Reconsideration of the Approvals and Registrations Associated with the Organophosphorous Insecticide Mevinphos

Supplementary Review Summary

October 2002

Pesticides Review

National Registration Authority
for Agricultural and Veterinary Chemicals

Canberra
Australia

ISSN No. 1443 - 2528

This document is published by the National Registration Authority for Agricultural and Veterinary Chemicals. For further information about this document or the Pesticide Review, contact:

Manager, Pesticide Review
National Registration Authority
PO Box E240
KINGSTON ACT 2604
Australia

Telephone: (02) 6271 6549
Facsimile: (02) 6272 3218

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 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 Ageing (Therapeutic Goods Administration), Environment Australia (Risk Assessment and Policy Section), National Occupational Health and Safety Commission (Chemical Assessment Division) and State and Territory 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 chemical reviews is a part of that process.

The NRA makes these reports available to the regulatory agencies of other countries as part of bilateral agreements or as part of the OECD *ad hoc* 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.

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 the NRA publications *Ag Requirements Series* and the *Vet Requirements Series*. These publications can be obtained by contacting the NRA.

The approvals and registrations relating to the broad-spectrum organophosphorous insecticide mevinphos were reconsidered as part of the NRA's first cycle of the Existing Chemical Review Program. A review of the existing data and information was completed in 1997 and the use of mevinphos was restricted to brassicas, pending further studies. For further details, see *The NRA review of Mevinphos*, published in 1997 (http://www.nra.gov.au/chemrev/mevinphos.pdf). Subsequently, new data have been made available to the NRA. The data have been assessed in the context of agricultural practices followed by the Australian brassica industry. This report outlines the findings of the supplementary review and the NRA's regulatory measures.

CONTENTS

REVIEW SUMMARY

1 BACKGROUND

Mevinphos, a broad-spectrum organophosphorous insecticide, was identified as a candidate for priority review under the Chemical Review Program (formerly known as the Existing Chemicals Review Program) of the National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

Reconsideration of the approval(s) and registration(s) associated with mevinphos were proposed due to concerns over high potential risk for acute and chronic toxicity; demonstrated potential adverse effects in users; major data gaps in occupational exposure and residues in food; worker poisoning overseas, during end use and upon re-entry; very high toxicity to wildlife, and possible incidents in the US; and possible implications for trade between Australia and overseas.

The NRA reviewed the data and information available at that time. The assessment of worker safety, environmental impact and residues in food was based on overseas studies, surrogate data and model predictions. The review found that (a) mevinphos poses significant unacceptable risks to the health of users who mix, load and apply the chemical, and (b) due to high toxicity, mevinphos could have a significant adverse impact on aquatic organisms. The review and resulting outcomes were published in 1997[1] (documents are available at http://www.nra.gov.au/chemrev/mevinphos.pdf).

In that review, the NRA considered the likely detrimental effect an immediate withdrawal of mevinphos would have on Australian agriculture. Mevinphos was considered essential for the production of brassicas. Over 80% of mevinphos sold in Australia was used on brassicas. This was the only registered chemical that gave consistent and acceptable control of the Diamondback Moth (DBM). The insect was becoming increasingly resistant to other organophosphates, carbamates and endosulfan.

It was anticipated that new chemical products would become available for the control of DBM in the following one to two years.

Consequently, the NRA took the following measures:

All uses of products containing mevinphos, except in those situations where it was considered essential, namely, brassica production in all States and Australian Capital Territory (ACT), were withdrawn. Use on brassicas was limited to the control of diamondback moth and to those brassica crops where Integrated Pest Management or resistance management strategies were practised.

To mitigate the risk that products containing mevinphos would present to users, the NRA stipulated strict conditions on their use. Buyers were required to have completed a Farm Chemical Users Course or equivalent training before being able to purchase products containing mevinphos. Employers were required to comply with the National Occupational Health and Safety Commission (NOHSC) guidelines and

relevant State legislation for health surveillance, including cholinesterase monitoring for employees.

To reduce the effect of spray drift on aquatic ecosystems, application of products containing mevinphos was limited to a maximum of three times per crop per season. Further, a minimum interval of two weeks was specified as necessary between applications.

Product labels were varied to include suitable warnings to protect the environment and worker safety.

All MRLs related to mevinphos, except for edible offal (mammalian) and meat (mammalian), were withdrawn. Based on US trials, a temporary MRL was set for brassicas. The withholding period was extended from two to seven days to ensure that residues do not exceed the MRL. The National Residue Survey was requested to include specific monitoring for mevinphos residues in Brassica crops.

The revised approvals and registration associated with the restricted use of mevinphos were to be effective until the end of 1998. Their continuation beyond 1998 was to be reconsidered if sufficient new data and information could be provided to satisfy the NRA that the chemical could continue to meet current standards relating to user safety, the environment and residues.

The registrant undertook to generate data to address the user safety concerns. The approvals and registration associated with mevinphos were twice extended to allow sufficient time to generate this data. Finally, the approvals and registration associated with mevinphos were suspended with effect from January 2001. The suspension is effective until 31 October 2002.

2 ASSESSMENT OF NEW DATA AND INFORMATION

The registrant provided (i) data from new studies on worker exposure to mevinphos during mixing/loading and application of mevinphos on brassica crops[2], (ii) data from new studies on worker exposure to mevinphos during hand-harvesting of brassica crops treated with mevinphos[3], (iii) a risk assessment based on the results from the preceding studies and (iv) detailed information on Australian agricultural practices in brassicas[4]. The data and information have been assessed by the NRA and its advisory agencies.

