Australian Government

Australian Pesticides and Veterinary Medicines Authority

# FENTHION

## PRELIMINARY REVIEW FINDINGS for PART 2: Food producing uses and revised OHS recommendations for PART 1: non-food producing uses

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# FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the Agvet Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The APVMA has legislated powers to reconsider the approval of an active constituent, registration of a chemical product or approval of a label at any time after it has been registered. The reconsideration process is outlined in sections 29 to 34 of Part 2, Division 4 of the Agvet Codes.

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product containing that chemical, or its label.

The reconsideration process (illustrated in Figure 1) includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be generated according to scientific principles. The APVMA conducts science and evidence-based risk analysis with respect to the matters of concern, analysing all the relevant information and data available.

In undertaking reconsiderations, the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety within the Department of Health, Food Standards Australia New Zealand (FSANZ), the Department of the Environment and the state departments of agriculture, as well as other expert advisers as appropriate.

The APVMA makes these reports available to the regulatory agencies of other countries as part of bilateral agreements. The APVMA recommends that countries receiving these reports will not utilise them for registration purposes unless they have access to the raw data from the relevant applicant.

## Figure 1: Chemical reconsideration process


**1. Nomination**. Any person or group (including the APVMA and its partner agencies) may nominate an active constituent, product or label for reconsideration, including the reasons and any supporting information.

**2. Prioritisation.** The APVMA (with input from its advisory agencies) determines whether a reconsideration is warranted and determines the priority for the reconsideration.

**3. Scoping and Work Plan.** A scope document is prepared that outlines the areas of concern which may include toxicology, occupational health and safety, residues and dietary risk, risks to international trade, environmental risks and efficacy. From 01 July 2014 the APVMA is also required to publish a work plan for new reconsiderations to provide predictability about the timeframe for the reconsideration.

**4. Notice of Reconsideration.** To begin a reconsideration, the APVMA gives each holder a written Notice of Reconsideration that invites the holder to make a written submission to the APVMA and may also publish the Notice and the Scope for public comment.

**5. Toxicology Assessment**
Office of Chemical Safety conducts the toxicology assessment and sets public health standards for exposure to the chemical, determines whether the active constituent can be supported and recommends first aid directions, scheduling and any necessary warnings for product labels.

**5. Environment risk assessment**
The Department of the Environment conducts the environmental risk assessment, including consideration of the potential hazards and the likely exposures resulting from their use of the chemical or products. The resulting risk characterisation determines whether or not the risk is acceptable and whether or not any risks may be mitigated by appropriate label advice or other action.


**Human exposure assessment:** Toxicology assessment findings are used in the Occupational Health and Safety (Human exposure assessment) conducted by the OCS. This assessment recommends safety directions, re-entry periods and restraints for all the uses supported by the assessment.

**Residues and dietary exposure risk assessment (includes trade):** Toxicology assessment findings and available residues data are used in the residues and dietary exposure risk assessment (APVMA). This assessment recommends withholding periods, MRLs and restraints for all use patterns supported by this assessment. It also considers the potential trade risks arising from all the supported uses of products.

**Efficacy:** If included in the scope of the review efficacy assessments are conducted by the APVMA.

**Further data.** During the assessments the APVMA may be advised that additional data or information is required for the assessments and may issue a notice requiring the holders to provide this data within the due date.

**Interim Regulatory Action** At any time during a reconsideration, the APVMA may take regulatory action to mitigate any risks identified in relation to the use of a chemical. The aim of any such action is to protect human health or the environment (or both) while a final decision is being reached through the reconsideration process.

**6. Draft Regulatory measure** (Preliminary Review Findings PRF) The APVMA considers all the assessments and develops draft recommendations for the reconsideration which summarise the results of the assessment, identified risks, risk mitigation measures, proposed review findings and draft regulatory decisions. The PRF and the assessment reports provided by the advisory agencies are released for public consultation.

**7. Consultation.** Further data or information may be submitted to the APVMA from a range of stakeholders including holders, users of the chemicals, peak industry bodies, interest groups, non-government organisations, state and territory governments and the public.


**8. Regulatory decision.** After the public consultation period has closed, the APVMA assesses all the comments received and amends the assessment, review findings and the proposed regulatory measures as necessary. We then make the final regulatory decision.

There are three possible regulatory outcomes from a reconsideration:

- affirm the approvals or registrations
- vary the relevant particulars or conditions and affirm the approval or registration, or
- suspend or cancel the approval or registration.

The APVMA will affirm the approval or registration only if satisfied that it meets all safety, efficacy, trade and labelling criteria and also complies with all requirements in the regulations

If the active constituent, product or label does not meets the criteria as described above, the APVMA will examine whether the relevant particulars or conditions of the approval or registration can be varied so that the criteria can be met. This may include varying the instructions for use on the label.

If product registrations or label approvals are cancelled the APVMA will examine whether a phase out period for dealing with or using cancelled products or products bearing cancelled labels is appropriate. Additional instructions may be applied during phase out. If a phase out period is not appropriate then recall action may be required.

**9. Implementation.** Once the decision is made to affirm, cancel or vary conditions of registrations or approvals the APVMA will send written Notices to the holders of registrations and approvals and publish Notices of affirmation, variation of conditions, and cancellation of actives, products or label approvals.

These Notices will include brief statements of the reasons for the actions, relevant particulars for any affirmed approvals or registrations and any appropriate instructions of use or phase-out periods for cancellations.

This document sets out the preliminary review findings (PRF) relating to the active constituent fenthion and products containing fenthion when used in accordance with label instructions. The PRF and proposed recommendations are based on information collected from a variety of sources.

This PRF and the technical reports for all registrations and approvals relating to fenthion are available from the APVMA website at www.apvma.gov.au .The technical 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).

# SUBMISSIONS FROM THE PUBLIC ARE INVITED

This PRF report:

- outlines the APVMA review process
- advises interested parties how to respond to the review
- summarises the technical assessments from the reviewing agencies
- outlines the proposed regulatory action to be taken in relation to the continued registration of fenthion products in Australia.

The APVMA invites persons and organisations to submit their comments and suggestions on this PRF directly to the APVMA.

Comments on this PRF will be assessed by the APVMA (and partner agencies where required) prior to finalisation of the review and publication of the Final Review report.

## Preparing your comments for submission

You may agree or disagree with or comment on as many elements of the PRF as you wish.

When making your comments:

- clearly identify the issue and clearly state your point of view
- give reasons for your comments, supporting them, if possible, with relevant information and indicating the source of the information you have used
- suggest to the APVMA any alternative solution you may have for the issue.

Please structure your comments in point form, referring each point to the relevant section in the PRF. This will help the APVMA assemble and analyse all of the comments it receives.

Note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes all submissions received will be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter or may be published in full as part of the finalisation of this review.

The APVMA reserves the right to reveal the identity of a respondent unless a request for anonymity accompanies the submission. If no request for anonymity is made, the respondent will be taken to have consented to the disclosure of their identity for the purposes of Information Privacy Principle 11 of the *Privacy Act 1988.*

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and the respondent has provided justification such that the material is capable of being classified as confidential or confidential commercial information in accordance with the *Freedom of Information Act 1982* or the Agvet Codes as the case may be.

**THE CLOSING DATE FOR SUBMISSIONS IS: 22 AUGUST 2014**

Submissions can be sent to:

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# EXECUTIVE SUMMARY

Fenthion is a broad spectrum organophosphorus (OP) insecticide that has been registered in Australia for over 50 years. Fenthion is used to control insect pests in agricultural, commercial and domestic situations and external parasites on cattle. Fenthion is also used to control pest birds in and around buildings.

The active constituent fenthion, all products containing fenthion and their associated labels were placed under review in 1998 because of concerns over its toxicology (especially acute toxicology), occupational health and safety (OHS), residues in food (including dietary exposure) environmental and trade aspects

This document summarises the conclusions of the component assessment reports prepared from 2008 to 2014 in relation to the fenthion review and the proposed consolidated regulatory measures based on these assessments.

## Preliminary Review Findings

### TOXICOLOGY

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..

### OCCUPATIONAL HEALTH AND SAFETY

The OHS assessment did not support the use of fenthion in the home garden, for home user pest control or in various other pest control situations, including pest bird control. The OCS established safety directions, re-entry periods and engineering controls for use of fenthion as a 1% dust in cracks and crevices and for the use of fenthion on horticultural crops.

### RESIDUES AND DIETARY RISK ASSESSMENTS

These assessments did not support use of the veterinary product on cattle nor any use on food producing plants other than post-harvest use in inedible peel varieties of tropical and subtropical fruit and preharvest use on nectarines and plums only.

