Australian Government
Australian Pesticides and Veterinary Medicines Authority

28 January 2014

Mr Tim Watling
Committee Secretary
Senate Rural and Regional Affairs and Transport References Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Mr Watling

Inquiry into the Implications of the use of Fenthion on Australia's horticultural industry

Thank you for the invitation on 13 December 2013 for the Australian Pesticides and Veterinary Medicines Authority (APVMA) to make a submission to the Rural and Regional Affairs Transport References Committee *Inquiry into the Implications of the use of Fenthion on Australia's horticultural industry*.

Please find enclosed the APVMA's submission to the Inquiry for consideration by the Committee.

Yours sincerely

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Australian Government

Australian Pesticides and Veterinary Medicines Authority

Senate Rural and Regional Affairs and Transport Reference Committee – Inquiry into the Implications of the use of Fenthion on Australia's horticultural industry

AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY SUBMISSION

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1. Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) welcomes the opportunity to provide a submission to the Rural and Regional Affairs and Transport References Committee Inquiry into the Implications of the use of fenthion on Australia's horticultural industry.

On 12 December 2013, the Senate moved that the following matters be referred to the Rural and Regional Affairs and Transport References Committee for inquiry and report by 25 June 2014:

a. the roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals;

b. the short-and long-term impact of the decision on stakeholders;

c. the effectiveness and sustainability of chemicals other than Fenthion to manage fruit fly;

d. transition arrangements following the restriction on the use of Fenthion, including Area Wide Management; and

e. any related matters.

2. Roles and responsibilities of the APVMA

2.1 Overview

The APVMA is an independent statutory authority responsible for the assessment, registration and regulation of agricultural and veterinary (agvet) chemicals in Australia.

The APVMA is part of a national regulatory system for agvet chemicals. In general terms:

- the APVMA regulates agvet chemicals up to the point of retail sale, and
- states and territories are responsible for regulating the use of chemicals (after the point of sale).

In fulfilling its role, the APVMA:

- undertakes assessments to evaluate the safety and performance of chemicals intended for sale in Australia to ensure that the health and safety of people, animals, crops and the environment are protected and international trade is not unduly jeopardised by the use of a chemical
- licenses and audits manufacturers to ensure adherence to APVMA-prescribed manufacturing standards
- monitors the market for compliance, and undertakes reviews and regulatory action on registered pesticides and veterinary medicines when concerns are identified, and
- conducts an Adverse Experience Reporting Program to provide early detection of unforeseen problems with registered chemicals.

The APVMA uses internationally developed and accepted methodologies for assessment and uses the best available evidence to support decision making.

As the regulator, the APVMA does not get involved with activities relating to the identification and meeting of market opportunities, research or data generation, and industry adjustment activities. It is up to chemical companies and individuals to identify a need and develop a suitable product for market. Alternatively, grower associations may identify gaps in the market and seek permits for existing products or new product registrations through chemical companies. Industry bodies, state authorities or other government agencies may assist by researching alternatives to meet identified needs and assist in any adjustment requirements as a result of any restrictions placed on chemical use by the APVMA.

2.2 Legislative Framework

The APVMA was established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act). The Administration Act sets out the APVMA's role, as an independent statutory authority, for undertaking the responsibilities conferred on it by the states and territories under the National Registration Scheme for Agricultural and Veterinary Chemicals. APVMA functions and powers are conferred by the Administration Act, the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code Act) and the *Agricultural and Veterinary Chemicals Code* (Agvet Code).

The Agvet Code makes provision for the evaluation, registration and control of agricultural chemicals and veterinary medicines and related matters, and the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Regulations) contain the statutory rules made under the Agvet Code.

The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act) received royal assent on 29 June 2013 and will take effect from 1 July 2014. It contains changes to registration and chemical review processes, new compliance tools and a new function for pre-application assistance. The Amendment Act does not change the role of the APVMA or its functions relating to evaluation, registration and control of agricultural chemicals and veterinary medicines.

3. APVMA functions

There are three main functions of the APVMA that are relevant to the decisions relating to fenthion: registrations of existing products, permits and chemical review.

3.1 Registration

All new agricultural and veterinary chemical products must be registered by the APVMA before they can be supplied, distributed or sold anywhere in Australia. In addition, active constituents - the substance/s in an agvet chemical product primarily responsible for a product's biological or other effects - must be approved by the APVMA either before, or at the same time, that the product is being registered.

In an application for registration, the manufacturer or applicant must demonstrate that, if used according to proposed label instructions, the product will:

- be safe for humans and non-target species
- not pose unacceptable risks to the environment or to trade with other nations, and
- be effective for the uses described on the label.

The APVMA conducts a significant proportion of the assessment in-house, but seeks expert scientific input from a number of external sources, including the Office of Chemical Safety (OCS) of the Department of Health (toxicology and occupational health and safety elements), the Department of the Environment (environmental assessments), and independent experts as needed.

