's use in orchards as acceptable with a buffer zone and spray drift warnings, the 2009 report, based largely on the same material, says its use on tree and vine crops is not supported. Yet the APVMA did not ban fenthion on tree and vine crops in 2009.

The 2014 report lists risk characteristics as:

- there is a potential risk to birds feeding in and frequenting orchards arising from a single treatment of fenthion;
- significant effects on mammal populations from spraying were unlikely, although some individual animals could be affected if they entered treated orchards. No recommendations were made on the basis of risks to mammals;
- bees are at risk if present when spraying occurs and recommended the following label precaution if any pre-harvest uses were retained;
- there were risks to invertebrates (including beneficial invertebrates) within the treated areas; and
- there was limited data regarding phytotoxicity and effects on non-target plants are expected to be minimal.

HOIG contends that the risks identified by the Department of Environment risk assessment report are based on worst case scenarios not applicable to pome and stonefruit usage and can be managed through the properly regulated use of fenthion under permit conditions.

Permits for other uses or at higher concentrations are not the subject of this submission. However, cancelling the permit for use on wingless grasshoppers and Oriental Fruit Moths would remove the main environmental risks identified.

The APVMA has asked that submissions made in relation to the review need to include evidence to substantiate any claims as to whether a chemical product when used according to label directions would or would not:

- adversely affect human beings;
- be harmful to workers;
- be hazardous to the environment;
- pose a threat to trade; or
- be effective.

The APVMA asked that such evidence be presented in point form. HOIG respectfully submits that the detailed history of the chemical review of fenthion and the quality of evidence that is being relied upon to remove this tool to control fruit fly cannot be properly examined in point form and addresses these issues below.

APVMA REVIEW OF FENTHION

The Hills Orchard Improvement Group Inc (HOIG) represents pome and stonefruit growers in the Perth Hills region of Western Australia. We begin by stating that we make no comment in this submission on permits for uses of fenthion other than for pome and stonefruit.

With regard to pome and stonefruit, it is helpful to consider the history of the APVMA review of fenthion in the light of the Chief Executive Kareena Arthy's comments to the Senate Rural and Regional Affairs and Transport Committee on July 7, 2014:

> *"When it comes to fenthion we have not seen any evidence that the risk can be managed."*

The APVMA has held seven positions on the safe level of the use of fenthion on fruit since September 2012:

1. Prior to September 11, 2012 the use of fenthion was unrestricted.
2. Consumption of edible skin stonefruit treated with fenthion is then deemed unsafe (fenthion suspension announced September 11, 2012).
3. Consumption of edible skin stonefruit treated with fenthion is safe (permit issued October 2012).
4. Consumption of edible skin stonefruit treated with fenthion is safe, except for peaches and apricots treated with fenthion, which is unsafe (permit suspension October 2013).
5. Nectarines and Plums can be safely sprayed with three applications in 2013, not two as in 2012.
6. Consumption of edible skin stonefruit treated with fenthion is safe (permit October 2013).
7. Fenthion products may pose unacceptable risks to human health through dietary and occupational exposures, and to the environment (permit suspended May 22, 2014).

The APVMA advised industry groups in 1994 of its intention to review fenthion, with the review starting in 1997. As part of the 1994 review of existing chemicals for reconsideration, the APVMA and its partner agencies prioritised fenthion for inclusion in the third cycle of the existing chemical review program (ECRP) in 1998. As part of the announcement of the fenthion review in 1998, the APVMA called for submissions from the public and interested groups.

Given Ms Arthy's comment that there is no evidence that the risk posed by fenthion can be managed and her evidence to the same Senate Committee hearing that "*fenthion is a nerve poison that can cause a range of adverse health impacts, including nausea, vomiting, diarrhoea, laboured breathing, coma and death*" the question arises, how could a responsible regulator continue to issue permits for 20 years since it signalled a review of this chemical?

The answer must lie in the fact that there is no demonstrable harm from this product when it is used according to the manufacturer's instructions.

The experience of HOIG members has been that used in accordance with the permit fenthion does not have deleterious effects on workers or consumer health. If there were Australian examples of fenthion causing harm to workers or consumer health, growers would be the first to call for its removal from sale.

It remains our contention that there is no recorded instance of workers or consumers having suffered any ill effects from the use of fenthion in Australia. HOIG has over the past two years requested the APVMA to provide proof of these claims, particularly in an Australian context. However, the APVMA has provided no evidence to the contrary. Had such evidence existed we are sure that fenthion would have been banned immediately.

HOIG believes as a regulator the APVMA must conform to the requirements of the scientific method and adopt proper scientific research protocols in the performance of its role.

The scientific method attempts to minimise the influence of a scientist's bias on the outcome of an experiment or evaluation. Given the importance of her evidence to the Senate Committee it would appear that the APVMA was testing Ms Arthy's hypothesis or theory that "w*hen it comes to fenthion we have not seen any evidence that the risk can be managed".* It is our contention that this hypothesis is the preferred and even pre-determined outcome of the APVMA given that the APVMA had already attempted to suspend the use of fenthion in September 2012 and again in October 2013.

Having signalled that it would suspend the use of fenthion twice, we contend that the APVMA had a "preference outcome" to deregister fenthion for most uses. The evidence is strengthened by the public statement of Executive Director, Raj Bhula, who told growers at a public meeting held at the Canning Vale markets in October 2012 that if fenthion was to continue being used then growers would be putting the health of young children at risk. At initial meetings with HOIG APVMA staff told HOIG and other growers well before the review was finalised that fenthion had been banned in the United States, Canada and in the European Community and would be banned in Australia. Before the public comment process was concluded, a staff member of the Minister for Agriculture Joe Ludwig advised consultants of HOIG that the APVMA would ban fenthion. The Western Australia Department of Agriculture and Food and FruitWest have on different occasions advised HOIG members that fenthion would be suspended.

The most fundamental error in the scientific method is to mistake the hypothesis for an explanation of a phenomenon, without performing experimental tests or diligently and conscientiously reviewing the literature on the topic. Sometimes "common sense," "precedent", "pattern" and/or "logic" tempt people and agencies into believing that no real or thorough test is needed.

Another common mistake is to ignore or rule out data which do not support the hypothesis. The refusal of the APVMA to provide to HOIG examples or instances of harm to workers or consumers perhaps highlights this shortcoming.

Ideally, the research has to remain open to the possibility that the hypothesis is correct or incorrect. Sometimes, however, a scientist may have a strong belief that the hypothesis is true (or false), or feels internal or external pressure to get a specific result. In that case, there may be a psychological tendency to find "something wrong", with data which does not support the scientist's expectations, while data which agrees with expectations may not be checked as carefully. We are concerned that not all data has been handled in the same way and we propose to highlight examples of this.

