Public Release Summary
on

The NRA review of

MEVINPHOS

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Existing Chemicals Review Program

National Registration Authority
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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 Branch), Worksafe Australia (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 which are part of the OECD *ad hoc* exchange program. Under this program it has been agreed 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 summary provides a brief overview of the review of mevinphos 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 the registrant, 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 mevinphos, 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: *Ag Manual: The Requirements Manual for Agricultural Chemicals; Vet Manual: The Requirements Manual for Veterinary Chemicals* and Volume II of *Interim Requirements for the Registration of Agricultural and Veterinary Chemical Products*.

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 2604 Australia.

CONTENTS

ABBREVIATIONS AND ACRONYMS

ac	active constituent
ADI	Acceptable Daily Intake (for humans)
ai	active ingredient
Bt	*Bacillus thuringiensis*
ChE	cholinesterase
d	day
DBM	Diamond Back Moth (*Plutella xylostella*)
DT_{50}	time required for 50% of a chemical to degrade
EC	emulsifiable concentrate
EC_{50}	concentration at which 50% of the test population are affected
EEC	estimated environmental concentration
EUP	end use product
GAP	Good Agricultural Practice
h	hour
ha	hectare
in vitro	outside the living body and in an artificial environment
in vivo	inside the living body of a plant or animal
IPM	Integrated Pest Management
kg	kilogram
L	litre
LC_{50}	concentration that kills 50% of the test population of organisms
LD_{50}	dosage of chemical that kills 50% of the test population of organisms
LOEL	Lowest Observable Effect Level
m	metre
mg	milligram
µg	microgram
mL	millilitre
MOE	margin of exposure
MRL	maximum residue limit
MSDS	Material Safety Data Sheet
NDPSC	National Drugs and Poisons Schedule Committee
NHMRC	National Health and Medical Research Council
NOEL	No Observed Effect Level
NOHSC	National Occupational Health and Safety Council
OP	organophosphate
POEM	Predicted Operator Exposure Model
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
RBC	erythrocyte
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGAC	technical grade active constituent
WHP	withholding period
WSA	Worksafe Australia

SUMMARY

The NRA has reviewed the registration of mevinphos, a broad spectrum insecticide (an organophosphate) registered for use in Australia to control a variety of insects, including *Helicoverpa*, aphids, loopers, leafhoppers, webworms and caterpillars, on lucerne, vegetables and gladioli.

The review, conducted under the NRA's Existing Chemicals Review Program, found that mevinphos poses significant unacceptable risks to the health of users who mix, load and apply the chemical. The NRA, therefore, recommends that registration of mevinphos for non-essential use patterns be cancelled, that registration for use on brassicas only be allowed to continue until 31 December 1998 (by which time effective alternative insecticides are likely to be available) and that greater restrictions be placed on the labelling, sale, supply and use of mevinphos until it is phased out.

Chemical description

Mevinphos is a racemic mixture containing between 630-642 g/kg of the E-isomer and 170-276 g/kg of the Z-isomer. It is primarily used for the control of insects in brassica crops (broccoli, cauliflower, cabbage and Brussels sprouts) and is particularly effective in controlling Diamond Back Moth.

Label directions require mevinphos to be applied, according to pest activity, by boomspray as medium to fine droplets. The maximum use rate, 65 mL per 100 L corresponds to 1100g ai/ha for brassicas, sweetcorn and trellis tomatoes. Label restraints indicate mevinphos is NOT to be applied by fogging machines, mist-blowers, back-mounted knapsacks or by aircraft. The withholding period for crops that have been sprayed is two days.

In Australia, one approval of the technical grade active constituent and one registration for a product containing mevinphos (product name: Phosdrin Insecticide) exist. Both are held by Cyanamid Australia Pty Ltd.

Major hazard to vegetable growers and other users

The major hazard associated with mevinphos is its high acute toxicity. The chemical produces rapid and significant inhibition of cholinesterase (ChE) activity by all routes of exposure. (Cholinesterase is a body enzyme found in humans and animals that helps regulate the activity of nerve impulses and is necessary for proper nerve function). Mevinphos has the potential to cause chronic depression of ChE on repeated exposure.

While no Australian data on human exposure to mevinphos alone are available, one study in New South Wales in 1992–93 showed that 5.5% of all vegetable growers tested, who used a variety of organophosphate insecticides including mevinphos, had cholinesterase levels below the reference range. The findings also suggested a high number of vegetable growers did not wear adequate personal protective equipment, which could explain high ChE levels.

The NRA has concluded, based on user exposure data, that mevinphos poses an undue hazard to users. Measured exposure, using surrogate data, predicts that mixers, loaders and applicators of mevinphos will be exposed to levels of the insecticide that exceed the proposed No Observed Effect Level (NOEL), equivalent to a dermal dose of 0.005 mL mevinphos/day. (NOEL refers to the highest concentration or amount of a substance, found by study or

observation, to cause no detectable (usually adverse) alteration of morphology, functional capacity, growth, development or life span of the most sensitive test organism).

As users are already required to wear extensive protective clothing when working with mevinphos, and the NRA does not believe that adding supplementary controls, such as enclosed mixing systems, would substantially reduce the margin of exposure.

Minimal hazards to other members of the community

For other members of the community, the NRA expects exposure to mevinphos to be minimal. No carcinogenicity or developmental toxicity has been attributed to mevinphos, while the genotoxicity potential of mevinphos is equivocal.

Mevinphos does not have any registered domestic uses in Australia. Its greatest potential for public exposure is via ingestion of mevinphos residues in food, but those residues have never exceeded the maximum residue limit (MRL). (MRL is the maximum concentration of a chemical residue that is legally permitted in or on a food).

The highest estimated intake of mevinphos (for a two-year old child) is 3% of the new ADI (Allowable Daily Intake), proposed as a result of this review.

While very few residue data were available for mevinphos (and no Australian data), data for brassicas were provided. The NRA considers these sufficient to support a temporary MRL of 0.25 mg/kg. Establishment of a permanent MRL will require residue data generated under Australian conditions.

Reducing potential hazard to the environment

Mevinphos is extremely toxic to aquatic invertebrates, birds and mammals; however, birds and mammals are not expected to be significantly exposed to the chemical unless they enter an area recently sprayed. Spray drift could have a significant adverse impact on aquatic invertebrates, even though this effect is expected to be temporary with repopulation from locally unaffected regions. Restricting the number of applications on any one crop would significantly reduce the effect spray drift may have on aquatic ecosystems.

Minimising the effects of withdrawal of mevinphos from the market

The NRA has taken into account the likely detrimental effect an immediate withdrawal of mevinphos would have on growers who use the chemical. It recognises that mevinphos is regarded as an essential chemical in the brassica industry which is a substantial producer of vegetables. Exports are estimated at $25 million/annum, and Flemington Markets, Sydney has an annual throughput of brassicas of about 90,000 tonnes. This is because mevinphos can be used close to harvest due to its short withholding period and because of its effectiveness against the Diamond Back Moth, a major pest of brassicas, which is showing increased resistance to many other organophosphates and to insecticides from other chemical groups.

Many growers use *Bacillus thuringiensis* (Bt) as an alternative to mevinphos but, under certain conditions, pest populations can build up quickly and control of them by Bt is no longer maintained. When this happens growers tend to rely on mevinphos to restore control.

Although there appear to be no current reliable substitutes for mevinphos, the NRA has evidence to suggest that new chemicals will probably become available to growers over the

next one to two years that will be viable substitutes. The NRA also believes the effective life of these chemicals could probably be doubled if they were introduced to the market simultaneously. This would involve retaining mevinphos in the short term, until several of these chemicals are available to growers.

The NRA proposes to allow the continued use of mevinphos until the end of 1998, but only in those situations where it is considered essential, namely, brassica production in all States and Territories, except the Northern Territory (where Diamond Back Moth-resistance is not considered to be a major problem).

All other uses of mevinphos will be withdrawn, as no evidence has been provided to the NRA to demonstrate that these are essential uses without alternatives. In addition, use of mevinphos will only be authorised when there has been a control breakdown. It will not be used as a mainline chemical throughout the growing season.

