Australian Government

Australian Pesticides and Veterinary Medicines Authority

DICHLORVOS

FINAL REVIEW REPORT AND REGULATORY DECISION

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

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the Agvet Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

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

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

The reconsideration process includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

In undertaking reconsiderations (hereafter referred to as reviews), the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety and Environmental Health within the Department of Health and Ageing, the Department of Sustainability, the Environment, Water, Population and Communities, and the state departments of agriculture, as well as other expert advisers as appropriate.

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

The APVMA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements. The APVMA recommends 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 basis for the current reconsideration is whether the APVMA is satisfied that continued use of the active constituent dichlorvos and products containing dichlorvos in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely 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.

The APVMA also considered whether product labels carry adequate instructions and warning statements.

This document, *Dichlorvos Final Review Report and Regulatory Decision: The reconsideration of approvals of the active dichlorvos, registrations of products containing dichlorvos and their associated labels*, relates to all products containing dichlorvos that were nominated for review by the APVMA. The review's findings and regulatory decision are based on information collected from a variety of sources.

The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

The Dichlorvos Final Review Report and Regulatory Decision containing the APVMA's assessment (including the technical reports for all registrations and approvals relating to dichlorvos) is available from the APVMA website at < http://www.apvma.gov.au/products/review/index.php>.

OVERVIEW

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has completed its review of the active constituent dichlorvos and all products containing dichlorvos and their associated approved labels.

Dichlorvos is an organophosphorus insecticide first synthesised in the late 1940s, having been first described as an impurity of the organophosphorus insecticide trichlorfon, . Commercial production of dichlorvos began in 1961. Insects are killed by interference with an enzyme (cholinesterase) in the nervous system, resulting in muscle paralysis.

Dichlorvos is commonly used in Australia against a large variety of insects that infest domestic, public and commercial buildings, recreational areas, abattoirs, wineries (non-food producing areas), animal houses, mushroom growing facilities, glasshouses, greenhouses and food storage areas. The major use of dichlorvos is as a disinfestant fumigant or spray for stored grain and for grain handling equipment. There is one veterinary use as an oral paste for the treatment of worms and Bot fly larvae in horses. Other formulations include slow-release strips (e.g. pest-strips), sprays and fumigants. The field use of dichlorvos is limited to the control of leaf roller on avocados.

The APVMA decided to review dichlorvos because of specific concerns about its high acute toxicity and its carcinogenic potential. The review began in December 1996. In June 2000 the APVMA released a dichlorvos draft review report (now called the Preliminary Review Findings (PRF) report) for public consultation. A large amount of additional toxicological data became available following the initial PRF and a subsequent PRF was released in June 2008.

This document, *The reconsideration of the active constituent dichlorvos, registrations of products containing dichlorvos and approvals of their associated labels*, summarises the revised assessments and the regulatory outcomes of the dichlorvos review. All public comments received since the release of the PRF report have been considered in the preparation of this report.

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ACRONYMS AND ABBREVIATIONS

LENGTH

km	kilometre
cm	centimetre
m	metre
µm	micrometre
mm	millimetre

WEIGHT

t	tonne
kg	kilogram
g	gram
µg	microgram
mg	milligram
wt	weight
bw	body weight

DOSING

id	intradermal
im	intramuscular
inh	inhalation
ip	intraperitoneal
iv	intravenous
po	oral
sc	subcutaneous
mg/kg bw/d	mg/kg bodyweight/day

VOLUME

L	litre
mL	millilitre

CONCENTRATION

ppb	parts per billion
ppm	parts per million

OTHER

Pa	Pascals
RH	relative humidity

CLINICAL CHEMISTRY, HAEMATOLOGY

AChE	anticholinesterase
BCF	bioconcentration factor
ChE	cholinesterase
RBC	red blood cell (erythrocyte)

CHEMISTRY

ac	active ingredient
CO_2	carbon dioxide
EC	emulsifiable concentrate formulation
LD	liquid formulation
PA	Paste formulation

TOXICOLOGY AND OCCUPATIONAL HEALTH AND SAFETY

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
ATDS	Australian Total Diet Surveys
EC50	Median Effective Concentration
LC50	Median Lethal Concentration
LD50	Median Lethal Dose
MATC	Maximum Acceptable Toxicant Concentration
MOE	Margin of Exposure
MRL	Maximum Residue Limit or Level

MRL Standard	*Maximum Residue Limits (MRL) in Food and Animal Feedstuff*
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short Term Intake
NOEL	No Observed Effect Level
PHED	Pesticide Handlers Exposure Database
POEM	Pesticide Operator Exposure Model
STMR	Supervised Trials Median Residue

ORGANISATIONS AND PUBLICATIONS

APVMA	Australian Pesticides and Veterinary Medicines Authority
FAO	Food and Agriculture Organization of the United Nations
FAISD	First Aid Instructions and Safety Directions
NOHSC	National Occupational Health and Safety Commission
NRA	National Registration Authority, the then-APVMA
NRS	National Registration Scheme
OCSEH	Office of Chemical Safety and Environmental Health
PRF	Preliminary Review Findings
US EPA	United States Environmental Protection Agency
WHO	World Health Organization

EXECUTIVE SUMMARY

Introduction

Dichlorvos is a volatile organophosphorus insecticide with fumigant and penetrant action. Insects are killed by its inhibition of an enzyme (acetylcholinesterase or AChE) in the nervous system, resulting in muscle paralysis.

Dichlorvos is commonly used against a large variety of insects that infest domestic, public and commercial buildings, recreational areas, abattoirs, wineries (non-food producing areas), animal houses, mushroom growing facilities, glasshouses, greenhouses and food storage areas. The major use of dichlorvos is as a disinfestant fumigant or spray for stored grain and for grain handling equipment. There is one veterinary use as an oral paste for the treatment of worms and Bot fly larvae in horses. Other formulations include slow-release strips (e.g. pest-strips), sprays and fumigants. The field use of dichlorvos is limited to the control of leaf roller on avocados.

Dichlorvos product registrations and label approvals are under review as part of the APVMA's Review Program because of specific concerns about its high acute toxicity and its carcinogenic potential.

In June 2000, the APVMA released a dichlorvos draft review report for public consultation. That draft report, now called the Preliminary Review Findings (PRF) report provided a summary of the data evaluated and the proposed regulatory decisions.

After the publication of that report, the APVMA became aware of a large package of dichlorvos toxicological and exposure studies, held by a United States manufacturer, which had not been submitted at the time of the original data call-in. The American and British regulators had assessed those studies. Under the Agvet Codes, the APVMA is obliged to consider all information of which it is aware before making a final decision regarding the future of dichlorvos. Therefore, the APVMA, exercising its powers under section 159 of the Agvet Codes, obtained those studies through the Australian approval holder of the dichlorvos active constituent. The new data consisted of laboratory animal studies on metabolism, percutaneous absorption, subchronic and chronic toxicity, reproductive and developmental toxicity, genotoxicity, neurotoxicity and forestomach irritation. In addition, a number of human volunteer studies not previously evaluated by Australian authorities were submitted.

After assessing the new data, the Office of Chemical Safety and Environmental Health (OCSEH) revised the Acute Reference Dose (ARfD) for dichlorvos. Consequently, the occupational health and safety assessment and acute dietary risk assessment were revised. A revised PRF report was published in June 2008.

This document, *The reconsideration of the active constituent dichlorvos, registrations of products containing dichlorvos and approvals of their associated labels*, summarises the revised assessments and regulatory outcomes of the dichlorvos review.

Review findings

Toxicological assessment

The toxicological assessment for the review of dichlorvos was undertaken by the OCSEH, which considered all the toxicological data and information submitted for the review.

In common with all organophosphorus insecticides, the primary mode of action of dichlorvos is via the inhibition of acetylcholinesterase activity, which causes over-stimulation of those parts of the nervous system that use acetylcholine to transmit nerve impulses.

Dichlorvos is absorbed via all exposure routes, and various animal studies have shown that it does not require activation to inhibit acetylcholinesterase. Dichlorvos has high acute toxicity in experimental animals. Signs of intoxication occur soon after dosing and are consistent with acetylcholinesterase inhibition, which include salivation, lachrymation, vomiting, diarrhoea and laboured breathing. If intoxication is severe, muscle twitching, loss of reflexes, convulsions and death can eventuate. Recovery from non-lethal doses is relatively rapid (within 24 hours). In rats, the time to peak effect following oral dosing ranges from 15 to 60 minutes, with recovery occurring by 24 hours. Dichlorvos is rapidly metabolised *in vivo*, with no parent compound detected in any laboratory animal studies.

Dose-related inhibition of plasma, red blood cell (RBC) and brain cholinesterase (ChE) activities was the most common manifestation of dichlorvos toxicity in short-term, subchronic and chronic studies in mice, rats and dogs. Cholinergic signs and occasional mortalities occurred in rats and dogs at the same doses as the inhibition of brain AChE activity. Plasma and RBC ChE activities were also inhibited following chronic inhalational exposure in rats.

There was little indication that repeated oral or inhalational exposure had any effect on haematology, clinical chemistry or urinary parameters, or on organ weights or gross pathology. In some rat and dog studies, histopathology revealed cytoplasmic vacuolisation of the liver.

Numerous *in vitro* and *in vivo* experiments have tested the genotoxic potential of dichlorvos. In the current submission, seven unpublished genotoxicity studies were evaluated, which showed that dichlorvos was genotoxic *in vitro* but not *in vivo*. These findings are consistent with the existing and extensive genotoxicity database for dichlorvos. The extensive genotoxicity database indicates that in the absence of metabolism, dichlorvos is mutagenic and clastogenic at the point of contact, where unchanged dichlorvos may be in direct contact with tissue. There is no evidence that dichlorvos has any systemic genotoxic potential. It is unlikely to pose a genotoxic risk to humans.

Successive Australian health advisory committees have independently examined the carcinogenic and genotoxic potential of dichlorvos on several occasions. These previous risk assessments have concluded that dichlorvos is unlikely to pose a carcinogenic risk to humans.

Dichlorvos is not considered to pose a reproductive hazard to humans. There was no evidence that it was teratogenic, based on a range of studies conducted in mice, rats and rabbits following oral or inhalational exposure.

Dichlorvos is acutely neurotoxic in chickens and rats by virtue of its ability to inhibit brain ChE activity. However, there was no evidence that dichlorvos causes delayed neuropathy.

As for other mammals, the inhibition of plasma ChE activity is the most sensitive toxicological endpoint in humans following repeated exposure.

Inhalational exposure to dichlorvos is considered to be the main exposure pathway in humans (the general public) based on its current use patterns. A number of studies have investigated the inhalational exposure of humans in residential and public premises under normal or exaggerated use conditions. Few studies have examined the dermal toxicity of dichlorvos in humans.

The existing Acceptable Daily Intake (ADI) for dichlorvos of 0.001 mg/kg bw/day (milligrams per kilogram of body weight per day) was reaffirmed in the present review. This ADI is based on the No-Observed-Effect-Level (NOEL) of 0.014 mg/kg bw/day in a 28-day human study that showed plasma ChE inhibition at and above 0.021 mg/kg bw/d, and using a 10-fold safety factor. The current Health Value for Australian drinking water was recommended for amendment from 0.001 to 0.007 mg/mL (milligrams per millilitre) to reflect this ADI. The present review identified a suitable acute oral dosing study in humans to allow the refinement of the existing acute reference dose (ARfD) of 0.003 mg/kg bw for dichlorvos. The new ARfD of 0.1 mg/kg bw/day was calculated by applying a 10-fold safety factor to the NOEL of 1 mg/kg bw for the inhibition of erythrocyte ChE activity.

There are no changes to the active constituent approval status following the review of dichlorvos. However, following the review, the APVMA will require approval holders to provide justification, on toxicological grounds, for the existing impurity limit for chloral at 5 g/kg (grams per kilogram). Based on the results of an inhalational exposure assessment, the registration of Sureguard Pest Strip Household Insecticide (APVMA product code 45596) was not supported as it poses an unacceptable chronic inhalational risk to human health. There is no objection on public health grounds to the continued registration of all other existing dichlorvos products.

The existing poisons schedule for dichlorvos remains appropriate (Schedule 5 for products containing 20 per cent or less dichlorvos and impregnated in plastic resin strips or in sustained release resin pellets; Schedule 6 for products containing 50 percent or less of dichlorvos except when included in Schedule 5; Schedule 7 except when included in Schedule 5 or 6). The review identified a number of additions and amendments to the existing First Aid Instructions and Safety Directions (FAISDs) for Australian dichlorvos products.

Occupational health and safety assessment

Due to its high acute toxicity, volatility and comparatively extensive dermal absorption, dichlorvos presents significant hazards and risks to persons who are occupationally exposed. Dichlorvos has caused severe or fatal cholinergic poisoning in workers through dermal contact with concentrated products or spray mixture.

Inhibition of plasma ChE activity (non-specific ChE) is the most sensitive toxicological endpoint in humans following repeated exposure. The NOEL in humans following repeated oral dosing is 0.014 mg/kg bw/d. There are no repeat-dose studies with dichlorvos by the dermal or inhalation routes that are suitable for occupational health and safety (OHS) assessment purposes. Based on studies in rats and pigs respectively, dermal and inhalation absorption factors of 30% and 70% have been used for risk assessment purposes. Therefore, the dermal OHS NOEL has been set at 0.047 mg/kg bw/d, and the inhalation OHS NOEL has been set at 0.02 mg/kg bw/d. Because these values were obtained using a pivotal NOEL from a study in humans, margins of exposure (MOE) of 10 were used in the risk assessment to account for variation within the human population.

In most of its currently registered situations of use, mixing, loading and applying dichlorvos are likely to cause toxicologically unacceptable levels of exposure and risk to operators. Based on exposure modelling, it appears that mixers and loaders can handle no more than approximately 1.4 kg of dichlorvos per day without eroding the MOE below the acceptable value of 10, even if enclosed mixing systems are used and gloves and chemical resistant clothing are worn. This amount of dichlorvos is insufficient to support the anticipated work rates associated with application of dichlorvos by indoor and outdoor fogging and misting, broadacre application to avocados and mechanical application to grain.

Operators applying dichlorvos are likely to be exposed extensively by the dermal and inhalation routes. Based on studies in pest control operators and using appropriate exposure models, this assessment has shown that even with the highest level of personal protective equipment, it is not possible to assure adequate MOEs to protect persons applying dichlorvos indoors or outdoors by surface and space spray. Similarly, MOEs are inadequate in situations where the operator has to remain inside the structure under fumigation while using hand-held CO_2 pressure guns and portable fogging and misting equipment, or applying dichlorvos by watering can or paintbrush. There is insufficient information to predict the extent of operator exposure during indoor crack and crevice treatment. Consequently, these uses of dichlorvos are no longer supported.

The situations in which operator exposure can be constrained within acceptable limits, by use of appropriate personal protective equipment, are fumigation treatments where dichlorvos is discharged from pressure cylinders into buildings, sealed plant fumigation chambers or other enclosed spaces using fixed installations, fumigation of the airspace within sealable silos, bins or other storage containers, where dichlorvos is discharged from manually released pressure cylinders by an operator remaining outside the space under treatment, fumigation of machinery and eradication of insect nests in outdoor settings, and administration of veterinary product (oral worm and Bot paste for horses) by pre-loaded syringe. However, although operator safety can be assured in these situations, there is a hazard to persons re-occupying treated buildings, even after ventilation. An experimental study has shown that workers re-entering treated industrial buildings will be exposed to toxicologically unacceptable airborne concentrations of dichlorvos for 3 days after application. A 4-day re-entry interval would be supportable, but compliance would be impractical in many situations. Therefore, dichlorvos should not be applied within industrial or similar buildings which are to be re-occupied within four days of treatment. By contrast, dichlorvos is significantly less persistent when applied in glasshouses, and a re-entry interval of 4 hours after ventilation is suitable for these and similar structures. There is insufficient information upon which to set a re-entry interval for use in mushroom houses.

New and revised label Safety Directions including warning statements and personal protective equipment have been recommended for 50 g/kg liquid (LD) products in pressure cylinders and veterinary preparations. To limit the inhalation exposure of workers involved in the manufacture of dichlorvos products to a toxicologically acceptable level, the OCSEH has recommended that the Australian exposure standard for dichlorvos in the workplace atmosphere be revised from 0.9 mg/m^3 (milligrams per cubic metre) to a time-weighted average concentration of 0.02 mg/m^3.

Residues assessment

The maximum residue limit (MRL) is the maximum amount 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. MRLs for chemicals 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. From the available residue data, the APVMA set MRLs for various foods. Then it carried out a dietary exposure evaluation to examine if the dichlorvos MRLs pose an undue risk to human health.

According to the existing product labels, dichlorvos may be used as a surface treatment of stored grain at rates of up to 0.27 g ac/m^2 (grams of active ingredient per square metre). Grain may be retreated as often as necessary to prevent infestations, and no withholding period is specified on some product labels. When dichlorvos is used as a one-off surface treatment of bulk grain at 0.27 g ac/m^3, it is unlikely that residues will exceed the cereal grain MRL of 5 mg/kg after treatment. However, the effect of repeated applications on residue levels in treated grain is unclear. It is therefore prudent to recommend a 7-day withholding period consistent with the label application rate.

Currently there are established MRLs for lentils (dry), peanuts and soya beans. With respect to application of dichlorvos on these crops, there are no specific use-patterns approved. No data have been provided to support the use of dichlorvos on, or the MRLs for, lentils, peanuts and soya beans or for other pulses. Hence the current MRLs for lentils (dry), peanuts, and soya beans will be deleted from the *Maximum Residue Limits (MRL) in Food and Animal Feedstuff* (the MRL Standard) as an associated outcome of the review.

Insufficient data are available for the purposes of establishing appropriate MRLs for potatoes, mushrooms and avocados. Due to public health and safety concerns of unknown dietary exposure, continued use of dichlorvos on potatoes, mushrooms and avocados cannot be supported. If there is a genuine need for continuation of dichlorvos treatment on these crops, the industries should clearly define the use-patterns and provide residue data to allow establishment of appropriate MRLs.

The use of dichlorvos in glasshouses and greenhouses represents approximately 1.7% of total usage of dichlorvos in Australia. Food commodities that may be grown in glasshouses and greenhouses include lettuce (head and leaf), tomato, cucumbers and capsicums. There were no residue data available to support treatment of these commodities.

Because of public health and safety concerns relating to unknown dietary exposure, the use of dichlorvos on greenhouse and glasshouse crops cannot be supported. The MRLs for lettuce, tomato and vegetables will be deleted from the MRL Standard as an associated outcome of the review.

The use of dichlorvos on ornamental crops grown under cover in greenhouses is not of concern from the point of view of residues.

Dichlorvos is registered for use as an oral paste in horses. No residue data were provided to support this use. However, based on available metabolism and animal transfer data, dichlorvos residues are unlikely to be present in tissues when the product is used as directed. The continued use of dichlorvos for horses is supported. There are no associated MRL outcomes of the review with respect to this use-pattern.

No residue data were provided to support the use of dichlorvos in animal houses and pens. Based upon available metabolism and animal transfer data, no detectable residues of dichlorvos are likely to occur in animal commodities following this type of treatment. The continued use of dichlorvos for treatment of animal housing and pens is supported. As an associated outcome of review, a Table 5[1] entry in the MRL Standard is recommended for dichlorvos treatment of animal housing and pens.

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[1] The MRL Standard lists MRLs of substances which may arise from the approved use of those substances or other substances, and provides the relevant residue definitions to which these MRLs apply. The Standard is made up of five Tables:
Table 1 Maximum Residue Limits of agricultural and veterinary chemicals and associated substances in food commodities;

No residue data were provided to support the continued use of dichlorvos for treating empty silos to control adult grain pests. It is noted that treatment applied to empty grain silos is not likely to result in detectable residues in untreated grain, or significantly increase the residue level of treated cereal grain stored in these facilities. This is based upon the high degree of volatility of dichlorvos and the bulk volume storage capacity of such facilities. Any contamination remaining after treatment will be effectively dispersed and result in no detectable residues.

Therefore the continued use of dichlorvos for treatment of empty grain silos is supported from a residues perspective. No labelling restraints are necessary with respect to residues following this use-pattern.

Several registered products allow the use of dichlorvos as pest-strips or surface sprays to control insect pests in domestic and commercial premises, including in food preparation areas. The use of dichlorvos-impregnated PVC pest strips in food preparation and storage areas has the potential to result in detectable dichlorvos residues in both uncooked food and prepared meals. It was postulated that commodities with fatty or waxy surfaces would accumulate the highest dichlorvos residues when exposed for extended periods. There are no residue concerns with respect to the continued use of dichlorvos in pest-strips or surface sprays to control insect pests in domestic and commercial premises. However, given the potential for significant dichlorvos residues to occur in food stored or prepared in areas containing dichlorvos pest strips, these products are restricted against use in food cupboards or food storage and food preparation areas. Registration of Sureguard Pest Strip Household Insecticide is not supported on public health grounds.

Metabolism studies show that trichlorfon (2,2,2-trichloro-1-hydroxyethyl phosphonate) is transformed to dichlorvos to a minor extent in plants and animals, and *in vitro* in alkaline media. Registered trichlorfon products are approved for use on horticultural crops. Potentially, the use of trichlorfon may result in detectable dichlorvos residues in trichlorfon-treated commodities or animals consuming trichlorfon treated commodities. As a consequence, the use of trichlorfon is considered in this residues review.

Based on the available information, it is concluded that no detectable dichlorvos residues should occur in trichlorfon treated commodities or in animal commodities resulting from the use of trichlorfon. There are no associated MRL outcomes of the review with respect to trichlorfon use.

Cereal grains and milled cereal grain by-products may be used as animal feeds. It is assumed that cereal grains and processed grain fractions may comprise up to 100% and 40% respectively, of livestock feeds.

Animal feeding and metabolism studies demonstrate that dichlorvos is rapidly and extensively eliminated, and very little tissue residue retention occurs. On the basis of these studies, detectable dichlorvos residues are unlikely to be found in animal tissues, milk or eggs when dichlorvos is used in

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Table 2 Portion of the commodity to which the MRL applies (and which is analysed);
Table 3 Residue definition;
Table 4 MRLs for pesticides in animal feed commodities;
Table 5 Uses of substances where MRLs are not necessary.

accordance with the approved use-patterns. As associated outcomes of the review, MRLs will be established at the limit of analytical quantitation for edible offal (mammalian), eggs, meat (mammalian), milks, edible offal of poultry and poultry meat.

The chronic dietary risk is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered and temporary uses of the chemical and dietary intake data from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with the World Health Organization's Guidelines for Predicting Dietary Intake of Pesticide Residues. The NEDI is estimated to be 23% of the ADI of dichlorvos. This NEDI estimate is consistent with dietary survey results. The daily intake of dichlorvos estimated by the Australian Market Basket Survey (and the Australian Total Diet Survey) in 1990, 1992, 1994, 1996 and 2000 was less than approximately 2% of the ADI. Therefore it is concluded that chronic dietary exposure to dichlorvos residues is below the toxicologically determined safe level (the ADI) and therefore should not present a health risk to consumers of treated produce.

Based upon the *new* ARfD of 0.1 mg/kg bw, the acute dietary risk to dichlorvos was estimated by the National Estimated Short Term Intake (NESTI) calculation encompassing all registered and temporary uses of the chemical, dietary intake data (97.5th percentile consumption figures) and mean body weights from the 1995 National Nutrition Survey. Calculations were made according to the method and formulae published by the JMPR.

The highest acute dietary intake was estimated at 13% of the ARfD. It was concluded that the acute dietary exposure to dichlorvos residues were acceptable with respect to uses of dichlorvos where MRLs are supported.

The major commodities to be considered with regards to trade are the cereal grains. The cereal grain MRL of 5 mg/kg recommended in this review is the same as the current Codex MRL.

When used as directed, dichlorvos residues are unlikely to exceed the current cereal MRL of 5 mg/kg. It was concluded that the continued registration of dichlorvos is unlikely to unduly prejudice Australian trade in cereal grains.

Detectable dichlorvos residues are not expected to occur in animal commodities as a result of the post-harvest use of dichlorvos on cereal grains or from other approved uses. Therefore, the use of dichlorvos is unlikely to unduly prejudice Australian trade in animal commodities.

Environmental assessment

Most of the available studies conducted with dichlorvos are old and many are available only as published literature. Often they did not meet current regulatory standards, or details of the methods used were lacking. However, the available dichlorvos chemistry and fate results were generally similar between comparable reports and consistent with the expected chemical behaviour of the molecule. The available ecotoxicity results were generally comparable with results from other studies provided to the United States Environmental Protection Agency (US EPA), which met their published guidelines.

Dichlorvos is volatile from dry surfaces. A significant proportion of the applied dichlorvos is expected to vaporise and enter the external atmosphere, but it is expected that emissions of dichlorvos to the external atmosphere will dissipate rapidly through dilution, degradation and removal in precipitation and that atmospheric concentrations will remain well below toxic levels. However, it is also readily soluble in water and hence only very slightly to moderately volatile from moist surfaces or water.

Estimates calculated from the physicochemical characteristics of dichlorvos indicate that this chemical has high to very high mobility in soil.

Dichlorvos is likely to dissipate rapidly in most situations where it is exposed to air, soil or water, due to volatilisation, hydrolysis and microbial degradation. Dichlorvos vapours are not expected to persist in air due to degradation and loss by various means. Residues in soil and water are expected to break down to less toxic metabolites due to hydrolysis and degradation by microorganisms. Mineralisation to CO_2, water and salts is expected through microbial activity.

Studies showed that dichlorvos is highly to very highly toxic to birds following a single oral dose and has slight to high toxicity with acute and subacute dietary exposure. Dichlorvos may be toxic to birds by inhalation, absorption through the skin and ingestion through preening of contaminated feathers or consumption of contaminated fruit, foliage or insects. A risk assessment of the use of dichlorvos in avocados indicates that residues of dichlorvos in treated orchards are unlikely to result in toxicity to birds or mammals by dietary exposure. Birds present are also likely to be disturbed by the noise and disruption from spraying, and residues are likely to dissipate rapidly.

Some risk to birds could also arise with fogging or misting of dichlorvos in outdoor situations such as refuse and garbage areas and picnic and recreational areas, but again the presence of people and disruption from spraying operations is likely to deter birds in the vicinity, at least during spraying.

There are reports of birds having been poisoned through consuming grain treated with dichlorvos, drinking water containing dichlorvos, and in one case, through consuming pellets containing dichlorvos deposited in manure.

Concentrations on bulk grain freshly treated with dichlorvos are expected to be well below dietary median lethal doses to birds comparable in magnitude to the No Observed Effect Concentration (NOEC) from various dietary and reproductive studies. Care to clean up spilt grain (e.g. around augers) is, however, indicated.

With acute exposure (24–96 hours), dichlorvos generally exhibits moderate to high toxicity to fish; but it is, in most cases, highly to very highly toxic to aquatic invertebrates (48-hour median effective concentration (EC50) to water fleas as low as 0.066 μg/L (micrograms per litre)). It is only slightly toxic to algae and generally has low toxicity to soil and sewage micro-organisms. Dichlorvos is an insecticide and acaricide used to control a wide range of arthropod pest species with respiratory, contact and stomach action. Therefore it is expected to be toxic to a wide range of terrestrial arthropods coming in contact with the spray, vapours or fresh residues. High toxicity to honey bees and to certain parasitic and predatory species has been observed. Tests indicate that dichlorvos is moderately toxic to earthworms exposed to soil residues.

The risk to aquatic organisms from dichlorvos is based on its use in avocados at an application rate of 500 g ac/ha (grams of active ingredient per hectare) through an airblast sprayer. Direct application to a shallow water body presented an unacceptable risk of harm to aquatic invertebrates and also potentially to fish, and a 10% drift scenario presented an unacceptable risk to aquatic invertebrates, but a mitigable risk to fish. Concentrations in a 15 centimetres (cm) deep water body downwind of a sprayed area were estimated using the AgDRIFT™ model. At 100 meters (m) and 200 m downwind, estimated dichlorvos concentrations exceeded the EC50 for the most sensitive organism (water fleas) by a factor of 7.4 and 3.6, respectively, but were well below toxic levels to fish. Consideration of mitigating factors such as deeper water (30 cm) and dissipation from the contaminated water did not reduce the risk to aquatic invertebrates from spray drift adequately. It is considered that the longer buffer distance that would be needed to protect aquatic organisms from drift would be impracticable. Hence the use of dichlorvos for leaf roller control in avocados will be deleted from product labels.

Dissipation of dichlorvos from leaf and soil surfaces is likely to minimise the risk of aquatic contamination by run-off unless rain follows within a few hours of application. Hence the product label should indicate that the product should not be used if rain is expected within 4 hours.

There is also a potential risk to aquatic organisms from dichlorvos if it reaches water from other uses, for example by drainage following spray application in storage areas or glasshouses and greenhouses.

The use of dichlorvos in field situations (orchards, ornamentals, refuse and garbage areas, recreational and picnic areas) is likely to be toxic to any arthropods exposed, including bees and insect predators and parasites, predominantly in the air and in plant canopies. However, the risk from dichlorvos is expected to be transitory only. Hence labels require a warning that dichlorvos is dangerous to bees and will kill bees and other pollinators foraging in the area sprayed or in hives that are over-sprayed or reached by spray drift.

Very little or no dichlorvos is expected to remain in horse faeces after administration of the worming paste. Any residues would continue to decline rapidly due to hydrolysis and microbial degradation. Hence little or no toxicity is expected to dung beetles or their larvae from residues in horse manure, with (at the most) minor effects on local populations.

Dichlorvos is likely to dissipate rapidly from the soil and foliage surfaces, minimising residues moving into the soil. In the case of application to poultry manure, even if dichlorvos did not dissipate before spreading and incorporation into soil, concentrations would be similarly low. In both cases, the expected maximum soil concentration is well below the 14-day median lethal dose of dichlorvos to the earthworm *Eisenia foetida*. With other uses of dichlorvos the potential for exposure is low, hence little risk pertains to earthworms from non-field use of dichlorvos.

In the few field use situations where dichlorvos is used, application from ground-based equipment is unlikely to lead to direct overspray of non-target vegetation and lower rates from spray drift are unlikely to cause phytotoxicity.

In summary, the overall environmental risk from most uses of dichlorvos products in Australia was expected to be acceptable. It is highly volatile and rapidly dissipates in the environment. Most uses of dichlorvos in Australia involve relatively little risk of exposure of terrestrial and aquatic environments—this pesticide is used to a large extent in non-agricultural production situations, in enclosed areas and in slow-release formulations such as pest-strips. Significant use on crops in the field currently occurs only for the control of leaf rollers on avocados. This use should be deleted from product labels as an impracticably large spray drift buffer would be needed to protect aquatic organisms. Concerns arising from this use also apply, but to a lesser degree, to the application of dichlorvos to outdoor recreational areas.

The overall hazard to birds and bees from the spraying of avocados is low, particularly as dichlorvos rapidly dissipates. Relevant labels should warn of the danger to bees and beehives from direct spray and spray drift. There could be a potential hazard to aquatic organisms resulting from runoff if it rains within a few hours of spraying, or from drainage following surface spray application in situations such as storage areas or glasshouses and greenhouses. Suitable label warnings are recommended to ensure that products are not used if rain is expected within four hours and that drainage water from freshly treated surfaces does not reach aquatic areas before degradation has occurred. However, because of the risk from spray drift, the use on avocadoes should not continue.

All other uses are supported from the environmental viewpoint but labels generally require updating to current standards.

In order to minimise risks to terrestrial and aquatic species from the use of dichlorvos, all labels should be revised to include warnings appropriate to the type of product and uses listed on the label. This particularly applies to products that might be used outdoors or might lead to drainage containing residues reaching the external environment. In addition, the current use on avocados should be deleted.

Public submissions

A submission was received from the Australian stored grain industry in response to the revised PRF report for dichlorvos. This submission emphasised that dichlorvos was an essential chemical for the grains industry, that the industry was heavily reliant on dichlorvos, and that no alternatives to dichlorvos were available. In response, the APVMA explored options to allow the uses essential to the grain industry to continue, which included implementation of measures to mitigate identified OHS risks and generation of worker exposure data.

AMVAC as the active constituent manufacturer, a registrant and the key data provider to the review, also provided a submission to the APVMA. That submission contested the value of the dermal absorption factor used by the OCSEH in its OHS risk assessment. AMVAC pointed out that the value used in arriving at the review findings was significantly higher than the one used internationally.

In light of AMVAC's submission, the APVMA asked OCSEH to review the value of the dermal absorption factor it used in the technical assessments. After considering the submission, the OCSEH re-affirmed the value it used in its assessments. OCSEH consulted with an external expert on the matter before affirming the value.

In summary, the information contained in the submissions received by the APVMA in response to the release of the PRF report did not necessitate any changes to the proposed review findings and regulatory actions.