HOIG contends that the scientific method if used distinguishes science from other forms of explanation because of its requirement for systematic experimentation and evaluation, transparency, empiricism and logical thinking. The APVMA's logical inconsistency in decision-making highlights the lack of scientific rigour and adherence to the scientific method.

Prior to September 11, 2012, permits issued by the APVMA for the use of fenthion to control Mediterranean fruit fly were for unrestricted usage. The number of applications was not limited or stated. The then permit commented that early in the season it was suggested two applications were sufficient, but there was no strict limit. Later in the season the permit recommended use based on certain intervals between sprays until one week before harvest.

On September 11, 2012, fenthion's use on edible skin produce was suspended; post-harvest uses on fruiting vegetables such as tomatoes was also banned. Use on all fruit and vegetable crops grown in the home garden was also suspended. The APVMA also published the revised toxicology component of the report prepared by the Office of Chemical Safety (OCS) in the Department of Health and Ageing in connection with the APVMA's review of fenthion: *Human Health Risk Assessment of Fenthion* (the OCS Report). The OCS Report confirmed the Acceptable Daily Intake (ADI) for fenthion of 0.002 mg/kg bw/day, and also confirmed the Acute Reference Dose (ARfD) of 0.007 mg/kg bw.

In December 2005, the APVMA released the Fenthion Preliminary Review Findings Report: Part 1 (PRF) which dealt with products used in non-food producing situations.

The APVMA has since claimed to have received new dermal absorption data indicating that fenthion is more readily absorbed than previously understood. This data led to revised OHS findings for products included in Part 1 of the review. These revised findings are included in the latest PRF, published 22 May 2014. The APVMA recommended further restrictions to the use of fenthion. The PRF brought together all risk assessments done to date, including toxicology, worker exposure and environmental effects.

The APVMA concluded that in a number of situations fenthion products may pose unacceptable risks to human health through dietary and occupational exposures, and to the environment. The APVMA proposes the following regulatory actions to manage these risks:

- cancellation of a cattle lice control product,
- cancellation of all pest control and home garden products except the fenthion 1% dust product
- variation of the label of the fenthion 1% dust product to remove use in ceilings, wall spaces and crawl spaces and update the safety directions, and
- a variation of the label of the horticultural product to remove all uses except post-harvest dipping of tropical and subtropical fruits with inedible peel, and to update safety directions and warnings.

This new set of label instructions is clearly at odds with Ms Arthy's position that "when it comes to fenthion we have not seen any evidence that the risk can be managed".

Ms Arthy will respond that she is not a scientist, but HOIG contends that as the Chief Executive of the organisation she speaks for its public position.

Over the past two years the APVMA has been claiming that growers can produce stonefruit crops without fenthion. Alternatives proposed by the APVMA include baits, traps and other pesticides. For some time the APVMA has been lauding the efforts of a Hills grower who described himself as developing a spray regime used on his orchards without fenthion in an article that he authored in the Australian Stonefruit Grower (No1/13 – February March 2013). He comments about the chemicals he uses that they are "*all to some extent against the label and therefore illegal in most jurisdictions".*

Knowing that his behaviour could be unlawful, the regulator repeatedly refers to his results, including in the PRF.

With regard to efficacy, equally as perplexing is the APVMA's position that there are alternatives to fenthion and in advancing this position they promote the use of:

- Thiacloprid - No proven in-field larvicidal properties
- Clothianidin - No proven in-field larvicidal properties. Suspended in four European countries under suspicion of killing bees. In the APVMA's 2007 assessment of clothianidin, the product is described as '...among the most toxic of all insecticides to bees'.
- Trichlorfon - No proven in-field larvicidal properties. Breaks down to the by-product Dichlorvos.
- Malathion - No proven in-field larvicidal properties.
- Spinosad/Spinetoram - No proven in-field larvicidal properties. Takes three days to kill flies from contact and meanwhile for that period the flies are alive and stinging fruit and causing further damage.
- Area Wide Management - Unproven system without the addition of Sterile Insect Technique, failed in several regions worldwide. Greek expert Nikos Papadopolous said AWM has failed multiple times when implemented in Greece and was only successful in three trials - a tiny area in Croatia, a trial site in the Israeli desert and in Valencia Spain on citrus trees. Great pressure often exists to declare successful Area Wide Management programs following an extensive and expensive control program. Population density data are rarely published during the program, and monitoring may stop once a project is heralded as a success. The evaluation of the pest is almost exclusively done by the affected industry and its support services. Often the cost of the proposed eradication program is paid for by government for the benefit of an industry. The evaluation of the impact of AWM concentrates primarily on the immediate effects on producers. If the pest does not influence all producers equally, those who manage to grow and harvest their crops will enjoy a large profit and potentially bias the evaluation.

At the Senate RRATC hearing Executive Director Dr Raj Bhula said "*In terms of alternatives that are available, the APVMA issued a permit for two years for use of existing pesticides, which is then extended to fruit fly control. People who have been using that insecticide according to the permit instructions are finding very, very good control – in fact better than if not the same as fenthion* (except it has no proven in-field larvicidal properties) *if you actually stick to the sprayer regime that is in that permit. Preliminary results have come through from New South Wales and some limited work from Western Australia*".

Ms Arthy said at the same hearing "*There are a lot of chemicals registered for the use of fruit fly control that are not based on fenthion. In particular, there are some new ones on the market which I understand are getting very good outcomes. There is also area-wide management which is being used. So there are alternatives".*

This is not correct. HOIG restates these alternative chemicals and Area Wide Management have no proven ovicidal or larvicidal properties. They do not kill fruit fly eggs or maggots and because of this our harvest is extremely vulnerable.

At the same hearing, when challenged, Dr Bhula confirmed that Samurai "*does not kill larvae".*

CURRENT REGULATORY STATUS OF FENTHION IN AUSTRALIA

On October 16, 2013, the APVMA again announced a suspension on the use of fenthion on peaches and apricots and allowed three applications, 10 days apart with a 14-day withholding period, on nectarines and plums. On October 29, 2013, a revised permit allowing

for one application of fenthion on peaches and apricots was allowed with a 21-day withholding period and three applications, 10 days apart, with a 14-day withholding period on nectarines and plums. Again, this permit contradicts the position of the agency that “when it comes to fenthion we have not seen any evidence that the risk can be managed”.
The announcement followed one a year earlier on October 31, 2012 when the APVMA, following consultation with interested parties issued a new permit applicable in Western Australia allowing for two applications on stonefruit 10 days apart and with a 7-day withholding period.

