Australian Government

Australian Pesticides and Veterinary Medicines Authority

# FENTHION

## FINAL REVIEW REPORT AND REGULATORY DECISION

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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 (or review) 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 overleaf) 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 these countries will not use them for registration purposes unless they have access to the raw data from the relevant applicant.


A full description of all stages of this process is included in the *Preliminary Review Findings for Fenthion (PRF)* as published 22 May 2014. The publication of the PRF marked the start of the consultation phase (Stage 7). The consultation phase ended on 22 August 2014 after which the APVMA commenced assessment of the information contained in the submissions as part of Stage 8 the Regulatory Decision.

**Stage 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. The submissions received by the APVMA have now been assessed and a final decision has been made.

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 can 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 meet 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.

**Stage 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 review findings and regulatory decisions (RF) relating to the active constituent fenthion and products containing fenthion when used in accordance with label instructions. The RF and regulatory decisions are based on information collected from a variety of sources.

This report, the preliminary review findings (PRF published 22 May 2014), public submissions received during the consultation period for the review of fenthion 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 and public submissions 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
- *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)
- Public Submissions in response to the Preliminary Review Findings for Fenthion.

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# EXECUTIVE SUMMARY

The Australian Pesticides and Veterinary Medicines Authority has completed its review of the active constituent fenthion and all products containing fenthion. This document summarises the regulatory decisions made by the APVMA and the final review findings. These decisions were made on the basis of the preliminary review findings and technical assessments, as well as the submissions received in response to the publication of the preliminary findings.

Fenthion is a broad spectrum organophosphorus (OP) insecticide that has been registered in Australia for more than 50 years. The active constituent fenthion, all products containing fenthion and their associated labels were placed under review in 1998 because of concerns about its toxicity (especially acute toxicity), occupational health and safety (OHS), residues in food (including dietary exposure) environmental and trade aspects. This review has considered the use of fenthion to control insect pests in agricultural, commercial and domestic situations, external parasites on cattle, and pest birds in and around buildings.

The Preliminary Review Findings (PRF) report for Fenthion was published 22 May 2014. This report summarised the findings of all assessments for the review of fenthion and the APVMA proposed regulatory actions for fenthion and products containing fenthion to mitigate the risks and concerns outlined in the assessments.

The PRF proposed the following regulatory actions:

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

As part of the APVMA's policy of encouraging openness and transparency in its activities and community involvement in its decision-making, public comments were invited during a public consultation period.

The APVMA received fifteen submissions following the publication of the PRF for fenthion on 22 May 2014 from various stakeholders including state governments, manufacturers, user groups and members of the public. These submissions did not include any further data or relevant information to be included in the technical assessments. Some submissions proposed changes to use patterns and the APVMA has assessed whether these mitigate the identified concerns.

## Final Review Outcomes

After consideration of all data including the advice received by the agencies in their respective risk assessments and consideration of submissions from industry and the public the APVMA was NOT satisfied under section 34(1)(a) of the Agvet Code that the continued use of fenthion products in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to them during their handling or people using anything containing its residues

- would not be likely to have an unintended effect that is harmful to human beings; and
- would not be likely to have an unintended effect that is harmful to animals, plants or to things or to the environment.

The APVMA was satisfied, however, that the instructions for use included on the labels for the products 32996 *Lebaycid Insecticide Spray* and 41138 *Amalgamated Pest Control 1% Fenthion* could be varied so that the use of these two products would meet the requirements above.

Specifically, in finalising the review, the APVMA has decided to:

- **Affirm** the active constituent approval for fenthion (Active Approval Number 44383) held by Bayer CropScience Pty Ltd.
- **Vary** relevant particulars of label approvals of the products below to satisfy the requirements for continued registration:
    - 32996 *Lebaycid Insecticide Spray*, label approval number 32996/0914
        - Delete the use instructions for all crops except post-harvest treatment by dipping or flood spray of tropical and subtropical fruit with inedible peel and update the First Aid and Safety Directions
    - 41138 *Amalgamated Pest Control 1% Fenthion*
        - Delete the use instructions for wall voids, crawl spaces and ceiling voids and update the First Aid and Safety Directions
- **Affirm** these product registrations with the new, varied labels
- **Cancel** the registrations and associated label approvals of the following products:
    - 33520, *Tiguvon Spot-on Cattle Lice Insecticide*
    - 42202, *Control-A-Bird Agent*
    - 50244, *Avigrease Pest Bird Eradication Compound*
    - 51627, *David Grays Mosquito and Spider Spray Insecticide*
    - 52075, *Avigel Pest Bird Control Agent*
    - 61308, *Lebaycid Fruit Fly & Insect Killer*

## Review of fenthion is concluded

These regulatory actions conclude the reconsideration of fenthion, products containing fenthion and their associated labels for all products.

## Phase out period

The APVMA has determined that there shall be a maximum period of 12 months from the date of the decision (the phase out period) during which a person may possess, have custody of, use, deal with or supply a cancelled product as labelled or a product bearing a cancelled label, in accordance with the instructions in the notice of cancellation.

The APVMA has determined that instructions for use of *Lebaycid Insecticide Spray* and *Lebaycid Fruit Fly & Insect Killer* during this phase-out period should match the previous suspension instructions (permits PER13840, PER13841 and PER 13843). These instructions for use include modifications and restrictions to the previously approved label instructions (use patterns) to mitigate identified concerns about public health (acute dietary exposure) risks and were first implemented in October 2012.

Maximum Residues Limits for fenthion will be removed from the APVMA Standard after the phase out period has ended.

