Australian Pesticides &
Veterinary Medicines Authority

The reconsideration of approvals of the active constituent fenitrothion, registrations of products containing fenitrothion and their associated labels.

DRAFT REVIEW REPORT

March 2004

Australian Pesticides &
Veterinary Medicines Authority

Canberra
Australia

This review report for fenitrothion is published by the Australian Pesticides and Veterinary Medicines Authority. For further information about this review or the Pesticides Review Program, contact:

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FOREWORD

The 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 Code scheduled to the *Agricultural and Veterinary Chemicals Code Act, 1994*.

The APVMA can reconsider the approval of an active constituent, the registration of a chemical product, or the approval of a label for a container for a chemical product, at any time. This is outlined in Part 2, Division 4 of the Agvet Code.

The basis for the reconsideration is whether the APVMA is satisfied that continued use of the active constituent fenitrothion and products containing fenitrothion in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely 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 requirements for continued approval of a label for containers for a chemical product are that the label contains adequate instructions. Such instructions include:

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

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

The process for reconsideration 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.

In undertaking reviews, the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety (OCS), the Department of Environment and Heritage (DEH), the National Occupational Health and Safety Commission (NOHSC), and State Departments of Agriculture as well as other expert advisors, as appropriate.

The APVMA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of review reports is a part of that process.

The APVMA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements. Under this program it is proposed that countries receiving these reports will not utilise them for registration purposes unless they are also provided with the raw data from the relevant applicant.

* Prior to March 2003, the APVMA was known as the National Registration Authority for Agricultural and Veterinary Chemicals (NRA). In this report, the name APVMA is generally used even when referring to the organisation prior to March 2003.

This document *'The reconsideration of approvals of the active constituent fenitrothion, registrations of products containing fenitrothion and their associated labels'* relates to all fenitrothion active constituents, and products containing fenitrothion and their labels, that have been nominated for review by the APVMA. The review's findings and recommendations are based on information collected from a variety of sources. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

The draft review report containing the APVMA's preliminary assessments and the technical reports from its advisory agencies for all registrations and approvals relating to fenitrothion are available from the APVMA website: http://www.apvma.gov.au/chemrev/chemrev.html.

COMMENT FROM THE PUBLIC IS INVITED

The APVMA invites persons and organisations to submit their comments and suggestions on this draft review report directly to the APVMA. Your comments will assist the APVMA in preparing the final report.

The draft review report outlines the APVMA review process, gives information to the public about how to respond to the review, summarises the technical assessments from the reviewing agencies and outlines the proposed regulatory action to be taken in relation to the continued registration of fenitrothion products. Also included are the full technical assessment reports from the National Occupational Health and Safety Commission and the Chemistry and Residues Program at the APVMA.

PREPARING YOUR COMMENTS FOR SUBMISSION

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

When making your comments:

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

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

Finally please tell us whether the APVMA can quote your comments in part or in full.

*THE CLOSING DATE FOR SUBMISSIONS IS **28 MAY 2004***

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ACRONYMS AND ABBREVIATIONS

ac	active constituent
ACVM	New Zealand Agricultural Compounds & Veterinary Medicines Group
ADI	Acceptable Daily Intake
ai	active ingredient
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
ChE	Cholinesterase
Codex	FAO/WHO Codex Alimentarius Commission
DEH	Department of Environment and Heritage (previously Environment Australia)
EA	Environment Australia
EC	Emulsifiable Concentrate
GAP	Good Agricultural Practice
GC-MS	Gas Chromatography-Mass Spectrometry
HPLC	High Performance Liquid Chromatography
IGR	Insect Growth Regulator
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC_{50}	The concentration at which 50% of a test population dies
LOD	Limit of Detection
LOQ	Limit of analytical Quantitation, also referred to as limit of determination
LOR	Limit of Reporting
M/L/A	Mixer/loader/applicator
MOE	Margin of Exposure
MRL	Maximum Residue Limit
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short-Term Intake
NHMRC	National Health and Medical Research Council
NOEL	No Observed Effect Level
NOHSC	National Occupational Health and Safety Commission
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
OCS	Office of Chemical Safety
OECD	Organisation for Economic Cooperation and Development
OHS	Occupational Health and Safety
PACSC	Pesticide and Agricultural Chemical Standing Committee
PHED	Pesticide Handlers Exposure Database
PMRA	Canadian Pest Management Regulatory Agency
POEM	Predictive Operator Exposure Model
PPE	Personal Protective Equipment
RBC	Red Blood Cell
TC	Transfer Coefficient
TMRL	Temporary MRL
ULV	Ultra Low Volume
WHP	Withholding Period

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EXECUTIVE SUMMARY

Fenitrothion is a broad spectrum, non-systemic organophosphate insecticide that is used for the control of insect pests such as grasshoppers, locusts, weevils, beetles, moths, mealworms, corbies and grubs. It is used on rice, cereals, lucerne, pastures, fruits, vegetables, stored grain, and on structures such as flour mills and poultry houses. Like other organophosphate pesticides, fenitrothion acts by inhibiting the activity of the enzyme acetylcholinesterase, which is important in the conduction of impulses to nerves and muscles. There is currently one active constituent approval and eight registered fenitrothion products (refer Appendices 1, 2 and 3).

Fenitrothion active constituent approvals, product registrations and label approvals were placed under review in 1996 due to potential worker and environmental exposure concerns and human health effects.

In 1999, the APVMA released an interim report that outlined key findings from the review. Considerable additional data (environmental, occupational health and safety, and residue data) were required to address the concerns identified in the interim report. These data were essential to address concerns including the potential risk that use of fenitrothion poses to non-target organisms, particularly associated with residues in runoff water from treated pasture, and the effects of high rates of application on birds and aquatic invertebrates. Concerns also included the health effects on workers for ground and hand-held application in all circumstances including (but not limited to) poultry housing, treatment of hides and skins, and post application insect checking. Finally, processing data were required to assess residues in rice, as were Australian data for grass-like situations and other forage crops for non-locust pests.

Previous Reconsideration Action

As an interim measure, pending submission and assessment of the additional data (due September 2002), new conditions for the use of fenitrothion were put into place. These conditions reduced chemical handling by workers and drift and runoff into water bodies. Such conditions included:

- The use of risk mitigation measures, including use of enclosed cabs, to protect manual flaggers in aerial spraying operations;
- Buffer zones around water bodies for control of locusts and grasshoppers in broadacre crops, sitona weevil in lucerne crops, and the control of black headed pasture cockchafer, corbie and winter corbie in pastures;
- Limitations on the quantity of fenitrothion applied in certain situations, such as for control of locusts and grasshoppers;
- Limitations on the number of applications per year for pastures;
- Deletion of instructions for use for control of grasshopper and white fly in tobacco from approved labels;
- Use limited to the control of locusts/grasshoppers only in vines, apple, cabbages, cherries, grapes, lettuce, soybeans and tomato crops;
- Amendments to withholding periods for harvest and grazing; and
- As related actions, amendments to maximum residue limits (MRLs).

Since the release of the interim report, additional data have been presented for assessment of residues in rice bran. However, data necessary for the APVMA to assess the remaining concerns have not been provided. Below are summaries of the findings of the residue assessment together with comments on the OH&S aspects associated with fenitrothion, based on surrogate data. The full assessment reports can be found in Sections 8 and 9, respectively.

Residues Assessment

A concern identified in the interim report was application of fenitrothion to cereal crops, particularly residue levels on treated forage and hay and subsequent use for animal feed. Based on additional submitted data, the sorghum, cereal straw and fodder grazing withholding period of 14 days is considered adequate with respect to fenitrothion use for locust control and is to be affirmed.

No Australian data is available to assess potential residues in horticultural crops, and thus the APVMA cannot be satisfied that use on horticultural crops would not be likely to have an effect that is harmful to human beings. Thus, instructions for use on apples, cabbages, cherries, grapes, lettuce, soybeans and tomatoes for grasshopper/locust control are to be deleted from labels.

Several fenitrothion products are currently used on pastures for the control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub. As a related outcome of the interim report, Australian data were required for lucerne, other grass-like pasture situations and other forage crops (e.g. sorghum) where non-locust pests are to be controlled. Since 1999, no Australian data for pasture situations has been submitted. These data are necessary to assess residues in animal commodities and thus estimate risks to human health. Therefore, because of unacceptable potential risks to human beings, uses on pastures for the control of pasture pests are to be deleted from labels.

Labels will be amended to reflect those specific forage crops for locust/grasshopper for which the data satisfy the criteria for continued registration, i.e., cereal crops and lucerne. Therefore, the term "forage crops" will be deleted from labels and instructions for locust/grasshopper control on broadacre crops will only include pastures, pasture seed crops, lucerne and cereal crops.

Occupational Health and Safety Assessment

The interim report determined that grain treatments could remain on labels, as generally closed mixing loading systems are used and operators do not usually enter the silo during mechanised application to the grain. Therefore, worker exposure is minimised. However, worker exposure data were requested for certain uses where data were either insufficient to conduct a risk assessment, or because acceptable margins of exposure could not be determined using the UK Predictive Operator Exposure Model (UK POEM).

Although no additional OH&S data were provided, the APLC requested the APVMA to consider the use of surrogate data (endosulfan worker exposure data). The end use worker exposure studies on endosulfan were considered suitable surrogate data to estimate exposure for workers using the EC formulation and ground application equipment.

Based on this risk assessment, it is concluded that the continued use of fenitrothion by ground boom and hand held applications poses unacceptable risks to workers. Therefore, these application methods, for both EC and ULV formulations, are to be deleted from labels. These label changes will remove ground application methods for: broadacre crops such as pastures, pasture seed crops, lucerne and cereal crops (to control locusts and grasshoppers); lucerne (to control sitona weevil); pastures (to control pasture pests); horticultural crops (to control locusts and grasshoppers); and use as a treatment for surfaces, structures and sheds (to control pests such as mealworms and beetles).

The available information indicates that the EC formulation is not generally applied by air. Since no data for aerial emulsifiable concentrate (EC) application were provided, concerns relating to the safety of workers remain unresolved. Because of this risk, all aerial application methods for EC formulations are to be deleted from labels. However, data indicate that aerial use of ULV formulations does not present an undue risk to workers due to closed mixing/loading systems and the physical protection against direct contamination afforded to the applicator (pilot).

Environmental Assessment

Although requested as an interim outcome of the review, no monitoring data for runoff and spray drift have been provided for high use rates (i.e., on pastures for the control of pasture pests), despite potentially high acute risks to birds and aquatic invertebrates. Therefore, concerns relating to the safety of animals remain. Because of these unacceptable potential risks to animals, uses on pastures for the control of pasture pests are to be deleted from labels. The interim report also concluded that risk to aquatic animals remains within acceptable bounds for a buffer of 1500m upwind or more of water bodies, when using the ULV formulation by air to control locusts/grasshoppers.

Proposed Final Review Recommendations

After consideration of all data including the additional assessments, the following regulatory actions are proposed:

a) Active constituent approvals are to be affirmed.

b) The following changes to label instructions are proposed:

- Instructions for treatment of surfaces, structures and sheds are to be deleted from labels due to risks to workers.
- Instructions for use on pastures for the control of pasture pests are to be deleted from labels due to risks to workers, human health and non-target organisms from the high application rates.
- Instructions for use on horticultural crops including apples, cabbages, cherries, grapes, lettuce, soybeans and tomatoes for grasshopper/locust control are to be deleted from labels due to potential residues in food and thus risks to human health.
- Instructions for use of fenitrothion EC formulations on broadacre crops including pastures, pasture seed crops, forage crops, soybean, grazing sorghum, cereal crops and lucerne for control of grasshoppers, locusts and sitona weevil are to be deleted from labels due to risks to workers.
- Ground and hand-held application methods for ULV formulations are to be deleted from labels due to risks to workers, however, aerial uses of ULV products will remain because closed mixing/loading systems are used and there is minimal application exposure.
- The term “forage crops” is to be deleted from the label. Instead, label instructions for use of fenitrothion products for locust/grasshopper control on pastures and forage crops will only include pastures, pasture seed crops, lucerne and cereal crops. Cereal crops are defined as the CODEX commodity group and thus include grazing sorghum, oats, etc.
- Withholding period instructions on ULV labels are to be amended.
- Buffer zone, application techniques, and precaution statements on ULV labels are to be amended to be more precise.
- Instructions for use of fenitrothion products on stored grains will remain on labels.
- Old approved labels are deemed not to contain adequate instructions and are to be cancelled.
- It is recommended that these variations to label instructions would then satisfy the requirements for continued registration of products.

c) Product registrations are to be affirmed.

1. INTRODUCTION

1.1 Regulatory status of fenitrothion in Australia

Fenitrothion is a broad spectrum, non-systemic organophosphate contact insecticide. Fenitrothion is used in Australian agriculture for the control of insects such as weevils, beetles and moths in stored grain, grain storage facilities and poultry houses, for control of locusts and grasshoppers in broadacre and horticultural crops, and for control of underground insect pests in pasture. Fenitrothion is available in emulsifiable concentrate and ultra low volume formulations and can be applied by various ground-based methods such as knapsacks, ground booms and misters. It is also applied by air. There are currently eight registered fenitrothion products and one active constituent approval (refer Appendices 1, 2 and 3).

1.2 Mode of action and toxicity of fenitrothion

Like other organophosphate pesticides, fenitrothion acts by inhibiting the activity of the enzyme acetylcholinesterase, which is important in the conduction of impulses to nerves and muscles. Fenitrothion is oxidized in animals, insects and plants to derivatives that are more potent inhibitors of cholinesterase than the parent compound. In mammals, both the parent compound and its derivatives are predominantly metabolised in the liver and then mostly excreted within a 24-hour period. However, in some cases, suppression of metabolism of the compound during its repeated administration can lead to an extended persistence in the body. In addition, ultraviolet radiation-induced breakdown products can be more toxic to mice than the parent compound. The complete toxicological assessment is contained in the interim report for the review of fenitrothion (1999).

Fenitrothion is highly toxic to gamebirds and slightly toxic to waterfowl. It is considered highly toxic to honeybees and earthworms and very toxic to crustaceans and aquatic insects. It is also toxic to fish. Fenitrothion is also reported to be phytotoxic to cotton, brassica and some fruit crops at high application rates.

1.3 Reasons for the review of fenitrothion

The review of fenitrothion was announced in December 1996 as part of the APVMA's second cycle of reviews of existing chemicals. Approvals of the active constituent fenitrothion, registration of products containing fenitrothion and approvals of product labels are being reconsidered due to concerns over:

- worker exposure;
- high avian and aquatic invertebrate toxicity;
- resistance in insect pests of stored products;
- moderate potential acute toxicity risk and high potential chronic risk;
- human ocular effects, and;
- lack of maximum residue limits (MRLs) for some use patterns on approved labels.

While these issues were the primary focus of the review, and the reason for giving the review a high priority, the scope of the review also covered all aspects for continued registration and approval of fenitrothion.

1.4 Regulatory options

The basis for a reconsideration of the registration and approvals for a chemical is whether the APVMA is satisfied that the requirements prescribed by the Agvet Code for continued registration and approval are being met. In the case of fenitrothion, these requirements are that the use of the product in accordance with the instructions for its use would not be likely to have an effect that is harmful to

human beings, 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 unintended effect that is harmful to animals, plants, or things or to the environment.

There are three possible outcomes to the reconsideration of the registration of products containing fenitrothion and their labels. Based on the information reviewed the APVMA may be:

- satisfied that the products and their labels continue to meet the prescribed requirements for registration and approval and therefore confirms the registrations and approvals.
- satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration and approval will be complied with and therefore varies the conditions of registration or approval.
- not satisfied that the requirements for continued registration and approval continue to be met and suspends or cancels the registration and/or approval.