2.1 Agricultural practices in brassicas

According to the registrant's submission, cabbage is typically grown over ten months of the year, whereas broccoli and cauliflower tend to be grown over a period of 8-9 months.
Australian brassica farms vary significantly in size from 2 ha up to 100 hectares; however not many farms greater than 10-20 ha exist.

Crop planting is staggered so that each farm would have multiple plots planted at one or two-weekly intervals. The use of multiple plots ensures that the crop is available for harvest throughout most of the year.

For most New South Wales farms, the plot size is typically 0.5 ha, while South Australian plot sizes are typically up to 2 ha and Queensland plot sizes are typically 1 ha. For exceptionally large farms in South Australia the plot size is typically 4 ha, although plot sizes up to 8 ha have been used on occasions.

Multiple growing seasons (up to three) per year can be expected.

Pesticide applications are made by the growers themselves. The same person usually performs mixing/loading and application operations. The typical practice is to mix, load and then apply a single tank of pesticide per day, during the early morning or late evening.

The amount and frequency of mevinphos application on brassica farms depend not only on the farm size, but also on the pesticide application strategy used by the farmer. A brassica farmer may choose from one of the following methods:

1. Calendar spraying: In this method, the farmer does not carry out scouting to determine the pest incidence and the need for pesticide application, but follows a schedule and applies pesticides at pre-determined regular intervals.

2. Pest scouting and block spraying: In this method, pest scouting and spraying are usually carried out in blocks of plots with an age spread of 4 weeks.

3. Pest scouting and spraying 'hot spots': In this method, scouting is carried out to determine the areas and level of pest incidence and then only those areas above a certain pest threshold are sprayed.

Typical harvesting periods tend to be 2-4 hours in duration, with some in South Australia extending to 6 hours. Professional harvesters are brought in to hand harvest the crops in most farms. On very small farms, the farm owner's family often does the harvesting (usually for 1-2 hours every day).

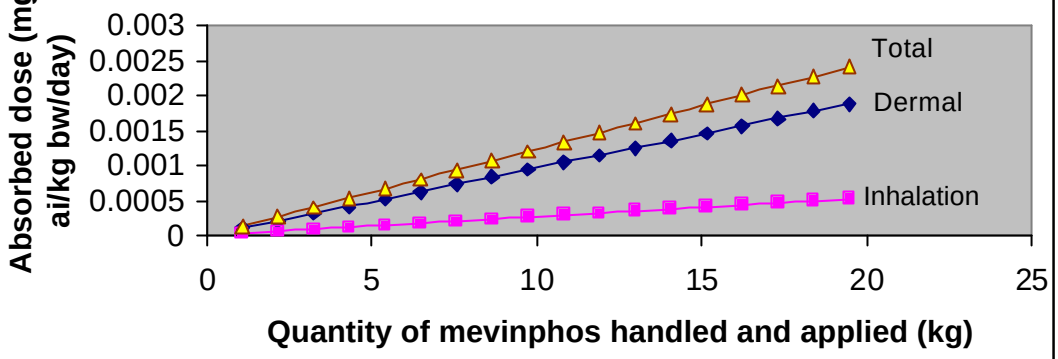
2.2 Occupational risk assessment

Since risk is a function of both toxicity and exposure, the occupational risk assessment takes into consideration the hazard of the chemical as determined by its toxicology profile, its use pattern in Australia and worker exposure for each exposure scenario.

Results from a human study[5,6], where volunteers were administered mevinphos orally for 30 days, were used to determine the No Observed Effect Level (NOEL). The NOEL is the highest amount of a substance found by a study to cause no detectable alteration of morphology, functional capacity, growth, development or life span. Based on assessment of the study, the NOEL for mevinphos was determined to be 0.015 mg/kg bw/day.

The worker exposure study[2] measured the quantities of mevinphos workers are exposed to, through dermal and inhalation routes, during mixing, loading and application of the chemical. Based on assessment of the study, the quantities of mevinphos absorbed by the workers can be estimated (Figure 1).

Figure 1. Absorption of mevinphos by workers who mix, load and apply the chemical



To characterise the risk to workers, these estimates were compared to the NOEL of mevinphos. The results are expressed as margins of exposure (MOE) in Figure 2. MOE is the ratio of NOEL to the quantity of chemical absorbed (MOE=NOEL ÷ quantity of chemical absorbed). When results from human studies are used in risk assessment, an MOE of 10 or more is usually considered to be acceptable.