Recognising the hazard that mevinphos will continue to present to users, the NRA is placing severe restrictions on mevinphos use. Users will have to demonstrate they are complying with these restrictions. In addition, monitoring of cholinesterase levels users will be required to ensure users' exposure to mevinphos is not harming their health.

Approval for mevinphos use beyond the end of 1998 will only be considered if sufficient new data and information can be provided to satisfy the NRA that this chemical can meet current standards for safety, efficacy and use; particularly those relating to user safety, the environment and residues.

Notwithstanding these measures, the NRA may withdraw the chemical at any time should health information indicate this is necessary.

The NRA is proposing that:

- Mevinphos use on all non-essential crops will be cancelled from 30 June 1997.
- Mevinphos use on brassicas will be allowed to continue until 31 December 1998 in all States/Territories except the Northern Territory to allow time for alternatives to be developed.
- Users will be required to implement the restrictions on use and undergo cholinesterase checks.

Full details of the review recommendations are available on pages 29 and 30 of this report.

1. INTRODUCTION

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

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 Agricultural and Veterinary Chemicals Code (scheduled to the *Agricultural and Veterinary Chemicals Act 1994*) 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 reviews

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 Proprietary Rights

To grant protection to providers of certain information relating to agricultural and veterinary chemicals, the NRA introduced a Proprietary Rights in Registration Data (PRRD) Program. The objectives of this program are:

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

In general, the NRA designates information as 'protected registration 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 Mevinphos Review

Mevinphos 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 avian wildlife;
- its association with worker poisonings overseas, during end use and upon re-entry;
- high worker exposure scenarios; and
- high potential acute and chronic risk.

Whilst the selection process ranked mevinphos 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 mevinphos.

1.4 Consultation Activities

In response to the widely publicised call for submissions on the review of mevinphos, the NRA received 18 submissions.

Responses from growers

In general, growers argued strongly for the retention of mevinphos, especially in the brassica industry. Its wide spectrum of activity and short withholding period (two days) means it can be used closer to harvest than other chemicals without any maximum residue limit (MRL) violations, and it is useful as a clean-up spray when other control measures fail and pest pressure builds up.

Growers are aware of no suitable alternatives to mevinphos. Although there are other chemicals that can be used, none can match the broad spectrum of activity, rapid knockdown and short withholding period of mevinphos. Because of this, growers state that the withdrawal of mevinphos would have a serious impact on the efficiency of production of many crops. They report that tolerance of pests in produce by the fresh market and processors is virtually nil and infestation will cause immediate rejection of produce for export. Therefore, the uncontrolled infestation by insect pests would make many crops worthless on the domestic market and preclude consideration of vegetable crops for export markets.

Most users explicitly acknowledge the high toxicity of the chemical and spray in the cooler parts of the day when protective clothing is more comfortable to wear and spray drift is reduced. Several state they are not aware of any adverse incidents involving mevinphos products, when used according to label instructions.

Responses from the community

Comments from the community focused on the high acute toxicity of mevinphos and the potential risks this poses to users. They identify it as one of the most toxic and potentially hazardous insecticides used in the horticultural sector. Also, one respondent commented that, when a commercial laboratory wanted to test for suspected contamination of export grade broccoli, this was not possible because the residue test was not available.

Mevinphos survey

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

1.5 Chemical and Product Details

History of registration

Mevinphos was developed in the 1950s. In Australia, a request for the minor use of mevinphos was made in 1986 but, due to lack of data, this request was not approved. In 1988, the Department of Health requested that the sponsor (then Shell Australia) submit toxicology and residue data on mevinphos and, in 1990, an extensive data package was submitted and assessed in support of an application for the clearance of the technical grade active constituent (TGAC) mevinphos.

In 1990–91, clearance was granted for the TGAC mevinphos and it was classified as Schedule 7 in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

In Australia, there is currently one TGAC approval and one product registration (product name: Phosdrin Insecticide) for mevinphos, both held by Cyanamid Australia Pty Ltd.

Use pattern

The currently registered label for Phosdrin Insecticide contains recommendations for use on the following crops:

Beans	Beetroot	Brassicas
Broadbeans	Capsicum	Carrots, parsnips
Celery	Cucurbits	Eggplants
Gladioli	Globe artichokes	Lettuce
Lucerne	Onions	Parsnips
Potatoes	Rhubarb	Silverbeet
Spinach	Sweetcorn	Tomatoes

According to Cyanamid Australia, approximately 80% of mevinphos use is for the treatment of brassicas close to harvest. The Diamond Back Moth (*Plutella xylostella*) is the major pest in brassica production because of its high degree of resistance to many different insecticides. Cabbage aphid is a particular problem in brussels sprouts production in Tasmania. Mevinphos is also widely used in the ornamental horticulture industries (cut flowers for control of aphids and thrips). This is an off-label use and involves significant retreatments, up to 6 times a season.

In Queensland, a pest not present on the label but controlled by mevinphos is the cabbage centre grub. In Tasmania, mevinphos is the only chemical currently registered for control of Vegetable Looper.

Three main use patterns of mevinphos are employed by growers. In the first, mevinphos is adopted as the main chemical for pest control. Growers apply between 10 and 20 sprays per crop to control pests throughout the growing season. Sprays may or may not be applied according to monitoring of pest numbers. This use pattern does not appear to be common in Australia as producers are now moving towards the use of Integrated Pest Management (IPM) programs and resistance management strategies.

The second pattern uses mevinphos in a limited way. The application of mevinphos in these systems is always in response to pest numbers, as recorded by monitoring, and is either part of a resistance management strategy or an IPM program. In these programs, there are limited numbers of spray applications, usually one to two applications per season. In some seasons, mevinphos may not have to be used at all.

A third, but related, limited use pattern is the so-called 'clean-up' spray before marketing. Growers and commodity organisations report that tolerance by consumers to pest damage in brassica crops is almost nil, especially in export markets. It appears that use of other insecticide sprays will inevitably leave some pests still on the crop at harvest. Mevinphos, therefore, is used just prior to harvest to ensure that produce does not have pest damage when marketed. It is suitable for this purpose because of its two-day withholding period and its superior effectiveness as a knockdown spray when compared to other registered chemicals such as Bt and methomyl.

Application methods

Mevinphos has a common use pattern across all Australian States. While use is seasonal according to locality, throughout the year mevinphos is in use somewhere in Australia. The most common method of applying mevinphos is by boomspray, with some use of ground-directed air blast sprayers. In most cases, the boomspray is tractor-mounted; sometimes tractors have enclosed cabs. Some variations in application equipment use drop tubes and air assistance to penetrate the crop canopy.

Spray volumes range from 300 to 1500 L/ha. The number of applications per crop varies between one and six per season, with a spray interval of one to 21 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.

Label restraints indicate that Phosdrin Insecticide is **not** to be applied by fogging machines, mist-blowers, back mounted knapsack or by aircraft.

Formulation

Mevinphos TGAC is imported from the USA. The End Use Product (EUP), Phosdrin Insecticide, is formulated by Autopak Vetlab Group Pty Ltd, St Marys, NSW. The EUP is formulated at 1110 g/L, according to the label.

Packaging

Mevinphos is provided in glass bottles, with shrink-wrapped screw-on caps, containing 500 mL product.

1.6. Overseas Regulatory Status

Mevinphos is registered in the following countries:

Austria	Belgium	Brazil
Chile	Czechoslovakia	Denmark
Finland	France	Germany
Greece	Hungary	Jordan
Luxembourg	Mexico	Netherlands
Norway	Philippines	Portugal
Romania	South Africa	Sweden
Switzerland	Thailand	Yugoslavia

Products containing mevinphos are not registered in the UK, US, Belize or USSR.

2. CHEMISTRY ASSESSMENT

2.1 Chemistry Aspects

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

2.2 Mevinphos Technical Grade Active Constituent

Mevinphos technical grade active constituent (TGAC) consists of a mixture of E and Z-isomers of mevinphos and contains 630-642 g/kg of the E-isomer and 170-276 g/kg of the Z-isomer. The specification limit for total mevinphos in the TGAC is 800 g/kg minimum.