2. INTERIM REPORT RECOMMENDATIONS (1999)

The APVMA's interim report for the review of fenitrothion was released in August 1999.

2.1 Key findings of the interim review assessment

Health risks to workers could not be adequately assessed because no measured worker exposure studies were submitted for the review. Studies submitted for the review and from the scientific literature were not designed to measure fenitrothion exposure and thus could not be used to estimate exposure or margins of risk. In addition, none of the studies were relevant to the current Australian use patterns. Therefore, because the health risks to workers were potentially high, additional data were required to allow a thorough assessment of the health risks to workers.

The interim report found that risk is potentially high for both bird and aquatic species from either spray drift or run-off into aquatic areas. However, further information was needed to determine the level of impact, particularly for the high rate uses (i.e., control of pasture pests and the high rates for grasshopper/locust control). Because of a reported incident of birds dying after consuming contaminated locusts, data on bird consumption of locusts after spraying were also required.

During assessment of data for the interim report, it was also determined that fenitrothion does not interact with genetic material and long-term cancer studies in animals provided no evidence of carcinogenicity in humans. Other studies indicate that fenitrothion exposure has no adverse effects on reproduction or development of the foetus in experimental animals. There is little evidence that it causes ocular toxicity. However, there is some concern that it may cause "Intermediate syndrome", in which there is delayed onset of muscular weakness affecting breathing, neck and limbs.

Related outcomes of the review

The assessment of residues in food was largely based on overseas data. However, sufficient data were available to confirm a number of MRLs, delete others, and to set a series of temporary MRLs relating to animal feed and tissue commodities as related outcomes of the review process. The temporary MRLs were subject to the requirement that Australian confirmatory trial data be provided for assessment of risk to human health associated with residues in food. Crops requiring Australian data also included apples, cherries, cabbages, grapes, lettuce, soybeans, sugarcane, tomatoes and tree nuts.

2.2 Data requirements to be addressed following the interim review

Additional studies and information were required to address the outstanding concerns over the potential risk that use of fenitrothion poses to human health and non-target organisms (data due September 2002). These data were essential to address concerns associated with the health effects on

workers for ground and hand-held application in all circumstances including poultry housing, treatment of hides and skins, and post application insect checking. In order to assess residues in animal commodities, processing data were also required to assess residues in rice, as were Australian data for lucerne, other grass-like situations and other forage crops for non-locust pests. Lastly, data were also required to address concerns relating to the effects of high rates of application on birds directly and associated with ingestion of contaminated locusts, and on aquatic invertebrates associated with spray drift and residues in runoff water from treated pasture.

2.3 Previous reconsideration action following the interim review

As an interim measure, pending submission and assessment of the additional data, new conditions for the use of fenitrothion were put into place. These conditions reduced potential residues in food, chemical handling by workers and drift and runoff into water bodies. They included:

- The use of risk mitigation measures, including use of enclosed cabs to protect manual flaggers in aerial spraying operations;
- Buffer zones around water bodies for control of locusts and grasshoppers in broadacre crops, sitona weevil in lucerne crops and the control of black headed pasture cockchafer, corbie and winter corbie in pastures;
- Limitations on the amount of fenitrothion applied in certain situations, such as for control of locusts and grasshoppers;
- Limitations on the number of applications per year for pastures;
- Deletion of instructions for use for control of grasshopper and white fly in tobacco from approved labels;
- Use limited to the control of locusts/grasshoppers only in vines, apple, cabbages, cherries, grapes, lettuce, soya beans and tomato crops;
- Amendments to withholding periods for harvest and grazing; and
- As related actions, amendments to maximum residue limits (MRLs).

Any future consideration of the continued use of fenitrothion required the provision of specific data and successful implementation of the new use regime. Previous label approvals for fenitrothion where labels did not comply with the conditions in the interim review were cancelled (relevant to one ULV and six EC fenitrothion products).

3. SUMMARY OF ADDITIONAL DATA ASSESSMENTS

Below are summaries of the findings of the residue assessment together with comments on OH&S aspects associated with fenitrothion. The full assessment reports can be found in Sections 8 and 9 respectively.

3.1 Residues

The interim report of fenitrothion identified concerns regarding residues in rice bran that may exceed the current Australian and Codex MRL of 20 mg/kg. In order to establish an appropriate rice bran MRL, the rice industry was required to generate additional processing data. These data, provided by The Rice Growers Co-operative Limited, were adequate to calculate maximum residue levels in rice bran and in rice hulls. These data indicate that residue levels in rice bran are unlikely to exceed the current MRLs. In addition, measured residues on hulls allow a MRL of 50 mg/kg to be established as an associated outcome of this review.

Another concern identified in the interim report was application of fenitrothion to cereal crops, particularly residue levels on treated forage and hay and subsequent use for animal feed. Based on additional submitted data, the sorghum, cereal straw and fodder grazing withholding period of 14 days is considered adequate with respect to fenitrothion use for locust control and is to be affirmed.

To complete the outstanding residue aspects, fenitrothion treatment of horticultural crops for locust control were assessed, and dietary intake (acute and chronic) calculations were performed. While old overseas studies of residues on apples were provided, the studies were not considered suitable to use in estimating residues on apples in Australia. Because no Australian data is available to assess potential residues in food, the APVMA cannot be satisfied that use on certain horticultural crops would not be likely to have an effect that is harmful to human beings. Thus, instructions for use on apples, cabbages, cherries, grapes, lettuce, soybean and tomatoes for grasshopper/locust control are to be deleted from labels.

Several fenitrothion products are currently used on pastures for the control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub at 480-1300 mL/ha (610-1650 g ai/ha). As a related outcome of the interim report, Australian data were required for lucerne, other grass-like pasture situations and other forage crops (e.g. sorghum) where non-locust pests are to be controlled. Since 1999, no Australian data for pasture situations has been submitted by the registrants of fenitrothion products. These data are necessary to assess residues in animal commodities and thus estimate risks to human health. Therefore, because of unacceptable potential risks to human beings, uses on pastures for the control of pasture pests are to be deleted from labels.

Labels will be amended to reflect those specific forage crops for locust/grasshopper for which the data satisfy the criteria for continued registration, i.e., cereal crops and lucerne. Therefore, label instructions for locust/grasshopper on broadacre crops control will only include pastures, pasture seed crops, lucerne and cereal crops.

The current animal commodity MRLs are appropriate. Related changes to MRLs are included in section 5.

3.2 Occupational health and safety

The 1999 OH&S assessment utilised the UK Predictive Operator Exposure Model (UK POEM) to estimate mixer/loader/applicator exposure for workers using ground, hand-held equipment or aerial application to treat various crops and situations. The interim report determined that grain treatments will remain on labels, as closed mixing/loading systems were used and thus worker exposure is minimised. However, worker exposure data were requested for certain uses where data were either insufficient to conduct a risk assessment, or because acceptable margins of exposure could not be determined using the above model.

Although no additional OH&S data were provided, the APVMA were requested by the APLC to consider the use of surrogate data (endosulfan worker exposure data). The end use worker exposure studies on endosulfan were considered suitable surrogate data to estimate exposure for workers using the EC formulation and ground application equipment.

Based on this risk assessment, the continued use of fenitrothion by ground boom and hand held applications has been found to pose unacceptable risks to workers. To minimise such risks to workers, these application methods, for both EC and ULV formulations, are to be deleted from labels. These changes will affect ground application methods for broadacre and forage crops including lucerne (to control locusts and grasshoppers), for lucerne (to control sitona weevil), for pastures (to control pasture pests), and for horticultural crops (to control locusts and grasshoppers). In addition, because of high potential risks for worker exposure during hand held application, uses for surface, structural and shed treatments are to be deleted from labels.

The surrogate endosulfan data also allowed the establishment of a re-entry interval of 48 hours (two days) to protect workers entering treated areas after both aerial and ground application of fenitrothion products.

Available data indicate that the EC formulation is not generally applied by air. As no data for aerial emulsifiable concentrate (EC) application were provided, concerns relating to the safety of workers remain unresolved. Because of this risk, all aerial application methods for EC formulations are to be

deleted from labels. However, existing data indicates that aerial use of ULV formulations does not present an undue risk to workers due to closed mixing/loading systems and the physical protection against direct contamination afforded to the applicator (pilot).

3.3 Environmental Assessment

Although required as an interim outcome of the review, no monitoring data for runoff and spray drift have been provided for high use rates (i.e., on pastures for the control of pasture pests, where rates are generally around 700mL to 1.3L/ha), despite potentially high acute risks to birds and aquatic invertebrates. Mortality in birds has been recorded at application rates above 280 g/ha, increasing markedly at rates above 560g/ha, with cholinesterase activity inhibited at lower rates. Therefore, concerns relating to the safety of animals remain. Because of these unacceptable potential risks to animals, uses on pastures for the control of pasture pests are to be deleted from labels. The interim report also concluded that risk to aquatic animals remains within acceptable bounds for a buffer of 1500m upwind or more of water bodies, when using the ULV formulation by air to control locusts/grasshoppers.

3.4 Summary of public submissions and conclusions

There were no additional public comments after the interim report.

3.5 International regulatory status

USA: In the USA, fenitrothion is only used in ant and roach baits. Earlier registered uses on outdoor ornamentals and greenhouses were voluntarily withdrawn after the Reregistration Eligibility Decision on Fenitrothion was released in July 1995 (US EPA, 2000). There is only one food tolerance value established and that is for wheat gluten imported from Australia.

Canada: Currently, only one product containing fenitrothion is registered in Canada, as a Restricted Class product, for use in forests and woodlands (PMRA 2003). The Canadian Pest Management Regulatory Agency (PMRA) has reported occasional findings of dead or incapacitated songbirds following large-scale operational forest sprays of fenitrothion (PMRA 2003). The PMRA has restricted use rates of fenitrothion to a maximum of 210 g ai/ha and buffer zones around specified aquatic habitats must be observed (PMRA 2003). Closed mixing and loading systems are now required and workers are required to use chemical-resistant gloves and coveralls when re-entering treated areas up to one month following application (PMRA 2003).

European Union: Fenitrothion is included the list of active substances to be assessed in the second stage of the European Commission review programme for existing active substances (European Commission 2001). These assessments are not yet complete.

Joint FAO/WHO Meeting on Pesticide Residues: Fenitrothion was evaluated by the JMPR in 1969, 1974, 1976, 1977, 1982, 1983, 1984, 1986, 1988 and 2000. In 1988, an ADI of 0.005 mg/kg was established, while an ARfD of 0.04 mg/kg bw was set in 2000. Although all ADIs are generally calculated the same way, differences between ADIs established by different countries can result due to differences in selected end-points, the studies available and so on. An early extract of the results of the 2003 Joint FAO/WHO Meeting on Pesticide Residues is already available online, and is expected to be published early in 2004 as Annex I to the 2003 JMPR report. The extract indicates that most Codex MRLs for fenitrothion are to be withdrawn, apart from those for mammalian meat (in the fat), cereal grains and wheat bran (unprocessed).

New Zealand: Two fenitrothion products are registered by the Agricultural Compounds & Veterinary Medicines (ACVM) Group in New Zealand.

4. PROPOSED REVIEW RECOMMENDATIONS

On the basis of outcomes from the interim stage of the review (completed August 1999), and the evaluation of supplementary information, this report makes the following recommendations with regard to the continued approval and registration of fenitrothion in Australia.

4.1 Affirmation

The approval of the active constituent fenitrothion (#44499) is to be affirmed.
The registrations of the following products are to be affirmed (Table 1)

Table 1: Affirmed product registrations

Product no	Product Name	Registrant
52034	NEVWEB Fenitrothion 1000 Grain Protectant	Australian Generics Pty Ltd
42272	David Grays Fenitrothion 1000	David Gray & Co. Pty Ltd.
47210	Farmoz Fenitrothion 1000 Insecticide	Farmoz Pty Limited
56170*	Kendon 1000 EC Fenitrothion Insecticide	Kendon Chemicals and MNFG Co Pty Ltd
32986	Nufarm Fenitrothion 1000 Insecticide	Nufarm Australia Limited
46127	Rentokil Fenitrothion 1000 Insecticide	Rentokil Initial Pty Ltd
50774	Sumitomo Sumithion ULV Premium Grade Insecticide	Sumitomo Chemical Australia Pty Limited
50775	Sumithion 1000 EC Insecticide	

* Product registered after the release of the interim report but registration conditional on the outcomes of the review.

4.2 Variation to approved labels

The following variations to approved labels are proposed:

a. Delete ground-based application methods for all uses except grain treatment
b. Delete uses in poultry housing, surface treatments and structural treatments.
c. Delete use on pastures for control of pasture pests
d. Delete use on horticultural crops (fruits and vegetables)
e. Amend use on forage crops to use on cereal crops and lucerne
f. Delete use of EC formulations on broadacre crops and lucerne
g. Amend withholding period instructions on ULV labels
h. Amend buffer zone, application techniques and precaution statements on ULV labels to be more precise, as follows:

   Applications and buffer zones

   Delete**:** DO NOT apply within a buffer zone of 1.5km upwind of sensitive areas.

   Insert: **DO NOT** apply within 1500 metres of people downwind, downwind structures that people occupy at any time, downwind parks and recreation areas or downwind aquatic and wetland areas including aquacultural ponds or surface streams and rivers.

   DO NOT apply with aircraft when nozzles are higher than 3 metres above the ground or crop canopy **AND** when wind speed is less than 3 or more than 20 kilometres per hour as measured by an anemometer at the application site or by an approved weather station within 5 kilometers of the site. Use fine to medium spray according to ASAE S572 definition. Use upwind swath displacement

Application techniques

Delete: Apply in a manner that will minimise off-target drift. Best results when spraying across a moderate breeze to achieve a broad swath and an incremental deposit. Use of differential GPS track guidance and smokers is strongly recommended.

Insert: Use of differential GPS track guidance is strongly recommended.

Precaution

Delete**:** It is highly desirable that aerial spray operators use closed mixing/loading systems only… or closed filling/loading systems.

Insert: Aerial spray operators MUST use closed mixing/loading systems only… or closed filling/loading systems.

Table 2 Summary of label changes by situation and pest

Situation	Pest	Recommendation
Broadacre crops Pastures, pasture seed crops, forage crops including cereal crops, grazing sorghum and lucerne.	Australian plague locust, spur throated locust, migratory locust, yellow-winged locust, wingless grasshopper, small plague grasshopper.	EC formulations: Significant OH&S concerns for all application methods. **Delete from labels.** ULV formulations: significant OHS concerns for ground and hand held application. Delete from labels. **Aerial use only**. Delete the term "forage crops" from labels
Lucerne	Sitona weevil	EC formulations: Significant OH&S concerns for all application methods. **Delete from labels.**
Pasture	Pasture cockchafer, corbie, winter corbie, underground grass grub, oxycanus grass grub	Significant OH&S, residues and environmental concerns for all application methods. **Delete from labels.**
Horticultural crops Apples, cabbages, cherries, grapes, lettuce, tomatoes, soybean	Australian plague locust, spur throated locust, migratory locust, wingless grasshopper, small plague grasshopper	Significant OH&S and residues concerns for all application methods. **Delete from labels.**
Structural treatments Cereal, grain stored on farm, produce stores, feed and flour mills, warehouses and processing plants, transport equipment, animal feed bins	Stored pests including susceptible maldison-resistant grain weevils, flour beetles, saw-toothed grain beetles, tropical warehouse moth and Indian meal moth, lesser grain borer	Significant OH&S concerns for all application methods. **Delete from labels.**
Surface treatments Bag stacks etc.		Significant OH&S concerns for all application methods. **Delete from labels.**
Grain protection Bulk storage		No concerns associated with use – **use can continue**.
Tank mix with IGR for treatment of stored cereal	Stored grain insect pests including lesser grain borer and rust re flour beetle (including OP resistant strains) excluding sitphilus	No concerns associated with use – **use can continue**
Poultry housing Broiler poultry house litter, walls, roof and feed sheds	Lesser mealworm (litter beetle), darking beetle	Significant OH&S concerns for all application methods. **Delete from labels.**

It is recommended that the following withholding period instructions be amended for the approved labels.

