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Item 5 a) i of the provisional agenda*

**INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED CONSENT
PROCEDURE - SUPPORTING DOCUMENTATION**

Parathion

Note from the Secretariat

1. Annexed to this note is the documentation provided by Australia in support of their notification of final regulatory action on parathion.

* UNEP/FAO/PIC/ICRC.4/1

List of Documentation Annexed to UNEP/FAO/PIC/ICRC4/10/Add.1

Supporting documentation on Parathion from Australia:

- The NRA review of parathion, Volume I, February 2000. NRA Review Series 00.2. National Registration Authority for Agricultural and Veterinary Chemicals. Australia.



**National
Registration
Authority**

For Agricultural & Veterinary Chemicals

The NRA review of

PARATHION

Volume I

February 2000

NRA Review Series 00.2

Existing Chemicals Review Program

**National Registration Authority
for Agricultural and Veterinary Chemicals**

**Canberra
Australia**

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FOREWORD

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals.

The NRA's Existing Chemicals Review Program (ECRP) systematically examines agricultural and veterinary chemicals registered in the past to determine whether they continue to meet current standards for registration. Chemicals for review are chosen according to pre-determined, publicly available selection criteria. Public participation is a key aspect of this program.

In undertaking reviews, the NRA works in close cooperation with advisory agencies including the Department of Health and Family Services (Chemicals and Non-Prescription Drug Branch), Environment Australia (Risk Assessment and Policy Section), National Occupational Health and Safety Council (Chemical Assessment Division) and State Departments of Agriculture.

The NRA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of evaluation documents for all ECRP reviews is a part of that process.

The NRA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements or as part of the OECD data exchange program. 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.

This report covers the review of parathion that has been conducted by the NRA and its advisory agencies. The review's findings are based on information collected from a variety of sources, including data packages and information submitted by registrants, information submitted by members of the public, questionnaires sent to key user/industry groups and government organisations, and literature searches.

The information and technical data required by the NRA 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. Details of required data are outlined in various NRA publications.

The full review report on parathion, containing assessments completed by the NRA and its advisory agencies, is also available. It can be viewed free of charge in the NRA Library or obtained by completing the order form in the back of this book.

Other publications explaining the NRA's requirements for registration can also be purchased or obtained by contacting the NRA. Among these are: *445* and the *4*

The NRA welcomes comment on this review and its review program. They can be addressed to Manager, Chemical Review, National Registration Authority for Agricultural and Veterinary Chemicals, PO Box E240, Kingston ACT 264 Australia .

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REVIEW 45**

DEFINITIONS AND ACRONYMS

| | | | |
|------------------------|---|--------------|---|
| µg | microgram | NOHSC | National Occupational Health and Safety Commission |
| ADI | Acceptable Daily Intake (for humans) | OP | Organophosphate |
| ai | active ingredient | POEM | Predicted Operator Exposure Model |
| ChE | cholinesterase | ppb | parts per billion |
| d | day | PPE | personal protective equipment |
| DT₅₀ | time required for 50% of a chemical to degrade | ppm | parts per million |
| EC | emulsifiable concentrate | RB | Erythrocyte |
| EC₅₀ | concentration at which 50% of the test population are affected | SUSDP | Standard for the Uniform Scheduling of Drugs and Poisons |
| EEC | estimated environmental concentration | TGAC | technical grade active constituent |
| GAP | Good Agricultural Practice | WP | withholding period |
| h | hour | HPLC | High Performance Liquid Chromatography |
| ha | hectare | IV | Intravenous |
| in vitro | outside the living body and in an artificial environment | AW | Australian Workers Union |
| in vivo | inside the living body of a plant or animal | AAVC | Australian Agricultural and Veterinary Chemicals Council |
| IPM | Integrated Pest Management | RUP | Restricted Use Pesticide |
| kg | kilogram | ECRP | Existing Chemicals Review Program |
| L | litre | ACGIH | American Conference of Governmental Industrial Hygienists |
| LC₅₀ | concentration that kills 50% of the test population of organisms | REP | Reentry Period |
| LD₅₀ | dosage of chemical that kills 50% of the test population of organisms | USEPA | US Environmental Protection Agency |
| LOEL | Lowest Observable Effect Level | OPIDN | Organophosphate induced delayed neuropathy |
| m | metre | TWA | Time weighted average |
| ME | Microencapsulated | BI | Biological Exposure Index |
| mg | Milligram | PNP | <i>p</i> -nitrophenol |
| mL | Millilitre | LV | Very Low Volume |
| MOE | margin of exposure | LV | Low Volume |
| MRL | maximum residue limit | MATC | Mean Acceptable Toxicant Concentration |
| MSDS | Material Safety Data Sheet | | |
| NDPSC | National Drugs and Poisons Schedule Committee | | |
| NHMRC | National Health and Medical Research Council | | |
| NOEL | No Observable Effect Level | | |

1. INTRODUCTION

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has reviewed the active ingredient parathion, all products containing parathion and associated labels.

The purpose of this document is to provide a summary of the data evaluated and of the regulatory decisions reached, as a result of the review of parathion.

1.1 Regulatory Information

Initiating a review

The NRA has statutory powers to reconsider the approval of active constituents, the registration of chemical products or the approval of labels for containers at any time. The basis for a reconsideration is whether the NRA is satisfied that the requirements prescribed by the regulations for continued approval are being met. These requirements are that the use of an active constituent or product, in accordance with the recommendations for its use:

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

Obligations to submit data and other information on chemicals under review

On initiating a review, the NRA has to notify relevant approval holders and registrants of the matters it intends to reconsider and its reasons for doing so, and to invite them to make written submissions on those matters. These parties are also requested to submit all existing information and data (regardless of its age or confidentiality) on the chemical under review. The NRA also notifies the community of the review through national and local newspapers, inviting them to make submissions.

In addition to inviting public submissions, the NRA may consult with persons, organisations or government agencies with relevant knowledge or interests for the purposes of obtaining information or advice relating to the review.

Once a review is under way, the NRA may request additional information from approval holders and registrants. If such a request is denied, the NRA may suspend or cancel the relevant approval or registration.

Outcomes of review

There are three possible outcomes to an ECRP review:

1. The NRA is satisfied that the chemical under review continues to meet the prescribed requirements for the initial approval or registration and confirms the approval or registration.
2. The NRA is satisfied that the conditions to which the approval or registration is currently subject can be varied in such a way that the requirements for continued approval or registration will be complied with and varies the conditions of approval or registration.
3. The NRA is not satisfied that the conditions continue to be met and suspends or cancels the approval or registration.

The NRA must notify the approval holders, registrants and the community of the outcomes of these reviews.

1.2 Protected Information

The NRA maintains a protected information program. The objectives of this program are:

- to grant protection to providers of certain information relating to agricultural and veterinary chemicals 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 NRA designates information as 'protected information' for a 'protection period' of two to seven years if the information:

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

If the NRA proposes to use the same information to determine whether to register, or continue registration, of another chemical product, the NRA 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 NRA is satisfied that it is in the public interest to use the information.

1.3 Reasons for the Parathion Review

Parathion was selected for review by the NRA Board after scoring highly against the agreed selection criteria for public health, occupational health and safety, and environment. In summary, the concerns over the chemical were:

- its very high toxicity to bees;
- its association with worker poisonings overseas, during end use and upon reentry;
- high worker exposure scenarios; and
- high potential acute and chronic risk

Whilst the selection process ranked parathion highly due to certain issues, the review was not confined only to those issues, but covered **all aspects** of the conditions of registration and approval of parathion.

1.4 Consultation Activities

In response to the widely publicised call for submissions on the review of parathion and parathion methyl, the NRA received 24 submissions.

Responses from growers

In general, growers argued strongly for the retention of parathion, especially in certain areas of horticulture. Its wide spectrum of activity and compatibility with IPM when used in conjunction with other chemical control measures were raised to highlight its value.

Growers are aware of several alternatives to parathion in most of their uses. Although there are other chemicals that can be used, it is claimed that none can match the broad spectrum of activity, rapid knockdown and comparable compatibility with IPM associated with parathion. Because of this, growers stated that the withdrawal of parathion would have a serious impact on the efficiency of production of several horticultural crops.

Most users acknowledge the high toxicity of parathion and advise that they apply this chemical during cooler parts of the day when protective clothing is more comfortable to wear and conditions are conducive to reduce spray drift. Several growers have stated that they are not aware of any adverse incidents involving parathion products, when used according to label instructions and point out that the levels of training in the handling of chemicals available to chemical users have risen substantially in recent times.

Responses from the community

Comments from the community focused on the high acute toxicity of parathion and the potential risk this poses to users and the environment. They identify parathion among the most toxic and potentially hazardous insecticides used in the horticultural sector.

Parathion survey

The NRA also surveyed various groups involved as advisers, users and registrants of parathions to gather information on use, performance, changed agricultural practices, adverse effects and trade and residues. The results of this survey form a part of the efficacy and trade reports which appear in section 6 of this summary.

1.5 Chemical and Product Details

History of registration

Parathion was developed during the late 1940s and was first registered in Australia by Bayer as Folidol Insecticide Spray.

In 1959, clearance was granted for parathion TGACs and they were placed in Schedule 7 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

In Australia, parathion is registered in 3 products and 1 technical grade active constituent (TGAC), produced by 4 companies (a full listing is available at Attachment 1). At this stage, parathion is available in Australia only as an emulsifiable concentrate. In some other countries parathion is also formulated in combination with other insecticides/ acaricides such as endosulfan, ethion, lindane, oxydemetonmethyl, petroleum oil, tetradifon, malathion, malathion + methoxychlor, parathionmethyl, thiometon and methamidophos.

Use pattern

Parathion has contact, stomach, and some respiratory action and is used to control sucking and chewing insects and mites in a wide range of agricultural and horticultural crops.

The currently registered label for a typical product containing ethyl parathion contains recommendations for use on the following crops:

| | |
|----------|-----------|
| Citrus | Nectarine |
| Pastures | Apricot |
| Lucerne | Cherry |
| Apples | Plum |
| Pears | Vines |
| Peach | Onions |

Application methods

The most common method of applying parathion is by air blast sprayers, with some use of boomsprayers for pasture and lucerne. In most cases, the boomspray is tractor-mounted; sometimes tractors have enclosed cabs. Some variations in application equipment use air assistance to penetrate the crop canopy.

According to label directions spray volumes can vary with growers using high volume methods in the range of 1500 -3000 L/ ha for pome fruits or low volume usage in the range 200 -500 L/ ha. Some growers are using electrostatic sprayers which use very low volume (50 -200 L/ ha) sprays. The number of applications per crop varies between one and six per season, with a typical spray interval of 10 -14 days. However, it would also appear that there is a variety of interpretations of the label directions regarding rates of use and volumes of water used through high volume equipment.

Formulation

Parathion products are formulated locally using imported TGAC.

Packging

Parathion products are supplied in 20 litre fluorinated plastic containers with self-adhesive labels.