Final review outcomes

On the basis of the evaluation of the submitted data and information (including protected information), the APVMA has taken the following regulatory action with regard to the continued registrations and approvals of dichlorvos use in Australia:

a) Affirm the approvals of the active constituent listed in Appendix 1.

b) Due to the likelihood of toxicologically unacceptable levels of operator exposure (either during use or re-entry after use), delete the following uses of dichlorvos from product labels:

- surface spray
- space spray
- crack and crevice treatment
- pressurised gas in enclosed spaces where the operator must enter the space under fumigation
- portable fogging or misting equipment in enclosed spaces where the operator must enter the space under fumigation
- watering can application
- paintbrush application

- outdoor and indoor application by fogging or misting
- broadacre application to avocados
- mechanical application to grain.

c) Because of a lack of information on residues (hence an inability to conduct a dietary intake risk assessment), delete the following uses of dichlorvos from product labels:

- application to bagged and stored potatoes
- application in mushroom houses
- application in glasshouses and greenhouses except when used for ornamentals.

d) Because of the likelihood of toxicologically unacceptable exposure, include a restraining statement on the label instructions to disallow the application of dichlorvos in buildings that are likely to be re-occupied within 4 days of fumigation, with the exception of glasshouses and similar plant production facilities.

e) Include in labels instructions a re-entry interval of 4 hours when dichlorvos is used for fumigation of glasshouses and similar plant production facilities.

f) In order to minimise risk to terrestrial and aquatic species from direct spray or spray drift and to reduce other risks to the environment from the use of dichlorvos, include precautionary statements on labels indicating the risks involved in specific uses.

g) Amend product labels to clearly state that dichlorvos is to be used on stored *cereal* grains only, since the risks of human dietary exposure are unknown when dichlorvos is applied to other stored grains such as pulses.

h) For consistency of label instructions across dichlorvos products, amend the product labels (refer Table 1):

Table 1:Dichlorvos product labels to be amended for improved cereal grain instructions

PRODUCT NO.	PRODUCT NAME	SITUATION	CHANGE TO:
55503	BARMAC DICHLORVOS 500 INSECTICIDE	Empty grain silos	<no change required>
53320	CHEMAG DICHLORVOS INSECTICIDE	Empty silos	Empty grain silos
48975	DAVID GRAYS D.D.V.P. 500 INSECTICIDE	Empty grain silos	<no change required>
55352#	GARRARDS DDVP 500 EC INSECTICIDE	Empty silos	Empty grain silos
32939	INSECTIGAS-D DDVP INSECTICIDE	Silos	Empty grain silos

 # Product stopped since the commencement of the review of dichlorvos.

i) If labels are varied to reflect the changes described in b, c, d, e, f, g and h above, then the product registrations and label approvals of the products shown in Appendix 2 can be affirmed.

Interim use and additional data requirements

1. The APVMA will allow for grain fumigation uses to continue during an interim use period by applying strict label restraints and control measures to mitigate OHS risk. The APVMA will allow interim use for a period sufficiently long enough to generate occupational exposure data to establish safe use parameters.

2. Since no information on the actual measured exposures arising from use in the grains industry are available, the OCSEH's advice to the APVMA was based on modelling the 'worst-case' scenario. The APVMA will exercise its data call-in powers (section 33 of the Agvet Codes) and call for worker exposure data in relation to grain protection uses. This will be to investigate the validity of the modelled risk assessment and provide measured exposure data, which, if acceptable in terms of OHS risk, will allow ongoing use of dichlorvos in the grains industry.

Cancellation as a consequence of review findings

A finding of this review was that continued use of or any other dealing with the product Sureguard Pest Strip Household Insecticide (APVMA product code 45596) is likely to have a harmful effect on human beings.

The registration of this product lapsed, effective from 1 July 2007. Normally a two-year sales period is allowed after product registrations lapse. This two-year period has since expired at the time of this review and Sureguard Pest Strip Household Insecticide is no longer registered.

1 INTRODUCTION

Dichlorvos is commonly used for the control of a large variety of insects that infest domestic, public and commercial buildings, recreational areas, abattoirs, wineries (non-food producing areas), animal houses, mushroom growing facilities, glasshouses, greenhouses and food storage areas.

Dichlorvos is widely used in vapour pest strips because of its relatively high volatility compared with other organophosphorus pesticides (vapour pressure 2100 mPa (millipascals) at 25°C compared to 18 mPa for fenitrothion, 12 mPa for diazinon, 2.7 mPa for chlorpyrifos, 0.74 mPa for fenthion and 0.41 mPa for parathion-methyl; for comparison, the vapour pressure of methyl bromide, a fumigant gas, is 227,000,000 mPa).

Because of its volatility, it is also suitable for use as a fog, aerosol or mist for fumigation and disinfestation of machinery and confined areas such as storage areas, warehouses, flour mills, silos, greenhouses and animal housing.

As a part of the reconsideration of dichlorvos products and labels, the APVMA has completed the review of all the available data and information. This document provides a summary of the data evaluated and the subsequent regulatory decisions.

1.1 Regulatory status of dichlorvos in Australia

First described as an impurity of the organophosphorus pesticide trichlofon, dichlorvos was first synthesised in the late 1940s and commercial production began in 1961. The active constituent approvals and product registrations, current as of 1 April 2010, are presented in Appendices 1, 2 and 3. Of these, some are home garden products while others are intended for use by the professional agricultural, pest control or veterinary sectors.

1.2 Reasons for the dichlorvos review

Dichlorvos was nominated for review as part of the APVMA's Chemical Review Program because of its high acute toxicity and concerns about its carcinogenic potential. In December 1996, the APVMA [then the National Registration Authority (NRA)] announced that dichlorvos was one of the seven chemicals selected for reconsideration in the second cycle of the NRA's Existing Chemical Review Program. The chemical was placed under reconsideration, in accordance with Division 4 Part 2 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet codes) because of:

- toxicological concerns and human poisoning
- adverse occupational health effects resulting from sprayed workplaces
- regulatory actions in the USA arising from environmental concerns
- residue violations in cereals and their products.

1.3 Scope of the review

When the extent of the review was scoped, the following were taken into account: the reasons for the nomination of dichlorvos, the information already available on this chemical, and the ways that it is approved for use in Australia.

The basis for a reconsideration of the registration and approvals for a chemical is whether the APVMA is satisfied that the requirements prescribed by the Agvet Codes for continued registration and approval are being met. In the case of dichlorvos, these requirements are that the use of the product in accordance with the instructions for its use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely 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.

The APVMA reviewed the toxicological, OHS, environmental residue and efficacy conditions of registration and approval for dichlorvos.

The APVMA also considered whether product labels carried adequate instructions and warning statements. Such instructions should include information on:

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

In June 2000, the APVMA released the dichlorvos draft review report for public consultation. The draft report, now called the Preliminary Review Findings (PRF) report provided a summary of the data evaluated and the proposed regulatory decisions.

After the publication of that report in 2000, the APVMA became aware of a package of dichlorvos toxicological and exposure studies held by a United States manufacturer. The American and British regulators had assessed those studies. Under the Agvet Codes, the APVMA is obliged to consider all information of which it is aware before making a final decision regarding the future of dichlorvos.

Therefore, the APVMA, exercising its powers under section 159 of the Agvet Codes, obtained those studies through the Australian approval holder of the dichlorvos active constituent. The new data consisted of laboratory animal studies on metabolism, percutaneous absorption, subchronic and chronic toxicity, reproductive and developmental toxicity, genotoxicity, neurotoxicity and forestomach irritation. In addition, a number of human volunteer studies not previously evaluated by Australian authorities were submitted.

The APVMA completed consideration of the new data and information, and published a revised PRF report in June 2008. The new assessments are included in this document as well as in the accompanying technical reports.

1.4 Regulatory options arising from a review

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

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

2 APPROVED DICHLORVOS USE PATTERNS

By far the largest user of dichlorvos is the grains industry. Some 55% of dichlorvos used is expended against pests of stored grain products. Major sectors include on-farm storage and stockfeed merchants. Currently, GrainCorp is the only bulk-handling authority utilising dichlorvos for grain treatment.[2] Dichlorvos is most commonly used as a disinfestant rather than a protectant. It is applied to lightly infested grain as it enters or leaves the storage facility, or to grain that has become infested during storage. In these situations, the most common application method is to use mechanical equipment to apply a coarse spray directly onto grain on the auger or conveyor. Up to 10,000 tonnes of grain can be treated per day. Grain applicator equipment operators often work for up to 12 hours a day, 7 days a week during the harvest period. Mixing times during this period can occupy up to an hour a day. Under normal operating conditions, workers are exposed to the chemical only during mixing and loading of spray tanks (which is done by open pour), as they do not need to be present continuously to supervise spray application.

Dichlorvos may also be applied by hand as a gas or surface spray on storage structures, equipment and machinery to prevent re-infestation of grain entering storage. The New South Wales and Queensland state agricultural authorities recommend the use of dichlorvos in spray programs for structural hygiene. According to the GrainCorp submission, dichlorvos is required for control of insect species that are not easily managed using other products and pest control techniques. Storage infrastructure includes silos, sheds and bunker storage. Silos have a grain storage capacity of 300–10,000 tonnes, and sheds hold 3000–100,000 tonnes. Grain storage bunkers are constructed from low walls (up to 1.8 metres high), placed in parallel on prepared ground. Grain is loaded onto the ground between the walls and tarpaulins are placed over the grain surface and secured to the walls with clamps.

The internal floor areas of silos and walls and floors of sheds and bunkers are treated once per year prior to intake of grain at harvest. Other internal and enclosed areas, including surfaces of under-storage tunnels and elevator pits, may be treated up to three times per year. Under-storage tunnels and elevator pits are not normally accessed by personnel other than for brief periods (usually less than 15 minutes) to check operation of equipment. External surfaces of grain stores may also be treated up to three times per year. Due to improved control of moths through use of grain protectants including phosphine, bulk handling facilities now seldom spray dichlorvos onto the surface of stored grain.[3] However, Clamp and Gazzard (2000) describe the fortnightly use of fogging to fumigate critical areas of a large grain-shipping terminal against psocids, an activity performed at night when the pests are most active and there are few personnel within the plant.

The GrainCorp submission to the APVMA stressed the lack of alternatives to dichlorvos in grain protection, where the chemical is essential in situations where infestations cannot be fumigated because of the age of storage infrastructure. Similarly, dichlorvos is effective in treating machinery, equipment and structures that cannot be fumigated satisfactorily by other chemicals.

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[2] Submission by GrainCorp to the OCSEH, February 2005.

[3] Mr Bill Murray, consultant to grains industry, personal communication.

The second largest use of dichlorvos in Australia is for pest control in industrial, commercial and domestic situations, including non-product areas of abattoirs, warehouses and other storage facilities such as flour mills. Approximately 26% of dichlorvos is used in this role, in which the chemical is considered as pivotal. The New South Wales and Victorian state agricultural authorities have nominated dichlorvos as being important for pest control strategies in these situations. Fogging, misting and aerosol discharge of Insectigas-D are the main methods employed. Almost all flour mills use Insectigas-D as a space and structural treatment of not only the mill itself but also the warehouses, machinery and sometimes infested wheat. The reliance on this use of dichlorvos has increased due to the phasing out of methyl bromide in 2005. The Northern Territory State Chemical Co-ordinator noted that three people had been hospitalised in Katherine after a building was fumigated with dichlorvos by a pest control operator, but further details were not available to the APVMA.

Household vapour strip products account for a further 15% of dichlorvos use. Minor uses of dichlorvos comprise animal housing (1.8%), greenhouses and glasshouses (1.7%), and veterinary applications (0.6%). At the beginning of the review in 1997, the APVMA conducted an assessment of how dichlorvos was used. According to that assessment, the principal use in greenhouses and glasshouses is for control of thrips on ornamentals, with dichlorvos recommended as part of a resistance management strategy by the New South Wales Department of Agriculture. There are further limited uses on a range of crops including tomatoes, cucumbers, and capsicums. Dichlorvos is also used to fumigate vegetable seedlings and cut flowers prior to export. One survey respondent described use of Insectigas-D in a chamber or enclosed fumigant bed at 64 mg dichlorvos/m^3 with pyrethrin at 5.2 mg/m^3. Dichlorvos is also used under permit in fruit fly traps in conjunction with pheromone lures for monitoring programs in South Australia, Queensland and Victoria.

Dichlorvos aerosols are considered essential for integrated pest management in mushroom cultivation. Mushroom growers use dichlorvos for control of small flies and midges, usually during the spawning phase of production, when inoculated compost is held within purpose-built rooms under a controlled atmosphere. Dichlorvos cylinders or fogging equipment are located outside the rooms and the chemical is introduced through the walls to eliminate any adult flies that have gained entry while the spawning rooms are being filled. Spawning rooms remain sealed for 10 days after being treated. If dichlorvos has to be applied during the growing or picking phases of production, which take place in different rooms, the growing rooms are left overnight and ventilated before re-entry. However, pyrethrins are the preferred option for use in growing rooms. One grower indicated that dichlorvos can also be applied at the end of cropping, with re-entry occurring at least 15 hours post-treatment and after at least 12 hours ventilation. Each holding has two to three growing rooms, with a total of 800-1200 m^2 growing surface. The grower indicated that he used only 5–10 litres of 500 g/L EC product annually. The APVMA observed that Insectigas-D (see Appendix 2 for details of Insectigas-D) is used by the mushroom industry even though the product label does not contain directions for use in mushroom production.

Foliar spray treatment of avocados to control leaf roller is the only direct crop use identified for dichlorvos. This use is minor and only 500 g/L EC formulations are employed. The APVMA has been advised that leaf roller is a significant but sporadic pest of avocados, with growers needing to treat it only once every two to three seasons, usually with a single application of dichlorvos in a tank mixer with chlorpyrifos. Dichlorvos is used for its action as a fumigant, flushing out the pest, while chlorpyrifos is used as the control agent. To ensure optimal fumigant activity, spraying is conducted on warm days.

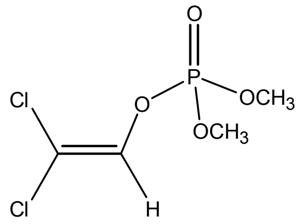
According to the New South Wales Department of Agriculture, dichlorvos has been part of a resistance management strategy for fly control in poultry houses, but its use in this situation is expected to decrease because of pest resistance. Although significant quantities of dichlorvos have been used in the past for protection of potatoes against tuber moths, chemical usage in this situation is declining due to improved management practices. Therefore, the APVMA concluded that there probably was little future need for dichlorvos to be used for control of tuber moths.

3 ACTIVE CONSTITUENT ASSESSMENT

3.1 Identity and properties

Dichlorvos is a volatile organophosphorus insecticide with fumigant and penetrant action. It has been commercially manufactured and used through out the world since 1961 and in Australia since the 1960s. Dichlorvos kills insects by interference with an enzyme (cholinesterase) in the nervous system, resulting in muscle paralysis. Its basic chemical identity is as indicated below.

Common name:	Dichlorvos
CAS Registry number:	[62-73-7]
Molecular formula:	$C_4H_7Cl_2O_4P$
Molecular weight:	221 g/mole



Technical grade dichlorvos is a colourless to light-yellow liquid. It has a relatively high vapour pressure (1.6 Pa at 20°C) which is consistent with its use as a fumigant. The octanol/water partition coefficient (log K_{ow}) is comparatively low at 1.5, indicating that dichlorvos is soluble in water and is not likely to accumulate in fat. The electrophilic phosphorus atom renders dichlorvos susceptible to attack: the molecule is easily destroyed by oxidising agents and moisture. Dichlorvos is reasonably stable in the absence of moisture and oxidising agents. It is corrosive to iron and mild steel.

3.2 Composition of dichlorvos active constituent

The APVMA has considered the production aspects of dichlorvos for the purposes of approval of the technical material. These aspects include the manufacturing process, quality control procedures, batch analysis results and analytical methods. The Minimum Compositional Standard for the technical purity of dichlorvos is 970 g/kg. Specifications for the impurities chloral and water are at a maximum concentration of 5 g/kg and 0.5 g/kg, respectively. This is consistent with the specifications of the Food and Agriculture Organization of the United Nations. Chloral is the synthetic starting material and is of less toxicological concern than the active. Water present at high concentrations can degrade dichlorvos, as indicated above.

Analytical methods are available for the determination of dichlorvos in technical material and formulations.

4 SUMMARY OF DATA ASSESSMENTS

4.1 Toxicology

The toxicological database for dichlorvos is extensive and consists of unpublished reports generated by industry, in addition to a range of published studies. There were no studies conducted on any products registered in Australia.

4.1.1 Mechanism of mammalian toxicity

In common with all organophosphorus compounds, the primary mode of action of dichlorvos is via the inhibition of acetylcholinesterase, which causes over-stimulation of those parts of the nervous system that use acetylcholine to transmit nerve impulses. Signs of intoxication are consistent with acetylcholinesterase inhibition and include salivation, lachrymation, vomiting, diarrhoea and laboured breathing. If intoxication is severe, muscle twitching, loss of reflexes, convulsions and death can eventuate. The onset of these signs and subsequent recovery from non-lethal doses is relatively rapid; the time to peak effect in rats following oral dosing is 15–60 minutes (Tyl et al. 990a; Lamb 1992; Lamb 1993b), with recovery occurring by 24 hours (Durham et al. 1957; Lamb 1992).

4.1.2 Metabolism and toxicokinetics

Dichlorvos is absorbed via all exposure routes and does not require activation to inhibit acetylcholinesterase. Dichlorvos is immediately inactivated in the liver, which has important implications for the consideration of its carcinogenic potential. Various studies have shown little interspecies variation in the metabolism, distribution and excretion of dichlorvos, which also appear to be independent of the dose route or sex of the animal (Hutson and Hoadly 1972a,b; Blair et al. 1975; Cheng 1989, 1990).

Dichlorvos is deactivated either by ester hydrolysis to yield dimethyl phosphate and dichloroacetaldehyde or by oxidative O-demethylation. Hydrolysis of the O-demethylated metabolite yields methyl phosphate and eventually phosphoric acid and methanol. The hydrolytic pathway is generally the predominant metabolic pathway, with the oxygen-vinyl bond split to generate dimethyl phosphate and DHA. The latter is further metabolised to dichloroethanol or possibly dichloroacetic acid, and eventually to dichloroethanol glucuronide, hippuric acid, urea and CO_2. As mentioned, dichlorvos is rapidly metabolised *in vivo*, with no parent compound detected in any laboratory animal studies.

The metabolism of dichlorvos in humans appears to be consistent with that of other mammals. There is no evidence that dichlorvos or its metabolites accumulate in tissues.

4.1.3 Percutaneous absorption

The extent of percutaneous absorption in rats was 22–30% when dichlorvos was applied to 12 cm^2 of skin at 3.6, 36 or 360 μg in a total volume of 100 μL (equal to 0.3, 3 or 30 $\mu g/cm^2$) (Jeffcoat 1990). Absorption occurred within the first 10 hours of exposure, and a substantial proportion (38–55%) of dichlorvos was found to evaporate from the skin surface following application. In the absence of such evaporation, it is plausible that close to 100% of the applied dose would have been absorbed. However, this scenario is unlikely under actual use conditions.

The concentration range tested in this study of 0.0036–0.36% is an accurate reflection of the working concentration of the eight emulsifiable concentrate products currently registered for use (0.1–1%). Therefore, the above level of percutaneous absorption is considered a reliable figure for use in the OHS assessment for dichlorvos.

4.1.4 Acute toxicity

Dichlorvos has high acute toxicity in experimental animals. Clinical signs of toxicity occur soon after dosing and are typical of organophosphorus poisoning (exophthalmus, salivation, lachrymation, tremors, dyspnoea, convulsions and death). Survivors recover completely within 24 hours (Durham et al. 1957; Lamb 1992). The time to peak effect in rats following oral dosing is 15–60 minutes (Tyl et al. 1990a; Lamb 1992; Lamb 1993b).

Dichlorvos was a slight skin irritant and a moderate eye irritant in rabbits (Pauluhn 1985) and a skin sensitiser in humans (patch-test) and guinea pigs (maximisation test) (Ueda 1994).

4.1.5 Repeat-dose toxicity

Dose-related inhibition of plasma, RBC and brain ChE activities was the most common manifestation of dichlorvos toxicity in short-term, subchronic and chronic studies in mice, rats and dogs. Cholinergic signs and occasional mortalities occurred in rats and dogs at the same doses as the inhibition of brain ChE activity. Plasma and RBC ChE activities were also inhibited following chronic inhalational exposure in rats (LOEC = 0.5 mg/m^3; Blair et al. 1974, 1976).

There was little indication that repeated oral or inhalational exposure had any effect on haematology, clinical chemistry or urinary parameters, or on organ weights or gross pathology. In some rat and dog studies, histopathology revealed cytoplasmic vacuolisation of the liver (Jolley et al. 1967; Witherup et al. 1967; Chan 1989).

4.1.6 Genotoxicity

Numerous *in vitro* and *in vivo* experiments have tested the genotoxic potential of dichlorvos, with the majority of data published in the open scientific literature. In the current review, seven unpublished genotoxicity studies were evaluated, which showed that dichlorvos was genotoxic *in vitro* but not *in vivo*. These findings are consistent with the extensive genotoxicity database for dichlorvos.

The extensive genotoxicity database indicates that in the absence of metabolism, dichlorvos is mutagenic and clastogenic at the point of contact, where unchanged dichlorvos may be in direct contact with tissue. There is no evidence that dichlorvos has any systemic genotoxic potential. Scenarios of prolonged exposure in the absence of metabolic activity are unlikely in the general population given the current patterns of use. Chronic inhalational exposure (the most likely exposure route in humans) failed to cause tumours (Blair et al. 1974) or to methylate nucleic acids in rats (Wooder et al. 1976). The failure of dichlorvos to methylate DNA or RNA *in vivo* has been attributed to its phosphorylating reactivity, leading to highly efficient biotransformation (Wright et al. 1979). Furthermore, the consistently negative *in vivo* genotoxicity findings consequent to rapid metabolism indicate that dichlorvos is unlikely to pose a genotoxic risk to humans.

4.1.7 Carcinogenicity

The carcinogenic potential of dichlorvos has received considerable attention in previous human health risk assessments undertaken by various countries and international agencies, including Australia.

Successive Australian health advisory committees have independently examined the carcinogenic and genotoxic potential of dichlorvos on several occasions. These previous risk assessments have concluded that dichlorvos is unlikely to pose a carcinogenic risk to humans.

While the majority of laboratory animal studies conducted in mice and rats have been negative (Witherup et al. 1967; Blair et al.1974; Enomoto 1981; Konishi et al. 1981; Horn et al. 1987; Horn et al. 1990), studies performed by the National Cancer Institute (1977) and the National Toxicology Program (Chan 1989) reported forestomach tumours in mice and a variety of tumours in rats. Historically, it is the results of these studies, in addition to positive *in vitro* genotoxicity findings, that have contributed to concern over the possible carcinogenic risk to humans from dichlorvos exposure.

Studies by Benford (1991, 1992) showed that dichlorvos was irritating to the forestomach of mice following a single oral gavage dose, causing oedema, epithelial cell hypertrophy and hyperplasia, but not unscheduled DNA synthesis (a genotoxic endpoint). These irritant effects were similar though less severe to those caused by butylated hydroxyanisole (antioxidant in human food), a non-genotoxic promoter of forestomach tumours in mice.

Dichlorvos is considered to have a localised irritant effect on the mouse forestomach following gavage dosing, leading to hyperplasia and possible tumour formation. The role of the mouse forestomach as a storage organ means that dichlorvos would be in prolonged contact with the epithelium thereby increasing the possibility of irritation. As there is no analogous structure in humans, such conditions of prolonged exposure to high concentrations of unchanged dichlorvos are unlikely and therefore the forestomach findings in mice are not considered relevant for human risk assessment.

The evidence of carcinogenicity in rats following long-term oral dosing is equivocal. The main potential exposure of the general population is by inhaling low concentrations of dichlorvos vapour when used indoors. A long-term inhalational study in rats (Blair et al. 1974, 1976), which simulated the most relevant exposure route in humans, showed no evidence of carcinogenicity. In addition, related compounds that are metabolised to dichlorvos *in vivo* showed no carcinogenic potential. On the weight-of-evidence, dichlorvos is not considered to pose a carcinogenic risk to humans.

4.1.8 Reproductive and developmental toxicity

Dichlorvos affected reproduction at maternotoxic doses in rats following administration for two generations via the drinking water (Tyl et al. 1992, 1993). However, as the NOEL for reproduction and pup toxicity is well above the NOEL for parental toxicity (2 mg/kg bw/day *versus* 0.5 mg/kg bw/day), dichlorvos is not considered to pose a reproductive hazard to humans.

There was no evidence that dichlorvos was teratogenic based on a range of studies conducted in mice, rats and rabbits following oral or inhalational exposure (Schwetz et al. 1979; Thorpe et al. 1971; Tyl 1990a, b).

4.1.9 Neurotoxicity

Dichlorvos is acutely neurotoxic in chickens and rats by virtue of its ability to inhibit brain ChE activity (Beavers 1988; Lamb 1993a). This is typified by the occurrence of cholinergic signs and abnormal FOB (rats) following single or repeated oral dosing. There was no evidence that dichlorvos causes delayed neuropathy (Beavers 1988; Redgrave et al. 1994a, b; Redgrave and Mansell 1994; Jortner 1994; Hardisty 1998; Lamb 1993b).

4.1.10 Toxicity to humans

As for other mammals, the inhibition of plasma ChE activity is the most sensitive toxicological endpoint in humans following repeated exposure [the NOEL following repeated oral dosing is 0.014 mg/kg bw/day (Rider 1967)]. For acute or short-term exposures, the inhibition of RBC AChE activity in Australia is taken as the relevant endpoint for establishing an ARfD [the NOEL following a single oral dose is 1 mg/kg bw/day (Gledhill 1996, 1997a; Morris 1996a)].

Inhalational exposure to dichlorvos is considered the main exposure pathway in humans based on its current use patterns. A number of studies on overseas dichlorvos products have investigated the inhalational exposure of humans in residential and public premises under normal or exaggerated use conditions. Inhalational exposure to dichlorvos resin strips installed according to the recommended directions for use did not result in the inhibition of plasma or RBC ChE activities (Zavon and Kindel 1966; Ueda and Nishimura 1967; Leary et al. 1974). In contrast, exaggerated exposure (10 or 17 strips per room) caused the inhibition of plasma ChE activity in adult males (RBC ChE activity was not inhibited in the 10-strip study, while no RBC ChE data were presented for the use of 17 strips; Ueda and Nishimura 1967). Air levels of dichlorvos in this study were up to 2.2 and 7.1 mg/m^3, respectively. Newborn babies exposed to air levels of 0.095–0.25 mg/m^3 for 18 hours/day showed no effects on plasma or RBC ChE activities (Cavagna et al. 1970). Two studies by Hunter (1970a, b) examined the effect of dichlorvos vapour on laboratory staff following exposure for up to 7.5 hours. There was no treatment related effect on RBC ChE activity, while plasma ChE was inhibited (≥20%) at and above approximately 580 mg $minutes/m^3$. Examination of the effects of inhalation exposure from Australian dichlorvos products is discussed in Section 4.4.

Few studies have examined the dermal toxicity of dichlorvos in humans. Repeated dermal exposure to resin strips for five days failed to perturb plasma or RBC ChE activities (Zavon and Kindel 1966). Plasma ChE was reportedly inhibited in two commercial pesticide applicators following the spraying of up to 20 residences (Gold and Holcslaw 1984). In this study, the level of dermal exposure was estimated to be 0.499 $\mu g/cm^2/hour$ (total dermal exposure of 0.028 mg/kg bw/hour).

4.2 Human exposure to dichlorvos

In Australia, sources of potential public exposure to dichlorvos include residues in food and drinking water (oral exposure) and residential exposure (inhalational exposure).

Dichlorvos is applied as a spray to food commodities such as stored grain and potatoes, to vegetables grown in green houses (e.g. tomatoes and cucumbers) and as a fog to mushrooms grown in mushroom houses. Label directions also state that it can be used in combination with chlorpyrifos on avocadoes. Besides these ‘direct’ food applications, dichlorvos is also used to treat a number of commercial food preparation or storage areas, which could potentially contribute to total food residues. These include dairy cattle sheds, stables, piggeries, abattoirs and meat works, wineries, food warehouses, mills and empty grain silos.

Neither the 19th nor the 20th Australian Total Diet Surveys (ATDS) (2002 and 2003, respectively) performed under the auspices of Food Standards Australia New Zealand (FSANZ), detected dichlorvos in any of the foods surveyed. Therefore, the dietary exposure for the population (including infants, children and adults) was estimated by FSANZ to be zero as the concentration of dichlorvos was less than the limit of detection.

Based on its current pattern of use, exposure of the general population to dichlorvos residues in drinking water is considered to be negligible.

At the beginning of the review of dichlorvos, there were two strengths of impregnated resin strips available for domestic use, containing either 186 or 328 g/kg dichlorvos. As of 1 April 2010, the 186 g/kg product is the only registered product. These strips are used predominantly in confined storage areas, such as in drawers and wardrobes, with only one product used to treat entire rooms. These types of home garden products are unlikely to pose an oral or dermal hazard due because the resin strips are encased in a plastic or cardboard housing and because the products are not recommended for use in food preparation or storage areas. However, due to the volatile nature of the chemical, the strips could pose inhalational hazard.

The public health risk assessment for domestic uses of dichlorvos is presented in Section 4.4.

Due to its volatility, dichlorvos is suitable for use as a fog, aerosol or mist for fumigation and disinfestation of machinery and confined areas, such as storage areas, warehouses, flour mills, silos, greenhouses and animal housing. Other applications for dichlorvos include crop protection and pest control in domestic, commercial and industrial areas. Dichlorvos also has limited veterinary use as an oral paste for horses.

The dichlorvos products used by professional agricultural, pest control or veterinary sectors can cause occupational exposure. The most likely potential routes of exposure would be by dermal contact with the undiluted products or spray mixture, and by inhalation of dichlorvos vapour or aerosols.

The use of dichlorvos within domestic residences, stores, other commercial premises and enclosed structures used for grain storage and plant or mushroom production can lead to exposure of the occupants to dichlorvos.

The OHS risks are assessed in Section 4.5, and the dietary risk arising from consumption of food treated with dichlorvos is assessed in Section 4.6.

4.3 Dose levels relevant for risk assessment

4.3.1 Dose levels relevant for the risk assessment of domestic use

To perform a residential inhalational risk assessment, suitable NOECs from laboratory animal or human inhalational studies are compared with the average air level of dichlorvos. The acceptable margin of exposure (MOE) is $\geq$10 for a NOEC based on human data (resulting from the application of a 10-fold uncertainty factor for intra-species variability) and $\geq$100 for a NOEC based on laboratory animal data (resulting from the application of a 10-fold intra- and 10-fold interspecies uncertainty factors).

As mentioned previously, the inhibition of plasma ChE activity is the most sensitive toxicological endpoint in humans following repeated exposure, and as such, was used as the basis for the inhalational exposure assessment. There are two inhalational studies in the toxicological database for dichlorvos that are considered appropriate for the establishment of a repeat-dose inhalational NOEC. The five-day study by Cavagna et al. (1970) established a NOEC of approximately 0.15 mg/m^3 in new-born babies, based on the absence of plasma and RBC ChE inhibition at and below this concentration. The two-year rat study by Blair et al. (1974) established a NOEC of 0.05 mg/m^3, based on the inhibition of plasma and RBC ChE activities at 0.5 mg/m^3.

In the absence of a suitable inhalational study or a NOEC, a NOEL from an oral dosing study can be converted to an inhalational NOEL following correction for inhalational absorption (route-to-route extrapolation). The average air level can then be used to derive an inhaled dose (mg/kg bw/d) and compared to this inhalational NOEL.

Therefore, an alternative approach to the use of the above NOECs inhalation studies is to use route-to-route extrapolation from oral dosing studies (inhalational to oral dose extrapolation). The most suitable study for this approach is the 28-day oral dosing study of Rider (1967), in which the NOEL was 0.014 mg/kg bw/d. The study was considered suitable because it demonstrated a NOEL and a LOEL for plasma ChE inhibition and was performed with human subjects, thereby eliminating uncertainty associated with inter-species extrapolation. Adjusting for the inhalation absorption factor of 70%,[4] the resulting inhalational NOEL becomes 0.02 mg/kg bw/d.