***Delete*:**

Crops for human consumption
Apples, cabbages, cherries, grapes, lettuce, soya bean, tomato, cereal crops
Do not harvest for 14 days after application.

Crops for animal consumption/stockfeed
Sorghum, Cereal straw and fodder, Pasture seed crops, Forage crops:
Do not graze or cut for stock feed for 14 days after application.

Crops for animal consumption/stockfeed
Pasture (including Lucerne) where stock has not been oversprayed:
Do not graze for 7 days after application or withhold stock from slaughter for 14 days after applications, whichever is appropriate.

Crops for animal consumption/stockfeed
Pasture (including Lucerne) where stock has been oversprayed:
Do not slaughter for 14 days after application.

Crops for animal consumption/stockfeed
Sorghum, Cereal straw and fodder:
Do not graze or cut for stock food for 14 days after application.

***Insert*:**

Withholding periods
Cereal crops
Do not harvest for 14 days after application.
Do not graze or cut for stock feed for 14 days after application.

Withholding periods
Pasture (including Pasture seed crop):
Do not graze or cut for stock feed for 14 days after application.

Please refer to Table 3 for the label approvals affected by these variations.

Table 3: Label approvals affected by the variations

Product Number	Label approval number
32986	32986/1100
42272	42272/0800
46127	46127/0700
47210	47210/0501
50774	50774/0500
50775	50775/0401
52034	52034/1102
56170*	56170/0702

* Labels approved after the release of the interim report but registration conditional on the outcomes of the review.

4.3 Cancellations

The following label approvals are deemed not to contain adequate instructions and thus are to be cancelled (Table 4).

Product Number	Label approval number
32096	32096/0100
40062	40062/0500
32984	32984/0400
	32984/0401
32986	32986/0400
46127	46127/0100
	46127/02
	46127/03
47210	47210/0400
50775	50775/0800
52034	52034/0202
	52034/0799
	52034/0802
	52034/0899

5. AMENDMENTS TO STANDARDS

The following amendments will be made to the *MRL Standard* as associated outcomes of the review (Tables 5 and 6):

Table 5: Amendments to MRL Standard

Compound	Food		MRL (mg/kg)
Fenitrothion			
Delete:	CM 1206	Rice bran, unprocessed	T20
	MO 0105	Edible offal (mammalian)	T*0.05
		Fruit	1
	MM 0095	Meat (mammalian) [in the fat]	T*0.05
	ML 0106	Milks [in the fat]	T*0.05
		Vegetables	0.5
Add:	CM 1206	Rice bran, unprocessed	20
	MO 0105	Edible offal (mammalian)	*0.05
	MM 0095	Meat (mammalian) [in the fat]	*0.05
	ML 0106	Milks [in the fat]	*0.05

Table 6: Amendments to MRL Standard

Compound		Animal Feed Commodity	MRL (mg/kg)
Fenitrothion			
Delete	AS 0161	Straw, fodder (dry) and hay of cereal grains and other grass-like plants	T10
	AL 1020	Alfalfa fodder [Lucerne]	T5
	AL 1021	Alfalfa forage (green) [Lucerne]	T5
		Canola forage (green)	T10
	AL 0157	Legume animal feeds (except alfalfa fodder and forage)	T10

Add	AS 0161	Straw, fodder (dry) and hay of cereal grains and other grass-like plants	10
		Rice hulls	50
	AL 1020	Alfalfa fodder [Lucerne]	5
	AL 1021	Alfalfa forage (green) [Lucerne]	5

6. CONCLUSION

Data for use of registered fenitrothion products on stored grains indicates that use in accordance with the instructions for use satisfies the criteria for continued registration and/or approval under section 34 of the Agvet codes. Therefore these use-patterns will remain on approved labels.

The risk assessment indicates that use of fenitrothion in hand held applications, such as for surface treatments and to control pests in structures, poses unacceptable risks to workers. Moreover, data on hand spraying of poultry houses indicated that the risk to workers was high and unacceptable. Therefore, the APVMA cannot be satisfied that use in accordance with the instruction for use would not be an undue hazard to the safety of people. For this reason, use-patterns for surface, structural and shed treatments (including poultry housing, broiler houses and warehouses) are to be deleted from approved labels.

Fenitrothion products can be used on horticultural crops including apples, cabbages, cherries, grapes, lettuce, soybeans and tomatoes for grasshopper/locust control, although existing information on actual use indicates that horticultural crops are not usually directly sprayed. No data were provided for Australian use-patterns and therefore potential residues in horticultural crops cannot be assessed. For this reason the APVMA cannot be satisfied that use of registered fenitrothion products on fruits and vegetables, in accordance with the instructions for their use, would not be likely to have an effect that is harmful to human beings. Therefore, instructions for use of registered fenitrothion products on horticultural crops including apples, cabbages, cherries, grapes, lettuce, soybeans and tomatoes for grasshopper/locust control are to be deleted from approved labels.

Fenitrothion EC formulations are used in broadacre and forage crops to control locusts and grasshoppers, and in lucerne to control sitona weevil. The risk assessment indicates that use of fenitrothion by ground boom, misters and in hand held applications poses unacceptable risks to workers. Survey data indicate that the EC formulation is not generally applied by air and there were no data provided to the APVMA pertaining to aerial EC applications. Therefore, the APVMA cannot be satisfied that use of registered fenitrothion EC products, in accordance with the instruction for their use, would not be an undue hazard to the safety of people. Moreover, despite potentially high acute risk to birds and aquatic invertebrates, monitoring data for runoff and spray drift with high use rate situations were not provided and therefore the level of impact to birds and aquatic invertebrates could not be determined. Thus, the APVMA cannot be satisfied that use of registered fenitrothion EC products on these pests and crops, in accordance with the instruction for their use, would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment. For these reasons, all application methods for EC formulations on broadacre and lucerne crops for the control of locusts and grasshoppers and also on lucerne to control sitona weevil are to be deleted from approved labels.

Several fenitrothion products are currently used on pastures for the control of pasture pests. The risk assessment indicates that use of fenitrothion by ground boom, misters and in hand held applications poses unacceptable risks to workers. Moreover, there are insufficient data for all application methods (ground and aerial) to assess residues in animal commodities and thus estimate risks to human health. Despite an estimated high acute risk to birds and aquatic invertebrates, there are also insufficient data to quantify the level of impact to birds and aquatic invertebrates. Therefore, the APVMA cannot be satisfied that use of registered fenitrothion products for control of pasture pests, in accordance with the instructions for their use, would not be an undue hazard to people using anything containing its residues, 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. Thus, uses on pastures for the control of pasture pests are to be deleted from approved labels.

Fenitrothion ULV formulations are used in broadacre crops to control locusts and grasshoppers. The risk assessment indicates that use of fenitrothion by ground boom, misters and in hand held applications poses unacceptable risks to workers. Therefore, the APVMA cannot be satisfied that use of registered fenitrothion ULV products by ground and hand held applications, in accordance with the instruction for their use, would not be an undue hazard to the safety of people. Therefore, ground and hand-held application methods for ULV products are to be deleted from approved labels. Existing limits on aerial rates are to remain on approved labels.

Fenitrothion products are currently used on forage crops for locust/grasshopper control. The labels will be amended to reflect specific forage crops for which the data satisfy the criteria for continued registration, i.e., cereal crops and lucerne. The term "forage crops" is to be deleted from labels and thus label instructions for locust/grasshopper on broadacre crops control will only include pastures, pasture seed crops, lucerne and cereal crops.

Based on the outcomes of the initial review, subsequent assessment of the required supplementary information and the variation to conditions of label approval ensuring the requirements for continued approval or registration will be complied with, the APVMA is satisfied that the continued use of products containing fenitrothion meets the criteria for continued registration and label approval as dictated by the Agvet Code.

7. REFERENCES

Canadian Pest Management Regulatory Agency (2003). Proposed Acceptability for Continuing Registration, Re-evaluation of Fenitrothion. PACR2003-08. Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada.

European Commission (2001). Commission Regulation (EC) No 703/2001 of 6 April 2001 laying down the active substances of plant protection products to be assessed in the second stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC and revising the list of Member States designated as rapporteurs for those substances.

US EPA (2000). Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for Fenitrothion. Office of Prevention, Pesticides and Toxic Substances

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8. RESIDUE ASSESSMENT REPORT

8.1 Introduction

The APVMA ECRP Review Report of fenitrothion (June 1999), highlighted concerns regarding fenitrothion residues in rice bran exceeding the current Australian and Codex Maximum Residue Limit (MRL) of 20 mg/kg. Processing data from a study conducted in Japan[1] showed that residues in rice bran were up to 65 mg/kg after post-harvest treatment of rice at 15 ppm fenitrothion. In Australia, approved labels specify treatment up to 12 ppm fenitrothion. Processing factors for rice bran could not be calculated from these data. However, according to the treatment rates of 2, 6 and 15 ppm used in the study, a rice bran processing factor was estimated to be in the order of 2-4. When applied to paddy rice (which is allowed to be treated at 12 ppm), maximum residues in rice bran may exceed the current MRL of 20 mg/kg for rice bran unprocessed. In order to establish an appropriate rice bran MRL, the rice industry was requested to generate additional processing data. The Rice Growers Co-operative Limited has conducted a processing trial on paddy rice and these data are reviewed in this report.

The other outstanding residue issue from the interim report was application of fenitrothion to cereal crops, particularly residue levels on treated forage and hay and subsequent use for animal feed. The principle registrant of fenitrothion (Sumitomo Chemistry Australia Pty Ltd) has provided an additional cereal study for confirmation of cereal MRLs, and this study is reviewed. For completion of residue aspects, use on horticultural crops for locust control is assessed, and dietary intake (acute and chronic) calculations have been performed.

The current Australian food and animal commodity MRLs for fenitrothion are shown in the following tables:

Table 7: Current Australian food and animal commodity MRLs for fenitrothion

Compound		Food	MRL (mg/kg)
Fenitrothion			
GC	0080	Cereal grains	10
MO	0105	Edible offal (mammalian)	T*0.05
PE	0112	Eggs	*0.05
		Fruit	1
MM	0095	Meat (mammalian) [in the fat]	T*0.05
ML	0106	Milks [in the fat]	T*0.05
PO	0111	Poultry, Edible offal of	*0.05
PM	0110	Poultry meat	*0.05
CM	1206	Rice bran unprocessed	T20
		Vegetables	0.5
CM	0654	Wheat bran, unprocessed	20
CF	1210	Wheat germ	20

[1] Ito et al, Report of Research Dept. Sumitomo Chemical Co. Ltd, Takawazaka City, Japan, 1976.

Table 8: Current Australian food and animal commodity MRLs for fenitrothion

Compound		Animal Feed Commodity	MRL (mg/kg)
Fenitrothion			
AL	1020	Alfalfa fodder [Lucerne]	T5
AL	1021	Alfalfa forage (green) [Lucerne]	T5
		Canola forage (green)	T10
AL	0157	Legume animal feeds (except alfalfa fodder and forage)	T10
AS	0161	Straw, fodder (dry) and hay of cereal grains and other grass-like plants	T10

There were 7 temporary MRLs established as related outcomes of the interim report recommendations. Because these temporary MRLs were based on overseas data, or in the case of animal commodity MRLs, additional data for pasture pests were requested; they were subject to the requirement that confirmatory data for Australian uses and conditions were provided by 30 September 2002. The following sections discuss where confirmatory data were or were not received.

8.2 Discussion

8.2.1 Grain Protectant – Treatment of Rice

Registered fenitrothion products may be used as a post-harvest treatment of cereal grains to control borers, weevils, grain beetles and moths. Fenitrothion is registered in Queensland, NSW, VIC, SA and Tasmania as an admixture for cereal grains stored less than 3 months at a treatment rate of 6 ppm. It is also registered in all states as an admixture treatment for cereal grains stored 3-6 months, with a treatment rate of 12 ppm. When treated at 12 ppm, there is a 90 day storage interval, where the grain must be withheld for that period from use as a human food or animal feed.

Assessment of data

The Ricegrowers Co-operative Limited conducted a trial in 2000 to determine processing factors for rice when fenitrothion is applied as an admixture. Limited details of the field component were provided. It is unclear as to how the rice was treated, and details of sampling and storage were minimal. The APVMA attempted to obtain further details of the trial work from the Cooperative. However, only limited information was received. Details of an analytical method and sample chromatograms were provided, with recovery data submitted later. Results of the trial are given in appendix 1.

Analytical method

Testing for fenitrothion residues in rice was conducted by the Ricegrowers' Co-operative Limited at their laboratory facility at Leeton. After treatment, samples are thoroughly mixed with methanol. The methanolic extract containing fenitrothion residue is removed and evaporated to dryness. The extract is reconstituted in methanol and injected into the GC. Detection of fenitrothion residues is by a flame photometric detector (FPD). External standard calibration based upon the response of a standard of known purity is used for quantification. Standard and sample chromatograms demonstrate acceptable peak resolution and no interference from other extraneous peaks. However, it is noted that analytical conditions are poor (low sensitivity, unstable baseline, broad peak width, electronic spiking occurring in some samples, low detector speed), and not ideally suitable for the task. In support of the method, recovery data were provided, and the results are summarised in the following table.

Table 9: Recovery of fenitrothion residues from paddy rice, hulls and bran (n=2, mean shaded)

Matrix	@ 1 ppm		@ 5 ppm		@ 10 ppm		Total mean
Paddy	62.6%	115.2%	90.8%	91.6%	69.9%	53.7%	80.6%
Hull	76.3%	64.0%	90.1%	100.7%	90.9%	85.3%	84.6%
Bran	66.9%	78.5%	67.8%	63.2%	42.6%	128.8%	74.6%

The recovery results above demonstrate that there is some variation within replicates. This is probably due to the analytical conditions being used to test the samples (ie using manual injection, poor integration conditions). However, the mean recovery demonstrates that fenitrothion residue is recovered from paddy rice, hulls and bran at 70-85%, which is within acceptable limits. The mean recovery of each matrix will be used as a correction factor when reporting the results.

Rice bran

When paddy rice was treated at 6 and 12 ppm, maximum fenitrothion residues in paddy rice were 4.0 mg/kg and 10.5 mg/kg, respectively (see appendix 1). These data indicate that appropriate treatment was applied in the trial, ie the residue levels were ~80% of the intended dose. The data for rice bran are therefore considered representative of cereals present after treatment at the Australian approved rates of 6 and 12 ppm.

The table below summarises the results for rice bran when fenitrothion was applied at 6 and 12 ppm to paddy rice and subsequently processed into bran at 0-12 weeks after treatment. The results have been corrected for recovery performed on this matrix.

Table 10: Fenitrothion residues in rice bran when applied to paddy rice at 6 and 12 ppm.

DATE	6 ppm treatment rate		12 ppm treatment rate	
	Raw	Corrected †	Raw	Corrected †
	mg/kg		mg/kg	
0 days	2.55	3.42	3.63	4.87
2 days	1.89	2.53	3.83	5.13
7 days	2.81	3.77	4.69	6.29
14 days	2.27	3.04	0.58	0.78
3 week	1.13	1.51	3.40	4.56
4 weeks	2.60	3.49	0.40	0.54
6 weeks	0.80	1.07	12.96	17.37
8 weeks	0.94	1.26	3.05	4.09
10 weeks	0.36	0.48	2.85	3.82
12 weeks	0.90	1.21	2.66	3.57

† Corrected using the mean recovery of 74.6 % for bran.