# 1 INTRODUCTION

Fenthion is an organophosphorus pesticide that has been registered in Australia to control insect pests (including fruit fly) in a variety of horticultural crops. Fenthion has also been used in non-food situations (not indoors) to control ants, flies, mosquitoes and spiders. It has also been used 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 (then known as the National Registration Authority) 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 the 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. This results 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 Stages of the APVMA review of fenthion

Stages of the fenthion review

**Nomination: Completed**

In 1994 fenthion was nominated for review as part of the call for nominations of existing chemicals for review. This nomination was assessed by the APVMA and its partner agencies.

**Prioritisation: Completed**

Fenthion was prioritised for inclusion in the third cycle of the existing chemical review program (ECRP) which was scheduled for 1998.

**Scoping: Completed**

The scope of this ECRP review included 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 considered whether product labels had adequate instructions and warning statements.

**Notice of reconsideration: Completed**

In April 1998, the APVMA announced the commencement of the third cycle of chemical reviews (Azinphos-methyl, Azinphos-ethyl, Aldicarb, Diquat, Paraquat, Methiocarb and Fenthion). The period for submission of data ended 31 January 1999 after which assessment commenced.

**Assessment, previous draft regulatory measures and consultation periods: Completed**

In December 2005 the APVMA released the Fenthion PRF Report: Part 1 in relation to the non-food uses of fenthion. This report made recommendations regarding user safety (OHS) and environmental risks and invited submissions as part of a public consultation period for the proposed actions. Some holders of registrations submitted voluntary label changes to certain products and after consideration of submissions further regulatory controls on the use of bird control products were imposed.

The toxicology report published in December 2005 established a new public health safety standard for short-term dietary exposure to fenthion (the Acute Reference Dose). A contemporary residues and dietary risk assessment of fenthion uses was required to determine whether potential dietary exposure to fenthion residues (in produce treated according to the label instructions) would exceed this safety standard. This was applicable to the fenthion review Part 2 which considered all fenthion products used in food-producing situations.

In 2006 and 2007, the APVMA identified that there was 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 a wide range of groups including states and territories (interstate certification) Low Chill Australia (representing low-chill stone fruit growers), 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 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* (for horticultural uses) which was published in September 2012.

The *Fenthion Residues and Dietary Risk Assessment Report* (September 2012) determined that the residues in produce treated according to the existing label directions were not acceptable for many crops. The APVMA proposed that the two products used on food-producing plants be suspended so that new instructions for use could be issued that would mitigate the risks identified in the residues report. At this time the APVMA requested information to assist in developing interim, modified instructions during the proposed suspension period. In some cases the submitted information allowed modified use instructions that were assessed as mitigating the concerns identified in the draft regulatory measures while other technical reports were being completed.

In October 2012, modified use instructions and restrictions for fenthion use in horticulture were imposed through a suspension of these two products and their labels and issuing of new instructions for use. These interim instructions for use were issued as permits, noting that the eventual use patterns could be changed according to the findings of the remaining environmental and OHS assessments. Sufficient residues data were also required to confirm that these use patterns were acceptable.

This suspension of fenthion products was continued until October 2014, with some further restrictions on the use of fenthion on horticultural crops included in October 2013.

**Draft regulatory measure for all parts of the review: Published May 2014**

After the veterinary residues, environmental and OHS (worker and user safety) assessments were completed and updated, the Preliminary Review Findings for Fenthion were published on 22 May 2014. This report summarised the findings of all assessments for the review of fenthion and all submissions received throughout the course of the review. In this report the APVMA proposed regulatory actions for fenthion and products containing fenthion to mitigate the risks and concerns outlined in all of the assessments as follows:

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

**Consultation period: Completed August 2014**

The APVMA received 15 submissions following the publication of the Preliminary Review Findings. These are summarised below in section 2 and are available in full from the APVMA website. The APVMA also consulted with state and territory chemical control of use representatives during this stage.

**Regulatory Decision: Current**

Following the assessment of submissions and other information received during the consultation period the APVMA has made decisions relating to changes to label instructions and approvals, continued registration and cancellation of certain registrations of product containing fenthion. These decisions are contained in this document and also published in the APVMA Gazette.

**Implementation: Ongoing**

Notices and permits have been issued that contain the instructions for possession, supply and use of cancelled products or product bearing cancelled labels during this phase out period. The implementation period ends when the phase out period for all cancelled products has ended.

## 1.1 Senate Inquiry into the implications of the restriction on the use of Fenthion on Australia's horticultural industry

During the second year of the suspension of fenthion, on 12 December 2013, the Federal Government Senate Standing Committees on Rural and Regional Affairs and Transport commenced an inquiry into the implications of the restriction on the use of Fenthion on Australia's horticultural industry (the Senate Inquiry).

The APVMA submitted documents and replies to questions on notice and further questions from the committee. These are:

- Submission 23 APVMA Submission to the Inquiry 28 January 2014
- Submission 23A APVMA Supplementary Submission 3 July 2014
- Additional Documents – APVMA reply of 21 July to request for further information regarding the human volunteer study and also regarding transition periods
- Answers to Questions on Notice from the hearing of 07 July 2014

The Committee reported its findings on 31 July 2013. This report, all submissions to the inquiry and additional documents requested by the Senate Inquiry are available from the Senate Inquiry webpage http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Rural_and_Regional_Affairs_and_Transport/Fenthion

The Committee made eight recommendations in its final report of 31 July 2014 which included recommendations to all relevant Commonwealth, state and territory agencies and governments regarding better communication of their roles and responsibilities, the arrangements for regulation of agricultural chemicals, management of abandoned orchards and implementation and funding of the National Fruit Fly Strategy.