4.3.2 Dose levels relevant for occupational health and safety (OHS) assessment

NOEL for dermal risk assessment

Short-term repeat-dose toxicity studies of up to 28 days duration are considered to be the most appropriate for derivation of NOELs for OHS assessment of product users who are exposed repeatedly. Although repeat-dose studies via the dermal route would be optimal for derivation of OHS NOELs, no such studies with dichlorvos are available. Therefore, the assessment was performed using studies undertaken by oral administration. A summary of NOELs determined in oral studies considered adequate for regulatory purposes is shown in the following table:

Table 2: Dichlorvos: Summary of oral NOELs relevant for OHS assessment

SPECIES	NOEL (mg/kg bw/d)	LOEL (mg/kg bw/d)	TOXICOLOGICAL ENDPOINT	REFERENCE
Acute Studies				
Rat po gavage	0.1	0.5	Clinical signs (exophthalmus, absent hind limb and reduced forelimb grasp) within 15–45 minutes of dosing	Lamb (1992) [GLP]
DEVELOPMENTAL STUDIES				
Rat po gavage	3.0	21.0	Dams: cholinergic signs (within 10–60 minutes of dosing) and reduced food consumption	Tyl et al. (1990a) [QA, GLP]
	21.0	–	Foetuses: no toxicity	
	21.0	–	Developmental toxicity: none	
Rabbit	0.1	7.0	Dams: mortalities	Tyl et al. (1990b)

[4] A study (Kirkland, 1971) evaluated by the WHO (1988) demonstrated that at dichlorvos concentrations of 0.1–2.0 mg/m^3, pigs retained 15–70% of the inhaled dichlorvos. Therefore, a 70% inhalation absorption factor was used for risk assessment purposes.

SPECIES	NOEL (mg/kg bw/d)	LOEL (mg/kg bw/d)	TOXICOLOGICAL ENDPOINT	REFERENCE
po gavage	7.0	–	Foetuses: no toxicity	[QA, GLP]
	7.0	–	Developmental toxicity: none	
ACUTE NEUROTOXICITY STUDIES				
Rat po gavage	0.5	35	Clinical signs of neurotoxicity	Lamb (1993a) [QA, GLP]
HUMAN STUDIES				
Single-dose, po gelatine capsules	1	–	Inhibition of RBC ChE activity	Gledhill (1996), Morris (1996a), Gledhill (1997a) [QA, GLP]
21-d po, gelatine capsules	–	0.1	Inhibition of RBC ChE activity	Gledhill (1997b,c) Morris (1996b) [QA, GLP]
28-d po, gelatine capsules	0.014	0.021	Inhibition of plasma ChE activity	Rider (1967)
	0.036	–	Inhibition of RBC ChE activity	

QA = quality assured study; GLP = statement of compliance with principles of good laboratory practice

It is considered that the most suitable endpoint for estimation of occupational risks for dermal exposures is an oral NOEL of 0.014 mg/kg bw/d, established in the 28-day oral study in humans by Rider (1967). The study is highly suitable because it demonstrated a NOEL and a LOEL for plasma ChE inhibition and was performed with human subjects, thereby eliminating the uncertainty associated with inter-species extrapolation. Adjusting for a dermal absorption factor of 30%, the resulting dermal NOEL becomes 0.047 mg/kg bw/d. The acceptable margin of exposure (MOE) is ≥10, resulting from application of a 10-fold uncertainty factor for intra-species variability. No correction for an internal dose is required since absorption from the gastro-intestinal tract is almost complete (93–96%).

NOEL for inhalational risk assessment

Due to the volatile nature of dichlorvos, there is significant potential for product users to be exposed via inhalation, especially during spray application. For product users, the frequency of inhalation exposure in an occupational setting would be the same as for dermal exposure, as discussed above. Persons exposed occupationally in treated buildings are likely to be exposed by inhalation repeatedly on successive days.

Several short-term studies have been undertaken in which ChE activity was measured in humans exposed to dichlorvos by inhalation. However, their usefulness is limited by uncertainty concerning the NOECs and the airborne concentrations of dichlorvos to which the subjects were exposed. Therefore, it was necessary to perform the assessment using studies carried out by oral administration. The most suitable study for estimation of occupational risks is that of Rider (1967), in which the NOEL was 0.014 mg/kg bw/d. Adjusting for the inhalation absorption factor of 70%, the resulting NOEL becomes 0.02 mg/kg bw/d. This value was used for risk assessment of professional users during application and on re-entry into treated areas. The acceptable margin of inhalation exposure (MOE) is ≥10, resulting from application of a 10-fold uncertainty factor for intra-species variability.

4.3.3 Dose levels relevant for health and safety assessment of building occupants

Studies by Durham et al. (1959), Gold and Holcslaw (1984) and Schofield (1993a,b) have demonstrated that dichlorvos persists within the atmosphere for up to 14 days after a single application in industrial or domestic environments, even when ventilated. Indeed, McDonald (1991) detected airborne dichlorvos in a hotel room treated by aerosol fogging a month previously. Hence, irrespective of whether a building is treated once or repeatedly, its occupants are likely to be exposed for several successive days. This precludes use of a NOEL derived from a single-dose (acute) study for risk assessment of persons re-entering treated premises.

Therefore, it is necessary to use the same pivotal NOEL adopted for risk assessment of persons applying dichlorvos: 0.014 mg/kg bw/d, established in the 28-day oral study in humans by Rider (1967). Adjusting for a dermal absorption factor of 30%, the resulting dermal NOEL becomes 0.047 mg/kg bw/d. Adjusting for the inhalation absorption factor of 70%, the resulting inhalation NOEL becomes 0.02 mg/kg bw/d. The acceptable margin of dermal and inhalation exposure (MOE) is $\geq$10, resulting from application of a 10-fold uncertainty factor for intra-species variability.

To ensure that the MOE for building occupants does not fall below 10, the maximum time-weighted average concentration of dichlorvos in the workplace atmosphere should be 0.02 mg/m^3. This value is derived on the assumption of 8 hours of exposure/day, an inhalation rate of 1 m^3/h, 70% absorption of inhaled dichlorvos and 70 kg bw.

4.3.4 Dose levels relevant for dietary risk assessment

To identify the lowest NOELs for the establishment of an ADI and ARfD, a summary of the NOELs determined in those studies considered adequate for regulatory purposes are shown in Tables 3a and 3b.

Table 3a: Studies relevant for the establishment of an ADI

SPECIES	NOEL (mg/kg bw/d)	LOEL (mg/kg bw/d)	TOXICOLOGICAL ENDPOINT	REFERENCE
SUBCHRONIC STUDIES				
Rats 13-week po gavage	0.1	1.5	Inhibition of plasma and RBC ChE activities	Kleeman (1988) [QA, GLP]
Dogs 90-day po, gelatine capsules	0.3	0.9	Inhibition of plasma and RBC ChE activities	Hine (1962)
CHRONIC STUDIES				
Rats 2-year dietary	0.23	2.3	Inhibition of plasma and RBC ChE activities	Witherup et al. (1967)
Dogs 2-year dietary	0.008	0.08	Inhibition of RBC ChE activity in males	Jolley et al. (1967)

SPECIES	NOEL (mg/kg bw/d)	LOEL (mg/kg bw/d)	TOXICOLOGICAL ENDPOINT	REFERENCE
Dogs 52-week po, gelatine capsules	0.05	1.0	Inhibition of plasma and RBC ChE activities	Markiewicz (1990) [GLP]
REPRODUCTION STUDIES				
Rats 2-generation	0.5	2	Parental toxicity: inhibition of plasma, RBC and brain ChE activities	Tyl et al. (1992 and 1993)
	2	8	Pup toxicity: decreased bw	
	2	8	Reproductive toxicity: reduced fertility and pregnancy indices, increased stillbirths (F2), reduced cycling and increased abnormal cycling (F1 maternal rats)	
NEUROTOXICITY STUDIES				
Rats 13-week, po gavage	0.1	7.5	Inhibition of plasma and RBC ChE activities, and cholinergic signs	Lamb (1993b)
HUMAN STUDIES				
28-day po, gelatine capsules	0.014	0.021	Inhibition of plasma ChE activity	Rider (1967)
21-day po, gelatine capsules	–	0.1	Inhibition of RBC ChE activity	Gledhill (1997b,c) Morris (1996b) [QA, GLP]

QA = quality assured study; GLP = statement of compliance with principles of good laboratory practice; po = oral

Table 3b: Studies relevant for the establishment of an ARfD

SPECIES	NOEL (mg/kg bw/d)	LOEL (mg/kg bw/d)	TOXICOLOGICAL ENDPOINT	REFERENCE
ACUTE STUDIES				
Rat po gavage	0.1	0.5	Clinical signs (exophthalmus, absent hind limb grasp, reduced forelimb grasp). Other signs observed at higher doses (10–80 mg/kg bw) and occurring within 15–45 minutes of dosing	Lamb (1992) [GLP]
DEVELOPMENTAL STUDIES				
Rat po gavage	3.0	21.0	Maternal rats: cholinergic signs (within 10–60 minutes of dosing) and reduced food consumption	Tyl et al. (1990a) [QA, GLP]

SPECIES	NOEL (mg/kg bw/d)	LOEL (mg/kg bw/d)	TOXICOLOGICAL ENDPOINT	REFERENCE
	21.0	-	Foetuses: no toxicity	
	21.0	-	Developmental toxicity: none	
Rabbit po gavage	0.1	7.0	Dams: mortalities	Tyl et al. (1990b) [QA, GLP]
	7.0	-	Foetuses: no toxicity	
	7.0	-	Developmental toxicity: none	
NEUROTOXICITY STUDIES				
Rat Acute, po gavage	0.5	35	Clinical signs of neurotoxicity in the FOB	Lamb (1993a) [QA, GLP]
HUMAN STUDIES				
Single-dose, po Gelatine capsules	1	-	Inhibition of RBC ChE activity	Gledhill (1996), Morris (1996a), Gledhill (1997a) [QA, GLP]

QA = quality assured study; GLP = statement of compliance with principles of good laboratory practice

4.4 Risks from domestic uses of dichlorvos

4.4.1 Characteristics of dichlorvos pest strips

The only dichlorvos products available for home garden use are impregnated resin strips used indoors to control insects in confined spaces or rooms, and naphthalene and dichlorvos blocks for use in outdoor garbage bins. The characteristics of the strips are summarised in Table 4. While there are differences in the concentration, size and application rate (number of strips/m^3) between the five strips, the amount of dichlorvos applied per cubic metre of space is similar.

Exposure via the use of the naphthalene and dichlorvos blocks is considered negligible because they are used outdoors only. Therefore the main potential residential exposure of the general population is by inhaling dichlorvos vapour from impregnated resin strips. On theoretical grounds, there is a slight potential for dermal exposure to dichlorvos vapour. However, given that the likely air concentration of dichlorvos would be low and the duration of exposure short, dermal absorption of dichlorvos vapour is not considered to pose a significant risk to residents.

Table 4: Characteristics of dichlorvos pest strips

PRODUCT	DICHLORVOS	NET STRIP WEIGHT	DICHLORVOS PER STRIP	APPLICATION RATE	TOTAL AMOUNT DICHLORVOS (g) PER m^3 SPACE*
Mortein Moth and Insect Strips#	328 g/kg	5 g	1.64 g	1 strip/m^3	1.64
Mortein Moth Guard for Wardrobes and Drawers#	328 g/kg	5 g	1.64 g	1 strip/m^3	1.64

PRODUCT	DICHLORVOS	NET STRIP WEIGHT	DICHLORVOS PER STRIP	APPLICATION RATE	TOTAL AMOUNT DICHLORVOS (g) PER m^3 SPACE*
Sureguard Pest Strip#	186 g/kg	103	19.2 g	1 strip/30 m^3 (room)	0.64
Sureguard MiniStrip#	186 g/kg	20 g	3.72 g	1 strip/3 m^3	1.24
Scuttle Bug Pest Strip#	186 g/kg	20 g	3.72 g	1 strip/3 m^3	1.24
Killmaster Zero Pest Strip	186 g/kg	65 g	12.09 g	1 strip/10 m^3	1.21

** either cupboard, drawer, wardrobe or room space, apart from the most recently registered product, Killmaster Zero Pest Strip. Killmaster Zero Pest Strip is not for use in confined spaces, such as cupboards and drawers, but for use in store rooms, storage spaces and other non-living areas.*

 # Products have been stopped or withdrawn since the commencement of the review of dichlorvos.

At the beginning of the review of dichlorvos, home gardens uses had access to two strengths of impregnated resin strips that which contain either 186 or 328 g dichlorvos/kg (see table above). As of 1 April 2010, the 186 g/kg product was the only registered product. These strips are used predominantly in confined storage areas, such as in drawers and wardrobes, with only one product used to treat entire rooms. These types of home garden products are unlikely to pose an oral or dermal hazard due to the encasement of the resin strip within a plastic or cardboard housing and because they are not recommended for use in food preparation or storage areas.

There was a limited amount of data on the levels of dichlorvos released from pest strips marketed in Australia. Therefore, surrogate data were obtained from various published and unpublished studies conducted using 20% (200 g/kg) room strips or vaporisers. These surrogate data are only relevant to a single Australian product, namely Sureguard Pest Strip, which is used for insect control in entire rooms. The majority of other resin strip products are available as ‘mini-strips’ and used in confined areas such as wardrobes, bookcases, linen cupboards, under sinks and in toilets.

The data summarised in the table below and the subsequent exposure calculations are not necessarily relevant for the ministrip products, which have a different use pattern; it is unlikely that persons would be continuously exposed to dichlorvos at the levels seen with the room strips. However, based on evidence indicating that a lack of ventilation (i.e. containment) results in relatively high levels of dichlorvos (Shell Chemicals 1965; Elgar and Mathews 1968), the concentration of dichlorvos within the confined space is likely to be relatively high. This could pose an acute risk, for example, every time someone opened a wardrobe or drawer or used the toilet. In the absence of data on the air levels generated from the use of dichlorvos ministrips, the probability and risk of such exposures cannot be ascertained.

Table 5 summarises various published and unpublished studies, which measured dichlorvos air levels generated by the use of the 20% room strips or vaporisers. There was no information available on the formulations of these products.

Table 5: Air levels of dichlorvos generated from the use of 20% pest strips

SAMPLE	CONDITIONS	AIR LEVELS (mg/m^3)	REFERENCE
20% vapona insecticide resin strips	1 strip/28.32 m^3 Closed, air conditioned hotel room with no air exchange 23°C, 55% RH	0.43 (4 h), 0.44 (8h), 0.34 (12 h), 0.34 (1 d), 0.36 (2 d), 0.30 (3 d), 0.25 (6 d), 0.09 (8 d), 0.16 (10 d), 0.12 (14 d), 0.13 (29 d), 0.09 (30 d); mean = 0.23	Shell Chemicals (1965)
Vapona resin vaporiser (20% dichlorvos)	1 vaporiser/144 m^3 1 vaporise/227 m^3 Installed over 6 months. Replaced monthly for 4 months	0.097 residence 1 0.087 residence 2 Detected 1 month after installation of last vaporiser	Zavon and Kindel (1966)[1]
Vapona strips (details unspecified)	1 strip/20.39 m^3 No ventilation (~1 air change per hour)	22°C/40% RH; max = 0.57 (d 2) min = 0.06–0.07 (d 72–84) 20°C/79% RH; max = 0.26–0.30 (d 1–10) min 0.05–0.07 (d 53–87) 34°C/46% RH; max = 1.10 (d 1) min 0.01–0.02 (d 76–90) 34°C/80% RH; max = 0.74 (d 2) min = 0.01–0.02 (d 36–43)	Elgar and Mathews (1968)
6.5 inch Vapona strip (details unspecified)	1 strip/18.4 m^3 24°C, 60% RH 5 air changes/hour	0.098, 0.068, 0.080, 0.066, 0.056, 0.042, 0.031, 0.024, 0.014, 0.015 at 1, 8, 15, 22, 29, 43, 57, 71, 99 and 120 d, respectively	Shell International Chemical Company (undated unspecified)
Vapona strips (details unspecified)	House trials in the UK, Holland and Southern France	0.015–0.079 from 3 days to 4 weeks after hanging strips	Shell Research Ltd (1968a, b; 1969a,b,c); Elgar and Steer (1972)
Dichlorvos slow-release strips (details unspecified)	1 strip/30m^3 House trial in Melbourne 24°C, 46% RH	Average concentrations: 0.02 (wk 1) 0.04 (wk 6) 0.01 (wk 11)	Elgar and Steer (1972)
	1 strip/30 m^3 House trial in Brisbane 21–27°C, 55–61% RH	Average concentrations: 0.02 (wk 1) <0.01 (wk 3) 0.005 (wk 4)	
No-Pest® Insecticide Strips 25 cm (details unspecified)	1 strip per 20.39–192.3 m^3 Both air conditioned and non air conditioned	Mean (range) at 1, 7, 14, 28, 56 and 91 days was 0.06 (0.02–0.11), 0.04 (0.01–0.09), 0.03 (0.01–0.06), 0.02 (<0.01–0.05), 0.01 (<0.01–0.02) and <0.01 (<0.01–0.02), respectively	Collins and DeVries (1973)

SAMPLE	CONDITIONS	AIR LEVELS (mg/m^3)	REFERENCE
25 cm commercial pest strips (20% vapona)	1 strip/28.32 m^3 Minimum ventilation Strips removed after 2 weeks	0.12–0.13 d 0–12 0.08–0.09 d 13–28	Leary et al. (1974)[1]

1 = studies evaluated as part of the current review; RH = relative humidity

The above data indicate some variability in dichlorvos air levels between the different studies. Some of the earlier studies conducted in the absence of ventilation found relatively high levels of dichlorvos (i.e. >0.3 mg/m^3) within the first few days (Shell Chemicals 1965; Elgar and Mathews 1968). In contrast, house trials conducted in a number of countries found much lower levels (<0.1 mg/m^3): this is most likely due to better ventilation.

Besides ventilation, other variables such as humidity and temperature are likely to affect dichlorvos air levels. Elgar and Mathews (1968) (see the table above) found that at high temperature (34°C), initial dichlorvos concentrations were approximately two-fold higher than at low temperature (20–22°C) under both low and high conditions of humidity (~40 and 80%, respectively). A more rapid rate of decline then occurred at the high compared to the low temperature. High humidity was found to increase the rate of decline in air levels of dichlorvos only at the high temperature, with little effect of humidity seen at the low temperature.

It is likely that within Australia, a degree of variability would occur in dichlorvos air levels due to differences in temperature and humidity between different climatic zones. Further, there is likely to be seasonal differences in ventilation rates within households. For example, homes in Melbourne were found to have higher average air levels than Brisbane and these levels were maintained for a longer period of time (see Table 5) (Elgar and Steel 1972), which was attributable to differences in ventilation rates.

Taking into consideration all of the above data, it is likely that when a 20% pest strip is used to treat a 30 m^3 room as recommended, the maximum level of dichlorvos would not exceed 0.15 mg/m^3 within the first few days of installation, dropping to levels of below 0.05 mg/m^3 for the duration of the four-month use period. It is acknowledged that higher levels than these have been reported in some studies when the number of strips used was greater than the recommended number and when there was inadequate ventilation. For the inhalational exposure calculations performed below, the figure of 0.05 mg/m^3 has been used as the average air concentration of dichlorvos over a four-month period.

4.4.2 Assessment of risk from residential uses

To perform a residential inhalational exposure assessment, the above average air level of 0.05 mg/m^3 has been used to estimate an inhaled dose and then compared to the pivotal inhalational NOEL of 0.02 mg/kg bw/day (see Table 6 below). Calculations were based on the US EPA's Exposure Factors Handbook (1996, see <http://www.epa.gov/ordntrnt/ORD/WebPubs/ exposure/>). Exposure periods of 24 and 8 hours were used to simulate the worse case scenario of someone remaining in a treated room continuously and also someone spending a proportion of their day at home, for example, to sleep.

Table 6: Chronic inhalational exposure assessment

AGE GROUP	BODYWEIGHT (kg)	VENTILATION RATE (m^3/day)*	DOSE* (mg/kg bw/d)		MOE**	
			24 HOUR	8 HOUR	24 HOUR	8 HOUR
Children <1 y	8	4.5	0.0281	0.009	0.7	2.1
Children 1–12 y	23	8.7	0.0189	0.006	0.9	2.7
Adult female	60	11.3	0.0094	0.003	2.1	6
Adult male	70	15.2	0.0109	0.004	1.8	5.4

** Dose (mg/kg bw/d) = dichlorvos concentration in air (0.05 mg/m^3) × ventilation rate (m^3/day) ÷ [bodyweight (kg) × exposure duration (1 or 0.33 days); ** margin of exposure [NOEL (0.02 mg/kg bw/d) ÷ Dose (mg/kg bw/d)]*

Based on the above calculations, continuous daily exposure to dichlorvos at the average air concentration generated during the use of a 20% pest strip results in MOEs of ≤10 of the pivotal inhalational NOEL for each population subgroup. While these findings suggest an unacceptable risk to human health, it is recognised that continuous 24-hour exposure is unlikely for most people, except the infirm or infants, who may be confined to a treated room for long periods of time. When a more common exposure scenario was used (8 hours) the MOE is still ≤10 for each population subgroup and is therefore considered unacceptable.

In support of the above findings utilising route-to-route extrapolation, when the NOEC of 0.15 mg/m^3 from Cavagna et al. (1970) is compared with the average dichlorvos concentration of 0.05 mg/m^3, the resulting MOE of 3 indicates an unacceptable inhalational risk. Further, when the NOEC of 0.05 mg/m^3 from Blair et al. (1974) is compared with the average dichlorvos concentration of 0.05 mg/m^3, the resulting MOE of one also indicates an unacceptable inhalational risk.

The use of pest strips containing 20% dichlorvos to treat entire rooms is not considered an acute or short-term risk to human health. However, chronic exposure calculations indicate an exceedance of safe levels for infants, children and adults (in terms of the inhibition of plasma and RBC ChE activities). On this basis, registration of dichlorvos pest strips to treat entire rooms is no longer supported. It should be noted that this recommendation affects only one product—Sureguard Pest Strip Household Insecticide (APVMA Product code 45596).

4.5 Occupational health and safety (OHS)

This OHS review is based on information obtained from the following sources: data submitted by industry, APVMA performance questionnaires (initiated as part of the review of dichlorvos), the APVMA Agriculture Report on dichlorvos, published studies, and the Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Dichlorvos, prepared by the OCSEH.

Currently, 11 dichlorvos products are registered in Australia (Appendices 2 and 3). Of these, four are home garden products, while the rest are intended for use by the professional agricultural, pest control or veterinary sectors. Only products with the potential for their use to result in occupational exposure

(Product numbers 32082, 32939, 38847, 42496[5], 48975, 49008[5], 49203, 49362, 53320, 55503 and 55352[6]) are discussed here.

4.5.1 Consideration of use patterns on product labels

1140 g/L emulsifiable concentrate (EC)

Nufarm Dichlorvos 1140 Insecticide and Divap 1140 Insecticide are emulsifiable concentrate (EC) formulations containing 1140 g/L dichlorvos and 180–190 g/L emulsifying agent. The products are available in pack sizes of 500 mL to 20 L, and they are intended for farm use for the control of insects infesting stored cereal grains. Grain is to be treated on the conveyor or at the auger when being moved into clean storage. The product labels do not give any further description of the application equipment used. The products are to be diluted either 530 or 1050 mL/100 L water (6.0 or 12.0 g dichlorvos/L) and applied at 1 L/tonne of grain to yield final concentrations of 6 or 12 ppm. Withholding periods of 7 and 28 days are specified at the two respective treatment rates. Alternatively, the products can be diluted 480 mL/100 L water (5.5 g dichlorvos/L) and applied at 1 L mixture/20 m^2 to the exposed top surface of bulk stored grain, as often as necessary to prevent infestation.

500 g/L EC

At the beginning of the review of dichlorvos, there were five EC products containing 500 g/L dichlorvos and 455 g/L hydrocarbon solvent. As of 1 April 2010, this has been reduced to four registered dichlorvos products in this category. These products also contain surfactants or emulsifying agents (or both). Pack sizes range from 1 to 200 L, but no further information is available on the type of containers used. Some labels warn that the product is too hazardous to be recommended for home garden use.

These products are intended for control of spiders, silverfish and insect pests in a wide variety of situations, and they can be used undiluted or diluted in water (as an emulsion), kerosene (as a solution) or in a recommended fogging diluent. All information on application methods included on the labels is summarised below.

Indoor uses include:

- households, against flying and crawling insects, spiders and silverfish, when diluted to 12 mL product/L (6 g dichlorvos/L) and sprayed or sprinkled with a watering can where pests occur
- dairies and cattle sheds, diluted to 2.5 g dichlorvos/L and applied as a coarse spray at a rate of 600 mL (1.5 g dichlorvos)/50 m^2
- stables and piggeries, applied as a space spray using a sprayer with a fine nozzle, or as a mist via a mister or atomiser. The dilution rate is 2.5 g dichlorvos/L and an application rate of 14 L (35 g dichlorvos)/1000 m^3 is specified

[5] These products have been withdrawn since the commencement of the dichlorvos review.

[6] This product has been stopped since the commencement of the dichlorvos review.

- animal houses and pens and meat works (non-product areas), against flies and mosquitoes, when diluted to 20 mL product (10 g dichlorvos)/10 L water and applied to walls and other surfaces as a coarse spray using 15 L (15 g dichlorvos)/100 m^2, or into the air as a mist (no further details provided)
- abattoirs and wineries, against flies and vinegar flies, diluted to 1–2.5 g dichlorvos/L and applied as a coarse spray onto the floor and around doorways and windows at 5.3–10 g dichlorvos/50 m^2, or diluted to 2.5 g dichlorvos/L for application by fogging at 14 L (35 g dichlorvos)/1000 m^3. Some labels also recommend application by space spray at 140 mL product (70 g dichlorvos)/1000 m^3 in a ‘convenient’ volume of water
- factories, stores, mills and food warehouses against flies, cockroaches, beetles and moths, diluted to 2.5 g dichlorvos/L and applied as a liquid bait. Liquid baits are made by dissolving 50 g sugar/L spray mixture and applied as a coarse spray, or painted on in strips or patches where insects harbour. Alternatively, for fogging, labels recommend dilution rates of 2.5–5 g dichlorvos/L diluent (kerosene or other suitable carrier). Fogging is performed at 17.5–35 g dichlorvos/1000 m^3 or 3–3.5 g dichlorvos/50 m^3, using a stationary fogging machine. Some labels advise that the fogger be set up to fill the building through a door or window on the windward side. For application by space spray, some labels recommend a use rate of 35–150 mL product (17.5–75 g dichlorvos)/1000 m^3 in a ‘convenient’ volume of water. Treatment is repeated as necessary, although some labels recommend two treatments/wk against beetles and moths.

Some labels further advise that when used indoors, the product should be applied away from cooking and eating utensils and foodstuffs. All doors and windows are to be closed before application and the site cleared of bystanders and animals. Operators are advised to start application at a point furthest from a door and work towards the door. Some (but not all) labels advise that indoor sites are to be kept closed for at least 4 hours following treatment and ventilated thoroughly before re-occupation.

Additional indoor uses of 500 g/L EC products include:

- poultry houses, against maggots, diluted to 60 mL product/10 L water (3 g dichlorvos/L) and applied by spray at 10 L spray mix per 12 m manure under cages, repeated at 3-week intervals
- empty grain silos, diluted to 100 mL product/10 L water (5 g dichlorvos/L) and sprayed onto the inside walls and exit chutes until runoff
- tobacco stores, warehouses, greenhouses, glasshouses and mushroom houses, against insects including flies, aphids and thrips, applied undiluted by the ‘wooden board method’, which entails sprinkling the undiluted product onto wooden boards. To enhance effectiveness, a fan may be set up to blow over each board. The treated area should remain closed overnight and be ventilated thoroughly before re-entry. After use, boards are hosed down and stored outdoors. Some labels recommend that gloves be worn when applying the product and handling boards. Other labels specify application as a spray or fog at 15 mL product (7.5 g dichlorvos)/100 m^3 in these situations, and they recommend twice-weekly treatment for control of cigarette beetle, tobacco moth, other moth species and saw-toothed grain beetle. A two-day withholding period applies to edible crops.

Outdoor uses cover:

- garbage dumps, beach, picnic and recreation areas applied at an unspecified dilution rate as a space spray at 300 mL/ha (150 g dichlorvos/ha), or undiluted through a portable or stationary fogger at 300 mL/ha (150 g dichlorvos/ha), or by misting machine at 30 L of 0.5% product/ha (75 g dichlorvos/ha)

- destruction of bee and wasp nests in trees, uncultivated ground, rockeries and buildings. For this use, the product is mixed at 12–20 mL/L water (6–10 g dichlorvos/L) and up to 1 L of the mixture is sprayed into each nest.

There are also several uses on crops and foodstuffs, as follows:

- stored grain, against moths, grain borers and beetles, when diluted to 100 mL product/10 L water (5 g dichlorvos/L), applied by spray at a rate of 5 L spray mix/100 m^2 grain surface. Some labels specify mechanised spray equipment for this purpose. A 7-day withholding period applies to stored grain
- infested grain held by flour millers, diluted to 120 mL product/10 L water (6 g dichlorvos/L) and applied at the elevator via specially designed and calibrated spray equipment at 1 L spray mix per tonne of grain, yielding a final concentration of 6 ppm
- bagged and stored potatoes, against tuber moths, when diluted to 50 mL product/5 L water (5 g dichlorvos/L) and applied by spray to bag surfaces, shed walls and surrounds at 5 L spray mix/16 bags
- avocados, against leaf rollers, applied at 1 L product (500 g dichlorvos)/ha together with 1 kg chlorpyrifos/ha. Application is performed at the first signs of pest activity and repeated as required. No application equipment is specified but airblast would be the most probable method in an orchard situation. A 7-day withholding period applies to avocados.

Users of David Gray’s DDVP 500 Insecticide and Barmac Dichlorvos 500 Insecticide are also advised to open, decant and mix the product only in well-ventilated outdoor areas. The required amount of product is to be added to the required amount of water in the mixing vessel or spray tank and thoroughly agitated.

250 g/L EC with 225 g/L chlorpyrifos

At the commencement of the review of dichlorvos, there was a single EC product, Permakill Insecticide, which contained 250 g/L dichlorvos in combination with 225 g/L chlorpyrifos in hydrocarbon solvent at 390 g/L. However this product was withdrawn from registration in June 2008. It was previously available in 5 L packs only, and was intended for the control of insect pests in residential, commercial and industrial situations by professional pest control operators. The label warns that the product is too hazardous for use by householders. The dichlorvos provides fumigant action, while the chlorpyrifos acts as a residual contact insecticide.

Directions for use specify the product is to be diluted using 240 mL (60 g dichlorvos, 54 g chlorpyrifos)/10 L water and applied as a low pressure spray to the point of run-off to cracks, crevices, harbourages and places where pests may occur. For use against ants, the preferred technique is direct injection into the nest. The label bears a precaution against application inside buildings except as a crack and crevice treatment, and warns against application to surface areas such as interior floors and walls. Application equipment is not specified, but would most probably comprise a knapsack sprayer or hand-held sprayer used in conjunction with a vehicle-mounted tank and pump.

The label directs users to open, decant and mix the product only in well-ventilated outdoor areas. The required amount of Permakill Insecticide is to be added to the spray tank when half full of water. The balance of the water is then added under agitation. Knapsack sprayers should be shaken gently before use. For indoor use, operators are advised to close windows and doors, clear the area of people, animals and unpacked foodstuffs, and to commence application at the furthermost area from entry and work back. The label warns that the product should not be applied to cooking and eating utensils or on food application areas. When used outdoors, the label states that it is preferable to apply the product when the air is reasonably still and dry and the treatment site will be clear of people and animals for at least 4 hours after treatment. Re-entry is not permitted until treated areas are completely dry (normally 4 hours). If prior entry is required, the duration of entry should be limited and protective clothing and equipment worn (see below).

Following use, the spray tank is to be thoroughly washed with a pressure hose, and drained. Spray equipment and lines are then to be washed by quarter filling the tank with clean water and circulating through the pump, lines and nozzles. The apparatus is then to be drained and the procedure repeated twice.

50 g/kg liquid (LD) in compressed liquid CO_2

There is a single pressurised liquid (LD) product, Insectigas-D DDVP Insecticide, containing 50 g dichlorvos/kg in carbon dioxide. It is available in 6 and 31 kg cylinders for control of flies, mosquitoes, moths, cockroaches, ants and silverfish in industrial and domestic premises, moths and beetles in stored product facilities (including farm machinery and silos), plant pests in greenhouses, and wasps in nests. The product is for professional use only, and it is usually applied as a space spray using a manual pressure gun or via a fixed installation, which may be operated using a manual or programmed time release. However, there is a label restraint against installing an automatic time-release system in food preparation areas or offices.

Indoor areas are to be closed and air movement minimised for 4 hours during treatment. Re-entry must not take place within 4 hours of treatment. Licensed or authorised personnel must thoroughly ventilate treated premises for 30 minutes prior to re-occupation. The product label advises that warning notices be placed on all door entries to treated areas, and that warning lights and an audible alarm system should be fitted in treatment areas where there are fixed systems.