### ENVIRONMENT ASSESSMENT

The environment assessment of food producing uses of fenthion did not support most horticultural uses of fenthion due to unacceptable risks to aquatic environments. The use of fenthion on cattle and the horticultural use for post-harvest treatment of fruits were acceptable from an environmental perspective.

The environment assessment for non-food producing uses was published in (2005). This assessment recommended that pest bird control products be declared Restricted Chemical Products and that aquatic mosquito control uses be restricted to artificial water bodies only (not containing fish). These recommendations have been implemented.

## Proposed Regulatory Actions

After consideration of all data, the APVMA proposes the following regulatory actions:

- **Affirm** the active constituent approval for fenthion (Active Approval Number 44383) held by Bayer CropScience Pty Ltd as recommended in the toxicology assessment.

- **Vary** relevant particulars of label approvals of selected products as follows to satisfy the requirements for continued registration of products:
  - For product 32996 Lebaycid Insecticide Spray
    - Delete all use instructions except post-harvest treatment by dipping or flood spray of tropical and subtropical fruit with inedible peel
  - For the product 41138 Amalgamated Pest Control 1% Fenthion
    - Delete all use instructions for ceiling voids, wall voids and crawl spaces
- **Affirm** these product registrations once the necessary label variations have been made
- **Cancel** all previous product label approvals for products 32996 and 41138 on the basis that they do not contain adequate instructions consistent with the review outcomes
- **Cancel** the following product registrations and all associated label approvals:
  - 33520, Tiguvon Spot-on Cattle Lice Insecticide
  - 42202, Control-A-Bird Agent
  - 50244, Avigrease Pest Bird Eradication Compound
  - 51627, David Gray's Mosquito and Spider Spray Insecticide
  - 52075, Avigel Pest Bird Control Agent
  - 61308, Lebaycid Fruit Fly & Insect Killer

# 1 INTRODUCTION

Fenthion is an organophosphorus pesticide registered in Australia to control insect pests in a variety of crops. It has been an important part of fruit fly control in many areas of Australia and has been used as a post-harvest treatment for Queensland fruit fly or Mediterranean fruit fly before interstate trade within Australia or movement to fruit fly free areas. Fenthion is also used in non-food situations to control ants, cockroaches, crickets, silverfish, flies, mosquitoes and spiders in and around commercial/industrial buildings and domestic/public buildings. It is also to control pest non-native birds around commercial and industrial buildings.

The active constituent fenthion, all products containing fenthion and their associated labels were placed under review by the APVMA in 1998 as part of the third cycle of the existing chemical review program (ECRP) because of concerns over toxicological, occupational health and safety, environmental and dietary exposure issues.

In common with all organophosphate compounds, the primary mode of action of fenthion is via the inhibition of an important enzyme, acetylcholinesterase (AChE). This inhibition of AChE results in the over-stimulation of those parts of the nervous system that use acetylcholine to transmit nerve impulses.

Insects are affected by fenthion by through direct contact or by eating treated plants resulting in paralysis and death of the insect.

Fenthion is also toxic to mammals and birds via the inhibition of AChE within nervous tissue (including the brain). Signs of intoxication are consistent with acetylcholinesterase inhibition and include inactivity, salivation (drooling), difficulty breathing, flaccid paralysis (weakness), vomiting, and diarrhoea. If intoxication is severe, muscle twitching, loss of reflexes, convulsions and death can eventuate.

## 1.1 Current regulatory status of fenthion in Australia

As of April 2014 there is one active constituent approval for fenthion (44383 Fenthion). There are six registered products and two suspended products (that may be used only by permit) containing the active constituent fenthion (Table 1).

Formulation types include emulsifiable concentrates, dust, paste or paint and topical solution/ suspension as listed in the table below.

### Agricultural Uses

There is currently one suspended 550 g/L emulsifiable concentrates (EC) product for use in agricultural crops that may be used under permit. In agriculture, fenthion products were registered for use both as a pre-harvest and post-harvest insecticide in horticultural situations (fruits, vegetables and ornamental plants). The use patterns include ground boom sprays, air blast sprayers, backpack sprayer, and as a fruit dip.

On 31 October 2012 the one agricultural product was suspended and new instructions for use issued limiting the use of fenthion to specific crops only with modified withholding periods. These changes arose from the residues and dietary risk assessment for fenthion.

### Pest Control and Home Garden Uses

There are currently three products permitted for insect pest control and three products registered for the control of pest bird species. Another 550g/L fenthion pest control product (32999 Baytex 550 Insecticide Spray) was registered for use on a range of pests and has been evaluated as part of this review however the registration of this product has not been renewed by the registrant.

The pest control use patterns include hand held sprays, application to artificial water bodies, flushing into septic systems and dusting into cracks and crevices to control insect pests. Of the three insect pest control products, two are available for domestic pest control use by householders. Of these two products one is also permitted for use on ornamental plants only in the home garden

Three products are registered for application to internal roost areas to control exotic pest bird species.

**Table 1.1: Currently registered and suspended fenthion products**

| PRODUCT NUMBERS | PRODUCT NAMES | FORMULATION | LEVEL OF FENTHION | TYPE OF USE |
|---|---|---|---|---|
| *61308 Suspended* | *Lebaycid Fruit Fly & Insect Killer*<br>*Registration suspended 16/10/2013 – See permit 13843 for use* | *Emulsifiable concentrate (EC)* | *80 g/L* | *Home pest control and garden uses* |
| *32996 Suspended* | *Lebaycid Insecticide Spray*<br>*Registration suspended 16/10/2013 – See permits 13840, and 13841 for use* | *EC* | *550 g/L* | *Horticultural uses* |
| 51627 | David Gray's Mosquito And Spider Spray Insecticide | EC | 117 g/L | Home pest control |
| 41138 | Amalgamated Pest Control Fenthion 1% Dust Insecticide | Dust | 10 g/L | Commercial pest control |
| 52075 | Avigel Pest Bird Control Agent | Paste | 110 g/L | Pest bird control |
| 50244 | Avigrease – Pest Bird Eradication Compound | Paste | 110 g/L | Pest bird control |
| 42202 | Control-A-Bird Agent | Paint | 110 g/L | Pest bird control |
| 33520 | Tiguvon Spot-On Cattle Lice Insecticide | Topical Solution/ suspension | 200 g/L | Veterinary – cattle external parasite control |

## 1.2 APVMA review of fenthion

Fenthion was recommended by a number of stakeholders to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for review in 1994 as part of the call for nominations of existing chemicals for reconsideration, due to human health concerns.

This nomination was assessed by the APVMA and its partner agencies and prioritised 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.

The review covers all aspects of the conditions of registration and approval of the active constituent fenthion, all products containing fenthion and their associated labels to evaluate whether the continuing use of the chemicals

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

The review also considers whether product labels carry adequate instructions and warning statements. Such instructions should include:

- the circumstances in which the product should be used
- how the product should be used
- times when the product should be used
- frequency of the use of the product
- the withholding period after the use of the product
- disposal of the product and its container
- safe handling of the product.

In addition to the data and use pattern information received from product registrants and the chemical coordinators representing the states and territories, the APVMA also received submissions from:

- A member of the public reporting illness following the use of a fenthion home garden product
- the RSPCA, NSW outlining their concerns regarding fenthion bird control products
- the National Residue Survey requesting that a Maximum Residue Level be set for fenthion in beef fat, and
- two farmers and two farmer groups supporting continued use of fenthion.

Later, two submissions were received from community groups concerned about effects on users of fenthion and consumers of treated produce during fruit fly control programmes.

## Preliminary review findings for non-food products (Part 1 of the review)

In December 2005 the APVMA released the Fenthion PRF Report: Part 1 in relation to the non-food uses of fenthion.

The report recommended that:

- home garden products should not contain more than 120g/l of fenthion,
- commercial pest control products should not be applied by motorised (high pressure) hand held sprays,
- fenthion should only be used to control mosquitoes on artificial bodies of water (without fish)
- further information was required to assess the environmental impact of the bird control products and
- bird control products be made restricted chemical products

Since this report was published, several products containing fenthion were discontinued (See Table 4.4 for a list of all products discontinued since the start of this review). In addition changes were made to the commercial pest control product to remove use by motorised hand held spray and to limit use to artificial bodies of water only, and the pest bird control products were declared to be Restricted Chemical Products (16 December 2009),restricting their use to authorised and trained personnel only.

Following publication of the PRF for Part 1 of the review, further information regarding the use of the pest bird control products was assessed by the Department of the Environment as part of the decision to declare them as Restricted Chemical products.