On October 16, 2013 the APVMA again suspended the usage of fenthion on peaches and apricots and allowed three applications, 10 days apart with a 14 day withholding period on nectarines and plums. On October 29, 2013 a revised permit allowing for one application of fenthion on peaches and apricots was allowed with a 21 day withholding period and three applications, 10 days apart, with a 14 day withholding period on nectarines and plums.
How fenthion was deemed to have been an unacceptable risk to the public through edible skinned fruit consumption in September 2012, yet deemed to be safe for public consumption of the exact same produce in October 2012, has not been explained. HOIG points out that there was no evidence of harm to growers or consumers in this period. The APVMA in less than two years has twice signalled the suspension of fenthion on peaches and apricots because of the unacceptable risk to consumers of using fenthion. On both occasions it reversed that decision. On one occasion it banned the use of fenthion on all stone fruit but now recommends the usage on plums and nectarines to three applications per season.

The APVMA bases its decision on Preliminary Review Findings Report (PRF) which calls upon a series of technical reports for all registrations and approvals relating to fenthion. These reports are the:

> Toxicology Assessment, *Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Fenthion* (2008 published 2012)
> *Occupational Health and Safety Assessment of Fenthion* (Dec 2013 published May 2014)
> *Fenthion Residues and Dietary Risk Assessment Report* (September 2012), which considered the horticultural uses of fenthion as permitted on the product labels, and
> *Supplementary Fenthion Residues and Dietary Risk Assessment Report* (October 2013), which considered new information submitted in July and August 2013 for the horticultural uses of fenthion
> The *Fenthion Veterinary Residues and Dietary Exposure Assessment* (April 2014),
> Environmental Risk Assessment for non-food uses (2005) contained in the *Preliminary Review Findings Report – Part 1: Uses of fenthion in non-food-producing situations Volume 2: Technical Reports*
> Environmental risk assessment of food uses *Environmental Chemical Review Assessment Report Fenthion: Food Uses only* (revised 2014).

HOIG has considered all technical reports applicable to the pome and stonefruit industry in the following sections of this submission.

INTERNATIONAL REGULATORY STATUS

The PRF notes that fenthion is not registered for use on food producing plants in Canada, the European Union (EU), New Zealand or the USA. The APVMA seems to place considerable weight on this fact but HOIG is of the view that it is incumbent on the regulator to prove its case in its own jurisdiction. . This position is contrary to the APVMA’s position of not taking overseas data into account to register a new product and is one of the reasons for lengthy delays. HOIG also wants to highlight that it is roughly a decade since fenthion was

removed from use these jurisdictions and there still has been no recorded instance of harm to workers or consumers from the use of fenthion in stone fruit production in Australia.
In general terms, HOIG is unconvinced that it is best practice to have the applicant and the decision-maker in these matters as the same party. But we are cognisant of the law and purely comment that when fairness is compromised then so is the prospect of just and equitable decisions. A fair process encompasses rules and practices that are known to all parties and adhered to by all. Fairness embodies freedom from bias and the opportunity to know the case against you in detail, and the opportunity to submit evidence to the contrary.

There is also an underlying tenet that all evidence will be publicly aired and laid open to scrutiny and that all parties will be treated equally.

We also remind the APVMA of the Australian Productivity Commission comments in 2008 when reviewing the APVMA's role in the chemicals and plastics industry:

> *"There is more likely to be a net benefit if regulation is tailored to the risk posed by a chemical in a particular circumstance (its use), rather than the blunter approach of intervening whenever there is a hazard*."

The Commission also said "regulation should wherever possible be light handed and commensurate with risk".

As we will be commenting on this fact later in our submission, we draw the APVMA's attention again to the fact that phase-out periods in these jurisdictions were implemented. Our research shows that this occurred in the EU, New Zealand and Canada.

SUMMARY OF ASSESSMENTS AND PROPOSED FINDINGS

The production of summaries in the PRF as the justification for cancelling the label approvals is far from satisfactory. Again there is little adherence to the scientific method when assessment outcomes are announced but the theoretical, experimental and research supposedly supporting the assessment outcomes is absent. We have to accept that the supporting evidence is in the technical reports and because the referencing is scant the reader has to find the support information. To compound this lack of transparency, there is no bibliography to support basis of the APVMA's recommendation. HOIG is aware from the RRATC Hansard that the scientific data upon which the APVMA is basing its recommendations made in the PRF are from 162 references.

To highlight the lack of transparency in the PRF the supporting evidence for the Coulston, Griffin and Rosenblum Report "Safety Evaluation of Fenthion in Human Volunteers: Final Report (1979) *(the Coulston Study)* should be examined. Ms Arthy told the RRATC *the Coulston Study* may not be perfect by contemporary standards (but) the committee still considered it to be the most appropriate study for setting the fenthion ADI when a weight for evidence approach was taken. This is a very different approach to that taken by the US EPA in 2001. The US EPA received an approach from Health Canada commenting on the use of the human study. "The extent to which the human study can be utilised in the modification of the interspecies factor should be reconsidered. This study may be of limited value in the consideration of an acute reference dose due to study limitations including the small group size, testing in one sex and the timing of cholinesterase determinations (24 hours after dosing)." Unlike the APVMA, The US EPA made a decision not to use the human data.

The APVMA places considerable credence on this study when the US EPA did not. The APVMA notes in their submission to the RRATC "the *Coulston Study* was considered by the US and Canada during their assessments of fenthion but was not included as the basis of any regulatory decision because of government policy that specifically excludes human

studies on pesticides because of ethical concerns over the conduct of such studies. This was a consideration but the US EPA appears to have been influenced in the consultation period of the Interim Reregistration Eligibility Decision for Fenthion by the submission from Health Canada. The US and Canada used the monkey study by Rosenblum (1980) as the basis of their health standards.

The APVMA in its submission to the RRATC states “the study by *Coulston et al* (1979) was determined to be the most suitable for establishing the Australian acute reference dose because it was:

- designed appropriately
- conducted in a relevant target species (humans)
- measured the most sensitive harmful effect relevant to humans
- is supported by the monkey study by Rosenblum (1980)

Health Canada questioned *the Coulston Study* because of the small group size, testing of only males and the timing of cholinesterase determinations (24 hours after dosing). Health Canada refers to the study as being of limited value and the US EPA agreed with this view. The US EPA also stated that the duration of the human study was too short for it to be considered in chronic dietary or intermediate-term risk assessments. The US EPA concluded that there was no evidence of fenthion-induced carcinogenicity, developmental toxicity or increased sensitivity of offspring; and no neuropathological effects associated with fenthion.

The Coulston F, Griffin T, Rosenblum I (1979) Safety Evaluation of Fenthion in Human Volunteers *Study* has never been peer reviewed for publication and is now nearly 35 years old and is one of many such documents the APVMA relies upon to justify its recommendation.