Once all relevant assessments are completed, under s14 of the Agvet Code, the APVMA must only grant an application if it is satisfied that use of the product in accordance with the label instructions:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
- would not be likely to have an effect that is harmful to human beings
- would not be likely to have an unintended effect that is harmful to plants, animals or things or to the environment, and
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

3.2 Permits

In Australia, chemicals must be used according to instructions on the label, except where use 'off-label' is allowed under state and territory legislation or there is a permit in place from the APVMA.

In most states, registered products must only be used for purposes that are specified on the label. In practice, situations often arise where chemicals are needed for a use not specified on the label; these are often termed 'off-label' uses. The APVMA can consider applications for permits that allow for the legal use of chemicals in ways different to the uses set out on the product label. In certain circumstances, the limited use of an unregistered chemical may also be allowed by permit.

Permits that may be considered by the APVMA are for one of five purposes:

1. **Minor Use** - applies to situations usually involving low acreage crops, small portions of high acreage crops, or animal species which are not covered by the product label.
2. **Emergency Use** - for situations such as outbreaks of exotic pests or diseases.
3. **Research** - allows for chemical products to be used in research trials of varying size for scientific purposes, such as determining the suitability of a product for a new use or generating data to support an application to register a product.
4. **Export** - allows for the holder to possess and supply an unregistered chemical product or an unapproved active constituent for export purposes only.
5. **Miscellaneous** - generally issued to allow the supply of a particular batch or batches of registered product where the product does not comply with the product specifications, but may be issued for any purpose that would nullify certain offences under sections of the Agvet Code.

3.3 Chemical Review

The Chemical Review Program was established in the 1990s as a post-market mechanism to re-evaluate 'older' pesticide products that had been authorised under the previous state-based registration arrangements. Given that some of these authorisations (including fenthion) dated back to the 1950s, it was important that any new, credible data arising since registration, which suggested that there may be new or greater human health or environmental risks than determined initially, be appropriately considered. This ensures the ongoing safety and effectiveness of agricultural and veterinary (agvet) chemical products for end users and the community.

The APVMA has powers under the Agvet Code to conduct reviews of registered chemicals. These powers include the authority to reconsider the registration of products and approvals of active ingredients and labels, and to require registrants to provide information. Relevant data or trial work can be requested to support APVMA reconsiderations.

A review may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical or product when used according to label instructions. Reviews may focus on one or more areas of concern including environmental safety, worker safety, public health, residues and trade, or less commonly, product efficacy. The scope of a review is determined by the specific concerns raised about the products and their uses.

The risk assessment process conducted for reconsiderations follows the same principles and legislative criteria as that for registration of all chemicals in Australia, and conforms with contemporary international methods. An essential part of this scientific process is the setting of human health and/or environmental standards for safe levels of exposure to the chemical. Use of the chemical can only proceed if the level of exposure is below these standards as this ensures, with a high degree of certainty, the safety of all members of the public, workers and the environment.

3.3.1 Chemical Review Process

The chemical review process comprises many stages. The current process is outlined at Figure 1, noting there will be some changes from 1 July 2014 as a result of the Amendment Act.

Figure 1: Current stages of Chemical Review

Nomination – APVMA becomes aware of concerns about a chemical (active constituent), product and label and decides a review is warranted based on credible new scientific information available at the time.

Prioritisation – Review is prioritised based on urgency and nature of the concerns.

Scoping – A detailed outline is prepared about the reason(s) for the review and assessment components to be considered as part of the review (including toxicology, environmental impact, occupational health and safety, residues).

Data call-in – APVMA notifies chemical companies with active constituent approvals and registered products (registrants and approval holders) and asks them to submit data relevant to the scope of the review. APVMA also calls for public submissions which address the current usage of, or problems with, the continued registration of the chemical under review.

Assessment – All submissions and scientific data are evaluated by the APVMA and external advisory Australian Government agencies as appropriate. Depending on the concerns outlined in the scope of the review, these assessments commonly include toxicology, residues, occupational health and safety and environmental safety.

Draft Regulatory Measure – Following the assessment stage, the APVMA develops a draft regulatory approach to the chemical under review.

Consultation – The draft report and draft regulatory measure are released for public comment for up to three months.

Regulatory Decision – Based on evidence gathered during the assessment and consultation phases, the APVMA CEO makes the final decision about the future use of the chemical under review. Note that an interim regulatory decision may be approved if identified risks can be managed through modified instructions of use or if generation and evaluation of additional data may be required.

Implementation – Review participants are notified of the outcome and regulatory actions implemented. Outcomes of the review are published in the APVMA Gazette.