## Consultation and submissions 2005-2010

The toxicology report published in December 2005 established an Acute Reference Dose (ARfD) which necessitated a contemporary residues and dietary risk assessment of fenthion uses.

In 2006 and 2007, the APVMA identified a lack of residues data to support the Australian use patterns for many crops. The APVMA consulted with user, industry and government representatives, advising that, without that data the APVMA would not be able to support ongoing use of fenthion on these crops. The APVMA participated in meetings with states and territories (interstate certification) Low Chill Australia (stonefruit grower group), Growcom, Plant Health Australia and the National Fruit Fly Strategy working group. As a result of these discussions, Horticulture Australia Ltd funded research to generate residues data for both dimethoate and fenthion.

In February 2007, the APVMA 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.

From 2008 to 2012, the APVMA participated in the Dimethoate and Fenthion Response Coordination Committee teleconferences and attended industry meetings to present updates on the progress of the fenthion and the dimethoate reviews.

In May 2010, Horticulture Australia Ltd (HAL) submitted additional residues data for fenthion in a range of crops. The APVMA assessed this and all other submitted residues information as part of the Fenthion Residues and Dietary Risk Assessment Report (published September 2012).

## Suspension of products used on food producing plants

In September 2012, the APVMA took the following action in relation to the review of fenthion:

- published the residues and dietary exposure assessment which determined that existing label directions were not acceptable for many crops including peaches and apricots
- proposed that the two affected products be suspended and proposed that modified instructions be issued for use of these products during the suspension
- requested information to assist in developing interim, modified instructions during the proposed suspension period.

The proposed suspension and consultation on new use instructions attracted a significant level of interest from a wide range of stakeholders. The APVMA attended stakeholder meetings and participated in teleconferences with stakeholder groups regarding the proposed suspension.

The APVMA received over seventy five submissions in response to the proposed suspension, some of which proposed modified interim instructions for the use of fenthion on horticultural crops and submitted additional information that could be used to assess those proposed use patterns.

- The Hills Orchard Improvement Group (WA) coordinated submissions from WA requesting consideration of modified use patterns for Mediterranean fruit fly control on:
    - stonefruit
    - cherries
    - apples and pears
    - persimmons
    - table grapes and
    - citrus.
- Residues monitoring data for a range of Western Australian fruit were submitted by the Hills Orchard Improvement Group members and FruitWest WA to assist the assessment of the requested use patterns.
- Apple and Pear Australia Ltd requested consideration of a 28 day withholding period for apples and pears.
- Another pear grower requested consideration of a reduced rate of 85mL/100L, however there was no residues data available to assess that use pattern.
- Summerfruit Australia requested consideration of use of fenthion on peach, nectarine, plum and apricot with a 21 day withholding period and a maximum of 3 sprays.
- The Australian Table Grape Association requested that the APVMA consider an extension of the withholding period for grapes from 7 to 21 days
- The Queensland Department of Agriculture, Fisheries and Forestry requested that the APVMA consider all possible use patterns when the maximum use pattern presents an unacceptable acute dietary risk. The APVMA was also asked to consider new clarified use patterns for a range of crops which replaced

fixed, weekly treatment times with the retreatment intervals and withholding periods supported by the residues assessment.

These submissions and information were assessed and considered in the APVMA decision to suspend the fenthion horticultural products and issue modified interim instructions for their use.

The APVMA, on 31 October 2012, suspended the registrations and label approvals of two fenthion products used on food producing plants

Modified instructions for use were issued for a 12 month suspension period, based on industry consultation and limited residues information. At this time, the APVMA identified that further residues data were required to support continued use.

### *Submissions received during the suspension of horticultural products*

During the suspension period 2012–2013, the APVMA received additional residues monitoring data from the Hills Orchard Improvement Group and FruitWest and further residues studies on stonefruit from HAL.

In October 2013 the APVMA continued the suspension of fenthion products. However the data provided during the suspension period that was assessed by the APVMA showed that showed that peaches and apricots treated with fenthion according to the 2012 suspension instructions could have residues at harvest that exceeded permissible levels.

- The resulting suspension instructions in 2013 discontinued the use on peaches and apricots whilst still allowing use on ornamental plants, nectarines, plums, apples and pears, tropical and subtropical fruits, capsicums, chillies, citrus (WA only) and cherries (WA only).

## Next steps for this review

In this report certain regulatory actions are proposed based on the assessments conducted by the APVMA and its partner agencies.

Persons and organisations are invited to submit their comments and related information on the PRF directly to the APVMA. This consultation period continues for three months ending on 22 August 2014.

At the end of the consultation period the APVMA will publish the submissions, assess the information received and will determine the final regulatory actions for this reconsideration.

# 2 INTERNATIONAL REGULATORY STATUS

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

## United Nations FAO/WHO Joint Meeting on Pesticide Residues (JMPR)

Fenthion was first evaluated by JMPR in 1971 and has been reviewed several times since, most recently in 2000. In1995 the JMPR established an Acceptable Daily Intake (ADI)[1] of 0-0.007 mg/kg bw. The Acute Reference Dose (ARfD)[2] for fenthion established in 2000 was 0.01 mg/kg bw. Codex MRLs were established for cherries, citrus fruits, olives and olive oil (virgin) and rice (husked). A short-term dietary risk assessment of fenthion has not yet been conducted by the JMPR.

## United States

There are currently no products containing fenthion registered for use on food producing plants in the US. The US EPA issued an Interim Reregistration Eligibility Decision (IRED) for fenthion in January 2001.which stated that dietary exposures from fenthion use on livestock were above the level of concern for the entire U.S. population and that the livestock products were being voluntarily cancelled by the registrant. Mosquito control products were voluntarily cancelled in 2003.

## Europe

Fenthion is not currently approved as a plant protection or biocidal product in the EU. In 1998 the Scientific Committee on Plants recommended that the use of fenthion on all crops (other than olives and citrus as bait applications) be phased out within three years[3]. In February 2004 the European Commission announced that all the remaining uses of fenthion (bait uses in citrus and olives) were to be withdrawn by 30 June 2007. The EU has no currently published standards for fenthion as it is not listed as a plant protection chemical.

## Canada

As stated in the Canadian Pest Management Regulatory Agency (PMRA) evaluation of March 2003 there are no registered uses of fenthion on food producing plants in Canada. Additionally there are no registered veterinary uses on food producing animals, and no maximum residue levels establish for fenthion in animal commodities.

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[1] ADI acceptable daily intake (for humans). a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable health risks to the consumer on the basis of all known facts at the time of the evaluation

[2] ARfD. Acute Reference Dose. An estimate of the amount a substance in food or drinking water, normally expressed on a body weight basis, that can be ingested in a period of 24 h or less without appreciable health risks to the consumer on the basis of all known facts at the time of the evaluation.

[3] Opinion of the Scientific Committee on Plants concerning the non-inclusion of Fenthion in annex I of Directive 91/414/EEC (Opinion expressed by the SCP on 2 October 1998), http://ec.europa.eu/food/fs/sc/scp/out22_en.html

## New Zealand

Fenthion is not currently approved for use on food producing plants or animals in New Zealand[4].

[4] New Zealand Ministry for Primary Industries – ACVM register.https://eatsafe.nzfsa.govt.nz/web/public/acvm-register

# 3 SUMMARY OF ASSESSMENTS AND PROPOSED FINDINGS

## 3.1 Toxicology

The following information summarises the findings of the:

- toxicology assessment, *Review of the mammalian toxicology and metabolism/toxicokinetics of fenthion* (2008 published 2012) which has assessed the potential toxicity of fenthion at high doses and established safe levels for exposure to fenthion.

This assessment is available from the APVMA website <www.apvma.gov.au>.

The toxicological assessment for the review of fenthion was undertaken by the OCS and is based on additional toxicology and occupational exposure data received from industry, together with all previously submitted registration data and relevant published data.

The assessment includes:

- Hazard identification—The identification of the type and nature of adverse effects that a substance has an inherent capacity to cause in an organism, animal species or human.
- Hazard characterisation (often referred to as the dose response characterisation) — The qualitative and, wherever possible, quantitative description of the inherent property of a substance having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties.
- This includes identification of a threshold (the No Observed Effect Level) below which no adverse effects occur following short-, medium or long-term exposure to the chemical. As part of the assessment the OCS also sets (or confirms) the public health standards for exposure to that substance. These are the Acceptable Daily Intake (for long term exposure) and if single or short term exposure is of concern the Acute Reference Dose (ARfD). These standards are used in any subsequent residues and dietary risk assessment.