In relation to this reconsideration of fenthion, the committee stated in Recommendation 4 that:

*4.94 The committee recommends that the maximum twelve month transition period allowed under the Agricultural and Veterinary Chemicals Code Act 1994 be initiated by the APVMA, that fenthion be permitted for sale during the first half of that period, and that the APVMA allow fenthion to be used during the full transition period, subject to appropriate 'conditions of use'.*

The APVMA has considered the content and recommendations of the Senate Inquiry, together with advice from the relevant state and territory regulatory agencies in determining the appropriate phase out period for cancelled fenthion products.

# 2 SUBMISSIONS IN RESPONSE TO THE PRELIMINARY REVIEW FINDINGS

The APVMA received 15 submissions following the publication of the Preliminary Review Findings (PRF) for fenthion on 22 May 2014. The full submissions are available from the APVMA website consultation page.

These submissions did not include any further data (such as residues data) or relevant information to be included in the technical assessments. Some submissions proposed changes to use patterns to reduce environmental of worker safety (OHS) risks. These proposed changes to instructions for use have been assessed and it was found that they do not mitigate the identified concerns.

These submissions are listed in order of receipt:

**Table 2.1: Submissions received in response to the PRF**

| NUMBER | SUBMITTING PERSON OR GROUP | SUMMARY OF SUBMISSION | APVMA ASSESSMENT |
|---|---|---|---|
| Submission 1 | Kiwifruit growers, Northern NSW | Request a phase-out period of at least 12 months | Phase-out periods for the cancelled product with this use will apply. |
| Submission 2 | Control-A-Bird Pty Ltd | Questions regarding the OHS findings | Continued use of fenthion for bird control is not supported on OHS grounds. Phase-out periods for cancelled products with these uses will apply. (Further details of the assessment are in Appendix D) |
| Submission 3 | Ms Rita Saffioti MP WA parliamentarian, Swan Valley WA | Requests for either continued use or a phase-out period for the use on grapes. No further information provided. | Continued use of fenthion on grapes not supported on dietary and environmental grounds. Phase-out periods for cancelled product with this use will apply. |
| Submission 4 | Custard Apples Australia | Requests for continued use of fenthion for pre-harvest fruit fly control on custard apples due to lack of alternatives. No additional residues data submitted. | Continued use of fenthion on custard apples is not supported on dietary and environmental grounds.<br>Phase-out periods for cancelled product with this use will apply |
| Submission 5 | ANC Bird Control | Questions regarding the OHS findings | Continued use of fenthion for bird control is not supported on OHS grounds. Phase-out periods for cancelled products with these uses will apply.<br>(Further details of the assessment are in Appendix D) |

| NUMBER | SUBMITTING PERSON OR GROUP | SUMMARY OF SUBMISSION | APVMA ASSESSMENT |
|---|---|---|---|
| Submission 6 | Cattle Council | Do not support removal of fenthion product. No further information provided. | Continued use of fenthion on cattle is not supported due to dietary risk. Phase-out periods for cancelled product with this use will apply. |
| Submission 7 | Stone fruit grower Forbes NSW | Opposed to removal of the use of fenthion. | Continued use of fenthion on stone fruit is not supported. Phase-out periods for cancelled product with this use will apply. |
| Submission 8 | Fruit grower | Can produce fruit without fenthion. | Continued pre-harvest use of fenthion on fruit is not supported.<br>Phase-out periods for cancelled labels with these uses will apply |
| Submission 9 | Stone fruit grower Forbes NSW | Opposed to loss of fenthion due to lack of economic alternates. | Continued use of fenthion not supported. Phase-out periods for cancelled labels with these uses will apply. |
| Submission 10 | Hills Orchard Improvement Group WA | Request continued use on pome fruit and stone fruit at lower use rates to reduce environment risks. | Pome fruit uses are not supported by the dietary assessment.<br>All pre-harvest orchard uses are not supported by the environmental assessment.<br>Phase-out periods for cancelled product with these uses will appl.y<br>(Further details of the assessment are in the Appendices E and F) |
| Submission 11 | Australian Mango Industry Association | Request that dip disposal to orchard floor be allowed, based on likely quantities used. | Dip disposal should be to bunded, flat land to control run-off risks.<br>(Further details of the assessment are in Appendix F) |
| Submission 12 | Summerfruit Australia Ltd | Request continued use at lower rates to reduce environment risks, also request phase out period. | All pre-harvest orchard uses not supported by the environmental assessment.<br>Phase-out periods for cancelled labels with these uses will apply.<br>(Further details of the assessment are in Appendix E) |
| Submission 13 | Australian Pest Bird Management | Questions regarding OHS findings with toxicology opinion provided. | Continued use of fenthion not supported on worker safety grounds. Phase-out periods for cancelled product with this use will apply.<br>(Further details of the assessment are in Appendix D) |

| NUMBER | SUBMITTING PERSON OR GROUP | SUMMARY OF SUBMISSION | APVMA ASSESSMENT |
|---|---|---|---|
| Submission 14 | Apple and Pear Australia Ltd | Request continued use at lower rates to reduce environment risks.<br>No residues or environmental data provided. | Continued use on pome fruit is not supported by the dietary assessment or the environmental assessment.<br>Phase-out periods for cancelled product with this use will apply<br>(Further details of the assessment are in Appendix E) |
| Submission 15 | Queensland Department of Agriculture, Fisheries and Forestry | Discusses protocols for access to interstate markets and likelihood of a phase out period. Questions were posed regarding the suitability of proposed dip disposal instructions. | Phase-out periods for cancelled products and product labels will apply.<br>Dip disposal concerns are noted and discussed.<br>(Further details of the assessment are in Appendix F) |

Particular submissions required assessment of proposed changes to use instructions, which are summarised in the appendices to this document.