There are a number of impurities (19 in all) in the TGAC. The principal impurities are dimethyl methyl-phosphonate (2.8%), trimethyl phosphate (1.8-3.0%) and dimethyl 1-methylethylenyl-phosphate (1.1%)

Microcontaminants

It is considered that other compounds of toxicological significance (sulfotep, N-nitrosamines, halogenated dibenzo-pi-dioxins or halogenated dibenzofurans and PCBs)

are not expected in mevinphos TGAC due to the raw materials and synthetic chemistry route used.

3. TOXICOLOGICAL ASSESSMENT

The toxicological database for mevinphos, which consists primarily of toxicity tests conducted using animals, is quite extensive. In interpreting the data, it should be noted that toxicity tests generally use doses which are high compared to likely human exposure. 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 Observed 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. (NOEL is the highest amount of a substance, found by study or observation, to cause no detectable (usually adverse) alteration of morphology, functional capacity, growth, development or life span.)

3.1 Toxicokinetics and Metabolism

Mevinphos does not persist in the tissues. When given orally to rats, it is rapidly absorbed by the gastrointestinal tract and rapidly excreted via the urine and faeces as hydrolysed products of mevinphos. Mevinphos is also absorbed through the skin, and about 18% of the applied mevinphos penetrates the skin within 24 hours of application.

3.2 Acute Studies

Mevinphos has high acute toxicity. The lowest oral LD_{50} (dosage of chemical that kills 50% of the test population) for mevinphos was 1.4 mg/kg in rats and 4.3 mg/kg in mice. The lowest dermal LD_{50} in rats was 4.2 mg/kg. The four-hour whole body inhalational LC_{50} (concentration that kills 50% of the test population) was 7.3 mg/m^3 in female rats.

The signs of intoxication are similar following exposure via all major routes of administration, and include 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 jowl muscles, coarse generalised body tremors, secretion of tears, urination and defecation, depression, prostration, epileptoid tremors, convulsions, respiratory failure, and death.

The severity of signs varies with the amount of exposure, and the onset of severe signs (including death) is swift in experimental animals and in humans after exposure to mevinphos. When mevinphos was placed in the eyes of rabbits, the administration of 0.2 mL/kg of a 6% solution (equivalent to a dose of approximately 12 mg/kg) was fatal within 1.5 to 3.5 minutes.

Despite the rapid onset of severe signs (including death) brought on by acute exposure to mevinphos, the chemical is only a slight eye irritant (in rabbits), and does not cause skin irritation (rabbits or guinea pigs) or skin sensitisation (guinea pigs).

Administration of mevinphos in combination with other organophosphorous insecticides in a number of studies of rats did not result in any increase in toxicity that would indicate potentiation. (Potentiation is a situation in which two or more substances together produce an effect which is greater than would be expected from adding the effects produced when the same substances are applied separately.)

The administration of atropine and oximes in combination appears to be the most effective treatment for mevinphos intoxication in laboratory animals.

3.3 Short-term Studies

When mevinphos was applied to the skin of rabbits for 6 hours/day, 5 days/week at doses up to 10 mg/kg most animals showed no signs of toxicity, but brain cholinesterase activity was decreased at doses of 1 mg/kg/day and above.

The oral administration of mevinphos to rats for 13 weeks at doses up to 1.5 mg/kg/day resulted in effects consistent with cholinesterase inhibition, including tremors, increased saliva, watering eyes and pinpoint pupils. Significant mortality was seen at 1.5 mg/kg/day, and the NOEL was 0.05 mg/kg/day, based on the decrease in plasma and brain cholinesterase activity at 0.5 mg/kg/day and above.

3.4 Long-term Studies

In long-term studies in experimental animals, mevinphos was administered in the food for two years at up to 0.6 mg/kg/day in rats and 0.75 mg/kg/day in dogs, and via stomach tube for two years at up to 0.7 mg/kg/day in rats, or via capsule for one year at up to 0.5 mg/kg/day to dogs. The effects of such long-term administration of mevinphos were almost exclusively limited to the inhibition of cholinesterase activity. No increase in cancer incidence was reported in any of these studies. The NOEL, based on the inhibition of cholinesterase activity, was 0.0175 to 0.0215 mg/kg/day in the rat dietary study and 0.025 mg/kg/day in the remaining long-term animal studies.

3.5 Reproduction Studies

In a study of reproduction in rats, where mevinphos was given by stomach tube at doses between 0.05 and 0.5 mg/kg/day for two generations, the main effect of treatment was cholinesterase inhibition. This effect was seen at all dose levels tested. Other effects included tremors and pinpoint pupils (signs that are consistent with cholinesterase inhibition), reductions in ovarian weights, reduced mating and fertility in males, and reduced offspring weights. All of these effects were only seen at the highest dose of 0.5 mg/kg/day, with a NOEL for these effects of 0.1 mg/kg/day.

In another, older study, where mevinphos was given in the diet to rats for three generations at doses of 0.06 or 1.2 mg/kg/day, the chemical's effects were limited to reducing body weights in adult animals when administered at 1.2 mg/kg/day. The NOEL for this effect was 0.06 mg/kg/day. No gross malformations in pups, or other effects related to treatment, were reported in this study.

3.6 Developmental Studies

When mevinphos was given to rats by stomach tube at doses up to 1.25 mg/kg/day to test for effects on the developing foetuses, the main effects observed were consistent with the anticholinesterase properties of mevinphos, including tremors, excess watering of the eyes and excess production of saliva. These effects were seen at the higher doses 0.75 to 1.25 mg/kg/day, but no such effects were seen at 0.2 mg/kg/day. At the highest dose only (1.25 mg/kg/day), deaths also occurred in the adult females, and this high dose was not continued throughout the entire study. No effects on reproduction were seen, and no effects on foetal development were reported, at any dose level, with a NOEL for developmental effects of 1.0 mg/kg/day.

After being administered by stomach tube to rabbits at doses up to 1.5 mg/kg/day, mevinphos' main effect was the inhibition of cholinesterase. At the highest dose level, adult females had reduced body weights, and one female died at this dose. At doses of 1.5 and 0.5 mg/kg/day, cholinesterase activity was inhibited, but no such inhibition was seen at the low dose of 0.05 mg/kg/day. No effect on reproduction or foetal development were seen at any dose level in this study.

3.7 Genotoxicity Studies

Mevinphos was shown to cause some mutations in bacteria and some mutations and chromosome abnormalities in cultured animal cells, but did not cause any genetic effects when tested in rat liver cell cultures or when given to mice.

3.8 Neurotoxicity

Specialised tests using hens are commonly conducted to determine the potential for organophosphates and related chemicals to cause degeneration of the nervous system—a syndrome called organophosphate-induced delayed neuropathy (OPIDN). No delayed neurotoxicity (OPIDN) was observed in hens, even when the mevinphos dose was at potentially lethal levels.

Potential neurotoxicity was also assessed in rats, dosed for up to 91 days. Rats given a single dose of mevinphos exhibited effects consistent with the anticholinesterase activity of mevinphos such as reduced coordination, tremors and convulsions. Motor activity functions were also affected. For a single dose of mevinphos, these effects were seen at 2 mg/kg and above, while no effects seen at 0.1 mg/kg or below.

When mevinphos was given daily for up to three months, the main effect was the inhibition of cholinesterase activity. Signs of this inhibition included tremors and increased saliva production. The inhibition of cholinesterase was seen at doses of 0.35 mg/kg/day and above, but no such effects were seen at 0.025 mg/kg/day. No other neurotoxic effects were seen at any dose level (up to 0.7 mg/kg/day).

3.9 Effects in Humans

The main effect of mevinphos in humans was, as with experimental animals, the inhibition of cholinesterase activity. The recovery of this enzyme activity to normal levels took between one and three months. No other signs of mevinphos poisoning were observed at the relatively low doses used in human studies (up to 0.035 mg/kg/day). However, one study suggested the possibility that mevinphos might also cause subtle neurological effects. A decrease in slow motor fibre nerve conductance was seen in human subjects when mevinphos was administered at 0.025 mg/kg/day. The relevance of this finding to an adverse health effect is unclear, as there are no comparable findings in the animal toxicological database.

A number of human poisonings have been reported for mevinphos, and exposure to relatively small doses on the skin (0.5–1.1 g) in humans have been shown to result in severe poisoning due to extensive cholinesterase inhibition.

