



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



AZINPHOS-METHYL REVIEW REGULATORY DECISIONS REPORT

The reconsideration of the approvals of the active constituent azinphos-methyl, registration of products containing azinphos-methyl and their associated labels

MARCH 2015

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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 credible 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 includes a call for data from a variety of sources, a review of that data 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 (OCS) 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.

This document, *Azinphos-methyl Review – Regulatory Decisions Report: The reconsideration of the approvals of the active constituent azinphos-methyl, registration of products containing azinphos-methyl and their associated labels*, sets out the regulatory decisions in relation to the APVMA's reconsideration of azinphos-methyl active constituent and products. These decisions are based on the review findings outlined in the *Azinphos-methyl Review Findings Report* published in July 2011. This document, the review findings report and all the technical reports relating to the azinphos-methyl reconsideration are available on the [APVMA website](#).

ACRONYMS AND ABBREVIATIONS

| | |
|--------------|---|
| ADI | Acceptable Daily Intake |
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| ARfD | Acute Reference Dose |
| bw | bodyweight |
| CDPR | California Department of Pesticide Regulation |
| cm | centimetre |
| EU | European Union |
| FAISD | <i>Handbook of first aid instructions, safety directions and warning statements for agricultural and veterinary chemicals</i> |
| GAP | good agricultural practice |
| IPM | integrated pest management |
| kg | kilogram |
| L | litre |
| m | metre |
| mg | milligram |
| mg/kg bw/day | milligrams per kilogram per bodyweight per day |
| MRL | maximum residue limit |
| NRS | National Residue Survey |
| OCS | Office of Chemical Safety |
| OHS | occupational health and safety |
| PMRA | Pest Management Regulatory Agency (of Health Canada) |
| PRF | Preliminary Review Findings |
| SC | suspension concentrate |
| USA | United States of America |
| US EPA | United States Environmental Protection Agency |

EXECUTIVE SUMMARY

Azinphos-methyl is a broad-spectrum, non-systemic insecticide that has been registered for use in Australia for over 40 years. It is used on fruit and nut crops primarily to control codling moth and light brown apple moth. It kills insects by interfering with the activity the enzyme, acetylcholinesterase, in the nervous system.

The active constituent azinphos-methyl, products containing azinphos-methyl and associated labels were placed under review in 1995 because of concerns about its toxicity and associated risks to public health, occupational health and safety (OHS), the environment, residues and trade.

After assessing all the available data, the Australian Pesticides and Veterinary Medicines Authority (APVMA) published the Preliminary Review Findings report (PRF) for public consultation in 2006. After considering submissions, the APVMA published the *Azinphos-methyl Review Findings Report: The reconsideration of the approvals of the active constituent azinphos-methyl, registration of products containing azinphos-methyl and their associated labels* in July 2011. At that time the APVMA did not finalise the review because of the regulatory decision to withdraw azinphos-methyl by pesticide regulators in other countries (USA, Canada, New Zealand and Europe) and the possible implications for the Australian review. However, to mitigate the public health, OHS and trade risks identified in the review findings report, the APVMA facilitated label amendments to bring them in line with the review findings.

The APVMA in collaboration with the Office of Chemical Safety (OCS) and the Department of the Environment has now reviewed the basis of the regulatory decisions made by these jurisdictions. It is concluded that the regulatory reports prepared in relation to these overseas regulatory decisions contain no new information that would warrant a revision of the APVMA's Review Findings Report published in July 2011.

The Review Findings Report published in July 2011 did not recommend any changes to the current pome fruit maximum residue limit (MRL) of 2 mg/kg. However, if residues in apples were at the MRL of 2 mg/kg this would result in an unacceptable acute dietary risk for children (147% of the acute reference dose). Data evaluated in the APVMA residues report indicated that this MRL can be reduced without the likelihood of it being exceeded. Accordingly, the APVMA has revised the MRL for azinphos-methyl on pome fruit from 2 mg/kg to 1 mg/kg. As the MRL is reduced from the previous value, the dietary intake of azinphos-methyl residues in food would not exceed the acute reference dose (ARfD) or acceptable daily intake (ADI) when good agricultural practice (GAP) is followed. All other MRLs specified in the 2011 review report remain appropriate.