Chemical reviews are large, complex projects that necessarily take a considerable period of time to complete for a number of reasons:

- There are large amounts of technical data that are scientifically evaluated, often by experts external to the APVMA. These rigorous processes use internationally established methods and can take a considerable period of time to complete. The conclusions of the scientific assessments are based on the best available information at a point in time.

- Often new information will become available during the course of a review, such as new published studies or unpublished studies conducted to address a data gap identified by the APVMA, or provided voluntarily by approval holders, registrants or users. Under the current system, this can often drive a review into an iterative process where reports are updated as new information becomes available or is submitted over relatively long periods of time.

- Any potential decision to restrict or remove a chemical from the marketplace may have a significant impact on user groups and primary producers. For this reason the communication activities and engagement around chemical reviews with the jurisdictions, approval holders/registrants and users can be lengthy and complex.

The length of time that reviews can take varies on a case-by-case basis, ranging from a few months for a basic label review through to many years for the more technically-complex reviews. More complex reviews may include reconsideration of several agvet chemical products with many use patterns and involve multiple assessments. If the APVMA has sufficient reason to be concerned about the risks of a particular product, it may (and often does) place restrictions on or suspend the use of product labels in question while the review is conducted.

3.3.2 Specialist advice

The APVMA draws on the specialist expertise of its own staff and that of other Australian government agencies in the review of agricultural and veterinary chemicals comprising:

- APVMA review managers, responsible for project management of individual chemical reviews
- specialist staff in the APVMA who review details of product efficacy, chemistry, residues (including dietary risk) and implications for trade
- scientists in the Department of the Environment, who evaluate the environmental risks of the selected chemicals, and
- scientists in the Office of Chemical Safety (OCS) of the Department of Health who conduct human health risk assessments (public health and occupational health and safety), including the establishment of public health standards used in the dietary risk assessment performed by the APVMA.

3.3.3 Consultation

The review process generally involves extensive consultation with the public and industry. Submissions from farmers, householders, local government authorities, pest controllers and other chemical users help the APVMA to construct a picture of how the chemical is currently used and obtain supplementary information to assist the APVMA with refining its risk assessment. This ensures that the risk assessment of label uses underpinning the regulatory decision is based on all the available relevant information.

The opportunity to provide feedback on the draft review recommendations is provided through the public comment period before the APVMA makes its final decision about future use of any chemical products.

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.

3.3.4 Outcomes

Section 34 of the Agvet Code Act provides that, at completion of the review process, the APVMA can only allow continued use of a registered product or an active constituent approval if satisfied that it:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
- would not be likely to have an effect that is harmful to human beings

- would not be likely to have an unintended effect that is harmful to plants, animals or things or to the environment
- would not unduly prejudice trade or commerce between Australia and places outside Australia, and
- would be effective according to criteria determined by the APVMA.

Depending on a review's findings, chemicals and the products containing them might be:

- confirmed as safe and appropriate for registered use
- restricted in access and use
- reformulated
- required to carry amended labels with new directions for use and/or safety directions, or
- suspended, cancelled or withdrawn from the market.

The APVMA may take a number of interim actions or suspensions during the course of a review based on the findings of a particular assessment while other components of the review are being completed. Under section 41 of the Agvet Code, the APVMA may suspend or cancel the approval or registration of a chemical product during the review process if a particular assessment finds that the use may be likely to have an effect that is harmful to human beings; may pose an undue hazard to the safety of people or the environment; or may unduly prejudice trade or commerce. Use instructions may change during a period of suspension, if following an assessment of new information or data, risk management decisions need to change to protect human health and safety. Suspensions may continue over a period of years, while assessment components are completed and new labels are developed.

Currently the APVMA is required to consult with designated co-ordinators for each state and territory prior to varying, suspending or cancelling an approval or registration, noting under the Amendment Act the consultation process is expanded to include anyone that has been given notice of the review commencing.

3.3.5 Setting of Health Standards and Maximum Residue Limits (MRLs)

An essential part of the risk assessment process is the setting of human health and/or environmental standards for safe levels of exposure to the chemical to allow its continued use.

The setting of health standards for determining dietary exposure through pesticide residues in food is undertaken by the Office of Chemical Safety within the Commonwealth Department of Health using a rigorous methodology that has been developed and refined over a 50 year period and is used internationally. A comprehensive scientific assessment is made by the OCS of all the studies conducted on a chemical and its adverse health effects. These studies include those conducted using laboratory animals in addition to all of the available data on humans. The studies cover a spectrum of adverse effects, including the potential of the chemical to cause effects following a single exposure or repeated exposures over long periods of time, the potential of the chemical to affect the brain, damage genetic material, cause cancer, disrupt reproduction, cause birth defects, damage the nervous system, or damage the immune system. Based on this assessment, the OCS identifies the most sensitive, relevant adverse effect, which then forms the basis of the public health standard. A pivotal study is chosen that demonstrates a clear threshold of dietary exposure for the adverse effect below which the effect does not occur.