### Summary of findings

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.

#### *Acceptable Daily Intake (ADI)*

The OCS assessment confirmed the current ADI for fenthion of 0.002 mg/kg bw/d based on a NOEL for the inhibition of plasma ChE of 0.02 mg/kg bw/d in a human study (Coulston et al 1979). This is the standard for assessing the long-term exposure to fenthion.

### *Acute Reference Dose (ARfD)*

The OCS report has confirmed the current ARfD for fenthion of 0.007 mg/kg bw, (as established 19 Oct 2000). This is the standard for assessing the short-term exposure to fenthion (24 hours or a single exposure). This ARfD is based on the NOEL of 0.07 mg/kg bw (the highest dose tested) for RBC AChE inhibition in a 28-day human study (Coulston, 1979) and using a 10-fold intraspecies safety factor.

This NOEL was also supported by the NOEL of 1 mg/kg bw for neurotoxicity findings seen in an acute oral neurotoxicity study in rats (Driest & Popp, 1997a ).

### *Poisons Schedule*

The OCS recommended that fenthion (in preparations containing 60 per cent or less of fenthion) should remain in Schedule 6 of the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP). Preparations containing 10 per cent or less of fenthion are included in Schedule 5.

## 3.2 Occupational Health and Safety (OHS)

### Overview

The following information summarises the findings of the:

- the *Occupational Health and Safety assessment of Fenthion* (Dec 2013 published April/May 2014)

This assessment is available from the APVMA website <www.apvma.gov.au>.

This assessment considered all OHS data and information submitted for the review as well as relevant scientific publications describing the health effects related to occupational exposure to fenthion.

The assessment also took into account new information regarding the dermal absorption of fenthion that had been submitted to the APVMA since the publication of the PRF for Part 1 (Non-Food producing Uses of fenthion) in December 2005. Therefore the current OHS assessment supersedes that published in December 2005 for the non-food producing products.

The OHS assessment considered the

- potential exposure during handling or use of the product by professional and/or domestic users
- potential post-application exposure, such as during re-entry to treated crops or areas or re-handling of treated produce such as seed, grain or treated timber products
- potential exposure of bystanders from the use of the product.

The occupational risk during mixing/loading/application and post-application is determined by the Margin of Exposure (MOE), which compares the estimated occupational exposure to a chemical to the No-Observed-Effect-Level (NOEL) for the critical effect of that chemical (as observed in a suitable laboratory animal or human study). The larger the MOE the lower the risk.

Based on the risk assessment, risk management measures are then recommended to reduce human exposures to an acceptable level. Those measures include engineering controls, safety directions (including for personal protective equipment), use restraints, re-entry intervals, and scheduling recommendations.

The NOEL of 0.02 mg/kg bw/day in a 4-week human study (Coulston, 1979) was used for the OHS risk assessment of fenthion. As this was a human study, a MOE of ≥10 to allow for variation in sensitivity within the human population was considered an acceptable safety threshold.

New Safety Directions including Personal Protective Equipment (PPE) and re-entry periods up to 11 days were established. The use of EC formulations of fenthion for pest control in domestic settings is not supported due to an unacceptable risk of exposure to children entering treated areas.

### *Use Patterns NOT supported by the OHS assessment*

The OCS recommended that fenthion will present an undue risk to human health when used::

- by low pressure hand held equipment (ornamental crops and for control of adult mosquitoes)
- by backpack equipment (except as a spot on to cattle)
- in greenhouses
- by members of the public in the home garden or for home pest control (due to excessive PPE requirements for user safety)
- in pest control in domestic areas (except for mosquito control in septic tanks or water bodies)
- for control of pest avian species in roosting areas
- as a 1% dust for treatment of ceiling voids, wall voids and crawl spaces (exposure on re-entry) .

The APVMA has considered these recommendations and proposes that these use patterns be deleted from product labels.

The APVMA is proposing that products containing fenthion that are intended for use by members of the public in the home garden or for home pest control (Home garden and home pest control products) or for control of pest bird species, be cancelled.

### *Use Patterns supported by the OHS assessment*

The OCS recommended that fenthion will not present an undue risk when used in accordance with new label instructions (including revised safety directions, precautionary and re-entry statements as listed below) for:

- vegetables and fruits by boomspray and airblast using a **closed cab tractor** (enclosed tractor cab fitted with a charcoal filter to filter incoming air);
- mosquito larvae in water and spiders and ants (commercial areas only) by high pressure spray equipment
- mosquitoes in septic tanks by pouring
- postharvest and postharvest quarantine treatment by dipping or floodspraying;
- crawling insects in cracks and crevices only by application of a 1% dust formulation

- cattle as a spot on ectoparasiticide when applied with a Spot-On Gun or Dial-a-dose cup.

## FIRST AID INSTRUCTIONS

The current First Aid Instructions and Safety Directions (FAISD 4/2013 December 2013) for Australian products containing fenthion are shown below. No amendments were considered necessary as part of this assessment.

**Table 3.1: First Aid Instructions for products containing fenthion**

| FENTHION IN HOME GARDEN PREPARATIONS AND ALL OTHER PREPARATIONS WHEN INCLUDED IN SCHEDULE 5 | |
|---|---|
| **CODE** | **FIRST AID INSTRUCTION** |
| a | If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 764 766. |
| **FENTHION IN OTHER PREPARATIONS WHEN INCLUDED IN SCHEDULE 6** | |
| **CODE** | **FIRST AID INSTRUCTION** |
| m | If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 131126; New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed. |

## SAFETY DIRECTIONS

The OCS assessment recommended changes be made to the current fenthion safety directions for supported fenthion products.

**Table 3.2: Recommended safety directions for products containing fenthion**

| EC 600 G/L OR LESS IN XYLENE 350 G/L OR LESS (INCLUDES THE 550G/L HORTICULTURAL PRODUCT) | |
|---|---|
| **CODE** | **SAFETY DIRECTIONS** |
| 130 133 | Poisonous if swallowed |
| 161 162 164 | Will irritate the eyes and skin |
| 210 211 | Avoid contact with eyes and skin |
| 190 | Repeated minor exposure may have a cumulative poisoning effect |
| 220 223 | Do not inhale spray mist |
| 279 281 290 292d 294c | When preparing spray wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, and elbow-length chemical resistant gloves |
| 279 280 286, 290 292d 294c 301 307 | When opening the container and pouring large quantities, wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves and a full facepiece respirator with organic vapour cartridge |
| 289 290 292d 294c | If applying by hand, wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, and elbow-length chemical resistant gloves |
| 340 342 | If product on skin, immediately wash area with soap and water |
| 340 343 | If product in eyes, wash it out immediately with water |
| 350 | After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water |
| 360 361 362 366 | After each day's use, wash gloves, face shield and contaminated clothing |

| DU 15 G/KG OR LESS (1% PEST CONTROL DUST INSECTICIDE) | |
|---|---|
| CODE | SAFETY DIRECTIONS |
| 120 129 133 | Product harmful if swallowed |
| 210 211 | Avoid contact with eyes and skin |
| 220 221 | Do not inhale dust |
| 279 283 290 294c 315 302 | When using the product wear elbow-length chemical resistant gloves and a disposable respirator with dust cartridge or canister |
| 351 | Wash hands after use |
| 360 361 | After each day's use, wash gloves |

## RECOMMENDED ENGINEERING CONTROLS (RESTRAINTS)

Additional restraints were recommended for the use of fenthion products:

- DO NOT apply by open cab airblast systems.
- DO NOT apply using spray equipment carried on the back of the user (Note that this does not preclude applying with a Spot-On Gun or Dial-a-dose cup for the treatment of cattle.)

## RE-ENTRY PERIODS

The OCS assessment recommended re-entry statements for the 550 g/L horticultural product (Lebaycid):

- Capsicums, chilli peppers and pineapple crops:
    - DO NOT allow entry into treated areas prior to 6 days.
- Banana crops:
    - DO NOT allow entry into treated areas prior to 8 days.
- Apples, stonefruit, pears, pomegranate, grapes, kiwi, and passionfruit crops:
    - DO NOT allow entry into treated areas prior to 10 days.
- Citrus, mangoes, papaya, avocado, sapote, breadfruit, jackfruit, durian, tamarind, longan, lychee, persimmon, feijoa, loquats, mangosteen, sapodilla and rambutan crops:
    - DO NOT allow entry into treated areas prior to 11 days.

If earlier re-entry is required to any of these crops wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.