Figure 2. Margins of exposure

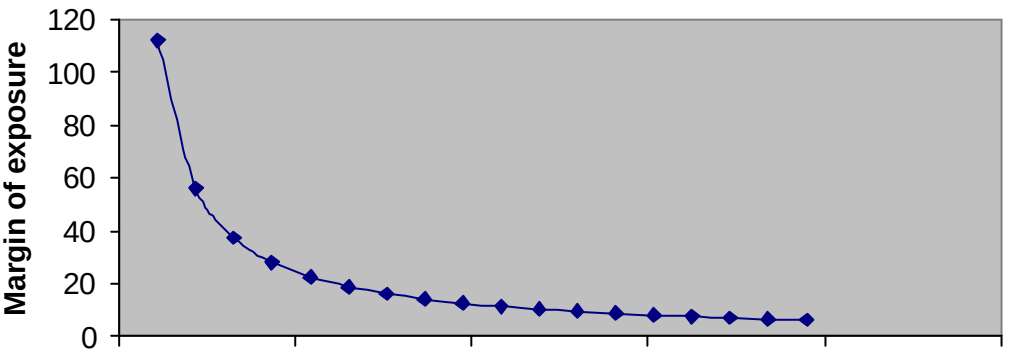


Figure 2 indicates that the margin of exposure is acceptable (≥10) when the quantity of mevinphos handled and applied ≤ 11.7 kg (equivalent to 11 ha spray area when sprayed at the maximum concentration permitted by the label) and applications are made on a maximum of 30 days in any 12-month period. In the study[5,6] from which NOEL was calculated, mevinphos was administered to the subjects daily for thirty days. Thus, the risk assessment is valid only for applications on a maximum of 30 days and when handling (mixing/loading and/or applying) a maximum of 11.6 kg of mevinphos per day. Similarly, the risk assessment is applicable only when the personal protective equipment (PPE) and engineering controls used in the worker

exposure study[2] are used. During mixing and loading of the chemical, according to the information provided by the registrant, the participants in the study wore, on top of their normal work cloths, either a tyvek suit, or water proof clothing over cotton overalls. In addition, they wore gloves, hat, respiratory protection and chemical resistant boots. The prepared chemical was applied to the crop using tractors with air-conditioned cabs fitted with pesticide filters. During application of the prepared chemical, the participants removed one layer of clothing, gloves and respirator, and replaced their chemical resistant boots with normal work foot wear.

The National Occupational Health and Safety Commission estimated the risk to workers using open cabs to apply the prepared chemical. For the purpose of estimating the risk, NOHSC used surrogate data in the Pesticide Handlers Exposure Database (PHED)[7]. The estimates demonstrate that the use of open cabs significantly increases worker exposure to mevinphos. For this reason, the NOHSC cannot support the use of open cabs to apply mevinphos.

The results from the risk assessment mean that: (1) mevinphos can only be applied using tractors with air-conditioned closed cabs fitted with pesticide filters; (2) workers wear PPE comparable to study participants; (3) an individual can handle and apply a maximum of 11.7 kg of mevinphos per day (equivalent to 11 ha spray area when sprayed at the maximum concentration permitted by the label); and (4) an individual can carry out a maximum of 30 applications in any 12-month period.

At present, Australian brassica growers generally do not employ contractors to apply pesticides. However, when tractors with closed cabs is stipulated as a regulatory requirement, those farmers who do not have such equipment may have to rely on other farmers or contractors (collectively referred to as contractors) for spraying mevinphos. Such contractors are likely to handle and apply mevinphos above the 11.7 kg/day and 30 times a year limit. NOHSC estimated risk to such contractors using the results from a long-term toxicology study on animals where mevinphos was administered for two years. When animal toxicology studies are used, an MOE of 100 or more is generally considered acceptable.

The risk assessment showed that for use regimes in excess of 30 applications per year, acceptable MOEs (based on a 2-year animal NOEL) are achieved for plot sizes $\leq$ 1.3 ha (equivalent to 1.4 kg mevinphos per day). Since such a plot size is impracticable for many operators, including contractors, to comply with, handling and use of mevinphos in excess of 30 days in any 12-month period, and in excess of 11.7 kg/day, cannot be supported.

When viewed in the context of the agricultural practices currently followed by the Australian brassica industry, compliance with these limitations can be expected.

Further, the NRA has consulted the brassica industry, entomologists and Horticulture Australia regarding the industry's capacity to use mevinphos within these limits. The advice received indicated that these maximum limits can be complied with by the industry. In the case of exceptionally large farms, the farmer will be able to comply with the maximum limits by employing more than one operator to handle and apply mevinphos.

To characterise the risk to workers entering/handling fields sprayed with the chemical, MOEs have been estimated (based on a 2-year animal NOEL) for intervals ranging from two hours to seven days following the application of the chemical. These estimates were made for an exposure period of 6 h, taking into account the dislodgeable foliar residues (DFR), transfer co-efficient (TC=dermal exposure/DFR) values and inhalation exposure. These estimates indicate that the risk to workers entering/handling the crops two days or later after the application of the chemical is acceptable ($MOE \geq 100$), provided they wear long pants and shirt, hat, gloves and footwear during harvesting operations.

NOHSC estimated acceptable re-entry times for workers without gloves using a generic transfer coefficient for brassica harvesters, as used in the Occupational Post-application Risk Assessment Calculator Version 1 (8/9/00) – US EPA policy 003.1. The estimated risk assessment indicates that re-entry workers would be adequately protected at 3 days post-application, during harvesting without gloves.

The 1997 occupational health and safety assessment[1] had to rely on overseas studies, surrogate data and model predictions, which did not accurately reflect the agricultural practices and use patterns followed by the brassica growers in Australia. The studies and information subsequently provided by the registrant addressed the data gaps that existed at the time of the 1997 review. Based on the assessment of the new data, NOHSC advised the NRA that use of mevinphos is unlikely to pose undue hazard to workers, provided that label instructions (Section 2.5.1) are observed.

2.3 Mevinphos residue entering food chain

The comprehensive nature of reviews means that the NRA will sometimes consider matters that involve taking regulatory action outside of the review scheme.