Safety directions recommended in the 2011 review report have been amended by the OCS to be consistent with current standards. Further, the OCS recommended the addition of a new restraint statement to the label instructions to prohibit the use of azinphos-methyl by hand-held spray equipment.

In addition, the old labels do not contain safety directions for mixing and loading the product. Safety directions for mixing and loading the product need to be added to the safety directions on the label.

The APVMA has varied the most recently approved product labels to incorporate the amended safety directions and to add the restraint statement on hand-held application.

By carrying out the above regulatory actions, the APVMA is satisfied that continued use of azinphos-methyl products, when used in accordance with the label instructions, does not pose an undue risk to human health

and the environment, and does not jeopardise Australia's international trade. Accordingly, the APVMA has affirmed azinphos-methyl active constituent approval and product registrations bearing the varied label.

1 INTRODUCTION

Azinphos-methyl is an organophosphorus compound (OP) that is used as an insecticide, acaricide and molluscicide. It kills insects by interfering with the activity of the enzyme, acetylcholinesterase, present in the insect nervous system. Azinphos-methyl is applied on fruit and nut crops using mechanised sprayers, primarily for the control of codling moth and light brown apple moth.

Azinphos-methyl was nominated for review in 1994 due to concerns about its toxicity, and potential risks to the public and OHS, and the environment. There were related concerns about residues and possible impacts on Australian trade. The active constituent, product registrations and associated label approvals were all placed under review in 1995.

After assessing all the available data, the APVMA prepared the Azinphos-methyl [Preliminary Review Findings \(PRF\) Report](#) and released it for public consultation in 2006. The key findings were:

- azinphos-methyl residues in apricots exceed the ARfD thereby posing an unacceptable dietary risk to consumers; therefore use on apricots should not be allowed;
- there is insufficient data to set an MRL for azinphos-methyl on kiwifruit; the use on kiwifruit should not be allowed.
- application of azinphos-methyl by hand-held spray equipment is likely to present an unacceptable risk to workers.
- more than two applications of azinphos methyl per season pose a risk to the environment; a ceiling of two applications per season needs to be imposed;
- aerial application of azinphos-methyl is not supported as it presents an unacceptable risk to the environment;
- use of azinphos-methyl on citrus poses an unacceptable environmental risk; the use on citrus should not be allowed; and
- downwind no-spray zones need to be imposed to protect aquatic organisms.

To minimise the risks from the use of azinphos-methyl, the APVMA proposed to implement regulatory measures to address the above findings, including appropriate warning statements and safety directions on product labels.

During the period of public consultation, several submissions were received regarding the deletion of the use of azinphos-methyl on apricots, the need for a downwind no-spray zone and the proposed limitation of two sprays per season.

The APVMA and its advisory agencies, OCS and the Department of the Environment revised the preliminary review findings, using the new information provided in the submissions.

The revised assessments indicated that

- the continued use of azinphos-methyl on apricots can be supported;
- use on kiwifruit and citrus cannot be supported;

- aerial application and application using hand-held equipment cannot be supported;
- downwind no-spray zones and a 28-day interval between sprays need to be imposed; and
- restraint statements were needed to further minimize potential aquatic, environmental and bee exposure to azinphos-methyl.

The APVMA published the [Azinphos-methyl Review Findings Report](#) in July 2011 which outlined these revisions.

In response to these findings, the registrants have voluntarily amended product labels in line with the review findings.

Although the APVMA published the Review Findings (RF) Report, it did not finalise the review because of the impending removal of azinphos-methyl from use by pesticide regulators in other countries (USA, Canada, Europe and New Zealand) and the possible implications for the Australian review. The APVMA undertook to examine the basis of these removals to determine whether there was any relevant information that would warrant revision of the APVMA review findings. However, to mitigate the previously identified public health, OHS and trade risks, the APVMA facilitated label amendments to bring them in line with the review findings.

Accordingly and subsequent to the publication of the RF Report, the APVMA sought advice from the OCS, the Department of the Environment, and the APVMA's Pesticides Residues Section on whether the overseas regulatory reports contained any new information that might be relevant for the continued registration and approval of azinphos-methyl in Australia.