No mixing is required prior to use. When applying Insectigas-D manually as a space spray in enclosed spaces, operators are directed to work away from spray drift and towards the exit when using the pressure gun. Wasp nests are treated by directing the nozzle into the cavity or nest. Empty cylinders are returned to BOC Gases for refilling. A single application rate of 200 g product (10 g dichlorvos)/300 m^3 is recommended for all situations. This amount of product is discharged in 70 seconds when applied with equipment specified on the product label.

7 g/L LD with 1 g/L pyrethrins and 6 g/L piperonyl butoxide

At the commencement of the review of dichlorvos, there was a single LD product, Knock-Down Residual Spray Insecticide, which contained dichlorvos (7 g/L), piperonyl butoxide (6 g/L) and pyrethrins (1 g/L) in de-aromatised mineral solvent (780 g/L). However this product was withdrawn from registration in June 2008. It was previously available in 25 and 205 L packs, and was intended for residual control of crawling insects, spiders and silverfish in houses, hospitals, factories and restaurants. The product is sprayed undiluted directly onto infested areas or insect hiding places. Inaccessible areas may be treated by application of a barrier spray around the opening. No further information appears on the product label.

100 g/kg paste (PA) with 200 g/kg oxibendazole

There is a single paste (PA) formulation used for the treatment of adult roundworms, blood worms, red worms, pin worms and bots in horses (Oximinth Plus Boticide Oral Worm and Bot Paste for Horses). This product contains 2.5 g/25 mL dichlorvos (i.e. 100 g/L) and 5 g/25 mL oxibendazole as the active constituents. It is supplied in a 25 mL syringe (for the treatment of a 500 kg horse), which is placed on the horse's tongue and the plunger pressed to administer the required dose. The label directions indicate that the horse's mouth should be kept closed until the paste has been swallowed. Adult horses are treated twice per year or as required. A meat withholding of 28 days applies.

4.5.2 NOELs for occupational health and safety assessment

As detailed in Section 3.2, the dermal NOEL is 0.047 mg/kg bw/day and the inhalational NOEL is 0.02 mg/kg bw/d. The acceptable margin of dermal and inhalation exposure (MOE) is $\geq$10, resulting from application of a 10-fold uncertainty factor for intra-species variability.

To ensure that the MOE for building occupants does not fall below 10, the maximum time-weighted average concentration of dichlorvos in the workplace atmosphere should be 0.02 mg/m^3. This value is derived on the assumption of 8 hours of exposure/day, an inhalation rate of 1 m^3/h, 70% absorption of inhaled dichlorvos and 70 kg bw.

4.5.3 Estimation of occupational exposure and risk

Dichlorvos products intended for professional use are most likely to be applied by pest control operators, horticulturalists and operators of grain storage facilities and flour mills. Depending on pest activity, operators may use dichlorvos products on several days or daily during the working week. Repeated use of dichlorvos for treatment of commercial and industrial buildings could result in daily exposure of building occupants because dichlorvos has been detected in workplace atmospheres for up to a fortnight after application (Schofield 1993). Grain storage operators and avocado growers are more likely to be exposed on a seasonal basis, but they are also more likely to be exposed on several days in succession. Exposure of horticulturalists would be dictated by the growth cycle of mushrooms or plants under cultivation, and could occur regularly on single days but with several days or more between uses. The most likely potential routes of exposure would be by dermal contact with the undiluted products or spray mixture, and by inhalation of dichlorvos vapour or aerosols.

The use of dichlorvos within domestic residences, stores, other commercial premises and enclosed structures used for grain storage and plant or mushroom production will cause exposure of the occupants. This is notwithstanding the 4-hour re-entry period and instructions to thoroughly ventilate treated premises before re-occupation which appear on some (but not all) product labels. Given the volatility of dichlorvos, the predominant route of exposure would be via inhalation in most circumstances, but there would also be scope for exposure via the dermal route, especially if dichlorvos was applied within a domestic residence.

Current label directions suggest that some structures such as factories and warehouses are fumigated twice per week.

Irrespective of whether a building is treated once or repeatedly, its occupants are likely to be exposed for several successive days (Durham et al. 1959, Gold and Holcslaw 1984, Schofield 1993a, b, and McDonald 1991).

Estimates of occupational exposure to, and of risk from, dichlorvos have been prepared utilising the results of the exposure studies evaluated, together with exposure modelling to cover situations for which no experimental data are available. Appropriate adjustments are made for the dilution rates, application rates and use patterns specified by the labels of Australian products. The following assumptions have been applied (Table 7):

Table 7: List of assumptions used in exposure and risk assessment

Bodyweight	70 kg	US EPA (1996)
Body surface area (adult)	1.94 m^2	Derelanko (2000)
Ventilation rate (light activities)	1.0 m^3/hour	US EPA (1996)
Normal workday	8 hours with an application period of 6 hours	
Average size of house	Area 170 m^2,Volume 430 m^3	
Average size of greenhouse	Area 150 m^2,Volume 375 m^3	
Average industrial building	Area 2500 m^2, Volume 12500 m^3	
Average office building	Area 7500 m^2, Volume 18,000 m^3	
Penetration through overalls	20%	Gold and Holsclaw (1984)
Penetration through chemical-resistant full body clothing	5%	Thongsinthusak et al. (1993)
Penetration through chemical-resistant gloves	10%	Thongsinthusak et al. (1993)
Protection afforded by half-facepiece respirator with gas/dust cartridges	90%	Thongsinthusak et al. (1993)
Protection afforded by full-facepiece respirator with gas/dust cartridges	98%	Thongsinthusak et al. (1993)
Protection afforded by supplied air respirator (air-hose respirator or SCBA)	100%	
Container neck width	Narrow	

SCBA – Self contained breathing apparatus

The situations of use for which exposure and risk estimates have been prepared are as follows:

Scenario (1) Application of 50 LD/CO_2 formulation as a space spray

Scenario (2) Mixing and loading 1140 and 500 EC formulations and mechanical application to grain

Scenario (3) Application of 500 EC formulation as a surface spray

Scenario (4) Indoor application of 500 EC formulation as a space spray

Scenario (5) Indoor application of 500 EC formulation as a fog or mist

Scenario (6) Outdoor application of 500 EC formulation by space spray, fog or mist

Scenario (7) Application of 500 EC formulation by the wooden board method

Scenario (8) Application of 500 EC formulation by watering can

Scenario (9) Application of 500 EC formulation as a liquid bait

Scenario (10) Application of 500 EC formulation to wasp and bee nests

Scenario (11) Application of 500 EC formulation to avocados

Scenario (12) Application of 250 EC formulation with 225 g/L chlorpyrifos#

Scenario (13) Application of 7 LD formulation with 1 g/L pyrethrins as a surface spray#

Scenario (14) Veterinary administration of 100 PA with 200 g/kg oxibendazole

 # These products have been withdrawn from registration since the commencement of the review of dichlorvos.

Scenario 1: Application of 50 LD/CO_2 formulation as a space spray

There is a single pressurised gas product, Insectigas-D DDVP Insecticide, containing 50 g dichlorvos/kg in carbon dioxide. It is available for control of arthropod pests in industrial and domestic premises, stored product facilities (including farm machinery and silos), greenhouses, farm machinery, storage bins and wasp nests. Insectigas-D is also used in mushroom houses and in plant fumigation chambers, although these uses are not included on the product label. The product is for professional use only, and is applied as a space spray using a manual pressure gun or via a fixed installation, which may be operated using a manual or programmed time release.

Indoor application using manual pressure gun

Operators are expected to use a 6 kg cylinder in conjunction with a pressure regulator and nozzle, which would probably be held at chest or head height as the operator moves through the treated building. Once ejected from the nozzle, volatilisation of dichlorvos would be almost instantaneous and complete. It is anticipated that operator exposure would arise principally from inhalation, with some additional exposure via the dermal route.

Although there is no need to handle and dilute a liquid concentrate, dermal exposure may occur through precipitation of dichlorvos from the effluxive stream or the vapour phase onto the operator's body or clothing, particularly if the building design requires the operator to traverse areas already treated. Operators may also be exposed to dichlorvos when changing cylinders, through contact with small amounts of liquid dichlorvos deposited in the connector fittings or on the nozzle.

No studies measuring the exposure of persons applying dichlorvos by manual carbon dioxide (CO_2) pressure gun are available for evaluation. Pesticide Handlers Exposure Database (PHED) modelling was used to estimate dermal exposure. Neither Pesticide Operators Exposure Model (POEM) nor PHED provide a suitable model for estimating inhalation exposure during use of a manual pressure gun because of the high volatility of dichlorvos. Nevertheless, it is possible to infer the potential for inhalation exposure from the recommended application rate and the length of time it would take an operator to treat the types of premises in which use of the product is registered.

The exposure estimates are based on an operator treating eight domestic residences, 10 greenhouses, two industrial buildings or two office buildings. These work rates have been chosen to represent the greatest number of fumigation operations likely to be performed in a single day.

There is scope for toxicologically significant dermal and inhalation exposure to dichlorvos when applying the 50 LD/CO_2 product with a manual pressure gun in enclosed spaces, even with personal protective equipment comprising elbow length butyl rubber gloves, chemical resistant clothing and an air-hose respirator/SCBA. Although several comparatively small structures could be treated without eroding the MOE to unacceptable levels (below 10), the maximum volume treated would be limited to about 15,000 m^3. However, it is considered impractical to impose any such limit on users. Therefore, indoor manual application of dichlorvos 50 LD/CO_2 products to buildings and other structures should be discontinued.

Indoor application using fixed installations

Application of Insectigas-D through fixed installations will cause markedly less dermal exposure than manual application. Under most reasonably foreseeable circumstances, the operator would not need to enter the space during fumigation, and exposure would be limited to manual contact with dichlorvos when changing cylinders. Operators of fumigation chambers may need to perform only a few cylinder changes per year. However, it is important to note that despite the relevant FAISD Handbook entry stating that gloves and overalls should be worn 'when opening the container', the safety directions shown on the label for this product specify personal protective equipment only 'when using in enclosed areas'. Operators following these directions are unlikely to wear gloves when changing cylinders, and could be exposed at the unacceptable margin of 2.4 when performing a single change. If gloves were worn, the dermal MOEs would be 24 and 12 for one or two changes, respectively. In practice, the MOEs may be higher if the gloves were worn for only a short time during cylinder changes, limiting the opportunity for dichlorvos to penetrate through the material to the skin.

Specialised fumigation chambers are gas tight and rooms within mushroom houses are sealed. Under normal conditions of use, there would be no inhalation exposure to dichlorvos when the cylinders are discharged into these spaces. Although it is improbable that completely gas tight entrances would be fitted to warehouses, mills, silos and other structures where fixed installations are present, operators are unlikely to remain in the vicinity for any significant time after releasing dichlorvos from the pressure cylinder. There would be no opportunity for exposure in situations where an automatic release system was employed.

The aggregate dermal and inhalation exposure for operators has been based on the assumption that, other than changing cylinders, there is no exposure when applying dichlorvos via fixed installations. For a single cylinder change, the aggregate MOE for an operator wearing gloves but no respiratory protection is 8.0, and is unacceptable. If gloves and a half-facepiece respirator were worn, the MOE would increase to 19.9. This is sufficiently high to support two cylinder changes per day, for which the MOE would be 10.

Application of dichlorvos 50 LD/CO_2 products via fixed installations is supported, provided operators wear personal protective equipment comprising elbow length butyl rubber gloves, overalls and a half-facepiece respirator with combined gas and dust cartridge when changing cylinders.

Manual treatment of grain storage containers

Registered uses for dichlorvos 50 LD/CO_2 products include fumigation of grain storage silos and bins. Grain storage containers may be treated on a regular basis to prevent infestation, or sporadically in response to a pest outbreak. To treat bins and small on-farm silos, operators would probably use a cylinder in conjunction with a manual pressure gun, which would be discharged into the opened silo valve or bin for sufficient time to achieve the target concentration of 33 mg dichlorvos/m^3 air space. Treated containers would then be closed immediately. There is little information upon which to base an estimated daily work rate for this activity, as the volume of air space requiring treatment would depend on the size, design and number of silos or bins fumigated and the volume of grain they contained. Treated air space volumes could range from a few hundred to several thousand cubic metres. Consequently, the OCSEH has based exposure estimates on a very high work rate of 9000 m^3/day with different combinations of personal protective equipment, followed by an estimate of the maximum volumes that could be treated to maintain acceptable levels of exposure.

The extent of dermal exposure while discharging the pressure gun would be similar to the value estimated for indoor manual application above. To achieve an acceptable MOE, a minimum of overalls and gloves would be required.

If an operator discharging Insectigas-D into a grain bin or on-farm silo would not have to enter the fumigated air space, inhalation exposure would be significantly less than estimated for indoor application. However, the MOEs without respiratory protection or with a half-facepiece respirator are unacceptable.

Provided operators do not enter the spaces being treated, manual application of dichlorvos 50 LD/CO_2 products to air space within grain bins, silos and similar sealed storage containers is supported, provided operators wear personal protective equipment comprising elbow length butyl rubber gloves, chemical resistant clothing and a full-facepiece respirator. It is important to note that this conclusion does not apply to fumigation of bulk storage silos or other situations that would require entry into the structure under fumigation.

Miscellaneous outdoor uses

Dichlorvos 50 LD/CO_2 products may be used to fumigate farm machinery and eradicate wasp nests in defined or confined spaces. These activities would probably occur outdoors on an *ad hoc* basis, and are unlikely to take longer than 30 minutes in any single day. The extent of operator exposure per unit mass of dichlorvos applied would be similar to exposure when treating storage containers. Hence, farm machinery and insect nest fumigation are supported, provided operators wear personal protective equipment comprising elbow length butyl rubber gloves, chemical resistant clothing and a full-facepiece respirator.

Scenario 2: Mixing and loading 1140 and 500 EC formulations and mechanical application to grain

Millers and bulk grain storage and handling facilities use dichlorvos for disinfesting lightly infested grain, which is generally treated as it arrives at the storage facility, during storage, or at outturn. Treatment usually occurs during the second half of the storage period, some weeks or months after harvest. The usual application method is as a coarse spray via mechanical equipment directly onto grain on the auger or conveyor. Grain applicator equipment operators can work for up to 12 hours a day, 7 days a week during the harvest period of about two months. Mixing times during this period may occupy up to an hour each day. Under normal operating conditions, workers are exposed to the chemical only during mixing and loading of spray tanks (which is done by open pour) because they do not need to be present during spray application and are unlikely to make contact with treated grain.

There is wide variation in estimates of how much grain would be treated with dichlorvos per day. Some large facilities may use up to 50 L of the concentrate in a single day, for between 1 and 10 individual days each year.[5] (A 50-L volume of the 1140 EC product is sufficient to treat 5000–10,000 tonnes of grain, depending on the application rate.) However, other operators use equipment with markedly less capacity.

Based on information from product labels, the APVMA Agriculture Report and information received from the grain handling industry, estimates of exposure have been prepared on the assumption that operators are exposed only during the mixing and loading phases of disinfestation procedures, and that they treat grain at the highest label rate of 12 g dichlorvos.

None of the available studies on operators using dichlorvos provides data on exposure through mixing and loading, as distinct from exposure through application. PHED has algorithms for predicting exposure of the mixer and loaders handling liquids by open pour and closed pour methods.

[5] GrainCorp submission to the OCSEH, February 2005.

Based on the available information, it is not possible to assure adequate protection of operators involved in grain disinfestation by mechanical spray. To maintain an aggregate MOE above the acceptable level of 10, operators wearing gloves, chemically resistant clothing and a full-facepiece respirator can handle only approximately 1.3 kg of dichlorvos active in liquid products, even when using closed mixing and loading systems and without additional exposure during spray application. Given that operators at large sites may be required to handle up to 50 L of dichlorvos 1140 EC in a single day (equivalent to 57 kg dichlorvos), there is evident potential for exposure to toxicologically significant doses of dichlorvos during grain treatment operations. Therefore, this use of dichlorvos should be discontinued.

Scenario 3: Application of 500 EC formulation as a surface spray

Application in houses

Dichlorvos 500 EC products are diluted to a concentration of 6 g/L and are applied by spray against flying and crawling insects, spiders and silverfish.

Gold and Holcslaw's study (1984) is considered to be the most relevant and highest quality pest control operator study for the purpose of exposure assessment.

None of the product labels nominates a specific application rate per unit area. However, rates of up to 0.2 g dichlorvos/m^2 are used for surface spray treatment of animal housing, meatworks and wineries, and pest control operators used a rate of 0.19 g/m^2 in houses in that study (Gold and Holcslaw 1984). A rate of 0.2 g/m^2 will therefore be assumed. Pest control operators are most likely to use a hand-held sprayer, a knapsack sprayer, or a hand wand supplied by a hose from a vehicle-mounted spray tank and pump.

Exposure has been estimated for a pest control operator treating one or six average-sized houses (total area: 170 m^2 or 1000 m^2) in a single working day, an activity which would require application of 33 g or 200 g dichlorvos.

Exposure assessment showed that an acceptable dermal MOE cannot be achieved for an operator treating even a single domestic house, and therefore, the aggregate MOE could not be acceptable. In this context, it is noteworthy that a pest control operator in Gold and Holcslaw's study developed cholinesterase poisoning after applying approximately 0.14 kg of dichlorvos to seven small homes while wearing overalls, gloves and a half-facepiece respirator.

When a low-pressure hand wand is used for application, about 10% of a mixer, loader or applicator's total dermal exposure occurs during mixing and loading, while the remaining 90% occurs during application. Over 99% of inhalation exposure occurs during application. Thus, even if the adoption of enclosed mixing and loading systems were to reduce dermal exposure to zero at that phase, or if mixing, loading and application were performed by different operators, there would still be a negligible reduction in inhalation exposure. Aggregate exposure would therefore remain unacceptably high.

Even if gloves and chemical-resistant clothing were worn, it is not possible to maintain an acceptable dermal MOE for operators mixing and applying sufficient dichlorvos to treat an area equivalent to an average domestic house by surface spray. Therefore, use of dichlorvos 500 EC as an indoor surface spray in domestic houses should be discontinued.

Other indoor situations including animal housing, milk and meat processing facilities, and grain storage structures

Animal housing, dairies, meatworks and abattoirs, and wineries are treated by indoor surface spray at rates of 0.03–0.2 g dichlorvos/m^2 using spray mixes containing dichlorvos at between 1 and 2.5 g/L. Although the size of such buildings would vary considerably, it is considered that operators would seldom treat areas smaller than 1000 m^2, which would require them to mix, load and apply 30–200 g dichlorvos. Some application sites would be significantly larger. Pest control operators are most likely to employ knapsack sprayers or hand wands used with a vehicle-mounted spray tank and pump. Although no exposure studies have been performed with dichlorvos in these situations, the extent of operator exposure will be at least that measured by Gold and Holcslaw (1984). Indeed, operator exposure may be increased if significant quantities of spray mix are discharged at or above chest height, leading to contamination of the upper body and the breathing zone air. As shown above, dermal contamination would be extensive enough to erode the MOE below 10, even if only 30 g dichlorvos were mixed and applied. Given that many applications would involve larger amounts of dichlorvos, there is clear potential for toxicologically significant exposure of operators.

In empty grain silos, a 5 g/L dilution is recommended, but no application rate is nominated. Grain storage infrastructure would require treatment of large areas, given that silos have a capacity of up to 10,000 tonnes and sheds can hold 3000–100,000 tonnes. Hand spraying equipment is likely to be used, and operators will probably discharge the spray mix at or above chest height, work in close proximity to the treated surfaces, and enter enclosed or confined spaces. Again, dermal and inhalation exposure would occur at or above the level measured by Gold and Holcslaw, leading to an unacceptable MOE even if only 30 g of dichlorvos were mixed and applied.

Even if respiratory protection, gloves and chemical-resistant clothing were worn, it would not be possible to maintain an acceptable MOE for operators mixing and applying sufficient dichlorvos to use indoor surface spray to treat animal housing and processing facilities, other large buildings, and grain storage structures. Therefore, use of dichlorvos as an indoor surface spray in these situations should be discontinued.

Scenario 4: Indoor application of 500 EC formulation as a space spray

Dichlorvos 500 EC products are applied as an indoor space spray in diverse situations. Stables and piggeries are treated at a rate of 35 mg dichlorvos/m^3, with application performed by space spray. Variable treatment rates of 17.5–70 mg/m^3 are recommended for factories, stores, mills, abattoirs and wineries. A rate of 75 mg/m^3 is used for fumigation of tobacco stores, warehouses, and greenhouse, glasshouses and mushroom houses. Operators would probably use a high-pressure hand wand in conjunction with a vehicle-mounted spray tank and pump.

Due to the variety of situations in which dichlorvos 500 EC products can be applied as a space spray, there will be wide variation in the volume of air space that has to be treated. This may range from a few hundred cubic metres (in the case of small greenhouse, glasshouses or mushroom houses) to several thousand cubic metres. Therefore, exposure estimates were computed to cover the range of volume treated (375 m^3, 3750 m^3 and 12,500 m^3).

None of the available exposure studies are directly applicable to indoor space spray application of dichlorvos. PHED was used to estimate exposure for this scenario.

It is evident that, although the MOE when wearing a half-facepiece respirator is acceptable, a maximum of only about 500 m^3 could be treated before the MOE was eroded below 10. Even if inhalation exposure was prevented by use of an air-hose respirator or SCBA, the highest acceptable volume (750 m^3) is well below the volume that it is anticipated may require treatment in a single workday.

When using a high pressure hand wand, about 20% of a mixer, loader or applicator's total dermal exposure occurs during mixing and loading, while the remaining 80% occurs during application. Approximately 1.5% of inhalation exposure occurs during mixing and loading, with the remainder occurring during application. Thus, even if exposure during mixing and loading were reduced to zero, or if mixing and loading and application were performed by different operators, there would be negligible reduction in inhalation exposure. The maximum treatable airspace volume would still lie below 1000 m^3.

Even if personal protective equipment comprising gloves, chemical resistant clothing and an air-hose respirator or self-contained breathing apparatus were worn, it would not be possible to maintain an acceptable dermal MOE for operators applying dichlorvos by indoor space spray. Therefore, this use of dichlorvos should be discontinued.

Scenario 5: Indoor application of 500 EC formulation as a fog or mist

Dichlorvos 500 EC products can be applied by fogger, mister or atomiser in situations such as stables, piggeries, abattoirs and wineries at a rate of 35 g/1000 m^3. Factories, stores, mills and warehouses may be fogged at 17.5–35 g/1000 m^3. Fogging is also nominated as a method of treating tobacco stores, warehouses, greenhouse, glasshouses and mushroom houses at 7.5 g dichlorvos/100 m^3 (75 mg/m^3).

Some labels advise that fogging should be performed using a stationary fogging machine, set up outside to fill the treated building through a door or window on the windward side. Otherwise, it is assumed that stationary or portable foggers or misters would be discharged inside the treated structure. There is evident potential for significant exposure of operators during indoor use of portable misters and foggers—these produce fine droplets (15–30 µm diameter in the case of foggers, and 50–100 µm diameter in the case of misters). Volatilisation of dichlorvos from droplets of these sizes would be rapid. In the absence of any relevant studies, the OCSEH made the assumption that the extent and pattern of operator exposure when using portable foggers or misters would be similar to those predicted for persons applying dichlorvos 50 LD/CO_2 products. In contrast, there would be considerably less operator exposure from stationary foggers and misters. Even if using equipment that required manual activation, an operator would not have to remain within the treated structure for more than a few minutes. Similarly, where foggers are set up outside a building, operator exposure to airborne dichlorvos would be low. Irrespective of the equipment used, there is potential for operators to be exposed to dichlorvos when decanting and mixing the concentrate and filling the reservoir. Therefore, estimates were prepared for operators mixing and loading the product, applying the product using stationary equipment, and applying by portable equipment at the highest label rate of 75 mg dichlorvos/m^3.

None of the available studies on operators using dichlorvos provided data on exposure through mixing/loading, as distinct from exposure through application. PHED modelling was used to estimate exposure for the purpose.

During the use indoors of portable fogging or misting equipment, operators are likely to be exposed to dichlorvos-containing aerosols that become deposited onto the body or clothing, particularly if the building design requires traversal of areas already treated. Dichlorvos may also precipitate from the vapour phase onto the operator. In the absence of relevant data, the OCSEH assumed that the extent of dermal exposure is similar to that associated with indoor application of dichlorvos 50 LD/CO_2 manual pressure guns.

No data were available to the review upon which to base estimates of inhalation exposure to persons applying dichlorvos indoors using portable fogging or misting equipment. Nevertheless, the potential for exposure can be inferred from the highest recommended application rate and the length of time over which an operator would be exposed. Operators would probably hold the fogger or mister nozzle at waist or chest height as they move through the treated building. Once ejected from the nozzle, volatilisation of dichlorvos from the aerosol would be rapid. Provided the operator did not walk through the effluxive stream, the highest airborne concentration of dichlorvos to which they would be exposed would be 75 mg/m^3. However, this concentration would be attained only at end of application. When treatment commenced, the airborne concentration of dichlorvos would be zero. Therefore, even when using the maximum application rate, operators are unlikely to be exposed to dichlorvos at a time-weighted average concentration of >37.5 mg/m^3 while fogging or misting in an enclosed space. The duration of exposure is unknown, but may be similar to the time taken for application of dichlorvos 50 LD/CO_2 by a manual pressure gun (70 sec/300 m^3).

Indoor application of dichlorvos by portable fogging or misting equipment is likely to cause toxicologically significant dermal exposure when mixing the product and dermal and inhalational exposure during application. Even if a closed mixing system were employed and operators wore gloves, chemical resistant clothing and an air-hose respirator or SCBA throughout mixing, loading and application, an acceptable MOE could not be maintained if a volume of >11,000 m^3 were treated. Given that it is impractical to impose any such limit on users, indoor application of dichlorvos 500 EC products by portable fogging or misting equipment should be discontinued.

When treating large structures, operators are likely to use stationary foggers or misters with either manual or automatic release systems. In the latter case, operators would be exposed only during mixing and loading activities. The only way they could maintain a MOE of $\geq$10 would be to handle only 1.4 kg of dichlorvos, sufficient to treat 18,750 m^3 at the maximum label rate. This is less than the highest anticipated work rate for a pest control operator treating industrial premises. The situation with respect to manual activation is considered below.

If manual activation were required, the operator could be exposed to dichlorvos by inhalation prior to vacating the fumigation site. The duration of exposure is not likely to exceed 1 or 2 minutes. Operators would not normally be exposed to dichlorvos when applying it via stationary automatic release foggers or misters, and the extent of inhalation exposure when using stationary manual release equipment can be constrained to acceptable levels by use of appropriate respiratory personal protective equipment. However, there is scope for unacceptably high dermal and inhalation exposure when mixing and loading dichlorvos 500 EC products, even using closed systems and wearing personal protective equipment comprising elbow length butyl rubber gloves, chemical resistant clothing and an air-hose respirator or SCBA. Only up to about 1.4 kg of dichlorvos could be mixed and loaded without eroding the MOE to unacceptable levels. The limiting factor is dermal exposure, especially on the hands. If treatment were performed at the maximum label rate of 75 mg/m^3, the volume treated would be limited to 18,750 m^3, which lies below the maximum anticipated work rate of 25,000 m^3. Given that it is impractical to impose a limit on the amount of dichlorvos that users could prepare or apply per day, application of dichlorvos 500 EC products to buildings and other structures by stationary indoor misting or fogging equipment should be discontinued.

Scenario 6: Outdoor application of 500 EC formulation by space spray, fog or mist

Dichlorvos 500 EC products have been applied to garbage dumps, beach, picnic and recreation areas at an unspecified dilution rate as a space spray at 150 g dichlorvos/ha, or undiluted through a portable or stationary fogger at 150 g dichlorvos per hectare, or by misting machine at 30 L of 0.5% product/ha (75 g dichlorvos/ha). No further information on these use patterns is available. Exposure estimates are prepared for operators treating an area of 1 or 5 ha, representative of the typical and largest areas likely to be treated within a workday. To treat an area of 1 or 5 ha, respectively, operators would handle 300 or 1500 mL of 500 EC product containing 0.15 or 0.75 kg of dichlorvos.

Exposure during the mixing and loading phases may be estimated by the same methods as used in Scenario 5.

Estimated aggregate MOEs for operators using closed mixing and loading systems have been prepared assuming work rates of 1 and 5 ha/d, with different combinations of personal protective equipment. Gloves and overalls would be sufficient to assure a marginally adequate MOE. Addition of respiratory protection or chemical resistant clothing would yield only a small increase in MOE because exposure is predominantly via the hands.

If treating the application site by space spray, operators are most likely to use a high-pressure hand wand in conjunction with a vehicle mounted tank and pump. There are no data available on operator exposure to dichlorvos during application by space spray. However, PHED (model 19) has an algorithm for high-pressure hand-wand application, derived from a combination of data gathered indoors and outdoors.

As discussed under Scenario 2, a correction factor of 50 should be applied to the PHED prediction for inhalation exposure to account for the high volatility of dichlorvos.

Aggregate exposures have been estimated for operators mixing and loading dichlorvos 500 EC in an enclosed system and treating an area of 1 ha while wearing chemical resistant clothing and different levels of respiratory personal protective equipment. It is clear that the aggregate MOE would be unacceptable unless gloves and chemical resistant clothing were worn and inhalation exposure was prevented by means of an air-hose respirator or SCBA. Even under these conditions, the maximum treatable area would be limited to 1 ha.

Even if personal protective equipment comprising gloves, chemical resistant clothing and an air-hose respirator or SCBA were worn, it would not be possible to maintain an acceptable MOE for operators applying dichlorvos outdoors by space spray unless the treated area were constrained to 1 ha. However, it is impractical to impose such a limit on operators and so this use of dichlorvos should be discontinued.

Prediction of operator exposure from outdoor application of dichlorvos by fogging and misting is difficult because these operations may be performed with a variety of equipment, and will be affected by variables including the size, type and topography of the fumigation site, the wind speed and direction, and the ambient temperature. Dichlorvos is typically applied using hand-held foggers or backpack misters, semi-portable misters mounted on utility vehicles or trailers, or stationary foggers and misters. Operator exposure is likely to be greater when using portable or vehicle-mounted equipment than stationary equipment, but even in the latter case, exposure may occur if the operator remains on site to supervise application. The extent of exposure depends heavily on whether the operator passes through the effluxive stream from the equipment in use, and the duration of exposure.

Therefore, the OCSEH has prepared reasonable worst-case exposure estimates for an operator mixing, loading and applying sufficient dichlorvos to treat a 5-ha area by fogging at the highest label rate of 150 g/ha, which would involve handling 0.75 kg of active ingredient. It is assumed that the extent of dermal exposure is the same as that estimated for indoor use of hand-held foggers, and that the duration of exposure is three hours. The exposure model also assumes that the operator will be exposed to a time-weighted average airborne concentration of 7.5 mg dichlorvos/m^3, the concentration that would be attained if 150 g dichlorvos were dispersed evenly within a volume of 100m x 100m x 2m = 20 000 m^3 of air.

In the absence of relevant data, the OCSEH assumed that the extent of dermal exposure would be similar to that estimated for indoor application of dichlorvos 50 LD/CO_2 with manual pressure guns. The dermal MOEs would be unacceptable unless the operator wore gloves and chemical resistant clothing. If treatment was performed at the label rate recommended for misting (75 g dichlorvos/ha), and if the operator wore overalls, exposure would be halved and the MOEs would double and become acceptable.

Aggregate exposures have been estimated for operators mixing and loading dichlorvos 500 EC in an enclosed system and fogging a 5-ha area at 150 g/ha while wearing gloves, chemical resistant clothing and an air-hose respirator/SCBA.

The aggregate MOE would be unacceptable even under conditions where inhalation exposure was prevented, and the maximum treatable area would be limited to 4.7 ha.

The exposure model developed by the OCSEH suggests that there is potential for toxicologically significant dermal and inhalation exposure to dichlorvos when mixing, loading and treating outdoor areas by fogging or misting. Even with the most conservative personal protective equipment (chemical resistant gloves, chemical resistant clothing and an air-hose respirator) it appears that less than 5 ha could be fogged at the current label rate. Therefore, outdoor application of dichlorvos by misting or fogging should cease unless supported by relevant exposure data or more detailed information on work rates and handling practices.

Scenario 7: Application of 500 EC formulation by the wooden board method

Dichlorvos 500 EC products may be applied in tobacco stores, warehouses, greenhouses, glasshouses and mushroom houses by the ‘wooden board method’. This entails sprinkling the undiluted product onto wooden boards at the rate of 20 mL/150 m^3 (i.e. 10 g dichlorvos/150 m^3 or 67 mg/m^3). To enhance effectiveness, a fan may be set up to blow over each board. The treated area remains closed overnight and after use, the boards are hosed down and stored outdoors.