As public health standards must protect all members of the community, including the most sensitive and vulnerable, they are set by dividing the determined threshold of safe exposure by a safety factor to ensure an adequate margin of protection. The safety factor incorporates the uncertainty in extrapolating observations in laboratory animals to humans and the variation in chemical sensitivity within the human population. Based on extensive data on human medicines, there is about a 10-fold difference in sensitivity to chemicals from the most sensitive to least sensitive people. For a health standard based on an animal study, a 100-fold safety factor would usually be applied, which incorporates a 10-fold factor for extrapolation from animals to humans and a 10-fold factor for human variation. For chemicals, like fenthion, where the public health standards are set on actual human data, only a 10-fold safety factor would be applied. These human-based public health standards are less conservative than those based on animals because they are based on observations in the target species that is being protected.

Another essential part of the scientific process is the setting of Maximum Residue Limits (MRLs), which are important for legal supply of domestic produce and international trade. The maximum residue limit (MRL) is the maximum concentration of a residue resulting from the registered use of an agricultural or veterinary chemical. An MRL is not a health standard but the legally permissible residual level of a chemical in a commodity when that chemical has been used according to principles of good agricultural practice (GAP) and specified on product labels.

In setting an MRL for a chemical, it is essential that the exposure of consumers to that chemical (and its defined breakdown products) through residues in the diet, is below the public health standard.

The APVMA uses the public health standards set by the OCS to complete its dietary risk assessment for a particular chemical. This dietary risk assessment includes a consideration of the concentration of the chemical in food (either an analysed concentration or the MRL), how much of certain foods Australian consumers eat, including consumption patterns by different age groups, including children. The APVMA uses comprehensive dietary information generated by Food Standards Australia New Zealand. The output of the APVMA dietary risk assessment is a determination of whether the short-term and the long-term exposure of the consumer to a particular chemical used on food is below the corresponding public health standards. If the exposures are below the health standard, then it would be concluded that no harm should come to people eating food containing residues when the chemical is used according to the approved label directions. Conversely, dietary exposures above the public health standard are a cause for concern because they have exceeded what is known to be a safe level for all consumers. Such thresholds of dietary exposure acceptability are also mandated by the United Nations Food and Agriculture Organisation together with the World Health Organisation for protection of human health in setting international standards for trade. If a particular chemical when used according to label instructions leaves residues in a food that results in an unacceptable dietary exposure, regulatory action must be taken to protect consumers.

4. Fenthion

4.1 What is fenthion and why review it?

Fenthion is a broad spectrum organophosphorus (OP) insecticide used to control insect pests in agricultural, commercial and domestic situations, and to control external parasites on cattle. Fenthion products are also used to control pest birds in and around buildings.

There are currently eight APVMA registered products containing fenthion that may be used (refer Annexure A). Two products are registered for pest control (mosquitoes, fleas, spiders and flies). Three products are registered for the control of introduced pest birds. One product is registered for use on beef cattle to control lice. Two products are currently suspended and are permitted for use on plants in the home garden and in horticulture respectively under the current suspension instructions.

Like all OPs, fenthion is a nerve poison that works by interfering with the nervous system of animals, including insects and birds. The nervous system includes the brain, spinal cord and nerves, and is responsible for controlling and co-ordinating voluntary and involuntary movement through the generation of chemical and electrical signals. Should exposure occur, the nervous system of humans is also a target for fenthion.

Fenthion was one of some 80 chemicals that were originally nominated as candidates for reconsideration at the inception of the Chemical Review Program back in 1994. It was nominated for review because of new data that raised concerns about public health, occupational health and safety, and environmental risks. The human health concerns in particular arose because, like other OPs, fenthion has the potential to cause significant adverse health effects (including death) in people following a single exposure (known as acute toxicity). Fenthion is reported to have both short-term and long-term effects on the brain and nerves of people.

Fenthion has several breakdown products (degradates or metabolites) that form in plants and the environment after spraying and can cause adverse health effects in people. These metabolites form a significant proportion of the total residue found on treated produce and are included in the "residue definition" for fenthion[1]. Maximum residue limits set for fenthion include these metabolites.

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

4.2 Chemical Review of Fenthion and decisions made so far

In April 1998, the then National Registration Authority requested information on fenthion from registrants and industry and invited public submissions about the current use, or problems with the continued use, of fenthion to assist the APVMA in defining the risk assessment components.

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[1] The Australian residue definition for fenthion is *Sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion*. The Australian residue definition 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.

The closing date for submissions was extended to 30 January 1999 and the review commenced after the submissions were received.