1.6 Overseas Regulatory Status

Parathion is registered for uses largely similar to those in Australia in a number of countries including:

| | |
|---------|-------------|
| Belgium | Luxembourg |
| France | Netherlands |
| Germany | Spain |
| Greece | USA |
| Italy | |

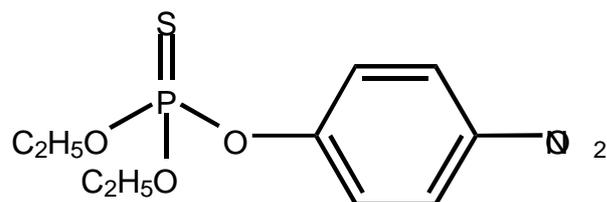
Parathion is no longer registered in many other European countries including the United Kingdom, Denmark and it is banned or severely restricted in Japan, New Zealand and Finland. In USA parathion is a restricted use pesticide (RUP) for all its uses.

2 CHEMISTRY ASSESSMENT

2.1 Chemical identity

Common Name: Parathion. "Parathion" is the common name for ethyl parathion and should not be confused with dimethyl parathion."

Structural Formula:



Purity: 99% minimum parathion.

Microcontaminants: The toxicologically significant impurity which may be formed in the manufacturing process is sulfotep. The maximum levels of sulfotep allowed may not exceed 2 g/kg. It is considered that other compounds of toxicological significance (nitrosamines, halogenated dibenzodioxins or halogenated dibenzofurans and PCBs) are not expected in parathion TGAC due to the raw materials and synthetic chemistry route used.

Empirical formula: $C_{10}H_{14}NO_5PS$

Molecular weight: 292.7

2.2 Chemistry Aspects

The chemistry aspects (manufacturing process, quality control procedures, batch analysis results and analytical methods) of parathions continue to meet current standards.

3 AGRICULTURAL ASSESSMENT

3 Efficacy

Introduction

In order to ascertain whether the current registration of parathion complies with contemporary assessment standards for efficacy, the NRA surveyed groups in the community who supply, provide technical advice on the use of, or use, parathion. Performance questionnaires were therefore designed for large and small scale users of the chemical, commodity organisations, State agricultural authorities and the chemical industry.

Use in Integrated Pest Management Programs in Pears

Information contained in Performance Questionnaires completed for parathion indicates that the inclusion of this chemical in Integrated Pest Management (IPM) programs for pears is the most significant development in its use since the chemical was first introduced. Growers advise that these programs have reduced chemical usage by up to 6% in the Goulburn Valley in Victoria. The importance of this chemical for IPM in the pear industry is endorsed by the Victorian Department of Natural Resources and Environment. The only other State agricultural authority to indicate any usage of parathion was South Australia which indicated that there was some use in one citrus growing area (Merrie). However, this use was not seen to be critical to the industry as a whole by either the South Australian agricultural authority or local crop consultants.

Changes in Application Technology

Another significant development is that many producers (and all producers surveyed) now use low volume or electrostatic ultra low volume equipment to apply parathion, whereas original rates of use (and MRL determinations) were based on high volume application methods. In this regard, it is noted that although growers indicate that they do not see any necessity to alter the rates of use for this chemical recommended on labels, they advise that they convert the high volume rates specified on the labels to rates per hectare for the purpose of application of the chemical through low or ultra low volume equipment.

However, since current labels do not specify either a rate per hectare or a total volume of water per hectare for various tree sizes or stages of growth, it is apparent that there can be considerable variation in the amounts of chemical applied by individual growers.

Although this is a major difficulty for orchard spraying in general, especially for chemicals which have been registered for some decades, it is particularly acute in relation to parathion (and parathionmethyl) because the major essential uses are in orchards. The need for minimisation of amounts of parathion applied has also been

emphasised in other aspects of the review. A review of the directions for use recommended on the labels for these products is necessary to ensure maximum effectiveness of spraying operations with a view to a reduction in use of these chemicals.

In this regard it is noted that a major project entitled 'Pesticide Reduction in Pomefruit Towards 2000,' has been undertaken by the Queensland Department of Primary Industries. A report on 'Pesticide Application Trials 1998' has been published and a further project, developed from the previous project and entitled, "Pomefruit Pesticide Reduction Strategies for the 2000s," is being undertaken between 1 July 1999 and 30 June 2000. The objectives of this project are:

1. Undertake grower case studies to demonstrate the pesticide reduction successes of the pomefruit industry for use in media releases.
2. Relate pesticide use to (i) pest and disease levels; (ii) tree size; and (iii) application method
3. Explore possible changes to pesticide labels that allow low volume spray application

Data already collected from this program and the data collected from the extension of the work to 30 June 2000 are likely to have a significant impact on this issue and should be considered in relation to any consideration of alterations to labelling of parathion products.

Other Considerations

In addition, it would appear that modifications to the registered formulations may be advisable in the light of advances in spray application technology. It is possible that residue detections and concerns related to nontarget effects of chemical application could be further reduced by attention to formulation types and rates of use. In this context, it is noted that some overseas countries have limited the level of parathion in agricultural formulations to 250 g/L and that microencapsulation of these types of chemicals has also been considered.

Producers have not recorded any difficulties with label directions or actual spray operations. Although there was general satisfaction with containers, one grower reported difficulty in decanting the first 24 litres of concentrate into the spray tank

Individual producers and the major commodity organisations emphasise the extent to which farmer/worker education programs have assisted in increasing the efficiency and effectiveness of spraying operations as well as decreasing the level of exposure to the chemical.

3 Trade

Introduction

The information available on the potential effects of the withdrawal of parathion, or modification of its availability, on the export of agricultural commodities has been examined and an estimate made of the impact on Australian trade with other countries. It is emphasised that this report focuses only on the export market and does not draw any conclusions on the impact of regulatory activity in relation to parathion on the domestic market. In this regard, it is clear that the impact on the industries overall will be greater since, in most cases, the domestic market is at least as large, if not, larger, than the export market.

Export Crops

Parathion is registered for use on the two most valuable Australian horticultural export crops and two other major export crops. These are citrus (oranges), apples, grapes/sultanas and pears respectively. The total contribution of these export crops to Australian trade is of the order of \$00 million. It should also be noted that wine exports totalled some \$3 million in 1980.

Information examined indicates that there is some use of parathion on citrus and that use on pears is very significant. Most of Australia's export apples are sourced from Tasmania, although the South Australian industry is experiencing growth. It would appear that use of parathion is not critical to the export apple industry. Use patterns on grapes are not as clear.

Significance in pear production

By far the greatest proportion of Australia's export pear crop (80%) is produced in the Goulburn Valley of Northern Victoria. Advice from the Northern Victoria Fruitgrowers Association, which represents the Goulburn Valley pear growers, is that this chemical is an integral and very important part of Integrated Pest Management programs which have been adopted by more than 90% of growers in the region. They consider that other chemicals cannot be used in IPM programs because either they adversely affect beneficial insect populations or they create other pest problems. Costs associated with spray programs involving these other chemicals are also significantly higher than those using parathion. The estimated cost of the loss of this chemical to the export pear industry is over \$3 million.

It is commented that the related chemical, parathion-methyl, which is also considered to be an important chemical in IPM programs for pear production, is being separately reviewed under the ECRP. Some comparison of these two chemicals and their respective positions in relation to control of pests in various situations is included in the respective reports.

Other crops

Although figures have not been supplied to enable some estimate of the benefit of this chemical to the citrus industry, advice has been received from some grower organisations that it is an important component of pest control strategies adopted in the ~~Marie~~ ^{Marri} area in South Australia, which is one of Australia's major citrus growing areas.

Although there is some support from the Victorian Department of Natural Resources and Environment and the South Australian Department of Primary Industries for use of parathion and/or parathionmethyl for control of mealybug and red scale in citrus and mealybug in grapes, neither authority appear to consider these as essential uses at this time.

The effect of regulatory activity in relation to parathion on the grape industry is more difficult to determine. Advice from commodity groups and state agricultural authorities suggests that this chemical is not frequently used in grape production. However, consistent detections of residues of parathion in table grapes have been made by the National Residue Survey, which would appear to indicate significant use by producers of export table grapes.

3 Residues

Introduction

All currently registered parathion products contain 500 g/L parathion and are registered for use on citrus, and other fruit trees (particularly pome and stone fruits), vines, vegetables, lucerne and pastures in Australia. Satisfactory analytical methods are available for parathion. These methods have adequate sensitivity and recovery.

The current residue definition for parathion is the parent parathion. The analytical methods measured this adequately. This residue definition is consistent with that used by Codex.

Current labels

The current labels do not specify the maximum number of applications or the interval between applications. The residue data submitted show that the number of applications does not significantly affect the residue profile at harvest. Residue data also indicate that the majority of the residue depletes within the first four days after the final application and therefore standard agricultural practices of repeat applications at 7 to 14 day intervals will not significantly affect the residue profile at harvest.

Metabolism of parathion in animals

In laboratory animals, parathion is quickly absorbed after oral administration. The major organs of distribution are liver and kidney with smaller amounts to fat and brain tissues. Metabolism is via activation or degradation pathways. Metabolism is rapid with half-lives between 1 and 10 hours depending upon route of administration and species. None of the metabolites, paraoxon included, were found to remain or

accumulate in the animals treated. Excretion is mainly urinary. Metabolism and the rate of metabolism were similar between laboratory animals and humans. The metabolic pathways in animals do differ between ruminants, poultry and monogastrics. There were no signs of accumulation in either the hen or goat tissues and offal tended to be the site of higher residues in all species.

Metablism of parathion in plants

Foliar treatment of plants with parathion only results in minor translocation of the active or metabolites with the residue present in seeds and tubers being an order of magnitude less than seen in treated parts.

Residue trials

No Australian residue data were presented.

The current entry in the ~~M~~ for fruits and vegetables are general entries, namely “fruits 0.5 mg/kg” and “vegetables 0.7 mg/kg.” Under current standards, such broad entries are no longer satisfactory and should be broken down to MRLs for the various fruit or vegetable groups or individual fruit or vegetable entries.

~~Based~~ on the residue data provided, deletion of the present “fruits” and “vegetables” MRLs and the MRLs for apricot, peach, cereal grains, cotton seed, crude cotton seed oil, and carrot from the MRL Standard was recommended.

The data presented allowed MRLs at the limit of quantitation to be set for leafy vegetables, fruiting vegetables other than cucurbits, legume vegetables, and potatoes. Temporary MRLs were able to be set for grapes, citrus fruit, pome fruit, stone fruit, bulb vegetables, brassica vegetables, fruiting vegetables, cucurbits and stalk and stem vegetables. The data also allowed MRLs to be set for fruit pomace, pastures, and legume animal feeds. Provided a use pattern can be established, an MRL at the limit of quantitation can also be set for pulses on the basis of the data evaluated.

Animal feed commodities

Metabolism studies in wheat and cotton and residue studies in wheat, rice, sunflowers, soybeans, peas and beans indicated that parathion concentrates more in the leaves and stems of the plant rather than the seed. The depletion of parathion residues in forages is similar to that seen in fruits and vegetables. US trials allowed establishment of MRLs of 5 mg/kg each for pastures and legume animal feeds. Fruit pomace would concentrate residues by up to 5 times that seen in fruit and hence the MRL in fruit pomace would not be expected to exceed 3 mg/kg.

Animal MRLs

No animal transfer studies were provided. Data on legume animal feeds indicated that residues would likely be around 510 ppm. No data on other pasture grasses were provided. Metabolism studies were able to demonstrate that residues in animal tissues would be less than 0.05 mg/kg at expected feed intakes. This supports the current mammalian MRLs. There are no current poultry MRLs but if cereal uses are to be retained, MRLs can be set at or about 0.05 mg/kg with a fair margin of safety.