## SAFETY DIRECTIONS TO BE DELETED

The APVMA also proposes that that the following categories of safety directions be deleted from the current FAISD for one or more of the following reasons:

- the OHS assessment does not support continued registration of these products (HG and PA products)
- there are no longer any registered products in these categories (HV, LD).
- The residues assessment does not support continued use of the product Cattle Spot-On.

**Table 3.3: Safety directions to be deleted**

| |
|---|
| **HG EC 125 G/L OR LESS IN XYLENE 750 G/L OR LESS** |
| Delete entry from the FAISD as Home/Garden use is no longer supported. |
| **PA 120 G/KG OR LESS IN GREASE** |
| Delete entry from the FAISD as this bird control use is no longer supported. |
| **HG EC 125 G/L FOR AQUEOUS FORMULATIONS WITH SURFACTANT 50 G/L OR LESS** |
| Delete entry from the FAISD as no products of this type are currently registered |
| **HV LC (SINGLE DOSE APPLICATION)** |
| Delete entry from the FAISD as no products of the type Home veterinary Liquid Concentrate (HV LC) are currently registered |
| **LD 25 G/L OR LESS IN PARAFFIN, LIGHT LIQUID** |
| Delete entry from the FAISD as no products of this type are currently registered |
| **LC SA 270 G/L OR LESS (CATTLE SPOT-ON ECTOPARASITE PRODUCT)** |
| Delete entry as this product is proposed for cancellation in the veterinary residues assessment |

## 3.3 Residues, Dietary Risk Assessment and Trade

The following information summarises 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
- The *Fenthion Veterinary Residues and Dietary Exposure Assessment* (April 2014),

These assessments are available from the APVMA website <www.apvma.gov.au>.

Residues data were received in 1999 and additional data (Horticulture Australia Limited (HAL)) were received in 2010. Residues monitoring data for a range of fruit were submitted during the consultation period for the suspension of products in October 2012 with further residues studies and monitoring data for stonefruit submitted in July 2013.

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 Organization (WHO)—United Nations

Food and Agriculture Organization's (FAO) recommended guidelines as agreed with Food Standards Australia New Zealand (FSANZ).

Field and laboratory phases of residue studies conducted in Australia, and used to support the establishment of MRLs in food and feed commodities, must be generated in accordance with the OECD principles of good laboratory practice (GLP).

## Veterinary residues and dietary risk assessment findings and recommendations

The *Fenthion Veterinary Residues and Dietary Exposure Assessment* (April 2014), considered the dietary exposure risks arising from the use of fenthion on cattle according to the approved label instructions.

This assessment is available from the APVMA website <www.apvma.gov.au>.

Currently, the only veterinary product containing fenthion is Tiguvon Spot-On Cattle Lice Insecticide (APVMA Number 33520).

- The continued registration of Tiguvon Spot-On Cattle Lice Insecticide was not supported for the following reasons:
    - The dietary exposure calculations determined that currently approved MRLs are not appropriate on the grounds that dietary exposure to these levels of fenthion would exceed the Australian ADI
    - The submitted residues data does not support the existing meat withholding period (WHP) of 10 days or a minimum re-treatment interval for Tiguvon Spot-On Cattle Lice Insecticide.

Therefore the APVMA is proposing to cancel the registration and associated label approvals of Tiguvon Spot-On Cattle Lice Insecticide:

- As the continued registration of Tiguvon Spot-On Cattle Lice Insecticide is not supported, it is recommended that the existing MRLs for fenthion in cattle based on veterinary uses be deleted from Table 1 of the MRL Standard
- Fenthion is currently not registered for use in poultry, pigs and sheep so it is recommended that the existing MRLs for fenthion in these species based on previous veterinary uses be deleted from Table 1 of the MRL Standard.

## Horticultural residues and dietary risk assessment findings and recommendations

The following information summarises 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.

These assessments are available from the APVMA website <www.apvma.gov.au>.

### *Supported use patterns of fenthion*

The following label use patterns for fenthion were supported by appropriate residue data that was sufficient to recommend MRLs. Residues arising from these uses were assessed and presented no significant dietary risk:

- tropical and sub-tropical fruit (inedible peel) post-harvest uses only (dip or flood spray)
- preharvest treatment of plums and nectarines only, with a WHP of 14 days and a maximum of three sprays per crop.

#### INTERIM USES TO BE DELETED

The following use patterns are not supported by the available residues data. It is proposed that these uses be deleted from labels:

- apples and pears; modified use patterns of 7 to 10 day WHP and maximum 2 sprays per crop in WA and 28 day WHP all other areas
- cherries; modified use patterns of 7 day WHP and maximum 2 spray per crop in WA only
- citrus fruit; modified use patterns of 14 day WHP and maximum 1 spray per crop in WA only
- grapes; modified use patterns of reduced rate 50ml/100L, 7 day WHP and 2 sprays per crop in WA and 21 d WHP QLD, NT
- nectarines; plums – modified use pattern of 14 day WHP and maximum 3 sprays per crop
- persimmons (edible peel only); modified use pattern of 14 day WHP and a maximum 2 sprays per crop
- tropical and sub-tropical fruits (inedible peel); including paw paw and inedible peel persimmons (pre harvest use)
- capsicums (pre harvest)
- chilli peppers (post-harvest)
- melons (post harvest)

#### DISCONTINUED USES TO BE DELETED

The following uses posed unacceptable acute dietary risks and were suspended in October 2012. These use patterns are not currently permitted.

- Use on food producing plants in the home garden
- egg fruit (pre harvest and post-harvest)
- fruiting vegetables (including cucurbits), all post-harvest uses (except post-harvest use on chilli peppers and melons as listed above
- pepino (pre harvest and post-harvest)
- tomatoes (pre harvest and post-harvest)
- apples and pears – previous use patterns with 7 day WHP and no limit on number of sprays
- Citrus fruit - except interim modified use of (14 day WHP and maximum 1 spray per crop in WA only)

- deciduous fruits (generally, other than stone fruits), except interim uses listed for specific fruit crops above
- figs
- fruit trees (generally), - except interim uses listed for specific fruit crops above
- loquats
- quince
- stonefruit – all uses except the interim uses on nectarines and plums listed above

### *Dietary exposure*

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

### *Residue-related aspects of trade*

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

## 3.4 Environment

The following information summarises the findings of the environmental risk assessment for Part 2 of the review (Food producing uses of fenthion) published as the *Environmental Chemical review Assessment Report Fenthion: food Uses only* in May 2014.

This assessment is available from the APVMA website <www.apvma.gov.au>.

The Environment Protection Branch in the Australian Government Department of the Environment undertook the environmental assessments for the review of fenthion, and considered all the environmental data and information submitted for the review.

The environmental assessment for Part 1 of the review (Non-food producing situations) was published in December 2005 as part of the PRF Report – Part 1: Uses of fenthion in non-food-producing situations: Volume 2 technical reports.

An environmental risk assessment consists of:

- the identification and classification of the toxicity to the environment and determination of the most sensitive endpoints in the various environmental compartments
- an exposure assessment to arrive at a predicted environmental concentration (or estimated environmental concentration ). Considerations include the method of use of the product, scale of use, situations in which the product is used, and fate of the active constituent in the environment. Various models may be used for which specific information is relevant; for example, to estimate the concentration in surface waters from spray-drift or runoff.

- risk characterisation, which compares the predicted or analysed environmental concentration to the most sensitive toxicological endpoints to determine whether or not the risk is acceptable and, if not, consider refinements of the process or models and if or how risks may be mitigated by appropriate label advice or other action. Risk quotients (RQs) are calculated for each scenario. For agricultural chemicals the acute RQ should be less than 0.1, and the chronic RQ should be less than 1.

In addition to evaluating toxicity to non-target organisms, consideration is given as to other concerns relating to the behaviour of the substance in the environment, including persistence in soil, sediment, water or the atmosphere, bioaccumulation or potential to move into groundwater.

## Environmental fate and degradation

The environmental assessment determined that fenthion is readily degraded in aquatic environments and in soils. Bioaccumulation is not expected. Due to the moderate binding of fenthion to soil and rapid degradation, leaching is not expected. However, the principal metabolites of fenthion are more stable and mobile in soils than fenthion itself and could leach from porous soils.

## Environmental toxicity

The environmental assessment determined that fenthion is highly toxic to most organisms and in particular birds and aquatic invertebrates. The assessment examined environmental risks to birds, mammals, terrestrial invertebrates, fish and aquatic invertebrates from direct overspray, dietary exposure, spray drift and run-off exposures. The assessment follows a tiered approach; if the environmental risk was determined to be unacceptable at a more conservative tier then the risk was re-assessed with refined assumptions.