The maximum residue level found in bran was 17.4 mg/kg at 6 weeks after treatment of 12 ppm fenitrothion. This result is inconsistent with other results from this trial, being substantially higher that those from other collection times. The likely reason is due to sampling error, and accordingly, this result will be disregarded from consideration. Therefore, the maximum residue encountered is 6.3 mg/kg at 7 days after treatment of 12 ppm. The results show that maximum fenitrothion residues in rice bran are unlikely to exceed the current temporary MRL for processed rice bran of 20 mg/kg.

The median rice bran residue level (STMR) is calculated to be 2.79 mg/kg (using all data points after 6 ppm treatment, and the 10 and 12 weeks data after treatment at 12 ppm). To observe the recommended storage period of 90 days after 12 ppm treatment, data from 0-8 weeks after 12 ppm treatment were not included in the estimation of the rice bran STMR.

In conclusion, the rice bran STMR of 2.8 mg/kg and the maximum residue level of 6.3 mg/kg found in the trial are well within the established TMRL of 20 mg/kg for unprocessed rice bran. On this basis, an MRL of 20 mg/kg remains appropriate for unprocessed rice bran.

Rice hulls

The table below summarises the results for rice hulls when fenitrothion was applied at 6 and 12 ppm to paddy rice and processed into hulls at 0-12 weeks after treatment. The results have been corrected for recovery performed on rice hulls.

Table 11: Residues in rice hulls when fenitrothion is applied at 6 ppm and 12 ppm to paddy rice.

DATE	6 ppm treatment rate		12 ppm treatment rate	
	Raw	Corrected †	Raw	Corrected †
	mg/kg		mg/kg	
0 days	18.03	21.31	43.41	51.31
2 days	20.14	23.81	45.33	53.58
7 days	5.74	6.78	40.73	48.14
14 days	16.93	20.01	25.64	30.31
3 week	0.5	0.59	23.6	27.90
4 weeks	3.1	3.66	44.84	53.00
6 weeks	3.31	3.91	11.7	13.83
8 weeks	2.17	2.57	34.9	41.25
10 weeks	21.45	25.35	35.28	41.70
12 weeks	10.89	12.87	23.88	28.23

† Corrected using the total mean recovery of 84.6 % for hulls.

The maximum rice hull residue (corrected) was 54 mg/kg, at 2 weeks after treatment of 12 ppm fenitrothion. Because rice treated at 12 ppm should not be processed for a minimum of 90 days (12 weeks), this result is not consistent with label instructions. Residues in hulls at 10-12 weeks after 12 ppm treatment were ~30-42 ppm. Residues on hulls processed from rice treated at 6 ppm did not exceed 26 mg/kg. These data support the following Animal Feed Commodity MRL:

Rice hulls 50 mg/kg.

8.2.2 Control of locusts on fruit and vegetable crops

Registered fenitrothion products are used for locust/ grasshopper control (spur-throated locust, migratory locust, wingless grasshopper, Australian plague locust, small plague grasshopper) on the following fruit and vegetables: apples, cabbages, cherries, grapes, lettuce, soybean and tomatoes. There are currently four products registered with these uses: 32986 Nufarm Fenitrothion 1000 Insecticide, 50774 Sumitomo Fenitrothion ULV Premium Grade Insecticide, 50775 Sumitomo Sumithion 1000EC Insecticide, and 56170 Kendon Fenitrothion 1000EC Insecticide. Each of these products is an EC formulation containing 1000 g ai/L (SG =1.27), with the exception of the ULV Sumitomo formulation, which contains 1.23 kg/L of fenitrothion. Treatment rates are 270-500 mL/ha (~343-700 g ai/ha). Generally, the labels do not specify the number of applications and the minimum re-treatment interval. The Sumitomo ULV label states a re-application interval of not less than 14 days. All approved labels state that the harvest withholding period associated with these uses is 14 days.

In the Interim Review report, it was noted that fenitrothion application on horticultural crops for locust control was rarely performed, and that there was only one authenticated treatment (on grapes) in the last 20 years or so. The Australian Plague Locust Commission (APLC) indicates that orchards are not over-sprayed for locust control but rather the verges and ground vegetation within the orchards are

sprayed. In addition, only spur throated locusts attack orchard trees, with serious damage from this pest occurring every 20-30 years. With respect to grapes, the report indicated that some over-spraying of young vines may occur, but there is no direct spraying of fruit. The situation for market garden crops (cabbages, lettuce and tomatoes) indicates that fenitrothion is rarely used for locust control; there are no authenticated records to date. With respect to soybeans, there were no authenticated records of use and no Australian data were available.

As an outcome of the interim report recommendations, the then-existing fruit MRLs (apple, cherries, grapes, and fruits except cherries and grapes) and vegetable commodity MRLs (head cabbages, head and leaf lettuce, tomato, and vegetables except head cabbages, head and leaf lettuce, tomato) were deleted, and a fruit MRL of 0.5 mg/kg and vegetable MRL of 1 mg/kg were established. The MRLs were to cover residues in fruit and vegetables resulting from emergency use situations, presumably as plague locust situations arose. In the current assessment, there are no Australian data supporting the fruit and vegetable MRLs. Without these data, the APVMA cannot be satisfied that the existing fruit and vegetable MRLs are acceptable from a dietary exposure and human health perspective. Accordingly, the fruit and vegetable MRLs should be deleted, and that the fruit and vegetable use-patterns should be removed from approved labels.

8.2.3 Animal Exposure to fenitrothion residues

Animal exposure to fenitrothion residues was considered in the Interim Review report for fenitrothion. Temporary animal commodity MRLs of T*0.05 mg/kg were set for mammalian meat and edible offal as related outcomes of the review. Animal commodity MRLs of 0.05 mg/kg were also established for eggs, and poultry meat and offal. All animal commodity MRLs are based upon a Maximum Feeding Level (MFL) of 100 ppm for cattle, pigs, sheep and poultry. In this section, consideration will be given to animal feeds resulting from treatment of cereals, pastures and other feed commodities.

Registered fenitrothion products are used on pasture, pasture seed crops, forage crops including grazing sorghum, lucerne, soybean, cereal crops for locust control situations (spur-throated locust, migratory locust, wingless grasshopper, Australian plague locust) at 270-550 mL/ha (343-700 g ai/ha). The maximum use-pattern indicates that up to 3 applications may be applied per paddock per year or growing season. Registered fenitrothion products are used on pastures to control various pests (pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub) at 480-1300 mL/ha (610-1650 g ai/ha). Product labels indicate that only one treatment can be applied per year. Registered fenitrothion products are used on lucerne to control sitona weevil at 250-650 mL/ha (315-825 g ai/ha). The maximum number of treatments is not specified, apart from "observing any use limitations advised from state authorities". In each situation, a re-treatment interval of 7 days (when used for grazing) or 14 days (when cut for stock feed, or where stock have been over-sprayed) applies.

In the Interim Review report, Australian data were requested for lucerne, other grass-like situations, and other forage crops (eg, pasture and sorghum) where non-locust pests are to be controlled. These data are required in order to establish appropriate grazing restraints and withholding periods.

Cereal forage and straw

The primary registrant of fenitrothion (Sumitomo Chemistry Australia Pty Ltd) submitted a supplementary residue study conducted on winter wheat, with residue data for treated forage, grain and straw. These data show that when fenitrothion is applied at 500 mL/ha (henceforth taken to be ~1× locust control rate) and after a 14 day withholding period (WHP), then maximum residues of 0.21 mg/kg in wheat grain and 4.1 mg/kg in straw were found. In a study on sorghum performed by the Queensland Department of Primary Industries (previously reviewed in the Interim report), fenitrothion was applied once at 768 g ai/ha (~1× locust control rate). Residues in forage were 4.8 mg/kg at 14 days after treatment. The residue levels found are well below the MFL of 100 ppm.

As the residue levels found are well within the MFL, these data show that when fenitrothion is applied for locust plague control in cereals, no detectable residues should occur in meat, meat by-products, eggs and milk as a result of animals consuming treated cereal forage, straw or grain. These data also

confirm that the MRL of 10 mg/kg for straw, fodder (dry) and hay of cereal grains and other grass-like plants is appropriate, when the existing grazing withholding period of 14 days is observed.

Lucerne forage and fodder

Registered fenitrothion EC products are applied to lucerne at 250-650 mL/ha (317-826 g ai/ha) to control sitona weevil, 270-550 mL/ha (~340-700 g ai/ha) for locust control situations (spur-throated locust, migratory locust), 300 ml/ha (~380 g ai/ha) to control wingless grasshopper and 270-400 ml/ha (340-510 g ai/ha) to control Australian plague locust. One registered fenitrothion ULV product is also used to control the yellow-winged locust in Queensland and the small plague grasshopper in South Australia at similar rates. Residue data previously considered in the Interim Report showed that following 1120 g ai/ha (~1.4× locust control rate) treatment on lucerne, residues of fenitrothion at 7 days after treatment were: forage 2 mg/kg dry weight (based upon 35% dry matter) and hay 1.1 mg/kg dry weight. Similarly, residues at 14 days after treatment were: forage 1.4 mg/kg and hay 0.7 mg/kg (both on a dry weight basis).

The Interim Review report requested additional data for lucerne, and for other pasture and forage (sorghum) crops where non-locust pests are controlled. However, with respect to the lucerne use-patterns, the above data are satisfactory to confirm that the lucerne forage and lucerne fodder MRLs of 5 mg/kg are appropriate, when the existing grazing intervals of 7 days, or cutting for stockfeed of 14 days, or slaughtering period of 14 days are observed, as instructed on product labels. In the case of the slaughter interval of 14 days, it also applies to stock that have been over-sprayed and have not been moved from the target area. Data in the Interim Review report show that resulting animal residue levels are similar to stock grazing treated foliage only.

The alfalfa fodder [lucerne] and alfalfa forage (green) [lucerne] MRLs of 5 mg/kg are satisfactory to account for residues in lucerne feed substances. The existing grazing interval of 7 days, or cutting for stockfeed of 14 days, or slaughtering period of 14 days as shown on the approved labels, are appropriate for the lucerne use-patterns.

Pasture and pasture seed crops

Residue data following fenitrothion application on pasture were reviewed in the Interim Review report. In one trial, fenitrothion was applied at 125 g ai/ha or 375 g ai/ha. When applied at 125 g ai/ha, residues of fenitrothion were 2.88 mg/kg at 1 day withholding period (WHP), and 0.52 mg/kg at 7 days WHP. Following application at 375 g ai/ha (~0.5 × locust control rate), residues were 6.59 mg/kg at 1 day WHP, 1.84 mg/kg at 7 days WHP, and 1.04 mg/kg at 10 days WHP. All results were expressed on an "as received" basis.

The JMPR reviewed a supervised trial conducted in New Zealand, prior to 1974. In this trial, fenitrothion was applied at 1680 g ai/ha (2.4 × locust control rate), and residues of fenitrothion were measured 0-14 days WHP. Residues of fenitrothion were 74.2, 37.7, 9.0 and 3.25 mg/kg at 0, 2, 7 and 14 days WHP, respectively.

Testing by the APLC was conducted on grass. Application of fenitrothion at 267 g ai/ha to grass pasture resulted in residue levels of 50 mg/kg at 0 days WHP, and 5 mg/kg at 7 days WHP. All results were expressed on an "as received" basis. Based upon the limited pasture residue data and extrapolation of the cereal and lucerne residue data, these results show that when fenitrothion is applied at rates permitted for locust plague control in pasture, resulting residues are below the straw, fodder (dry) and hay of cereal grains and other grass-like plants MRL of 10 mg/kg. This is in conjunction with the existing grazing withholding period of 14 days and therefore this withholding period is adequate.

Registered fenitrothion products are used on pasture for control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub at 480-1300 mL/ha (610-1650 g ai/ha). As a related outcome of the interim report, Australian data were required for lucerne, other grass-like pasture situations and other forage crops (eg sorghum) where non-locust pests are to be controlled.

Since 1999, no Australian data has been forthcoming from the registrants of fenitrothion products for pasture situations. In the absence of these data, the non-locust uses on pasture should not continue. Therefore, the uses on pasture for control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub should be removed from the approved labels.

Soybean

In the Interim Review report, limited residue data were available for soybean forage and fodder. Sumitomo Chemical Australia Pty Ltd have recently indicated that they have no residue data from trials conducted on soybeans. Residue data reviewed by the 1974 JMPR show that when fenitrothion is applied at 710 g ai/ha (~1× locust control rate), consisting of 3 applications at 14 day intervals, the maximum residue level encountered at 9-15 days after treatment was 0.01 mg/kg in the harvested grain. There were no residue data available for forage or fodder. An associated outcome of the interim report was the removal of the soybean MRL due to the lack of supporting Australian data and the absence of authentic records of use. However, at the time, no changes were made to the approved labels, which allow the use of fenitrothion on soybean for locust control. Since 1999, there has been no Australian data generated in support of the soybean use. In the absence of these data, and an existing MRL, the use should not continue. Therefore, the soybean use-patterns should be removed from approved labels.

Legume animal feeds (except alfalfa fodder and forage) and canola

In 2000, temporary animal feed MRLs (to account for residues in animal feed substances) were established as part of a permit approval (PER 4175) of fenitrothion for the control of locusts in WA for failed crop situations. As the permit is no longer current, the temporary MRLs of T10 mg/kg for legume animal feeds and T10 mg/kg for canola forage (green) can be deleted. Because the legume animal feeds MRL is relevant to the soybean use-pattern on approved labels, deletion of this MRL should be made as an action related to this review. With respect to canola forage, the MRL will also be deleted as an action related to this review.

Rice hulls and bran

Following post-harvest storage treatment of paddy rice, processed commodities thereof may be used as animal feed, namely rice hulls and bran. Rice hulls are recognised as an animal feed commodity, which may constitute about 10% of an animal's diet[2]. The maximum residue level in hulls is not expected to exceed the recommended MRL of 50 mg/kg. Accordingly, at 10% of dietary intake, the expected animal exposure of 5ppm is well below the MFL of 100 ppm. Similarly for rice bran, residues are unlikely to exceed the MRL of 20 mg/kg. Rice bran may be consumed by animals, providing up to 40% of their dietary needs. Exposure at this level would be equivalent to 8 ppm in the diet. Again, this is well within the MFL of 100 ppm for fenitrothion. Therefore, rice hulls and bran derived from treated grain are not likely to result in violations of animal commodity MRLs when used as animal feed substances.

Other Crop Uses: Label descriptions

The label permits the use of fenitrothion on forage crops *per se* for locust control situations (Spur-throated locust, Migratory locust, Wingless grasshopper, Australian plague locust). The current labels provide instructions for treating grazing sorghum, lucerne, soybeans, and cereal crops for control of spur-throated locust, migratory locust and wingless grasshopper. The label instructions for Australian plague locust control includes grazing sorghum, lucerne, cereal crops, soybeans, apples, cabbages, cherries, grapes, lettuce and tomatoes. In this case, apples, cabbages, cherries, grapes, lettuce and tomatoes do not constitute forage crops, and these uses should be deleted from the approved labels. In both cases, the current entry can be interpreted to include other forage crops like grasses, legume and brassica crops, which may be "generally considered" as forage crops, and these situations have not

[2] *FAO Manual on the Submission and Evaluation of Pesticide Residues Data, Appendix IX*

been assessed against the criteria for continued registration or approval. Therefore, the approved use-pattern should be revised to show only specific forage crops to which fenitrothion may be applied for locust control. The following entry should remove any confusion as to which forage crops may be treated:

"Pastures, pasture seed crops, lucerne and cereal crops"

This is noting that cereal crops refers to the Codex commodity group. This commodity group includes sorghum and oats, which are commonly used for grazing. In the event of a failed cereal crop situation such as wheat, grazing may also be permitted, so long as the grazing interval is observed.