# 3 REVIEW OUTCOMES AND REGULATORY DECISIONS

On the basis of the evaluation of the submitted data and information (including protected information) the APVMA was NOT satisfied under section 34(1)(a) of the Agvet Codes that the continued use of fenthion products in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to them during their handling or people using anything containing its residues
- would not be likely to have an unintended effect that is harmful to human beings; and
- would not be likely to have an unintended effect that is harmful to animals, plants or to things or to the environment.

With the exception of the products 32996 Lebaycid Insecticide Spray and 41138 Amalgamated Pest Control Fenthion 1% Dust Insecticide, the APVMA was not satisfied under section 34(5) of the Agvet Codes, that the relevant particulars or the conditions of approval or registration could be varied so that the requirements for continued registration will be complied with.

Therefore, the following recommendations were made in regards to the continued registrations and approvals of fenthion in Australia:

- affirmation of the active approval for fenthion
- variation of the labels of the products 32996 Lebaycid Insecticide Spray and 41138 Amalgamated Pest Control Fenthion 1% Dust Insecticide as specified in Table 3.2 below
- affirmation of the registration of these products, following variation of the labels and cancellation of previous labels
- cancellation of the cattle lice control product
- cancellation of all pest control and home garden products.

## 3.1 Affirm approval of the active constituent

The APVMA is satisfied that the active constituent fenthion meets the requirements for continued approval.

**Table 3.1: Active constituent approval affirmed**

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

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

These variations to label instructions satisfy the requirements for continued registration of this product and the APVMA has AFFIRMED the product registration listed as the labels have been varied and previous labels have been cancelled.

**Table 3.2 Products affirmed following variation of label approvals.**

| 1. PRODUCT NUMBER | 2. PRODUCT NAME | 3. REGISTRANT | 4. LABEL APPROVAL TO BE VARIED OR CANCELLED | 5. NEW VARIED LABEL APPROVAL NUMBER |
|---|---|---|---|---|
| 32996 | Lebaycid Insecticide Spray | Bayer Cropscience Pty Ltd | 32996/0110 | 32996/1014 |
| Label variation 32996/1014. Updated first aid and safety directions and dip disposal directions. Deleted all use patterns except *postharvest treatment (dipping or flood spray) of tropical and sub-tropical fruits (inedible peel varieties only)* because of unacceptable dietary and environmental risks | | | | |
| 41138 | Amalgamated Pest Control Fenthion 1% Dust Insecticide | Amalgamated Pest Control Pty Ltd | 41138/0900 to cancel<br>41138/1208 to vary | 41138/1014 |
| Label variation 41138/1014. Updated first aid and safety directions and deleted use patterns for wall voids, crawl spaces and ceiling voids due to OHS risks on re-entry of treated areas | | | | |

## 3.3 Cancellation of product registrations and label approvals as an outcome of the review findings

As an outcome of the findings of the review, the APVMA is not satisfied that the requirements for continued registration and approval of the products listed in Table 3.3 below continue to be met.

Therefore, under s 40 of the AgVet Code, the APVMA has cancelled these registrations and label approvals as listed in Table 3.3 below.

**Table 3.3: Products and label approvals cancelled as an outcome of the review of fenthion**

| PRODUCT NUMBER | NAME OF CANCELLED PRODUCT | REGISTRANT | CANCELLED LABEL APPROVAL NUMBERS | REVIEW FINDINGS |
|---|---|---|---|---|
| 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 public health (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 CANCELLED PRODUCT | REGISTRANT | CANCELLED LABEL APPROVAL NUMBERS | REVIEW FINDINGS |
|---|---|---|---|---|
| 51627 | David Grays 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 worker safety (OHS) risks |
| 61308 | Lebaycid Fruit Fly & Insect Killer | Bayer Cropscience Pty Ltd | 61308/0907 | Not supported unacceptable user safety and public health (dietary) risks |

## Review of fenthion is concluded

These regulatory actions conclude the reconsideration of fenthion, products containing fenthion and their associated labels.

# APPENDICES

# APPENDIX A: SUMMARY OF LABEL VARIATIONS

## Directions for Use 32996 Lebaycid Insecticide Spray

### *Varied label*

**Table A1: Directions for Use for Product 32996 *Lebaycid Insecticide Spray***

| CROP | PEST | RATE | WHP | COMMENT ON CHANGES |
|---|---|---|---|---|
| POST-HARVEST TREATMENTS | | | | |
| Tropical and sub-tropical fruits (inedible peel[1]) | 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 dip or flood 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, wear cotton overalls over normal clothing, buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves and a full face-piece 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.

[1] **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**

### *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 three months. The disposal site must be adequately bunded (the soil should at least be 15 cm high).

## Directions for Use 41138 Amalgamated Pest Control Fenthion 1% Dust Insecticide

**Table A2: Pest Control 10 g/kg dust product –Changes to the Directions for Use**

| SITUATION | PEST | RATE | CHANGES PROPOSED |
|---|---|---|---|
| Cracks and crevices | Cockroaches, ants, silverfish, crickets | Apply dust as necessary | Maintained for cracks and crevices only. |
| ~~, wall voids, crawl spaces~~ | | | Deleted 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.