The assessment noted that there have been incidents of poisoning of non-target birds by fenthion, both in Australia and overseas.

### *Risk characterisation (SECTION 11.1 OF THE ENVIRONMENT REPORT)*

The environmental assessment noted that:

- there is a potential risk to birds feeding in and frequenting orchards arising from a single treatment of fenthion. In particular, the use of fenthion to control wingless grasshoppers in orchards could lead to significant exposure to birds, as many birds, especially small raptors, may feed on dead and dying grasshoppers that have been treated with 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 preharvest uses were retained:
    - *"Dangerous to bees. Will kill bees foraging in the crop to be treated or in hives which are over-sprayed or reached by spray drift. Residues may remain toxic to bees for several days after application".*
- there were risks to invertebrates (including beneficial invertebrates) within the treated areas and therefore the use of fenthion could disrupt Integrated Pest Management programs.

- there was limited data regarding phytotoxicity and effects on non-target plants are expected to be minimal.

## AQUATIC RISKS DUE TO SPRAY DRIFT OF FENTHION

The endpoints used to determine the risk quotients were based on the most sensitive aquatic invertebrates for which data was available (*Daphnia magna* and pink shrimp *Penaeus duorarum*).

The spray drift risk assessment used the AgDRIFT® model[5] to predict the deposition rates of fenthion at various distances up to 300 m downwind of the sprayed area for the different use patterns on the fenthion labels.

*Orchard and Grape Situations (Airblast Sprays)*

Even after taking aqueous photodegradation and sediment adsorption into consideration, the aquatic risk arising from spray drift was assessed as unacceptable for a single application of fenthion to all orchard and vineyard crops. The assessment did not support the retention of the use of fenthion for these crops.

*Field Crops (Boom Sprays)*

Even taking aqueous photodegradation and sediment adsorption into consideration the aquatic risk arising from spray drift was assessed as unacceptable for a single application of fenthion to vegetables and ornamental plants by boom spray. Therefore the assessment did not support the retention of spraying fenthion on vegetables or ornamentals.

*Aerial Application*

The aquatic risks arising from aerial application were unacceptable for both the medium and coarse spray nozzles at the various wind speeds up to the limit of the model's capability. The assessment recommended that the aerial application of fenthion was not supported.

## AQUATIC RISKS DUE TO RUN OFF FOLLOWING APPLICATION OF FENTHION

The risk was assessed as unacceptable for a single spray application for rain events up to 3 days after application, with mitigation for soil adsorption, heterogeneity of the field, interception of fenthion by the foliage and dilution of the run-off into a 1500 $m^3$ body of water. Therefore the assessment determined that the use of fenthion on orchard crops, vineyard crops and vegetables cannot be supported on the basis of risks to aquatic invertebrates arising from run-off events.

[5] AgDRIFT® Spray Drift Task Force Spray Software, Version 2.0.07

### RISK ASSESSMENT OF OTHER USE PATTERNS

#### POST-HARVEST TREATMENT

The assessment noted that the environmental exposure is limited to that occurring due to the disposal of spent dips and recommended an interim label statement regarding dip disposal of:

*"Dispose of used dip solution and sludge at a rate not exceeding 20 000 L/ha over an area of dedicated and bunded flat land, away from watercourses and any drainage areas, etc, that could contaminate watercourses, and restrict access to humans and stock for a period of at least 3 months."*

#### VETERINARY USE

Fenthion is also registered for use a spot-on application for cattle. The assessment determined that this use pattern is unlikely to result in significant environmental exposures.

## Conclusion

The APVMA has considered the recommendations made by the Department of the Environment and proposes that on the basis of the findings:

#### HORTICULTURAL PRODUCTS

- All uses except post-harvest dipping and flood sprays be removed from labels
- the following dip disposal statement be added to labels:

  "*Dispose of used dip solution and sludge at a rate not exceeding 20 000 L/ha over an area of dedicated and bunded flat land, away from watercourses and any drainage or other areas, that could contaminate watercourses, and restrict access to humans and stock for a period of at least 3 months."*

#### VETERINARY PRODUCT

The APVMA notes the recommendation that if this product registration continues the disposal statements for used containers should be updated.

# 4 PROPOSED REGULATORY ACTION

There are three possible regulatory outcomes from any reconsideration. The APVMA may:

- affirm the approvals or registrations
- vary the relevant particulars or conditions and affirm the approval or registration, or
- suspend or cancel the approval or registration.

The APVMA will affirm the approval or registration only if satisfied that it meets all safety, efficacy, trade and labelling criteria and also complies with all requirements in the regulations

If the active constituent, product or label does not meets the criteria as described above, the APVMA will examine whether the relevant particulars or conditions of the approval or registration can be varied so that the criteria can be met. This may include varying the instructions for use on the label.

If product registrations or label approvals are cancelled the APVMA will examine whether a phase out period for dealing with or using cancelled products or products bearing cancelled labels is appropriate. Additional instructions may be applied during phase out. If a phase out period is not appropriate then recall action may be required.

## 4.1 Affirm approvals of the active constituent

The APVMA is satisfied that, the, the active constituent fenthion meets the requirements for continued approval. The APVMA recommends that active constituent approval listed in Table 4.1 be affirmed.

**Table 4.1: Active constituent approval to be affirmed**

| APPROVAL NUMBER | ACTIVE CONSTITUENT | APPROVAL HOLDER |
|---|---|---|
| 44383 | Fenthion | Bayer CropScience Pty Ltd |

## 4.2 Vary conditions of label approval, cancel previous labels and affirm products with varied labels

The APVMA proposes to find that it is NOT SATISFIED that the labels for the products listed in Column 4 of Table 4.2 contain adequate instructions in relation to the criteria set out in s.14(3)(g) of the Agvet Codes.

Therefore the APVMA is proposing to VARY the current label approval for these products to generate a new label approval for these products as listed in Column 5 of Table 4.2 and to CANCEL any previous label approvals so that there will be only one approved label for each of these products.

These variations to label instructions would satisfy the requirements for continued registration of products and the APVMA proposes that product registrations listed be affirmed once labels have been varied and previous labels cancelled.

**Table 4.2 Products to be affirmed following variation of label approvals.**

| 1. PRODUCT NUMBER | 2. PRODUCT NAME | 3. REGISTRANT | 4. LABEL APPROVALS TO BE CANCELLED OR VARIED |
|---|---|---|---|
| 32996 | Lebaycid Insecticide Spray | Bayer Cropscience Pty Ltd | 32996/0110 |
| Proposed label variation. Update first aid and safety directions. Delete all use patterns because of unacceptable dietary and environmental risks except:<br>• postharvest treatment (dipping or flood spray) of tropical and sub-tropical fruits (inedible peel varieties only) | | | |
| 41138 | Amalgamated Pest Control Fenthion 1% Dust Insecticide | Amalgamated Pest Control Pty Ltd | 41138/0900<br>41138/1208 |
| Proposed label variation. Update first aid and safety directions and Delete use patterns for wall voids, crawl spaces and ceiling voids due to OHS risks on re-entry of treated areas. | | | |

## 4.3 Proposed registration cancellation as an outcome of the review findings

As an outcome of the proposed finding of the review, the APVMA is not satisfied that the requirements for continued registration and approval of the products listed below continue to be met.

Therefore, the APVMA proposes that the registrations and label approvals for the following products be cancelled.

**Table 4.3: Products proposed for cancellation**

| PRODUCT NUMBER | NAME OF PRODUCT TO BE CANCELLED | REGISTRANT | LABEL APPROVAL NUMBERS TO BE CANCELLED | REASONS |
|---|---|---|---|---|
| 33520 | Tiguvon Spot-on Cattle Lice Insecticide | Bayer Australia Ltd (Animal Health) | 33520/51509<br>33520/0598<br>33520/02<br>33520/01 | Not supported unacceptable dietary risks |
| 42202 | Control-A-Bird Agent | Control-A-Bird Pty Ltd | 42202/1208 | Not supported unacceptable OHS risks |
| 50244 | Avigrease Pest Bird Eradication Compound | Australian Pest Bird Management Pty Ltd | 50244/1208 | Not supported unacceptable OHS risks |

| PRODUCT NUMBER | NAME OF PRODUCT TO BE CANCELLED | REGISTRANT | LABEL APPROVAL NUMBERS TO BE CANCELLED | REASONS |
|---|---|---|---|---|
| 51627 | David Gray's Mosquito and Spider Spray Insecticide | David Gray & Co Pty Limited | 51627/0899<br>51627/0704 | Not supported unacceptable OHS risks |
| 52075 | Avigel Pest Bird Control Agent | ANC Bird Control | 52075/1208 | Not supported unacceptable OHS risks |
| 61308 | Lebaycid Fruit Fly & Insect Killer | Bayer Cropscience Pty Ltd | 61308/0907 | Not supported unacceptable OHS risks |

## 4.4 Withdrawn fenthion products

A number of fenthion products have been voluntarily withdrawn since the commencement of the review (once cancellation of registration is formally effected, reconsideration is no longer required). These are listed below.