8.2.4 Conclusions

Livestock exposure to fenitrothion from feeding of treated cereals and pastures (for locust control situations), lucerne fodder and forage (for sitona weevil or locust control situations), or other feed substances, including rice hulls and bran, are unlikely to result in detectable residues in animal commodities. Therefore, the current 'at or about' limit of quantification animal commodity MRLs of *0.05 mg/kg are appropriate.

8.3 Human dietary exposure

NEDI: The chronic dietary risk is estimated by the National Estimated Daily Intake calculation encompassing all registered / temporary uses of the chemical and dietary intake data from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with the Guidelines for predicting dietary intake of pesticide residues (revised) (World Health Organisation, 1997).

The TGA has established an ADI of 0.002 mg/kg bw/day for fenitrothion, based upon an NOEL of 0.2 mg/kg bw/day and applying a 100 fold safety factor. The NEDI calculation shows exposure to fenitrothion residues is equivalent to 12% of the ADI.

NESTI: There is an acute reference dose (ARfD) of 0.03 mg/kg bw established for fenitrothion. Using the 97.5th percentiles for children (2-6 years, body weight 19 kg) and 2 years plus (body weight 67 kg), the acute intake of fenitrothion was estimated and the results are summarised in the following table.

Table 12: Percent Acute Exposure to Fenitrothion

Commodity		2-6 years	2+ years
MM 0095	Meat (mammalian)	1.2	0.7
PM 0110	Poultry meat	2.0	1.1
MO 0105	Edible offal (mammalian)	2.3	0.5
PO 0111	Poultry, edible offal of	2.0	0.5
ML 0106	Milks [in the fat]	0.5	0.2
PE 0112	Eggs	0.1	0.3
GC 0080	Cereal grains	0.7	0.8
CF	Cereal grain milling fractions	0.4	0.9
CM	Early milling products	1.8	0.5

The highest acute exposure was estimated to be <3% in the 2-6 year age group and <2% for the general population (2 years plus age group). In all cases, the acute exposure was calculated using the MRL as the Highest Residue (HR) for that commodity.

In summary, the acute and chronic exposure to fenitrothion residues are within prescribed safety levels and the risk is acceptable.

8.4 Trade

The 2003 Joint FAO/WHO Meeting on Pesticide Residues reviewed the fenitrothion MRLs in September 2003. Currently, MRLs for cereal grains and wheat bran (unprocessed) have been retained and that for mammalian meat (in the fat) is still being reviewed. The Codex MRLs for these commodities are consistent with fenitrothion use as a protectant on cereal grains. The Australian MRLs for cereal grains of 10 mg/kg, rice bran of 20 mg/kg and animal commodities are consistent with the equivalent Codex MRLs.

The horticulture commodity MRLs deleted by Codex include: apples, cabbages, cherries, citrus fruits, grapes, lettuce (head) and tomato. In Australia, registered fenitrothion products are used for locust control situations (spur-throated locust, migratory locust, wingless grasshopper, Australian plague locust) on these commodities, and fenitrothion residues therein are covered under the Fruit MRL of 1 mg/kg and Vegetable MRL of 0.5 mg/kg. Removal of the fruit MRL of 1 mg/kg and vegetable MRL of 0.5 mg/kg is unlikely to cause an undue prejudice to trade, because removal of instructions for fenitrothion uses on fruit and vegetables for locust control from approved labels will mean that no fruit and vegetable commodities will contain fenitrothion residues.

8.5 Overview and conclusion

Dietary consideration leads to the conclusion that acute and chronic exposure to fenitrothion from residues in food does not pose a risk to human health.

The proposed deletion of the fruit and vegetable MRLs is unlikely to cause an undue prejudice to Australian trade. When the recommended changes to approved labels are implemented, fruit or vegetable commodities will not be permitted to contain fenitrothion residues.

A study conducted by Sumitomo Australia Pty Ltd in cereal grains has confirmed that the sorghum, cereal straw and fodder grazing withholding period of 14 days is adequate with respect to fenitrothion use for locust control. In addition, the current MRL of 10 mg/kg for straw, fodder (dry) and hay of cereal grains and other grass-like plants is appropriate.

The processing study conducted by the Ricegrowers Co-operative Limited has confirmed that residues in rice bran are unlikely to exceed the temporary MRL of T20 mg/kg. Therefore, the MRL may be amended to 20 mg/kg as a related action of the review

Rice hulls are an animal feed commodity that may be fed to livestock. The residue data allow the establishment of an MRL of 50 mg/kg for rice hulls as a related action of this review.

Consideration of animal exposure to feed substances that may contain fenitrothion residues, including rice bran and rice hulls, leads to the conclusion that the current animal commodity MRLs are appropriate.

Rice processing data

The table below summarises the rice processing data provided by Ricegrowers Co-operative.

Table 13: Rice processing data

Rate	**6 ppm**					**12 ppm**				
Fraction / DAT	**Paddy**	**Brown**	**White**	**Hulls**	**Bran**	**Paddy**	**Brown**	**White**	**Hulls**	**Bran**
0 days	0.28	0.73	0.06	18.03	2.55	9.28	0.99	0.06	43.41	3.63
2 days	3.73	0.36	ND	20.14	1.89	10.54	1.00	<0.05	45.33	3.83
7 days	2.69	0.43	ND	5.74	2.81	10.24	0.91	<0.05	40.73	4.69
14 days	3.77	0.43	ND	16.93	2.27	6.43	0.61	ND	25.64	0.58
3 week	4.02	0.4	ND	0.5	1.13	5.3	0.7	<0.05	23.6	3.4
4 weeks	4.6	0.3	0.4	3.1	2.6	22.7	0.7	<0.05	44.84	0.4
6 weeks	3.1	1.0	ND	3.31	0.8	6.34	0.55	0.05	11.70	12.96
8 weeks	2.46	0.22	ND	2.17	0.94	3.36	1.37	ND	34.90	3.05
10 weeks	2.13	0.30	ND	21.45	0.36	4.52	0.35	ND	35.28	2.85
12 weeks	2.44	0.30	ND	10.89	0.90	3.77	0.52	ND	23.88	2.66

Summary of processing factors

	6 ppm		12 ppm	
	Paddy to bran	Brown to bran	Paddy to bran	Brown to bran
	9.11	3.49	0.39	3.67
	0.51	5.25	0.36	3.83
	1.04	6.53	0.46	5.15
	0.60	5.28	0.09	0.95
	0.28	2.83	0.64	4.86
	0.57	8.67	0.02	0.57
	0.26	0.80	2.04	23.56
	0.38	4.27	0.91	2.23
	0.17	1.20	0.63	8.14
	0.37	3.00	0.71	5.12
Mean	**1.33**	**4.13**	**0.62**	**5.81**
Max	**9.11**	**8.67**	**2.04**	**23.56**
Min	**0.17**	**0.80**	**0.02**	**0.57**

Paddy to bran = conversion of paddy rice to bran
Brown to bran = conversion of brown rice to bran

Chronic and Acute Dietary Assessment Calculations

Table 14: NEDI for fenitrothion

NEDI for FENITROTHION 23/06/2003

ADI for fenitrothion = 0.002 mg/kg of body weight

Commodity	Food Consumption g/kg bw/day	MRL/ STMR mg/kg	NEDI mg/kg bw	%NEDI	Comment
GC 0081 Cereal Grains (except rice)	2.2917	0.05	0.000114585	5.73%	CF + CM + GC - rice - wheat bran and germ. #2
CM 1205 Rice, polished	0.2333	0.26	0.000060658	3.03%	ECRP data
CM 0654 Wheat bran, processed	0.0393	0.05	0.000001965	0.10%	#2: NRS data, 2000-2002
CF 1210 Wheat germ	0.0039	0.05	0.000000195	0.01%	#2: NRS data, 2000-2002
CM 1206 Rice bran, unprocessed	0.0004	2.79	0.000001116	0.06%	ECRP data
MM 0095 Meat (mammalian) [in the fat]	0.1756	T* 0.05	0.00000878	0.44%	
MO 0105 Edible offal (mammalian)	0.0151	T* 0.05	0.000000755	0.04%	
ML 0106 Milks [in the fat]	0.3597	* 0.05	0.000017985	0.90%	
PM 0110 Poultry meat	0.5596	T* 0.05	0.00002798	1.40%	
PE 0112 Eggs	0.2228	* 0.05	0.00001114	0.56%	
PO 0111 Poultry, Edible offal of	0.0024	T* 0.05	0.00000012	0.01%	
Total			**0.000245279**	**12.3%**	

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimate of Dietary Intake
ADI - Acceptable Daily Intake
MRL - Maximum Residue Limit
T- MRL associated with a temporary use. Also used where a use may be being phased out.
NC - not consumed in diet

Table 15: Fenitrothion acute dietary intake

Fenitrothion Acute Dietary Intake _ 2 years + Date 23/06/2003

Acute RfD 0.03 mg/kg bw

Commodity

Code	Name	MRL mg/kg	STMR or STMR-P, mg/kg	Process factor	HR or HR-P, mg/kg	Large portion, g/kg bw	Body weight, kg	Large portion, kg	Unit weight, g	% edible portion	Unit weight, edible portion, kg	Variability factor	Case	NESTI, mg/kg bw/day	% acute RfD
Fat Soluble Componds:															
MM 0095	Meat (mammalian)	*0.05				7.782	67	0.521			0.000		Case 1	0.0002	0.674
	Muscle 80% consumption				0.02	6.2256	67	0.417			0.000		-	0.0001	
	Fat 20% consumption				0.05	1.5564	67	0.104			0.000		-	0.0001	
PM 0110	Poultry meat	*0.05				6.436	67	0.431			0.000		Case 1	0.0003	1.073
	Muscle 90% consumption				0.05	5.7924	67	0.388			0.000		-	0.0003	
	Fat 10% consumption				0.05	0.6436	67	0.043			0.000		-	0.0000	
MO 0105	Edible offal (mammalian)	*0.05			0.05	3.104	67	0.208			0.000		Case 1	0.0002	0.517
PO 0111	Poultry, edible offal of	*0.05			0.05	3.299	67	0.221			0.000		Case 1	0.0002	0.550
ML 0106	Milks [in the fat] #1	*0.05	0.05		0.05	1.18616	67	0.079			0.000		Case 3	0.0001	0.198
PE 0112	Eggs	*0.05	0.05		0.05	1.703	67	0.114			0.000		Case 3	0.0001	0.284
GC 0080	Cereal grains	10	0.05		0.05	4.854	67	0.325			0.000		Case 3	0.0002	0.809
CF	Cereal grain milling fractions	20	0.05		0.05	5.189	67	0.348			0.000		Case 3	0.0003	0.865
CM	Early milling products	20	0.05		0.05	3.275	67	0.219			0.000		Case 3	0.0002	0.546

Case 1. Composite sampling data reflect the residue level in the food, based upon HR or HR-P
Case 2. Composite residue data do not reflect the residue level in individual food commodity units.
Case 2a. Unit weight edible portion is less than large portion weight.
Case 2b. Unit weight edible portion exceeds large portion weight.
Case 3. Processed commodity, where bulking or blending means that the STMR-P represents the likely highest residue

Notes:
#1: Dietary intake = 4% of ML entry.

Fenitrothion Acute Dietary Intake _ 2-6 years Date 23/06/2003

Acute RfD	0.03 mg/kg bw

Commodity

Code	Name	MRL mg/kg	STMR or STMR-P, mg/kg	Process factor	HR or HR-P, mg/kg	Large portion, g/kg bw	Body weight, kg	Large portion, kg	Unit weight, g	% edible portion	Unit weight, edible portion, kg	Variability factor	Case	NESTI, mg/kg bw/day	% acute RfD
Fat Soluble Componds:															
MM 0095	Meat (mammalian)	*0.05				13.715	19	0.261			0.000		Case 1	0.0004	1.189
	Muscle 80% consumption				0.02	10.972	19	0.208					-	0.0002	
	Fat 20% consumption				0.05	2.743	19	0.052					-	0.0001	
PM 0110	Poultry meat	*0.05				11.776	19	0.224			0.000		Case 1	0.0006	1.963
	Muscle 90% consumption				0.05	10.5984	19	0.201					-	0.0005	
	Fat 10% consumption				0.05	1.1776	19	0.022					-	0.0001	
MO 0105	Edible offal (mammalian)	*0.05			0.05	13.715	19	0.261			0.000		Case 1	0.0007	2.286
PO 0111	Poultry, edible offal of	*0.05			0.05	11.776	19	0.224			0.000		Case 1	0.0006	1.963
ML 0106	Milks [in the fat] #1	*0.05	0.05		0.05	3.053	19	0.058			0.000		Case 3	0.0002	0.509
PE 0112	Eggs	*0.05	0.05		0.05	0.847	19	0.016			0.000		Case 3	0.0000	0.141
GC 0080	Cereal grains	10	0.05		0.05	3.954	19	0.075			0.000		Case 3	0.0002	0.659
CF	Cereal grain milling fractions	20	0.05		0.05	2.629	19	0.050			0.000		Case 3	0.0001	0.438
CM	Early milling products	20	0.05		0.05	11.083	19	0.211			0.000		Case 3	0.0006	1.847

Case 1. Composite sampling data reflect the residue level in the food, based upon HR or HR-P
Case 2. Composite residue data do not reflect the residue level in individual food commodity units.
Case 2a. Unit weight edible portion is less than large portion weight.
Case 2b. Unit weight edible portion exceeds large portion weight.
Case 3. Processed commodity, where bulking or blending means that the STMR-P represents the likely highest residue

Notes:
#1: Dietary intake = 4% of ML entry.

9. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT REPORT

9.1 Background

The National Occupational Health and Safety Commission (NOHSC) reviewed fenitrothion in 1999.

In order to estimate exposure and determine the risk to workers using fenitrothion for the various agricultural activities (including re-entry), NOHSC followed the three-tiered approach comprising three levels of assessment based on the information available and adequacy of modelling, with increasing refinement of data requirements, such as specificity, as determined by the outcomes of the risk assessment.

In the absence of specific and/or adequate surrogate data and as a first tier approach, NOHSC utilized the UK POEM to estimate occupational exposure for ground applications. Modelling was conducted to determine exposure for workers using boomsprayers for locust control in broadacre and horticultural crops. Data were inadequate to estimate exposure for workers using misters and knapsack sprayers for perimeter spraying and spot spraying of certain broadacre and horticultural crops. Occupational exposure assessment for aerial applicators could not be modelled due to the lack of suitable model scenarios.

In conducting the occupational health and safety (OHS) risk assessment, occupational exposures estimated as described above were compared against the no-observable-effect-level (NOEL) of 0.2 mg/kg bw/d based on plasma ChE inhibition in females determined from a 12 month dietary study in dogs to calculate the Margin of Exposure (MOE), as a measure of risk.

POEM modelling revealed that occupational exposure during ground boom spraying was significant. The MOE calculated for ground boom spraying were found to be very low for users who mix, load and apply the chemical even with the use of personal protective equipment (PPE) and closed cabs. It was therefore concluded that fenitrothion posed unacceptable risks to the health of these workers.

Although it was not possible to conduct an OHS risk assessment for other ground and hand-held uses, NOHSC concluded that given the unacceptable risks determined for ground boom sprayers, that those other uses were likely to pose unacceptable risks to the health of workers.

Therefore, in the absence of suitable surrogate data, and in line with the tiered risk assessment approach, NOHSC recommended that measured worker exposure data be generated for fenitrothion uses by ground and hand directed spraying for locust control, and re-entry to treated areas.

This review considered the OHS risk assessment of fenitrothion using the PHED data-subsets and the submitted worker exposure studies in support of endosulfan and their implications on the previous OHS risk assessment of fenitrothion (June 1999).

The current review reports on the use of PHED to assess worker exposure to fenitrothion as well as the use of endosulfan exposure studies (Spraying- air assist spray) to extrapolate worker exposure to fenitrothion during ground applications. Assessment of worker exposure to fenitrothion during re-entry activities was extrapolated from re-entry exposure data supplied for endosulfan.