Fat solubility

Parathion has a $\text{LogP}_{\text{ow}} = 3.8$ indicating some lipid solubility. Residue studies indicated a concentration in processed oil commodities. Animal metabolism studies however did not indicate that parathion would accumulate in fat. Therefore, though parathion is oil soluble, due to metabolism by animals it cannot be considered as a fat accumulator.

Conclusions

Some use patterns, particularly cotton and cereal grains, are no longer included in the currently registered labels for parathion. Also these uses are not recommended by State Departments of Agriculture. These MRLs have therefore been recommended for withdrawal.

The MRL entries for general commodity types such as fruits and vegetables are no longer satisfactory by current national and Codex standards. These types have therefore been expanded into their groups where applicable and appropriate MRLs recommended. Some of these groups (all fruit and some vegetable groups) do require confirmatory Australian residue studies.

34 Residue Assessment Conclusions

1. There are no objections, from a residues point of view, to the continued registration of products containing parathion, if additional confirmatory studies for the T MRLs are completed and evaluated.

2. The following amendments to the ~~MP~~ are recommended:

Table 1

| Compound | Food | MRL (mg/kg) |
|--------------------|--|-------------|
| Parathion | | |
| Delete: | | |
| | Fruits (except apricot; peach) | 0.5 |
| FS 0240 | Apricot | 1 |
| FS 0247 | Peach | 1 |
| GC 008 | Cereal grains | 0.5 |
| SO 008 | Cotton seed | 1 |
| OC 008 | Cotton seed oil, crude | 0.5 |
| | Vegetables (except carrot) | 0.7 |
| VR 0577 | Carrot | 0.5 |
| Add: | | |
| FB 028 | Grapes | T0.5 |
| FC 0001 | Citrus fruit | T0.5 |
| FP 0009 | Pome fruit | T0.5 |
| FS 0012 | Stone fruit | T0.2 |
| VA 0035 | FB vegetables | T0.05 |
| V B 040 | B assica vegetables | T0.05 |
| VC 0045 | Fruiting vegetables, cucurbits | T0.05 |
| VL 0053 | Leafy vegetables | 0.05 |
| VO 0050 | Fruiting vegetables other than cucurbits | 0.05 |
| VP 006 | Legume vegetables | 0.05 |
| VR 058 | Potato | 0.05 |
| VS 0078 | Stalk and stem vegetables | T0.7 |

Entries for meat (mammalian), edible offal (mammalian) and milk remain unchanged at 0.05 mg/kg.

Table 4

| Compound | Animal Feed | MRL (mg/kg) |
|------------------|---------------------|-------------|
| Add: | | |
| Parathion | | |
| | Fruit pomace | 3 |
| | Pastures | 5 |
| AL 0157 | Legume animal feeds | 5 |

- T refers to MRLs that will expire in three years after this review is finalised or as determined by the NRA. Maintenance of a temporary MRL is dependent on the registrant or person or group wishing to retain the MRL formally undertaking to generate the requested residue data within the allocated time frame.
- The current 14 day ~~MP~~ before harvesting for human consumption and grazing and cutting for stockfeed remains unchanged.

5. The following commodities would require confirmatory Australian residue data to confirm MRLs:

- Stone fruit (peaches). The MRL could be lowered with further data on apricots and cherries.
- Pome fruit (apples and pears)
- Citrus fruit (oranges and lemons)
- Grapes
- Stalk and stem vegetables (celery and one other)
- Root and tuber vegetables (carrots)
- Fruiting vegetables, cucurbits (one other than cucumber)
- Onion vegetable (onion)
- Broccoli and Brussels sprouts (broccoli or Brussels sprouts)

Supply of residue data from all the commodities listed and establishment of equal MRLs for them with comparable use patterns would allow establishment of the relevant group MRL. Otherwise MRLs for individual commodities could be set on the basis of the commodity residue data provided.

6. Where additional residue data are required, the trials should be conducted according to appropriate NRA requirements at maximum label rates.
7. The following amendments to the MRL can be recommended only if a use/use pattern is identified:

Table 1

| Compound | Food | MRL (mg/kg) |
|------------|--------|-------------|
| Add | | |
| VD 0070 | Pulses | 0.05* |

8. The residue definition of parathion remains unchanged as the parent parathion.

4. TOXICOLOGICAL ASSESSMENT

The extensive toxicological database for parathion consists primarily of toxicity tests conducted using animals, with some experiments using human volunteers, and a number of reports of human exposure by accidental, occupational or deliberate means.

In interpreting the data, it should be noted that toxicity tests generally use doses which are high compared to likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No Observable Effect Level (NOEL) are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

4.1 Public Health Aspects

Toxicology

Parathion is an organophosphate pesticide that has been in use in Australia and other countries for almost 50 years. Parathion exhibits high acute toxicity. Like a number of other pesticides, parathion is an anti-cholinesterase compound, and this accounts for the insecticidal activity as well as the human hazard associated with exposure to parathion. Regardless of whether parathion is taken orally, applied to the skin, or breathed in, the effects of poisoning are similar. Signs of parathion poisoning are typical of those seen with other organophosphorus insecticides, and in mammals include: increased salivation, excessive saliva, rapid breathing, pinpoint pupils, loss of coordination, excitement, twitching and rapid contractions of the neck and jaw muscles, coarse generalised body tremors, secretion of tears, urination, defecation, depression, prostration, convulsions, respiratory failure, and death. The severity of signs increases with the amount of exposure, and the onset of severe signs (including death) is swift in experimental animals and humans after exposure to parathion. There is an effective antidotal treatment for parathion poisoning.

Parathion is extensively absorbed, metabolised and excreted by humans and other mammals. Long term exposure to a low concentration of parathion in the diet was without serious consequences in animal studies, although high concentrations caused the symptoms listed above. Parathion does not interact with genetic material, and long term cancer studies in animals provided no evidence that parathion would be associated with cancers in humans. Parathion exposure had no adverse effects on reproduction or development of the fetus in experimental animals.

Conclusion

In Australia, parathion is not registered for use in or around the home and garden. The most likely exposure to parathion for the public is via residues in food. Based on the current restricted uses of parathion, it is considered that there should be no adverse effects on public health from the continued use of parathion in Australia.

4.2 Metabolism and Toxicokinetics

Parathion is reasonably fat-soluble and is readily absorbed by all routes of exposure, however the toxicity ensuing from an exposure episode varies considerably with the dose and exposure route. The toxicity of parathion is directly related to the inhibition of cholinesterases by the major parathion activation product, paraoxon, formed in the liver mainly, but also in other tissues. The liver functions as the major controller of the circulating level of parathion. In oral exposures, essentially all of the dose is bound to blood proteins and passes through the liver. The liver activates the parathion to paraoxon, and then proceeds to rapidly break it down, hence all of the parathion may well be totally detoxified within the liver. However a large dose of parathion may overwhelm the detoxification abilities of the liver and allow parathion or paraoxon to leave the liver and enter the general blood circulation. Genetic variation between individuals accounts for the greater than 6-fold difference seen for paraoxon metabolism in humans. Animal studies have found that when parathion is breathed in, applied to the skin, injected IV, given as a single dose orally or fed at high dose, then signs of poisoning may appear. Studies in rats, rabbits and goats indicate that parathion that enters the general circulation can be widely distributed throughout the body but will generally be excreted very rapidly in the urine and faeces, with low concentrations of residues remaining in tissues such as fat, lung, liver and brain.

Parathion absorption through the skin is highly variable. Studies of the absorption of parathion in mice, rats and humans have shown that the applied dose is readily absorbed and metabolised, but these studies also demonstrated species, gender and individual differences in the amount of the applied dose that is absorbed. Differences in absorption are, for example, seen between sexes, where male rats absorb less than females. Variation between application sites is also seen; for example, human forearm skin will absorb about 10% of an applied dose, but the head and neck areas will absorb 40% of the same dose, and the scrotum about 100%. Human subjects have exhibited up to a 5-fold variation in the measured amount of percutaneous penetration under identical exposure conditions. The dermal absorption of parathion in humans is also known to vary with temperature, solvent, skin integrity, occlusion of the application site by clothing and other factors.

4.3 Acute Studies

There is a substantial literature, both published and unpublished, on the lethal dose toxicity of parathion, and the acute toxicity appears to depend upon the age and nutritional status of the animals, and on the vehicle used for dose administration. The oral LD₅₀ values in rats are generally lower than 10 mg/kg using a range of vehicles. Species differences in sensitivity to acute intoxication following exposure to parathion were evident, and tended to the order human > rat > mouse > rabbit.

Clinical signs following parathion exposure by all major routes of administration are typical of cholinesterase inhibition and included increased swallowing, excessive saliva, rapid breathing, twitching of the ears, pinpoint pupils, tail lashing, loss of coordination,

excitement, twitching and rapid contractions of the neck and jaw muscles, coarse generalised body tremors, secretion of tears, urination, defecation, depression, prostration, epileptoid tremors, convulsions, respiratory failure, and death. In rats, signs of poisoning commenced generally within 0.5 h of treatment and peaked at 6 h. Deaths occurred within 12 d, and signs were evident up to 5 d postdose. When tested on rabbits, parathion was a slight eye irritant and a slight skin irritant. A microencapsulated form of parathion was of low to moderate toxicity to rats when tested by the oral and dermal routes. The microencapsulated product is a slight eye irritant and a slight skin irritant in rabbits, and is a weak skin sensitiser in guinea pigs.

4.4 Short Term Repeat Dose studies

In a 4 week mouse dietary study where the doses ranged from 150 mg/kg/d, deaths occurred at the highest doses and signs of poisoning including weight loss were seen at all doses. In a 3 week inhalational study in rats, there were no effects at the low dose of 0.25 mg/m³, reductions in plasma, erythrocyte or brain cholinesterase activity at the mid (0.9 mg/m³) or high doses (9.9 mg/m³), and clinical signs of poisoning and deaths at the high dose.

4.5 SubChronic studies

In a 3 month mouse dietary study, where the doses ranged from around 3.5-25 mg/kg/d, there were no deaths or signs of poisoning, although cholinesterase levels were not measured. The NOEL was 7.7 mg/kg/d based on lower body weights and decreased organ weights seen at 25 mg/kg/d.

In a 3 month rat dietary study, where the doses ranged from 0.04-4.0 mg/kg/d, there were no treatment related deaths but there were lower body weights and other signs of poisoning at 4.0 mg/kg/d. Plasma or brain cholinesterase levels were reduced at 0.4 mg/kg/d and above. Tests of eye function (electroretinogram) revealed some toxicity at 0.4 and 4.0 mg/kg/d. not measured. The NOEL for this study was 0.04 mg/kg/d based on plasma cholinesterase inhibition at 0.4 mg/kg/d and electroretinogram changes occurring at 0.4 mg/kg/d and above.

In another 3 month rat dietary study, where the doses were around 0.2, 2, and 7 mg/kg/d, there were deaths and clinical signs at 7 mg/kg/d. At 2 and 7 mg/kg/d there were lower body weights and abnormalities in blood measurements. A NOEL for this study was not able to be established since erythrocyte cholinesterase was lowered at the lowest dose of 0.2 mg/kg/d and plasma cholinesterase was lowered from 2 mg/kg/d.