3.10 Conclusions for Public Health Standards

Poisons scheduling

Mevinphos is currently in the restrictive Schedule 7 of the Standard for the Scheduling of Drugs and Poisons (SUSDP), and this is appropriate for a compound with the acute toxicity potential of mevinphos. Provisions exist 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 for mevinphos is 0.015 mg/kg/day, based on erythrocyte cholinesterase inhibition in a repeat oral dose study in human volunteers. The lowest NOEL for animal studies is 0.0175 mg/kg/day based on inhibition of cholinesterase activity, which is similar to that established in humans.

The recommended Acceptable Daily Intake (ADI) is 0.0008 mg/kg/day, based on a NOEL of 0.015 mg/kg/day for cholinesterase in humans, and using a 20-fold safety factor.

4. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

4.1 Existing Regulatory Controls for Occupational Health and Safety

Hazardous substances

Mevinphos is listed in the National Occupational Health and Safety Commission's (NOHSC) *List of Designated Hazardous Substances*, with the following cut-off concentrations: 0.1%—Harmful; 1.0%—Toxic and 7.0%—Very Toxic.

Phosdrin Insecticide contains 1110 g/L mevinphos and is therefore a hazardous substance. Hazardous substances come under the controls for workers specified in NOHSC's *Control of Workplace Hazardous Substances*.

Atmospheric monitoring

There is a NOHSC Exposure Standard for mevinphos of 0.01 ppm (0.092 mg/m^3) time weighted average with a skin notation (significant skin absorption) and short-term exposure limit of 0.03 ppm (0.27 mg/m^3).

Health surveillance

Organophosphate pesticides are on the *NOHSC Schedule for Health Surveillance* (Schedule 3 Hazardous Substances for Which Health Surveillance Is Required). Employers are responsible for providing any health surveillance required as a result of the workplace assessment process.

4.2 Toxicity and Contamination Relevant to Occupational Exposure

After single doses, mevinphos has high acute oral, dermal and inhalation toxicity in experimental animals. It is a slight eye irritant but not a skin irritant or skin sensitiser. Extrapolating to 60 kg humans, workers would need skin contamination of 252 mg mevinphos, 0.227 mL Phosdrin Insecticide or 324 mL working strength spray (at 0.07% mevinphos) to reach the dermal LD_{50}. The acute risk of the concentrate is considered to be extreme.

The toxicity of mevinphos on repeated exposure comes from studies of repeated oral ingestion in human volunteers. From these studies, an oral No Observed Effect Level of 0.015 mg/kg bw/day (1 mg/day) is assigned, based on erythrocyte cholinesterase inhibition at doses of 1.5 mg/day and above. Erythrocyte cholinesterase activity recovered slowly.

A statistically significant decrease in slow motor fibre nerve conduction velocity was observed at 0.025 mg/kg/day. This is taken as the Lowest Observed Effect Level (LOEL). A NOEL for neurological effects cannot be assigned as this effect was observed at the lowest dose tested in the study.

There are no experimental studies of absorption of mevinphos through human skin. An animal dermal *in vivo* absorption study (rat) indicates that 18.2% is the value most relevant for occupational risk assessment.

Using the human oral NOEL and rat dermal absorption factor it can be extrapolated that an average 60 kg worker would need skin exposure of more than 4.945 mg mevinphos, 0.005 mL Phosdrin Insecticide or 6.364 mL the working strength solution per day to experience the toxic effects of mevinphos. These volumes are low.

The amounts of mevinphos workers may be exposed to during spraying operations and re-entry were estimated to assess the likelihood of toxic effects. The human oral NOEL and rat dermal absorption factor were considered against estimated exposures, to give margins of exposure (MOE). The findings appear in later sections of this summary.

4.3 Reported Mevinphos Effects

Literature reports

The published scientific literature for mevinphos included frank reports of poisoning incidents during use and at re-entry and indirect exposure studies (measurement of cholinesterase). The documented poisoning incidents mostly concerned large groups of workers. Mevinphos could be acutely toxic, with some affected workers, including re-entry workers, requiring hospital treatment. Some workers who used mevinphos under routine conditions had depressed cholinesterase with no accompanying clinical symptoms. As only limited Australian information exists, most reports come from overseas investigations.

For example, US data from the Worker Health and Safety Branch of the California Department of Pesticide Regulation (DPR) indicated 438 illness reports amongst agricultural workers in California involving mevinphos between 1982 and 1989.

One Australian study, conducted in New South Wales during 1992–93, investigated pesticide exposure (via erythrocyte and plasma cholinesterase activity in pre- and post-exposure samples), pesticide usage, work practices and use of protective clothing in fruit and vegetable growers. Vegetable growers used a range of organophosphate insecticides, including mevinphos. The study found that the growers had plasma, erythrocyte and/or whole blood cholinesterase activity below the normal range. They

paid poor attention to safe practices and the wearing of personal protective equipment. A high percentage (81%) felt that pesticides had at some time affected their health. The report concluded that inadequate safety precautions were practised within the industry.

4.4 Mevinphos Use Pattern in Australia

Handling prior to end use

Mevinphos is imported from the USA. It is formulated by Autopak Vetlab Group Pty Ltd (NSW) into Phosdrin Insecticide and packaged in 500 mL glass bottles, with shrink-wrapped screw-on caps. Formulators may be exposed to mevinphos and Phosdrin Insecticide.

Transport and storage workers handle only the packaged active constituent or product so should not become contaminated with mevinphos unless the packaging is damaged.

Handling by end users

Information on end use pattern of mevinphos came from the Phosdrin Insecticide label and from a survey the registrant was required to undertake for this review.

The product label allows use on a variety of row crops, gladioli and lucerne, and carries the specific restraints:

- Do not apply with fogging machines or mist-blowers.
- Do not apply with a back mounted knapsack.
- Do not apply by aircraft.

The application rate is 65 mL/100 L (0.07% mevinphos) for all row crops and 700 mL/ha (0.7 kg/ha) and 350 mL/ha (0.35 kg/ha), for gladioli and lucerne, respectively. The label allows for spray volumes of 400 to 1500 L/ha on row crops and a minimum of 250 L/ha on gladioli (0.28% mevinphos) and lucerne (0.14% mevinphos).

Individuals or contractors may use Phosdrin Insecticide, and contractors are likely to receive the most frequent exposure. Mevinphos has a similar use pattern across all Australian States. It is most commonly applied by boomspray, with some use of ground-directed air blast sprayers. The number of applications per crop varies between one and 6, with a spray interval of one to 21 days. Growers using mevinphos as a single final spray prior to harvest commonly spray the entire crop area as well as the plot to be harvested. This use pattern also results in repeated applications per crop.

Some survey respondents noted that it was difficult to wear the recommended personal protective clothing if conditions were hot and humid. Users commonly found spraying more comfortable during early morning and late evening.

4.5 Occupational Exposure and Risk

Workers may be exposed to mevinphos when mixing/loading, applying spray, cleaning up spills and maintaining equipment. In addition, re-entry workers may contact mevinphos residues on treated foliage. The low vapour pressure of mevinphos and the small container size indicate that inhalation of vapours from the concentrate is unlikely. An enclosed mixing system for automatically adding the concentrate to the spray tank is not practical with the current container. The main routes of occupational exposure are skin contamination with concentrate and diluted solutions, inhalation of spray mist during spraying and contact with contaminated plants during re-entry.

Measured worker exposure

While no measured exposure studies directly relevant to the Australian use pattern of mevinphos in row crops, gladioli and lucerne were available, a literature study on greenhouse use in Finland and the 1994 report of the California Environmental Protection Agency (EPA) on mevinphos field use were examined.

Airborne residues of mevinphos in greenhouse air and in the workers' breathing zone, measured during application by knapsack and jug spraying, were below the NOHSC exposure standard. However, this does not demonstrate safe use because comparisons with the exposure standard need to consider that significant dermal absorption may also occur and the result may not be applicable to all types of manual spraying.

The California EPA reported on mevinphos exposure for workers performing all tasks (mixer/loader/applicators) during ground operations. It used dermal exposure data from a study with a similar chemical, oxydemeton-methyl (surrogate data), and mevinphos exposure data for inhalation.