The scope of the fenthion review included public health (incorporating a toxicological and residue assessment), worker safety, environment and trade. The toxicological and worker safety assessments were conducted by the OCS, the environment assessment by the Department of the Environment and the residue and trade assessment by the APVMA.

The APVMA split the review of fenthion into two parts. Part 1 dealt with products used in non-food producing situations. This included products used in the home garden (flea products for dogs and home insecticide sprays) and products used to control pest birds. Decisions on these product types were made in 2005, with some home garden products being cancelled and fenthion in bird control products being declared as Restricted Chemical Products (RCPs). Part 2 included products used on food; commercial and home garden products for fruits and vegetables and a veterinary cattle product.

In 2000, the OCS implemented a policy of setting acute reference doses for the first time in Australia. As part of that policy, an acute reference dose was set for fenthion. The assessment of other aspects of the health effects of fenthion continued for a number of years to enable the full scientific assessment of the extensive toxicological database on fenthion. The full human health assessment of fenthion was completed in 2005 and in December 2005, the APVMA published the toxicology report on fenthion. In this report both the acute reference dose and acceptable daily intake previously set by the OCS (i.e. the short-term and long-term health standards) were published. The APVMA also published the Preliminary Review Findings (PRF) on the pest control products (non-food producing uses).

In 2004-05, the APVMA had discussions with the registrant and user industry on the lack of residue data to allow establishment of MRLs for use of fenthion products in fruits and vegetables, particularly for fruit fly control. The APVMA allowed the industry time to generate the necessary residue data to provide an opportunity for a full and comprehensive review of uses approved on the registered label. Some uses included post-harvest dipping of fruit and vegetables for fruit fly control.

In July and August 2010, Horticulture Australia Limited (HAL) submitted Australian residue data on fenthion and dimethoate for assessment by the APVMA as part of each review.

On 11 September 2012 the *Fenthion Residues and Dietary Risk Assessment Report* (September 2012 report) was published. This report is available on the APVMA website at www.apvma.gov.au/products/review/current/fenthion.php. The assessment clearly showed that when fenthion products are used according to label instructions, young children are exposed to fenthion residues in food at levels that are many times over the health standard.

The particular use patterns of concern detailed in the September 2012 report were for fruit trees (apples, pears, citrus, figs, loquats, quince and stonefruit), grapes, pepinos, eggfruit and tomatoes. Additionally the use of fenthion as a postharvest dip or flood spray on vegetables such as tomatoes was of high concern.

The September 2012 report outlined that for peaches, the dietary exposure of children (aged from two to six years old consuming fruit treated according to the registered label directions) was more than 10 times above the acute reference dose. These dietary exposures were so high in some cases to put particularly sensitive children at risk as the buffers designed to completely protect all consumers were eroded. Where the dietary exposure exceeds the public health standards the APVMA cannot be satisfied that the use of

the product with the existing label instructions would be safe for people and MRLs cannot be established, thereby leading to use patterns being removed.

On 11 September 2012, being the date the September 2012 report was published, the APVMA:

- proposed that all uses patterns of concern on apples, pears, citrus, figs, loquats, quince and stonefruit, grapes, olives, pepinos, eggfruit, tomatoes and postharvest use on vegetables be suspended, and

- called for proposals from industry for modified use instructions for crops where safety concerns had been identified in recognition that the risk to consumers arising from the use of fenthion on those crops could be addressed by reducing the residues on those crops of concern.

Submissions were due to be received by 25 September 2012. The APVMA received over 70 submissions, 67 of which came from Western Australia. Several industry groups responded, proposing alternate, reduced use patterns for fenthion. However, these proposals contained no or limited additional residues data to support the proposed modified use patterns. Residues monitoring data submitted to the APVMA was mostly sourced from Quality Assurance testing schemes. Such schemes typically only test for the fenthion parent compound, not all of the relevant metabolites, thereby being of limited regulatory value for establishing new MRLs.

Following assessment of the submissions, on 31 October 2012 the APVMA suspended the registration and labels of the two fenthion products used on food producing plants. As part of the conditions of suspension of these products, they could only be used according to new, modified instructions. The modified instructions for use were developed based on reduced use patterns proposed by industry which were assessed for safety and in most cases accepted by the APVMA. New lower MRLs were established to support these new use instructions.

In relation to stonefruit, the new instructions for use by farmers issued on 31 October 2012 included use for control of Queensland fruit fly up to a minimum of 21 days before harvest (the 'withholding period'). However for the Mediterranean fruit fly in Western Australia the available data supported a seven day withholding period with a maximum of two sprays per season. These instructions were developed on advice from relevant industry bodies and represented a modification of the initial recommendations in the 11 September 2012 report to completely delete the stonefruit uses.