MRLs are the maximum concentrations of a chemical residue in or on a food, agricultural commodity, or animal feed, resulting from the registered use of an agricultural or veterinary chemical. The MRLs are set at levels that are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions, which take into account Good Agricultural Practice or Good Veterinary Practice.

To ensure these MRLs do not pose an undue hazard to human health, the NRA undertakes a dietary exposure evaluation and risk analysis.

2.3.1 MRLs

Current Australian MRLs for mevinphos are listed below:

Brassica vegetables	0.25 mg/kg
Meat (mammalian)	0.05 mg/kg
Edible offal (mammalian)	0.05 mg/kg

At the time of the 1997 Review, no Australian crop residue data were made available to the NRA. Based on US trials, an MRL of 0.25 mg/kg was set for brassicas. The 1997 Review stated that Australian residue studies were needed to confirm this MRL.

Subsequent to the 1997 review, the registrant of Phosdrin Insecticide provided nine Australian residue studies conducted in multiple locations on different brassica crops. These studies were assessed by the NRA.

The results have been analysed in the context of agricultural practices followed by the Australian brassica industry. The analysis showed that the MRL set in 1997 is not adequate to cover the use of mevinphos on brassica vegetables. The MRL for brassica vegetables would need to be set at 0.3 mg/kg with a two-day withholding period to be acceptable

2.3.2 Assessment of risk from mevinphos residues in the diet

The Acceptable Daily Intake (ADI) of a chemical for humans is the level of intake of the chemical that can be ingested daily over an entire lifetime without any appreciable risk to health. (For details on ADI, see http://www.health.gov.au/tga/docs/pdf/adi.pdf). Based on human studies, mevinphos has an Acceptable Daily Intake (ADI) of 0.002 mg/kg bw/day.

The chronic dietary risk arising from mevinphos residues in brassica vegetables is estimated by the National Estimated Daily Intake (NEDI) calculation using the chemical and dietary consumption data from the 1995 National Nutrition Survey of Australia (Table 1, page 20).

Human dietary intake of mevinphos could occur via intake of brassicas (including products made from brassicas) and via the intake of livestock fed on discarded brassica wrapper leaves. For this reason, the NEDI calculation in Table 1, takes brassica vegetables, offal, meat and milk into account.

Feeding of discarded brassica wrapper leaves to livestock may occur but is likely to account for only a small percentage of animal diet. If brassicas contribute 10% to livestock diet, then the mevinphos levels in the total diet would be 2.4 ppm. In a study by Craine (1992), when goats were fed radio-labelled mevinphos, at up to 18 ppm in their diet, mevinphos or mevinphos-related metabolites were not observed in any tissue or milk. Thus, there is no reasonable expectation of residues of mevinphos or any related metabolites occurring in animal tissues, even at exaggerated dose rates.

The calculations presented in Table 1 (page 20) show that the NEDI for mevinphos is equivalent to 1% of the ADI, which suggests that when mevinphos is used according to good agricultural practice, the chronic human dietary exposure is small. Such a small exposure is unlikely to have an effect that is harmful to human health.

The NEDI calculation reflects the expected residue levels in commodities (which are represented by the supervised trials median residue-STMR) rather than the maximum residue limits (MRLs). This is in accordance with the *Guidelines for Predicting Dietary Intake of Pesticide Residues (revised)* (WHO, 1997). Based on the study by Craine (1992), the STMR values for offal, meat and milk are considered to be zero.

The Australian Total Diet Survey, formerly known as the Australian Market Basket Survey, assesses consumers' dietary exposure to pesticide residues and contaminants. The survey is conducted approximately every two years. The estimated dietary intake

of mevinphos for six age-sex categories ranged 0.24 – 1.19, 0, 0.025 – 0.11 and 0.01 – 0.03% of the ADI in 1992, 1994, 1996 and 1998 respectively. Further details of the Survey can be found at www.foodstandards.gov.au.

In summary, the new Australian residue data allowed revision of the previously established MRLs for mevinphos and the establishment of new MRLs (Section 2.5.1). These new MRLs, with a 2-day withholding period on harvest are unlikely to pose a significant risk to human health from a dietary intake perspective.

2.3.3 Potential for undue prejudice to trade arising from mevinphos residues

Export of treated produce containing detectable chemical residues may pose a risk to Australian Trade in situations where: (i) no residue tolerance or import tolerance is established in the importing country; or (ii) where residues in Australian produce are likely to exceed a residue tolerance or import tolerance established in the importing country.

The total value of export broccoli, Brussels sprouts, cauliflowers and cabbages (crops on which use of mevinphos is permitted by label instructions) was approximately $40 million in 1999/2000. This accounts for approximately 0.2% of the value of Australia's farming exports (Australian Commodity Statistics, ABARE, 2000). On this basis, it is unlikely that any disruption to trade in brassica vegetables could be considered to unduly prejudice trade between Australia and places outside Australia in the general sense.

The Codex Alimentarius Commission (Codex) is an international body of government representatives that establishes food standards. The Codex Committee on Pesticide Residues (CCPR) meets annually to establish and review Codex MRLs. Decisions are based on evaluations conducted by the Joint Meeting on Pesticide Residues (JMPR) which is an expert panel representing the FAO and WHO.