Exposures are estimated for daily treated volumes of 375–12,500 m^3.

When decanting the concentrate, operators are likely to experience similar levels of dermal exposure to those arising from mixing and loading liquid formulations by open pour methods. Therefore, in the absence of relevant data, PHED model 3 (open mixing and loading of liquids) is used to estimate the extent of dermal exposure.

After the undiluted liquid formulation is decanted onto the wooden board, the airborne concentration of dichlorvos would probably increase more slowly than would occur during application by spray, pressure gun, fog or mist. This is due to the relatively small surface area of the liquid pool from which dichlorvos could volatilise, compared with the surface area of droplets within an aerosol cloud.

In studies in which dichlorvos was applied by watering can in mushroom houses and warehouses, Hussey and Hughes (1963 and 1964) reported that airborne dichlorvos levels rose no further than 0.04% of the nominal application rate, while Durham et al. (1959) detected dichlorvos at up to 2.3% of the application rate. However, there is no evidence in either study to suggest that forced aeration was employed to hasten evaporation. Hence, airborne dichlorvos levels may approach the target value of 67 mg/m^3 more closely in situations where fan-assisted evaporation is occurring. The OCSEH assumed that operators are exposed to a time-weighted average concentration of 6.7 mg dichlorvos/m^3 (i.e. 10% of the nominal application rate), and are exposed for 2, 20 and 60 minutes respectively when treating 375, 3750 or 12 500 m^3 of air space.

Aggregate exposure calculations showed that although there was an acceptable MOE if gloves, overalls and a full-facepiece respirator were worn, a maximum of about 4300 m^3 could be treated while wearing this level of personal protective equipment. Use of chemical resistant clothing would enable a modest increase in MOE and maximum permissible volume, but a significant gain in protection could be obtained only by preventing inhalation exposure with an air-hose respirator or SCBA. Under these conditions, the maximum volume that could be fumigated without eroding the aggregate MOE below 10 is approximately 7500 m^3.

Operators treating small to medium-sized buildings by the wooden board method could do so without incurring an unacceptable level of exposure to dichlorvos, provided that gloves, overalls and a full-facepiece respirator were worn. However, there is potential for toxicologically significant exposure when treating larger structures (up to a maximum of 7500 m^3 which is within the range of anticipated daily work rates). Based on this potential exposure risk, dichlorvos should not be applied by the wooden board method.

Scenario 8: Application of 500 EC formulation by watering can

Several 500 EC product labels nominate application by watering can as a treatment method against insects in domestic households, using a 6 g dichlorvos/L water solution. There is some uncertainty as to the amount of dichlorvos that would be handled in this situation, as no treatment rates are given. However, if the application rate was similar to that used for indoor surface spraying (0.2 g dichlorvos/m^2), this would involve delivering 33 mL of the diluted solution per m^2. An average house of 170 m^2 would require 33 g dichlorvos, while a total of 200 g would be applied to six houses, the highest number likely to be treated in a single workday.

No data is available to the review on exposure to dichlorvos through watering can application, and neither POEM nor PHED have models for this application method. Nevertheless, the potential for operator exposure is probably similar to that arising from application by the wooden board method, discussed in Scenario 7. A dermal MOE of 17 was estimated for an operator applying 250 g dichlorvos by the wooden board method while wearing gloves and overalls, and the inhalation MOE would be 35 if a full-facepiece respirator was worn. The aggregate MOE for an operator wearing this combination of personal protective equipment was 11. If 200 g dichlorvos were handled and applied by watering can using the same personal protective equipment, the dermal, inhalation and aggregate MOEs would be 21, 44 and 14, respectively. Although these values are acceptable, it can be seen that the aggregate MOE would be eroded below 10 if the mass of dichlorvos applied exceeded about 275 g.

If personal protective equipment comprising gloves, overalls and a half-facepiece respirator were worn, exposure from application of dichlorvos via watering can may remain within acceptable levels, assuming that the pattern and extent of operator exposure are similar to those associated with application by the wooden board method. However, this finding is based on the inference that pest control operators are likely to mix and apply no more than 200 g dichlorvos per day when treating domestic households. Even a relatively small increase in the mass of dichlorvos applied per day could cause unacceptable exposure to operators. Therefore, application of dichlorvos by watering can cannot be supported.

Scenario 9: Application of 500 EC formulation as a liquid bait

Factories, stores, mills and food warehouses may be protected against insect pests by diluting dichlorvos 500 EC products to 2.5 g active/L and adding 50 g sugar/L water. The resulting liquid bait may be applied as a coarse spray or painted on in strips or patches where insects harbour. Product labels do not nominate any specific application rate per unit area, which limits the accuracy of any estimates of operator exposure. However, the application rate would probably be similar to those recommended for surface spray treatment of wineries and animal housing and processing facilities (up to 0.2 g/m^2; see Scenario 3).

Application by surface spray

Many of the buildings that may be treated with liquid baits are large, and the area requiring treatment is likely to reach several hundred square metres. As discussed under Scenario 3, dermal and inhalation exposure to dichlorvos would probably occur at the extent measured by Gold and Holcslaw (1984) in their study of pest control operators treating domestic housing by surface spray. Given that it is not possible to maintain an acceptable dermal MOE for operators treating a 170 m^2 building by surface spray, even if gloves, chemical resistant clothing and respiratory protection are worn, application of liquid baits by this method can not supported.

Application by paintbrush

The only available means of estimating operator exposure to dichlorvos when using this application method is PHED model 22.

Given that paintbrush application occurs within the operator’s breathing zone, significant inhalation exposure to the active constituent would be expected. This is confirmed by the relevant PHED model, which predicts an exposure of 616 µg/kg handled. In estimating inhalation exposure, a 50-fold factor was applied to account for the enhanced volatility of dichlorvos (see Scenario 2).

Even if the highest possible level of personal protective equipment were worn, there is potential for toxicologically unacceptable dermal exposure to operators when applying dichlorvos as a liquid bait by surface spray or paintbrush. Therefore, this use of dichlorvos should be discontinued.

Scenario 10: Application of 500 EC formulation to bee and wasp nests

Dichlorvos 500 EC products may be diluted to 6–10 g/L and sprayed into bee and wasp nests. Up to 1 L of the spray mix can be discharged into each nest. Such activities would be performed outdoors, and operators are likely to use a low-pressure hand wand fitted with a crack or crevice tool. On most occasions, pest control operators would be required to destroy a single nest, with five nests being a reasonable ‘worst case’ situation. Exposure estimates are therefore prepared for an operator handling 50 g dichlorvos and treating five nests.

The most suitable method of estimating operator exposure is PHED model 37, which is for open pour mixing and loading of liquid formulations and applying them by injection as a termiticide.

In estimating inhalation exposure, a 50-fold factor to account for the enhanced volatility of dichlorvos (see Scenario 2, above) was applied.

The aggregate MOE for an operator treating five insect nests was estimated at 10 if gloves and overalls were worn. Addition of a half-facepiece respirator would yield negligible benefit.

Principally because of the low quantity of dichlorvos that would be applied when eradicating wasp and bee nests, and the method of treatment, the potential for operator exposure is relatively low and can be constrained to acceptable levels by gloves and overalls. Consequently, this use pattern is supported.

Scenario 11: Application of 500 EC formulation to avocados

A further use for dichlorvos 500 EC products is on avocados, applied at 1 L product (500 g dichlorvos)/ha together with 1 kg chlorpyrifos/ha. No application equipment is specified but upwards airblast would be the most probable method in an orchard situation. Up to 30 ha/day can be treated by airblast, which would require 15 kg of dichlorvos and 30 kg chlorpyrifos. This assessment will examine firstly the extent to which mixers and loaders would be exposed to dichlorvos. As both POEM and PHED contain predictive models for mixer and loader exposure in a broadacre setting, estimates are prepared using each of the two methods.

Exposure modelling by both PHED and POEM suggest the potential for toxicologically significant exposure of mixers and loaders handling sufficient dichlorvos to treat more than 3 ha of avocados, which is considerably less than the anticipated work rate. Both models suggest that exposure could not be reduced to acceptable levels even with the most conservative personal protective equipment. Consequently, the use of dichlorvos 500 EC formulations for treatment of avocados is not supported.

Scenario 12: Application of 250 EC with 225 g/L chlorpyrifos

At the commencement of the review of dichlorvos, there was a single EC product which contained 250 g/L dichlorvos in combination with 225 g/L chlorpyrifos in hydrocarbon solvent at 390 g/L. However this product was withdrawn from registration in June 2008. It was previously available in 5 L packs, and was intended for the control of insect pests in residential, commercial and industrial situations. The product is diluted to 240 mL (60 g dichlorvos, 54 g chlorpyrifos)/10 L water and applied as a low pressure spray to the point of run-off to cracks, crevices, harbourages and places where pests may occur. No specific application rate is nominated. For use against ants, the preferred technique is direct injection into the nest. The label warns against application inside buildings except as a crack and crevice treatment. Application equipment would most probably comprise a knapsack sprayer or low-pressure hand wand used in conjunction with a vehicle-mounted tank and pump.

OHS NOELs for chlorpyrifos

An OHS assessment of chlorpyrifos was performed by the NOHSC in 2000. As with dichlorvos, the most sensitive toxicological end-point with chlorpyrifos is plasma ChE inhibition. Therefore, this risk assessment was based on the assumption that the toxicity of dichlorvos and chlorpyrifos will be additive. The OHS risk assessment NOEL was 0.03 mg/kg bw/d, established in a repeat-dose study in humans in which plasma ChE inhibition occurred at the next highest dose of 0.1 mg/kg bw/d. A dermal absorption factor of 3% was used in the OHS risk assessment. Adjusting for the dermal absorption factor, the dermal NOEL for OHS risk assessment purposes is therefore 1.0 mg/kg bw/d. The acceptable MOE is $\geq$10, resulting from application of a 10-fold uncertainty factor for intra-species variability. The inhalation absorption of chlorpyrifos was assumed to be complete, and so the inhalation NOEL for OHS risk assessment is 0.03 mg/kg bw/d. Again, the acceptable MOE is $\geq$10, resulting from application of a 10-fold uncertainty factor for intra-species variability.

Application by surface spray, and crack and crevice treatment

The final concentration of dichlorvos in the spray mix (6 g/L) is the same as that recommended for the 500 EC formulations when applied in domestic housing. When using the 250/225 dichlorvos/ chlorpyrifos EC, operators would therefore be expected to mix, load and apply similar amounts of dichlorvos to the mass handled when using the 500 EC. Buildings that may be treated with the dichlorvos/chlorpyrifos combination product may be large, and the area requiring surface spray treatment may reach several hundred square metres. Although the product is intended for surface spray application only in outdoor situations, this would have little mitigating effect on the extent of dermal exposure to dichlorvos, which would be similar to that measured by Gold and Holcslaw (1984). Based on these authors' findings, as discussed under Scenarios 3 and 9 (above), an acceptable dermal MOE cannot be maintained for operators applying dichlorvos by surface spray, even at very low work rates while wearing gloves, chemical resistant clothing and respiratory protection. Consequently, it is not possible to support surface spray application of the 250 EC formulation with 225 g/L chlorpyrifos.

No suitable experimental data for estimating operator exposure to dichlorvos and chlorpyrifos when performing crack and crevice treatment, and neither POEM nor PHED contain relevant exposure models. The type of spray equipment used could have a major influence on the extent of exposure. Sprayers fitted with simple orifice tips for insertion into cavities may have significantly lower potential for operator exposure than those designed to produce a flat fan or conical spray jet. In the latter cases, dermal exposure may be similar to that associated with surface spraying, which is toxicologically unacceptable. Given this use of dichlorvos/chlorpyrifos 250/225 EC product as an indoor crack and crevice treatment cannot be supported.

Direct injection into ant nests

The dichlorvos/chlorpyrifos 250/225 EC product is diluted to 6 g/L dichlorvos and 5.4 g/L chlorpyrifos and injected into bee and wasp nests. A volume of 1 L is the largest amount of the spray mix likely to be discharged into a nest. Such activities would be performed outdoors, and operators are likely to use a low pressure hand wand fitted with a crack/crevice tool. On most occasions, pest control operators would not be required to destroy more than 5 nests. Exposure estimates are therefore prepared for an operator handling 5 L spray mix (30 g dichlorvos and 27 g chlorpyrifos).

As discussed under Scenario 10, PHED model 37 (for open pour mixing and loading and application of termiticides) is the most relevant method for estimating operator exposure in this situation.

An aggregate MOE of 11 is estimated for an operator wearing overalls. This value is acceptable but would be eroded below 10 if the operator applied more than 33 g dichlorvos and 30 g chlorpyrifos. A combination of gloves and overalls would assure a more adequate MOE of 16.

Principally because of the low quantity of dichlorvos and chlorpyrifos that would be applied when eradicating ant nests and the method of treatment, the potential for operator exposure is relatively low and can be constrained to acceptable levels by gloves and overalls. Consequently, this use pattern is supported.

Scenario 13: Application of 7 LD formulation with 1 g/L pyrethrins as a surface spray

At the commencement of the review of dichlorvos, the LD product, Knock-Down Residual Spray Insecticide, was a registered product containing dichlorvos (7 g/L), piperonyl butoxide (6 g/L) and pyrethrins (1 g/L) in de-aromatised mineral solvent (780 g/L). However this product was withdrawn from registration in June 2008. It was intended for residual control of arthropods in houses, hospitals, factories and restaurants. The product is sprayed undiluted directly onto or around infested areas. Pest control operators would probably use hand or knapsack sprayers, or a hand wand in conjunction with a vehicle-mounted tank and pump.

The absence of any requirement to prepare a dilute spray mixture would tend to reduce the extent of operator exposure. However, as discussed under Scenario 3, it is not possible to maintain an acceptable MOE for operators applying the required amount of dichlorvos to treat domestic housing or large buildings by indoor surface spray, even when wearing respiratory protection, gloves and chemical-resistant clothing. Therefore, use of the product Knock-Down Residual Spray Insecticide as a surface spray should be discontinued.

Scenario 14: Veterinary administration of 100 PA with 200 g/kg oxibendazole

The formulation is used as an anthelmintic in horses. It is supplied in 25 mL units and presented as a pre-loaded syringe for oral administration. There are no experimental data or models suitable for predicting operator exposure to the active constituents. However, there is some potential for hand contamination, particularly when withdrawing the syringe from the horse's mouth. If 0.1% of the syringe's contents (25 mg) was transferred onto the operator's hands, this would result in dermal exposure to 2.5 mg dichlorvos and 5.0 mg oxibendazole.

OHS NOEL for oxibendazole

Toxicological assessments of oxibendazole and benzimidazole anthelmintics were performed by the DoHA in 1998 and 1994, respectively. The most sensitive toxicological end-point for oxibendazole is testicular toxicity, seen as reduced absolute and relative testicular weights in a three-month dog study at 30 mg/kg bw/d. The NOEL in this study was 10 mg/kg bw/d. Although OHS NOELs would not normally be based on organ weight displacements from control values, testicular toxicity appears to have occurred in several studies with benzimidazoles. Therefore, the OHS risk assessment NOEL for oxibendazole was taken as 10 mg/kg bw/d. No data on the dermal absorption of oxibendazole or other benzimidazoles were available for this review. Therefore, a dermal absorption factor of 100% was used, and so the dermal NOEL for OHS risk assessment purposes was 10 mg/kg bw/d. The acceptable MOE is $\geq$100, resulting from application of 10-fold uncertainty factors for inter-species extrapolation and intra-species variability. Because dichlorvos and oxibendazole have different mechanisms of toxicity, it is assumed that the two chemicals would act independently.

Operator exposure to dichlorvos and oxibendazole can be constrained to acceptable levels by use of gloves when administering the product. Therefore, continued use of dichlorvos in veterinary 100 PA formulations with 200 g/kg oxibendazole is supported, provided the product labels bear appropriate Safety Directions.

4.5.4 Re-entry and re-handling intervals

Entry into sealed grain storage would not normally be required, and treated grain would seldom be handled manually before the withholding had expired.

It is also unlikely that exposure to dichlorvos would result from handling an animal that had received the chemical orally. Hence, calculation of re-entry intervals or RHIs for these situations is unnecessary.

Re-entry into treated buildings

The label of the sole registered 50 LD/CO_2 product recommends that indoor areas remain closed for 4 hours during treatment, and warns against re-entry within 4 hours of treatment. Label directions stipulate that licensed or authorised personnel must thoroughly ventilate treated premises for 30 minutes prior to re-occupation. Ventilation would undoubtedly reduce the airborne concentration of dichlorvos. However, over a 3-day period, Schofield (1993) detected airborne dichlorvos within a bakery after it had been ventilated for 1 hour post-treatment, and also detected dichlorvos on workers' hands. Indeed, dichlorvos was still present in the building's atmosphere and on workers' hands a fortnight after a previous fumigation. Thus, even if a building is treated once, the occupants may be exposed for many successive days. If a building is treated repeatedly, occupants may be exposed continually. This precludes setting OHS NOELs for building occupants based on single dose exposure, and so the exposure and risk assessment must utilise the OHS dermal and inhalation NOELs already set in Section 4.5.2.

Persons re-occupying a fogger-treated workplace building are exposed to dichlorvos mainly by inhalation (Schofield 1993). Therefore, dermal exposure need not be taken into account in setting a re-entry interval for workplace building occupants.

Entry into treated areas before ventilation may not be necessary if the structure is ventilated mechanically, by means of an air conditioning system. However, if ventilation entails opening doors, windows or vents from inside, pest control operators would have to enter and remain within the premises for some time while doing so. This task would probably take only a few minutes, and would seldom exceed 30 minutes. The concentration of dichlorvos vapour to which a pest control operator would be exposed on re-entry can be estimated from Schofield (1993), in which a large industrial building was fogged with dichlorvos at a target concentration of 85 mg/m^3.

To maintain an acceptable inhalation MOE for a person entering a treated building prior to ventilation, a half-facepiece respirator should be worn. To assure an adequate inhalation MOE for workplace building occupants re-entering a premises treated with dichlorvos 50 LD/CO_2 at the Australian label rate of 33 mg/m^3, a re-entry interval of 4 days would have to be applied. Therefore, the OCSEH considers that dichlorvos should not be applied within industrial or similar buildings which are to be re-occupied within 4 days of treatment.

Re-entry into treated glasshouse or greenhouses

Workers re-entering treated glasshouses or similar plant production facilities would be exposed to dichlorvos by inhalation and dermal exposure, but the extent of exposure may not be the same as would occur in a large industrial building. The airborne concentrations of dichlorvos in treated glasshouses will be influenced by structure layout, temperature, airflow and photochemical degradation, all of which may vary from the conditions in other structures. Furthermore, workers may be exposed to dichlorvos from handling vegetation onto which dichlorvos has been deposited. However, this may not be a significant source of exposure if there is a delay between treatment and handling, given that only about 5% of dichlorvos applied on leaf surfaces remains on the surface after 20 minutes (WHO/IPCS 1971).

A person re-entering the treated glasshouse to ventilate it would be exposed by inhalation at approximately 1.25 mg/m^3 (Brouwer et al. 1992). If the duration of exposure were 30 minutes, the worst-case upper limit, the inhalation MOE would be acceptable if a half-facepiece respirator were worn.

To maintain an acceptable inhalation MOE for a person entering a treated glasshouse or similar plant production facility prior to ventilation, a half-facepiece respirator should be worn. To assure an adequate inhalation MOE for persons re-entering a glasshouse treated with dichlorvos 50 LD/CO_2 at the label rate of 33 mg/m^3, a re-entry interval of 4 hours has to be applied.

Re-entry into mushroom houses

Little information is available on the off-label use of dichlorvos 50 LD/CO_2 in mushroom production, except that the product is most often applied via fixed installations to spawning rooms after the rooms have been filled and sealed. Spawning rooms remain closed under controlled atmosphere for 10 days, during which time entry would not normally occur. It is unknown whether growers apply dichlorvos 50 LD/CO_2 at the label rate of 33 mg/m^3, or use a different rate.

The APVMA Agriculture Report indicates that mushroom growers may also apply dichlorvos during or after the growing or picking phases of production, which are undertaken in different rooms than spawning. However, a separate re-entry interval for use during growing and picking cannot be set because there are no suitable data for estimating the rate of dichlorvos dissipation under these circumstances.

A re-entry interval to support the use of dichlorvos 50 LD/CO_2 products in mushroom houses cannot be set at present because there is inadequate information on the rates of use or dissipation of dichlorvos in this situation.

Re-handling flowers after treatment in fumigation chambers

Dichlorvos 50 LD/CO_2 is used by some growers for fumigating cut flowers in sealed chambers. Although operators would not be exposed to dichlorvos during fumigation itself, they may be exposed dermally to small quantities of the chemical on the plants when removed from the chamber after treatment. Given that the plants would be handled immediately after fumigation, there would be little opportunity for any dichlorvos residues to degrade or be absorbed into and metabolised by the plants. Exposure to dichlorvos residues from this source could potentially reach unacceptable levels. A dermal exposure of 0.329 mg (or 0.23 µL volume) of dichlorvos is the highest to which an operator could be exposed without eroding the MOE below 10.

4.6 Residues

Products containing dichlorvos are registered for use in a variety of food situations. The maximum treatment regimes for crop and food uses and direct animal treatment of horses are listed in Table 8 below. Dichlorvos is also registered for use in treatment of animal housing, and in domestic, commercial and industrial situations such as warehouses, empty silos, factories, and wineries.

Table 8: Maximum treatment regime

CROP OR HOST	FORMULATIONS	RATE (AC)	WITHHOLDING PERIOD	METHOD OF APPLICATION
Avocados	500 g/L EC	500 g/ha	7 days	Foliar spray
Bagged and stored potatoes	500 g/L EC	1.56 g/bag	2 days	Surface spray
Glasshouses, greenhouses and	50 g/kg PG	0.075 g/m^3	2 days	Space spray, fog, mist, wooden board method

CROP OR HOST	FORMULATIONS	RATE (AC)	WITHHOLDING PERIOD	METHOD OF APPLICATION
mushroom houses	500 g/L EC			
Stored grain (cereal grain)	500 g/L EC 1140 g/L EC 1140 g/L LD	6 g/tonne 12 g/tonne 0.27 g/m^2	7 days 28 days 7 days	Spray to bulk Spray to bulk Surface spray
Horses	5 g/25 mL Paste	1 g/100 kg bw	28 days[6]	Oral drench

MRLs are the maximum concentrations of a chemical residue in or on a food, agricultural commodity, or animal feed where the residue results 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. The current Australian MRLs for dichlorvos are listed in Table 9 below. To ensure these MRLs do not pose an undue hazard to human health, the APVMA undertook a dietary exposure evaluation and risk analysis.

Table 9: Current Australian Maximum Residue Limits (MRLs) for dichlorvos

COMPOUND	FOOD	MRL (mg/kg)
Dichlorvos		
GC 0080	Cereal grains	5
SB 0715	Cacao beans [cocoa beans]	5
SB 0716	Coffee beans	2
MO 0105	Edible offal (mammalian)	0.05
PE 0112	Eggs	0.05
	Fruits	0.1
VD 0533	Lentil (dry)	2
VL 0482	Lettuce, Head	1
VL 0483	Lettuce, Leaf	1
MM 0095	Meat [mammalian]	0.05
ML 0106	Milks	0.02
VO 0450	Mushrooms	0.5
SO 0697	Peanut	2

[6] Slaughter withholding period.

COMPOUND	FOOD	MRL (mg/kg)
PO 0111	Poultry, Edible offal of	0.05
PM 0110	Poultry meat	0.05
SO 0495	Rape seed	T0.1
CM 1206	Rice bran, unprocessed	10
VD 0541	Soya bean (dry)	2
VO 0448	Tomato	0.5
TN 0085	Tree nuts	2
	Vegetables [except lentil (dry); lettuce, head; lettuce, leaf; soya bean (dry)]	0.5
CM 0654	Wheat bran, unprocessed	10
CF 1210	Wheat germ	10

The current Australian residue definition, for which the above MRLs apply, is:

Dichlorvos: Dichlorvos

4.6.1 Cereal grains

Wheat

In Australian trials, dichlorvos was applied to stored wheat grain according to Good Agricultural Practice. The application rate of 6 g ac/tonne has a 7-day withholding period and the application rate of 12 g ac/tonne has a 28-day withholding period.

The decline of dichlorvos in treated grain was dependent on the storage conditions. In one trial, wheat grain was stored at 0, 20 and 30°C for up to 8 weeks after treatment. In the grain stored at 0°C, dichlorvos residues declined by less than 15% after 4 weeks storage, however a more marked decline occurred in grain stored at 20°C or 30°C. Dichlorvos residues declined with an estimated half-life of approximately 7 and 2.5 days for grain stored at 20 and 30°C respectively.

The residue trials carried out at 20°C more accurately reflect actual conditions likely in Australian grain storage facilities than those carried out at 0 and 30°C. Therefore, it is appropriate to consider the residue data generated at 20°C for the purpose of establishing adequate MRLs for stored grains.

In a separate set of three Australian trials, wheat grain contained dichlorvos residues between 2.6 and 4.1 mg/kg at 7–10 days after application at 6 g ac/tonne. When treated at 12 g ac/tonne, dichlorvos residues of 1.4 and 2.2 mg/kg were detected in two grain samples at 28 days after treatment, and 5.3 mg/kg in another sample 10 days after treatment.

A number of residue trials on wheat and barley were evaluated by the Joint FAO/WHO Meeting on Pesticide Residues in 1993; dichlorvos was applied at close to Australian rates using an aerosol formulation. Only a tabulated summary of trial results was reported and full trial details were not available. Dichlorvos residues in cereals treated at 5.6–7.4 g ac/tonne ranged from 0.53–3.0 mg/kg at

0–1 day after application. Following application at 14–17.5 g ac/tonne residues ranged from 0.2–5.2 mg/kg at 21 days after treatment.

Rice

Four residue trials on rice were previously provided to the APVMA (then the NRA) in support of a permit application.

Of the four trials provided, two were at commercial rice storage facilities and two were laboratory scale experiments. Dichlorvos was applied to paddy rice[7] at 6 or 12 g ac/tonne then stored for up to 28 days after application, and samples were taken at various times during the storage period and analysed for dichlorvos residues. The results from the four trials are summarised in Table 10 below.

Table 10: Dichlorvos residue trial results from four studies in rice

TRIAL LOCATION	RATE	DICHLORVOS RESIDUES (mg/kg) AND WITHHOLDING PERIOD (days)							
		0	3-4	7	11-13	16-17	20-22	24	27-28
Griffith depot	12 g/t	11.4	11.6	4.1	7.4	12.1	7.0	5.8	5.2
Walsh depot	12 g/t	3.6	2.6	2.5	5.3		2.4	2.0	2.8
Lab 1	12 g/t	6.4	5.3	4.6	3.2	2.8	1.9		1.9
Lab 2	6 g/t	5.1	3.8	2.9					

Dichlorvos residues in treated paddy rice were variable but generally declined over time. At the 6 g ac/tonne rate, dichlorvos residues of 2.9 mg/kg were detected in paddy rice at 7 days after application. Residues of 5.2, 2.8 and 1.9 mg/kg were detected at 27 or 28 days after application at 12 g ac/tonne.

Residues in husked rice (brown or white rice) would easily comply with the cereal grains MRL. Processing factors for paddy rice to brown rice, and paddy rice to white rice, were 0.16 and 0.03, respectively.

Dichlorvos residues in cereal grains (wheat and rice) treated at 6 ppm (7-day withholding period) and 12 ppm (28-day withholding period) in Australian trials were, in rank order, 1.4, 1.9, 2.2, 2.8 (2), 2.9, 3.4, 4.1 and 5.2 mg/kg. A supervised trials median residue (STMR) of 2.8 mg/kg is estimated based on these data and was used in dietary assessment calculations.

In the trial conducted at Griffith, one sample contained dichlorvos residues slightly above the current cereal grain MRL of 5 mg/kg at 27–28 days after treatment. However, National Residue Survey (NRS) testing since 1988 indicates than only a very small percentage of samples tested contained dichlorvos residues above 2 mg/kg. There is no reasonable expectation that violation of the current cereal grain MRL of 5 mg/kg will occur, and therefore no change to the cereal grain MRL is recommended. The

[7] Paddy rice (also called rough rice) is the term used to describe the whole grain taken off the plant at harvest. This includes the hulls, bran and white rice.

withholding periods of 7 days for cereal grain treated at 6 g ac/tonne (6 ppm) and 28 days for grain treated at 12 ppm are appropriate.

According to current product labels, dichlorvos may be used as a surface treatment of stored grain at rates of up to 0.27 g ac/m^2. Grain may be retreated as often as necessary to prevent infestations, and no withholding period is specified on some product labels. If the bulk grain to be surface treated is assumed to be 1m^2 × 1m deep and the density of cereal grain is 500–750 kg/m^3, then surface application at 0.27 g ac/m^2 corresponds to between 0.36–0.54 g ac/tonne (i.e. 6–9% of 6 ppm rate). When dichlorvos is used as a one-off surface treatment of bulk grain at 0.27 g ac/m^2, it is unlikely that residues will exceed the cereal grain MRL of 5 mg/kg after treatment. However, the effect of repeated applications on residue levels in treated grain is unclear. Therefore it is prudent to recommend a 7-day withholding period, which is consistent with the label application rate of 6 ppm.

Currently, some product labels refer to 'stored grain', whereas others refer to 'stored cereal grain'. Grain, according to international definition[8], refers to starchy seeds produced by a variety of plants, primarily of the grass family (*Gramineae*). Therefore it does not include pulses or oilseed crops. To remove any confusion, the wording 'stored grain' on those labels should be changed to 'stored cereal grain'.

Based on evaluation of processing studies, it is apparent that dichlorvos residues are higher in outer layers of treated grains. The data support establishment of dichlorvos MRLs for unprocessed bran of cereal grain (20 mg/kg) and rice hulls (50 mg/kg).

MRLs are not required for other milled cereal grains or processed commodities as dichlorvos residues do not concentrate in significant amounts. Residues detected in these commodities must comply with the cereal grain MRL of 5 mg/kg. As associated outcomes of this review, MRLs for wheat bran, rice bran and wheat germ will be deleted from the MRL Standard as the unprocessed cereal grain bran MRL is satisfactory to account for residues in these commodities.

4.6.2 Pulses

There are Table 1 MRLs of 2 mg/kg established for lentils (dry), peanuts and soya beans. With respect to application of dichlorvos on these crops, there are no specific use-patterns approved. In past NRS monitoring conducted on pulses, a small number of samples had detectable dichlorvos residues present. This would suggest that there is a degree of confusion as to the use of dichlorvos on pulses. The existing grains use-pattern may be misinterpreted to include grains of pulses and oilseeds. As discussed in the previous section, only cereal grains should be considered under this use pattern, and appropriate labels should be amended to avoid any confusion.

No data have been provided to support the use of dichlorvos on pulses, or the MRLs for lentils, peanuts and soya beans. If there is a genuine need from the pulse industry for dichlorvos treatment, a clearly defined use-pattern and residue data should be provided to the APVMA for assessment. Without this support, MRLs for lentils (dry), peanuts, and soya beans will be deleted from the MRL Standard as associated outcomes of the review.

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[8] Codex Alimentarius commission, Guide to Codex Recommendations Concerning Pesticide Residues, Part 4, Codex Classification of Foods and Animals Feeds, 2nd Edition, Rome, 1989.

4.6.3 Potatoes

Dichlorvos is approved for use on stored and bagged potatoes at a rate of 50 mL product (25 g ac)/5 L water for every 16 bags, which corresponds to 1.56 g ac/bag. The application rate is ambiguous since the bag size to be treated is not specified. The use of dichlorvos on potatoes is covered by the Vegetables MRL of 0.5 mg/kg.

In the single trial available for the review, dichlorvos was applied to 8.7 kg of potatoes using a spray volume of 50 mL of a 0.2% dichlorvos solution. A theoretical maximum initial residue of 11.5 mg/kg in potato is calculated from this application rate. Initial dichlorvos residues of 1.1 mg/kg were detected.

Given the ambiguity of label directions it is unclear whether the above residue trial was carried out according to the Australian use pattern. Insufficient data are available for the purpose of establishing an appropriate MRL for potatoes. Due to public health and safety concerns of unknown dietary exposure, continued registration for potatoes cannot be supported without the provision of additional data. If there is a genuine need for continuation of dichlorvos treatment from the potato industry, they should clearly define the use-pattern and provide residue data to allow establishment of an appropriate MRL.

4.6.4 Mushrooms

Residue data for mushrooms available to the review was not derived from trials that were conducted according to Australian Good Agricultural Practice (i.e. fog application of up to 0.075 g ac/m^3, post-harvest interval of 2 days). Therefore the data are insufficient for the purposes of establishing an appropriate mushroom MRL. Due to public health and safety concerns of unknown dietary exposure, continued registration for mushrooms cannot be supported. The mushroom MRL of 0.5 mg/kg will be deleted from the MRL Standard as an associated outcome of the review.