9.2 Occupational Exposure & Risk Assessment

9.2.1 End use- exposure and risk assessment using PHED

In the 1999 review of fenitrothion, Sumitomo Chemical Australia Pty Ltd submitted occupational exposure estimates derived from PHED together with calculated MOE (20 October 1998). The information provided pertained to occupational exposure during mixing and loading and applying the

prepared spray by ground boom spraying of broad acre crops and hand spraying of poultry houses with EC fenitrothion.

The following parameters were used in the PHED exposure estimates for ground boom scenarios:

- 350 grams of active ingredient in 100 litres of water
- 100 litres of spray per hectare
- 20 hectares per hour
- 6 hours of spraying per day

The total exposures and MOE from PHED data-subsets provided for ground boom and hand-held spray applications for workers wearing long pants and long sleeved shirts are outlined in Table 1.

However, details or print-outs of the PHED data-subsets created to estimate worker exposure and calculate MOE were not provided. In the absence of such details it was not possible to determine the identity and grading of the PHED surrogate studies utilised, and therefore the reliability of the data, measured by quality and replicates for each estimate, could not be established.

In its current assessment, NOHSC has re-calculated worker exposure using the parameters submitted in 1999, but created new PHED data-subsets to reflect the use-pattern and use conditions in Australia to estimate occupational exposures resulting from hand-held use and application methods (Table 17).

Exposure to the product or the spray was estimated with workers wearing normal clothing (long pants and long sleeved shirts) with or without gloves. For some use scenarios, PHED contained no data-subsets (i.e. exposure studies) in which observations were recorded for hand exposure measures (presented in parentheses, Table 17). Therefore, hand contamination in such subsets cannot be determined and thus, total exposure values from these subsets are incomplete and as such are unacceptable. In addition, subsets with very low numbers of observations reported were also considered unacceptable (values with asterisk).

The MOE were calculated by comparing occupational exposures estimated from PHED with the NOEL of 0.2 mg/kg bw/d based on plasma ChE inhibition in females determined from a 12 month dietary study in dogs. Considering the intra-species variability and to account for interspecies differences, MOE of 100 or above are considered acceptable.

Table 16: Occupational exposure calculated from PHED data-subsets and MOE for ground boom and hand-held applications (Fenitrothion Technical OH & S Assessment, NOHSC, 1999).

Type of application	Exposure[(1)] (mg/kg bw/day)	Margin of Exposure[(2)] (NOEL 0.2 mg/kg bw/day)
Groundboom (at 350 g ai/ha)		
Mixer/loader, open mixing, no gloves	28.38	0.07
Mixer/loading, open mixing, gloves	3.10	0.65
Mixer/loader, closed mixing, no gloves	No data	
Mixer/loader, closed mixing, gloves	0.01	259.89
Applicator, open cab, no gloves	0.12	16.99
Applicator/open cab, gloves	0.06	34.41
Applicator, closed cab, no gloves	0.03	73.19
Applicator, closed cab,Gloves	0.04	45.79
Mixer/loader/applicator, open mixing, no gloves	0.10	20.00
Hand-held application (at 1000 g ai/100 L water)		
Mixer/loader/applicator, open mixing, no gloves	0.01	233.88

(1) Only dermal exposure considered for mixer/loader/applicators

(2) MOE calculated using oral NOEL of 0.2 mg/kg bw/day and 10% dermal absorption

The total exposure, absorbed dose and MOE are outlined in Table 17.

Table 17: Total occupational exposure estimated from PHED data-subsets, absorbed dose and MOE for ground boom and hand-held applications

Scenarios	Study reference (replicates)	Active ingredient used/day (kg)	Exposure (mg/kg bw/day)			Total absorbed dose (mg/kg bw/day)	MOE		
			Dermal	Inhalation	Total		Dermal	Inhal.	Total
GROUND BOOM APPLICATION									
Mixer/loader									
Mixer/loader, open mixing, no gloves[#]	1 (16)	42	(0.00714)	(0.000046)	(0.0071846)	(0.0007603)	(280)	(4348)	(263)
Mixer/loader, open mixing, gloves[#]	1 (16)	42	0.01366	0.000046	0.0137119	0.001413	146	4348	141
Mixer/loader, closed mixing, no gloves[*$]	2 (4)	42	(0.02941)	(0.000620)	(0.0300267)	(0.003567)	(68)	(322)	(56)
Mixer/loader, closed mixing, gloves[*$]	2 (4)	42	0.04719	0.000620	0.0478155	0.00534	42	322	37.4
Applicator									
Applicator, open cab, no gloves [#]	3 (19)	42	0.02429	0.000723	0.0250176	0.0031526	82	276	63
Applicator, open cab, gloves[#]	3 (19)	42	(0.008677)	(0.000723)	(0.0094)	(0.0015908)	(230)	(276)	(126)
Applicator, closed cab, no gloves [$]	4 (6)	42	0.00709	0.000018	0.0071086	0.0007275	282	111111	275
Applicator, closed cab, gloves [$]	4 (6)	42	(0.00414)	(0.00018)	(0.0041549)	(0.0004321)	(483)	(11111)	(462)
Mixer/loader/applicator[W]									
Mixer/loader/applicator, open mixing, no gloves[$]	5 (43)	42	0.45090	0.00157	0.4525009	0.0466628	4.5	127	4.2
Mixer/loader/applicator, open mixing, gloves [$]	5 (43)	42	0.07319	0.00157	0.0747607	0.0088917	27	127	22.5
Mixer/loader/applicator, closed mixing			No records available				-	-	-
HAND-HELD APPLICATION									
Mixer/loader									
Mixer/loader, open mixing, no gloves[#]	1 (16)	4.78	(0.0008123)	(0.0000053)	(0.008176)	(0.0000865)	(2463)	(37735)	(2312)
Mixer/loader, open mixing, gloves[#]	1 (16)	4.78	0.001555	0.0000053	0.0015605	0.0001608	1286	37735	1243
Mixer/loader, closed mixing, no gloves*[$]	2 (4)	4.78	0.0033467	0.0000706	0.0034173	0.0004052	498	2833	494

Scenarios	Study reference (replicates)	Active ingredient used/day (kg)	Exposure (mg/kg bw/day)			Total absorbed dose (mg/kg bw/day)	MOE		
			Dermal	Inhalation	Total		Dermal	Inhal.	Total
Mixer/loader, closed mixing, gloves [*] [$]	2 (4)	4.78	0.0053712	0.0000706	0.0054418	0.0006077	372	2833	329
Applicator									
Applicator, Hand wand (low pressure),no gloves [$]	6 (13)	4.78	1.80616	0.121828	1.928032	0.302444	1	1.5	<1
Applicator, Hand wand (low pressure), gloves [$]	6 (13)	4.78	1.06719	0.121828	1.189021	0.228547	1.8	1.5	<1
Applicator, Hand wand (high pressure) no gloves [$]	7 (9)	4.78	(0.10297)	(0.11777)	(0.114776)	(0.128067)	19)	(1.7)	(1.5)
Applicator, Hand wand (high pressure), gloves [$]	7 (9)	4.78	0.105091	0.11777	0.116868	0.128279	19	1.7	1.5
Mixer/loader/applicator									
Mixer/loader/applicator, Hand wand (low pressure), no gloves [$]	8 (9)	4.78	(0.029309)	(0.00392)	(0.033235)	(0.006851)	(68)	(51)	(29)
Mixer/loader/applicator, Hand wand (low pressure), gloves [$]	8 (9)	4.78	0.029623	0.0039257	.0335488	0.006889	68	51	29
Mixer/loader/applicator, Hand wand (High pressure)			No records available				-	-	-

Dermal and inhalation exposures are adjusted for total active ingredient handled per day.
Values in parentheses represent estimates where observations on hand contamination were not available.
Values in square brackets indicate PHED record numbers for each subset; please refer to the reference list.
[Ω]Open cab application; scenarios for closed cab applications for Mixer/loader/applicator are not available.
* refers to values where the estimate subsets had less than 5 observations.
[#] Grade AB; [$]Grade ABC (Each study in PHED has been graded from "A" to "E" according to quality of the study. PHED runs having any combination of A and B grade or A, B and C grade data are listed as 'Grade AB' or Grade ABC, respectively).
Daily dermal or inhalation exposure (mg ai/kg bw/day)=geometric mean exposure obtained from PHED calculation (µg/kg ai handled/day) x 42 kg ai÷70 kg (bw)/1000.
Daily dermal absorbed dose= Daily dermal exposure (mg ai/kg bw/day) x 0.1 (10% dermal absorption); Daily inhalation absorbed dose is same as inhalation exposure considering 100% absorption from the inhalation route.
MOE (NOEL/daily exposure) were calculated separately for dermal and inhalation exposures and for combined dermal and inhalation (total) exposure.

Ground boom applications

Mixer/loader exposure

PHED calculations indicate that mixer/loader exposure to fenitrothion using gloves is low when using an open system. Exposures determined without gloves are unreliable because no hand contamination measures were available. Exposures determined for closed mixing systems without gloves are also unreliable due to the lack of hand contamination measures and the small number of replicates reported. As already discussed, the data-subsets identified for the closed mixing/loading scenario with gloves cannot be used to determine hand contamination (see above and Table 2).

Applicator exposure

Applicator exposure during ground boom application is high when open cabs, and no gloves, were used, but is significantly reduced when closed cabs without gloves were used. Exposures determined from other data-subsets for both open and closed cabs (with gloves) are not reliable due to the small number of replicates available.

Worker exposures resulting from both activities combined; that is, the same worker carries out M/L/A, were found to be significant when open cabs were used (with and without gloves). No data are available for closed cabs.

Hand-held spray applications

Data-subsets were identified for hand wand spray applications with both high and low pressure sprayers. Although exposures resulting from open or closed mixing and loading activities were low whether gloves were used or not, only those obtained when using open system and gloves are reliable (see Table 17). However, applicator exposure was found to be significantly high regardless of glove use. Again, M/L/A exposures in all scenarios were found to be significantly high.

Discussion

The above exposure estimates reveal that for the reliable PHED subsets, total MOE for M/L/A are very low indicating that the risk to the workers using fenitrothion for ground boom and/or hand-held applications is unacceptable. Although mixing/loading activities revealed acceptable risk to workers generally, the same does not apply for application activities using different application methods. However, these are not considered independently given that the same worker carries out both mixing/loading and application. The PHED search investigated various scenarios of PPE combinations and engineering controls (e.g. closed cabs), but no other relevant data-subsets were available (Table 17).

9.2.2 End-use- Exposure and risk extrapolated from endosulfan worker exposure studies

In July 2001, NOHSC were requested to provide advice on the suitability of additional OH&S data provided for endosulfan to support the locust use patterns of fenitrothion for mixing/loading/application using ground application equipment.

It must be noted that the fenitrothion EC formulations are used for locust control in broadacre (including pastures) and horticultural crops and are applied by either ground or aerial application. The ULV formulations are used for aerial spraying.

The worker exposure studies submitted for endosulfan (July 2002) used the EC formulation for ground and aerial applications.

The studies were undertaken during the 1999/2000 and the 2000/2001 seasons and were conducted at 11 different sites in south eastern Queensland. The study subjects were workers undertaking mixing loading and application of endosulfan, using air-assist spray, and cleaning operations. It should be

noted that in practice, the operation of mixing/loading and spraying is mostly undertaken by the same operator as part of the one operation.

The EC formulation of endosulfan @ 350 g ai/L, diluted at the rate of 150 mL/100 L of water, were used in the study. The application rates used were generally in accordance with label specifications for tree crops and nurseries.

To measure dermal exposure, chromatographic paper patches were fixed either on the singlets or overalls of workers, or fixed on cloth pads (10 cm x 10 cm size), which were placed on the internal and external shoulder, back and front of neck, forearms, thigh, knees, and lower leg and foot. Cotton gloves were used to measure residue deposition on hands.

A member of the field monitoring team (but not involved in mixing/loading) was 'patched' with three field blanks, which served as background counts. Some patches and gloves were also fortified with levels expected for actual exposure and exposed to weather.

Meteorological conditions for the subjects and the sessions were recorded.

Endosulfan was extracted from the patches with hexane and quantified by gas chromatography

A short summary for each of the studies conducted in nurseries and tree crops is outlined below. The various parameters and assumptions used in the studies are included in Table 4.

- *Worker exposure to endosulfan (EC) in the course of application to nursery crops (Mixing/loading)– Lyn Fragar, Report No. H-3-1 (February, 2002) and*
- *Worker exposure to endosulfan (EC) in the course of application in tree crops (Mixing/loading)– Lyn Fragar, Report No. H-1-1 (February, 2002).*

The above two studies were conducted to define levels of worker exposure to endosulfan when mixing and loading endosulfan products for spraying of nursery and tree crops. Endosulfan was stored in its original container, fully labelled in a cool, locked, ventilated area. The workers mixed the endosulfan by first pouring the concentrate from 10/20 L steel drums into cylinder measuring jugs. The endosulfan was then poured into 200 L spray tanks with water. The pad and mixing area were considered to be contaminated areas. Where possible, mixing/loading was carried out in conditions where the wind would blow any spray or fumes away from the workers, thereby minimising the risks of inhaling spray or fumes and contamination of equipment.

- *Worker exposure to endosulfan (EC) in the course of application to nursery crops (Spraying)– Lyn Fragar, Report No. H-3-2 (February, 2002).*
- *Worker exposure to endosulfan (EC) in the course of application in tree crops (Spraying air-assist spray-tractor without cabin)– Lyn Fragar, Report No. H-1-2U (February, 2002).*
- *Worker exposure to endosulfan (EC) in the course of application in tree crops (Spraying air-assist spray-tractor with cabin)– Lyn Fragar, Report No. H-1-2C*

The above three studies were conducted to define levels of worker exposure to endosulfan when spraying in nurseries, and tree crops using air-assist spray-tractor with and without cabins. It must be noted that, in practice, the operation of mixing/loading and spraying are mostly undertaken by the same operator as part of one operation.

The typical operation of spraying in nurseries is by a spray tank on a trailer with a retracting hose and a handgun that moves forwards and backwards to cover the whole nursery. The two types of spray systems used in nursery applications are high- and low-pressure systems. The high-pressure system tends to produce fine mister spray, whereas the low-pressure system tends to produce a lower pressure with larger droplets. Nozzles can be adjusted in both systems, which also impacts on the rate and size of the spray pressure. Both systems were used in the study.

In air-assisted sprayers, (tractors with and without cabins), the spray droplets are generally produced by standard hydraulic nozzles with air blown over the nozzle or spray plume to direct the spray into the tree canopy.

A comparison of the parameters used in the endosulfan study and those while using fenitrothion are outlined in Table 18.