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

The entries in Table 1 of the MRL Standard for fenthion relating to label uses that will apply once the phase out period for cancelled labels has ended will be 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 |

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

# APPENDIX C: FIRST AID INSTRUCTIONS AND SAFETY DIRECTIONS

## First Aid Instructions

No amendments were considered necessary to the First Aid instructions as a result of this assessment.

**Table C1: First Aid Instructions**

| 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 C2: Recommended safety directions for products containing fenthion 15g/kg or less**

| 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. |

### Table C3: Recommended safety directions for products containing fenthion 600g/L or less

| 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 or dip 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. |
| 350 360 361 362 366 | 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. |

The APVMA also notes that that the following categories of safety directions should 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 C4: 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. |

# APPENDIX D: SUBMISSIONS 2, 5 AND 13: BIRD CONTROL PRODUCTS AND OHS RISKS

Below is the Office of Chemical Safety (OCS) response to submissions regarding the worker safety (OHS) findings for the use of fenthion in the control of pest birds.

## *Submission 2: Control-A- Bird Pty. Ltd.*

**Comments on dermal absorption**

The stakeholder makes an assumption that the dermal absorption factor (DAF) used was only applicable to a 100% fenthion solution and that the DAF for the 110 g/L paint product would be "assumed" to be lower than that of the concentrated form. In the case of the OHS review, the DAF used was based on data for a 50% formulation with both animal and human data taken into consideration to give a final figure of 9% dermal absorption. The stakeholder's assumption that a more dilute formulation would have a lower DAF than a concentrated formulation is not based on scientific principle. It is a well-established scientific principle that while dermal absorption does not increase linearly with increasing dilution, it does increase (not decrease as the stakeholder postulated). Therefore, it is likely that the DAF for an 11% formulation would be greater than that used by OCS in the OHS risk assessment. To review the dermal absorption factor for a 110 g/L formulation, an in vivo dermal absorption study in rats would be required to enable the triple pack approach to DAF determination.

**DotPoint 1**

The risk assessment for application was solely conducted for professional licensed pest-control workers with the assumption of access to full and extensive PPE. The outcome of this assessment was that the risk posed by application of the product in accordance with the label directions was unacceptable (by a very large margin). Further, the addition of a second layer of clothing over normal clothes, a washable hat and gloves when worn during application was unable to mitigate the risk posed from dermal exposure to fenthion.

**Dot Points 2 and 3**

OCS did not investigate the re-entry or rehandling or bystander exposure for this application method and as such can't comment on the assertions made by the stakeholder.

**Dot Point 4**

OCS does not support the continued use of fenthion via paint brush/roller for the control of pest bird species in roost areas, based on an unacceptable risk to human health of workers from the application of these products. The request for an extended five-year phase-out is outside the scope of OCS recommendations to APVMA.

### *Submission 5: ANC Bird Control*

The stakeholder submitted an assertion that workers using their product (Avigel Pest Bird Control Agent) would have NIL dermal absorption. There is no scientific basis for this assumption, nor was any study or information presented to support this statement. Exposure was modelled by the most appropriate PHED scenario (Paintbrush) which is based on surrogate data indicating that exposure does occur and that the level of potential exposure during the use of bird pest control agents presents an unacceptable risk to workers, which cannot be mitigated with the use of extensive PPE.

Although the stakeholder claims that application of the product to "duct tape" secured to the roost area (slight variation to the label directions) makes it easier to remove, thus reducing re-handling of the product, the worker must still apply the product to the tape and OCS has determined that exposure of workers to fenthion during the application is unacceptable.

### *Submission 13: Redcap Solutions*

Redcap Solutions (letter dated 22 August 2014) has presented an argument for reconsideration of APVMA's decision to cancel the registration and label approval of Avigrease, based on information provided to them by APBM and an expert report prepared by Clinical Network Services Pty Ltd. The argument comprises the following issues, as presented in the letter from Redcap Solutions:

1. Avigrease use rates per day are lower than the OCS estimates of 1L/hour for 3 hours/day
2. xposure of workers does not occur on a daily basis.
3. the expert report suggests that an incorrect reduction in exposure may have been applied in the OCS calculations for the use of a double layer of clothing. The Pesticide Handlers Exposure Database (PHED) referenced in the review findings states that for a double layer of clothing, body exposure is calculated from available single layer exposure data by dividing by 2 (i.e. a 50% reduction in exposure) however in the OCS report only an 8% reduction has been applied in the exposure calculations
4. the expert report presented a recalculated MOE of 10.7 when realistic Avigrease usage and revised dermal exposure are considered, which is 10-fold higher than the MOE

**OCS Response**

**Dot Points 1 and 4**

Redcap Solutions argue that the OCS has grossly overestimated the quantity of product used per day (i.e. 3L or 3kg product per day). OCS has re-modelled both 2.1 kg/day and 0.5 kg/day values for completeness with the following assumptions: A second layer of clothing over normal clothes, a washable hat, respirator and gloves worn during application, no mixing and loading exposure and the use of scenario 22 in PHED (the only applicable scenario that covers both paintbrush and roller application), a 9% dermal absorption factor for fenthion and a NOEL of 0.02 mg/kg bw/d from a human study. Based on the use of a human study a margin of exposure (MOE) of ≥ 10 is considered acceptable. The following tables summarise the exposure and resultant MOEs for both quantities of paint used per day.