The 2002 meeting of the CCPR recommended that the current MRLs for mevinphos on broccoli, Brussels sprouts and cauliflower be deleted. It was decided to retain the Codex MRL for cabbage. The majority of Brassica vegetables will therefore not be covered by Codex MRLs. The Australian delegation to the 2002 CCPR indicated that residue data for broccoli, Brussels sprouts and cabbage would be submitted to the JMPR.

As residues in Brassica vegetables may not have continuing coverage by Codex MRLs it is suggested that growers establish an export harvest interval for markets where residues must be non-detectable or may exceed country specific MRLs. The residue data assessed indicate that a pre-harvest interval of 7 days is likely to be adequate to allow residues of mevinphos to decline to undetectable levels.

2.4 Environmental assessment

The NRA review of mevinphos in 1997 identified gaps in data, and a need for additional studies in relation to environmental hazard assessment.

The 1997 review did not have any data on the degradation of mevinphos in aquatic systems. Based on its rapid degradation in soils, mevinphos was considered to degrade in microbiologically active aquatic systems. It was noted that studies were needed to confirm this assumption and to determine the rate of degradation. Mevinphos was found to be highly toxic to birds by the oral route. The avian toxicity assessment was based on the studies submitted by Shell Chemical (Australia) Pty Ltd in 1989 for active constituent approval. The studies were not conducted to the existing regulatory standards and were deficient in a number of experimental details. As there was only one poorly reported avian dietary test in the data set, additional studies were considered necessary for a more comprehensive assessment of avian toxicity of mevinphos.

Pending resolution of these data deficiencies, the NRA assessed that, based on the strength of rapid degradation of mevinphos in soil, and predicted low likelihood of direct exposure or exposure to spray drifts, the potential environmental risks could be managed for the proposed interim use pattern of mevinphos for brassicas.

Since the 1997 review, the registrant provided results from two studies on aquatic metabolism. In addition, new studies on avian and aquatic toxicity have become available in the US EPA database. Using these new studies, the risk to aquatic organisms and birds from exposure to mevinphos has been re-examined.

2.4.1 Assessment of risk to aquatic organisms

The 1997 review of mevinphos did not have any aquatic metabolism studies available to it. Hence, the fate of mevinphos in aquatic systems and prediction of hazard to aquatic organisms was assessed on the premise that the degradation of mevinphos in aquatic systems would be analogous to its degradation in soils. Using the toxicity data to aquatic organisms and the estimates of likely spray drift, the 1997 review recommended limiting use to a maximum of three applications per season. The review also recommended spacing these applications by at least 14 days to allow repopulation of affected aquatic systems.

The new studies on aquatic metabolism submitted to NRA were conducted using a loam sediment. These studies were conducted to US EPA Guidelines, which meet NRA requirements. Results from these new studies show that the half-lives of the two isomers of mevinphos are extremely short. E-mevinphos has a half-life of 5.6 hours and the Z-isomer 16.4 hours. The results confirm that mevinphos readily degrades in aquatic systems.

Aquatic organisms are highly sensitive to mevinphos. Direct application to a 15 cm deep body of water at 1.1 kg ai/ha (label-recommended rate) results in a concentration of 730 µg/L of mevinphos. However, as the pesticide is normally applied by boom spray, direct application to aquatic ecosystems is unlikely.

Spray drift is the most likely route of exposure for aquatic organisms. Recent studies measured a 0.7% drift at 5 m from boom sprayers with medium to coarse droplets, and 1% and 0.2% spray drift at 7.5 and 15 m, respectively, with a fine spray. The EEC and EEC/EC_{50} ratios, estimated for a range of water depths 5 m away from the spray site assuming 1% spray drift, are presented in Table 2 (page 20).

Effects on fish would be localised to those animals that were beside areas being sprayed and to sensitive individuals in the population. In contrast, effects on aquatic invertebrates in water bodies adjacent to treated areas are likely to be severe and result in significant mortalities. However, given that both the isomers of mevinphos have short half-lives in water, a significant reduction in the total concentration is expected after 24 hours. Using these figures and assuming that mevinphos contained 63% of E-isomer and 27% of Z-isomer, Table 3 (page 20) presents the quotient for up to 96 hours after application on the most sensitive organism *D. pulex*. (Calculation used separate degradation curves for each isomer, and assumed that the two isomers are equally toxic.)

With rapid degradation in water, the toxicity of mevinphos is expected to be of short duration. Repopulation from unaffected areas is expected to occur, limiting any longer term effects on local aquatic invertebrate populations. Further, with many streams being seasonal and the deposition of spray drift from boom sprayers decreasing rapidly with distance (eg. <0.1% at 10 m), the environmental impact of mevinphos is expected to be limited to areas beside sprayed crops, provided the chemical is applied using boom sprayers. However, finer droplets will give higher drift values than the medium to coarse droplets used in Table 3.

Good Agricultural Practice requires that brassica crops should be situated away from the river bank, with a farm track or other buffer between the crop and the river. Therefore, the number of crops close enough to natural flowing water to be affected by spray drift (i.e. within 10 m) is expected to be relatively small.

The endpoint used in Table 3 applies to *D. pulex*, the most sensitive species. Environment Australia was unsure of certain details of the particular study, as only the results were available but not the experimental details. Environment Australia accepted the results as the study was rated as core (meets guidelines) by the US EPA.