It was emphasised to industry that for some use patterns (notably stone fruit) the limited data could only support use under the suspension for 12 months from 31 October 2012 to 30 October 2013. Industry was advised that prior to 30 October 2013, the APVMA would reconsider the suspension and the conditions under which fenthion could be used. Industry groups were invited to collect and submit further residue data to the APVMA.

Since the 31 October 2012 decision, the APVMA received further residues monitoring data from two industry groups in Western Australia for the 2012-13 season to support the continued use of fenthion under the modified use instructions put in place as part of the suspension. Residues monitoring data results were received on 17 and 31 July 2013. These submissions did not include comprehensive testing of all the metabolites of fenthion. The APVMA also received a study on 9 August 2013, funded by Horticulture Australia Limited, reporting the residues in stone fruit following treatment with fenthion under the modified use regime. This study included testing for all of the metabolites of fenthion as specified in the Australian residues definition for fenthion and was conducted according to required standards of good laboratory practice.

In August and September 2013, this supplementary residues data was assessed by the APVMA. After analysing the new data provided by industry, the APVMA could no longer be satisfied that stonefruit sprayed with fenthion would have safe residue levels after a withholding period of only seven days. The residues assessment supported a withholding period of 14 days for nectarines and plums. For peaches and apricots the assessment did not support any continued use of fenthion (two or three sprays with a withholding period of seven or 21 days). On 16 October 2013 the APVMA further restricted the use instructions for fenthion on stonefruit and the suspension was continued until 30 October 2014. The *Supplementary Fenthion Residues and Dietary Risk Assessment Report* (the October 2013 report) was published on the APVMA website at the time of this decision at www.apvma.gov.au/products/review/current/fenthion.php.

On 25 October 2013 Summerfruit Australia applied for a permit to use a single spray of fenthion on peaches and apricots with a withholding period of 21 days before harvest. On 29 October 2013 this permit for a more restricted pattern of use was approved on the basis that the dietary risk was reduced to an acceptable level, in relation to the public health standard and the existing lower MRL could still be met. The permit is held by Summerfruit Australia with use up until 30 April 2014. This permit is not linked with the APVMA use instructions under the suspension continuation issued on 16 October 2013 which expires 30 October 2014.

What are the next steps in the review?

At this stage, the APVMA is intending to publish the Preliminary Review Findings (PRF) Report, including the veterinary residues, occupational health and safety and environmental assessments in April or May 2014. The PRF will outline the actions the APVMA intends to take in relation to fenthion. There will then be a three month public consultation process. As with the previous consultation periods, information may be submitted about the current, or proposed modified uses of fenthion and any other information or data that could be useful to refine the APVMA's risk assessments. Following assessment of information received during the public consultation process, the APVMA will make its final decision. It is expected the whole process will be finalised by October or November 2014.

4.3 Permits

From 2011 onwards, the APVMA has issued permits for:

- alternate uses of fenthion to control fruit fly, and
- alternative chemicals for the control or suppression of fruit fly in certain crops.

Requests for permits have been from grower groups, industry bodies and states and territories. Permits have been issued using science-based decision making, involving consideration of all available data at the point the decision is being made. In particular, in relation to fenthion, the proposed pattern of use (that is number of sprays and associated withholding periods) has been assessed to confirm compliance with the relevant public health standards. Details of these permits are included at Annexure B and can be found on the APVMA website at *Alternatives for fruit fly control* . These permits are in addition to the other registered chemicals for control of fruit fly that can be accessed from PUBCRIS on the APVMA website at https://portal.apvma.gov.au/pubcris.

5. Annexures

Annexure A – Products containing fenthion that may be used

Product Number	Product Name	Concentration	Type of use
61308	Lebaycid Fruit Fly and Insect Killer	80 g/L	Home garden and home pest control excluding use on food producing plants. Registration suspended 31 October 2012 with modified instructions for use issued in permit 13143
52075	Avigel Pest Bird Control Agent	110 g/kg	Control of pest birds restricted to state/territory authorised users
51627	David Grays Mosquito and Spider Spray Insecticide	117 g/L	Home pest control not for use on plants
50244	Avigrease - Pest Bird Eradication Compound	110 g/kg	Control of pest birds restricted to state/territory authorised users
42202	Control-A-Bird Agent	110 g/kg	Control of pest birds restricted to state/territory authorised users
41138	Amalgamated Pest Control Fenthion 1% Dust Insecticide	10 g/kg	Pest control
33520	Tiguvon Spot-On Cattle Lice Insecticide	200 g/L	Treatment of lice on cattle
32996	Lebaycid Insecticide Spray	550 g/L	Insecticide for horticultural industry use. Registration suspended 31 October 2012 with modified instructions for use issued in permits 13140 and 13141.