2 CONSIDERATION OF OVERSEAS REGULATORY REPORTS

2.1 Human Health Assessments

The OCS examined the regulatory reports from the European Union (EU), New Zealand, United States Environmental Protection Agency (US EPA), the Canadian Pest Management Regulatory Agency (PMRA) and the California Department of Pesticide Regulation (CDPR). It also examined any peer reviewed scientific papers published since 2005. The reports from the Canadian PMRA relied heavily on the reports from the US EPA. Only brief summary reports were available for the EU and New Zealand.

The OCS's advice to the APVMA regarding the overseas reports is as follows:

1. Overseas regulatory agencies have deregistered, or are phasing out the use of azinphos methyl due to environmental and OHS concerns.
2. OCS used human data to establish the Australian dietary health standards (ARfD and ADI) and occupational exposure limit for azinphos-methyl whereas the US EPA and PMRA used laboratory animal data. The use of human data typically reduces the magnitude of the safety factor (usually by a factor of 10) applied to the pivotal No-Observed-Adverse-Effect-Level (NOAEL) resulting in a more refined health standard than those based on animal data. Consequently, the Australian risk assessment of azinphos-methyl (based on a comparison of Australian-specific dietary or occupational exposures with the more refined health standards) gave rise to a much lower risk estimate than that calculated by the US EPA or PMRA.
3. The conclusions regarding risk to workers, outlined in the OCS's Supplementary OHS Assessment Report of 2005 remain unchanged. The OCS recommends that the APVMA accept those conclusions¹.

It is not uncommon for regulators to use different studies to set health standards. Toxicity studies and other studies used in azinphos-methyl risk assessments have been conducted over more than five decades and submitted to various regulatory agencies internationally at different times. Consequently, the international pesticide regulatory authorities differ in their choice of studies to set regulatory values based on the date of reconsideration, the availability of studies at that time and, the underpinning regulatory policy regarding acceptability of the studies. Despite the differences in the risk assessments, these different regulators agree that an analysis of the developmental and reproductive toxicity studies reveals no concerns for these endpoints and no evidence of increased pre- or post-natal sensitivity to azinphos-methyl. Additionally the regulators also agree that the weight-of-evidence indicates that azinphos methyl is not likely to be a human carcinogen.

The above advice from the OCS does not warrant any revisions to the APVMA's RF Report of 2011. The APVMA RF Report reflects the conclusions outlined in the Supplementary OHS Assessment Report of 2005, and hence no revisions are necessary to the APVMA RF Report of 2011.

¹ The key conclusions of the OCS report stated "... azinphos-methyl products may be prepared and applied by orchard airblast without causing unacceptable levels of worker exposure, provided that appropriate engineering control and/or personal protective equipment are used", and "... post-application activities including harvesting can be performed manually without incurring unacceptable levels of worker exposure."

2.2 Environmental Risk Assessments

The Department of the Environment examined the regulatory reports from the EU, US EPA, and the Canadian PMRA. In some cases only summaries, rather than full reports were available. The Department of the Environment's advice to the APVMA regarding the overseas reports is as follows:

1. In so far as the environmental risks are concerned, the removal or severe restrictions of the use of azinphos-methyl by the overseas regulators was based on concerns about the adverse effects of spray drift on aquatic organisms; the overseas authorities considered that impracticably large no-spray zones need to be imposed to protect aquatic zones.
2. Overseas assessments offer no new information pertinent to the aquatic risk assessment carried out by the Department of the Environment.
3. While there is additional information in the EU report in regard to terrestrial invertebrates, it has no bearing on the overall outcome of the risk assessment carried out by the Department of the Environment

The above advice does not warrant any revisions to the APVMA's RF report as discussed below.

While overseas authorities, for example the EU, considered that even 50 or 100 metre no-spray zones to be impracticable and therefore restricted or removed the use of the chemical, the APVMA, instead of removing the use of the chemical, imposed a 200 metre down-wind no-spray zone for Macadamia orchards, and 100 metre down-wind no-spray zones for all other crops, to protect aquatic organisms.