For mysid shrimp (a very sensitive marine organism for which Environment Australia has full test details) with a 96-hour EC_{50} of 1.2 µg/L, the results in Table 3 are reduced by the ratio of the EC_{50}s, i.e. 0.18/1.2 = 0.15 times and are acceptable after 48 hours (Q = 0.1) for 15 cm deep water.

Following the 1997 Review, mevinphos application was limited to a maximum of three applications per crop per season, with two weeks between applications. With the very rapid degradation, residue after 14 days is not expected. Therefore, no increase in the environmental concentration and hazard is expected through the cropping period.

Run off from treated areas is not expected to present significant problems due to the very short half-lives in soil. The field studies clearly showed very short half-lives in soil, with most soils having no detectable residues one day after application.

2.4.2 Assessment of risk to birds

The 1997 review found mevinphos to be highly toxic to birds by the oral route. However, based on the estimates of residues on crops and dietary intake of sprayed crops by birds, birds were not expected to be at significant risk. New studies in the

US EPA database confirm that mevinphos is highly toxic to birds, but do not change the level of risk predicted by the 1997 review to birds from crops sprayed with mevinphos.

Residues on leafy crops are expected to be 133 mg ai/kg at an application rate of 1.1 kg ai/ha (label rate). Table 4 (page 20) shows the Estimated Environmental Concentration (EEC) and the ratio of LC_{50} (dietary, 250 ppm from US EPA database) to EEC for small birds (eg silvereyes, which consume fruit) and large birds (eg swamphens and magpie geese, which are known to damage vegetables). Fruit was included as a general model used for avian toxicity. It was assumed that the birds ingest approximately 50% of their dietary intake as sprayed crops. Note that when the ratio is <0.2, the hazard is considered low. Table 4 indicates that birds are not at significant risk from use of mevinphos if they enter the crop and start to feed immediately after spraying.

In summary, the new studies confirmed the 1997 review findings regarding the environmental impact of mevinphos. Mevinphos is highly toxic to birds and mammals, and very highly toxic to fish and aquatic invertebrates. Birds and mammals are not expected to be significantly exposed unless they enter an area recently sprayed. Direct application of mevinphos to aquatic systems is expected to significantly affect aquatic invertebrates and is prohibited by label instructions. Spray drift could present a significant hazard to aquatic invertebrates. However, the effect is expected to be temporary and with limited applications and allowance for repopulation from locally unaffected populations, significant environmental damage is not expected.

The 1997 review of mevinphos recognised that mevinphos is harmful to important beneficial insects in Australia (see Table 5, page 21) and therefore the use of mevinphos needs to be taken into account when following integrated pest management programs. The current environmental assessment of mevinphos is applicable for the use pattern specified in the labels for brassicas. Using mevinphos on brassicas alone, as per the label instructions, is unlikely to have an unintended effect on the environment.

2.5 Supplementary review findings and regulatory actions

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.

Following the 1997 Review, mevinphos use was limited to brassica crops, with a maximum of three applications per crop per season, and at least two weeks between applications. This supplementary review confirms that these limits need to be continued for broccoli, cabbage and cauliflower. However, for Brussels sprouts, the maximum number of applications can be set at six per crop per season, with the frequency of application limited to no more than two applications per fortnight. This must be followed by an interval of at least four weeks before a re-application is made. Only one crop of Brussels sprouts can be grown in a year, compared to the two or three crops for other brassicas. Advice from the industry is that six applications of mevinphos will only be necessary if DBM pressure is extremely high. Even when mevinphos is applied six times per season on a Brussels sprouts crop, the total number

of applications in a year will still be less than or equivalent to the total number of applications that can be made on other brassica crops in a year. The review has determined that at the stipulated maximum number and frequency of applications, use of mevinphos on Brussels sprouts is unlikely to have an unintended effect that is harmful to the environment.

Based on the assessment of worker exposure studies, the NRA is satisfied that mevinphos is unlikely to pose an undue hazard to users, provided that label directions and restrictions are observed; exposure mitigation methods specified are instituted; the product is used in accordance with Good Agricultural Practices; and, safe work practices are followed.

An analysis of the residue studies supplied by the registrant led to the revision of the previously set MRL for mevinphos in brassica vegetables. It is concluded that the establishment of a mevinphos MRL for brassica vegetables of 0.3 mg/kg with a 2-day withholding period before harvest is unlikely to pose a significant risk to human health from a dietary intake perspective. Use of mevinphos on broccoli, Brussels sprouts, cabbage and cauliflower is unlikely to unduly prejudice trade or commerce between Australia and places outside of Australia.

Mevinphos readily degrades in natural systems (half life<1 day), in aerobic soil and aquatic systems. The chemical is highly toxic to birds, mammals and aquatic organisms. Birds and mammals are not expected to be significantly exposed to the chemical unless they enter an area recently sprayed. Direct application of mevinphos to aquatic systems is expected to significantly affect aquatic organisms and must be avoided. Spray drift could present a significant hazard to aquatic organisms, but the effect is expected to be temporary and, with repopulation from locally unaffected populations, significant environmental damage is not expected. When the product is used on brassicas (broccoli, Brussels sprouts, cabbage and cauliflower) only, in accordance with the label instructions, it is unlikely to have an unintended effect that is harmful to the environment.

Mevinphos should only be applied using closed air-conditioned cabs fitted with pesticide filters. Given the hazardous nature of mevinphos, this special equipment is necessary for the safe application of the product.