In a 3 month dietary study in dogs, where the doses were 0.3, 1.0 or 3.0 mg/kg/d, there were no clinical signs, bodyweight changes or deaths, and blood and urine parameters were unaffected by treatment. A NOEL for this study was not established due to inhibition of plasma and RBC cholinesterase occurring at the lowest dose tested of 0.3 mg/kg/d.

In another 3 month dietary study in dogs, where the doses were 0.0024, 0.008 and 0.8 mg/kg/d, there were no clinical signs, body weights were lower in females at the high dose, and there were no deaths. The NOEL for cholinesterase effects was 0.0024 mg/kg based on inhibition of plasma cholinesterase levels in males at 0.008 mg/kg/d and above. Thorough testing of the eyes revealed no abnormalities, and hence the NOEL for ocular effects was 0.8 mg/kg/d.

In a 12 month dietary study in dogs, where the doses were 0, 0.01, 0.03 and 0.1 mg/kg/d, there were no bodyweight changes, clinical signs or deaths. An extensive series of biochemical and physiological measurements revealed no effect of treatment. The NOEL for the study is 0.01 mg/kg/d based on inhibition of plasma and RBC cholinesterase levels at 0.03 mg/kg/d and above.

4.6 Chronic studies

In an 18 month dietary study in mice the achieved doses were approximately 8.14 and 21 mg/kg/d. Clinical signs of poisoning were seen at all doses and there were some abnormalities recorded in blood tests seen at 18 months. There was an increased incidence of lung tumours seen at 8 mg/kg/d only. These animals had been misdosed for a week at 8 times the correct dose, and these results are difficult to interpret. No conclusions on the toxicity of parathion can be drawn from this study.

In a two year study in rats, the achieved doses were approximately 0.04, 0.4 and 4 mg/kg/d. There were no treatment related deaths but there were lower body weights and other signs of poisoning at 4.0 mg/kg/d. Males and/or females at 4 mg/kg/d displayed some peripheral nerve damage, lower brain cholinesterase values, some defects of the eye, some liver damage and blood abnormalities. Some of these effects also were seen in a few 0.4 mg/kg/d animals. Males at 4 mg/kg/d recorded an increase in thyroid tumours. The NOEL for inhibition of plasma cholinesterase was 0.04 mg/kg/d, while that for brain and erythrocyte cholinesterase was 0.4 mg/kg/d.

In a two year study in rats, the achieved doses were approximately 0.12, 0.5 and 2.1 mg/kg/d.

There were treatment related deaths and signs of poisoning in females at 2.1 mg/kg/d. Females especially, and/or males dosed at 2.1 mg/kg/d displayed lower brain cholinesterase values, some defects of the eye, some liver damage, decreased organ weights and blood abnormalities. Some of these effects also were seen in a few 0.5 mg/kg/d animals. Proliferative effects were seen in the pancreas of males and the haemolymphoreticular system of females at 0.5 and 2.1 mg/kg/d, but these were similar to control values for males and not dose related in females. The NOEL for inhibition of plasma and erythrocyte cholinesterase was 0.12 mg/kg/d, and for brain cholinesterase was 0.5 mg/kg/d.

4.7 Reproduction studies

In a reproduction study in rats, where parathion was given by stomach tube at doses approximating 0.05, 0.9 and 2.3 mg/kg/day for two generations, there were clinical signs of poisoning in only a few animals at 2.3 mg/kg/d, including bodyweight loss. None of the measures of mating, pregnancy or fertility were affected by parathion treatment, and the measures of pup growth and survival were normal except at 2.3 mg/kg/d where there was reduced early survival of the second generation pups, probably reflecting maternal stress. The NOELs for parental toxicity and reproductive toxicity were both 0.9mg/kg/d.

In a reproduction study in rats, where parathion was given by stomach tube at doses approximating 0.06 and 1.6mg/kg/day for two generations, there were clinical signs of poisoning in only a few female animals at 1.6mg/kg/d, and some bodyweight loss in both sexes. Fertility, pup survival and pup weight were reduced at 1.6mg/kg/d in the first generation only, and all other measures of breeding success and pup growth were normal in both generations. The NOELs for plasma, RBC and brain cholinesterase inhibition were 0.06 and 0.6mg/kg/d respectively. The NOEL for paternal effects was 0.06mg/kg/d, and for reproductive effects was 0.6mg/kg/d.

4.8 Developmental Studies

In a study where parathion was given to rats by stomach tube at dose levels of 0, 0.1, 0.3 and 1.0 mg/kg/d, there were deaths and clinical signs of toxicity including weight loss at 1.0 mg/kg/d. Parathion treatment did not affect fertilisation/pregnancy rate or other parameters measured other than causing a reduced placental weight at 1.0 mg/kg/d, reflecting the maternal toxicity seen at this dose. A single litter at 1.0 mg/kg/d recorded an apparent increase in the incidence of fetal malformation, but this was not attributed to treatment, and there was no significant variation in malformation rate in other treatment groups. The NOEL for maternal toxicity in this study was 0.3 mg/kg/d based on clinical signs, mortality, and decreased body weights seen at 1.0 mg/kg/d. Under the conditions of this study, parathion did not show teratogenic potential.

In a study where parathion was given to rats by stomach tube at dose levels of 0, 0.25, 1.0, and 1.5 mg/kg/d, there were deaths and clinical signs of toxicity including weight loss at 1.5 mg/kg/d. Parathion treatment did not affect fertilisation/pregnancy rate or other parameters measured other than causing a reduced fetal weight at 1.5 mg/kg/d, reflecting the maternal toxicity seen at this dose. There were no fetal skeletal, visceral or soft tissue anomalies or malformations attributable to treatment. The NOEL for maternal toxicity in this study was 1.0 mg/kg/d, based on mortality and clinical signs at the high dose. Under the conditions of this study, parathion did not show teratogenic potential.

In another study, parathion was given to rabbits by stomach tube at dose levels of 0, 0.03, 0.1, and 0.3 mg/kg/d. Treatment with parathion caused no deaths, clinical signs or weight loss in any of the dams and autopsy of dams showed no treatment related effects. Parathion treatment did not alter the fertilisation rate or the incidences of fetal malformations. No toxicity to the dams or embryos were seen with doses of parathion up to 0.3 mg/kg/d.

When parathion was given to rabbits by stomach tube at dose levels of 0, 1, 4, and 16 mg/kg/d, no deaths occurred, but at 16 mg/kg/d there were minor clinical signs in the dams and some slight reductions in measures of fetal development. Examination of dams showed no treatment related effects. Examination of fetuses showed an increased incidence of a minor skeletal malformation at 16 mg/kg/d probably reflecting maternal toxicity at this dose. The NOEL for maternal toxicity was 4 mg/kg/d. Under the conditions of this study, parathion did not show teratogenic potential.

4.9 Genotoxicity Studies

Parathion does not interact with genetic material and has been shown not to cause: mutations in bacterial or mammalian cells, chromosomal damage in mouse or human blood cells or mouse germ cell cells, inhibition or stimulation of DNA repair.

4.10 Neurotoxicity

Specialised tests using hens, compared the ability of parathion and 2 other organophosphates to cause degeneration of the nervous system -a syndrome called organophosphate induced delayed neuropathy (OPIDN). None of the signs of delayed neurotoxicity were observed in the parathion treated hens, whereas definite and severe signs were recorded after treatment with the other known neurotoxic compounds.

In an acute neurotoxicity study, rats were given single oral doses of parathion between 0.025 and 10 mg/kg. At 10 mg/kg there were deaths and clinical signs of toxicity. Neurological effects were typical of acute cholinesterase inhibition and were seen at doses which caused significant inhibition of plasma, RBC and brain cholinesterase activity. Substantial recovery of cholinesterase levels was seen at day 14 post treatment. The NOEL for the study was 0.5 mg/kg/d based on inhibition of plasma, RBC and brain cholinesterase and acute neurological effects seen at 2.5 mg/kg and above. No delayed neurotoxicity was evident.

In a subchronic neurotoxicity dietary study, rats were exposed to parathion at doses between 0.05-2.5 mg/kg/d for 13 weeks, with some animals recovering on a normal diet for an extra 4 weeks. There were no deaths during the study, but body weights were reduced in high dose males and females. Plasma and RBC cholinesterase activities were inhibited from 1.25 mg/kg/d, and brain cholinesterase activity from 0.05 mg/kg/d. There were no findings at autopsy, and the clinical signs reflect inhibition of cholinesterase activity. No delayed neurotoxicity was evident following parathion treatment.

4.11 Effects in Humans

Parathion is highly acutely toxic to man and most mammals. Human poisonings as a consequence of exposure to parathion have occurred through accidental, occupational and deliberate exposure by all routes. The course of acute parathion intoxication in

man is identical to the acute toxicity seen in laboratory animal studies and is mediated by cholinesterase inhibition. Symptoms range from flu like chest tightness and fever in mild cases, through to respiratory paralysis and death at high dose. There exists an effective antidotal regime for parathion intoxication. Neither acute or chronic exposure to parathion in humans appears to lead to delayed neuropathy, but some claims as to the possibility of neuropsychiatric effects cannot be completely eliminated. There appear to be no long term sequelae for immunotoxicology, reproductive effects, developmental effects or cancer induction in humans.

In various early studies in human volunteers, oral doses of parathion of 0.05-0.07 mg/kg may be asymptomatic. Doses of 0.1 mg/kg and above gave signs and symptoms typical of cholinesterase inhibition, as well as measured reductions in plasma and whole blood cholinesterase activity. In later studies, oral intake of up to 0.1 mg/kg/d for up to 14 weeks produced no clinical signs but inhibited plasma cholinesterase markedly and erythrocyte cholinesterase slightly with significant individual variability. The NOEL for these studies ranged from 0.05 to 0.1 mg/kg/d.

In a well conducted epidemiological study of humans occupationally exposed to OPs, parathion was not found to have significant delayed neurotoxicity. In two other epidemiological studies of humans occupationally exposed to OPs, the potential of parathion to cause delayed neurotoxicity was not able to be determined due to insufficient information.

4.12 Conclusions for public health standards

Poisons Scheduling

Parathion is currently in the restrictive Schedule 7 of the Standard for the Scheduling of Drugs and Poisons (SUSDP). There are provisions for appropriate safety directions on the product label aimed at limiting exposure, and first aid instructions in the event of poisoning.

No Observed Effect Level / Acceptable Daily Intake

The lowest No Observed Effect Level (NOEL) for parathion is 0.0024 mg/kg/day, based on plasma cholinesterase inhibition in a 6 month oral study in dogs, the lowest NOEL in dietary animal studies was 0.01 mg/kg/d, based upon the inhibition of erythrocyte and plasma cholinesterase activity in a 12 month dog study, and the inhibition of plasma cholinesterase in a 2 year rat study. The lowest NOEL in human oral studies was 0.05 mg/kg/d.

The current Acceptable Daily Intake (ADI) for parathion is 0.005 mg/kg/d. It is recommended that parathion have a revised ADI of 0.001 mg/kg/d based on the human NOEL of 0.05 mg/kg/d, and applying a 50 fold safety factor to account for the reported variability in human populations.

5 OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

5.1 Existing regulatory controls for occupational health and safety

Hazardous substances Parathionethyl (parathion) is listed in the National Occupational Health and Safety Commission (NOHSC) List of Designated Hazardous Substances with the following risk and safety phrases:

- R27 Very toxic in contact with skin.
- R28 Very toxic if swallowed.