The EU was also concerned about the potential toxicity of azinphos-methyl to earthworms, bees and non-target invertebrates. While there is additional information in the EU report in regard to terrestrial invertebrates, it has no bearing on the overall outcome of the risk assessment carried out by the Department of the Environment. The RF report noted the hazard to bees and other non-target beneficial insects and proposed that an appropriate warning statement be included on product labels; a specific hazard statement has been added to the label instructions.

The Department of Environment's spray drift assessment for the review had been carried out prior to the finalisation of the APVMA's policy on spray drift assessment. Similarly, the assessment of run-off was undertaken prior to the development of a consistent, tiered approach to modelling run off. While the Department of the Environment recommended that the risks associated with spray drift and run-off need to be reassessed, it is not possible to do this while both methodologies are still under development. Rather than leaving the current review open until an unknown future date when validated methodologies are endorsed, the APVMA has determined that current mitigation measures are adequate to manage the identified risks arising from spray drift and run-off based on the currently available assessment methods. This conclusion is based on the following considerations:

- To minimise any risk arising from spray drift, the APVMA has imposed downwind no-spray zones of up to 200 metres.
- Information from overseas indicates that there is potential for azinphos-methyl contamination of aquatic bodies to occur from run-off from treated areas; however the Department of the Environment's advice is that there is little evidence of this occurring in Australia.

-
- The use of azinphos-methyl at high application rates on citrus was previously considered to pose a high risk to aquatic invertebrates. However, the use of azinphos-methyl on citrus is no longer allowed in Australia.
 - According to the ecological incident database of the US EPA, aquatic incidents associated with azinphos-methyl were mainly associated with use on sugarcane and cotton crops, in areas where intense and frequent rainfall favoured run-off into nearby water. Azinphos-methyl is not registered for use in cotton or sugarcane production in Australia.
 - One of the reasons suggested for the occurrence of run-off included the use of aerial application in field crops (hence a greater risk of spray drift). In Australia, aerial application of azinphos-methyl is not allowed.
 - In Australia, the use of azinphos-methyl is prohibited if heavy rain or storms are forecast with greater than 50% probability within 48 hours after application. Users are required to allow at least 28 days between consecutive applications of azinphos-methyl. This reduces the frequency of use and therefore minimises the probability of run-off occurring. Further, these restrictions, coupled with the need to observe the 100 or 200 metre downwind no-spray zones reduce the risk of contamination of aquatic bodies from surface run-off.
 - Most orchardists in Australia manage the inter-row area and limit erosion by such strategies as maintaining grass between rows, inter-row mulching and contour plantings. These factors reduce the risk of run-off occurring. In addition, the current use pattern in many situations reduces the frequency of use and therefore minimises the probability of run-off occurring.

3 MINOR AMENDMENTS TO MRL STANDARDS AND SAFETY DIRECTIONS

3.1 MRL for pome fruit

The RF Report published in July 2011 did not recommend any changes to the pome fruit MRL of 2 mg/kg. However if residues in apples were at the MRL of 2 mg/kg this would result in an unacceptable acute dietary risk for children (147% of the ARfD).

In the pome fruit residue trials considered in the RF Report, residues tested at day 14 were 0.11, 0.11, 0.15, 0.17, 0.18, 0.27, 0.29, 0.29, 0.8 and 1.1 mg/kg. The highest residue of 1.1 mg/kg was measured in a trial which involved 5 - 6 applications at 1 - 2 times the label concentration. The re-treatment interval was 12 – 14 days, which is different to the recommendations of the Review Findings Report, which restricted the application interval to at least 28 days. The next highest residue of 0.8 mg/kg was measured in a trial which involved 13 applications at the label rate and a 14 day retreatment interval.

Data from state-based monitoring programs considered as part of the review indicated that for 349 samples of apples and pears from NSW and Victoria (from 1987 – 2002) there were 99 detections of azinphos-methyl all of which were less than half of the MRL of 2 mg/kg. Data from the National Residue Survey (NRS) summarised in the initial evaluation indicates that for 385 samples of apples and pears tested from 1999 – 2000 there were 60 detections of azinphos-methyl all of which were less than half of the MRL (58 were less than 20% of the MRL). Other monitoring data considered as part of the review did not specify the level of detections (only that they were below the MRL). In NRS data published for 2010 – 2011 there were no detections of azinphos-methyl at or above 1 mg/kg in 420 samples of apples and 150 samples of pears. Similarly for 2011-12, there were no detections of azinphos-methyl at or above 1 mg/kg in 346 samples of apples and 142 samples of pears.