Combined dermal and inhalation exposure was calculated as absorbed daily dose for mixer/loader/applicators using open and closed tractor cabs. The workers used enclosed mixing/loading systems and a 50% mevinphos formulation, in contrast to the Australian use pattern of open mixing with an approximately 100% mevinphos product. Despite the limitations, these data were extrapolated to estimate the risks to Australian workers. Margins of exposure were calculated to be low and unacceptable.

Predicted worker exposure

The measured worker exposure data was supplemented with exposures generated using one of the exposure models developed by overseas regulatory agencies. The UK Predictive Operator Exposure Model (POEM) was derived from pooled measured exposure data collected in worker field trials. The model was used to calculate exposure for the Australian use pattern in row and field crops. The ten end-use scenarios tested in the POEM came from survey information. The end-use scenarios covered the two main ground application methods, boom and airblast spraying, for various sized spraying operations.

Mixer/loader/applicators wearing gloves had predicted absorbed doses above the human NOEL. In addition, almost all predicted exposures to mevinphos were above the human lowest observed effect level (LOEL) for neurological effects. The margins of exposure for the workers were consequently low and unacceptable.

The addition of waterproof clothing for applicators did not provide any substantial improvement in risk for mixer/loader/applicators or applicators alone. Therefore the use of enclosed systems where mixer/loader dermal exposure was eliminated would not substantially influence the overall margins of exposure for mixer/loader/applicators. The respiratory dose was up to 6% of the total absorbed dose, so the use of respiratory protection by applicators would not substantially reduce the risk.

Re-entry exposure—greenhouses

The Finnish greenhouse study showed that airborne mevinphos residues and leaf residues were higher with automatic fogging than with manual spraying techniques. Airborne residues dissipated rapidly if greenhouses were ventilated but could be detected 40 hours later without ventilation. Protective measures for re-entry workers included protective clothing and greenhouse ventilation. Mevinphos residues in the workers' breathing zone were below the mevinphos exposure standard on the day after manual spraying. However, the study did not contain sufficient information on worker dermal exposure to enable a safe re-entry period to be identified.

Re-entry exposure—row and field crops

The 1994 California EPA report estimated skin exposure at re-entry for harvesters. Conditions of use were similar to the Australian use pattern.

Absorbed daily doses were calculated for workers harvesting various vegetables after the re-entry period of 48 hours plus the relevant harvest withholding period. Estimations of risk for comparable Australian workers indicated that a safe re-entry period of $\geq$ 7 days would be required.

4.6 Conclusions

- The occupational health and safety risk assessment could not demonstrate safe use of mevinphos. Measured exposure using surrogate data and predicted exposure using the POEM are unacceptable for mixer/loader/ applicators even with the use of extensive personal protective equipment.

- All predicted exposures exceed the human NOEL (equivalent to a dermal dose of 0.005 mL Phosdrin Insecticide per day) and most exceed the human LOEL for neurological effects, in the routine end use scenarios tested.

- The acute toxic risk for mevinphos is extreme, with a human dose of 0.227 mL of Phosdrin Insecticide equivalent to the dermal LD_{50} in animals.

- Exposures generated via POEM indicate that the risk would not be substantially influenced by the addition of controls that eliminate worker exposure during the mixing/loading process. This finding is supported by the unacceptable margins of exposure derived from the California EPA report where enclosed mixing/loading was used.

- No scope exists to reduce the risk via additional personal protective equipment requirements. The existing safety directions contain extensive personal protective equipment requirements for workers, namely: 'When opening the container, preparing the spray and using the prepared spray, wear waterproof clothing, cotton overalls buttoned to the neck and wrist, washable hat, elbow-length PVC gloves, impervious footwear and full-face respirator with combined dust and gas cartridge'. In both the California EPA report and POEM estimates, extensive personal protective equipment was included for the assessment. Respondents in the NRA survey commented that the existing personal protective equipment was difficult to wear under certain weather conditions.

5. ENVIRONMENTAL ASSESSMENT

5.1 Environmental Chemistry and Fate

Hydrolysis and photolysis

Mevinphos E and Z isomers are readily soluble in water and hydrolyse slowly at pH 7, with half-lives of 29 and 63 days, respectively. Hydrolysis is faster at higher pHs, with half-lives of 2.8 and 7.5 days at pH 9 for the E and Z isomers, respectively. Significant degradation of mevinphos by photolysis is unlikely. The major effect of photolysis is isomerisation of the E and Z isomers. Mevinphos is also a volatile compound, but the Henry's Constant indicates that it is unlikely to volatilise from water.

Aerobic soil metabolism

From the laboratory studies in one soil it is clear that both isomers of mevinphos degrade rapidly. In one fully reported study using a sandy loam soil half-lives were extremely short—1.2 and 3.8 hours for the E and Z-isomers, respectively. Other literature studies showed longer half-lives, up to 20 hours and 3 days for the E and Z-isomers, respectively. The longer half-lives are associated with slightly acidic soil (pH approximately 5).

No degradation products were identified. Mevinphos is rapidly incorporated into the soil matrix, then mineralised to carbon dioxide.

Anaerobic soil metabolism

No study for anaerobic soil metabolism was presented; however, the California EPA report indicates the half-life of mevinphos under anaerobic conditions to be approximately 12 days. Due to its rapid degradation in aerobic soils and high water solubility, mevinphos is unlikely to reach anaerobic conditions.

Aquatic metabolism

No studies on aquatic metabolism were presented. However, based on mevinphos rapid degradation in soils, it is anticipated that the chemical would be readily

degradable in water, with DT_{50} <20 days. Confirmatory test results are highly desirable as this is an important assumption made in the assessment of aquatic hazard.

Mobility

Adsorption/desorption No studies on adsorption/desorption were presented. Based on the adsorption/ desorption constants, the estimated leaching potential of mevinphos was rated by the California EPA as medium to high in a range of soils.

Leaching No studies on leaching were presented. It can be concluded though, based on its physico-chemical properties and desorption constants, that mevinphos has the potential to leach. However, due to its rapid soil degradation, leaching is not expected. This was confirmed in the field studies where no leaching was observed.

Volatility Based on its physico-chemical properties, mevinphos is rated as having moderate volatility. However, mevinphos is not volatile from the surface of soil due to rapid degradation. The major volatile compound obtained from application of mevinphos was carbon dioxide.

Mevinphos has the potential to move but is not expected to be mobile in the environment because of its rapid degradation in soil. The rapid degradation precludes leaching and volatility, but again confirmatory results would be highly desirable.

Field dissipation

Field studies of mevinphos support the aerobic laboratory studies and show that degradation of both isomers of mevinphos is fast, with half-lives of less than one day. There was no evidence of leaching.

Accumulation in soils

No information on mevinphos accumulation in soils was presented. Based on its physical properties, rapid degradation in soils and field data, mevinphos accumulation in soil is not expected.

Bioaccumulation

No information on mevinphos bioaccumulation was presented. Based on its physical properties, rapid biodegradation and hydrolysis, bioaccumulation is not expected.

Conclusion

Mevinphos is expected to be rapidly degraded once applied to soils and is expected to hydrolyse in the aquatic environment, particularly if alkaline. The metabolites and the hydrolysis product are similar and these metabolites degrade further and quickly mineralise.

A number of crucial studies were either missing or not presented to the NRA review, in particular, an adsorption/desorption study (Warren 1987), which was provided to the Californian EPA, and an aerobic aquatic metabolism study. These studies are critical to a hazard assessment.

Any additional studies on the mobility of mevinphos that are available or likely to be available should be presented to Environment Australia.

5.2 Environmental Effects

Available results on environmental effects are summarised below.

Avian toxicity

Mevinphos is very highly toxic to birds by the oral route (LD_{50} range of 1.1 to 23.7 $mg.kg^{-1}$). Chronic dietary exposure of mallard ducks caused reduced fertility at 12.7 ppm.

No other data on field studies or palatability of mevinphos to birds were found in the literature. Environment Australia found no US or Australian reports of bird kills from label use of the emulsifiable concentrate.

Aquatic toxicity

Mevinphos is very highly toxic to fish and aquatic invertebrates. The acute LC_{50} to fish ranges from around 10 to 25 $\mu g.L^{-1}$ for several freshwater species. Though the toxicity for the marine species sheepshead minnow (810 $\mu g.L^{-1}$) is moderate compared to that for the freshwater species, mevinphos is still rated as highly toxic to sheepshead minnow. The acute toxicity to aquatic invertebrates is very high, with an LC_{50} of 0.18 $\mu g.L^{-1}$ for daphnia (water fleas). While this is an old unsupported 1969 result, it is relatively consistent with results from more modern tests.