- S28 After contact with skin wash immediately with plenty of ... (to be specified by manufacturer).
- S36 Use suitable protective clothing.
- S37 Use suitable gloves.
- S45 In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

All parathion products registered in Australia are determined to be hazardous substances as they contain 500 g/L active ingredient. Hazardous substances come under the controls for workers specified in NOHSC Control of Workplace Hazardous Substances.

Atmospheric monitoring There is a NOHSC Exposure Standard for parathion of 0.1 mg/m³ Time-Weighted Average (TWA) with an skin notation, indicating that absorption through the skin may be a significant source of exposure.

Biological Exposure Index (BI) NOHSC has not established a BI for parathion. The American Conference of Governmental Industrial Hygienists (ACGIH) BI for parathion is 0.5 mg p-nitrophenol (PNP)/g creatinine. The BI is based on the assumption that red blood cell (RBC) cholinesterase (ChE) inhibition is unlikely to be observed when the concentration of PNP in urine is 0.5 mg/L or less.

Health surveillance NOHSC has placed organophosphate pesticides (including parathion) on the Schedule for Health Surveillance. The employer is responsible for providing health surveillance which has been established as a result of the workplace assessment process.

5.2 Toxicity relevant to occupational exposure

Technical parathion is of high acute toxicity by the oral, dermal and inhalation route. It is a slight skin and eye irritant. The skin sensitisation potential of technical parathion has not been determined. No acute toxicity studies were available for parathion formulations, however, they are expected to exhibit a similar toxicity profile to the technical material.

In a single dose dietary neurotoxicity study in rats, the no observable effect level (NOEL) was determined to be 0.5 mg/kg, based on inhibition of plasma, red blood cells and brain ChE and acute neurological effects. In a 90 day dietary neurotoxicity study in rats, the NOEL was determined to be 0.05 mg/kg/d, based on the inhibition of plasma, red blood cells and brain ChE and neuromotor effects.

Species differences in sensitivity to acute intoxication following parathion exposure was evident from animal studies. Humans may be among the more sensitive species to parathion, with marked individual variations. A 6 fold variation was observed in the activity of the enzyme responsible for parathion metabolism in humans.

The estimated human oral lethal dose for parathion is 1.43 mg/kg.

In a range of volunteer studies, NOELs in the range 0.05 - 0.1 mg/kg/d were established for red blood cells ChE inhibition.

Neither single or repeated exposure to parathion in humans appears to lead to delayed neuropathy, but the possibility of neuropsychiatric effects cannot be completely eliminated.

Paraoxonethyl (paraoxon) is the major degradation product of parathion. It is of similar acute toxicity to the parent compound.

Studies in human volunteers indicate that approximately 10% of a parathion dose applied to human skin is absorbed, with approximately a 5 fold difference between individuals.

5 Reported health effects of parathion

In Australia, there are no incident reporting systems for pesticide poisoning. There have been a number of documented cases of illness/poisoning following organophosphate pesticide exposures. It is not known how many of these are related to parathion exposure.

Several overseas reports exist of illness/poisoning in workers occupationally exposed to parathion. These reports cover formulation workers, agricultural workers and aerial applicators. A study conducted in the US, concluded that urinary PNP was a sensitive indicator of parathion exposure, while ChE levels were more indicative of the severity of poisoning. Urinary PNP levels decreased sharply between exposures and disappeared from urine 48 hours after cessation of exposure.

In another US study, 44 of the 238 illness reports among 10,000 agricultural workers were related to the use of parathion alone. Twenty five were following exposure of 3 consecutive work days and 13 following 3 or fewer consecutive work days. Seven illnesses were due to accidents resulting in massive exposure, 21 due to safety violations and 6 due to adverse weather conditions.

Other reports suggest the persistence of parathion on clothing and on the skin. In one instance, the wearing of laundered uniforms previously contaminated with parathion resulted in poisoning.

5.1 Use pattern for parathion in Australia

Handling prior to end use Parathion and one end use product are imported while one product is formulated in Australia. Formulators may be exposed to parathion and products by the dermal and inhalation routes. Formulation workers require protective equipment where efficient engineering controls are not in place.

Transport and storage workers and retailers only handle the packaged active ingredient and/or products. They could potentially be exposed to parathion if packaging were breached.

Parathion products are available as liquids only. Container sizes vary from 20 L to 200 L.

Handling by end users Parathion is applied in Australia to the following crops: stone and pome fruit, citrus, vines, vegetables, and pastures and lucerne. Information on the Australian use pattern of parathion derives from product labels, chemical industry submissions, performance questionnaires obtained through the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) Existing Chemicals Review Program and NRA advice. It is used to estimate worker exposure under Australian conditions and is summarised in Table 1.

Table 1. End use parameters used to estimate worker exposure and risk

| Crop | Application method | Maximum application rate (g ai/ha) | Maximum workrate (ha/day) |
|-------------|--------------------|------------------------------------|---------------------------|
| Stone fruit | | | |
| Pome fruit | airblast spraying | 0.75 | 21 ^h * |
| Vines | airblast spraying | 0.25 | 27 |
| Citrus | airblast spraying | 7.5 | 15 |
| Vegetables | boom spraying | 0.3 | 50 ^h * |
| Pastures | | | |
| lucerne | boom spraying | 0.08 | 240 |
| Pastures | | | |
| lucerne | aerial spraying | 0.08 | 100 - 3000 |

*based on estimates received from grower groups

The maximum parathion concentration in working strength spray is 0.05% in horticultural crops and 0.08% in field crops.

Open pour or closed methods may be used for mixing/loading. Open or closed cabs may be used for spray application. In most ground spraying operations, it is anticipated that the same workers would mix/load and apply the chemical. In aerial operations, the mixing/loading and spraying would be conducted by different workers.

Workers may be exposed to parathion concentrate when opening containers, preparing spray, cleaning up spills and maintaining equipment. Exposure to the diluted solution

can occur during spray application and maintenance operations. Reentry workers, harvesters and workers handling harvested fruit may be exposed to parathion and its degradation products, mainly paraoxon.

Workers may handle parathion repeatedly throughout the season(s). The application of parathion products can occur 27 times per season in any given crop. Some vegetable growers may produce 23 crops per year. Each horticultural crop application of parathion in Australia is likely to take place over 12 days. Contract workers can be exposed to these products more frequently and over longer periods.

The main route of occupational exposure to parathion is expected to be via skin contamination. Inhalation exposure to parathion vapour is not expected to be significant because it has a low vapour pressure. Inhalation of spray mist is possible.

5 Estimation of worker exposure

Estimations of worker exposure relied on measured field studies and a predictive model. Where appropriate, extrapolations were made from similar use patterns in the studies. Estimates of exposure (and risk) used the maximum application rates and workrates specified in Table 1 and assumed that maximum PPE was worn (e. gloves, overalls and waterproof clothing).

The application rates and workrates summarised in Table 1 were used in the UK Predictive Operator Exposure Model (POEM) estimates, together with the assumptions used to assess measured worker data (refer above for details).

Measured end use exposure A number of worker studies of varying quality and applicability to the Australian use pattern were used in the assessment of exposure to parathion during end use. The Australian exposure study used parathion and a closely related chemical, parathionmethyl. It is summarised separately below. Considering the similarity between parathion and parathionmethyl, parathionmethyl data exposure data generated from this study was used as a surrogate for parathion. The studies used in the riskassessment were:

- * airblast and electrostatic spraying of parathions in orchards -an Australian study, under local use conditions;
- * airblast spraying of parathion in orchards -three studies conducted in the US;
- * airblast application of a surrogate chemical (chemical similar to parathions) in orchards -one US study;and
- * aerial and ground boom) application of parathion in field crops -one US study.

Exposure assessment of the Australian study during airblast spraying of parathions in orchards Only one Australian exposure study was available. In this study, worker

exposure during mixing/loading and application (combined functions) were measured under typical Australian conditions during airblast and electrostatic spraying of parathion and parathionmethyl in orchards.

Workers followed their usual practices with respect to spray techniques and use of PPE. However, exposures were adjusted to assume full PPE was worn as per the label and health risk to workers assessed on that basis. The results included exposures during spray application using open tractors and wearing full protective clothing and closed cabs wearing gloves and one layer of clothing. Penetration of parathion through gloves and each layer of protective clothing was taken as 10%. Because each worker in this study conducted mixing/loading and application, it is not possible to determine the influence of each function on overall exposure.

Exposure assessment (all studies) Data from worker studies indicate the importance of engineering controls in reducing worker exposure. Exposure during mixing/loading was greater when using the open pour method. Applicator exposure was greater when in open cabs and when cab windows were left open. Hand exposure was the main contributor to total skin exposure during both mixing/loading and application. All studies showed that exposure by the dermal route was greater than by the inhalation route.

Limited exposure data was available for aerial mixer/loaders and spray applicators using fixed wing aircraft.

Flaggers involved in aerial spray operations may be contaminated with spray mist. Some information was available on bystander exposure and was used to assess the health risk to human flaggers.

Predicted end use exposure The measured worker exposure data was supplemented by modelling where possible. The UK POEM was used to estimate parathion exposure for the Australian use pattern in horticulture and field crops. Four application methods were chosen:

- * airblast spray:ie. vehicle mounted (without cab) air assisted (V500);
- * vehicle mounted (without cab) air assisted (V100);
- * vehicle mounted (without cab) air assisted rotary discs (VRDA2);and
- * boom spray:ie. vehicle mounted (with cab) hydraulic nozzles (VNoz).

POEM is not suitable for the estimation of worker exposure during aerial spraying and electrostatic spraying.

Reentry exposure No Australian reentry exposure data or field residue data were available. Overseas measured worker reentry exposure data was available from the published literature. Overseas residue data was available in various crops from spray application to 25 days after application. Parathion residues were measured for up to 7 days and on day 14 postapplication. No studies were available to evaluate residues between 7 and 14 days after application. Paraoxon residues were measured for up to 25 days post application.

56 Assessment of health risk to workers

In estimating health risk to workers from exposure data, an average body weight of 60 kg per worker and a skin penetration rate of 10% for parathion, were used.

Single exposure Theoretically, the estimated human lethal dose of parathion (1.43 mg/kg) is equivalent to skin contamination with 88 mg parathion or 1.7 mL of the undiluted end use products.

Repeated exposure The human NOEL of 0.05 mg/kg/d is selected for the occupational health and safety risk assessment of parathion.

An average 60 kg worker would need a daily skin contamination with more than 30 mg parathion, 0.06 mL of the concentrate, 6 mL of the most concentrated spray in horticultural crops (0.05% parathion) and 34 mL of the most concentrated spray used in field crops (0.0% parathion), to exceed the human NOEL of 0.05 mg/kg/d.

Assessment of risk was based on calculations of margins of exposure (MOE). MOE for Australian use patterns were calculated by comparing the NOEL with measured and/or predicted worker exposure. An MOE of 50 or more was considered acceptable. This takes into account the significant human variability in percutaneous absorption of parathion (5 fold) and its highly variable metabolism (6 fold) following absorption by any route.

Assessment - ground application Worker health risk was assessed from measured exposure data including the study conducted in Australian orchards and model data. A range of control measures were considered including maximum PPE, closed mixing systems and closed cabs.