It is considered that the highest residue of 1.1 mg/kg in the residue trials considered in the review report can be discounted due to the high application concentration and the short re-treatment interval. The residue trials data and the available monitoring data indicate that the MRL for azinphos-methyl on pome fruit could be reduced to 1 mg/kg without any expected MRL exceedance.

Accordingly, the APVMA has revised the maximum residue limit (MRL) for azinphos-methyl on pome fruit from 2 to 1 mg/kg. As the MRL is reduced from the previous level, the dietary intake of azinphos-methyl from food residue would not exceed the ARfD or ADI.

All the other MRL standards outlined in the review report published in July 2011 remain appropriate.

3.2 Safety Directions

Although the safety directions outlined in the RF report published in July 2011 provided the requisite hazard, precautions and use statements, they do not fully conform to the current FAISD Handbook standard statements and codes.

Therefore the OCS has amended the safety directions to align them with contemporary standards. The amended safety directions are below.

| Safety Directions | Statement Codes |
|--|--|
| <p>HAZARDS</p> <p>Poisonous if absorbed by skin contact or inhaled or swallowed.</p> <p>Will irritate the eyes and skin.</p> <p>May irritate the nose and throat.</p> <p>Repeated exposure may cause allergic disorders.</p> <p>Repeated minor exposure may have a cumulative poisoning effect.</p> | <p>130 131 132 133</p> <p>161 211</p> <p>160 163</p> <p>180</p> <p>190</p> |
| <p>PRECAUTIONS</p> <p>Avoid contact with eyes and skin.</p> <p>Do not inhale vapour or spray mist.</p> | <p>210 211 212</p> <p>220 222 223</p> |
| <p>MIXING OR USING</p> <p>When opening the container, and preparing spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and protective waterproof clothing and elbow-length PVC gloves and water resistant footwear and face shield or goggles.</p> <p>When using the prepared spray by open cab wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and protective waterproof clothing including a hood or waterproof hat and elbow length PVC gloves and water resistant footwear and half face piece respirator with combined dust and gas cartridge.</p> | <p>279 280 281 290 292b 291 294 298b 299</p> <p>279 282 420 (open cab) 290 292b 291c* 294 298b 300 303</p> |

| Safety Directions | Statement Codes |
|--|--|
| <p>MIXING OR USING</p> <p>When using the prepared spray by closed cab fitted with charcoal filters wear cotton overalls buttoned to the neck and wrist (or equivalent clothing).</p> <p>If clothing becomes contaminated with product or wet with spray remove clothing immediately.</p> <p>If product on skin, immediately wash area with soap and water.</p> <p>If product in eyes, wash it out immediately with water.</p> | <p>279 282 420 (closed cab fitted with charcoal filters) 290 292b</p> <p>330 331 332</p> <p>340 342</p> <p>340 343</p> |
| <p>AFTER USE</p> <p>After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.</p> <p>After each day's use wash gloves and respirator and if rubber wash with detergent and warm water and face shield or goggles and contaminated clothing.</p> | <p>350</p> <p>360 361 364 365 366</p> |

* A new entry to be added to the FAISD Handbook; will appear in the quarterly FAISD update following the finalisation of the review.

The OCS also recommended adding the following restraint statement to the label instructions to prohibit the use of azinphos-methyl by hand-held spray equipment. The APVMA has accepted this recommendation.

Restraint

DO NOT apply using handheld spraying equipment.

4 ACTIVE CONSTITUENT AND PRODUCTS

The active constituent approvals and product registrations current as at 6 February 2015 are shown in Tables A1 and A2 below. Active constituent approvals and product registrations which lapsed during the course of the review are shown in Table A3.