Nevertheless the APVMA in 1997 accepted that the most sensitive biological effect was the most appropriate end-point to base the NOEL. A NOEL of 0.02 based on plasma ChE inhibition at 0.07 mg/kg bw/d in a 4-week 1979 human study was acceptable (*The Coulston Study*) a 10-fold safety factor on the NOEL was satisfactory and the ADI was amended to 0.002 mg/kg bw/d.

At the RRATC hearing on JULY 7 the APVMA said it is common practice for regulatory agencies to receive both published and unpublished data. They also said in their Additional Submission dated July 2014 irrespective of the age of a study, whether it is an unpublished company study or one published in a scientific journal, all studies are assessed on their scientific merits. This includes a consideration of the design and conduct of a study, in addition to the results of the study and that all studies are benchmarked against international standards of experimental design and analysis, such those published by the Organisation for Economic Cooperation and Development as part of their Test Guideline Program. In the reports released there is no indication of where this assessment was made and by whom.

The heart of the problem is that any research or experiment relied upon by the APVMA cannot be replicated to test its veracity.

While so many of these reports relied upon by the APVMA remain unpublished – and not available to the public - this round of community consultation is severely compromised because there is no access to expert and peer commentary of research purportedly relied on by the APVMA in making the recommendations on fenthion it has. The *Coulston Study* is one of the cornerstone reports but was not publicly available and the APVMA was not able to supply a copy to the RRATC.

In March 2011, the APVMA said in a document entitled *Review of the uses of dimethoate and fenthion - Frequently asked questions":* the APVMA has a Chemical Review Program that considers new research or evidence regarding the use or safety of particular chemicals or products. As the APVMA had commenced its review of fenthion in 1994 there is an expectation that there would be some new research or evidence. But that seems not to be the case.

In 2007 the Office of Chemical Safety prepared for the APVMA a review of the "*Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Fenthion"* and found "*no changes to the approval status of fenthion have been proposed in this review …There is no objection on public health grounds to the continued registration of all other existing fenthion products except for three pesticides for home garden which were no longer supported*".

Of the references provided, all but two of the studies were conducted before the year 2000. See Table No. 1 below.

Table No.1
Year research papers published or produced that the APVMA relies upon in the PRF

Year	Number of references
1947	1
1948	
1949	1
1950	
1951	
1952	
1953	
1954	
1955	
1956	
1957	
1958	
1959	1
1960	5
1961	6
1962	2
1963	6
1964	1
1965	2
1966	3
1967	4
1968	2
1969	2
1970	5
1971	3
1972	1
1973	1
1974	3
1975	4
1976	1
1977	1
1978	6
1979	6

1980	**7**
1981	
1982	**7**
1983	**3**
1984	
1985	**6**
1986	**2**
1987	**14**
1988	**11**
1989	**6**
1990	**15**
1991	**4**
1992	**2**
1993	**6**
1994	**5**
1995	**1**
1996	
1997	**3**
1998	
1999	**1**
2000	**2**
2001	
2002	
2003	
2004	
2005	
2006	
2007	
2008	
Total	**162**

Since the announcement by the APVMA that it would review fenthion in 1998 only three new research papers have been considered, none from this century. On average research considered by the APVMA was produced in 1980 and at the time of the release of the Review of Toxicology by the OCS the information relied upon was on average 28 years old.

OCCUPATIONAL HEALTH AND SAFETY (OHS)

The APVMA placed public notices seeking information from anyone who felt they may have suffered ill-effects from fenthion usage (for example the Good Fruit & Veg Magazine). From these initiatives the APVMA has not reported any instances of anyone with evidence to show any worker or consumer has been harmed by the use of fenthion in fruit industry produce.
The APVMA's response as to the lack of any evidence was the "reporting program for health issues said there had been no reports through this program of any human health or poisoning cases due to dimethoate or fenthion. However, it is often difficult to recognise if a health issue is directly related to a specific chemical, particularly if the effects are subtle. The fact that an incident is not reported does not mean it has not happened." Nor that it has, particularly when Ms Arthy described the adverse health effects of fenthion as *"nausea, vomiting, diarrhoea, laboured breathing, coma and death*".

The OHS risk assessment recommendations based on drafts prepared in August 2001, May 2005, September 2010 and finally revised again in December 2013 were made for fenthion products currently registered under permit in Australia. In February 2007, the APVMA advises that it had received new scientific data regarding the dermal absorption of fenthion. This was assessed as part of the revised toxicology report (2008). The occupational exposure assessment for all products was revised using this new data. And the final report incorporated the new data and made the following comments: the OCS "*recommends that the APVMA should be satisfied that fenthion will not present an undue risk to human health via occupational exposure when used on: vegetables and fruits by boomspray and closed cab airblast*."

The *Occupational Health and Safety Assessment of Fenthion* (December 2013 published May 2014) recommends fenthion applications for stone fruit (except cherries) for Mediterranean fruit fly in Western Australia as a cover spray to provide additional protection over and above fruit fly baiting. Fenthion is recommended to be applied at a maximum of 2 sprays per season, no less than 10 days apart if signs of fruit fly strike are seen, or monitoring numbers indicate that treatment is required.
In Queensland, New South Wales and Victoria it is recommended: Spray fruit thoroughly. Apply full cover sprays at a minimum 7 days interval, until 3 weeks before picking commences. DO NOT apply more than 3 sprays per season

The OCS recommended that the APVMA can be satisfied that all fenthion products will not cause adverse effects to the health and safety of persons preparing and applying these products when used in accordance with the amended label instructions regarding safety directions, precautionary statements and re-entry statements.

To quote the report:
OCS recommends that the APVMA should be satisfied that fenthion will not present an undue risk to human health via occupational exposure when used on:

- *vegetables and fruits by boomspray and closed cab airblast;*
- *mosquito larvae in water when using high-pressure spray equipment and on adult mosquitoes and larvae in septic tanks and commercial areas for the control of control of spiders and ants;*
- *produce for quarantine treatment;*
- *treatment of cracks and crevices for crawling insects as a 1% dust formulation; and*
- *on cattle as a spot-on ectoparasiticide when applied with a Spot-On Gun or Dial-a-dose cup.*

TOXICOLGY

The Office of Chemical Safety, Department of Health and Ageing (OCS), has reviewed the available toxicology data for fenthion and confirmed the Acceptable Daily Intake (ADI) of 0.002 mg/kg bw/d. The OCSEH has also recommended an acute reference dose (ARfD) of 0.007 mg/kg bw be established for fenthion.

The OCS had no objection on toxicological grounds to the ongoing approval of the active constituent fenthion as they have established threshold levels for safe exposure to fenthion. These are the Acceptable Daily Intake (for long term exposure) and the Acute Reference Dose (for short term exposure). The continued use of fenthion is only supported if these established thresholds are not exceeded.

The PRF Part 1 Uses of fenthion in non-food producing situations was released in December 2005 in two volumes, technical reports and the review summary.