### Table D1. Exposure estimates for 2.1 kg or 0.5 kg Avigrease per day (*mg/kg bw/d).

| Exposure scenario | Application and work rates[(1)] | Gloves and/or PPE | Applicator dermal* | Applicator Inhalation* | Total Exposure* |
|---|---|---|---|---|---|
| Application of (110 g/L paint) scenario 22 (paintbrush/roller) | 2.1 kg/d<br><br>(0.231 g ai/d) | Gloves plus second layer clothing and washable hat<br><br>+ respirator during Application | 0.0119 | 0.0002 | 0.0121 |
| | 0.5 kg/d<br><br>(0.055 g ai/d) | Gloves plus second layer clothing and washable hat<br><br>+ respirator during Application | 0.00283 | 0.00005 | 0.00287 |

### Table D2. MOE estimates from Table

| Exposure scenario | Application and work rates[(1)] | Gloves and/or PPE | Applicator dermal MOE | Applicator Inhalation MOE | Total MOE |
|---|---|---|---|---|---|
| Application of (110 g/L paint) scenario 22 (paintbrush/roller) | 2.1 kg/d<br><br>(0.231 g ai/d) | Gloves plus second layer clothing and washable hat<br><br>+ respirator during Application | 2 | 98 | 2 |
| | 0.5 kg/d<br><br>(0.055 g ai/d) | Gloves plus second layer clothing and washable hat<br><br>+ respirator during Application | 7 | 412 | 7 |

The risk assessment for application was conducted solely for professional licensed pest-control workers with the assumption of access to full and extensive PPE. The outcome of this re-assessment was that the risk posed by application of the product in accordance with the new use rates as proposed by Redcap Solutions was unacceptable. Further, the addition of a second layer of clothing over normal clothes, a washable hat (which was modelled in the original calculation in the review document but not implicitly stated) and gloves, when worn during application was unable to mitigate the risk posed from dermal exposure to fenthion, even at a rate of usage of 0.5 kg/d.

OCS conclusion: Exposure calculations using the revised use estimates indicate unacceptable dermal risks (MOEs) for users of Avigrease.

**Dot Point 2.**

Redcap Solutions have provided argument that a single person would not use this product every day of the week. OCS notes that there is no stipulation on the product label to restrict usage in terms of number of days per week or for divided shifts for application. In any event, the OCS considers that such label restrictions would not be acceptable to APVMA. It is therefore assumed that the revised quantity used per 'occasion' as stipulated by Redcap solutions in Dot Point 1 may be applied on a daily basis.

Redcap Solutions have also provided information provided by APBM on the specific use of Avigrease by their organisation which could reduce exposure further. OCS accepts that this specific use pattern may well lessen the exposure of applicators to fenthion to acceptable levels when only applying an average of 500 g Avigrease per day, however there has been no evidence provided to demonstrate that this application method would provide an acceptable MOE.

However, this use pattern would not necessarily reflect the use patterns for other similar formulations of fenthion paints and is not articulated in any current or proposed enforceable label instructions.

**OCS Conclusion:** OCS not able to take into consideration the additional use practices information provided, as there were no enforceable label statements proposed for product labels to articulate these practices, nor are there any modelling tools/data available for OCS to quantitate any reduction in risk, associated with the practices outlined. In addition, the label for Avigrease currently includes the use of paint brushes as well as rollers for application.

**Dot Point 3**

Redcap Solutions asserts that the OCS has incorrectly adjusted the single layer dermal exposure estimates in PHED for calculation of a second layer of clothing. Redcap Solutions claim that the second layer of clothing reduces the total dermal exposure by a factor of 50%. This assertion is erroneous for two reasons:

i) OCS has used a 90% reduction in exposure to the body for a second layer of clothing (Thongsinthusak et al. 1993); and

ii) a second layer of clothing only reduces the body dermal exposure component of the PHED estimation, and has no impact on exposure to the head, neck and hands. No further reduction can be made to the exposure component to hands, further to the PHED estimate with gloves. An additional 90% reduction in head and neck exposure was factored into PHED calculations by the use of a washable hat. While this was modelled in the PHED calculations in the OHS Review, it was not implicitly stated in the description of the PPE in the exposure table.

**OCS conclusion:** Exposure calculations for a second layer of clothing over normal clothes remain valid in the original review report and in the re-assessment in Table  and Table  above.

### *Overall conclusion for the worker safety assessment for bird control products*

In summary, the submissions from these three stakeholders, do not justify a re-assessment of the OHS risk assessment for any of the bird control products, or a revision of the recommendations in the OCS OHS Review report.

OCS considers that the recommendation to **NOT** support use of fenthion via paint brush/roller for roost areas of pigeons, starlings, sparrows and Indian mynahs remains valid.

# APPENDIX E: SUBMISSIONS 10, 12 AND 14: PRE-HARVEST USES ON STONEFRUIT AND POMEFRUIT

## Dietary exposure risks

In Submissions 10 and 14, the Hills Orchard Improvement Group (HOIG) and Apple and Pear Australia (APAL) both requested that the APVMA continue to allow the use of fenthion on pome fruit (apples and pears). However, there was no further data submitted to support these uses.

In the *Preliminary Review Findings for Fenthion* (PRF May 2014), the APVMA noted that the apple and pear use patterns were not supported by the available residues data and proposed that these uses be deleted from labels. There has been no additional residues data made available to the APVMA and this assessment is unchanged.

## Environmental risks arising from spray drift

HOIG and Summerfruit Australia Limited (SAL) proposed that the APVMA consider refining the risk characterization by considering a maximum water volume of 1500 L/ha and maximum dilution spray concentration of 75mL/100L.This results in an application of 0.62 kg of active ingredient fenthion per hectare (two significant figures).