Annexure B – Permits for control of fruit fly

Permits issued by APVMA for alternate uses of fenthion on fruit fly in agriculture						
Permit Number	**Chemical**	**Crops**	**States issued for**	**Permit Holder**	**Date issued**	**Expiry date**
14501	Fenthion	Peaches and Apricots	All States	Summerfruit Australia Ltd	29 Oct 2013	30 Apr 2014
13860	Fenthion	Chilli peppers	All States	Growcom	7 Dec 2012	30 Oct 2014
13841	Fenthion	Use during suspension. Various crops	ACT, NSW, NT, Qld, SA, Vic and Tas	APVMA	31 Oct 2012	30 Oct 2014
13840	Fenthion	Use during suspension. Various crops	WA only	APVMA	31 Oct 2012	30 Oct 2014
13808	Fenthion	Avocado & Mango (post-harvest)	NSW, QLD& NT only	Australian Mango Industry Association	7 Dec 2012	30 Oct 2014
13765	Fenthion	Tamarillo (Tree tomato) Post Harvest	WA only	DAFWA	12 Oct 2012	1 Nov 2014
13674	Fenthion	Grapevines	NSW only	Hunter Valley Vineyard Association Inc.	15 Nov 2012	30 Oct 2014
13159	Dimethoate, Fenthion and other compounds	Various crops during outbreak	SA only	PIRSA	6 Oct 2011	30 Jun 2015

Permits issued by APVMA for other chemicals for control of fruit fly in agriculture						
Permit Number	**Chemical**	**Crops**	**States issued for**	**Permit Holder**	**Date issued**	**Expiry date**
14562	Thiacloprid	Pome Fruit & Stone Fruit / Mediterranean Fruit Fly	WA only	Growcom	13 Dec 2013	30 Nov 2018
14252	Clothianidin	Persimmons, Pome Fruit & Stone Fruit / Fruit Flies	All States	Growcom	5 Sep 2013	30 Jun 2015
13858	Several	Post-harvest treatment	SA only	PIRSA	28 Jun 2013	30 Jun 2015
13815	Maldison	Persimmon / Queensland and Mediterranean Fruit Fly	ACT, NSW, NT, QLD, SA, TAS and WA (permit not required in Vic)	Growcom	20 Feb 2013	31 May 2016

Permits issued by APVMA for other chemicals for control of fruit fly in agriculture						
Permit Number	**Chemical**	**Crops**	**States issued for**	**Permit Holder**	**Date issued**	**Expiry date**
13782	Dichlorvos pest strips	Surveillance crops Insect pests	WA, NT	DAFWA	30 Nov 2012	31 Dec 2014
13770	Dichlorvos	Monitoring fruit fly hosts	WA	DAFWA	11 Oct 2012	31 Dec 2014
13749	Maldison	Strawberries (perimeter bait spray only to noncrop areas)	ACT, NSW, QLD, SA, VIC, NT, WA only.	Growcom	29 Oct 2012	31 May 2014
13677	Maldison	Rubus, Ribes and Blueberry / Fruit Fly bait spray	ACT, NSW, NT, QLD, SA, TAS and WA (permit not required in Vic)	Aust Blueberry Growers Assoc	28 Jun 2013	30 Jun 2016
13675	Maldison	Tomatoes / Mediterranean and Lesser Queensland Fruit Fly and Cucumber Fly	All States	Growcom	16 May 2013	31 May 2018
13567	Bifenthrin	Tomatoes & Capsicums	Growing districts of Bowen and Gumlu QLD only.	Growcom	7 Dec 2012	31 May 2014
13566	Methomyl	Tomatoes & Capsicums	Growing districts of Bowen and Gumlu QLD only.	Growcom	7 Dec 2012	30 May 2014
13565	Hy-Mal Insecticide	Grapevines and Passionfruit – bait sprays	NSW, QLD	CropCare	1 Oct 2012	30 Sep 2014
13564	Maldison, Cue-Lure	Towns in Victoria –block baits / Queensland fruit fly	Vic – outbreak control	Vic DPI	16 Aug 2012	30 Sep 2017
13514	Spinosad	Non-crop vegetation & other fruit fly resting sites	QLD	Biosecurity QLD	31 May 2012	30 Jun 2014