While the chronic exposure studies show that mevinphos is extremely toxic to both trout (early life stages) and daphnia—with toxic effects between 1.54 to 3.6 $\mu g.L^{-1}$ and 0.029 to 0.065 $\mu g.L^{-1}$, respectively—chronic exposure in the environment is not expected due to mevinphos rapid degradation.

No standard studies were presented on the toxicity of mevinphos to algae but at 0.5 $mg.kg^{-1}$ mevinphos significantly affects the nitrofixation of *Anabaena flos aquae* and at 1 $mg.L^{-1}$ there was no effect on phytoplankton.

Non-target invertebrates

Mevinphos is very toxic to bees and other insects by contact or oral exposure. Residues of mevinphos on foliage are not toxic to bees after 4 hours.

Mevinphos has minimal effects on soil micro-organisms at the concentrations expected in the soil following application at the label rate.

Conclusion

Mevinphos is highly toxic to birds, mammals, fish, aquatic invertebrates and insects. It has minimal effects on soil micro-organisms at typical exposure levels and is non-toxic to plants.

While most of the studies presented were old and did not meet current requirements, they were consistent with the modern studies that were provided and are therefore considered acceptable. Any available modern studies (performed to recent international standards) on the toxicity of mevinphos to aquatic organisms should be provided as well as any studies available on the toxicity of mevinphos to algae.

As there is only one poorly reported avian dietary test in the data set, any additional studies on the dietary toxicity of mevinphos to birds should be provided, since it is pivotal for assessing avian hazard.

5.3 Prediction of Environmental Hazard

Hazard arising from use

Mevinphos is used mainly for the control of aphids, caterpillars (including *Helicoverpa* spp), thrips and leafhoppers on a range of vegetables crops together with lucerne and gladioli. Approximately 80% of use is for treatment of brassicas close to harvest. Mevinphos is also widely used in the ornamental horticulture industries (cut flowers) which is indicated by Agriculture Victoria as off-label use.

The use pattern on the label is for application by boomspray as medium to fine droplets. The maximum use rate, 65 mL per 100 L, corresponds to 1100 g ai.ha^{-1} for brassicas, sweet corn and trellis tomatoes.

Label restraints indicate that Phosdrin is **not** to be applied by fogging machines, mist-blowers, back-mounted knapsack or by aircraft.

Terrestrial organisms

Terrestrial organisms are at risk from mevinphos by direct contact when applications are made, or afterwards by contact with sprayed surfaces.

As applications are made by boomspray (tractor powered spraying equipment), accidental direct spraying of larger non-target organisms, such as marsupials and birds, is considered unlikely. Bees are at risk if spraying occurs when they are present in the crop The exposure has been estimated at 6.6 µg per bee (based on 1100 g ai.ha^{-1}) and is approximately 20 times the EC_{50} for bees. As mevinphos is normally used as a late season spray, bees are unlikely to be present in vegetable crops when they are sprayed. However, with the cut flower applications, bees could be present if open flowers were present. To limit the exposure of bees to the pesticide, the crop should not be sprayed when bees are present. If the crop is in flower, spraying should be delayed until evening as tests show that sprayed foliage is unlikely to be toxic by morning.

A number of bird species are known to feed on vegetable crops and could be at risk if they feed on treated crops shortly after application. Residues on leafy crops are expected to be 133 mg ai.kg^{-1} and for tomatoes 15 mg ai.kg^{-1} at an application rate of 1100 g ai.ha^{-1}. Assuming that birds ingest approximately 50% of their dietary intake as treated crops, i.e. tomatoes (small bird) or leafy crops (large bird), calculations show that birds are not at significant risk from use of mevinphos even if they enter the crop and start to feed immediately after spraying. However, additional avian dietary tests are required to confirm the EC_{50} used and therefore the hazard to birds.

While the half-life of mevinphos residues on plants is unknown, tests using aged foliage residues on bees would appear to indicate that residues of mevinphos after fours hours in the field are not toxic. As it is likely that this is due to significant degradation of mevinphos (the vapour pressure of mevinphos would be sufficient to kill the bees), the window of exposure to birds and mammals is expected to be very short. Chronic toxicity is not expected.

Earthworms could be exposed to the pesticide. At an application rate of 1 kg ai.ha^{-1}, the top 5 cm of soil would contain mevinphos residues at 1.5 mg.kg^{-1} of soil (assumes no crop cover, density of soil 1300 kg.m^{-3}). Other soil invertebrates may be significantly affected unless they can move away from sprayed areas or are resistant to mevinphos. There are no toxicity data available for these organisms. Owing to mevinphos rapid degradation in soil, chronic effects are unlikely.

Beneficial insects such as parasitic wasps, predatory mites and other carnivorous insects are likely to be significantly affected if they are directly sprayed. Unless they have developed resistance to mevinphos, direct spraying will cause high mortality among such insects, which are used in Integrated Pest Management programs in Australia. Mevinphos is likely to significantly affect important beneficial insects in Australia.

Apart from bees and other insects present in the crop at the time of application, terrestrial organisms are not expected to show significant effects from the use of mevinphos.

Aquatic organisms

The ecotoxicity data reviewed indicates that aquatic organisms are the most sensitive to the toxic effects of mevinphos. The application of mevinphos directly to a body of water 15 cm deep at a rate of 1.1 kg ai.ha^{-1} is calculated to give a concentration in the water of 0.73 mg.L^{-1} (730 µg.L^{-1}). However, as the pesticide is normally applied by boomspray, direct application is unlikely.

Spray drift is a likely route of exposure for aquatic organisms. Using the US EPA assumption that 10% spray drift occurs provides a concentration of 73 µg.L^{-1} in water 15 cm deep. It is unlikely that 10% spray drift would occur from a boomspray with medium to fine droplets sprayed under reasonable conditions (the US EPA uses 10% for aerial applications).

For a body of water 5 metres away from the site of application, a more likely figure for spray drift is approximately 1%, based on UK studies using herbicides applied by boomsprayers. Using this assumption, Environment Australia calculated the estimated environmental concentration (EEC) and ratio (EEC/EC) for a range of water depths (see Table 1 below). The results indicated that while fish were unlikely to be significantly affected, daphnia and other aquatic invertebrates were likely to be significantly affected. Due to the rapid degradation expected, chronic exposure is unlikely. Algae are unlikely to be affected at this concentration.

Effects on fish would be localised to those beside areas being sprayed and to sensitive individuals in the population. With further dilution of mevinphos in streams, rivers and irrigation ditches and the expected degradation in water, any toxic effects are expected to be of short duration.

While daphnia in the areas close to where mevinphos is being used might be killed, the effect would be very localised and of very short duration due to mevinphos dilution in flowing waters and degradation. Rapid repopulation from unaffected areas would occur, limiting any longer term effects on daphnia populations. Likewise other aquatic invertebrates in the immediate area could be affected, but repopulation would occur.

	Depth of water		
	15 cm	30 cm	45 cm
EEC	7.3 $\mu g.L^{-1}$	3.7 $\mu g.L^{-1}$	2.4 $\mu g.L^{-1}$
Rainbow trout, EC50=11.9 $\mu g.L^{-1}$	0.6	0.3	0.2
Daphnia pulex EC50=0.18 $\mu g.L^{-1}$	40	20	13

Table 1 EEC and ratio of EEC to EC_{50} for trout and daphnia at different depths of water

Effects on aquatic organisms, particularly aquatic invertebrates, are expected. As these effects are likely to be of short duration, repopulation from unaffected areas is expected and will limit longer term impacts on populations.

It is important that mevinphos not be used extensively, therefore the numbers of repeats should be limited. As it is understood that IPM programs use between one and two sprays per season, the maximum number of applications per season should be three with a minimum of 14 days between each spray. Warnings about the dangers of spray drift to non-target organisms should also be stated on the label.

Desirable vegetation

As mevinphos is not phytotoxic and direct application to desirable terrestrial plants and vegetation is not expected, significant effects on desirable plants is unlikely. No data on the effects of mevinphos on Australian native plants were readily available.