4.6.5 Avocados

A single Australian residue trial on avocadoes was available for the review. In this trial, dichlorvos residues in whole fruit declined to below the limit of quantitation (0.02 mg/kg) one day after foliar application of 50 g ac/100 L spray solution to runoff stage.

The residue data available are insufficient for the purpose of determining an appropriate MRL for avocados. Due to public health and safety concerns of unknown dietary exposure, continued registration for avocados cannot be supported. The Fruits MRL of 0.1 mg/kg will be deleted from the MRL Standard as an associated outcome of the review.

4.6.6 Greenhouse and glasshouse crops

The use of dichlorvos in glasshouses and greenhouses represents approximately 1.7% of total usage of dichlorvos in Australia. Food commodities that may be grown in glasshouses and greenhouses include lettuce (head and leaf), tomato, cucumbers and capsicums. There were no residue data available to support treatment of these commodities.

Due to public health and safety concerns of unknown dietary exposure, use of dichlorvos on greenhouse and glasshouse crops cannot be supported. The MRLs for lettuce, tomato and vegetables will be deleted from the MRL Standard as associated outcomes of review.

The use of dichlorvos on ornamental crops grown under cover in greenhouses and glasshouses remains acceptable with respect to residue consideration.

4.6.7 Horses

Product No. 38847, Oximinth Plus Boticide Oral Worm and Bot Paste for Horses is registered for use as an oral paste in horses with application at 1 g ac/100 kg bw (equivalent to 500 ppm in feed assuming animals weighing 500 kg consume 10 kg dry matter per day). A slaughter (for human consumption) withholding period of 28 days applies to this use.

No residue data were provided to support this use. However, based on available metabolism and animal transfer data, dichlorvos residues are unlikely to be present in tissues when the product is used as directed. The continued use of dichlorvos for horses is supported. As no detectable residues are likely to occur in horse meat following this type of treatment, there is no MRL to meet.

4.6.8 Animal housing and pens

No residue data were provided to support this use. Based upon available metabolism and animal transfer data, no detectable residues of dichlorvos are likely to occur in animal commodities following this type of treatment. The continued use of dichlorvos for treatment of animal housing and pens is supported from a residues perspective. As an associated outcome of review, a Table 5 entry in the MRL Standard is recommended for dichlorvos treatment of animal housing and pens.

4.6.9 Silo treatment

Some of the registered products have dichlorvos treatment of empty silos to control adult grain pests. The labels use various descriptions such as ‘Empty grain silos’, or ‘Empty silos’, or ‘Silos’. For consistency, the labels should be amended to show treatment of ‘Empty grain silos’.

No residue data were provided to support this use. It is noted that treatment applied to empty grain silos is not likely to result in detectable residues in untreated grain, or to significantly increase the residue level of treated cereal grain stored in these facilities. This is based upon the high degree of volatility of dichlorvos and bulk volume storage capacity of such facilities. Any contamination remaining after treatment will be effectively dispersed and result in no detectable residues.

No labelling restraints are necessary with respect to residues following this use-pattern. As an associated outcome of review, a Table 5 entry in the MRL Standard is recommended for this type of treatment.

4.6.10 Residues in food from use of dichlorvos pest strips and residual sprays

Several registered products allow the use of dichlorvos as pest-strips or surface sprays to control insect pests in domestic and commercial premises, including food preparation areas.

The use of dichlorvos impregnated PVC pest strips in food preparation and storage areas has the potential to result in detectable dichlorvos residues in both uncooked food and prepared meals. In trials carried out in which dichlorvos pest strips were hung in food preparation and storage areas of domestic homes and commercial restaurants at the recommended rates, dichlorvos residues were detected at varying levels in a number of stored commodities and in prepared meals. In one trial, the highest dichlorvos residues were detected in apples (3.4 mg/kg) and cheese (1.0 mg/kg) after 28 days exposure, and in bacon (0.6 mg/kg) after 14 days exposure. These results were confirmed in a later trial where apples, cheese and cooked meats exposed to dichlorvos at label rates contained dichlorvos residues. It was postulated that commodities with fatty or waxy surfaces tend to accumulate the highest dichlorvos residues when exposed for extended periods.

The continued use of dichlorvos in pest-strips or surface sprays to control insect pests in domestic and commercial premises is supported. However, given the potential for significant dichlorvos residues to occur in food stored or prepared in areas containing dichlorvos pest strips, it is recommended that the restrictions be uniformly imposed on these products against use in food cupboards or food storage and food preparation areas.

4.6.11 Dichlorvos residues resulting from trichlorfon use

Registered products allow trichlorfon treatment on horticultural crops. Metabolism studies show that trichlorfon ((2,2,2-trichloro-1-hydroxyethyl) phosphonate) is transformed to dichlorvos to a minor extent in plants and animals, and *in vitro* in alkaline media. Potentially, the use of trichlorfon may result in detectable dichlorvos residues in trichlorfon-treated commodities or animals consuming trichlorfon treated commodities. As a consequence, the use of trichlorfon has been considered in this review.

The metabolism and residue behaviour of trichlorfon in both plants and animals have been reviewed by the Joint FAO/WHO Meeting on Pesticide Residues, in 1971, 1975, 1978 and 1987. A summary of these reviews is discussed here.

The conversion of trichlorfon to dichlorvos occurs in plants and animals to a very minor extent. No dichlorvos residues were detected in brain, heart, kidneys and fat of pigs 4 days after dosing with approximately 125 mg trichlorfon in drinking water (trichlorfon concentration in water was 1500 ppm). Following percutaneous administration of trichlorfon to sheep at 50 mg/kg bw, dichlorvos was detectable in only ‘slight’ amounts (actual levels not specified).

In one study, less than 5% of total trichlorfon residues were present as dichlorvos in blood and <2% in milk of lactating dairy cows administered trichlorfon at 20–45 mg/kg bw. In another study, cows were treated with a pour-on application of trichlorfon at 40 mg/kg bw. No dichlorvos residues were detected (<0.05 mg/kg) in any tissue except in fat close to the application site (0.142 mg/kg) 24 hours after treatment, but no dichlorvos residues were detected after 3 days. In a similar trial with the same treatment regime no dichlorvos residues were detected (<0.0025 mg/kg) in milk up to 7 days after treatment.

The metabolism of trichlorfon was studied in cotton plants (Bull and Ridgway 1969). Following foliar applications of trichlorfon to cotton leaves, less than 2% of total radioactive residues were dichlorvos. In other studies, strawberries, sugar beets and radishes were treated with trichlorfon (rate not specified) then analysed for trichlorfon and dichlorvos residues (Limit of Detection = 0.005 mg/kg). Dichlorvos residues 20–30 times lower than total trichlorfon residues were detected only in strawberries and in leaves of sugar beets and radishes.

Table 11 shows the Current Table 1 MRL Standard entries for trichlorfon, and the calculated maximum dichlorvos residue expected in that commodity (based on half of the trichlorfon MRL).

Table 11: Current Table 1 MRL Standard Entries for trichlorfon and the calculated maximum dichlorvos residue expected

	COMMODITY	CURRENT TRICHLORFON MRL (mg/kg)	CALCULATED MAXIMUM DICHLORVOS RESIDUE (mg/kg)
FI 0327	Banana	0.2	0.01
VR 0574	Beetroot	0.2	0.01
VB 0402	Brussels sprouts	0.2	0.01
MO 0812	Cattle, Edible offal of	0.1	0.005
MF 0812	Cattle fat	0.1	0.005
MM 0812	Cattle meat	0.1	0.005
VB 0404	Cauliflower	0.2	0.01
VS 0624	Celery	0.2	0.01
GC 0080	Cereal grains	0.1	0.005
DF 0167	Dried fruits	2	0.1
PE 0112	Eggs	*0.05	0.0025
	Fruits [except banana; dried fruits; peach]	0.1	0.005
VL 0480	Kale	0.2	0.01
ML 0106	Milks	0.05	0.0025
SO 0088	Oilseed [except peanut]	0.1	0.005
FS 0247	Peach	0.2	0.01
SO 0697	Peanut	0.1	0.005
VO 0051	Peppers	T0.5	0.025
PO 0111	Poultry, Edible offal of	*0.05	0.0025
PM 0110	Poultry meat	*0.05	0.0025
MO 0818	Pig, Edible offal of	0.1	0.005
MF 0818	Pig fat	0.1	0.005
MM 0818	Pig meat	0.1	0.005
VD 0070	Pulses [except soya bean (dry)]	0.2	0.01
VD 0541	Soya bean (dry)	0.1	0.005
VR 0596	Sugar beet	0.05	0.0025

	COMMODITY	CURRENT TRICHLORFON MRL (mg/kg)	CALCULATED MAXIMUM DICHLORVOS RESIDUE (mg/kg)
GS 0659	Sugar cane	*0.05	0.0025
VO 0447	Sweet corn (corn-on-the-cob)	0.2	0.01
TN 0085	Tree nuts	0.1	0.005
	Vegetables [except beetroot; brussels sprouts; cauliflower; celery; kale; peppers, pulses (dry); sugar beet; sweet corn (corn-on-the-cob)	0.1	0.005

Dichlorvos residues of ≤0.025 mg/kg are estimated for all trichlorfon-treated commodities except dried fruit, in which maximum dichlorvos residues were estimated at 0.1 mg/kg.

However, the calculated maximum dichlorvos residues are conservative and overestimate likely residues because:

- the calculations are based on the trichlorfon MRL, rather than a highest or median residue from residue trials
- dichlorvos is likely to account for less than 5% of total trichlorfon residues in treated produce
- the curing and drying process involved in drying fruit is likely to significantly reduce dichlorvos residues.

Therefore it is concluded that no detectable dichlorvos residues should occur in trichlorfon-treated commodities or in animal commodities resulting from the use of trichlorfon. With respect to the consideration of dichlorvos residues, The APVMA supports the continued use of products with trichlorfon in horticultural crops. There are no associated MRL outcomes of review with respect to trichlorfon use.

4.6.12 Other commodities

The current MRL Standard contains Table 1 entries for cocoa beans, coffee beans, and tree nuts. Currently registered products have no approved uses of dichlorvos on these crops. As there are no apparent uses of dichlorvos on these crops and no residue data, the MRLs will be deleted from the MRL Standard. Note that this amendment is not subject to the final review outcomes.

4.6.13 Animal transfer studies

Animal feeding studies in poultry, swine and horses and other trials (inhalation and topical administration) were available for review and are summarised below.

Oral studies

Hens were dosed with dichlorvos at 15 or 30 ppm in the diet (about 0.9 and 1.8 mg/kg bw/day) for 28 days then sacrificed on days 28 and 42. No dichlorvos residues were detected in tissues or eggs on the last day of dosing or 14 days after cessation of treatment.

Dichlorvos was administered to pregnant pigs at 4 mg/kg bw/day (about 100 ppm in feed, assuming animals weighing 60 kg consume 2.4 kg dry matter per day) for 28 days prior to birth. No dichlorvos residues were detected in tissues of the adult pigs or piglets at sacrifice after birth. Radioactivity present in tissues was attributed to normal cell components such as amino acids, proteins and glucose.

No dichlorvos residues were detected in tissues of pigs 2, 7 or 14 days after administration of a single oral dose of dichlorvos at 40 mg/kg bw (equivalent to 1000 ppm in feed), formulated as an impregnated PVC pellet. In another trial, dichlorvos was not detected in tissues of pigs administered dichlorvos directly into the lumen at 1 mg/kg bw/hour (total 99 mg dichlorvos) for 4 hours. Unchanged dichlorvos was recovered from the lumen.

In an unpublished report cited by Snelson (1987), it was reported that pigs dosed orally with dichlorvos at 9450 ppm in feed for 90 days contained no detectable dichlorvos residues in tissues 0 and 1 day after the last dose.

Horses orally administered dichlorvos/PVC slow release pellets at 37 mg/kg bw (*ca.* 1850 ppm in feed) as a single dose contained no detectable dichlorvos residues in tissues or organs 24 hours after the dose.

Topical applications

No dichlorvos residues were detected in milk (<0.003 mg/kg) or tissues (<0.002 mg/kg) of cattle given a topical spray application of dichlorvos at 1.1 mg/kg bw/day for 31 consecutive days.

Inhalation studies

Inhalation studies were carried out at dichlorvos concentrations of 0.05 to 90 μg/L. Dichlorvos was detected in tissues of rats exposed to atmospheric dichlorvos concentrations of 10 μg/L (about 250 times normal concentration) and above.

Although the animal transfer data are limited, but when considered as a whole, it is apparent that dichlorvos residues should not occur in animal tissues, milk or eggs following animal exposure to dichlorvos from direct (oral paste for horses) or indirect treatment (spraying of animal housing and pens, feeding of treated produce).

4.6.14 Animal feed commodities and animal MRLs

Cereal grains and milled cereal grain by-products may be used as animal feeds. It is assumed that cereal grains and processed grain fractions are up to 100% and 40% respectively, of livestock feeds.

The maximum daily intake of dichlorvos residues would occur if the following feed mixture were used (outlined in Table 12). The calculations are made based on a dry matter consumption of 20 kg/day and assuming each animal feed item contains dichlorvos residues at the MRL.

Table 12: Calculated dietary exposure to dichlorvos for cattle and poultry

SPECIES / FEED ITEM	FEED ITEM	MAXIMUM % IN FEED	FEED INTAKE kg/ANIMAL/DAY*	MRL mg/kg	INTAKE OF DICHLORVOS mg/ANIMAL/DAY
Cattle					
Cereal grain Fractions (total 40%)	Cereal bran	40%	8	20	160

Cereal grains (total 60%)	Grain	60%	12	6	72
				Total	**232 mg/animal/day**
Poultry					
Cereal grain Fractions (total 40%)	Cereal bran	40%	0.06	20	1.2
Cereal grains (total 60%)	Grain	60%	0.09	6	0.54
			0.15	**Total**	**1.74 mg/animal/day**

For cattle, the maximum dichlorvos intake is calculated at 232 mg/animal/day, which corresponds to 0.464 mg/kg bw/day or 11.6 ppm in the feed assuming a 500 kg body weight and feed intake of 20 kg dry matter per day. The maximum dichlorvos intake for poultry is calculated at 1.74 mg/animal/day, which corresponds to 0.87 mg/kg bw/day or 11.6 ppm in the feed assuming a body weight of 2 kg and feed intake of 0.15 kg dry matter per day.

Animal feeding and metabolism studies demonstrate that dichlorvos is rapidly and extensively eliminated: very little tissue residue retention occurs. Hens administered dichlorvos at 15 or 30 ppm in the diet for 28 consecutive days gave no detectable dichlorvos residues in tissues or eggs. When dichlorvos was administered to pregnant pigs at 4 mg/kg bw/day (about100 ppm in the feed) for 28 days no dichlorvos was detected in tissues of the adult pigs or in piglets when sacrificed at birth. Another study on pigs involved administration of dichlorvos as a single dose of slow-release dichlorvos-impregnated PVC pellets at 40 mg/kg bw (about 1000 ppm in feed). In this study, no dichlorvos residues were detected in tissues at 2, 7, or 14 days after administration.

On the basis of these studies, detectable dichlorvos residues are unlikely to be found in animal tissues, milk or eggs when dichlorvos is used in accordance with the approved use-patterns. As associated outcomes of review, MRLs will be established at the limit of analytical quantitation for edible offal (mammalian), eggs, meat (mammalian), milks, edible offal of poultry and poultry meat.

4.6.15 Fate of residues during frozen storage

No storage stability studies were provided for review in residue evaluations conducted by the NRA/APVMA, however some studies reviewed by the Joint FAO/WHO Meeting on Pesticide Residues (1993) and by Rowlands (1971, 1975) are discussed below. No storage stability data were available for commodities other than cereal grains.

Wheat samples with moisture contents ranging from 13 to 17% were fortified with dichlorvos at 24 mg/kg and stored at -15°C. After 2 months, 63% of the initial residue was lost. When stored at 5°C, 50% and 80% of the initial residue was lost after 7 and 30 days, respectively. In contrast, only between 2 and 22% of initial dichlorvos residues were lost from fortified samples of wheat containing 9.3–13.7% moisture and stored for 11 months at -15°C in a separate study.

In addition to stability studies on frozen samples, data on the stability of dichlorvos residues in cereal grains and milled products stored at 0°C were also available. Approximately 1-kg samples of wheat grain, flour and bran and chickpea grain were fortified with dichlorvos at between 1 and 12 mg/kg then stored for up to 8 weeks after treatment. After storage for 4 weeks at 0°C up to 40% of initial residues were lost, and after 8 weeks under the same conditions up to 75% of initial residues were lost.

Overall, it is apparent that the stability of dichlorvos residues may vary between samples stored under comparable conditions, and may be influenced by the moisture content of the sample. However, data generated on samples stored at 0°C suggest that dichlorvos residues are not as unstable as would be expected. This is supported by residue trials in which the decline of dichlorvos residues in grain and other commodities stored at ambient temperatures occurs relatively slowly.

4.6.16 Dietary exposure to dichlorvos

Chronic dietary exposure

The chronic dietary risk is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered and temporary uses of the chemical and dietary intake data from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with the Guidelines for Predicting Dietary Intake of Pesticide Residues (revised) (WHO 1997).

The NEDI is estimated at 23% of the ADI of dichlorvos (Appendix 2) and the results are summarised in Table 13.

These NEDI calculations are consistent with dietary survey results. The daily intake of dichlorvos estimated by the Australian Market Basket Survey (and the Australian Total Diet Survey) in 1990, 1992, 1994, 1996 and 2000 was less than about 2% of the ADI. It is concluded that the chronic dietary exposure to dichlorvos residues is below the toxicologically determined safe level (the ADI) and therefore should not present a health risk to consumers of treated produce.

Table 13: Chronic dietary risk (or NEDI estimate) for various commodities

COMMODITY †	% NEDI	COMMENT
CEREAL GRAIN FRACTIONS		
Cereal brans, processed	0.0	not consumed
Maize flour	0.2	cereal STMR 2.8 x wheat flour PF 0.1 x 15% treated
Maize meal	0.0	not consumed
Rice bran, processed	0.0	not consumed
Rye bran, processed	0.0	not consumed
Rye flour	0.0	not consumed
Rye wholemeal	0.0	not consumed
Wheat bran, processed	4.8	cereal STMR 2.8 x wheat bran PF 2.9 x 15% treated
Wheat flour	6.5	cereal STMR 2.8 x wheat flour PF 0.1 x 15% treated
Wheat germ	0.2	cereal STMR 2.8 x wheat germ PF 1.0 x 15% treated
Wheat wholemeal	2.7	cereal STMR 2.8 x wheat wholemeal PF 0.37 x 15% treated

COMMODITY †	% NEDI	COMMENT
EARLY MILLING PRODUCTS		
Bran, unprocessed	2.1	cereal STMR 2.8 x wheat bran PF 2.9 x 15% treated
Rice bran, unprocessed	0.0	
Rice, husked	0.0	not consumed
Rice, polished	0.0	nil residues after cooking
Rye bran, unprocessed	0.0	not consumed
Wheat bran, unprocessed	0.9	cereal STMR 2.8 x wheat bran PF 2.9 x 15% treated
CEREAL GRAINS		
Barley	0.2	cereal grain STMR 2.8 x 15% treated
Barley, beer only	0.0	nil residues after fermentation
Buckwheat	0.6	cereal grain STMR 2.8 x 15% treated
Maize	0.0	not consumed
Millet	0.0	cereal grain STMR 2.8 x 15% treated
Oats	4.5	cereal grain STMR 2.8 x 15% treated
Popcorn	0.1	cereal grain STMR 2.8 x 15% treated
Rice	0.0	nil residues after cooking
Rye	0.0	not consumed
Sorghum	0.0	not consumed
Wild rice	0.0	nil residues after cooking
Wheat	*0.0*	*not consumed*
ANIMAL COMMODITIES		
Edible offal (mammalian)	0.0	nil residues expected in animal commodities
Eggs	0.0	nil residues expected in animal commodities
Meat [mammalian]	0.0	nil residues expected in animal commodities
Milks	0.0	nil residues expected in animal commodities
Poultry meat	0.0	nil residues expected in animal commodities
Poultry, edible offal of	0.0	nil residues expected in animal commodities
TOTAL	22.8%	

† There are no residue data available to support MRLs for mushrooms, lettuce, tomatoes, and vegetables. Until there is appropriate residue data available, along with industry commitment for horticultural uses of dichlorvos, dietary exposure cannot be assessed for these commodities.

Acute dietary exposure

Based upon the amended ARfD of 0.1 mg/kg bw, the acute dietary risk to dichlorvos is estimated by the National Estimated Short Term Intake (NESTI) calculation encompassing all registered and temporary uses of the chemical, dietary intake data (97.5th percentile consumption figures) and mean body weights from the 1995 National Nutrition Survey. Calculations were made according to the method and formulae published by the Joint FAO/WHO Meeting on Pesticide Residues.

The summary of the NESTI calculations for the whole population (aged 2 years and older) and children aged between 2 and 6 years, is given below:

Table 14: Acute dietary risk (or NESTI estimate) for various commodities

COMMODITY †	WHOLE POPULATION, % ARFD	CHILDREN 2-6 YEARS, % ARFD	COMMENT
CEREAL GRAIN FRACTIONS			
Cereal brans, processed	0.0	0.0	not consumed
Maize flour	0.4	0.9	
Maize meal	0.0	0.0	not consumed
Rice bran, processed	0.0	0.0	not consumed
Rye bran, processed	0.0	0.0	not consumed
Rye flour	0.0	0.0	not consumed
Rye wholemeal	0.0	0.0	not consumed
Wheat bran, processed	3.9	2.8	PF 2.9 for bran x PF 0.5x for heat treatment
Wheat flour	1.2	2.9	
Wheat germ	0.6	0.5	
Wheat wholemeal	0.5	1.0	
EARLY MILLING PRODUCTS			
Bran, unprocessed	4.5	5.5	bran PF 2.9
Rice bran, unprocessed	2.5	0.0	not consumed
Rice, husked	0.0	0.0	not consumed
Rice, polished	1.5	2.7	brown rice PF 0.16
Rye bran, unprocessed	0.0	0.0	not consumed
Wheat bran, unprocessed	3.8	12.8	bran PF 2.9
CEREAL GRAINS			
Barley	0.7	2.0	
Barley, beer only	0.0	0.0	nil residues after

COMMODITY †	WHOLE POPULATION, % ARFD	CHILDREN 2-6 YEARS, % ARFD	COMMENT
			fermentation
Buckwheat	0.8	1.8	
Maize	0.0	0.0	not consumed
Millet	4.2	0.0	not consumed
Oats	0.1	0.2	PF 0.125x for heat treatment x 0.17 after hulling
Popcorn	2.1	2.8	PF = 0.5 with cooking
Rice	0.8	1.1	PF for brown rice
Rye	0.0	0.0	not consumed
Sorghum	0.0	0.0	not consumed
Wild rice	0.3	0.0	not consumed
Wheat	0.0	0.8	PF for brown rice
ANIMAL COMMODITIES			
Meat, mammalian	0.4	0.7	
Milk	0.6	1.5	
Offal, mammalian	0.1	0.0	
Poultry eggs	0.1	0.2	
Poultry meat	0.3	0.6	
Poultry offal	0.2	0.1	

† There are no residue data available to support MRLs for mushrooms, lettuce, tomatoes, and vegetables. Until there is appropriate residue data available, along with industry commitment for horticultural uses of dichlorvos, dietary exposure cannot be assessed for these commodities.
PF – processing factor

The highest acute dietary intake was estimated at 13% of the ARfD. It is concluded that the acute dietary exposure of dichlorvos is acceptable with respect to uses of dichlorvos where MRLs are supported.

4.6.17 Residues aspects of trade

The major commodities to be considered with regards to trade are the cereal grains. A summary of Australian exports of cereal grains for 2003–04 is outlined in Table 15.[9]

Table 15: Australian exports of cereal grains for 2003-04

	EXPORTS	
	VOLUME (kt)	VALUE ($MILLION)
Rice	690	82
Wheat (and flour)	17,987	4,068
Sorghum	502	98
Oats	206	37
Barley	6,643	1,348

The cereal grain MRL of 5 mg/kg recommended in this review is the same as the current Codex MRL.

Although the cereal grain residue data evaluated in this review suggests that residues could exceed 5 mg/kg in some instances when dichlorvos is used post-harvest on cereal grains, residue monitoring data generated over several years by the NRS indicate that violations of the MRL are highly unlikely when stored grain is treated according to Good Agricultural Practice. Since 2000, the number of samples with residue levels exceeding the Australian standard of 5 mg/kg has been decreasing. In 2000–01, there were 15 samples out of 1000 exceeding the standard. In 2003 and 2004, only one or two samples exceeded the standard from a total of about 5000 samples collected. The non-compliance rate is equivalent to <0.05%. The results indicate compliance to Good Agricultural Practice is very good, and unlikely to result in residues above the Australian standard.

In summary, when used as directed, dichlorvos residues are unlikely to exceed the current cereal MRL of 5 mg/kg. In addition, since the post-harvest use of dichlorvos on cereal grains is essentially unchanged, there is no change to the situation with regards to trade. It is concluded that the continued registration of dichlorvos is unlikely to unduly prejudice Australian trade in cereal grains.

Detectable dichlorvos residues are not expected to occur in animal commodities as a result of the post-harvest use of dichlorvos on cereal grains or from other approved uses. Therefore, the use of dichlorvos should not unduly prejudice Australian trade in animal commodities.

It is noted that monitoring performed by the Victorian Department of Primary Industries found no detectable residues of dichlorvos have been found in fruit and vegetable samples in 2004 and 2005.

[9] Source: Australian Commodity Statistics 2004.

4.7 Environmental assessment

Most uses of dichlorvos in Australia involve relatively little risk of exposure of terrestrial and aquatic environments as this pesticide is used to a large extent in non-agricultural production situations, in enclosed areas, or in slow release formulations. Significant use on crops in the field currently occurs only on avocados.

Most of the available studies conducted with dichlorvos are dated or are available as published literature only. Often they did not meet current regulatory standards, or details of the methods used were lacking. However, the available dichlorvos chemistry and fate results were generally similar between comparable reports and consistent with the expected chemical behaviour of the molecule. The available ecotoxicity results were generally comparable with results from other studies provided to the US EPA, which met their published guidelines.

The toxicity of dichlorvos to mammals is examined in the toxicology assessment in Section 4 of this report. The active constituent is imported, and formulation and packaging in Australia is expected to be in accordance with local environmental regulations, minimising environmental exposure and risks.

4.7.1 Environmental chemistry and fate

Hydrolysis

The hydrolysis of dichlorvos has been studied under a wide range of conditions. It is found to hydrolyse moderately to readily (half-life = 1–30 days) at 15–30°C and at pH values expected under ambient conditions (pH 4–9). The rate of hydrolysis is slowest under very acid (low pH) conditions and becomes increasingly rapid with increasing pH.

Photochemical transformation

The UV-absorption spectrum for dichlorvos indicates that direct photolysis should not occur under normal environmental conditions. Two dated aqueous photolysis studies provided some evidence to confirm this, at least in distilled water. However, while direct photolysis of dichlorvos is not expected under normal environmental conditions, indirect photolysis may occur in the presence of sensitisers in water or on various surfaces. For example, studies of dichlorvos photolysis on glass plates indicated degradation in the presence of UV radiation or sunlight (half-life of <20 hours). In outside air, dichlorvos is likely to be readily degraded (half-life <0.5 to 2 days) by reaction with hydroxyl radicals produced by photochemical reactions.

Degradation in soil

Two relatively modern aerobic soil degradation studies were conducted with ^{14}C-labelled dichlorvos using three soil types at 22°C. Degradation of dichlorvos occurred rapidly in non-sterile soils, with half-lives <1–2 days. Intermediate metabolites included desmethyldichlorvos, 2,2,-dichloroacetaldehyde and dichloroethanol. Further degradation continued at a similar rate, leading to mineralisation of the molecule (i.e. the metabolites broke down to form CO_2, water and salts). Degradation in soil sterilised by autoclaving was much slower (half-life of 8.7 days), and little mineralisation occurred during the 60-day incubation period. Thus soil microbial activity presumably leads to faster degradation of dichlorvos and is important for mineralisation. In another study, the half-life was only 25% longer (and still <1 day) in the absence of biological activity.

Rapid degradation was also reported in three earlier studies at 20–25°C with non-sterile soils, while two other studies indicated slightly longer half-lives (3–7 days at temperatures of 15–40°C). However, a further study indicated a longer half-life of approximately 16 days in two soils at 25°C. The degradation rate in the various studies was presumably affected by soil characteristics, incubation conditions and microbial activity.

Degradation in water

An aquatic metabolism study with dichlorvos in two water–sediment systems indicated rapid degradation of dichlorvos (half-life ≤ 1 day). Similar intermediate metabolites were identified to those found in soil studies and a high degree of mineralisation occurred within 16 days of application. Several studies suggest that in unsterilised water, degradation may be faster than occurs due to hydrolysis alone, and that microorganisms also enable the products of hydrolysis to degrade further.

Mobility

Dichlorvos is volatile from dry surfaces. However, it is also readily soluble in water and hence only very slightly to moderately volatile from moist surfaces or water.

Estimates calculated from the physicochemical characteristics of dichlorvos indicate that this chemical has high to very high mobility in soil. Thin layer chromatography studies suggest at least intermediate mobility. Brief reports of soil column leaching studies indicated no dichlorvos in leachate, suggesting limited mobility in soil despite leaching with the equivalent of 190 mm rain over a 2.25-day period. However, it is likely that extensive hydrolysis and microbial degradation of dichlorvos occurred during leaching and prior to measurement. The highly water-soluble metabolites of dichlorvos are expected to be even more mobile, but this may be limited by rapid mineralisation. A field experiment found dichlorvos penetrated soil to a depth of 30 cm within 5 days of application, suggesting significant mobility. It is concluded that while dichlorvos may be mobile in soil, it is unlikely to reach water tables or persist because of its rapid degradation through hydrolysis and microbial activity.

Dissipation following use

There is little specific information regarding field dissipation of dichlorvos. From the available evidence, it is considered that the direct application of dichlorvos on crops or animals would result in residues disappearing rapidly by volatilisation and hydrolysis in the atmosphere to dimethylphosphate and dichloroacetaldehyde. Other losses occur by absorption and hydrolysis on surfaces, and possibly diffusion into certain materials.

There is some information on the dissipation of dichlorvos and its aldehyde degradation product in unventilated mushroom houses. In this situation, the recorded peak concentrations of dichlorvos plus aldehydes were well below the potential peak concentration if all the applied dichlorvos volatilised rapidly without loss. This indicates incomplete and relatively slow volatilisation. After application by a fine spray into the space of the house, air concentrations declined rapidly over the measurement period. However, when dichlorvos was applied at a high rate to the floor, effective insecticidal concentrations remained in the air of the house for at least 5 days. The rate of dissipation was also affected by the nature of the surfaces treated, with dissipation most rapid from cement (half-life <1 h) and glass, slower from soil (half-life <3 days) and much slower from wood (39% remaining after 33 days).

Uptake and metabolism by plants

Dichlorvos has been found to dissipate rapidly from treated leaf surfaces, with a half-life of 4.6 to 6.8 hours, presumably due principally to volatilisation and hydrolysis. Enzymatic breakdown may also occur but a test using plant homogenates showed they did not hasten degradation. The dissipation rate from treated grain has been found to increase with increasing moisture content and increasing storage temperature. One study, for example, indicated half-lives of 7–20 days at 21°C with a moisture content of 9–14%.

Bioaccumulation

A bioconcentration and excretion study carried out on the fish species willow shiner *Gnathopogon caerulescens* indicated a low bioconcentration factor (BCF) for dichlorvos (BCF ≤1.2). This is consistent with a calculation based on water solubility (BCF = 3). Hence dichlorvos is not expected to bioaccumulate in fish exposed to residues in water.

Conclusions

Dichlorvos is likely to dissipate rapidly in most situations where it is exposed to air, soil and water, due to volatilisation, hydrolysis and microbial degradation. Dichlorvos vapours are not expected to persist in air due to degradation and loss by various means. Residues in soil and water are expected to break down to less toxic metabolites due to hydrolysis and degradation by microorganisms. Mineralisation to CO_2, water and salts is expected through microbial activity.

4.7.2 Ecotoxicity

Birds

Dichlorvos rates as highly to very highly toxic to birds, with the median lethal dose (LD50) ranging from about 5 to 42 mg/kg bw for 11 species. Available studies indicated that the median lethal concentration (LC50) with the standard 8-day dietary exposure test ranged from 298 to 568 ppm for Japanese quail and ring-necked pheasant, to >1317 and >5000 ppm for mallard ducks. Studies with domestic fowl exposed to dichlorvos in their diets for 28 days indicated a dietary LC50 value of 500 ppm. Thus the acute and subacute dietary toxicity of dichlorvos to birds ranges from slight (LC50 in the range 1001–5000 ppm) to high toxicity (LC50 in the range 51–500 ppm).