Stone and pome fruit The NRA identified critical uses of parathion as being ground application in stone and pome fruit. In the Australian study, MOE generated for parathion were unacceptable, at ≤ 2 . This was for workers performing combined functions and using high pressure airblast and electrostatic equipment with and without air conditioned cabs. Biological monitoring results indicated that one out of seven workers in the parathion group exceeded the ACGIH BI for parathion.

Both measured exposure data, including the Australian parathion study and a US surrogate study, and modelled data indicate unacceptable exposures, under current use conditions in stone and pome fruit. The data on the influence of mixer/loader exposure on overall exposure is conflicting. Predicted applicator exposure appears acceptable for low volume and ultra low volume spraying. Further data would be required to assess whether use is safe with closed mixing/loading systems and closed cabs.

Other crops The assessment of parathion use in other crops found an unacceptable level of risk during ground spraying. Further data would be required to assess whether use is safe with closed mixing/loading systems and closed cabs.

Assessment -aerial application Limited measured exposure data indicated that worker exposure and risk during aerial application of parathion in field crops is acceptable. However, further data would be required to show that exposures are acceptable for aerial loading teams.

Handheld uses and greenhouse uses of parathion These use patterns potentially cause high worker exposure. No data was available to assess these uses, therefore, they are not supported.

Bystander exposure Limited data was available to assess bystander exposure. Available information indicates that human flagging during aerial application of parathion is not acceptable, unless workers have additional protection.

Tankmixing with other chemicals The risk assessment indicates unacceptable risk where parathion is used alone. The additional risk to workers posed by tankmixing parathion products with other anticholinesterase products would be unacceptable. Therefore, this practice is not supported.

Reentry assessment Available data indicated that the current reentry period of 5 days for parathion is inadequate. A comparison of measured foliar residues against an acceptable residue level, suggests that parathion residues decline to a safe level between 7 and 14 days after application. Paraoxon residues up to 25 days post-application exceeded the level considered to be acceptable. No data was available on oxon levels after 25 days.

In addition to foliar residue data, actual reentry worker exposure data was also considered (thion data only). MOE calculated for reentry workers were unacceptable up to and including 7 days postapplication. MOE were acceptable on day 14. No oxon data was available.

For all uses, an interim minimum reentry period of 14 days is recommended for parathion, pending submission of further data.

5 Conclusions

The OHS risk assessment utilised measured worker exposure studies, published literature and predictive exposure modelling to estimate the risk to workers currently using parathion.

The risk assessment found that the health risk to workers during ground spraying (airblast, electrostatic and boom spraying) of parathion products using current practices in all crops was not supported. Where the appropriate authorities allow continued use of parathion, upgraded training plus restrictions on application rates, spray intervals, engineering controls, reentry periods and tankmixing are required. Parathion labels should be amended to include clear instructions for low volume applications.

The OHS risk was not acceptable in current uses for pastures and lucerne where parathion is applied aerially.

The OHS risk assessment concluded that field workers were at risk when reentering parathion treated areas. Reentry restrictions currently on parathion product labels are inadequate. An interim reentry period of 14 days is to be introduced, pending submission and assessment of suitable reentry information.

No data was available to assess handheld uses and greenhouse uses of parathion.

Parathion and the products under review are hazardous substances and are covered by regulations to control workplace hazardous substances.

Tank mixing with parathion is part of current practice. The OHS risk assessment indicated unacceptable risk when using parathion alone. The additional risk posed by tank mixing with other anticholinesterase products is unacceptable.

6 ENVIRONMENTAL ASSESSMENT

In Australia parathion is used as part of IPM programs in orchards, mainly for pears and other pome fruits, but it may also be used for vines, vegetables and lucerne. Application is normally by groundbased equipment.

Studies submitted and other information that has been reviewed by Environment Australia may be summarised as follows:

6.1 Environmental Chemistry and Fate

Physicochemical data

From the physicochemical properties parathion is expected to be moderately soluble in water and highly soluble in organic solvents. It has a moderate to strong partition coefficient and binding to sediment/soil is expected. It is volatile but has low volatility from water.

Hydrolysis

The hydrolysis of parathion is expected to be slow in the environment. The half-life due to hydrolysis ranged from 100 days at pH 9 to 133 days at pH 5.

Photolysis

In laboratory studies, parathion was directly photodegraded in pure water (pH 5) with a half life of 30 days. With a photosensitiser (acetone) the first order half life was 4.5 days but the reaction was not first order and the calculated half life is not considered as accurate. Using a calculated method, based on the laboratory determined quantum yield, the half life in natural sunlight (close to surface, clear skies) at 30 ° latitude was 46 days in summer and 112 days during winter.

Photolysis of parathion on soil was determined to be slow, with a half life of 73 days. This test was not performed to any international testing protocols, apart from GLP.

The vapour phase photolysis of parathion was studied according to US EPA Guidelines, with the half life determined to be 6.4 days. Direct photolysis in the vapour phase by natural sunlight is expected to be slow. However, the calculated half-life in the atmosphere, due to indirect photolysis via atmospheric hydroxyl radicals, is 9 hours and indicates rapid degradation. Degradation is expected to limit the persistence of parathion in the vapour phase.

Parathion can be expected to be photolysed in clear natural water containing humic acids (photosensitiser) but in Australia, where most rivers are turbid, photolysis is not expected to be a significant degradation pathway.

Metabolism

All metabolism studies were performed to US EPA guidelines and used the same single sandy soil.

Aerobic Soil Metabolism

The aerobic aquatic metabolism shows that the first half-life of parathion is approximately 58 days in a single soil. Parathion can be rated as fairly degradable. There were three metabolites identified by HPLC, which were less than 10% of the original dose at all times during the study. The other products of the soil metabolism were incorporated into the organic soil matrix or completely mineralised carbon dioxide.

Aerobic Aquatic Metabolism

The aerobic aquatic metabolism shows that the first half-life of parathion is approximately 2 days with an overall half life of 5.2 days. Parathion can be rated as readily degradable. There were three metabolites observed by HPLC with the principal metabolite, approximately 20% of the applied dose after 31 days, unidentified. The concentration in the water phase was measured as 9% after 31 days but this is considered high given that after 14 days the concentration was measured as 2.2% of the applied dose.

The study showed that parathion is readily absorbed by the sediment. Within one day of application approximately 70% of the chemical was absorbed to the sediment with the remainder either degraded or remaining in the aquatic phase. Degradation was faster in the aquatic phase.

The aerobic degradation in natural waters is expected to be a major route of degradation.

Anaerobic Aquatic Metabolism

The half-life of parathion under anaerobic aquatic conditions is approximately two days and as for aerobic conditions can be rated as readily degradable. There were three metabolites observed by HPLC with the principal metabolite, present in the soil at approximately 20% of the applied dose and in the water at 6% of applied dose after 31 days, unidentified. Almost all of the applied material was incorporated into the organic matter in the sediment.

Literature

Literature reports indicate that metabolism of parathion gives mainly aminoparathion and 4-nitrophenol as the major metabolites. However, in soils that have received multiple applications of parathion, the only metabolite is 4-nitrophenol and the rate of degradation is faster.

Mobility

The mobility studies of parathion from four soils using standard flask equilibrium tests indicate that it can be rated as having low mobility, with K_{oc} of 1130 to 1710 for adsorption and 129 to 180 for desorption, depending upon soil type. There was no evidence of leaching in the laboratory column leaching studies using aged parathion in 3 soils (all remained in top 6cm) or EC and encapsulated formulation in two soils. However, parathion has been reported to have been detected in ground water in the Netherlands.

The volatilisation of parathion from a sandy loam soil was found to be 40% and was rated as low. However, in a German field study volatilisation from plant leaves was significant, with up to 30% of the initially applied parathion being lost from leaf surfaces in the first 24 hours under relatively cool weather conditions.

Volatilisation of parathion from soil is not expected to be a major route for the dissipation from soil. However, volatilisation of parathion from other nonadsorbing surfaces could be.

Spray Drift

The spray drift studies showed that aerial application of an EC as a very low volume (VLV) formulation causes significant spray drift, which is toxic to bees up to 1200 metres away. As the droplet sizes used were approximately twice the size used in Australia, under Australian conditions spray drift could be a greater problem. As aquatic invertebrates are very sensitive to parathion (see environmental effects), significant effects on these organisms are possible and at distances greater than one kilometre away from the application site.

The spray drift from ground-based orchard application was significant and toxic to bees up to 400 metres away. In Australian conditions, where there is a significant use of low volume (LV) formulations, droplet sizes are likely to be smaller than those used in these studies and therefore the potential for spray drift is higher. Significant effects on the more sensitive aquatic invertebrates are possible at 400 metres from the site of application.

Field Studies.

The six field studies presented, two of which were from an irrigated crop (rice), support the results of the laboratory studies in that parathion is readily degraded in the soil and in particular water. The half-lives determined in the soil ranged from 3 days to 32 days and were below that found in the laboratory study for a single aerobic soil (57 days). Dissipation from water was very fast, with no residues being detected (0.01 ppm) 24 hours after application. No metabolites of parathion were detected but the tests are considered relatively insensitive. Parathion or its metabolites were not detected below 10 cm in the soil, confirming the laboratory studies on mobility which showed that leaching was unlikely.

Bioaccumulation

The steady state bioaccumulation factors were moderate, with the highest being 90 times for nonedible tissues. Elimination of parathion from these tissues was rapid, with a half life of 12 hours, indicative of rapid depuration. Bioaccumulation in the environment is not expected.

Conclusion

The physicochemical properties of parathion indicate that it is volatile with moderate solubility in water and is likely to bind to soil.

Parathion is expected to degrade once in the environment. Degradation is rapid in the aquatic compartment, with a first half-life of approximately 2 days. In the soil degradation is slower, with half-lives ranging from 3 days to 58 days. Moderately strong binding to the organic soil fraction occurs, which while limiting degradation, also limits leaching potential and bioavailability.

Photolysis could be a significant contributor to the degradation of parathion with a half life of approximately 4.5 days (photosensitised). In turbid waters photolysis is not expected to be significant. The half-life of indirect photolysis in the vapour phase, calculated as approximately 10 hours, will limit atmospheric transport.

6 Environmental Effects

Parathion is a highly toxic organophosphate insecticide. It is toxic to most organisms and in particular aquatic invertebrates.

Avian

Based on results in the literature parathion is highly toxic to birds by the single dose oral route (LD₅₀ of 1.3 to 24 mg/kg) but this toxicity is significantly moderated when ingested as part of the diet in short term tests. It is also highly toxic to birds via dermal exposure. Effects on mallard duck reproduction were noted at 7.1 ppm in the feed in a 20 week study and in the same study 50% mortality occurred at 20 ppm in the feed. Field reports indicate that parathion has been associated with several incidents of bird kills in the USA.

No other data was data on field studies or palatability of parathion to birds was found in the literature. No Australian reports of bird kills from label use of the EC have been found.

Aquatic

The toxicity to aquatic organisms is very high, especially to invertebrates. From the submitted studies the reliable LD₅₀s for fish were 20 g/L and 0.8 mg/L for Sheepshead minnow and rainbow trout respectively. Life cycle studies have not been performed, however the embryonic and larvae life stages of Sheepshead minnow have been tested and the maximum acceptable tolerated dose was determined to be between 1.3 and 0.76 g/L. The early life stages are considered to be normally the most

sensitive.) The US EPA AQIRE data base has LC50s for fish ranging from 56 µg/L to 10 mg/L for guppy (*Poecilia reticulata*) and rainbow trout respectively.