The Summary of Data Assessments concluded for:

- toxicology - “Based on the toxicological assessment this product is considered appropriate for continued use.”
- occupational health and safety – Water, septic tanks
  The risk to workers involved in this use is not expected to be significant provided the products are used in accordance with label instructions. Commercial and domestic areas it was assumed that fenthion products will be applied by registered pest control operators, therefore there is the potential for significant and repeated use.
- the environmental assessment for the review of fenthion was undertaken by the Department of the Environment and Heritage (DEH)
  The following use patterns are determined to be acceptable, provided that the products are used in accordance with label instructions:
- companion animal usage for the control of fleas on dogs
- use for the control of crawling insects (dust formulation in commercial pack sizes).
  Products used for the control of mosquitoes require label changes to reduce environmental concerns. If this information is added these products would be considered acceptable. Products used for bird control require label updates to reduce environmental concerns.

In 2013, with the APVMA, the stonefruit industry and HOIG conducted residue testing trials of the new spray permits. HOIG was surprised when the results of the residue of fenthion testing conducted by Horticulture Australia Limited (HAL) by Agrisearch (Agrisearch draft report) indicated levels above the accepted MRL. On examination of the results published in the Agrisearch draft report, orchardists considered the results were too high and an analysis of the figures by our consultants was instigated immediately. It was found that the methodology to determine the residue of total fenthion was scientifically questionable, if not flawed. The most contentious element of the methodology was the treatment of residues that were reported as <0.05 or below the Limit of Detection (LOD). These results were reported consistently through the report as a residue level of 0.05mg/kg.

HOIG sought clarification from HAL as to why this interpretation of the residue analysis had occurred. HAL advised it had sought feedback from the APVMA regarding fenthion residue results and the APVMA requested that the approach adopted be to record a residue figure of 0.05mg/kg, even though the test result of <0.05 was below the LOD.

This then brought into question the accuracy of all test results. To verify the methodology HOIG obtained informal advice from a scientist at a chemical laboratory to which we received this response: “*Any test results under 0.05mg/kg should be more accurately measured to 0.000mg/kg and to do otherwise was farcical*”. HOIG was then told a “methodology” that adopted an approach that recorded something below the LOD as being equivalent to 0.05mg/kg was “logically, mathematically and scientifically flawed”.

Because of the “methodology” that converts <0.05 into 0.05 we then saw the phenomenon where the 'untreated' or control sample fruit returned a residue level of 0.3mg/kg, that is, above the allowable MRL of 0.20 or 0.25mg/kg even though the fruit was not sprayed.
HOIG subsequently engaged Dr Mark Imisides to provide advice on the methodology used by Agrisearch, at the instruction of the APVMA. Dr Imisides questioned the methodology of the Agrisearch Study. In particular, where a result of <.05 is recorded as 0.05 and the cumulative result of six individual data points which are below the detection limit being recorded as 0.3mg/kg – even in fruit that has not been treated. In short he was of the opinion that the methodology was not scientific.

HOIG also conducted a residue surveillance protocol and trial developed by the APVMA to establish whether standard orchard practice used in the Hills orchards would allow the continued use of fenthion on pome and stone fruit crops. What HOIG was unaware of was that without reference to them the required testing as stipulated by the APVMA was altered to a 6-component residue. Analyses for fenthion oxon sulphone and fenthion oxon sulphoxide were not provided and therefore the APVMA did not appear to consider HOIG's trial results.

The APVMA's decision also had the effect of rendering approximately 4000 residue test results supplied from Western Australia over the period October 1, 2008, to 2012 invalid. The level of compliance of all MRLs was 100per cent. Jason Lutze was made aware of these results on October 19, 2012. Residue results were also available from 2002 to September 2008. Over this period there were nearly another 1200 samples and only 10 reported detections of fenthion above the MRL.

Jason Lutze said *to* Chris Hall and others on October 22, 2012 of these results: *"Acknowledging that none of the detections for stone fruit exceed the currently established MRL …. it would be instructive to know if the detections were associated with only a small number of growers. …there may be a geographical or management practice reason for this that may be worth further follow up in our consideration of the alternative proposals."* Instead of pursuing this line of inquiry Lutze removed this data from the review's consideration.

The results of the HOIG study indicated that the use of fenthion had been applied successfully and residue testing showed that fruit was below the relevant MRL. There were observable and measurable parameters that allowed control and evaluation of the efficacy of the program. The percentage of the samples with NO detectable residues of fenthion was 64%.

The results highlight that fenthion can be used as a tool to control fruit fly numbers and to assist in the production of quality fruit. At the same time monitoring provides assurances that environmental and health impacts are controlled within acceptable standards. Despite the difference in the residue levels, it has to be pointed out that all the analysed pome and stone fruit were absolutely safe for consumers according to FAO/WHO (1998) MRLs. The APVMA fails to acknowledge changing the residual methodology or failing to communicate this alteration to HOIG. We will discuss this issue further later in this commentary.

RESIDUES, DIETARY RISK ASSESSMENT AND TRADE

The PRF details that in conducting a dietary risk assessment, the exposure to fenthion by different age groups within the population are compared with the reference health standards set by the OCS, namely the ARfD and the ADI. Dietary exposures below these health standards are considered acceptable while those exceeding these health standards would be considered unacceptable. 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 (NEDI) and National Estimated Short-Term Intake (NESTI) calculations were undertaken in accordance with the World Health Organisation (WHO) - United Nations Food and Agriculture Organization's (FAO) recommended guidelines as agreed with Food Standards Australia New Zealand (FSANZ).
The PRF summarised the findings of the:

- *Fenthion Residues and Dietary Risk Assessment Report* (September 2012), which considered the horticultural uses of fenthion as permitted on the product labels, and
- The *Supplementary Fenthion Residues and Dietary Risk Assessment Report* (October 2013), which considered new information submitted in July and August 2013, and
- The *Fenthion Veterinary Residues and Dietary Exposure Assessment* (April 2014),

In September 2012 the APVMA announced the proposed suspension of fenthion for use on a variety of fruit crops in Australia and called for submissions. The APVMA issued new instructions that proposed to restrict the use of fenthion on a number of food crops due to alleged potential short term dietary risks.

HOIG responded seeking a further review based on standard orchard practice and for the introduction of a three spray regime with a 7-day withholding period until the review had been concluded.

As the Review was based on the permitted label use, which allowed for multiple applications of fenthion, representations by HOIG and others convinced the APVMA to permit the continued use of fenthion on a restricted basis for one year. On October 31 2012 the APVMA issued a temporary permit in Western Australia that allowed for two sprays of fenthion on commercially grown pome and stone fruit, 10 days apart and with a 7-day withholding period. HOIG agreed to participate in a residue surveillance protocol and trial developed by the APVMA to establish whether standard orchard practice used in the Hills orchards would allow the continued use of fenthion on pome and stone fruit crops based on new MRLs.