Environmental hazard arising from formulation, handling and disposal

The environmental hazard from formulation of the technical grade active constituent in Australia is expected to be minimal. As formulation is expected to be carried out in suitable facilities, with relevant environmental controls to limit environmental exposure and with waste water treated before discharge to the environment (mevinphos is expected to degrade during normal sewage treatment), the environmental hazards are expected to be minimal. Any spills are expected to be cleaned up and treated according to the Material Safety Data Sheet.

5.4 Controls/Labelling

The label directions for use of mevinphos should be amended to include a minimum period before retreatment and a statement limiting the number of treatments in any season. To limit the environmental damage to aquatic organisms and other non-target organisms, the following label warning is recommended:

> DO NOT apply under meteorological conditions or from equipment which could be expected to cause spray drift onto adjacent areas, particularly wetlands, waterbodies or watercourses.

5.5 Conclusions

Mevinphos is used to control a range of insects including aphids, thrips, *Helicoverpa* spp., leafhoppers, webworm etc. in vegetables.

Mevinphos readily degrades in natural systems, with the first half-life of <1 day in aerobic soil. It is expected to degrade in aqueous conditions, under both aerobic and anaerobic conditions but there is no information on the half-lives. However, due to the very rapid degradation in soil, degradation in aqueous conditions is expected to be quick. As a result of the rapid soil degradation, leaching is not expected, though limited data have been provided.

Mevinphos is rated as moderately volatile and could have a fumigant effect. Volatilisation could be a significant method of loss, particularly from foliage. When deposited on soil, mevinphos is not volatile due to rapid degradation. Degradation in the air from ultraviolet light or free radicals is expected.

The chemical is very toxic to birds, mammals and aquatic invertebrates. 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 mevinphos to aquatic systems is expected to significantly affect aquatic invertebrates and must be avoided. Spray drift could present a significant hazard to aquatic invertebrates but the effect is expected to be temporary and, with repopulation from locally unaffected populations, significant environmental damage is not expected. However, every effort should be made to minimise spray drift

To confirm the assumptions used in the hazard assessment, the following additional studies should be provided to fill major data gaps in the report:

- the adsorption/desorption study which was presented to the California EPA (Warren 1987);
- a study of aerobic aquatic metabolism; and
- additional avian dietary studies.

These studies are considered critical to the hazard assessment.

In addition, any studies on the mobility of mevinphos, any modern studies (performed to recent international standards) on the toxicity of mevinphos to aquatic organisms and any studies on the toxicity of mevinphos to algae should be presented to Environment Australia.

6. AGRICULTURAL ASSESSMENT

6.1 Efficacy

As already indicated, over 80% of mevinphos is used on brassicas. Mevinphos is considered essential for the production of brassicas in Queensland, New South Wales, Tasmania and South Australia, and extremely important for this use in Victoria and Western Australia.

The basis for these assessments is the same, in that this chemical is the only registered organophosphate insecticide which still gives consistent, acceptable control of the Diamond Back Moth. This pest is becoming increasingly resistant to other organophosphates, carbamates and endosulfan. Therefore, mevinphos continues to grow in importance for use as an organophosphate rotation to carbamates and endosulfan.

Alternatives

Although *Bacillus thuringiensis* (Bt) is widely used in brassica production, it is limited in its use as a knockdown spray and in its ability to handle rapid pest build-ups when conditions favour particular pests.

The Diamond Back Moth is a major pest of brassicas and is becoming increasingly difficult to control because of its ability to rapidly develop resistance to a wide range of chemicals. Development of a national strategy to manage resistance in this pest is under consideration, with use of mevinphos seen as being a key factor in any strategy developed.

Research is also being conducted on other methods (including chemical control) of controlling the Diamond Back Moth. It is anticipated that over the next one to two years, applications will be made to register several new chemicals, each with a different mode of action, for use against the moth in brassicas. Preliminary trials indicate these chemicals are more effective than Bt

at controlling the moth. Because of this, the requirement for mevinphos to control breakdowns in Integrated Pest Management systems and resistant pest build-ups should be greatly reduced.

However, if mevinphos were not available in the short term, growers would be forced to rely solely on the first of the newly available chemicals. This would result in high selection pressure for Diamond Back Moth resistance to the new chemical and shorten its effective life. Introducing two or more chemicals while mevinphos is still available could double the effective life of these new chemicals.

Use patterns

Mevinphos has three main use patterns. The first, which does not appear to occur widely, uses mevinphos as a mainline chemical control with regular sprays at 8-10 day intervals throughout the growing season. The second, and more widely applied pattern, uses mevinphos in a targeted way, only spraying as part of a resistance or Integrated Pest Management strategy, to control IPM breakdowns. Mevinphos is also used, in a third way, as a clean-up spray close to harvest.

6.2 Trade

Mevinphos is not widely used in Australian agriculture, but is seen, by all segments of primary production which made submissions to the review, to be a very important chemical for the production of brassica crops (broccoli, Brussels sprouts, cabbage/chinese cabbage and cauliflower).

Exports

Brassicas contribute approximately $25 million annually to Australia's exports, with the main export destination being South East Asia, particularly Hong Kong and Singapore. Growers indicate that only the highest quality produce is acceptable in these markets (nil tolerance to pest damage) and that production of this sort can only be sustained using a clean-up chemical close to harvest. The only chemical currently available which meets their criteria of effectiveness and short withholding period is mevinphos.

Use

Mevinphos is not used in great volumes because of its cost and toxicity. However, it is seen as an essential chemical for use in Integrated Pest Management programs and as part of the rotation of chemical groups in resistance management strategies.

Growers also indicate that mevinphos is an important chemical for controlling Diamond Back Moth, which is becoming increasingly resistant to other organophosphate chemicals such as methamidophos and acephate, and alternative insecticide groups such the carbamates. In addition, Tasmania's Department of Primary Industries and Fisheries indicates that the chemical is essential for the control of cabbage aphid in brussels sprouts in that State.

Evidence in review submissions indicated that mevinphos was being used in at least one minor export crop—an off-label use. The reasons given for its use in that situation would apply to other situations. It is therefore possible that mevinphos is being used off-label in other minor use situations. Although the NRA has not issued any permits (for off-label use) for mevinphos, in some States the use of a registered chemical is permitted unless it is specifically prohibited for that purpose.

Residue detections

One of mevinphos' main advantages is its short withholding period. The registrant and growers point to the fact that no residue violations for mevinphos have ever been recorded.

However, further investigations show that mevinphos is not unequivocally detected by the current organophosphate screening process used by the National Residue Survey and may therefore be present but not detected. It is also noted that mevinphos was detected in white bread and oranges by the Australia New Zealand Food Authority's Market Basket Survey, but that it is not registered for any crops associated with this produce. Advice from State chemical coordinators indicates that these detections might be attributed to use of mevinphos as a vermin (including birds) control. This use has now been prohibited in Victoria.

Major commodity organisations and grower groups emphasised the importance of farm chemical training schemes and indicated that the practices advocated by these schemes had been readily adopted by most producers.

6.3 Residues

The current temporary MRL for vegetables is 0.25 mg/kg. Establishment of a permanent MRL would require confirmatory trials to be performed in Australia, based on the maximum use patterns permitted by Australian labels. Residue results based upon US trials in brassicas are consistent with the Australian use pattern and would support a temporary MRL of 0.25 mg/kg for the use of mevinphos on brassicas in Australia in the short term. A withholding period of seven days would ensure that residues do not exceed the MRL.

6.4 Conclusions

Mevinphos is seen as essential to the production of brassicas in Queensland, New South Wales, Tasmania and South Australia.

An alternative to mevinphos, *Bacillus thuringiensis*, is widely used in brassica production, but is limited in its ability to handle rapid pest build-ups under favourable conditions. More alternative chemicals are currently being trialed against the DBM but are not expected to be commercially available for one to two years. The advantage these chemicals confer is increased efficacy against the DBM, when compared with Bt, and fewer control breakdowns. It is probable that they will be viable alternatives to mevinphos in IPM programs and in resistance management strategies. However, to

prolong the effective life of these chemicals for as long as possible, it would be necessary to allow growers access to more than one of them at the same time.