Table A1: Active constituents included in the review

| APPROVAL NUMBER | ACTIVE CONSTITUENT NAME | APPROVAL HOLDER |
|-----------------|-------------------------|-----------------------------|
| 44188 | Azinphos-methyl | Adama Australia Pty Limited |

Table A2: Products included in the review

| PRODUCT NUMBER | PRODUCT NAME | REGISTRANT | LABEL APPROVALS ASSOCIATED WITH THE PRODUCT |
|----------------|--|------------------------------------|---|
| 53215 | Campbell Benthion 200 Flowable Insecticide | Colin Campbell (Chemicals) Pty Ltd | 53215/0511 |
| 62221 | Farmoz Gusathion 200 SC Insecticide | Adama Australia Pty Limited | 62221/0511 |

Table A3: Products and active constituents that were included at the commencement of the review, but are no longer registered or approved

ACTIVE CONSTITUENTS

| APPROVAL NUMBER | ACTIVE CONSTITUENT NAME | APPROVAL HOLDER |
|-----------------|-------------------------|---------------------------|
| 44081 | Azinphos-methyl | Bayer CropScience Pty Ltd |

PRODUCTS

| PRODUCT NUMBER | PRODUCT NAME | REGISTRANT |
|----------------|--|-------------------------------------|
| 39216 | Campbell Benthion 350 Flowable Insecticide | Colin Campbell (Chemicals) Pty Ltd |
| 39427 | Cotnion 350 FL Insecticide | Makhteshim Agan (Australia) Pty Ltd |
| 45727 | Gusathion 200 SC Insecticide | Bayer CropScience Pty Ltd |

In 2011, the APVMA worked with the registrants and facilitated amendments to the labels of the current azinphos-methyl products to bring them in line with the recommendations made in the APVMA review

findings report of July 2011. Thus, the labels with label approval numbers 53215/0511 and 62221/0511 conform to the review findings. However, they do not contain appropriate safety directions including those for mixing and loading, and the restraint outlined in Section 3.2 above.

5 REGULATORY DECISIONS AND ACTIONS

Based on the review findings as described in the review findings report of July 2011, the APVMA has made the following regulatory decisions and implemented regulatory actions to give effect to those decisions.

1. In accordance with s.34(1)(a) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) the APVMA is satisfied that the continued use of, or any dealing with, the active constituent (APVMA No. 44188) in accordance with the instructions for its use or for such a dealing that the APVMA has approved:
 - a. 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
 - b. would not be likely to have an effect that is harmful to human beings; and
 - c. would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
 - d. would not unduly prejudice trade or commerce between Australia and places outside Australia
2. The APVMA is not satisfied that product labels contain adequate instructions in relation to the criteria set out in s.14(3)(d) and s.14(3)(g) of the Agvet Codes as well as those referred to in regulations 11 and 12 of the Agvet Code Regulations. However, in accordance with s.34(5) of the Agvet Codes the APVMA is satisfied that the relevant label particulars can be varied in such a way that the requirements prescribed by the regulations for continued approval or registration will be met.

Accordingly, under s.34(5)(a)(ii) of the Agvet Codes, the APVMA proposes to vary the relevant particulars of the approvals of the product labels 5321/0511 and 6222/0511. Specifically, the APVMA will update the safety directions and add the restraint outlined in Section 3.2 above. Each of the varied labels will be given a new approval number as shown below:

| LABEL APPROVAL NUMBER BEFORE VARIATION | LABEL APPROVAL NUMBER AFTER VARIATION |
|---|--|
| 53215/0511 | 53215/0315 |
| 62221/0511 | 62221/0315 |

3. Following the label variation, the APVMA would be satisfied, under s.34(1)(a) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code), that the continued use of, or any dealing with, the products Campbell Benthion 200 Flowable Insecticide (APVMA No. 53215) and Farnoz Gusathion 200 SC Insecticide (APVMA No. 62221) in accordance with the instructions for their use or for such a dealing that the APVMA has approved:
 - a. 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
 - b. would not be likely to have an effect that is harmful to human beings; and

- c. would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
 - d. would not unduly prejudice trade or commerce between Australia and places outside Australia
- 4. The APVMA then, under s.34(1)(a) of the Agvet Codes, proposes to affirm the approval of the active constituent (APVMA No. 44188) and the registrations of the products Campbell Benthion 200 Flowable Insecticide (APVMA No. 53215) and Farnoz Gusathion 200 SC Insecticide (APVMA No. 62221) with the varied label approvals.