Special knowledge, skills and qualifications are required in the preparation and handling of mevinphos products. To use the chemical safely it is not sufficient that the workers wear the recommended PPE, and spray only from an enclosed, air-conditioned cab fitted with pesticide filters; the worker requires higher than average level of knowledge and skill in pesticide application technology. A Farm Chemical Users Course or equivalent training would provide users with sufficient knowledge and skills to prepare and handle mevinphos products safely.

2.5.1 Regulatory actions to implement the review outcomes

On the basis of the findings of the supplementary review of mevinphos, the NRA has revoked the suspension of the approval of active constituent mevinphos (44575), revoked the suspensions of the registration of Phosdrin Insecticide (47468) and the

approval of its current label (47468/0498) ; and affirmed the approval of mevinphos active constituent.

The NRA has determined that special knowledge, skills, qualifications and equipment are required for safe preparation and handling of the products. Accordingly, the NRA intends to certify that it is in the public interest for mevinphos products to be declared as Restricted Chemical Products, and to recommend that the Agvet Code Regulations declare mevinphos products to be Restricted Chemical Products.

The conditions to which the registration of Phosdrin Insecticide is subject are varied. The following condition is imposed on the registration of Phosdrin Insecticide.

"Pending the regulations declaring products containing mevinphos to be restricted chemical products, a person must not supply this chemical product, or cause or permit it to be supplied, except to a person who has completed a Farm Chemical Users Course or equivalent training and who is authorised to use the product under State or Territory legislation".

The conditions to which the approval of the label of Phosdrin Insecticide are varied. The following instruction must be included on the label. The instructions relating to the WHP, the maximum number of applications per crop per season and the interval between applications replace the corresponding instructions imposed by the NRA following the 1997 Review.

For application on cabbages, cauliflowers and broccoli: DO NOT apply more than three sprays of mevinphos per crop per season. DO NOT re-apply mevinphos within two weeks of a previous application of this chemical.

For application on Brussels sprouts: DO NOT apply more than six sprays of mevinphos per crop per season. This use is restricted to two applications within two weeks, which must be followed by at least four weeks before reapplication of mevinphos is made.

***WITHHOLDING PERIOD**: DO NOT harvest for two days after application.*

Note: The withholding period stated on the label applies only to produce destined for the Australian domestic market. Some export markets apply different standards which may require an export harvest interval. If crops on which this product is to be used may be sold outside Australian domestic markets, details of overseas standards should be obtained from the product manufacturer or growers' association.

The following instructions must also be included on the label. These are additional to those imposed by the 1997 Review.

***SAFETY DIRECTIONS**:*

An individual must not handle and/or apply mevinphos in excess of thirty days in any 12-month period. An individual must not handle and/or apply more than 11 kg of mevinphos (12 kg Phosdrin Insecticide) on any day.

(Explanatory note: handling on one day and spraying on another constitutes two days of handling and/or applying. That is, each separate activity counts).

When opening the container and preparing spray, wear protective waterproof clothing, cotton overalls buttoned to the neck and wrist and washable hat, elbow-length PVC gloves, chemical resistant footwear, and a full-face piece respirator with combined dust and gas cartridge. Mevinphos must only be applied using air-conditioned closed cabs, fitted with pesticide filters designed to remove particulate matter and vapours. When applying the spray, waterproof clothing, gloves and respirator may be removed, however clean waterproof clothing, gloves, footwear and respirator must be carried in the cab when applying the spray. If there is a need to exit the cab (for example, to check spray nozzles or remove an obstacle) when applying the spray, it is preferable to drive outside the sprayed field and then protective waterproof clothing, gloves footwear and respirator must be worn before attending to equipment or re-entering field. If it is necessary to exit the cab in the field, the clean waterproof clothing, gloves, footwear and respirator must be worn.

After each day's use, wash gloves, contaminated clothing and respirator, and if rubber wash with detergent and warm water.

***RE-ENTRY TO TREATED AREA:** The following conditions MUST be observed when re-entry is required within a period of two days after application:*

Wear cotton overalls buttoned to the neck and wrists (or equivalent clothing) and elbow-length PVC gloves.

After each day's use, wash gloves and clothing.

2.5.2 Other regulatory decisions

The comprehensive nature of reviews means that the NRA will sometimes consider matters that involve taking regulatory action outside of the review scheme. In view of the information from the new residue studies examined for the Supplementary Review (1.2.3), the NRA has decided that the MRLs for mevinphos in brassica vegetables, edible offal (mammalian) and meat (mammalian) be changed as shown below.

Compound		Food	MRL (mg/kg)
Mevinphos			
Delete:			
	VB 0040	**Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas**	**0.25**
	MM 0095	Meat [mammalian]	*0.05
	MO 0105	Edible offal (Mammalian)	*0.05
Add:	VB 0040	**Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas**	**0.3**
	MM 0095	Meat [mammalian]	*0.05
	MO 0105	Edible offal (Mammalian)	*0.05
	ML 0106	Milks	*0.05

Appendix 1 List of product registrations and active constituent approvals affected by this review.

Following is a list of active constituent approval holder(s) and product registrant(s). Any new product registration or active constituent approval will be subject to all recommendations made in this report together with those that were made in the 1997 review.