Table 18: Parameters used in the endosulfan study and while using fenitrothion for treatment of broadacre and horticultural crops

Parameters	**Endosulfan**	**Fenitrothion**
Formulation/conc of ai g/L	EC 350	EC 1000; ULV 1280
Application rate	199-666 mL/100L (nursery) 30-160 mL/100L (tree crops)	0.25-1.3 L/ha
Spray volume (kg ai handled/day)	25-200 L (nursery) (0.04-0.13) 750-2100 L (tree crops) (0.39-1.103)	5000 L/day (EC) ***(12.5-65-ground application)*** 1000 L/day (ULV) (1280–aerial application)
Application equipment	Spray tank on a trailer with retracting hose and hand gun (nursery) Air-assist sprayers with and without cabin (tree crops)	EC-Hand-held sprayers, knapsack sprayers, small booms mounted on ATVs (all terrain vehicles) ULV-aerial
Crops	Nursery Tree crops	Broadacre (including pastures) and horticultural crops
PPE	Waterproof or cotton overalls done up to neck and wrists (or full-length waterproof apron), washable cotton hat, full face shield/or goggles and half-face respirator, elbow-length gloves and water resistant footwear	Cotton overalls buttoned to the neck and wrist,a washable hat, elbow-length PVC gloves and faceshield

The parameters used for mixing/loading and application of endosulfan in nurseries and tree crops are presented in Table 19

Table 19: Parameters used for mixing/loading and application of endosulfan in nurseries and tree crops

Parameters	**Mixing/Loading Nursery (Study H-3-1)**	**Mixing/Loading Tree crops (Study H-1-1)**	**Application Nursery (Study H-3-2)**	**Application Tree crops (Study H-1-2U)***	**Application Tree crops (Study H-1-2C)****
Formulation & concentration of active ingredient (ai)	EC 350 g ai/L	EC 350 g ai/L	EC 350 g ai/L	EC 350 g ai/L	EC 350 g ai/L
Number of subjects/replicates	8/12	16/19	12/18	7/15	14/23
Duration of study(days)/ No. of sites	5/5	7/7	6/7	3/3	8/8
Time taken for procedure (minutes)	4-16	5-65	15-76	16-50	20-55
Application rate	190-666 mL/100 L	30-375 mL/100 L	190-666 mL/100 L	150 mL/100 L	30-60 mL/100 L
Spray volume	25-200 L	750-2100 L	25-200 L	100-1500 L	500-2100 L
Total active ingredient (ai) handled/day	0.03-0.13	0.39-1.103	0.39-1.103	0.05-0.79	0.052-1.102
Container size	10/20 L	20 L	10/20 L	20 L	20 L
Tank size	200 L	1200-3000 L	200 L	1200-3000 L	1200-3000 L
Tasks involved	Transport of pesticide drums, transferring chemicals to and from the storage area, pouring and mixing the chemical, loading the spray unit, removing empty containers from the working area and cleaning up spills.		Towing trailer to site, unrolling spray hose, spraying nursery beds, rolling up hose to move to new area		
PPE	Waterproof or cotton overalls done up to neck and wrists (or full-length waterproof apron), washable cotton hat, full face shield/or goggle, and half-face respirator, elbow-length gauntlet gloves and water resistant footwear.		Waterproof or cotton overalls done up to neck and wrists (or full-length waterproof apron), washable cotton hat, full face shield/or goggle, and half-face respirator, elbow-length gauntlet gloves and water resistant footwear.		

*Spraying air-assisted, no cabin;
**Spraying air-assisted, cabin

Measured dermal exposure values for mixer/loaders/applicators determined from the endosulfan studies were used to estimate absorbed dose of fenitrothion in workers (Table 20) and subsequently to calculate the MOE (Table 21).

Table 20: Exposure during application of endosulfan formulations in nursery and orchard (tree) crops and estimated absorbed dose of fenitrothion using the endosulfan study data

Situation	Standardised measured exposure in endosulfan studies mg/kg bw/kg ai handled[a]				Estimated absorbed dose of Fenitrothion mg/kg bw/day[b]			
	Mixing / loading	Application	Cleaning down	Total	Mixing / loading	Application	Cleaning down	Total
Nursery crops	0.0043	0.0082	0.0024	0.0149	0.0181	0.03444	0.01008	0.0626
Orchard crops (no cab)	0.0005	0.0048	0.0005	0.0058	0.0021	0.02016	0.0021	0.0244
Orchard crops (with cab)	0.0005	0.0014	0.0005	0.0024	0.0021	0.00588	0.0021	0.0101

[a]Calculated from the extrapolated whole body exposure using the endosulfan deposition on patch or glove samples on different body parts of workers
[b]Estimated absorbed dose = exposure to endosulfan x the amount of fenitrothion handled/day (42 kg) x 10% dermal absorption

Table 21 Margin of Exposure (MOE) estimates for workers during mixing/loading and application of fenitrothion

Situation	MOE[a]			
	Mixing/loading	Application	Cleaning down	Total
Nursery crops	11	6	20	3
Orchard crops (no cab)	95	10	95	8
Orchard crops (with cab)	95	34	95	20

[a]MOE = NOEL (0.2 mg/kg bw/day)/absorbed dose (mg/kg bw/day)

Discussion

Nursery crops

The above extrapolated exposure estimates for fenitrothion, determined by standardising the exposure values from the endosulfan-measured exposures, reveal significant exposures during mixing, loading and application activities determined in the nursery (hand-held) study (Table 20). Individual and total MOE for mixer/loader/applicators and cleaners (M/L/A/C) were low indicating unacceptable risk to workers (Table 21).

Orchard (tree) crops

Although exposure was low for mixing/loading and cleaning activities extrapolated from data from the tree crop studies, exposure for applicators not using cabins was high. Applicator exposure using cabins improved to some extent while using cabins, but was still considered low (Table 20). Individual MOE for mixer/loaders/cleaners for workers using and not using cabins were acceptable, however total MOE for mixer/loader/applicators/cleaners (MLAC) were not acceptable. The risk to workers is therefore unacceptable.

It must be noted that exposure for workers was reduced, and the MOE increased to some extent, when tractors with cabins were used, however the improved MOE were <100 highlighting that the risk to workers is significant and unacceptable.

9.2.3 Re-entry- exposure and risk extrapolated from endosulfan re-entry and DFR measured data

Following the OH&S assessment of fenitrothion in 1999, it was identified that re-entry exposure and risk for workers spending substantial time checking locust and other kills soon after spraying could not be quantified. From subsequent records (July 2002 report) the time spent in treated fields conducting re-entry activities was determined to be 2 hours, and therefore the endosulfan exposure data were standardised to 2 hours of fenitrothion re-entry activities. A study of a representative number of workers was recommended to a) establish the exposure to fenitrothion residues and b) to set a re-entry interval after spraying, when the risk is acceptable for workers to re-enter treated areas to conduct this activity.

Re-entry studies for fenitrothion were not provided, instead, re-entry exposure data for workers involved in cotton chipping (RC 1-1), crop checking (RC 1-2) and irrigation (RC 1-3), siphon (RC 1-4) and foliar residue (RC 1-5) data from areas treated with endosulfan were provided to be used as surrogate data to estimate the re-entry risk for workers spraying fenitrothion to kill locusts.

The measured dislodgeable foliar residues (DFRs) for endosulfan were used to evaluate fenitrothion re-entry risks. Because the vapour pressure of fenitrothion is much higher than that of endosulfan, it is expected that it would volatilise off leaves much faster than would endosulfan. For this reason, use of endosulfan DFR values should be appropriately conservative in assessing risks to workers when re-entering areas treated with fenitrothion.

The following two studies were used as surrogate data to estimate exposure for workers re-entering areas treated with fenitrothion:

- *Worker exposure to Endosulfan (EC) in the course of re-entry in broadacre cropping industries, Study RC 1-2:Crop Checking, Lyn Fragar, (February, 2002).*

- *Worker exposure to Endosulfan (EC) in the course of re-entry in broadacre cropping industries, Study RC 1-5, Foliar Residue, Lyn Fragar, (February, 2002).*

The above two studies were undertaken to estimate exposure for workers entering areas treated with endosulfan by ground rig and aerial applications for the purpose of crop checking at three study sites, (RC 1-1A, RC 1-1B, RC 1-1C), and to estimate endosulfan residue deposition following aerial application of endosulfan at two study sites (RC 1-1B and RC 1-1C).

In the Crop Checking Study (RC 1-2), ten dosimetry-patched workers wearing full length cotton trousers, long sleeved cotton shirts, washable cotton hat, cotton gloves and boots were allowed to enter the field 48 hours after endosulfan application for their normal work which included checking the crops for pests, counting flowers, bolls, number of nodes and measuring plant height in 1 linear metre of crop. This was then repeated once at random within sprayed block. The crop checkers usually spent 30 minutes in the field.

The points/areas of potential contamination were identified as during contact with contaminated leaves, plants and soil, and while moving around sprayed sites.

In the Foliar Residue Study (RC 1-5) endosulfan residues deposition on foliar samples and the dissipation pattern on the foliage were studied. Sixty 22 mm leaf discs (total surface area was 228.17 cm^2) were cut from leaves sampled at random from the first fully expanded leaf on primary and secondary terminals. The leaf discs were then placed in 350 mL jars, sealed and sent for analysis. This procedure was repeated for each of the three blocks of the selected site.

Details of the parameters used in both studies are outlined in Table 22.

Table 22: Parameters used in the Crop checking and Foliar Residue Studies

Study site	Activity	Application method	Volume of endosulfan (350 EC) applied (L)	Total volume of spray mix applied (L)	Total endosulfan active ingredient used (kg)	Area sprayed (ha)	Rate (ai g)/ha	Crop height (cm)	Post application re-entry days
RC 1-1A	Crop checking	Ground rig	98	1400	34.3	46.7	735	82	2,3,4,5,7,13
RC 1-1B	Crop checking	Aerial	21	300	7.35	10.00	735	26	2,3,4
RC 1-1C	Crop checking	Aerial	21	300	7.35	10.00	735	26	2,3,4
RC 1-5A	Foliar residue estimation	Aerial	98	1400	34.3	46.67	735	82	-1[(1)],0,1,2,3,4,5,7,13
RC 1-5B	Foliar residue estimation	Aerial	4.2	60	1.47	2	735	26	-1[(1)],0,1,2,3,4,5

[(1)] refers to entry the day before spraying

To determine a re-entry interval for fenitrothion, measured dermal exposure data, and DFR data from the endosulfan re-entry studies were standardised to the application rate and dermal absorption factor for fenitrothion. The results are presented in Tables 23 and 24 respectively.

Table 23: Measured dermal exposures for workers re-entering endosulfan treated fields and extrapolated exposure values and Margins of Exposure (MOE) for fenitrothion

Crop checking study	Re-entry time (hours)	Standardised measured dermal exposure based on endosulfan studies (mg/kg bw/day)[(1)]	Estimated absorbed dermal dose of fenitrothion (mg ai/kg bw/day)[(2)]	MOE[(3)]
RC 1-2A (ground-rig)	48	0.0025	0.00025	790
	72	0.0011	0.00011	1871
	96	0.0008	0.00008	2602
	120	0.0005	0.00005	4437
	168	0.0004	0.00004	5122
	312	0.0002	0.00002	9782
RC 1-2B (aerial)	48	0.0005	0.00005[(4)]	4192
	72	0.0005	0.00005	4176
	96	0.0003	0.00003	6774
RC 1-2C (aerial)	48	0.0010	0.00010	2086
	72	0.0006	0.00006	3580
	96	0.0004	0.00004	4943

[(1)] Geometric mean of measured (dosimeters) dermal exposure (mg/kg bw/day) based on 2 hours of re-entry activites.
[(2)] Absorbed dermal dose (mg ai/kg bw/day) = dermal exposure measured in endosulfan studies x 10% dermal absorption
[(3)] MOE = NOEL (0.2 mg/kg bw/day) ÷ absorbed dose (mg ai/kg bw/day)
[(4)] Extrapolated from data using EC formulation of endosulfan. However, ULV formulation of fenitrothion is used for aerial applications

Discussion

In Table 23 it is noted that measured exposure data were available for workers after a 48 hr re-entry period only. Based on a 2-hour exposure period for workers conducting crop checking, a dermal absorption factor of 10%, and the standardised MOE determined from the EC endosulfan ground-rig application study (RC 1-1A), measured exposure data were found to be high, and the risk acceptable for workers entering fields treated with EC fenitrothion for crop checking after 48 hours and later.

The standardised MOE determined from the EC endosulfan aerial application studies (RC 1-2B, and RC 1-2C), measured exposure data were found to be acceptable for workers entering fields treated with the ULV fenitrothion formulation at 48 hours following application.

To estimate re-entry exposure at other time intervals and determine a suitable re-entry interval, the dislodgeable foliar residue (DFR) values and specific (Table 24) and generic (Table 25) transfer coefficients (TC) were used. The specific TC (21 and 11) were determined from the measured endosulfan exposure data provided for the various re-entry activities. The generic TC (486-2760) were empirically developed TC for defined crop groups (provided in the USEPA Policy 003.1 Occupational Post Application Risk Assessment Calculator Version 1). An exposure duration of 2 hours/day, and an application rate of 1.28 kg ai/ha (ULV fenitrothion, aerial application) was used to standardise the data and determine the MOE. The results are presented in Table 24.

Table 24: Dislodgeable foliar residues from the EC endosulfan aerial application study standardized to ULV fenitrothion aerial application, using specific transfer coefficient

Study Sites/ Crop Height	Foliar sampling days	Measured DFR Endosulfan[(2)] µg/cm^2	TC Endosulfan[(3)]	Calculated Dermal Exposure Endosulfan[(4)] mg/day	Standardised dermal absorbed dose[(5)] Fenitrothion (mg/kg bw/day)	MOE[(6)] Fenitrothion
RC 1-5A	-1[(1)]	0.0011	21	0.0002	0.0000005	400000
82 cm	0	2.826		0.47	0.001	200
	1	4.927		0.8	0.002	100
	2	2.526		0.4	0.001	200
	3	0.444		0.07	0.0002	1000
	4	0.48		0.08	0.0002	1000
	5	0.278		0.05	0.0001	2000
	7	0.332		0.06	0.0001	2000
	13	0.15		0.03	0.0001	2000
RC 1-5B	-1	0.0019	11	0.0002	0.0000004	500000
26 cm	0	3.003		0.26	0.001	200
	1	3.407		0.30	0.001	200
	2	0.929		0.08	0.0002	1000
	3	0.582		0.05	0.0001	2000
	4	0.381		0.03	0.0001	2000
	5	0.263		0.02	0.0001	2000

(1) refers to the day before endosulfan was sprayed
(2) DFR: Dislodgeable Foliar Residues, based on endosulfan at concentrations of 34.3 kg ai, and 1.47 kg ai used/day (both achieving ~750 g ai/hectare) in study sites RC1-5A and RC1-5B
(3) TC: Transfer coefficient was calculated using measured dermal exposures and measured DFR for endosulfan (aerial application); TC (cm^2/hr) = dermal exposure (mg/day) / (time spent on activity hr/day x DFR mg/cm^2).
(4) Dermal exposure for endosulfan at various entry times was calculated using the specific TC (see note 3) and DFR at each time point adjusted for 8 hours.
(5) Dermal exposure standardised based on the amount of fenitrothion ULV at 1.28 kg ai/hectare according to label rates.
(6) MOE (Margins of exposure)=NOEL (0.2 mg/kg bw/day) ÷ absorbed dose (mg ai/kg bw/day)

The above estimates indicate a safe re-entry interval on application day using the specific TC (21, 11) determined from the measured dermal exposure data when DFR samples were collected 2 hours after spraying. However, it was noted that DFR increased by 2 fold on day 1 following application. The study authors believe that this could be a result of incomplete settlement of air residues, and accordingly NOHSC excluded this data. A safe re-entry interval (MOE 769) on day 2 (48 hours) following application, based on 2 hours of activity was determined.

As a comparison, MOE were determined for fenitrothion using DFR data provided in the endosulfan studies, and generic TC (ranging from 486-2760 for the different activities). The data are presented in Table 25:

Table 25: Dislodgeable foliar residues from the EC endosulfan aerial application study standardized to ULV fenitrothion aerial applications, using generic transfer coefficients.