The relevant MRLs for the purpose of this trial are listed in the table below.

Variety	Mg/kg
Apricot	**0.20**
Cherry	**0.40**
Nectarine	**0.25**
Peach	**0.20**
Persimmon	**0.30**
Plums	**0.25**
Pome fruit	**0.25**

Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRLS Standard) 2012

The APVMA saw the program as a tool to mitigate the risk of unacceptable residues associated with the supported interim uses of fenthion in orchards. HOIG accepted this premise but also saw an opportunity to evaluate the impact of a two-spray fenthion regime and other changes made by the APVMA to the use of fenthion on the sustainability of their orchards.

The program was supported by 46 orchardists out of 60 HOIG members. Of those 44 successfully completed the trial. No test result exceeded the MRL standard of 0.20mg/kg for peaches, 0.25mg/kg for apricots, nectarines, plums and pome fruit, and 0.30mg/kg for persimmon/fuyu and 0.40mg/kg for cherries. Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRLS Standard) 2012 (see Appendix 2 MRL results). Of the 19 nectarines tested, 10 results, or 53%, were <0.05mg/kg; four were between 0.05 and 0.099mg/kg; three were between 0.10 and 0.149mg/kg; one was 0.16mg/kg; and one was 0.21mg/kg.

For peaches there were 9 test results: three tested at <0.05mg/kg; three were between <0.05 and 0.099mg/kg; one was 0.14mg/kg; one was 0.18mg/kg; and one was 0.20mg/kg.

HOIG agreed in writing and agreed to by the APVMA to participate in a residue surveillance protocol and trial developed by the APVMA to establish whether standard orchard practice

used in the Hills orchards would allow the continued use of fenthion on pome and stone fruit crops.
The residue monitoring program was stipulated by Jason Lutze Manager Pesticide Residues Manager APVMA He confirmed his instructions to HOIG by e-mail and also in an e-mail dated November 5, 2012, to Graham McAlpine Executive Manager FruitWest and copied to Raj Bhula Executive Director Pesticides APVMA. The APVMA required:

- "residue testing for fenthion must be according to the residue definition of sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion. Analysing only for parent compound is not acceptable;
- sample collection must be targeted at samples that are likely to have been treated with fenthion and at times of maximum likely use of fenthion;
- treatment records or spray diaries, including dates of fenthion application, rates of application, and harvest date must be collected for each sample;
- survey results, including the treatment history for each sample, must be reported to the APVMA by 1 June 2013 (revised to 14th July). In the event of a residue being detected that exceeds the MRL the result must be reported to the APVMA within 48 hours; and
- sample numbers for the 2012 - 2013 should be no less than those specified by the APVMA. (Modified by mutual consent as HOIG does not include citrus fruit growers, there are only a few cherry growers in the hills area and it was unlikely that HOIG could provide 50 test results from peach and nectarine growers".

INFORMATION OBTAINED UNDER FOI

In November 2012 the APVMA changed the MRL testing requirements for fenthion including metabolites and although they allegedly claim to have informed HOIG, e-mail evidence shows Jason Lutze did that by getting FruitWest to include the new instructions in an undated e-mail titled "*FruitWest – Medfly Update.* Lutze seeks confirmation that the e-mail was sent and McAlpine confirms this on November 27. HOIG contends that the agreement to conduct testing was with the APVMA and that a generic e-mail from FruitWest did not supersede the agreement. Sending a generic e-mail to growers at the busiest time of harvest is unlikely to be read let alone absorbed.

In another round of e-mails McAlpine assures Lutze that Chris Hall, Total Quality Assurance Systems Pty Ltd, has informed HOIG of the changed testing requirements. Hall denied this and performed the testing on the original instructions. HOIG and, it appears Chris Hall, were of the view that the arrangement agreed to with the APVMA had not been altered.

Although heavily edited, an APVMA file note (G00108) titled Contact with FruitWest WA suggests that the APVMA is concerned that there was a decline in submitted data and that FruitWest had not submitted any samples for 2012-13. The APVMA is also concerned that HOIG had supplied 44 samples and none from citrus and grape growers. They clearly had taken no notice of the agreement where we said "HOIG does not include citrus fruit growers, there are only a few cherry growers in the hills area."

The APVMA said the HOIG residue monitoring undertaken for the samples did not address the full residue definition as established by the APVMA. It was not suitable for regulatory purposes. Bearing in mind the significant cost and time associated with our residue monitoring, HOIG believes the APVMA decision not to consider the data is not a matter to be laid at the feet of HOIG.

The APVMA did not consider FreshTest data, which has been compiled over the past decade containing tens of thousands of samples from random testing conducted with produce

collected from wholesale markets around Australia. FreshTest's data shows 98% of fresh produce has a nil residue return for fenthion.

It should be noted that during this period the Pest Free Areas (PFAs) of Victoria were still under care and maintenance. PFAs were areas the Victorian government attempted to keep fruit fly-free. The Victorian Government legislated under ICA21 that produce entering Victoria from another State had to be sprayed with fenthion around 5-7 times to ensure that the imported produce was fruit fly-free.
The standard usage pattern in Western Australia was 1-2 applications, with a 3rd application available in times of extreme fruit fly instigated crop losses.
The reliance of the APVMA on international research and the decisions of international regulators for re-registration is perplexing. For the registration of pesticides the APVMA will not consider international research. The fact that 98% of produce over a decade returned nil fenthion residue detection at a time when fenthion was being applied at around more than twice the current permit rate, or 5-7 times the current permit rate for peaches and apricots, was not taken into account.

In terms of trade implications, it is HOIG's contention that the use of fenthion would not breach any sea freight protocols. These protocols require a 22-day cold treatment if the fruit comes from a district with fruit fly. From the day of spraying, then picking and assembling the fruit, inspection by DAFF and delivery to the wharf and shipping takes at least a month before it gets to market. This period of time would contribute to the degradation of any residue and consequently reduce the risk of exceeding the MRL.

The Perth Hills exports little of its produce except for plums which are shipped by sea to overseas markets. Occasionally small quantities of peaches are shipped to the Middle East by airfreight but there has never been an instance of this produce exceeding the MRL. Victoria accounts for 71% of summer fruit exports and approximately 95% of pear exports. Queensland accounts for 32% of apple exports and Tasmania accounts for 40% of cherry exports. These figures highlight the small exports emanating from the Perth Hills and the low likelihood that the use of fenthion may impact on Australia's trade.

ENVIRONMENTAL

Despite its admitted failings, the use of *the Coulston study* to set the Australian Acute Reference Dose for fenthion was endorsed by Australia's Advisory Committee on Pesticides and Health in 2000. This leaves industry at a disadvantage as neither *the Coulston Study* or the Driest and Popp Study (1997) are publicly available and therefore cannot be considered by those asked to comment on the APVMA's recommendations.