No early-life or reproductive studies were provided, but the 28-day dietary studies with domestic fowls above indicated effects such as reduced food consumption and depression of egg production at dietary concentrations as low as 30–50 ppm.

Studies gave some indication of the toxicity of dichlorvos by inhalation, but did not indicate specific values for harmful concentrations. There have been reports of mortality in domestic fowl, mallard ducks and English game bantams arising from accidental exposure to residues in grain, feed water or pellets present in horse manure (a formulation not registered in Australia). These indicate a need for caution in handling and using dichlorvos in situations where birds might be exposed.

Aquatic organisms

Fish

In general, studies showed that with acute exposure (up to 4 days), dichlorvos is highly toxic (LC50 in the range 0.1–1 mg/L) to moderately toxic (LC50 in the range 1 to 10 mg/L) to fish. A few reports indicated slight toxicity (LC50 in the range 10–100 mg/L). Data available on the chronic toxicity of dichlorvos indicated a 60-day Maximum Acceptable Toxicant Concentration (MATC) to carp of 1 6–20 μg/L, and a 30-day MATC for African catfish of 36.7 μg/L. Various studies have shown biochemical effects on fish at sublethal concentrations. However, as dichlorvos was found to be much less toxic to fish species (for example, salmon) than to their parasites (for example, salmon louse) it has been used widely to control parasites in finfish culture. As yet this is not a use in Australia.

Aquatic invertebrates

The range in acute toxicity (LC50) of dichlorvos to aquatic invertebrates from studies with a range of freshwater, estuarine and marine crustacea, molluscs and aquatic insects was 0.066 μg/L to 881 μg/L for exposure of 24–96 hours. Dichlorvos was in most cases very highly toxic (LC50 <0.1 mg/L) and sometimes highly toxic (LC50 0.1–1 mg/L) to the species tested. Thus the acute toxicity of dichlorvos is in most cases much higher to aquatic invertebrates than it is to fish.

Available data on the chronic or reproductive toxicity of dichlorvos to aquatic invertebrates include a study with a water flea, *Daphnia magna*. In this study, the NOEC for adult immobilisation, total cumulative number of young and mortality of young up to 14 days was the highest concentration tested, 0.00256 μg/L. However, there was a significant delaying effect of dichlorvos on the length of time for the appearance of the first brood at a lower concentration of 0.00064 μg/L. Thus dichlorvos may have subtle effects on aquatic invertebrate populations at concentrations well below lethal levels. Studies with the common lobster *Homarus gammarus* indicated a 23-day LC50 of 1.25 μg/L and 23-day NOEC of 0.63 μg/L. Various studies have also shown biochemical effects on other aquatic invertebrates at sublethal concentrations

A study with the alga *Scenedesmus subspicatus* indicated an EC50 based on 96-hour biomass production of 52.8 mg ac/L. This indicates that dichlorvos is only slightly toxic to algae (EC50 10–100 mg/L). No studies investigating dichlorvos toxicity in aquatic plants are available but it is presumed to have similar toxicity to that found with algae.

Amphibians

The 48-hour LC50 for an EC formulation of dichlorvos to tadpoles of the toad *Bufo japonicus* was 76 mg/L, presumably expressed in terms of active constituent concentration. The US EPA AQUIRE database lists 48-hour LC50 values to the frog species *Rana hexadactyla* and *Rana limnocharis* of 9.7 and 10 mg/L, respectively. This limited evidence suggests that dichlorvos residues in water are slightly to moderately toxic to amphibians (LC50 10–100 mg/L or 1–10 mg/L, respectively).

Terrestrial invertebrates

Dichlorvos is an insecticide and acaricide used to control a wide range of arthropod pest species with respiratory, contact and stomach action. It is therefore expected to be toxic to a wide range of terrestrial invertebrates. Laboratory tests have shown that it is highly toxic (LD50 <1.0 μg/bee) to honey bees *Apis mellifera*. Topical application or oral dosing gave LD50 values ranging from 0.052 μg/bee to approximately 0.9 μg/bee, and the LD50 resulting from residues on foliage was approximately 0.2 kg ac/ha. A laboratory study indicated a 14-day LC50 of dichlorvos to the earthworm *Eisenia foetida* of 80.9 mg/kg dry soil, with a NOEC <12.3 mg/kg. There were some problems with this study but it suggests dichlorvos has a moderate toxicity to earthworms. Literature reports also indicate that dichlorvos is highly toxic to *Apanteles plutellae*, a parasite of the Diamond Back Moth, and to the predatory mite *Amblyseius longispinosus*.

Microorganisms

From a range of evidence, it may be concluded that dichlorvos generally has low toxicity to soil and sewage microorganisms.

Conclusions

In birds, dichlorvos is highly to very highly toxic following a single oral dose and has slight to high toxicity with acute and subacute dietary exposure. With acute exposure (24–96 hours), dichlorvos generally has moderate to high toxicity to fish, but in most cases it is highly to very highly toxic to aquatic invertebrates (48-hour EC50 to water fleas as low as 0.066 μg/L). It is only slightly toxic to algae and generally has low toxicity to soil and sewage microorganisms. Dichlorvos is an insecticide and acaricide used to control a wide range of arthropod pest species with respiratory, contact and stomach action. It is therefore expected to be toxic to a wide range of terrestrial arthropods coming in contact with the spray, vapours or fresh residues. High toxicity to honey bees and to certain parasitic and predatory species has been confirmed. Tests indicate that dichlorvos is moderately toxic to earthworms exposed to soil residues.

4.7.3 Environmental risk assessment

Risk from vapour release to the atmosphere

Dichlorvos is volatile and a significant proportion of the applied substance is expected to vaporise and enter the external atmosphere, but it is expected that emissions of dichlorvos to the external atmosphere will dissipate rapidly through dilution, degradation and removal in precipitation and that atmospheric concentrations will remain well below toxic levels.

Risk to birds

Agricultural spray application and outdoor misting and fogging applications

Dichlorvos could be toxic to birds by inhalation, absorption through the skin and ingestion through preening of contaminated feathers or consumption of contaminated fruit, foliage or insects. A risk assessment of the use of dichlorvos in avocados indicates that residues of dichlorvos in treated orchards are unlikely to result in toxicity to birds or mammals by dietary exposure. Use of dichlorvos in avocado orchards as described could present a risk to birds and mammals such as flying foxes if they are directly exposed to spray or spray drift or enter freshly sprayed trees while they are still wet. However, this risk is relatively low, as avocados are not Australian natives and do not carry attractive ripe fruit, birds present are likely to be disturbed by the noise and disruption from spraying, and residues are likely to dissipate rapidly.

Some risk to birds could also arise with fogging or misting of dichlorvos in outdoor situations such as refuse and garbage areas, and picnic and recreational areas, but again disturbance from spraying operations is likely to remove birds from the vicinity. Use on refuse and garbage areas is likely to be of minimal environmental significance, provided wind does not carry drift to sensitive areas, though in some cases recreational and picnic areas could be near sensitive environmental locations.

Other uses

There are reports of birds having been poisoned through consuming grain treated with dichlorvos, drinking water containing dichlorvos, and in one case, through consuming pellets containing dichlorvos deposited in manure.

Concentrations on bulk grain freshly treated with dichlorvos are expected to be well below dietary LD50s for birds and comparable in magnitude to the NOEC from various dietary and reproductive studies. It appears that harmful exposure may have followed accidental or deliberate contamination of grain at much higher concentrations than those normally used, or consumption of freshly treated grain from only the surface layer of grain. Care to clean up spilt grain (around augers) is therefore indicated, while adequate safety to birds or other animals should be provided where treated grain is not moved until the withholding period for human or animal feed consumption is reached.

Risk to aquatic organisms

The aquatic risk from dichlorvos was assessed on the basis of its use in avocados at an application rate of 500 g ac/ha through an airblast sprayer. Direct application to a shallow water body presented an unacceptable risk of harm to aquatic invertebrates and also potentially to fish, and a 10% drift scenario presented an unacceptable risk to aquatic invertebrates, but a mitigable risk to fish. Concentrations in a 15 cm deep water body downwind of a sprayed area were estimated using the AgDRIFT™ model. At 100 metres and 200 metres downwind, estimated dichlorvos concentrations were 0.49 and 0.24 µg/L (0.15% and 0.07% drift) respectively, exceeding the EC50 for the most sensitive organism (waterfleas, 48-hour EC50 = 0.07 µg/L) by a factor of 7.4 and 3.6, respectively, but well below toxic levels to fish. Consideration of mitigating factors such as deeper water (30 cm) and dissipation from the contaminated water did not reduce the risk to aquatic invertebrates from spray drift adequately. It is considered that the longer buffer distance that would be needed to protect aquatic organisms from drift would be impracticable. Hence it is recommended that use of dichlorvos for leaf roller control in avocados be deleted from product labels.

There is also a potential risk to aquatic organisms from dichlorvos if it reaches water from other uses, by drainage following spray application in storage areas or glasshouse and greenhouses.

Risk to non-target terrestrial invertebrates

Bees and other non-target arthropods

The use of dichlorvos in field situations (orchards, refuse and garbage areas, recreational and picnic areas) is likely to be toxic to any arthropods exposed, including bees and insect predators and parasites, predominantly in the air and in plant canopies. However, the risk from dichlorvos is only expected to be transitory. Hence labels should warn dichlorvos is dangerous to bees and will kill bees and other pollinators foraging in the area sprayed or in hives that are over-sprayed or reached by spray drift.

Very little or no dichlorvos is expected to remain in horse faeces after administration of the worming paste. Any residues would continue to decline rapidly due to hydrolysis and microbial degradation. Hence little or no toxicity is expected to dung beetles or their larvae from residues in horse manure, with at most minor effects on local populations.

Earthworms

Expected concentrations in soil reached directly by spray at the rate of 500 g dichlorvos/ha would be 0.7 mg/kg if confined to the surface 5 cm of soil. Furthermore, dichlorvos is likely to dissipate rapidly from the soil and foliage surfaces, minimising residues moving into the soil. In the case of application to poultry manure, even if dichlorvos did not dissipate before spreading and incorporation into soil, concentrations would be similarly low. In both cases, the expected maximum soil concentration is well below the 14-day LC50 of dichlorvos to the earthworm *Eisenia foetida*. With other uses of dichlorvos the potential for exposure is low, hence little risk posed to earthworms from non-field use of dichlorvos.

Terrestrial plants

In the few field use situations where dichlorvos is used, application from ground-based equipment is unlikely to lead to direct over spray of non-target vegetation and lower rates from spray drift are unlikely to cause phytotoxicity.

Conclusions of the environmental assessment

The overall environmental risk from the use of dichlorvos products in Australia is expected to be minimal. It is highly volatile and dissipates in the environment rapidly. Most uses of dichlorvos in Australia involve relatively little risk of exposure of terrestrial and aquatic environments, as this pesticide is used to a large extent in non-agricultural production situations, in enclosed areas and in slow release formulations such as pest-strips. Significant use on crops in the field currently occurs only for the control of leaf rollers on avocados and it is recommended that this use be deleted from product labels as an impracticably large spray drift buffer would be needed to protect aquatic organisms. Concerns arising from this use also apply, but to a much lesser degree, to the application of dichlorvos to outdoor recreational areas.

All other uses are supported from the environmental viewpoint but labels generally require updating to current standards.

4.7.4 Label warnings for environmental protection

In order to minimise risks to terrestrial and aquatic species from direct spray or spray drift and to reduce other risks to the environment from the use of dichlorvos, all labels should be revised to include warnings appropriate to the type of product and uses listed on the label. This particularly applies to products, which may be used outdoors or may lead to drainage containing residues reaching the external environment.

4.8 International regulatory status

The European Union made a decision in 2006 not include dichlorvos in Annex 1, the list of active constituents approved for continued use in the European Union. This followed a review of the chemical, which concluded that it was not possible to define a technical specification for dichlorvos owing to a poor data package and dossier. If any registrant was interested, they could supply the missing data and apply for inclusion of dichlorvos in Annex 1 at any time.

Unlike the European Union, the US EPA determined that it had sufficient information on the human health and ecological effects of dichlorvos to make interim decisions. Pending completion of the organophosphate cumulative risk assessment, the US EPA determined that dichlorvos was eligible for re-registration. It released the Interim Registration Eligibility Decision document for dichlorvos in 2006. As a result, most uses in and around homes are no longer permitted. The home-related uses that remain are pressurized aerosol spray cans, pet collars and a limited use of dichlorvos pest strips; these remain because the most recent analyses available to the US EPA show these can be used safely. Various foggers, crack and crevice, lawn, turf, and ornamental plant uses are no longer permitted. The uses of two larger sizes of pest strips will also be phased-out.

The Canadian regulatory authority, the Pest Management Regulatory Agency, initiated a review of dichlorvos in 1999. At the time of this review, ‘The Proposed Acceptability for Continued Registration’ document was in preparation. The details of recommended regulatory path will not be known until this document is published.

Pest Management Regulatory Agency took measures to effect reformulation of pest strip products and changes to use directions (to restrict use to areas that are generally unoccupied) for domestic products. It is also requiring registrants to make changes to certain dichlorvos product labels to limit user exposure (http://www.pmra-arla.gc.ca/english/pdf/rev/rev2008-04-e.pdf).

The Joint FAO/WHO Meeting on Pesticide Residues scheduled dichlorvos for review of toxicology and residues in 2011.

4.9 Protected data

At the commencement of the review, registrants were required under s.32 of the Agvet Code to provide data and information to the APVMA that is relevant to the reconsideration. The Agvet Codes provide that a person who authorised the use of protected information by the APVMA in conducting the review of the continued approvals or the registration of a product of another party may be eligible to receive compensation from that other party. Protected information remains protected for a period of time determined by the regulations to the Agvet Codes. The APVMA must not use protected information to support the approval (or the continued approval) of another, active constituent for a proposed or existing chemical product or registration (or the continued registration) of another chemical product, unless the two parties have agreed as to the terms of compensation to be paid by the registrant of that other chemical product to the owner of the protected information. Data that were relied on for the reconsideration and the periods of protection are listed in Table 16.

Table 16: Protected data that was relied on for the reconsideration

DATA NO.	AUTHOR (S)	TITLE	DATE	DATA PROTECTED UNTIL	AUTHORISING PARTY
DPS 5576	Debruyne, E.	Carbaryl 52-Week Toxicity Study In The Cd1 Mouse Target Organs Cell Cycling Assessment	1998	12 November 2006	Bayer CropScience Pty Ltd
DPS 5577	Irisarris, E.	Carbaryl 52-Week Toxicity Study In the Rat And Mouse Target Organs Cell Cycling Assessment Pathology Report (Post-Mortem)	1996	12 November 2006	Bayer CropScience Pty Ltd
DPS 5622	Hamada, N.	One-Year Oral Toxicity Study In Beagle Dogs With Carbaryl Technical	1997	10 December 2007	Bayer CropScience Pty Ltd
DPS 7726	Austin, E.W.	E.W.4-Week Repeated-Dose Dermal Toxicity Study With Carbaryl Technical In Rats	2002	21 May 2006	Bayer CropScience Pty Ltd

5 REVIEW OUTCOMES AND REGULATORY DECISIONS

On the basis of the evaluation of the submitted data and information (including protected information), the APVMA has taken the following regulatory action with regard to the continued registrations and approvals of dichlorvos use in Australia.

1. Affirm active constituent
2. Vary conditions of label approval
3. Affirm product registrations
4. Cancel product registrations

5.1 Affirm active constituent

Based on the data provided the APVMA is satisfied that the active constituent dichlorvos meets the requirements for continued approval. It is recommended that the active constituent approvals for dichlorvos be affirmed.

5.2 Vary conditions of label approval

5.2.1 Label variations that do not include changes in use patterns

The APVMA was NOT SATISFIED that labels for products listed in Table 17 contained adequate instructions in relation to the criteria set out in s.14(3)(g) of the Agvet Codes. However, these labels can be varied to satisfy the APVMA, in accordance with s.34(5) of the Agvet Codes.

Once the label variations have been made the APVMA can be SATISFIED that labels contain adequate instructions. On this basis the APVMA can also be SATISFIED that continued registration of the product in accordance with its instructions for use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely 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.

On this basis the registration of products in the following table have been AFFIRMED.

Table 17: Product registration to be affirmed with label variations

PRODUCT NO.	PRODUCT NAME	REGISTRANT	EXISTING LABEL APPROVAL NO.	NEW LABEL APPROVAL NO.
38847	OXIMINTH PLUS BOTICIDE ORAL WORM AND BOT PASTE FOR HORSES	VIRBAC (AUSTRALIA) PTY LTD	38847/1200	38847/0111
47695	BINKILL	LAZCO INVESTMENTS PTY LTD	47695/1108 47695/0602	47695/0111 Cancelled
59750	KILLMASTER ZERO PEST STRIP	BARMAC INDUSTRIES PTY LTD	59750/1006	59750/0111

5.2.2 Label variations that include deletion of use pattern

As an outcome of the review, changes to approved labels have been recommended. These changes are detailed in sections 5.2.3, 5.2.4 and 5.2.5 below.

5.2.3 Deletion of use patterns

1. Because of public health and safety concerns of unknown dietary exposure:
   - Delete post-harvest use of dichlorvos on pulses, and use on avocados, mushrooms, potatoes, and greenhouse and glasshouse crops excepting ornamentals.
2. Because of the likelihood of toxicologically unacceptable levels of operator exposure:
   - Delete use patterns involving surface spray; space spray; crack and crevice treatment; outdoor and indoor application by fogging or misting; mechanical application to grain; pressurised gas in enclosed spaces where the operator must enter the space under fumigation; portable fogging or misting equipment in enclosed spaces where the operator must enter the space under fumigation; application by watering can; application by the wooden board method; application by paintbrush; and broadacre application to avocados.
3. In order to minimise risks to terrestrial and aquatic species from direct spray or spray drift and to reduce other risks to the environment from the use of dichlorvos:
   - Use for the control of leaf rollers in avocados should be deleted from the label, as an impractically large buffer would be needed to protect aquatic invertebrates from spray drift.

5.2.4 Interim use and additional data requirements

1. By applying risk mitigation measures to bring modelled OHS risk down to acceptable levels, the APVMA will allow for grain fumigation uses to continue during an interim use period. These measures will include additional label restraints, developed in consultation with the Australian stored grains industry and the OCSEH. The APVMA will allow interim use for a period sufficiently long enough to generate occupational exposure data to establish safe use parameters.
2. Since no information on the actual measured exposures arising from use in the grains industry are available, the OCSEH's advice to the APVMA was based on modelling the 'worst-case' scenario. The APVMA concluded that, by applying strict restraints and control measures to mitigate OHS

risk, it could support uses essential to the grain industry for an interim period. Additional label restraints will be required to bring OHS risks down to acceptable levels.

3. The APVMA will exercise its data call-in powers (s.33 of the Agvet Codes) and call for worker exposure data in relation to grain protection uses. This will be to investigate the validity of the modelled risk assessment and provide measured exposure data, which, if acceptable in terms of OHS risk, will allow ongoing use of dichlorvos in the grains industry.

5.2.5 Additional label statements

1. Because of public health and safety concerns of unknown dietary exposure:
    - With respect to the use of dichlorvos on stored grain, amend product labels to specify that dichlorvos is to be used only on stored cereal grains.

      Amend the descriptions ‘empty silos’ and ‘silos’ to ‘empty grain silos’.
    - With respect to grain or surfaces treated at 6 ppm dichlorvos, include instructions for withholding periods as below:

      ‘DO NOT use treated grain for human consumption (or stockfeed) within 7 days of treatment.’

      ‘DO NOT outturn treated grain within 7 days of treatment.’
    - With respect to grain or surfaces treated at 12 ppm dichlorvos, include instructions for withholding periods as below:

      ‘DO NOT use treated grain for human consumption (or stockfeed) within 28 days of treatment.’

      ‘DO NOT outturn treated grain within 28 days of treatment.’
2. Because of the likelihood of unacceptable dietary exposure, with respect to pest strips and residual sprays, add the restriction:

      ‘DO NOT use in food cupboards or food storage and food preparation areas.’
3. Because of the likelihood of toxicologically unacceptable levels of operator exposure -
    - Add the restraining statement:

      ‘DO NOT use this product in buildings (other than glasshouses and similar plant production facilities) that are likely to be re-occupied within four days of fumigation.’
    - Specify a re-entry period of 4 hours for glasshouses and similar plant production facilities.
    - Amend Safety directions to bring them in line with entries in the current First Aid Instructions and Safety Directions Handbook.
4. Amend label instructions for all products to bring them in line with contemporary standards with respect to risks to terrestrial and aquatic species from the use of dichlorvos:
    - Risk to birds: Labels pertaining to any use on grain should specify that spilt grain potentially containing dichlorvos residues should be cleaned up promptly, particularly around augers where application has been made during transfer.
    - Risk to aquatic organisms: Various labels are unsatisfactory in instructions and warnings regarding use and labels generally need to be made more consistent. The following warnings should be added or amended on product labels as relevant to retained uses with each formulation:
        - All products should contain suitable label warnings under ‘Protection of Wildlife, Fish, Crustaceans and Environment’ alerting users to the toxicity of dichlorvos to aquatic

organisms and stressing the need to avoid contamination of streams, rivers or other water bodies with dichlorvos by any means which might arise with the particular product, including direct spray, spray drift, concentrate, used containers, and spray mix residues or rinsate. Label statements may need to be altered to suit various products according to the particular formulation, including warnings such as the following:

All EC or liquid formulations should carry the warning:

'DO NOT contaminate streams, rivers or waterways with the chemical or used containers or rinsate.'

All products which might be used in field situations, including avocado orchards, refuse and garbage areas, picnic and recreational areas, etc., should carry the following spray drift warning:

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

- To minimise the risk of the pesticide entering run-off water by excessive spraying (particularly where surfaces are sprayed directly, as in empty silos) or by application followed by rain, washing or irrigation before spray residues have dried, suitable statements should be added to all labels, drawn from the following and adapted as necessary:

  'Avoid excess spraying causing run-off from treated surfaces into untreated areas.'

  'Allow treated areas to dry before washing (or irrigating).' (with any use in glasshouses, greenhouses, animal houses, meatworks etc where washing or irrigation may occur)

  'Do not apply to exposed areas if rain is expected within 4 hours.' (any outdoor use)

  'Do not allow drainage water from freshly treated areas to contaminate streams, rivers or waterways.' (any indoor or outdoor areas where drainage water may be produced)

5. Bee and non-target terrestrial invertebrate hazard:
   - All products used in outdoor situations (at least in avocados and recreational/picnic areas) or in glasshouses and greenhouses where plants are present and bees may be used should have a warning such as the following included under 'Protection of livestock,' in accordance with current APVMA policy to indicate the risks to bees rather than provide advice as to how those risks should be managed:

     'Dichlorvos is dangerous to bees and will kill bees foraging in sprayed areas or in hives which are over-sprayed or reached by spray drift.'

   - To avoid unnecessarily drenching the general vicinity of European wasp nests and minimise harm to soil dwelling invertebrates, advice on labels regarding control of European wasps should be made consistent in warning that the product should not be applied to areas other than the nest openings, including trees, ground, rockeries or buildings (compare with David Gray's DDVP 500 Insecticide label).
   - In regard to the use of dichlorvos on plants, a warning to indicate the potential impact of application on insect and mite predators and parasites should be provided, for example:

     'This treatment may harm predators and parasites – check compatibility with IPM programs.'

5.2.6 Summary

A summary of the above label changes by crop and pest is listed in Table 18.

Table 18: Summary of label changes by situation and pest

SITUATION	PEST	RECOMMENDATIONS
Post-harvest use of dichlorvos on pulses, and use on avocados, mushrooms, potatoes, greenhouse and glasshouse crops excepting ornamentals	Aphids, thrips, spider mites, whiteflies, caterpillars, sciarid flies, Avocado leaf roller, Ivy leaf roller, Potato tuber moth	Because of public health and safety concerns of unknown dietary exposure. **Delete from labels**
Avocados	Avocado leaf roller, Ivy leaf roller	Because of the likelihood of toxicologically unacceptable levels of operator exposure. **Delete from labels**
Household, animal housing, milk and meat processing facilities Grain storage structures	Flies, mosquitoes Grain storage pests	Because of the likelihood of toxicologically unacceptable levels of operator exposure as a 500EC formulation. **Delete from labels**
Stored cereal grain (mechanical application only) Infested grain held by flour millers	Stored grain insect pests	Because of the likelihood of toxicologically unacceptable levels of operator exposure. **Delete from labels**
Industrial including factories, warehouses and domestic premises	Flies, mosquitoes, moths, cockroaches, ants, silverfish.	Because of the likelihood of toxicologically unacceptable levels of operator exposure from application as a dichlorvos/CO_2 space spray (indoor use, unless using fixed installations). **Delete from labels**
Factories, abattoirs, stores, mills, warehouses Glasshouses and mushroom houses Wineries Stable, piggeries Tobacco stores and warehouses OUTDOORS: Garbage dumps, beach, picnic and recreation areas, drive-in cinemas	Cigarette beetle, tobacco moth, tropical warehouse moth, saw-toothed grain beetle, grain insect pests, flies, carpet beetles, ants, Mediterranean flour moth, mosquitoes, fleas, cockroaches, whiteflies, spiders, aphids, thrips, silverfish, vinegar flies.	Because of the likelihood of toxicologically unacceptable levels of operator exposure from application as a space spray, fogging or misting (outdoor and indoor). **Delete from labels**
Tobacco stores and warehouses Greenhouses Glasshouses Mushroom houses	Tobacco moth, Cigarette beetle, Insect pests (including aphids, thrips)	Because of the likelihood of toxicologically unacceptable levels of operator exposure from application using the wooden board method. **Delete from labels**

Indoors, dairies, cattle sheds, stables, piggeries, abattoirs, factories, stores, food warehouses, wineries, household.	Tropical warehouse moth, saw-toothed grain beetle, flies, carpet beetles, ants, Mediterranean flour moth, mosquitoes, fleas, cockroaches, spiders, silverfish, vinegar flies, European wasps, bees.	Because of the likelihood of toxicologically unacceptable levels of operator exposure, add the restraint 'DO NOT use this product in buildings (other than glasshouses and similar plant production facilities) that are likely to be re-occupied within four days of fumigation'. **Amend labels**
Glasshouses and similar plant production facilities	Insect pests including aphids and thrips.	Because of the likelihood of toxicologically unacceptable levels of operator exposure, specify a re-entry period of 4 hours for glasshouses and similar plant production facilities. **Amend labels**
Stored grain, empty grain silos, infested grain.	Stored grain insect pests	Because of public health and safety concerns of unknown dietary exposure, specify 'stored cereal grains' for improved clarity, rather than 'stored grain'. Amend the descriptions 'empty silos' and 'silos' to 'empty grain silos'. **Amend labels**
Empty grain silos	Grain insect pests	Because of public health and safety concerns of unknown dietary exposure, include withholding periods (7 days for 6 ppm dichlorvos and 28 days for 12 ppm dichlorvos) for grain or surfaces treated. **Amend labels**
Home garden use of pest strips and residual sprays.	Flies, moths, mosquitoes, fleas, ants, cockroaches, spiders, silverfish.	Because of the likelihood of unacceptable dietary exposure, add the restriction: DO NOT use in food cupboards or food storage and food preparation areas. **Amend labels**
All situations	All insect pests	Amend Safety directions to bring them in line with entries in the current First Aid Instructions and Safety Directions Handbook. Amend label instructions for all products to bring them in line with contemporary standards with respect to risks to terrestrial and aquatic species from the use of dichlorvos. Include bee and non-target terrestrial invertebrate hazard statements. **Amend labels**

5.2.7 Label variations

The APVMA was NOT SATISFIED that labels for products in Table 19 contain adequate instructions in relation to the criteria set out in s.14(3)(g) of the Agvet Codes. Product labels also contained use patterns recommended to be deleted. However the APVMA IS SATISFIED that the conditions of label approval have been VARIED, in accordance with s.34(5) of the Agvet Codes.

Once the label variations have been made, the APVMA can be SATISFIED that labels contain adequate instructions. On this basis the APVMA can be SATISFIED that continued registration of the product in accordance with its instructions for use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely 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.

On this basis, the registration of products in Table 19 has been AFFIRMED.

Table 19: The following registered products and their labels have been varied

PRODUCT NO.	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NO. TO BE VARIED OR CANCELLED	NEW LABEL APPROVAL NO.
32082	NUFARM DICHLORVOS 1140 INSECTICIDE	NUFARM AUSTRALIA LIMITED	32082/0606 32082/0405 32082/02	32082/0111 Cancelled Cancelled
32939	INSECTIGAS-D DDVP INSECTICIDE	BOC LIMITED	32939/0600	32939/0111
48975	DAVID GRAYS D.D.V.P. 500 INSECTICIDE	DAVID GRAY and CO. PTY LIMITED	48975/01	48975/0111
49203	DIVAP 1140 INSECTICIDE	UNITED PHOSPHORUS LTD.	49203/0907 49203/0105 49203/0604 49203/01	49203/0111 Cancelled Cancelled Cancelled
49362	DIVAP 500EC INSECTICIDE	UNITED PHOSPHORUS LTD.	49362/0805 49362/0300 49362/01	49362/0111 Cancelled Cancelled
53320	CHEMAG DICHLORVOS INSECTICIDE	IMTRADE AUSTRALIA PTY LTD	53320/0900	53320/0111
55503	BARMAC DICHLORVOS 500 INSECTICIDE	BARMAC INDUSTRIES PTY LTD	55503/0402	55503/0402
64358	FARMALINX DICHLORVOS INSECTICIDE	FARMALINX PTY LTD	64358/0510	64358/0111

5.3 Cancellations of registrations and label approvals

The APVMA was NOT SATISFIED that the labels for the product listed in Table 20 contained adequate instructions in relation to the criteria set out in s.14(3)(g) of the Agvet Codes.

The APVMA was NOT SATISFIED that the conditions of registration of this product could be varied in such a way that the requirements for continued registration will be complied with. On this basis the APVMA was NOT SATISFIED that continued registration of this product, in accordance with its instructions for use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely 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.

The registration of this product lapsed, effective from 1 July 2007. Normally a two-year sales period is allowed after product registrations lapse. This two-year period has since expired at the time of this review and Sureguard Pest Strip Household Insecticide is an archived product.

Table 20: Products that have been cancelled

PRODUCT NO.	CANCELLED PRODUCT REGISTRATIONS	REGISTRANT	LABEL APPROVAL NO.
Reason: may be likely to have an effect that is harmful effect to human beings			
45596	SUREGUARD PEST STRIP HOUSEHOLD INSECTICIDE	PENTAL PRODUCTS PTY LTD	45596/01

5.4 Cancellation of all but the most recently approved label

The APVMA was NOT SATISFIED that old previously-approved product labels for currently registered products listed in Table 21 contain adequate instructions in relation to the criteria set out in s.14(3)(g) of the Agvet Codes.

On this basis, previously approved labels have been cancelled.

Table 21: Labels deemed not to contain adequate instructions and have been cancelled

PRODUCT NO.	PRODUCT NAME	REGISTRANT	OLD LABEL APPROVAL NO. TO BE CANCELLED
32082	NUFARM DICHLORVOS 1140 INSECTICIDE	NUFARM AUSTRALIA LIMITED	32082/0606 32082/0405 32082/02
32939	INSECTIGAS-D DDVP INSECTICIDE	BOC LIMITED	32939/0600
38847	OXIMINTH PLUS BOTICIDE ORAL WORM AND BOT PASTE FOR HORSES	VIRBAC (AUSTRALIA) PTY LTD	38847/1200
47695	BINKILL	LAZCO INVESTMENTS PTY LTD	47695/1108 47695/0602

PRODUCT NO.	PRODUCT NAME	REGISTRANT	OLD LABEL APPROVAL NO. TO BE CANCELLED
48975	DAVID GRAYS D.D.V.P. 500 INSECTICIDE	DAVID GRAY and CO. PTY LIMITED	48975/01
49203	DIVAP 1140 INSECTICIDE	UNITED PHOSPHORUS LTD.	49203/0907 49203/0105 49203/0604 49203/01
49362	DIVAP 500EC INSECTICIDE	UNITED PHOSPHORUS LTD.	49362/0805 49362/0300 49362/01
53320	CHEMAG DICHLORVOS INSECTICIDE	IMTRADE AUSTRALIA PTY LTD	53320/0900
55503	BARMAC DICHLORVOS 500 INSECTICIDE	BARMAC INDUSTRIES PTY LTD	55503/0402
59750	KILLMASTER ZERO PEST STRIP	BARMAC INDUSTRIES PTY LTD	59750/1006
64358	FARMALINX DICHLORVOS INSECTICIDE	FARMALINX PTY LTD	64358/0510

5.5 Withdrawn dichlorvos products

A number of dichlorvos products (Table 22) have been voluntarily withdrawn since the commencement of the review (once cancellation of registration is formally effected, reconsideration of them is no longer required).