**Table 4.4: Products withdrawn since the commencement of the review**

| PRODUCT NUMBER | PRODUCT NAME | REGISTRANT |
|---|---|---|
| 32999 | Baytex 550 Insecticide Spray | Bayer CropScience Pty Ltd |
| 40084 | Exelpet Flea Liquidator For Dogs Over 10kg | Exelpet Products (A Division of Effem Foods Pty Ltd) |
| 46206 | Bay-O-Pet Spotton Flea Control For Dogs | Bayer Australia Ltd (Animal Health) |
| 46222 | Bay-O-Pet Spotton Flea Control For Small Dogs | Bayer Australia Ltd (Animal Health) |
| 54065 | Exelpet Flea Liquidator for Dogs between 2.5kg and 10kg | Exelpet Products (A Division of Effem Foods Pty Ltd) |
| 55646 | Yates Fruit Fly & Insect Killer | Orica Australia Pty Ltd |

These products were once included in the review of fenthion, however as these products are no longer registered there is no further regulatory action required. There are also some other fenthion products that had previously been registered with the APVMA (then NRA) that were no longer registered at the commencement of the review and are not listed here.

# APPENDICES

# APPENDIX A: SUMMARY OF PROPOSED CHANGES TO DIRECTIONS FOR USE OF PRODUCTS CONTAINING FENTHION

## Proposed Changes to the Directions for Use 550 g/L EC Horticultural product

### *Use patterns to be deleted,*

This refers to the original label of this product (currently suspended).

**Table A1: Product 32996 *Lebaycid Insecticide Spray*– Proposed deletions from the Directions for Use**

| CROP | PEST | RATE | WHP | CHANGES PROPOSED |
|---|---|---|---|---|
| TREE AND VINE CROPS –PRE HARVEST USES | | | | |
| ~~Apples, Pears~~ | ~~Mediterranean fruit fly (WA only)~~ | ~~150 mL/100 L~~<br>~~Apple 75mL/100L~~<br>~~Pear 90 - 100mL/100L~~ | ~~7 days~~<br>~~10 days~~<br>~~7 days~~ | **DELETE: Unacceptable dietary and environmental risks**<br>**RESTRICTED**: since Oct 2012 lower rates and increased WHPs |
| | ~~Queensland fruit fly (NSW, Vic, WA only)~~ | ~~150 mL/100 L~~ | ~~7 days~~<br>~~28 days~~ | |
| | ~~Codling moth (NSW, Vic, SA only)~~ | ~~95 mL/100L~~ | ~~7 days~~<br>~~28 days~~ | |
| | ~~Lightbrown apple moth (NSW, Vic, SA, WA only)~~ | ~~95 mL/100L~~ | ~~7 days~~<br>~~28 days~~ | |
| ~~Citrus~~ | ~~Fruit fly (Qld, WA, NT only)~~ | ~~75 mL/100L~~ | ~~7 days~~ | **DELETE**: **Unacceptable dietary and environmental risks**<br>Prohibited since Oct 2012 |
| | ~~Mediterranean fruit fly (WA only)~~ | ~~150 mL/100 L~~<br>~~75 mL/100L~~ | ~~7 days~~ | **DELETE: Unacceptable dietary and environmental risks**<br>**RESTRICTED**: since Oct 2012 lower rates WA only. Insufficient residues data to support this restricted use. |
| | ~~Queensland fruit fly (NSW, Vic, WA only)~~ | ~~150 mL/100 L~~ | ~~7 days~~ | **DELETE**: **Unacceptable dietary and environmental risks**<br>Prohibited since Oct 2012 |
| ~~Deciduous fruit~~ | ~~Fruit fly (QLD non-coastal) only~~ | ~~75 mL/100L~~ | ~~7 days except stonefruit 3 days~~ | **DELETE: Unacceptable dietary and environmental risks**<br>**RESTRICTED**: since Oct |
| | ~~Rutherglen bug~~ | ~~95 mL/100L~~ | | |

| CROP | PEST | RATE | WHP | CHANGES PROPOSED |
|---|---|---|---|---|
| | ~~QLD, NSW, Vic, SA, WA only~~ | | | 2012 lower rates and increased WHPs |
| ~~Figs (dessert)~~ | ~~Fruit fly (Qld, WA, NT only)~~ | ~~75 mL/100L~~ | ~~7 days~~ | **DELETE**: **Unacceptable dietary and environmental risks** Prohibited since Oct 2012 |
| ~~Fruit trees~~ | ~~Wingless grasshopper~~ ~~(NSW, Vic)~~ | ~~95 mL/100L~~ | ~~7 days except stonefruit 3 days, papaws, guava 14 days~~ | **DELETE: Unacceptable dietary and environmental risks** **RESTRICTED** :since Oct 2012 certain types of fruit trees only with lower rates and increased WHPs |
| ~~Grapes~~ | ~~Fruit fly (Qld, WA, NT only)~~ ~~Mediterranean fruit fly WA only (since Oct 2012)~~ | ~~75 mL/100 L~~ ~~50mL/100L~~ | ~~7 days~~ ~~21 days~~ ~~7 days (WA)~~ | **DELETE: Unacceptable dietary and environmental risks** **RESTRICTED**: since Oct 2012 7 day WHP and lower rates WA only, 21 day WHP other states Insufficient residues data to support the restricted uses |
| ~~Loquats~~ | ~~Fruit fly (Qld, WA, NSW only)~~ | ~~75 mL/100 L~~ | ~~7 days~~ | **DELETE**: **Unacceptable dietary and environmental risks** Prohibited since Oct 2012 |
| ~~Papaws~~ | ~~Yellow peach moth~~ ~~(Qld, NT, WA only)~~ | ~~75 mL/100 L~~ | ~~14 days~~ | **DELETE: Unacceptable dietary and environmental risks** |
| ~~Pepinos~~ | ~~Fruit fly~~ ~~(Qld, WA only)~~ | ~~75 mL/100L~~ | ~~7 days~~ | **DELETE**: **Unacceptable dietary and environmental risks** Prohibited since Oct 2012 |
| ~~Persimmons~~ | ~~Greenhouse thrips~~ ~~(Qld only)~~ | ~~90 mL/100L~~ | ~~7 days~~ | **DELETE: Unacceptable dietary and environmental risks** |
| | ~~Queensland fruit fly~~ ~~(Qld, NSW, WA only)~~ | ~~75 mL/100L~~ | ~~7 days~~ | |
| | ~~Mealybug (Qld, NSW, WA only)~~ | ~~75 mL/100L~~ | ~~7 days~~ | |
| | ~~*(Mediterranean fruit fly)*~~ | ~~*75 mL/100 L*~~ | ~~*14 days*~~ | |
| ~~Quince~~ | ~~Mediterranean fruit fly (WA only)~~ | ~~150 mL/100 L~~ | ~~7 days~~ | **DELETE**: **Unacceptable dietary and environmental risks** Prohibited since Oct 2012 |
| | ~~Queensland fruit fly (NSW, Vic, WA only)~~ | ~~150 mL/100 L~~ | ~~7 days~~ | |