Product(s)		**Registrant**
47468	Phosdrin Insecticide	BASF Australia Ltd
Active constituent(s)		**Approval holder**
44575	Mevinphos	BASF Australia Ltd

Table 1. Dietary exposure calculations: calculation of NEDI for mevinphos

Commodity	Food consumption (g/kg BW/day)	MRL (mg/kg)	STMR (mg/kg)	NEDI (mg/kg BW/day) Based on MRL	NEDI (mg/kg BW/day) Based on STMR
Brassica vegetables	0.3249	0.3	0.07	0.00009747	0.000022743
Edible offal, mammalian	0.0151	0.05	0	0.00000755	0
Meat, mammalian	1.7276	0.05	0	0.00008638	0
Milk	8.9933	0.05	0	0.000449665	0
Total				0.00063427	0.000022743
As % of the ADI				31.7	1.1

Table 2. EEC and ratio of EEC to EC50 for trout and sensitive aquatic invertebrates at different depths of water 5 m away from spray site

	Depth of water 15 cm	30 cm	45 cm
EEC for 1% spray drift	7.3 µg/L	3.7 µg/L	2.4 µg/L
Rainbow trout, EC_{50} = 11.9 µg/L	0.6	0.3	0.2
Mysid shrimp, EC_{50} = 1.2 µg/L	6.1	3.1	2.0
Simocephalus EC_{50} = 0.42 µg/L	17.4	8.8	5.7
Daphnia pulex EC_{50} = 0.18 µg/L	40	20	13

Table 3. Quotient for *D. pulex* at different depths of water 5 m from spray site after degradation of up to 96 hours.

	Depth of water 15 cm	30 cm	45 cm
Initial EEC:EC_{50}	40	20	13
24 hours later	3.65	1.87	1.21
48 hours later	0.72	0.37	0.24
72 hours later	0.17	0.09	0.06
96 hours later	0.04	0.02	0.01

Table 4. EEC and quotient for birds feeding on sprayed fruit or leafy crop. Quotient based on dietary EC50 of 250 mg/kg.

Birds size and weight	Daily consumption of fruit or leafy crop	Amount of mevinphos ingested	Quotient dietary
Small 15 g	2.5 g (fruit)	0.037 mg	0.03
Large 750 g	75 g (leafy crop)	10.0 mg	0.27

Table 5. Toxicity of mevinphos to a range of beneficial arthropods.

	Arthropod Species	Laboratory exposed	Laboratory protected	Semi-field initial	Semi-field persistence	Field
WASPS	*Trichogramma cacoeciae**	4	4		2	
	*Encarsia formosa**	4	1		1	
	*Aphidius matricariae**	4	3			
	Cales noacki	2				
	Leptomastix dactylopii	4				
	Phygadeuon trichops	4		1		
	Coccygomimus turionellae	4			2	
MITES	*Phytoseiulus persimilis* R	1				
	*Phytoseiulus persimilis**			4		
	*Amblyseius potentillae**	4				
	*Amblyseius finlandicus**					4
	*Typhlodromus pyri**	4				3
	Typhlodromus p R	2				
	Chiracanthium mildei	3				
INSECTS	*Chrysopa carnea**	3		3		
	*Syrphus corollae**	4				
	Semiadalia 11-notata	4	3			
	*Harmonia axyridis**	1				
	*Bembidion lampros**	4				
	*Pterostichus cupreus**	1				
	Anthocoris nemoralis	1	1			
	*Coccinella septempunctata**			4		

Taken from IOBC/WPRS working Group (Hassan, S.A., Bigler, F., Bogenschütz, H., Boller, E., *et al* 1988).

Laboratory Toxicity (mortality): 1=<50%, 2=50-79%, 3=80-99%, 4=>99%.

Field, Semi-field initial (mortality): 1=<25%, 2=25-50%, 3=51-75%, 4=>75%.

Semi-field, persistence (duration of harmful effects): 1=<5 days, 2=5-15 days. *Indicates that insect is used as part of IPM programs in Australia.

R = resistant strain

References

1. Public Release Summary on the NRA Review of Mevinphos (1997). NRA. p. 43 (Available at http://www.nra.gov.au/chemrev/mevinphos.pdf).
2. AMVAC Chemical Corporation (2001) Determination of dermal and inhalation exposure of mevinphos to professional pesticide mixer/loader/applicators. Study No. ERS99001 [Agrisearch Services Pty Ltd (field facility) and ITA PROBE Analytical (analytical facility), Australia]. AMVAC Chemical Corporation 1999 LA, CA.
3. AMVAC Chemical Corporation (2001) Determination of dermal and inhalation exposure to mevinphos to re-entry workers performing hand harvesting in brassica. Study No. ERS99002 [Agrisearch Services Pty Ltd (field facility) and ITA PROBE Analytical (analytical facility), Australia]. AMVAC Chemical Corporation 1999 LA, CA.
4. AMVAC Chemical Corporation (1999) An overview of brassica farming in Australia. Report number JH 007.
5. Rider, J.A., Swader, J.I., and Puletti, E.J. (1972) Anticholinesterase toxicity studies with Guthion, Phosdrin, Di-syston and Trithion in human subjects. *Interim results Fed. Proceedings* 31: 1730.
6. Rider, J.A., Puletti, E.J., and Swader, J.I. (1975) The minimal oral toxicity level for mevinphos in man. *Toxicol. Appl. Pharmacol.* 32:97-100.
7. Pesticide Handlers Exposure Database (PHED) Surrogate Exposure Guide. (1998) Estimates of worker exposure from the Pesticide Handler Exposure Database, version 1.1, August 1998.