Ms Arthy has said the APVMA is "about managing risk and we are convinced from the evidence that has been supplied based on all these different studies from all over the world that there is sufficient risk to humans from fenthion, even though in Australia we have not specifically asked for human studies". HOIG understands this simplistic position but is unable to deduce from the published data whether the risk applies when the product is used according to the label. The OCS report suggests not.

The APVMA advised the public in the PRF of the technical reports for all registrations and approvals relating to fenthion were contained in the seven reports listed earlier in our comments. They listed two environmental reports as the basis to their comments in the PRF pertaining to the environment:

- Environmental Risk Assessment for non-food uses (2005) contained in the *Preliminary Review Findings Report – Part 1: Uses of fenthion in non-food-producing situations Volume 2: Technical Reports* and the

- Environmental risk assessment of food uses *Environmental Chemical Review Assessment Report Fenthion: Food Uses only* (revised 2014).

The APVMA has overlooked the 2002 Environmental Chemical Review, produced by the Department of the Environment. The 2002 report considered fenthion's use in orchards as acceptable with a buffer zone and spray drift warnings. The APVMA responded by updating spray drift guidelines.

The vast bulk of the 2002, 2009 and 2014 reports are identical. There were two new studies considered after the 2002 report with the majority of additional information being revised or updated guidance manuals or regulations of other regulatory agencies.

The 2009 Report includes 17 additional references. However, just one appears to be a new study conducted post-2002 - Probst et al. (2005) Scenario-Based Simulation of Runoff-Related Pesticide Entries into Small Streams on a Landscape Level.

- Animal Health Australia (2009). Australian Wildlife Health Network, Pesticide Poisoning. *Animal Health Surveillance Quarterly* Vol. 14, Issue 4, 6, 1 October – 31 December 2009. Published.
- APVMA (2008) How the APVMA determines the size of protective no-spray zones. Australian Pesticides and Veterinary Medicines Authority. Website (as of September 2008): http://www.apvma.gov.au/users/spraydrift/no_spray_zones.pdf.
- APVMA (2008a) APVMA Operating Principles in Relation to Spray Drift. Website (as of 24 November 2008): http://www.apvma.gov.au/users/downloads/spraydrift_op_principles_July2008.pdf
- APVMA (2008b) APVMA Veterinary Labelling Code. Website (as of 16 December 2008): http://www.apvma.gov.au/MORAG_vet/vol_5/vet_labelling_code.html.
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- Australian Wildlife Health Network (2012). Disease Events, Western Australia. *Wildlife Health in Australia (Newsletter of the AWHN)* Vol 10, Issue 2, 5, November 2012. Published.
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- European and Mediterranean Plant Protection Organisation (2003). Environmental Risk Assessment Scheme for Plant Protection Products (Honeybees). *Bulletin*, 33, 141 – 145. Published.
- European Commission (2004). Commission Decision of 11 February 2004. Website as of 15 January 2009: http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Commission_Decision_2004_140_EC_Fenthion.pdf

- Probst et al. (2005) Scenario-Based Simulation of Runoff-Related Pesticide Entries into Small Streams on a Landscape Level. ScienceDirect - Ecotoxicology and Environmental Safety available http://www.sciencedirect.com/science.
- US EPA 2004: Refined (Level II) Terrestrial and Aquatic Models for Probabilistic and Ecological Assessment of Pesticides March 30 - April 2, (Available www.usepa.gov).
- US EPA (2008). OPP Pesticide Ecotoxicity Database. Website as of 4 December 2008: http://www.ipmcenters.org/Ecotox/index.cfm However, just one, Probst et al (2005) Scenario-Based Simulation of Run-off-Related Pesticide Entries into Small Streams on a Landscape Level, appears to be a new published study, conducted post-2002.

The 2009 report found that the risk assessment for agricultural uses for fenthion indicated that it could not be used safely when sprayed on trees and vine crops as well as non-tree/vine crops listed on the current label. However, the risk was not deemed great enough to compel the APVMA to act.

From FOI documents, HOIG was interested to note that an unknown senior assessor in the Chemical Assessment Section in the Department of Environment tells other staff members preparing a response to the RRATC enquiry into fenthion that the updated 2009 report differs from the earlier 2002 report but none of this is in the public domain. How it differs is redacted and still remains not in the public domain. Of interest to industry is why the need for secrecy?

Perhaps it is because the 2002 report conclusion and recommendations unlike the 2009 and 2014 reports considered the use of fenthion in orchards as acceptable with a buffer zone and spray drift warning. The use in tropical orchards was considered acceptable with similar safeguards. The hazard to aquatic organisms was from applications to grapes and other minor crops on labels, kiwifruit and blueberries was determined to be acceptable under certain circumstances. The 2002 assessment suggested additional warnings be added to the label.

The 2014 Report includes in the list of references three new reports not included in the 2009 review.

The 2014 environmental risk assessment listed the risk characteristics as:

- there is a potential risk to birds feeding in and frequenting orchards arising from a single treatment of fenthion;
- significant effects on mammal populations from spraying were unlikely, although some individual animals could be affected if they entered treated orchards. No recommendations were made on the basis of risks to mammals;
- bees are at risk if present when spraying occurs and recommended the following label precaution if any pre-harvest uses were retained;
- there were risks to invertebrates (including beneficial invertebrates) within the treated areas; and
- there was limited data regarding phytotoxicity and effects on non-target plants are expected to be minimal. (Summary of data assessments)

Of interest, the Department of the Environment noted that several of the studies used were old and did not meet current requirements and standards. HOIG submits that this new information does not support the conclusion of the PRF that the possible risks to the environment from the use of fenthion on pome and stonefruit cannot be managed by adherence to the permit and spraydrift guidelines.

The APVMA may claim to review many chemicals on a continuous basis in which it assesses new information and data as it becomes available. Interim regulatory actions and other

measures are often taken throughout the review process to address urgent concerns. This does not appear to have occurred here.

The inclusion within the literature reports in the 2014 assessment are media reports alleging various negative effects of fenthion that may have occurred in Australia. These inclusions seem far from scientific or even appropriate without supporting evidence.

To illustrate this point, a story from the Bowen Independent, dated August 11, 1999, saying fenthion was involved in a reported bird poisoning incident in the Bowen area. How the link with fenthion is made is not substantiated. Mention is also made by reference to various articles appearing in November 2004 of a potential risk of fenthion being carried to outdoor dining areas via the claws of poisoned birds. The newspapers in which this story is carried are not referred to. The Victorian "Herald Sun" also ran articles on the deaths of a pair of peregrine falcons and their chicks that had lived in the Melbourne Central Business District with the suggestion that the deaths were caused as a result of the falcons' eating pigeons that had been poisoned by the use of fenthion. No proof of these allegations is provided by the APVMA or presumably the newspaper.