The current temporary MRL for vegetables is 0.25 mg/kg. Residue results would support a temporary MRL, in the short term, of 0.25 mg/kg and a withholding period of seven days for the use of mevinphos on brassicas in Australia.

7. OVERALL DISCUSSION AND CONCLUSIONS

7.1 Summary

In determining the outcomes of the mevinphos review the NRA has to be satisfied that the registration and approval of mevinphos meets current regulatory requirements (as set out in section 1.1 on page 1). The main findings of the review are as follow.

No carcinogenicity or developmental toxicity has been attributed to mevinphos and the genotoxicity potential of mevinphos is equivocal. The major hazard associated with mevinphos is its high acute toxicity and, like a number of other insecticides, mevinphos is an anticholinesterase compound, producing rapid and significant inhibition of cholinesterase activity by all routes of exposure.

Based on the information evaluated as part of the review, the NRA concludes that mevinphos poses an undue hazard to users. Measured exposure using surrogate data predicts that mixers, loaders and applicators of mevinphos will be exposed to levels of the insecticide that exceed the proposed NOEL (equivalent to a dermal dose of 0.005 mL Phosdrin Insecticide/day). Users are already required to wear extensive protective clothing and the NRA does not believe that adding supplementary controls, such as respiratory protection, would substantially reduce the margin of exposure.

The large number of illnesses associated with mevinphos use caused the US EPA to place it into special review. No Australian data on human exposure is available, although one study in New South Wales in 1992–93 showed that 5.5% of all vegetable growers tested, who used a variety of organophosphate insecticides including mevinphos, had cholinesterase levels below the reference range. The findings also suggested a high number of vegetable growers did not wear adequate personal protective equipment.

For other members of the community, exposure to mevinphos is expected to be minimal. In Australia, mevinphos does not have any registered domestic uses, and the greatest potential for public exposure is via ingestion of mevinphos residues in food. The highest estimated intake (for a two-year old child) is 30 times lower than the proposed ADI.

The NRA has also taken into account the likely detrimental effect an immediate withdrawal of mevinphos would have on growers who use the chemical. It recognises that mevinphos is regarded as an essential chemical in the brassica industry which is a substantial producer of vegetables. The reasons for this are that mevinphos can be used close to harvest because of its short withholding period and is still effective against the

Diamond Back Moth, a pest of brassicas that is showing increasing levels of resistance to many other organophosphates as well as insecticides from other chemical groups.

Many growers use *Bacillus thuringiensis* as an alternative to mevinphos but, under certain conditions, pest populations can build up quickly and control of the pest is no longer maintained. When this happens growers tend to rely on mevinphos to restore control.

Although there appear to be no current reliable substitutes for mevinphos, the NRA has reason to believe that several new chemicals will become available to growers over the next two years that could be viable substitutes for mevinphos. The NRA also believes the effective life of these chemicals could probably be doubled via the simultaneous introduction of these chemicals.

It is also necessary to restrict the use of mevinphos to reduce the potential hazard it poses to animals, plants and the environment. Mevinphos is extremely toxic to aquatic invertebrates, birds and mammals. Birds and mammals are not expected to be significantly exposed to the chemical unless they enter an area recently sprayed. However, spray drift could have a significant adverse impact on aquatic invertebrates, even though this effect is expected to be temporary with repopulation from locally unaffected regions. Restricting the number of applications on any one crop will significantly reduce any effect spray drift may have on aquatic ecosystems.

Therefore, the NRA proposes to allow the continued use of mevinphos until the end of 1998 in those situations where it is considered essential, namely, brassica production in all States and Territories except the Northern Territory (where DBM-resistance is not considered a major problem). All other uses of mevinphos will be withdrawn, as no evidence has been provided to the NRA to demonstrate that these are essential uses without alternatives. In addition, use of mevinphos will only be authorised when there has been a control breakdown. It will not be used as a mainline chemical throughout the growing season.

The NRA recognises the hazard this chemical will continue to present to users in the brassica industry and is placing severe restrictions on its use. Users will have to demonstrate they are complying with these restrictions, and evidence of non-compliance will result in the immediate withdrawal of the chemical.

Employees should also ensure they are complying with current NOHSC guidelines and State legislation, for health surveillance. This includes cholinesterase monitoring for employees who, in the workplace, have been assessed as having a significant risk to health from mevinphos. This monitoring will also provide individual users with feedback on their cholinesterase levels.

Approval for mevinphos use beyond the end of 1998 will only be considered if sufficient new data and information can be provided to satisfy the NRA that this chemical can continue to meet current standards for safety, efficacy and quality; particularly those relating to user safety, the environment and residues.

Notwithstanding these measures, the NRA may withdraw the chemical at any time should health information indicate this is necessary.

7.2 Review Recommendations

Restrictions on use

1. All uses of mevinphos will be withdrawn in the Northern Territory from **30 June 1997**.

2. All uses of mevinphos, **except** use on brassicas, will be withdrawn in Queensland, Victoria, Tasmania, Australian Capital Territory, New South Wales, Western Australia and South Australia from **30 June 1997**.

3. Use on brassicas will be withdrawn from **31 December 1998**.

4. Use on brassicas will be restricted to the produuction of brassica crops where Integrated Pest Management or resistance management strategies are practised.

Residues

5. All current MRLs will be withdrawn, **except** for edible offal (mammalian) and meat (mammalian) from **31 July 1997**. This will allow the feeding of treated brassica produce to animals.

6. The MRLs for edible offal (mammalian) and meat (mammalian) will be withdrawn from **31 January 1999.**

7. A temporary MRL of 0.25 mg/kg will be set for brassicas. This will expire on **31 January 1999.**

8. The National Residue Survey will be requested to include specific monitoring for mevinphos residues in brassica crops.

Labelling

9. A minimum period of two weeks will be specified before re-treatment. Treatments are to be limited to no more than three per crop per season.

10. The withholding period will be extended from two to seven days.

11. The Directions for Use table will be amended as follows:

CROP	INSECT PESTS	STATE	RATE
Brassicas: cabbages, cauliflowers,	Diamond Back Moth	Qld, NSW, Vic, Tas, SA, WA, ACT only	65 mL/100 L

broccoli, Brussels sprouts			

12. To limit the environmental damage to aquatic organisms and other non-target organisms, the following label warning will appear:

> DO NOT apply under meteorological conditions or from equipment which could be expected to cause spray drift onto adjacent areas, particularly wetlands, waterbodies or watercourses.

Health

13. Employers should ensure they are complying with the NOHSC guidelines and relevant State legislation for health surveillance. This includes cholinesterase monitoring for employees who, in the workplace, have been assessed as having a significant risk to health from mevinphos.

Sale and supply

14. The registrant will provide resellers with information leaflets on the toxic effects of mevinphos and the NRA review recommendations. These will be provided to all purchasers of mevinphos.

15. Buyers will have to provide proof to resellers they have completed a Farm Chemical Users Course or equivalent training before being able to purchase mevinphos. The following restriction will appear on the label:

> This product can only be supplied to or used by a person who holds a current Farm Chemical Users Course certificate.

Compliance

16. The NRA and relevant State departments will monitor the supply and restricted use regime to ensure the restrictions are being complied with.

Development of alternatives

17. Three-monthly progress updates on the development of alternatives to mevinphos will be provided to the NRA by the representative group researching Diamond Back Moth Resistance Management

8. PRRD 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: PRODUCT AND TGAC AFFECTED BY THIS REVIEW

Product

67468 Phosdrin Insecticide Registrant: Cyanamid Agriculture Pty Ltd

TGAC

P44575 Mevinphos Approval Holder: Cyanamid Agriculture Pty Ltd

NRA ORDER FORM

To receive a copy of the full technical report for the NRA's evaluation of mevinphos, please fill in this form and send it, along with payment of $30 to:

Ms Nikki Dack
Chemical Review Section
National Registration Authority for Agricultural and Veterinary Chemicals
PO Box E240
Kingston ACT 2604

Alternatively, fax this form, along with your credit card details, to Nikki Dack on (06) 272 3551.

Name (Mr, Mrs, Ms, Dr)_____

Position _____

Company/organisation _____

Address _____

Contact phone number (___) _____

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

Bankcard Visa Mastercard Amex

Card number

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

Signature_____Date _____