APAL likewise suggested a maximum spray volume of 1500 – 2000 L/ha and a reduction in the current labelled rate for fruit fly control on apples and pears from 150mL/100L to 75mL/100L. There was no evidence provided to demonstrate that this lower rate is efficacious on apples and pears and, as noted above, the apple and pear use patterns were not supported by the available residues data.

HOIG also raised concerns that the species of aquatic invertebrates used in the assessment of the environmental risks were not native to Australia. As noted in the Environmental Risk Assessment (2014) there were no data provided on the toxicity of fenthion to Australian aquatic species. The assessment was based on available data for standard test species for the three trophic levels of aquatic organisms (fish, aquatic invertebrates and algae/aquatic plants).

SAL included recalculations of the spray drift risk quotients using the proposed rate per hectare of 0.619 kg/ha, the “Normal” orchard spray setting and an allowance for aquatic photodegradation over one day reducing the levels of fenthion in water to either 55% or 40% of original values.

In the SAL estimates (Table 3 of Submission 14) the risk quotient for pink shrimp was above 1.0 (not manageable) with a buffer zone of 60 m and above 0.1 (mitigation required) with a buffer zone of 300m when allowing for only 40% of the fenthion remaining in water after one day.

On this basis SAL proposed that the use should continue with the following restraints:

- DO NOT apply in water volumes greater than 1500 L/ha
- DO NOT apply within 100m of a downwind aquatic and wetland area including agricultural ponds or surface streams and rivers.

## *APVMA spray drift risk assessments for stone fruit orchard application of fenthion*

The APVMA has re-assessed the aquatic environment spray drift risk assessment for stone fruit orchard application of fenthion that was conducted by the Department of the Environment and published on 30 April 2014 with the following modification:

The water volume is proposed to be limited to 1500 L/ha at a rate of 75 mL/ha which results in an application rate of 0.62 kg ac/ha (two significant figures as per application rate).

Two endpoints were assessed:

- $EC_{50}$ (*Daphnia magna*) = 5.2 µg/L, RQ = 0.1
- $EC_{50}$ (Pink shrimp *Penaeus duorarum*) = 0.11 µg/L, RQ = 0.1

The impact of accounting for aqueous photodegradation and sediment adsorption is to be assessed at a level 40% of the initial concentration which is the lower limit of the expected concentration 1 day post application. Practically this will be conducted on the basis of assuming 40% of the application rate (i.e. 0.25 kg ac/ha) for modelling with AgDRIFT.

It should be noted that it may not be appropriate to consider aqueous photodegradation and sediment adsorption post application for endpoints from acute toxicity studies as the toxicity studies used to establish these endpoints were for short-term exposure of these aquatic species.

It is also noted that the Department of the Environment risk assessment built on a previous risk assessment where the 'Normal' orchard/airblast scenario setting of AgDRIFT was used. The use of this scenario for consideration by the APVMA ceased in 2010[2] but the calculations were not revised by the Department of the Environment because:

*It is noted that the APVMA Operational Notice (2010) advises against the use of the setting 'Normal Orchard' and instead to use 'Composite Orchard', 'Dense Orchard' or 'Sparse Orchard'. Although the following calculations have not been updated in line with the Operational Notice (2010) the Department of the Environment believes the various distances will not vary significantly and the final outcomes of acceptable or unacceptable risk are expected to remain unchanged.*[3]

Due to the proposed modifications above this rationale may no longer be valid, so both the 'Normal' and 'Composite' scenarios will be assessed below. It should be noted, however, that the 'Composite' scenario is the current approved scenario used by the APVMA for the consideration of stone fruit orchard applications.

[2] http://archive.apvma.gov.au/transition/morag/notices/op_notice_spray_drift_supp1.php

[3] Page 66 of assessment report by Department of the Environment and published on 30 April 2014

### Spray drift risk assessments

Firstly, the application rate without adjustment for aqueous photodegradation and soil adsorption was assessed for the surrogate 95th percentile deposition curves for the 'Normal' and 'Composite' scenarios for each of the endpoints:

**Table E1: Risk quotients when 1500L/ha application rate is assumed and 75mL product/100L (i.e. 0.62 kg ac/ha)**

| Downwind distance (m) | Risk Quotients (RQ) | | | |
|---|---|---|---|---|
| | 'Normal' orchard scenario | | 'Composite' orchard scenario | |
| | $EC_{50}$ (*Daphnia magna*) = 5.2 µg/L | $EC_{50}$ (Pink shrimp *Penaeus duorarum*) = 0.11 µg/L | $EC_{50}$ (*Daphnia magna*) = 5.2 µg/L | $EC_{50}$ (Pink shrimp *Penaeus duorarum*) = 0.11 µg/L |
| 20 | 0.212 | 10.036 | 3.018 | 142.673 |
| 40 | 0.107 | 5.064 | 1.095 | 51.773 |
| 60 | 0.069 | 3.273 | 0.615 | 29.055 |
| 80 | 0.050 | 2.364 | 0.418 | 19.782 |
| 100 | 0.038 | 1.818 | 0.315 | 14.900 |
| 200 | 0.016 | 0.764 | 0.138 | 6.536 |
| 300 | 0.009 | 0.445 | 0.086 | 4.073 |

Key: Shading represents RQ that is unacceptable; no shading represents RQ that is acceptable (RQ is 0.1 for $EC_{50}$ studies).