Table 22: Dichlorvos products included in the review were withdrawn prior to the completion of the review

PRODUCT NO.	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NO.
54007	BAYGON OUTDOOR BIN GUARD	S.C. JOHNSON and SON PTY LTD	54007/1101
55352	GARRARDS DDVP 500 EC INSECTICIDE	GARRARDS PTY LTD	55352/0502
56540	SCUTTLE BUG PEST STRIP	BARMAC INDUSTRIES PTY LTD	56540/0403

6 AMENDMENTS TO STANDARDS

Arising from the OCSEH assessment of data submitted to the review of dichlorvos and consideration of the toxicological database, the following advice was provided by the OCSEH.

6.1 Public health standards

6.1.1 Approval status

The APVMA is satisfied that, provided the conditions to which an approval is currently subject are complied with, the continued use of, or any other dealings with, the active constituent dichlorvos would not be likely to have an effect that is harmful to human beings. Accordingly, the active constituent approvals listed in Appendix 1 have been affirmed.

6.1.2 Impurity limits

Chloral (5 g/kg) is listed in the APVMA's minimum compositional standard for dichlorvos. Chloral is used as an intermediate in the production of dichlorvos and is rapidly converted to chloral hydrate in aqueous solutions. Neither the OCSEH nor any current or past Committee within the Australian Government Department of Health and Ageing have raised any toxicological concerns regarding this impurity. Declarations of composition for two of the three sources of dichlorvos indicate that chloral levels of <0.1% are achievable and therefore approval holders should be asked to justify the continued listing of chloral in the APVMA's compositional standard.

6.1.3 Acceptable daily intake (ADI)

The present review reaffirmed the current ADI of 0.001 mg/kg bw/d. The ADI was calculated by applying a 10-fold safety factor to the NOEL of 0.014 mg/kg bw/day for the inhibition of plasma ChE activity in a 28-day human study.

6.1.4 Acute reference dose (ARfD)

The present review identified a suitable acute oral dosing study in humans to allow the refinement of the current Australian ARfD for dichlorvos. The new ARfD of 0.1 mg/kg bw was calculated by applying a 10-fold safety factor to the NOEL of 1 mg/kg bw for the inhibition of RBC ChE activity.

6.1.5 Health value for Australian drinking water

It was recommended that the NHMRC revise the existing Health Value for dichlorvos in drinking water from 0.001 mg/L to 0.007 mg/L to reflect the current ADI of 0.001 mg/kg bw/d.

6.1.6 Poisons schedule

The existing poisons Schedule for dichlorvos remains appropriate.

6.1.7 First-aid instructions

The existing first aid instructions for dichlorvos remain appropriate. The instruction to induce vomiting following ingestion is no longer appropriate and should not appear on any dichlorvos product labels.

6.1.8 Warning statements and general safety precautions

There are no warning statements or general safety precautions for dichlorvos or hydrocarbon (liquid) that appear in the FAISD handbook.

6.1.9 Safety directions and personal protective equipment

As agreed between the APVMA, OCSEH and National Occupational Health and Safety Commission (NOHSC), the following recommendations by the OCSEH on hazard-based Safety Directions have been forwarded to the NOHSC who will respond in due course with Safety Directions related to personal protective equipment. The Safety Directions to be provided by NOHSC and those provided here, together form the Safety Directions, which will be included in the FAISD Handbook, and which should be included on the product label.

6.1.10 Existing safety directions and personal protective equipment

The existing safety directions for Australian products containing dichlorvos, as recommended in the FAISD Handbook, are shown below.

CODE	SAFETY DIRECTIONS
AE 50 g/kg OR LESS	
210 211	Avoid contact with eyes and skin
BA 10 g/kg OR LESS	
130 133	Poisonous if swallowed
210 211	Avoid contact with eyes and skin
250	Do not touch bait
251	Use scoop or measure
252	If on skin and after each baiting, wash thoroughly with soap and water
EC 1140 g/l OR LESS	
120 121 130 131 132 133	Product and spray are poisonous if absorbed by skin contact, inhaled or swallowed
190	Repeated minor exposure may have a cumulative poisoning effect
	Avoid contact with eyes and skin

CODE	SAFETY DIRECTIONS
210 211	Do not inhale spray mist
220 223	Obtain an emergency supply of atropine tablets 0.6 mg
373	When opening the container, preparing and using in enclosed areas, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves, goggles, half-facepiece respirator with combined dust and gas cartridge
279 280 281 284 290 292 294 297 300 303	
	If product on skin, immediately wash area with soap and water
	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
340 342	
350	After each day's use, wash gloves, goggles, respirator and if rubber wash with detergent and warm water and contaminated clothing.
360 361 363 364 366	
LD 50 g/kg OR LESS IN COMPRESSED LIQUID CARBON DIOXIDE	
130 131 132	Poisonous if absorbed by skin contact and inhaled
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 223	Do not inhale spray mist
279 280 290 292 294 301 303	When opening the container, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves, full-facepiece respirator with combined dust and gas cartridge or canister
	Thoroughly ventilate treated areas before reoccupying
320	
349	Avoid re-entry for (time to be inserted by registering authority) after use in glasshouses or other confined spaces. If re-entering, wear all protective clothing including respirator
	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
350	After each day's use, wash gloves, respirator and if rubber wash with detergent and warm water and contaminated clothing.
360 361 364 366	
SR	
380	Do not open inner (envelope) (pouch) until ready for use
351	Wash hands after use

AE = aerosol; BA = bait; EC = emulsifiable concentrate; LD = liquid; SR = slow release generator

The existing safety directions for Australian products containing naphthalene, as recommended in the FAISD handbook, are shown in the Table below.

HG ALL FORMS AND STRENGTHS	
130 132 133	Poisonous if inhaled or swallowed
161 162 164	Will irritate the eyes and skin
180	Repeated exposure may cause allergic disorders
220 222	Do not inhale vapour
210 211	Avoid contact with eyes and skin
351	Wash hands after use

6.1.11 Amendments to existing safety directions and personal protective equipment

Based on a consideration of the toxicity of each constituent in registered dichlorvos products, the following amended hazard-based safety directions and personal protective equipment are appropriate:

CODE	SAFETY DIRECTIONS
EC 1200 g/l OR LESS	
100	Very dangerous
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
	Will irritate the eyes and skin
161 162 164	Repeated exposure may cause allergic disorders
180	Repeated minor exposure may have a cumulative poisoning effect
190	Avoid contact with eyes and skin
210 211	Do not inhale vapour or spray mist
220 222 223	Obtain an emergency supply of atropine tablets 0.6 mg
373	If clothing becomes contaminated with product or wet with spray, remove clothing immediately
330 331 332	If product on skin, immediately wash area with soap and water
340 342	If product in eyes, wash it out immediately with water
340 343	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
350	
SR 350 g/kg OR LESS	
380	Do not open inner (envelope) (pouch) until ready for use
381	Do not remove the insecticidal strip from the plastic case
382	Do not allow children to play with the strip
351	Wash hands after use
LD 60 g/kg OR LESS IN COMPRESSED LIQUID CARBON DIOXIDE	
130 131 132 **133**	Poisonous if absorbed by skin contact or inhaled or **swallowed**
207 162 164	Will damage the eyes and skin
180	Repeated exposure may cause allergic disorders
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 **222** 223	Do not inhale **vapour or** spray mist
373	Obtain an emergency supply of atropine tablets 0.6 mg
330 331 332	If clothing becomes contaminated with product or wet with spray remove clothing immediately
	If product or spray on skin immediately wash area with soap and water
340 341 342	If product or spray in eyes, wash it out immediately with water
340 341 343	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
350	

6.1.12 Add new entries

Based on a consideration of the toxicity for each constituent in registered dichlorvos products, the following new hazard-based safety directions and personal protective equipment are appropriate:

CODE	SAFETY DIRECTIONS
EC 550 g/l OR LESS WITH SURFACTANT IN HYDROCARBON SOLVENT 500 g/l OR LESS	
100	Very dangerous
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
207 162	Will damage the eyes
161 163 164	Will irritate the nose and throat and skin
180	Repeated exposure may cause allergic disorders
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 222 223	Do not inhale vapour or spray mist
373	Obtain an emergency supply of atropine tablets 0.6 mg
330 331 332	If clothing becomes contaminated with product or wet with spray remove clothing immediately
340 342	If product on skin, immediately wash area with soap and water
340 343	If product in eyes, wash it out immediately with water
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water

CODE	SAFETY DIRECTIONS
EC 550 g/l OR LESS IN HYDROCARBON SOLVENT 500 g/l OR LESS	
100	Very dangerous
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
161 162 163 164	Will irritate thee eyes, nose and throat, and skin
180	
190	
210 211	Repeated exposure may cause allergic disorders
220 222 223	Repeated minor exposure may have a cumulative poisoning effect
373	Avoid contact with eyes and skin
330 331 332	Do not inhale vapour or spray mist
	Obtain an emergency supply of atropine tablets 0.6 mg
340 342	If clothing becomes contaminated with product or wet with spray remove clothing immediately
340 343	
350	If product on skin, immediately wash area with soap and water
	If product in eyes, wash it out immediately with water
	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water

CODE	SAFETY DIRECTIONS
EC 300 g/l OR LESS WITH CHLORPYRIFOS 250 G/L OR LESS WITH SURFACTANT IN HYDROCARBON SOLVENT 420 g/l OR LESS	
100	Very dangerous
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
207 162	Will damage the eyes
161 163 164	Will irritate the nose and throat and skin
180	Repeated exposure may cause allergic disorders
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 222 223	Do not inhale vapour or spray mist
373	Obtain an emergency supply of atropine tablets 0.6 mg
330 331 332	If clothing becomes contaminated with product or wet with spray remove clothing immediately
340 342	If product on skin, immediately wash area with soap and water
340 343	If product in eyes, wash it out immediately with water
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water

CODE	SAFETY DIRECTIONS
LD 10 g/l OR LESS WITH PYRETHRINS 2 g/l OR LESS IN HYDROCARBON SOLVENT 800 g/l OR LESS	
161 162 163 164	Will irritate the eyes and nose and throat and skin
180	Repeated exposure may cause allergic disorders
190	Repeated minor exposure may have a cumulative poisoning effect
373	Obtain an emergency supply of atropine tablets 0.6 mg
210 211	Avoid contact with the eyes and skin
220 222 223	Do not inhale vapour or spray mist
272	Ensure adequate ventilation during use
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water

CODE	SAFETY DIRECTIONS
SO 100 g/l OR LESS WITH NAPHTHALENE 850 g/kg OR LESS IN PLASTIC HOUSING	
351	Wash hands after use
PA 120 g/l OR LESS WITH OXIBENDAZOLE 230 g/l OR LESS	
130 131 133	Poisonous if absorbed by skin contact or swallowed
160 162 164	Will irritate the eyes and skin
180	Repeated exposure may cause allergic disorders
190	Repeated minor exposure may have a cumulative poisoning effect
373	Obtain an emergency supply of atropine tablets 0.6 mg
210 211	Avoid contact with eyes and skin
340 342	If product on skin, immediately wash area with soap and water

351	Wash hands after use

6.1.13 Deleted entries

The following entries for dichlorvos will be deleted from the FAISD handbook by OCSEH, as there are no longer any aerosol or bait products registered in Australia.

CODE	SAFETY DIRECTIONS
AE 50 g/kg OR LESS	
210 211	Avoid contact with eyes and skin
BA 10 g/kg OR LESS	
130 133	Poisonous if swallowed
210 211	Avoid contact with eyes and skin
250 251 252	Do not touch bait. Use scoop or measure. If on skin and after each baiting, wash thoroughly with soap and water.

6.2 MRL standards

Arising from the assessment of data submitted to the review of dichlorvos, the following changes to the MRL Standard are to be made.

Table 23: Changes to be made to Table 1 MRLs

COMPOUND	FOOD		MRL (MG/KG)
Dichlorvos			
DELETE:	MO 0105	Edible offal (mammalian)	0.05
	PE 0112	Eggs	0.05
	VD 0533	Lentil (dry)	2
	VL 0482	Lettuce, Head	1
	VL 0483	Lettuce, Leaf	1
	MM 0095	Meat [mammalian]	0.05
	ML 0106	Milks	0.02
	VO 0450	Mushrooms	0.5
	SO 0697	Peanut	2
	PM 0110	Poultry meat	0.05
	PO 0111	Poultry, Edible offal of	0.05
	CM 1206	Rice bran, unprocessed	10
	VD 0541	Soya bean (dry)	2
	VO 0448	Tomato	0.5
		Vegetables [except lentil (dry); lettuce, head; lettuce, leaf; soya bean (dry)]	0.5
	CM 0654	Wheat bran, unprocessed	10
	CF 1210	Wheat germ	10
ADD:	MO 0105	Edible offal (mammalian)	*0.05
	PE 0112	Eggs	*0.05
	MM 0095	Meat [mammalian]	*0.05
	ML 0106	Milks	*0.02
	PO 0111	Poultry, Edible offal of	*0.05
	PM 0110	Poultry meat	*0.05
	CM 0081	Bran, unprocessed of cereal grain	20

** Denotes MRL set at or about the limit of analytical quantification.*

Table 24: Changes to be made to Table 4 MRLs

COMPOUND	FOOD		MRL (MG/KG)
Dichlorvos			
ADD:		Rice hulls	50

Table 25: Changes to be made to Table 5 MRLs

COMPOUND	USE
Dichlorvos	
ADD:	Treatment of animal houses and pens.
	Treatment of empty silos.

As there are no current dichlorvos registrations or permit approvals for cacao beans (cocoa beans), coffee beans, fruits and tree nuts, the following MRLs will be deleted from the MRL Standard. These amendments are not subject to final review outcomes.

Table 26: MRLs to be deleted from Table1 MRLs

COMPOUND	FOOD		MRL (MG/KG)
Dichlorvos			
DELETE:	SB 0715	Cacao beans [cocoa beans]	5
	SB 0716	Coffee beans	2
	TN 0085	Tree nuts	2

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APPENDIX A. Active constituent and products included in the review

Table A1: Active Constituents included in the review

APPROVAL NO.	PRODUCT NAME	REGISTRANT
44578	DICHLORVOS	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY LTD
48353	DICHLORVOS	UNITED PHOSPHORUS LTD
49486	DICHLORVOS	SARA LEE HOUSEHOLD AND BODY CARE (AUSTRALIA) PTY LTD
56689	DICHLORVOS	AMVAC CHEMICAL UK LTD

Table A2: Products with continuing registration from the commencement of the review

PRODUCT NO.	PRODUCT NAME	REGISTRANT	DESCRIPTION	LABEL APPROVAL NO.
32082	NUFARM DICHLORVOS 1140 INSECTICIDE	NUFARM AUSTRALIA LIMITED	EC; S7; grain fumigant	32082/02 32082/0405 62082/0606
32939	INSECTIGAS-D DDVP INSECTICIDE	BOC LIMITED	CG; S6; pest control in domestic and commercial premises and storage facilities	32939/0600
38847	OXIMINTH PLUS BOTICIDE ORAL WORM AND BOT PASTE FOR HORSES	VIRBAC (AUSTRALIA) PTY LTD	PA; S6; veterinary medicine; also contains oxibendazole (5 g/25 mL)	38847/1200
47695	BINKILL	LAZCO INVESTMENTS PTY LTD	SO; S6; home garden product; also contains naphthalene (800 g/kg); controls flies and maggots in bins	47695/1108 47695/0602

S5 = Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP); S6 = Schedule 6 of the SUSDP; S7 = Schedule 7 of the of SUSDP; CG=compressed gas; EC = emulsifiable concentrate; LD = Liquid PA = paste; SO = solid; SR = slow release generator; TA = tablet;

Table A3: Products registered after the commencement of the review that are subject to the outcomes of the review

PRODUCT NO.	PRODUCT NAME	REGISTRANT	DESCRIPTION	LABEL APPROVAL NO.
48975	DAVID GRAYS D.D.V.P. 500 INSECTICIDE	DAVID GRAY and CO. PTY LIMITED	EC; S6; also contains hydrocarbon solvent (455 g/L); commercial and domestic insect control	48975/01
49203	DIVAP 1140 INSECTICIDE	UNITED PHOSPHORUS LTD.	LD; S7; grain fumigant	49203/0105 49203/0907 49203/0604 49203/01
49362	DIVAP 500EC INSECTICIDE	UNITED PHOSPHORUS LTD.	EC; S6; also contains hydrocarbon solvent (455 g/L); commercial and domestic insect control	49362/01 49362/0300 49362/0805
53320	CHEMAG DICHLORVOS INSECTICIDE	IMTRADE AUSTRALIA PTY LTD	EC; S6; also contains hydrocarbon solvent (455 g/L); commercial and domestic insect control	53320/0900
55503	BARMAC DICHLORVOS 500 INSECTICIDE	BARMAC INDUSTRIES PTY LTD	EC; S6; also contains hydrocarbon solvent (455 g/L); commercial and domestic insect control	55503/0402
59750	KILLMASTER ZERO PEST STRIP	BARMAC INDUSTRIES PTY LTD	SR; S5; pest control in domestic and commercial premises and storage facilities	59750/1006

S5 = Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP); S6 = Schedule 6 of the SUSDP; S7 = Schedule 7 of the of SUSDP; CG=compressed gas; EC = emulsifiable concentrate; LD = Liquid PA = paste; SO = solid; SR = slow release generator; TA = tablet;

Table A4: Products archived after the commencement of the review

PRODUCT NO.	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NO.
32083	SHELL VAPONA 120 WMC INSECTICIDE	BASF AUSTRALIA LTD	Ψ
32137	SHELLTOX PEST STRIP HOUSEHOLD INSECTICIDE FUMIGANT	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	Ψ
32138	SHELLTOX MINISTRIP HOUSEHOLD INSECTICIDE FUMIGANT	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	Ψ
32139	SHELLTOX PESTAMATIC HOUSEHOLD INSECTICIDE FUMIGANT	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	Ψ
32217	NO FRILLS SURFACE SPRAY HOUSEHOLD INSECTICIDE	FRANKLINS LTD	Ψ
32295	BAYER BAYGON HOUSEHOLD INSECTICIDE SURFACE SPRAY – SEE 32296	BAYER AUSTRALIA LTD	Ψ
32297	BAYER BAYGON PLUS INSECTICIDE SURFACE SPRAY	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32301	BAYGON PLUS BAYER INSECTICIDE SURFACE SPRAY	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32304	OPEN SEASON SURFACE SPRAY RESIDUAL INSECTICIDE	ECOLAB PTY LIMITED	Ψ
32379	FLICKTRAX AEROSOL HOUSEHOLD INSECTICIDE	WA FLICK and CO PTY LTD	Ψ
32601	ICI GOLDEN MALRIN FLY BAIT	CROP CARE AUSRALASIA PTY LTD	Ψ
32607	BAYER TUGON PLUS FLY BAIT	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32647	BLATTANEX PROFESSIONAL INSECTICIDE	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32648	BLATTANEX PLUS PROFESSIONAL INSECTICIDE SPRAY	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32910	LANE SPIDER KILLER SURFACE SPRAY	ARTHUR YATES and CO LIMITED	Ψ

32927	LANE DDVP 1140 INSECTICIDE	BAYER CROPSCIENCE PTY LTD	Ψ
32928	ANTIPEST DICHLOROTHRIN 50 DDVP INSECTICIDE	ANTIPEST P/L	Ψ
32929	ANTIPEST VATECH TECHNICAL INSECTICIDE	ANTIPEST P/L	Ψ
32930	MAFU PM 200 INSECTICIDE	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32931	BAYER MAFU 500 INSECTICIDE SPRAY	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32932	BAYER MAFU 120 INSECTICIDE	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32933	MAFU H 500 INSECTICIDE	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32934	MAFU 500 INSECTICIDE SPRAY	BAYER CROPSCIENCE PTY LTD	Ψ
32935	MAFU H 500 BAYER INSECTICIDE	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	Ψ
32936	CIBA-GEIGY NUVAN 50 EC CONTACT INSECTICIDE WITH FUMIGANT ACTION	SYNGENTA CROP PROTECTION PTY LIMITED	Ψ
32937	CIG INSECTIGAS 20% DDVP INSECTICIDE	BOC LIMITED	Ψ
32938	CIG INSECTIGAS-D 5% DDVP INSECTICIDE	BOC LIMITED	Ψ
32940	DIVERSEY TIMES UP INSECTICIDE	JOHNSONDIVERSITY AUSTRALIA PTY LIMITED	Ψ
32941	DIVERSEY TIMES UP INSECTICIDE FOR INSECT CONTROL IN INDUSTRIAL DOMESTIC and AGRI	JOHNSONDIVERSITY AUSTRALIA PTY LIMITED	Ψ
32942	FLICK PEST CONTROL FLICKTRAX 50 EC INSECTICIDE	WA FLICK and CO PTY LTD	Ψ
32943	FLICK PEST CONTROL NUMIST and INSECTICIDE	WA FLICK and CO PTY LTD	Ψ
32944	REGENCY FUMIGANT CANDLE	REGENCY	Ψ
32945	RENTOKIL CHEKS ALL EC 50 INSECTICIDE	RENTOKIL PTY LTD	Ψ
32946	RENTOKIL CHEKS ALL EC 500 INSECTICIDE	RENTOKIL PTY LTD	Ψ

32947	LANE DDVP 500 INSECTICIDE	BAYER CROPSCIENCE PTY LTD	Ψ
32948	SHELL VAPONA 500 INSECTICIDE	BASF AUSTRALIA LTD	Ψ
33121	RENTOKIL DDVP 10 OIL INSECTICIDE	RENTOKIL PTY LTD	Ψ
33666	PET GUARD ISOLATED INSECTICIDAL FLEA CONTROL COLLAR FOR CATS	SCHERING-PLOUGH PTY LTD	Ψ
33667	PET GUARD ISOLATED INSECTICIDAL FLEA CONTROL COLLAR FOR LARGE DOGS	SCHERING-PLOUGH PTY LTD	Ψ
33668	PET GUARD ISOLATED INSECTICIDAL FLEA CONTROL COLLAR FOR SMALL DOGS	INTERVET AUSTRALIA PTY LIMITED	Ψ
33669	GO-PET FLEA COLLAR FOR CATS	FRISKIES PET CARE PTY LTD	Ψ
33670	GO-PET FLEA COLLAR FOR DOGS	FRISKIES PET CARE PTY LTD	Ψ
33671	GO-PET FLEA TAG FOR DOGS	FRISKIES PET CARE PTY LTD	Ψ
33672	GO-PET FLEA TAG FOR CATS	FRISKIES PET CARE PTY LTD	Ψ
33673	EXELPET BECAUSE YOU CARE FOR YOUR CAT 3 MONTH FLEA COLLAR FOR CATS	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
33674	EXELPET BECAUSE YOU CARE FOR YOUR DOG FLEA MEDALLION	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
33675	EXELCAT RECOMMENDED BY WHISKAS PEDIGREE FLEA COLLAR	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
33676	EXELDOG RECOMMENDED BY PAL PROTECTIVE FLEA TAG	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
33677	EXELCAT PEDIGREE FLEA COLLAR	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
33678	EXELDOG PROTECTIVE FLEA TAG	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
33679	EXELPET BECAUSE YOU CARE FOR YOUR CAT FLEA CONTROL COLLAR FOR CATS	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ

33680	EXELPET BECAUSE YOU CARE FOR YOUR DOG 3 MONTH FLEA CONTROL COLLAR	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
33681	EXELPET RED 3 MONTHS FLEA COLLAR FOR CATS	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
33682	EXELPET RED 3 MONTH FLEA COLLAR FOR DOGS	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
33683	PETCARE DOG FLEA COLLAR	CROP CARE AUSTRALASIA PTY LTD	Ψ
33684	PETCARE CAT FLEA COLLAR	CROP CARE AUSTRALASIA PTY LTD	Ψ
33685	VETCARE DOG FLEA COLLAR	CROP CARE AUSTRALASIA PTY LTD	Ψ
33686	VETCARE CAT FLEA COLLAR	CROP CARE AUSTRALASIA PTY LTD	Ψ
33687	ST AUBREY ISOLATED INSECTICIDAL FLEA COLLAR FOR CATS	JOHN THORN IMPORTS PTY LTD	Ψ
33688	ST AUBREY ISOLATED INSECTICIDAL FLEA COLLAR FOR LARGE DOGS	JOHN THORN IMPORTS PTY LTD	Ψ
33689	ST AUBREY ISOLATED INSECTICIDAL FLEA COLLAR FOR SMALL DOGS	JOHN THORN IMPORTS PTY LTD	Ψ
33690	SHELLGARD CATBAND INSECTICIDE	BASF AUSTRALIA LTD	Ψ
33691	SHELLGARD DOGBAND INSECTICIDE	BASF AUSTRALIA LTD	Ψ
33692	FLEA FREE ISOLATED INSECTICIDAL DOG COLLAR	VIRBAC (AUSTRALIA) PTY LTD	Ψ
33693	PETCARE PRODUCTS FLEA COLLAR FOR DOGS	VIRBAC (AUSTRALIA) PTY LTD	Ψ
33694	PETCARE PRODUCTS FLEA COLLAR FOR CATS	VIRBAC (AUSTRALIA) PTY LTD	Ψ
33695	SHELLGARD DOG MEDALLION INSECTICIDE	BASF AUSTRALIA LTD	Ψ
33696	FLEA FREE ISOLATED INSECTICIDAL CAT COLLAR WITH ELASTIC SAFETY STRAP	VIRBAC (AUSTRALIA) PTY LTD	Ψ
33697	FLEA FREE SUPA DOG ISOLATED INSECTICIDAL LARGE DOG COLLAR	VIRBAC (AUSTRALIA) PTY LTD	Ψ

33698	SOFTEE FLEA FREE ISOLATED INSECTICIDAL SMALL DOG COLLAR - SEE 38875	VIRBAC (AUSTRALIA) PTY LTD	Ψ
33699	FLEA FREE INSECTICIDAL DOG TAG	VIRBAC (AUSTRALIA) PTY LTD	Ψ
33700	FLEA FREE SOFTEE ISOLATED INSECTICIDAL SMALL DOG COLLAR - SEE 33698	VIRBAC (AUSTRALIA) PTY LTD	Ψ
33701	FLEA FREE ISOLATED SUPADOG INSECTICIDAL LARGE DOG COLLAR - SEE 33697	VIRBAC (AUSTRALIA) PTY LTD	Ψ
33702	ZOECON DICHLORVOS INSECTICIDAL COLLAR FOR DOGS	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY LIMITED	Ψ
36921	EXELPET RED 3 MONTH FLEA COLLAR FOR DOGS	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
36922	EXELPET RED 3 MONTH FLEA COLLAR FOR CATS	EXELPET PRODUCTS A DIV OF MARS AUSTRALIA PTY LTD	Ψ
37565	FULLGUARD CATBAND FLEA COLLAR INSECTICIDE	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	Ψ
37566	FULLGUARD DOGBAND FLEA COLLAR INSECTICIDE	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	Ψ
38807	ORALJECT SPECTRUM-4 PASTE BROAD SPECTRUM PARASITICIDE PASTE FOR HORSES	VETSEARCH INTERNATIONAL PTY LTD	Ψ
38863	FLEA FREE ISOLATED SUPADOG INSECTICIDAL LARGE DOG COLLAR - SEE 33697	PET CARE PRODUCTS C/- VIRBAC	Ψ
38875	FLEA FREE SOFTEE ISOLATED INSECTICIDAL SMALL DOG COLLAR	VIRBAC (AUSTRALIA) PTY LTD	Ψ
39192	SHELLTOX SUREGUARD PEST STRIP HOUSEHOLD INSECTICIDE FUMIGANT	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	Ψ
39202	SHELLTOX SUREGUARD MINISTRIP HOUSEHOLD INSECTICIDE FUMIGANT	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	Ψ
39568	FLEA FREE INSECTICIDAL DOG TAG - SEE 33699	PET CARE PRODUCTS C/- VIRBAC	Ψ
41186	MAFU H 500 BAYER INSECTICIDE	ARYSTA LIFESCIENCE NORTH AMERICA CORPORATION	Ψ

41499	DICHLORVOS 100 INSECTICIDE	NUFARM AUSTRALIA LIMITED	Ψ
41644	CHEMICAL ENTERPRISES DICHLORVOS 500EC INSECTICIDE	CHEMICAL ENTERPRISES (QUEENSLAND) PTY LTD	Ψ
41816	ADDIMIX DICHLORVOS INSECTICIDE 500 EC	ADDIMIX PTY LTD	Ψ
42285	D.D.V.P. 50	DAVID GRAY and CO. PTY LIMITED	Ψ
42329	DIVIPAN 1000 E INSECTICIDE	MAKHTESHIM-AGAN (AUSTRALIA) PTY. LIMITED	Ψ
42496	KNOCK-DOWN RESIDUAL SPRAY INSECTICIDE	CHEMICAL FORMULATORS PTY LTD	Ψ
45040	CHEMICAL ENTERPRISES TERMINATOR INSECTICIDE SURFACE SPRAY	CHEMICAL ENTERPRISES (QUEENSLAND) PTY LTD	45040/01
45596	SUREGUARD PEST STRIP HOUSEHOLD INSECTICIDE - FUMIGANT	PENTAL PRODUCTS PTY LTD	45596/01
45598	SUREGUARD MINISTRIP HOUSEHOLD INSECTICIDE - FUMIGANT	PENTAL PRODUCTS PTY LTD	45598/0299 45598/01 45598/0400
47517	VAPONA 500 INSECTICIDE	BASF AUSTRALIA LTD	47517/02 47517/01
48087	PEA-BEU MOTH and INSECT STRIPS HOUSEHOLD INSECTICIDE	RECKITT BENCKISER (AUSTRLIA) PTY LIMITED	48087/4977
48700	DOOM 500 EC INSECTICIDE	UNITED PHOSPHORUS LTD.	48700/01
48716	CATCH SMALL SPACE FLY KILLER HOUSEHOLD INSECTICIDE - FUMIGANT	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	48716/01
48717	CATCH FLY KILLER HOUSEHOLD INSECTICIDE - FUMIGANT	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	48717/01
48718	CATCH MOTH KILLER HOUSEHOLD INSECTICIDE - FUMIGANT	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	48718/01

48719	CATCH COCKROACH KILLER HOUSEHOLD INSECTICIDE - FUMIGANT	SARA LEE HOUSEHOLD and BODY CARE (AUSTRALIA) PTY LTD	48719/01
49008	PERMAKILL INSECTICIDE	MOUNTVILLA PTY LTD	49008/0401 49008/0902 49008/01 49008/02
49945	MORTEIN MOTH and INSECT STRIPS	RECKITT BENCKISER (AUSTRLIA) PTY LIMITED	49945/01 49945/1098
50384	SCIENTIFIC PROFESSIONAL FORMULATION INSECTICIDE	DAVID GRAY and CO. PTY LIMITED	50384/0698
50386	QM PROVAP 500EC INSECTICIDE	QUADRON MANUFACTURING PTY LTD	50386/0198
52447	NEVWEB DICHLORVOS 1140 INSECTICIDE	AUSTRALIAN PHARMACEUTICAL PARTNERS PTY LIMITED	52447/0900 52447/1299
55607	MORTEIN MOTH GUARD FOR WARDROBES AND DRAWERS	RECKITT BENCKISER (AUSTRLIA) PTY LIMITED	55607/0502

Ψ Labels transitioned from the states and not having and approval number.

Table A5: Products 'stopped' prior to the completion of the review

PRODUCT NO.	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NO.
54007	BAYGON OUTDOOR BIN GUARD	S.C. JOHNSON and SON PTY LTD	54007/1101
55352	GARRARDS DDVP 500 EC INSECTICIDE	GARRARDS PTY LTD	55352/0502
56540	SCUTTLE BUG PEST STRIP	BARMAC INDUSTRIES PTY LTD	56540/0403

Table A6: Products voluntarily withdrawn prior to the completion of the review

PRODUCT NO.	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NO.
54007	BAYGON OUTDOOR BIN GUARD	S.C. JOHNSON and SON PTY LTD	54007/1101
55352	GARRARDS DDVP 500 EC INSECTICIDE	GARRARDS PTY LTD	55352/0502
56540	SCUTTLE BUG PEST STRIP	BARMAC INDUSTRIES PTY LTD	56540/0403

Table A7: Products waiting approval since the commencement of the review

PRODUCT NO.	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NO.
64358	FARMALINX DICHLORVOS INSECTICIDE	FARMALINX PTY LTD	NA