Parathion is extremely toxic to invertebrates, with acute toxicity figures of EC50 of 2.5 µg/L and 0.08 µg/L for daphnia and mysid shrimp respectively. The chronic toxicity to mysid shrimp has been determined and the MATC was determined to be 4.1 ng/L. However, it should be noted that there were some significant problems with the study in relation to background levels and the results have to be considered with some caution. In the studies with results below 0.1 µg/L there was difficulty in the analysis due to the extremely low concentration. The AQIRE data base indicates that most aquatic invertebrates would be expected to be effected by parathion at around 0.1 to 1 µg/L.

The toxicity of parathion to Australian freshwater macrocrustacea has not been determined but an EC50 of 40 ng/L to a freshwater crayfish species (early instar) has been reported, but the figure is not considered reliable. The AQIRE data base indicates that macrocrustacea are the most sensitive group of aquatic organisms.

Non-Target Invertebrates

Parathion (EC formulation) is toxic to bees by all routes of exposure, contact EC50 = 0.131 µg/bee. Residues of parathion on foliage are toxic to bees for up to 48 hours.

The toxicity to earthworms is high and it should be noted that the major metabolite, 4-nitrophenol, is even more toxic to earthworms. Surprisingly there were no data or information on the toxicity to predators or parasites as used in IPM programs.

Phytotoxicity

There is limited information on the toxicity of parathion to plants. The toxicity to green algae is moderate to high, with EC50s of 0.5 mg/L for *Chlorella* and EC50 of 1.8 mg/L for *Scenedesmus*. Parathion is nonphytotoxic, except to some ornamentals, cucurbits, sorghum and some varieties of apples, pears and tomatoes.

6 Prediction of Environmental Hazard

Hazard arising from use

Parathion is registered for use on citrus, pome fruit, stone fruit, vines, vegetables, pastures and lucerne, with the major use being in orchards. It is used to control mites, scale, aphids, moths, mealy bugs, lucerne fleas and thrips. Parathion is considered a soft chemical which does not cause significant harm to predatory insects and as such is used as an integral part of IPM programs, especially by growers in the stone and pome fruit industries.

Among the significant current uses of parathion identified by the efficacy review is to control codling and light brown apple moths in IPM programs for pome fruits. The

application rate to control the moths is 50 mL per 100 L of spray, which corresponds to 750-1500 mL/ha (750-1500 g ai/ha) for typical high volume spray of 1500-3000 L/ha.

The current labels are for high volume spraying but many users are using low volume equipment (in some cases very low volume, VLV) and electrostatic equipment. The actual rate used by growers is unclear as it depends on individual growers but it is considered that the rates used are lower than those specified on the labels.

Parathion has been known to be used up to 12 times a season for control of moths but normal use is 6-8 times a season.

There is no information on types of spray equipment used or any information concerning the use of low volume application equipment. Information on minimising spray drifts or of spray droplets etc., is also not given on the label.

As the major use of parathion is currently to control moths as part of IPM in pome fruit orchards at the rate noted above, this is the use pattern used in this hazard assessment.

6 Terrestrial Organisms

Mammals

As the applications are normally made by tractor powered equipment, accidental direct spraying of larger nontarget organisms, such as marsupials, is considered unlikely as it is expected that these animals will move some distance from the area where spray operations are occurring, while smaller mammals will be undercover. Thus they are unlikely to be exposed.

Birds

Parathion is very highly toxic and has the potential to harm birds through ingestion of residues. For fruit sprayed at 750 g ai/ha the concentration of parathion residues on the fruit is calculated as 10 mg/kg wet weight. This concentration indicates a low hazard to birds from the toxicity data reviewed by Environment Australia, in spite of some literature reports of birds dying from ingestion of poisoned emerging wheat plants or insects.

Birds entering an area that has been recently sprayed could be exposed either dermally or orally from preening contaminated feathers. This type of exposure is difficult to estimate and given the low hazard, this route of exposure is not expected to cause a significant increase in the overall hazard.

Bees

Bees are at risk if spraying occurs when they are present in the crop. Even at the lowest rate, 375 g ai/ha, the dose estimated by Environment Australia (0.25 g ai/bee)

is significantly above the contact EC50 (0.131 µg/bee). In order to limit the exposure of bees to the pesticide, the crop should not be sprayed when bees are present or when the crop is in flower. Spray drift from orchard application is also likely to be toxic to bees.

Soil and Terrestrial Invertebrates

Earthworms could be exposed to the pesticide, and at an application rate of 750 g ai/ha, the top 5 cm of soil would contain parathion residues at 1.1 mg/kg of soil (assumes no crop cover, density of soil 1300 kg/m³, direct application). As the concentration of pesticide in the soil due to direct application is significantly below the EC50 (5 mg/kg of soil) for earthworms, effects on earthworms from orchard spraying are not expected.

Other soil invertebrates may be significantly affected unless they can move away from the sprayed areas or have become resistant due to parathion use in the past. No data are available for these organisms or terrestrial invertebrates.

Conclusion

Apart from bees and possibly soil invertebrates, terrestrial organisms are not expected to show significant effects when parathion is used in pome fruit orchards according to current label directions. To strengthen the current label warning with regard bees, the label should be modified to read:

Do not spray any plants in flower, including ground covers and adjacent foliage, or while bees are present. Spray drift is also highly toxic to bees.

6 Aquatic Organisms

Direct overspray onto water

Aquatic organisms are the most sensitive to the toxic effects of parathion, based on the ecotoxicity data reviewed. The application of parathion directly to a body of water 15 cm deep at the lowest rate of 0.375 g ai/ha¹ is calculated to give a concentration in water of 250 µg/L¹. As this is above the EC50s for all aquatic organisms tested, except algae, there is a potential hazard to all other aquatic organisms.

Effects on daphnia and other aquatic insects/invertebrates from direct overspray are likely to be severe, with the concentration in water approximately 5 times the EC₅₀ for daphnia from the lowest application rate. While the current use pattern would not be expected to cause direct overspray, aerial application could. It is therefore recommended that the current ban on aerial applications in Tasmania be extended to the mainland Australia should registration be retained.

Spray Drift Scenarios

Some Land Use Considerations

Pome fruits are grown in a number of locations with considerable variation in land use adjacent to these crops. Environment Australia expects that ponds and drainage channels (both manmade/modified or natural) would be a common feature of the landscape in which pome fruits are grown, with subsequent movement of parathion into natural receiving waters such as swamps, marshes, lakes and rivers.

Acute hazard, single application

The major use of parathion currently is for pome fruit orchards, which are sprayed by orchard air blasters or similar equipment. From the information on spray drift presented to Environment Australia, and allowing for adsorption to sediment, the acute hazard due to spray drift is acceptable for fish but unacceptable to most aquatic invertebrates that are up to 100 m away from an orchard where parathion is being used. Using more realistic scenarios, this hazard is moderated and is acceptable for application rates of less than 500 g ai/ha. After 24 hours there still exists an unacceptable hazard at high application rates.

For the most sensitive organisms, which could include juvenile macroinvertebrates, ie yabbies, calculations show an unacceptable hazard at 200 m for the worst case for spray drift at all application rates. Even in the most realistic scenarios, there is an unacceptable hazard at this distance for application rates of 500 and 750 g ai/ha, which is reduced by adsorption after 24 hours to acceptable levels for 500 g ai/ha only.

While the above calculations were for ponds, a pulse of contaminated water is likely in flowing streams and the acute hazard calculations used above are considered an approximation of this pulse. It is expected that the hazard will be less than that calculated for natural lentic ponds etc receiving water from streams near orchards.

Modern LV and ULV equipment used by some growers is of concern due to the higher potential for spray drift from the small droplet size used. Environment Australia does not have data for the spray drift from such equipment but considers that analysis above could underestimate the distance that the drift would affect (finer droplets move further horizontally than coarse droplets). Further information is required before a conclusion about the hazard to aquatic organisms from such equipment can be determined.

Multiple applications

The above analysis is for a single application but in practice there are expected to be multiple applications. It is expected that in most situations there would be at least 7 days between sprays. Assuming the worst case, the concentration in water due to carryover is expected to be 2% or less of the initial concentration. Therefore a significant increase in acute toxic effects on aquatic organisms from multiple applications is not expected, provided there is at least 7 days between applications.

However, the main problem is repeated effects on sensitive organisms and 7 days between sprays would not allow affected populations to recover. A recovery period is required to minimise the impact of repeated applications, especially as parathion may be used up to 8 times a season (see efficacy report). As parathion is most likely to

affect aquatic invertebrates, a recovery period of at least 21 days is required. This corresponds to 23 life cycles for daphnia, an important invertebrate in aquatic ecosystems.

Chronic exposure

Chronic effects are not considered likely in fish given the concentrations of parathion expected from spray drift and then rapid adsorption and degradation reducing the concentration further.

Using the a realistic case for spray drift and a mathematical model, used as a substitute in the absence of actual data, chronic effects on daphnia are unlikely. However, chronic effects on sensitive aquatic organisms are possible for up to 15 days after application at a distance of 100 meters away. The model used clearly shows that chronic effects from spray drift are possible for ponds etc that are near orchards where parathion is used.

As it is likely that a chronic hazard exists from spray drift, there must be very significant chronic hazard from direct application. Any situation that significantly increases the spray drift or allows direct overspray must be avoided.

Metabolites

Metabolites of parathion could be present and represent a hazard to aquatic organisms. However, the major metabolite expected, 4-nitrophenol, is not as toxic as the parent compound and degrades in the environment.

Runoff and Leaching

Current management practices for orchards is expected to limit the occurrence of runoff. However, when runoff does occur it is not expected to cause a significant environmental hazard due to dilution and degradation in both soil and water.

As there was no evidence of leaching in the laboratory column leaching studies, leaching of parathion to subsurface water is unlikely. Nevertheless, analysis of ground water in the Netherlands has show that parathion was present in some ground water samples. This indicates that at high usage, low level contamination of ground water is possible.

Algae

As the spray drift studies show that the concentration of parathion in shallow water is greater than an order of magnitude below the algae EC50, effects on algae are unlikely.

Desirable terrestrial vegetation

Parathion is in general nonphytotoxic to plants and as direct application to desirable plants and vegetation is not expected, significant effects on desirable plants is unlikely.

6 Controls/ Lablling

Parathion must not be allowed to contaminate waterways.

The current warning to prevent exposure of bees should be strengthened (see below).

If registration is to be maintained, the following warnings should be added to the label under the heading of Use?

DO NOT APPLY ~~N~~ AIRCRAFT.

DO NOT apply under meteorological conditions or from spraying equipment which could be expected to cause spray drift onto a natural streams, rivers or waterways.

Do not spray any plants in flower, including ground covers and adjacent foliage, while bees are present. Spray drift is also highly toxic to bees.

RESTRICTED TO IPM programs for pome fruit. The number of recommended sprays is ~~X~~ per season with a minimum of 21 days between each.

Disposal

The instructions for disposal on the labels are different for different products. Again, if registration is to be retained all labels should be changed to the current statement labels requirements, ie:

Triple rinse or pressure rinse empty containers before disposal. Add rinsings to the spray tank Do not dispose of undiluted chemical on site.

Conclusions

Parathion is very toxic to birds, mammals and aqatic invertebrates. ~~B~~ds and mammals are not expected to be significantly exposed to the chemical unless they enter an area recently sprayed.