Secondly, the impact of accounting for aqueous photodegradation and sediment adsorption was assessed:

**Table E2: Risk quotients 1 day after application (i.e. 0.25 kg ac/ha)**

| Downwind distance (m) | Risk Quotients (RQ) | | | |
|---|---|---|---|---|
| | 'Normal' orchard scenario | | 'Composite' orchard scenario | |
| | $EC_{50}$ (*Daphnia magna*) = 5.2 µg/L | $EC_{50}$ (Pink shrimp *Penaeus duorarum*) = 0.11 µg/L | $EC_{50}$ (*Daphnia magna*) = 5.2 µg/L | $EC_{50}$ (Pink shrimp *Penaeus duorarum*) = 0.11 µg/L |
| 20 | 0.086 | 4.045 | 1.217 | 57.527 |
| 40 | 0.043 | 2.045 | 0.442 | 20.882 |
| 60 | 0.028 | 1.318 | 0.248 | 11.718 |
| 80 | 0.020 | 0.955 | 0.169 | 7.973 |
| 100 | 0.015 | 0.727 | 0.127 | 6.009 |
| 200 | 0.007 | 0.309 | 0.056 | 2.636 |
| 250 | 0.005 | 0.227 | 0.043 | 2.036 |
| 300 | 0.004 | 0.182 | 0.035 | 1.645 |

Key: Shading represents RQ that is unacceptable; no shading represents RQ that is acceptable (RQ is 0.1 for $EC_{50}$ studies).

Note that the slight variation in RQ from the Summerfruit Australia Limited submission are caused by the use of three significant figures for the application rate when only 2 should have been used (due to the application rate only being two significant figures).

The risk quotients are unacceptable for sensitive aquatic species at a distance of 300m from aquatic areas. By extrapolation, the risk quotients are therefore also unacceptable for a maximum spray volume of 2000 L/ha and a reduction in the rate for fruit fly to 75 mL/100 L

## Environmental risks arising from run-off from treated areas

Submission 10 from HOIG included the request that the run-off risk should consider the lower rate per hectares that would result from the fruit fly use rate of 75mL/100L and the proposed maximum water volume per hectare of 1500 L/ha. This results in an application of 0.62 kg of active ingredient fenthion per hectare.

HOIG also requested consideration of the likely maximum daily rainfall events in summer in the Perth Hills region and stated that, in regards to a 100mm rainfall event in the Perth Hills, "an event of this dimension would be rare but almost exclusively restricted to the winter months". There was no data or information presented to substantiate this statement.

The APVMA has considered the lower application rate proposed in the submission that results from 75mL of product per 100L being applied at a rate of 1500L/ha, (0.62 kg of the active ingredient per hectare). This assessment included mitigation for soil adsorption, heterogeneity of the field, interception of fenthion by the foliage and dilution of the run-off into a body of water.

### Table E3 Risk quotients from run-off after mitigation for environmental receiving waters

| | Proposed rate of 0.62kg ac/ha 75ml product/100L and 1500 L/ha | Previously assessed rate of 1.57 kg ac/ha 95 ml product/100L and 3000 L/ha |
|---|---|---|
| PEC (µg/L) | 0.74 | 1.9 |
| $Q_{DM}$ | 0.14 | 0.36 |
| $Q_{PS}$ | 6.7 | 17 |

Key: PEC = predicted Environmental concentration. Dark shading is Q > 0.5; light shading = 0.1≤Q≤0.5; $Q_{DM}$ = risk quotient for *Daphnia magna*; $Q_{PS}$ = risk quotient for pink shrimp (*Penaeus duorarum*).

These risk quotients are not acceptable.

Considering that the aquatic risks arising from spray drift are also assessed as being unacceptable the APVMA has not refined this run-off risk assessment further.

# APPENDIX F: POST-HARVEST USES SUBMISSIONS 11 AND 15: DIP OR FLOOD SPRAY WASTE DISPOSAL RISKS

In submission 11 the Australian Mango Industry Association (AMIA) stated that the likely volumes of spent dips had been overestimated in the report as there was no longer a requirement for compulsory dipping of fruit prior to transport to Victoria. They estimated that there would be less than a few thousand litres per week over the three to four- week harvest season for one orchard. They requested consideration of in-field disposal with restraints on frequency and volume, rather than requiring a dedicated, bunded land area.

In submission 15 the Queensland Department of Agriculture, Fisheries and Forestry (QDAFF) questioned whether land-based disposal was practical for larger enterprises and adequate to control run-off risks in high rainfall areas. Preliminary advice to QDAFF indicated that up to 40,000L of waste could be generated by the larger packing enterprises within one season, which would require up to 2 ha of suitable, flat, land per enterprise.

There was no additional data submitted to be assessed and there is conflicting advice about the amounts of dip or flood spray waste that is likely to require disposal.

For dip disposal in general, current standards for land based disposal are described on the APVMA website http://apvma.gov.au/node/906

These require that:

- the half-life of the active in soil is less than 10 days at the likely concentrations following dip disposal, AND / OR
- the active constituent(s) should be able to be denatured safely, quickly and completely (more than 98 per cent in two hours) prior to disposal
- if repeat applications are to be made to the same site and denaturing is not possible, these should not occur until four half-lives have passed
- the spent dip should be evenly spread over flat land at a rate not exceeding 100 000 litres per hectare for spent sheep dips and 20 000 litres per hectare for spent fruit dips
- the disposal site must be dedicated and adequately bunded (the soil should at least be 15 centimetres high).

These requirements assume that the waste is not sprayed out on to the area in a manner that would create spray drift and that users are able to select and maintain a suitable area of land with adequate bunding (ridge or wall around the area) to prevent run-off. If users cannot meet these requirements then land-based disposal should not occur.

# 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 Codes | 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 hours 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 instructions 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 |