Permits issued by APVMA for other chemicals for control of fruit fly in agriculture						
Permit Number	**Chemical**	**Crops**	**States issued for**	**Permit Holder**	**Date issued**	**Expiry date**
13253	Maldison	Table grapes	QLD, NSW, SA, WA, NT, ACT & TAS	Growcom	31 Jan 2012	31 May 2014
13031	Maldison	Capsicum & cucumber	QLD, NSW, SA, WA, NT, VIC & ACT	Growcom	6 Oct 2011	31 May 2014
12961	Lambda-cyhalothrin	Soil drench (tree fruit, nuts, vines & vegetables)	SA, NT, WA, NSW & TAS	PIRSA	15 Nov 2011	31 Mar 2016
12940	Maldison	Strawberries, rubus & blueberries	QLD, NSW, SA, WA, NT, VIC & ACT	Growcom	6 Oct 2011	31 May 2014
12927	Spinetoram	Strawberries, Rubus & Rubus hybrids and Blueberries	QLD, NSW, SA, WA, NT, ACT & TAS	Growcom	6 Oct 2011	31 May 2014
12907	Maldison	Stone fruit	ALL	Growcom	6 Oct 2011	31 May 2014
12875	Chlorpyrifos	Compost heaps and ground under infested trees	Vic – Outbreak control	Vic DPI	18 Aug 11	31 Mar 2016
12753	Spinosad	Ornamentals, amenity trees, fruit & nut trees, vines and vegetables	SA and WA – Departmental employees only	Biosecurity SA	18 Mar 11	31 Mar 2014
12690	Trichlorfon	Stone fruit and guava	WA	Fruit West	14 Oct 2011	31 May 2014
12590	Spinetoram	Pome & stone fruit	QLD, NSW, SA, WA, NT, VIC & ACT	Growcom	6 Oct 2011	31 May 2014
12486	Trichlorfon	Berry fruits	QLD, NSW, SA, WA, NT, VIC & ACT	Growcom	6 Oct 2011	31 May 2014
12450	Trichlorfon	Tree, bush & vine fruit crops	ALL	Growcom	6 Oct 2011	31 May 2014
12442	Trichlorfon	Eggplant, pepino & cape gooseberry	QLD, NSW, SA, WA, NT, ACT & TAS	Growcom	10 Aug 2011	31 May 2014

Permits issued by APVMA for other chemicals for control of fruit fly in agriculture						
Permit Number	**Chemical**	**Crops**	**States issued for**	**Permit Holder**	**Date issued**	**Expiry date**
12439	Trichlorfon	Table grapes	QLD, NSW, SA, WA, NT, ACT & TAS.	Growcom	30 Aug 2011	31 May 2014
12389	Methyl Bromide	Fumigation / Fruit fly, whiteflies, thrips	NT only. Licenced persons	DoR NT	1 Sep 2010	31 Aug 2015
12336	Maldison	Fruit trees and fly traps / Asian papaya fruit fly, melon fly and other fruit flies	Torres Strait and CapeYork, QLD approved staff only.	NAQS	31 Oct 2010	31 Oct 2015
12185	Dichlorvos & Maldison	Monitoring Lures for fruit fly trapping / Fruit Flies	Tas approved staff only	Tas DPIPW&E	17 Aug 2010	31 Mar 2015
12011	Maldison and dichlorvos	Monitoring Fruit fly traps / Targeted insects	Qld approved staff only	Biosecurity QLD	7 May 2010	31 Mar 2015
11915	Dichlorvos & Malathion	Monitoring of fruit fly / Fruit fly	NSW approved staff only	NSW DII	1 Apr 2010	31 Mar 2015
11772	Killmaster Zero Pest Strip	Monitoring Native Forests, Bushland, Rural & Urban / Fruit Fly	QLD approved staff only	Biosecurity QLD	1 Oct 2009	30 Jun 2020
11491	Dichlorvos	Rural & Urban areas / Fruit fly monitoring	NSW approved staff only	NSW DPI	30 Jul 2009	30 Jun 2020
11251	Maldison	Fruit fly host species / Fruit fly surveillance	WA approved staff only	DAFWA	10 Aug 2009	30 Sep 2015
11092	Methyl bromide	Fruit & Fruiting Vegetables / Fruit fly control	QLD only licensed users	Growcom	19 Oct 2009	30 Oct 2014
10169	Maldison + cuelure +/- methyl eugenol	Fibre board blocks / Queensland fruit fly	NSW approved staff only	NSW DPI	1 Oct 2007	30 Sep 2017

Permits issued by APVMA for other chemicals for control of fruit fly in agriculture						
Permit Number	**Chemical**	**Crops**	**States issued for**	**Permit Holder**	**Date issued**	**Expiry date**
10145	Methyl Bromide	Fruit & Fruiting vegetables / Fruit fly & Thrips	TAS only licensed users	Tas DPIPW&E	19 Oct 2009	30 Oct 2014
9941	Dipterex	Cherries / Fruit Flies	SA	PIRSA	13 Mar 2007	31 Mar 2015
6338	Dichlorvos	Monitoring Traps / Mediterranean Fruit Fly	SA approved staff only	PIRSA	21 Feb 2005	31 Mar 2015
6337	Maldison	Monitoring Traps / Queensland and Papaya Fruit Fly	SA approved staff only	PIRSA	14 Feb 2005	31 Mar 2015
5896	Maldison & yeast autolysate	Baits / Organically grown fruit / QFF	NSW	PIRSA	10 Jan 2007	31 Mar 2017