HOIG is concerned that the Department of Environment and the APVMA's review findings on aquatic species is based in part on the impact to two species that do not occur in Australia; Daphnia Magna – a fresh water flea of northern and western America, Eurasia and Africa and Penaeus Duorarum – a salt water shrimp of the USA. (11.2.2). These two species are listed as the most sensitive species to fenthion. HOIG is consequently concerned that the suspension of fenthion is going to be based in part on protecting organisms that are not known to exist in Australia.

The Department of Environment refers to Mysid Shrimp (a non-native, invasive species) and that fenthion's impact is of concern. Then at 11.2 it says the risk to aquatic invertebrates of coming into contact with fenthion seems flimsy.

The Department of Environment also expresses concern for the raptor species of bird. The report contends raptor birds may eat wingless grasshoppers that have been sprayed by an application of fenthion.

The Department of Environment makes no reference to the fact that fenthion is NOT registered for use on wingless grasshoppers in Western Australia; the only registrations are applicable to New South Wales and Victoria.

The Department of Environment admits fenthion has limited application in orchards for control of wingless grasshoppers saying: "Use for control of wingless grasshoppers in orchard situations appears to be very minor".

Since 2001 there has been a range of other products (126 registered – source: APVMA's app for iphone) available for use against wingless grasshoppers. HOIG agrees that wingless grasshoppers treated with fenthion could be eaten by raptors, causing harm or death to birds and the permit for this use should be cancelled.

Any other incidental or other harm to birdlife in Australia is linked to illegal usage practices or is not connected to horticultural usage.

The APVMA position is that it is acceptable to dump post-harvest treatment waste fenthion mixed at 75ml/100L for post-harvest dipping at 20,000L/ha but fenthion mixed at 75ml/100L in an airblast application at around 1,500L/ha is not acceptable. This is not a logical application of the data.

Also illogical in the Western Australian context is the identified risk that that there might be a rainfall event within 3 days of application. Rainfall figures for Western Australia suggest events of this intensity over the harvest period in the Perth Hills are rare, particularly that the runoff of fenthion is based upon a single (not cumulative) 100mm rainfall event. (11.2.2.7). an event of this dimension would be rare but almost exclusively restricted to the winter months. This is similar in regulatory terms to banning the use of Diuron in Western Australia because of the risk it poses from runoff to the Great Barrier Reef.

In the environment report in the assessment of orchards and other fruits section it is claimed normal practice in orchards is to spray fenthion to the point of run-off, requiring 1500-3000 L/ha of spray solution for mature pome and stone fruit trees, but this could be as high as 4000 L/ha for large pear trees and mango trees at a strength of 95ml/100litres.

With application to stonefruit, the Department of Environment is basing its risk assessment on the use of fenthion for control of Oriental fruit moth – at the worst case scenario rate of 3000L/ha and 95ml/100L. Again this is illogical.

This is not applicable to stonefruit production in the Perth Hills, where orchard practice is to use fenthion for Mediterranean fruit fly control at the rate of 1500 L/ha at 75ml/100L. We are of the view this is fairly constant Australia-wide and produces a demonstrably smaller environmental impact and therefore risk.

HOIG is of the view that based on the Department of Environment calculations, if the water volume was capped at 1500 L/ha and the rate of 75 mL/100L was used the environmental loading would be reduced by 60%. Unfortunately, HOIG doesn't have access to the models used by the Department of Environment in calculating the predicted environmental concentrations but we predict that a 60% reduction would be sufficient for the use of fenthion to remain justified on most if not all stonefruit. Assuming our assumptions are correct, HOIG wants to highlight another example of questionable "scientific" assessment that has been used in this process. These concentrations may be correct for Oriental Fruit Moth control but they are not for fruit fly control and the very least the Department should have done was conduct separate analysis for the control of each pest.

In any event, the APVMA lists 27 other registered products for control of Oriental Fruit Moth, so removing the registration of fenthion for this use on environmental grounds would address the risk identified.

HOIG also questions how the comment in the 2014 assessment of the statement "Photodegradation in soil could be a significant route of environmental degradation in Australia, given the high light levels during summer" came to be made. This is not a conclusion that could be drawn from any of the studies reviewed because no soil degradation studies published or unpublished were listed in the reference list.

Like the danger posed to species that do not occur in Australia, this is another factor that casts doubt on the grounds for suspension of fenthion.

PROPOSED REGULATORY ACTION

The APVMA said it was compelled to wait until the health and safety and environmental assessments had been completed because they might indicate the need for the immediate removal of fenthion from registration for use on pome and stonefruit.

On the evidence presented in the PRF there is no new evidence to support the immediate removal of fenthion from registration. Indeed, if used according to the label instructions, fenthion is deemed safe for human health and occupational exposure. HOIG contends that

as with all chemical use in food production, environmental risks can be managed by appropriate guidelines.

HOIG recommends that if permits are suspended the APVMA should allow a two-year phase-out period for the chemical to allow industry to transition to alternatives now in development.

HOIG relies on the precedents set by:

- Nufarm Dichlorvos 1140 Insecticide which was deregistered in 2010 and allowed to be used until 30 June 2012.
- Parathion Methyl, which was deregistered in 2011 and allowed to be supplied and used until July 26, 2013.

The APVMA advised HOIG that a phase-out period was not something contemplated by other jurisdictions. Our research clearly indicates that this occurred in Canada, the EU and in New Zealand for the very reasons advanced by HOIG. The Canadian Pest Management Regulatory Agency allowed a two-year phase-out period for the sale and use of any remaining fenthion product.

In 2003, the European Commission announced that proposed use of fenthion baits in olive and citrus plantations had raised concerns with regard to the possible impact on birds. On February 11, 2004, the Commission announced that all authorisations for plant protection products containing fenthion were to be withdrawn by August 11, 2004, except for bait applications in citrus, olives and peaches, which would be withdrawn by June 30, 2007 (European Commission, 2004).

In the event that the APVMA refuses to allow a phase-out period, HOIG urges the APVMA to adopt the recommendation of the Senate Regional and Rural Affairs and Transport Committee regarding a transition period.

The Senate Regional and Rural Affairs and Transport Committee report “Implications of the restriction on the use of fenthion on Australia's horticultural industry”, (July 2014), Recommendation 4: “The committee recommends that the maximum twelve month transition period allowed under the *Agricultural and Veterinary Chemicals Code Act 1994* be initiated by the APVMA, that fenthion be permitted for sale during the first half of that period, and that the APVMA allow fenthion to be used during the full transition period, subject to appropriate 'conditions of use'.