| CROP | PEST | RATE | WHP | CHANGES PROPOSED |
|---|---|---|---|---|
| ~~Stone fruit~~ | ~~Lightbrown apple moth NSW, Vic, SA, WA only~~ | ~~75 mL/100L~~ | ~~21 days~~ | **DELETE: Unacceptable dietary and environmental risks**<br>Unacceptable dietary risk applies to all uses except the modified use on plums and nectarines in PER 13840 and 13841<br>**RESTRICTED:**since Oct 2012 lower rates and increased WHPs |
| | ~~Oriental fruit moth (NSW, Vic, SA only)~~ | ~~75 mL/100L~~ | ~~21 days~~ | |
| | ~~Mediterranean fruit fly (WA only)~~ | ~~75 mL/100L~~ | ~~7 days~~ | |
| ~~Stone fruit (except low chill varieties grown in coastal areas)~~ | ~~Queensland fruit fly (NSW, Vic, WA only)~~ | ~~75 mL/100L~~ | ~~21 days~~ | |
| ~~Stone fruit (low chill varieties)~~ | ~~Queensland fruit fly (Qld & NSW (coastal areas), Vic only)~~ | ~~75 mL/100L~~ | ~~21 days~~ | |
| ~~Tropical and sub-tropical fruits (inedible peel)~~ | ~~Fruit fly (Qld, NSW, Vic, WA, NT only)~~ | ~~75 mL/100 L~~ | ~~7 days (except guavas & pawpaws 14 days)~~ | **DELETE**: **Unacceptable environmental risks**<br>Insufficient residues data to support this use |
| NON-TREE/VINE CROPS | | | | |
| ~~Capsicums~~ | ~~Fruit fly (Qld, NT only)~~ | ~~75 mL/100 L or 750 mL/ha~~ | ~~7 days~~ | **DELETE**: **Unacceptable environmental risks**<br>Insufficient residues data to support this use. |
| ~~Eggplants~~ | ~~Fruit fly (Qld, NT only)~~ | ~~75 mL/100 L or 750 mL/ha~~ | ~~7 days~~ | **DELETE: Unacceptable dietary and environmental risks**<br>Prohibited since Oct 2012 |
| ~~Ornamentals~~ | ~~Mealybug (SA, WA only)~~ | ~~100 mL/100 L~~ | ~~-~~ | **DELETE: Unacceptable dietary and environmental risks** |
| ~~Tomatoes~~ | ~~Fruit fly (Qld, NT only)~~ | ~~75 mL/100 L or 750 mL/ha~~ | ~~7 days~~ | **DELETE**: **Unacceptable dietary and environmental risks**<br>Prohibited since Oct 2012 |
| | ~~Mediterranean fruit fly (WA only)~~ | | | |
| | ~~Queensland fruit fly (NSW, Vic only)~~ | | | |
| POST-HARVEST TREATMENTS | | | | |
| ~~Fruiting vegetables (including cucurbits)~~ ~~*Melons and watermelons*~~ | Fruit flies<br>(Quarantine treatment only)<br>(Qld, NSW, WA, NT only) | 75 mL/100 L | - | **Delete** All fruiting vegetables (including chillies, cucurbits, melons and watermelons)<br>**Unacceptable dietary risks** |

| CROP | PEST | RATE | WHP | CHANGES PROPOSED |
|---|---|---|---|---|
| ~~Chillies (Flood spray)~~ | | 75 mL/100 L | - | **Delete** Chillies<br>Insufficient residues data to support this use<br>Dip disposal instructions recommended on grounds of environmental risks |

WHP = Withholding period

### *Use patterns to remain on varied label*

**Table A2: Proposed Directions for Use for Product 32996 *Lebaycid Insecticide Spray***

| CROP | PEST | RATE | WHP | CHANGES PROPOSED |
|---|---|---|---|---|
| POST-HARVEST TREATMENTS | | | | |
| Tropical and sub-tropical fruits (inedible peel[6]) | Fruit flies<br>(Quarantine treatment only)<br>(Qld, NSW, WA, NT only) | 75 mL/100 L | - | **Note** that use on fruiting vegetables (including chillies, cucurbits, melons and watermelon**s) is no longer included**<br>Dip disposal instructions recommended on grounds of environmental risks |

WHP = Withholding period

### *First aid instructions (Schedule 6)*

If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 131126; New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

### *Safety directions*

Poisonous if swallowed. Will irritate the eyes and skin. Avoid contact with eyes and skin. Repeated minor exposure may have a cumulative poisoning effect. Do not inhale spray mist. When preparing spray wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, and elbow-length chemical resistant gloves. When opening the container and pouring large quantities,

[6] **Tropical and sub-tropical fruits (inedible peel) include avocado, banana, breadfruit, custard apple, durian, feijoa, jackfruit, lychee (litchi), longan, mango, mangosteen, pawpaw, passionfruit, , pineapple, pomegranate, rambutan, sapodilla, sapote, tamarind and the inedible peel varieties ONLY of guava, kiwi fruit and persimmon**

wear cotton overalls over normal clothing, buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves and a full facepiece respirator with organic vapour cartridge.
If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, face shield and contaminated clothing.

### *Dip disposal instructions*

Dispose of used dip solution and sludge at a rate not exceeding 20 000 L/ha over an area of dedicated and bunded flat land, away from watercourses and any drainage areas, etc, that could contaminate watercourses, and restrict access to humans and stock for a period of at least 3 months

## Proposed Directions for Use 10 g/kg Dust Pest Control product

**Table A3: Pest Control dust product – Proposed changes to the Directions for Use**

| SITUATION | PEST | RATE | CHANGES PROPOSED |
|---|---|---|---|
| Cracks and crevices | Cockroaches, ants, silverfish, crickets | Apply dust as necessary | Maintain for cracks and crevices only. |
| ~~, wall voids, crawl spaces~~ | | | Delete use in wall voids and crawl spaces due to re-entry exposure risks |
| ~~Ceiling voids~~ | ~~Spiders~~ | ~~Apply dust as necessary~~ | Delete use pattern due to re-entry exposure risks |

### *First aid instructions (Schedule 5)*

If poisoning occurs, contact a doctor or Poisons Information Centre (131126). Phone New Zealand 0800 764 766.

### *Safety directions*

Product harmful if swallowed. Avoid contact with eyes and skin. Do not inhale dust. When using the product wear elbow-length chemical resistant gloves and a disposable respirator with dust cartridge or canister. Wash hands after use. After each day's use, wash gloves.

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# APPENDIX B: PROPOSED ENTRIES IN TABLE 1 OF THE MRL STANDARD

Following implementation of the recommendations of this PRF, the proposed entries in Table 1 of the MRL Standard for fenthion relating to label uses are as follows:

**Table B1 Proposed entries in the Table 1 of the MRL Standard following this review**

| COMPOUND | | FOOD | MRL (mg/kg) |
|---|---|---|---|
| **Fenthion** | | | |
| FI | 0030 | Assorted tropical and sub-tropical fruits—inedible peel | 5 |

An asterisk '*' denotes that the MRL or the ERL is set at or about the limit of analytical quantitation

Of the horticultural crops that continue to be supported, none are considered to be significant animal feeds, and therefore no animal commodity MRLs have been proposed as a consequence of these horticultural uses.

# GLOSSARY

| | |
|---|---|
| AChE | Acetylcholinesterase an enzyme that regulates nerve signals in nervous system |
| ADI | acceptable daily intake (for humans) a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable health risks to the consumer on the basis of all known facts at the time of the evaluation. |
| Agvet Code | Agricultural and Veterinary Chemicals Code, Schedule to the Agricultural and Veterinary Chemicals Code Act 1994 |
| ai | active ingredient |
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| ARfD | An estimate of the amount a substance in food or drinking water, normally expressed on a body weight basis, that can be ingested in a period of 24 h or less without appreciable health risks to the consumer on the basis of all known facts at the time of the evaluation. |
| bw | body weight |
| Codex | FAO/WHO Codex Alimentarius Commission |
| ChE | Cholinesterase |
| EC | emulsifiable concentrate – a liquid formulation |
| g | gram |
| HG | home garden – category of product |
| FAISD | First Aid Instruction and Safety Directions |
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues |
| kg | kilogram |
| L | litre |
| LOAEL | lowest adverse observable effect level |
| LOEL | lowest observable effect level |
| $LC_{50}$ | median lethal concentration |
| $LD_{50}$ | median lethal dose |
| LOC | level of concern |
| mg | milligram |
| mg/kg bw/day | milligrams of ingredient per kilogram of bodyweight per day |
| mL | millilitre |
| MOE | margin of exposure |

| | |
|---|---|
| MRL | maximum residue limit |
| NDPSC | National Drugs and Poisons Scheduling Committee |
| NEDI | National Estimated Short-Term Intake (dietary sources) |
| NHMRC | National Health and Medical Research Council |
| NOAEL | no observable adverse effect level |
| NOEL | no observable effect level |
| OCS | Office of Chemical Safety within the Australian Government Department of Health |
| OHS | occupational health and safety |
| OP | organophosphorus pesticide |
| PACC | The Pesticide and Agricultural Chemicals Committee - responsible for the establishment and revision of Australian MRLs and ADIs for pesticides, from 1967 until November 1992 when the Department of Health and Ageing became directly responsible for setting ADIs. |
| PPE | personal protective equipment such as gloves and overalls |
| SUSMP | Standard for the Uniform Scheduling of Medicines and Poisons. Formerly the SUSDP Standard for the Uniform Scheduling of Drugs and Poisons) |
| US | United States |
| US EPA | US Environmental Protection Agency |
| WHO | World Health Organization |