Study Sites/ Crop Height	Foliar sampling days	Measured DFR Endosulfan[2] µg/cm^2	Transfer coefficient[3]	Extrapolated DFR For Fenitrothion[4] µg/cm^2	Standardised dermal absorbed dose[5] Fenitrothion (mg/kg bw/day)	MOE[6] Fenitrothion
RC 1-5A	-1[1]	0.0011	486-2760	0.002	0.000003-0.00002	66,666-10,000
	0	2.826		4.82	0.0066-0.038	28-5.6
82 cm	1	4.927		8.41	0.012-0.066	16-3
	2	2.526		4.31	0.006-0.034	33-5.8
	3	0.444		0.76	0.001-0.006	200-33
	4	0.480		0.82	0.001-0.006	200-33
	5	0.278		0.47	0.0006-0.004	333-50
	7	0.332		0.57	0.0008-0.004	250-50
	13	00.150		0.26	0.0004-0.002	500-100
RC 1-5B	-1	0.0019	486-2760	0.003	0.000004-0.00002	50,000-10,000
	0	3.003		5.13	0.007-0.04	28-5
26 cm	1	3.407		5.81	0.008-0.046	25-4.3
	2	0.929		1.59	0.002-0.01	100-20
	3	0.582		0.99	0.001-0.008	200-25
	4	0.381		0.65	0.0009-0.005	220-40
	5	0.263		0.45	0.0006-0.004	333-50

[1] refers to the day before endosulfan was sprayed
[2] DFR: Dislodgeable Foliar Residues, based on endosulfan at concentrations of 34.3 kg ai, and 1.47 kg ai used/day (both achieving ~750 g ai/hectare) in study sites RC1-5A and RC1-5B
[3] Transfer coefficient used is the generic value provided for Field/row crop, low/medium Group, for forage plants, low height and full foliage development (scouting activity with medium exposure potential) provided in the USEPA Policy 003.1 Occupational Post Application Risk Assessment Calculator Version 1
[4] based on the amount of fenitrothion ULV at 1.28 kg ai/hectare according to label rates.
[5] dermal exposure standardised using the formula DFR (µg/cm^2) x Transfer coefficient÷1000 (µg/mg) X 2 hours/day/70 kg body weight
[6] MOE (Margins of exposure)=NOEL (0.2 mg/kg bw/day) ÷ absorbed dose (mg ai/kg bw/day)

Discussion

The use of generic TC shows that the MOE, and the safe re-entry intervals, differ from the MOE determined using the specific TC. Safe re-entry is obtained on day 2 (48 hours) with MOE 100 using a TC of 486 and crop height 26 cm, and on day 3 (72 hours) with MOE 200 using a TC of 486 and crop height 82 cm.

As measured exposure data provided acceptable MOE at 48 hours (MOE, 790), and DFR data using specific TC (21 for crop checking activities) at 48 hours also provided acceptable MOE (MOE, 769), NOHSC considers the endosulfan measured dermal exposure data and MOE determined for crop checking activities using specific TC to be more appropriate to determine a safe re-entry interval for workers entering treated fields.

9.3 Conclusions and recommendations

This review considered the OHS risk assessment of fenitrothion using the PHED data-subsets and the submitted worker exposure studies in support of endosulfan, and their implications on the previous OHS risk assessment of fenitrothion (NOHSC, 1999).

9.3.1 End-use

The end use worker exposure studies on endosulfan (H-3-1, H-3-2, H-1-2U, H-1-2 U, H-1-2C) were considered suitable surrogate data to estimate exposure for workers using the EC formulation and ground application equipment to treat broadacre and horticultural crops with fenitrothion. It is noted that this review conducted an extensive analysis and assessment of PHED subsets (based on measured worker exposure studies) and the provided endosulfan data, which showed that the risk to workers was unacceptable for all these uses. Table 26 shows a summary of the total MOE.

Table 26: Standardised MOEs for fenitrothion based on PHED and worker exposure studies provided for endosulfan

Source	Total MOE[1] M/L/A
PHED[2]	
Ground boom application (42 kg ai/day)	4.2 (no gloves)
	22.5 (gloves)
Hand-held application (4.78 kg ai/day)	29 (no gloves)
	29 (gloves)
Endosulfan studies[3]	
Nursery (hand-held) (42 kg ai/day)	4
Air-assisted Ground boom, no cab (Tree crop) (42 kg ai/day)	3
Air-assisted Ground boom, with cab (Tree crop) (42 kg ai/day)	28

[1]Based on exposures measured for workers performing mixing, loading and spray application
[2]PPE used was: long pants, long sleeved shirt and with or without gloves; exposure included both dermal and inhalation.
[3]PPE used was: waterproof or cotton overalls done up to neck and wrists (or full-length waterproof apron), washable cotton hat, full face shield/or goggle, and half-face respirator, elbow-length gauntlet gloves and water resistant footwear. Only dermal exposure was measured.

Recommendation

Based on the risk assessment, NOHSC cannot endorse the continued use of fenitrothion by ground boom and hand held applications. In addition, no data for aerial EC application were provided and therefore the risk to workers cannot be determined.

9.3.2 Re-entry

Crop checking following ground rig and aerial applications were considered suitable surrogate data to estimate exposure for workers entering areas treated with the fenitrothion EC formulation using ground and aerial application equipment.

Recommendation

Based on extrapolated estimates, NOHSC recommends a re-entry interval of 48 hours (2 days) following ground and aerial application of fenitrothion.

9.4 References

Fragar, L (2002). Dislodgeable Foliar Residue. Report No. RC -1-5.

Commonwealth Department of Health and Family Services and National Occupational Health and Safety Commission (1998). Handbook of First Aid Instructions and Safety Directions. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994). Control of Workplace HazardousSubstances [NOHSC:1005(1994), 2007(1994)], Australian Government Publishing Service,Canberra.

National Registration Authority (1997) The NRA Review of Fenitrothion, Existing Chemical Review Program, Canberra, Australia.

PHED (2002). Record numbers: 0422*A*01, 0422*A*02, 0427*A*01, 0427*C*02, 0427*E*03, 0427*G*01, 0440*KM*02, 0440*NV*01, 1001*M*01, 1001*M*02, 1001*M*03, 1001*M*04, 1001*M*05, 1001*N*01, 1001*N*02, 1001*N*03.

PHED (2002). Record numbers: 1001*I*03, 1001*I*04, 1001*K*03, 1001*K*04.

PHED (2002). Record numbers: 0427*F*03, 0427*H*01, 0437*JF*01, 0437*RT*03, 0437*TS*02, 0438*PA*01, 0438*PA*02, 0438*PA*03, 0440*CS*02, 0440*JE*01, 0465*D*1, 0465*E*1, 0465*F*1, 1025*AA*01, 1025*BB*01, 1025*CC*01, 1025*GG*01, 1025*HH*01, 1025*II*01.

PHED (2002). Record numbers: 0423*C*01, 0423*E*02, 0427*B*01, 0427*D*02, 0502*KM*01, 0502*RM*01.

PHED (2002). Record numbers: 0411*I*1, 0411*I*2, 0411*I*3, 0411*I*4, 0411*I*5, 0411*I*6, 0411*J*1, 0411*J*2, 0411*J*3, 0411*J*4, 0411*J*5, 0411*J*6, 0411*K*1, 0411*K*2, 0411*K*3, 0411*K*4, 0411*K*5, 0411*K*6, 0439*DE*01, 0439*DL*01, 0439*JO*01, 0446*B*01, 0446*B*02, 0446*B*03, 0446*B*04, 0514*A*01, 0514*A*02, 0514*B*01, 0514*C*01, 0514*D*01, 0514*E*01, 0514*E*02, 0514*F*01, 0514*F*02, 0514*G*01, 0514*G*02, 0514*I*01, 1009*AT*01, 1009*BC*01, 1009*EL*01, 1009*EL*02, 1009*GG*01, 1009*GG*02, 9005*I*01.

PHED (2002). Record numbers: 0416*E*1, 0416*F*1, 0416*G*1, 0416*H*1, 0468*A*01, 0468*B*01, 0468*C*01, 0468*D*01, 0468*E*01, 0468*F*01, 0468*G*01, 0468*H*01, 0468*I*01.

PHED (2002). Record numbers: 0471*J*1, 0471*K*1, 0471*L*1, 0471*M*1, 0471*N*1, 0471*O*1, 0471*P*1, 0471*Q*1, 0471*R*1.

PHED (2002). Record numbers: 0471*AA*1, 0471*BB*1, 0471*S*1, 0471*T*1, 0471*V*1, 0471*W*1, 0471*X*1, 0471*Y*1, 0471*Z*1.

Fragar, L (2002). Worker exposure to endosulfan (EC) in the course of application to nursery crops (Mixing/loading). Report No. H-3-1.

Fragar, L (2002). Worker exposure to endosulfan (EC) in the course of application to nursery crops (Spraying). Report No. H-3-2.

Fragar, L (2002). Worker exposure to endosulfan (EC) in the course of application in tree crops (Mixing/loading). Report No. H-1-1.

Fragar, L (2002). Worker exposure to endosulfan (EC) in the course of application in tree crops (Spraying air-assist spray-tractor without cabin). Report No. H-1-2U.

Fragar, L (2002). Worker exposure to endosulfan (EC) in the course of application in tree crops (Spraying air-assist spray-tractor with cabin). Report No. H-1-2C.

Appendix 1 Registered products containing fenitrothion that are affected by this review

Product number	Product Name	Registrant
32986	Nufarm Fenitrothion 1000 Insecticide	Nufarm Australia Limited
42272	David Grays Fenitrothion 1000	David Gray & Co Pty Ltd
46127	Rentokil Fenitrothion 1000 Insecticide	Rentokil Initial Pty Ltd
47210	Farmoz Fenitrothion 1000 Insecticide	Farmoz Pty Limited
50774	Sumitomo Sumithion ULV Premium Grade Insecticide	Sumitomo Chemical Australia Pty Limited
50775	Sumithion 1000EC Insecticide	Sumitomo Chemical Australia Pty Limited
52034	NEVWEB Fenitrothion 1000 Grain Protectant	Australian Generics Pty Ltd
56170*	Kendon 1000EC Fenitrothion Insecticide	Kendon Chemicals and MNFG Co Pty Ltd

* Product registered after the release of the interim report but registration conditional on the outcomes of the review.

Appendix 2 Approved active constituents affected by this review

Product number	Product name	Registrant
44499	Fenitrothion Active Constituent	Sumitomo Chemical Australia Pty Limited

Appendix 3 Active constituents and products containing fenitrothion that have not had their registrations renewed or were voluntarily cancelled since the interim report

Approval or product number	Product name	Registrant	Date when registration not renewed or when voluntarily cancelled
Active Constituent			
44006	Fenitrothion	Sumitomo Australia Ltd	August 1997
Products			
32096	Fenitrogard Liquid Insecticide	Bayer Cropscience Pty Ltd	June 2003
48078	Tugon Poultry Shed and Storage Pest Insecticide	Bayer Australia Ltd	June 2001
32983	Insectigas F Fenitrothion Insecticide	BOC Gases Australia Limited	Sept 2000
42237	Insectigas FP Fenitrothion Insecticide		Sept 2000
42038	David Grays Outdoor Fogger	David Gray & Co Pty Ltd	June 2002
32984	Davison Fenitrothion 1000 Insecticide	Davison Industries an activity of Joyce Rural Pty Ltd	June 2002
42612	Davison Fenitrothion 1280 ULV Insecticide		Jan 2000
40062	Synergen F Insecticide	Ecolab Pty Ltd	June 2003
32091	Nufarm Fenitrothion Grain Protectant Powder Insecticide	Nufarm Australia Ltd	Sept 2000
41502	Nufarm Fenitrothion ULV Insecticide		Nov 2000

Approval or product number	Product name	Registrant	Date when registration not renewed or when voluntarily cancelled
39242	SJ Fenitrothion Insecticide	S Jay Industries Pty Ltd	April 2000
32992	Sumithion ULV Premium Grade Insecticide	Sumitomo Australia Ltd.	June 2001
45267	Sumitomo Sumithion 1000 EC Insecticide		June 2001

Appendix 4 Status of protected information

The APVMA operates a program of data protection that provides compensation to those who submit data for a review and which meets the criteria specified in the Agvet Codes. The objectives of the program are:

- to provide an incentive for the development of products and data applicable to Australian or local conditions
- to encourage the availability of overseas products and data; and
- to provide reciprocal protection for Australian products and data under overseas' data protection systems.

In general the APVMA designates information as protected registration information for a protection period of two to seven years if the information:

- is requested by the APVMA for the purposes of a review; and
- relates to the interaction between the products and the environment of living organisms or naturally occurring populations in ecosystems, including human beings.

If the APVMA proposes to use the same information to determine whether to register or continue registration of another chemical product, the APVMA must not use the information until the parties come to an agreement as to terms for compensation, unless the protection period has expired or the APVMA is satisfied that it is in the public interest to use the information.

There were forty four (44) studies submitted for the review that were eligible for protection. At the completion of the interim review report in August 1999, only seventeen (17) still remained protected. As of March 2004 there remains one study (DPS 4710) protected as a result of the initial fenitrothion review with the protection period due to expire 23/10/2004.

One supplementary residue study submitted for the review of fenitrothion was eligible for protection, with a protection period due to expire in October 2002.

Two endosulfan studies, submitted in February 2002, were used as surrogate data to estimate exposure for workers re-entering areas treated with fenitrothion. These are eligible for protection, with a protection period due to expire in 2005. Companies wishing to maintain their approvals or registrations for these uses will need to negotiate compensation with the providers of these studies for access to the information.

Appendix 5 Standard labels for fenitrothion products

Table 27 – Label directions permitted for fenitrothion EC products

Situation/crop	Product numbers	Pest	Rate	WHP	Critical comments
Grain protection All cereal grains stored in bulk for periods of 3-6 months	***47210*** ***42272*** ***46127*** ***56170*** ***32986*** ***52034*** ***50775***	Stored product insect pests including susceptible maldison resistant grain weevils, flour beetles, saw-toothed grain beetle, tropical warehouse moth and Indian meal moth (but not lesser grain borer)	1.2 L in 110 L water (12 ppm)	90 days (for processing into food for human consumption or stock food)	Apply 1 L dilute spray per tonne to the grain flow. The spray rate measured in litres per hour must equal the auger or elevator uptake in tonnes per hour, e.g. for an update of 20 tonnes per hour the nozzle(s) must deliver 20 L per hour.
All cereal grains stored in bulk for periods of less than 3 months			0.6 L in 100 L water (6 ppm)		
Grain Protection	***52034*** ***50775*** ***46127*** ***56170***	As above and lesser grain borer*	Specific product recommendations**		Apply 1 L of mixture per tonne of grain

***** **52034 and 46127** – stored grain pests including lesser grain borer and rust red flour beetle (including organophosphate resistant strains) excluding *Sitophilus* spp.

** **50775 & 56170** – rates as above plus Sumithrin synergised grain protectant at the recommended rate

46127 – up to 9 months protection (6ppm): mix 300 mL with 1 L rentokil IGR grain protectant with 50L water

52034 – up to 9 months protection (6ppm): mix 300 mL with 250 mL NEVWEB IGR 200 or 1 L NEVWEB IGR with 50 L water

Table 28: Modified directions for inclusion onto the front panel of the ULV label:

"ONLY APPLY BY AIRCRAFT"

Situation/crop	Pest	States	Rate	WHP	Critical comments
Pastures, pasture seed crops, cereal crops and lucerne	Australian plague locust, spur throated locust, migratory locust	Qld, NSW, Vic, SA, WA only	200 - 400 mL/ha	14 days	Spray when locusts are evident in damaging numbers. Use the lowest rate possible to achieve effective control. Higher rates may be necessary where vegetation is either very sparse or very dense
	Yellow-winged locust	Qld only	200 – 320 mL/ha	14 days	
	Wingless grasshopper	Qld, NSW, Vic, SA, WA only	250 mL/ha	14 days	Monitor regularly and spray newly emerged hoppers at hatching sites or spray adults before egg laying. Apply in heat of day when insects congregate. Spray infested areas when necessary in summer and autumn.
	Small plague grasshopper	SA only	200 – 300 mL/ha	14 days	Apply to infested areas. Use lowest rate possible to achieve effective control. Higher rates may be necessary where vegetation is either very sparse or very dense