The direct application of parathion to aqatic systems is expected to cause significant mortalities among most aqatic organisms and must be avoided. Spray drift represents a significant hazard to aqatic organisms and conditions of use that limit spray drift must be used to prevent significant environmental damage. Even with these precautions, the hazard to aqatic invertebrates and macroerustacea is unacceptably high. Despite the rapid degradation, chronic effects are possible on sensitive organisms at application rates ≥ 500 g ai/ha.

Although there are no Australian data on the toxicity of parathion to freshwater macrocrustacea, overseas data indicate that these organisms are the most sensitive to effects of parathion and a major hazard exists. Information on the toxicity of parathion to suitable Australian species is required to support the current use pattern. Information on the actual application rate, droplet size and potential for spray drift from low volume and ULV applications is also required.

Parathion readily degrades in natural systems, with the first half-life of approximately 2 days in aqueous conditions, in both aerobic and anaerobic conditions. It degrades in soil but the process is slower, with a half-life in the field of between 3 and 32 days. Parathion is not expected to leach.

Parathion is sufficiently volatile to have a fumigant effect, and volatilisation is expected to be a significant method of loss, particularly from foliage. When it deposits on soil, parathion will be bound to the soil and therefore volatilisation is limited. Degradation in the air from free radicals is fast, with a calculated half-life of approximately 10 hours.

The chemical is very toxic to birds, mammals and aquatic invertebrates. Its toxicity to birds decreases when it is incorporated into the diet, therefore the environmental toxicity depends on the route of exposure. Birds and mammals are not expected to be significantly exposed to the chemical unless they enter an area recently sprayed. However, the direct application of parathion to aquatic systems is expected to significantly affect aquatic invertebrates and must be avoided.

Spray drift presents a very significant hazard to aquatic invertebrates and at considerable distance from the site of application. A buffer zone or inner buffer is highly desirable. While this would reduce the hazard to environmentally sensitive areas, additional measures such as vegetative buffers are required to reduce the hazards to more acceptable levels.

Taking into account the unknown effects of applications of mixed insecticides, Environment Australia cannot rule out that an unacceptable hazard exists application of parathion in the current fashion, due to both possible direct overspray and spray drift from orchard application. Information on spray drift from mixed applications should also be provided.

While we are aware of no actual aquatic mortality incidents, the reports of bee deaths are a clear indication that unacceptable spray drift can occur. In order to limit the exposure of bees to parathion, the crops should not be sprayed when bees are present or when the crop is in flower. Further, to protect sensitive species and limit broader environmental damage, use should be restricted to IPM programs when there are no other alternatives. A very tight product stewardship would also be required with the company(s) limiting the rate and type of application equipment used by growers.

Calculations for the spray drift from conventional high volume orchard air blast equipment shows there is a high hazard to sensitive aquatic organisms. After 24 hours, there is still likely to be significant effects on these sensitive aquatic organisms, particularly at the highest rate.

For orchards (especially older citrus orchards) with very large trees where a higher application volume could be required, ie up to 10,000 L/ha, one option to limit the environmental damage is that the last 3 downwind rows should not be sprayed, ie an inner buffer. This is based on evidence from citrus orchards indicating these rows are largely responsible for the majority of the spray drift.

Modern LV and ULV equipment used by some growers is of concern due to the higher potential for spray drift from the small droplet size used. Environment Australia does not have data for the spray drift from such equipment and further information is required before a conclusion about the hazard to aquatic organisms from such equipment can be determined.

Parathion has been used for the last 30 years and large numbers of aquatic invertebrates are likely to have been affected during this time. While the calculations clearly show that the hazard to sensitive organisms is high past exposure of these aquatic organisms may have resulted in the current populations being more tolerant to parathion. Considering the above, and that the most sensitive sub populations are likely to have already been significantly effected, it is recommended that the label rate be reduced to 375 g ai/ha.

A recovery period is required to minimise the impact of repeated applications to sensitive aquatic organisms, a minimum recovery period of at least 14 days between applications is desirable.

7 PROTECTED INFORMATION STATUS OF SUBMITTED DATA

All data considered as protected registration information by the NRA are identified in the bibliographies of the full review report with a letter "P" placed next to them in the left hand margin.

ATTACHMENT 1: PRODUCTS AND TGACS AFFECTED BY THIS REVIEW

Products

| | |
|-------------------------------------|---|
| 33070 Tebing Parathion Insecticide | Registrant: Tebing Pty Ltd |
| 4558 Farnoz Parathion E Insecticide | Registrant: Farnoz Pty Ltd |
| 488 Novafos E 500 Insecticide | Registrant: Cheminova Australia Pty Ltd |

TGAC

| | |
|-----------------|--------------------------------|
| 44225 Parathion | Approval Holder: Cheminova A/S |
|-----------------|--------------------------------|

ATTACHMENT 2: SUMMARY OF PUBLIC RESPONSE TO THE DRAFT PARATHION REVIEW

Following consultation with stakeholders in Commonwealth and State authorities and industry, the NRA released a draft parathion review report in September 19 for public comment. This release was widely publicised and notices were sent to all who had expressed interest in or who had participated in the review thus far. The draft review report was placed on the NRA website and printed copies were available on request. The parathion draft report emphasised concerns and data gaps identified during the assessment of data. The public comments phase lasted two months during which comments and submissions from the public were obtained on the draft report.

The public comment was limited to some eight responses. This summary describes the main issues raised in response to the release of the draft review report. As expected, the proposed restrictions and data gaps identified in the draft report attracted most comment.

The majority of submissions came from grower and commodity organisations, followed by chemical industry, individual growers and State regulatory authorities.

Public comments while supportive of the risk management approach taken by the NRA, were of the view that the risks identified are not real. The requirement for additional data were seen as an unnecessary impost on the users and chemical industry. As the result that neither the registrants nor the user groups have provided a commitment to fill the environmental and occupational health and safety data gaps or implement the required restrictions. Some user groups have showed an interest in providing limited residue data.

While there was acceptance of the need for maximum care and caution in the use of parathion, none of the submissions contained data or arguments to address the risks identified. Public concerns and comments are presented in normal font. The NRA responses to those concerns or the manner in which the NRA proposed to address these concerns are in *italics*.

General comments

Re-entry Period

The proposed interim reentry period of a 14 days attracted vigorous comment. Respondents commented that the proposed interim reentry statement does not distinguish between reentry into a densely cropped field and that in to an orchard where the reentry work exposure would be significantly different. In addition, orchardists pointed out that the potential for reentry exposure would vary significantly depending on the type of tasks such as fruit thinning, scouting, setting up irrigation and weeding etc. It was suggested that several specific reentry requirements be specified to differentiate between the reentry task and situations encountered in various crops.

~~The requirement for elbow-length PVC gloves during re-entry to the field is impractical given the nature of some tasks (e.g. pest monitoring) that are required to be carried out during re-entry. It was argued that elbow-length PVC gloves, do not provide the necessary flexibility to conduct these tasks effectively. As a cotton overall buttoned to the wrist and neck is also specified to be worn during re-entry, the aim is to prevent possible dermal exposure through the hands below the wrists. It was argued that this would be achieved using chemical resistant gloves.~~

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~~pest monitoring~~

~~practical~~

The requirement for elbow-length PVC gloves during re-entry

As for parathionmethyl, respondents argued that the requirement for elbow-length PVC gloves was impractical given the nature of some task (e.g. pest monitoring) that are required to be carried out during reentry. It was argued that elbow-length PVC gloves, do not provide the necessary flexibility to conduct these task effectively. As a cotton overall buttoned to the wrist and neck is also specified to be worn during re-entry, the aim is to prevent possible dermal exposure through the hands below the wrists. It was argued that this would be achieved using chemical resistant gloves.

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Limitations on amount of active used per application

The proposed rate limitation to 375 g a.i./ha has attracted vigorous comment from producers of citrus and orchard crops. Parathion user organisations argued that in most practical situations, a rate of 375g a.i./ha would not be adequate to protect crops because the variability of tree and canopy size and growth stage etc. They pointed out that the efficacy of this rate prescription remains untested under a variety of conditions encountered in normal use situations of parathion.

Respondents objected that the proposed limitation, if adopted, would force them to use other, possibly more disruptive chemicals to protect their crops from pest infestations. It was argued that most alternative chemicals would also eliminate beneficial insects whereas parathion use allows significant numbers of beneficial insects to survive. The loss of beneficial insects, especially early in the season, would result in greater pest

pressures later in the season leading to the use of more pesticides than would be needed if parathion was not restricted in this manner.

For crops where larger trees are encountered such as pome fruit and citrus, this limitation was considered to be entirely unworkable due to efficacy concerns and the desirability to maintain populations of beneficial insects in the orchards.

~~The following information is provided for the purpose of providing information to the public regarding the use of parathion-methyl in Australia. The information is provided for the purpose of providing information to the public regarding the use of parathion-methyl in Australia.~~

Minimum interval between spray applications

Some respondents objected to the proposed requirement to maintain specific intervals between parathion applications as this requirement conflicts with common objectives of any integrated pest management (IPM) or resistance management programs. IPM programs require spraying of pests when the pest numbers reach appropriate thresholds. Where users are prevented from using parathion, then a different chemical, arguably more harmful to beneficial insects would be used when the pest activity requires it. This would disrupt IPM programs, resulting in greater use of arguably more ecotoxic chemicals. Resistance management programs are also likely to be compromised due to inability to use different classes of chemical as and when required.

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Training requirements/competencies for supply and use of parathion-methyl

Some respondents questioned the need for the requirement that the chemical be made available only to users having completed current Farmcare course or equivalent qualification. Several respondents raised the issue of establishing equivalence between the various training courses available. State authorities expressed the view that competencies/level of training required for the use of chemicals such as parathion should be identified and communicated to the users via the label.

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Work Exposure Data Requirements

The call for Australian work exposure data was objected to by some respondents on the grounds that new studies would be expensive and that parathion had been in use for over 30 years with no pronounced work safety problems becoming evident. Some respondents questioned the POEM modelling approach cited in the review as being too conservative and based on inadequate data or data not appropriate for Australian conditions. The extent to which theoretical modelling, and in particular, margins of exposure (MOE) were relied upon in the OHS assessment was also questioned.

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Residue Data Requirements

The proposed requirement that industry provide residue data to fill existing data gaps caused concern for some user groups mainly for the reason that generating the new data would be expensive and timeconsuming. This requirement was viewed as an unnecessary impost given that for many commodities, parathion residue violations have not been a problem.

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Importance of parathion to particular uses

Submissions from the respective grower organisations argued that parathionmethyl is vital to the viability of pome and stone fruit industries in the Goulburn Valley.

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NRA ORDER FORM

To receive a copy of the full technical report for the NRA's evaluation of parathion, please fill in this form and send it, along with payment of \$00 to:

Chemical Review Section
National Registration Authority for Agricultural and Veterinary Chemicals
PO Bx E240
Kigston ACT 264

Alternatively, fax this form, along with your credit card details, to Chemical Review on (02) 672 3551.

Name (Mr, Mrs, Ms, Dr) _

Position _

Company/organisation _

Address _

Contact phone number ☎ _

I enclose payment by cheque, money order or credit card for \$

~~Bank~~ card

Visa

Mastercard

Amex

Card number

Expiry date/...../.....

Signature Date _