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For Agricultural & Veterinary Chemicals

The NRA Review of

ALDICARB

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FOREWORD

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

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

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

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

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

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

The information and technical data required by the NRA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken. Details of required data are outlined in various NRA publications.

The full review report on aldicarb, containing assessments completed by the NRA and its advisory agencies, is also available. It can be viewed free of charge in the NRA Library, on the NRA website *http://www.nra.gov.au/nra* or obtained by contacting the NRA.

ABBREVIATIONS AND ACRONYMS

µg	microgram	LD_{50}	dosage of chemical that kills 50% of the test population of organisms
ACPH	Advisory Committee on Pesticides and Health	LOEL	lowest observed effect level
ADI	acceptable daily intake (for humans)	ME	microencapsulated
ACGIH	American Conference of Governmental Industrial Hygienists	mg	Milligram
ai	active ingredient	mg/kg bw/day	mg/kg bodyweight/day
BEI	Biological exposure index	MOE	Margin of exposure
ChE	cholinesterase	MRL	Maximum residue limit
DT_{50}	time required for 50% of a chemical to degrade	NDPSC	National Drugs and Poisons Scheduling Committee
EC	emulsifiable concentrate	NHMRC	National Health and Medical Research Council
EC_{50}	concentration at which 50% of the test population are affected	NOEL	no observed effect level
ECRP	Existing Chemicals Review Program	NOHSC	National Occupational Health and Safety Commission
EEC	estimated environmental concentration	OP	Organophosphate
GAP	Good Agricultural Practice	POEM	Predicted Operator Exposure Model
GLP	Good Laboratory Practice	ppb	parts per billion
h	hour	PPE	personal protective equipment
ha	hectare	ppm	parts per million
in vitro	outside the living body and in an artificial environment	RBC	red blood cells/erythrocyte
in vivo	inside the living body of a plant or animal	SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
IPM	integrated pest management	TGAC	technical grade active constituent
IV	Intravenous	ULV	ultra low volume
kg	kilogram	USEPA	United States Environmental Protection Agency
L	Litre	WHP	withholding period
LC_{50}	concentration that kills 50% of the test population of organisms		

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EXECUTIVE SUMMARY

Aldicarb has been reviewed as part of the NRA's Existing Chemical Review Program. This review covered all aspects related to the registration of aldicarb, including approvals of labels and active constituents. Assessments conducted as part of this review considered the existing use patterns of aldicarb in terms of their impact on public health, occupational health and safety, the environment and trade. Summarised below are the main review findings. Specific details of the regulatory approach and risk mitigating measures proposed by the NRA are provided in Section 8 of this document.

Current uses

Aldicarb is a carbamate pesticide of high acute toxicity that has been marketed in Australia for over 20 years. It is a systemic pesticide that is applied beneath the soil in granular form and drawn up by the roots of the target plant. It is registered in only two products in Australia, neither of which is available for home or garden use.

Aldicarb is used in cotton, sugarcane and citrus for control of nematodes and other insect pests. It is only applied at planting, at emergence or in the case of established trees at first foliage and remains effective for a significant period of time.

Reasons for review

Aldicarb was nominated highly for review on environmental, public health and occupational exposure grounds. Human poisoning incidents as well as bird kills have been associated with the use of aldicarb in the US. The potential for water contamination under situations of high use such as citrus was of concern particularly as water contamination has been demonstrated in the US following application of aldicarb.

Toxicology and Public health

Like other organophosphorous and carbamate pesticides, aldicarb kills insects by interfering with the activity of an enzyme (acetylcholinesterase) in the nervous system.

Aldicarb is highly toxic to humans and animals if it is swallowed, applied to the skin or inhaled. Clinical symptoms associated with poisoning include dizziness, drooling, excessive sweating, nausea, cramps, vomiting, diarrhoea, blurred vision, non-reactive contracted pupils, difficulty in breathing due to excessive secretions, coarse generalised body tremors, convulsions, breathing failure and death. There is an effective antidote treatment for the immediate poisoning effects of aldicarb if medical assistance is prompt.

In laboratory animals, aldicarb was shown to be rapidly absorbed after ingestion, then eliminated quickly from the animals, mainly in the urine. Long-term exposure to a

low concentration of aldicarb in the diet was without serious consequence in animal studies. Aldicarb does not interact with genetic material, and long-term exposure studies in animals provided no evidence that aldicarb can cause cancer in humans. Similarly, exposure to low concentrations of aldicarb had no adverse effects on reproduction or development of the foetus in experimental animals.

Exposure of the public to low levels of aldicarb may occur through ingestion of food residues, but based on the current uses of the compound, it is considered that there is little chance of this occurring. Therefore there should be no adverse effects on public health from the continued use of aldicarb in Australia in accordance with Good Agricultural Practice (GAP).

Residues

Aldicarb is applied at early stages in the growth/production of the crop with withholding periods of at least 6 months being applied after last application. Plant metabolism data showed that in all plants aldicarb was rapidly metabolised to the sulfoxide that is in turn further oxidised to the sulfone. Quantifiable residues of aldicarb or its metabolites are not expected to occur in most crops where aldicarb is used. No changes to the use patterns of aldicarb are recommended however additional label statements are required.

The residue data presented for the review contained sufficient information for the NRA to confirm the current aldicarb maximum residue limits (MRLs) for commodities where registered uses exist. Currently there are a number of MRLs for aldicarb for which no registered use exists and is recommended that these MRLs be deleted from the MRL standard.

Calculations showed that the NEDI (National Estimated Daily Intake) is equivalent to only 13% of the ADI. Therefore chronic dietary exposure to aldicarb at this level is unlikely to pose an undue risk to human health.

Occupational health and safety

All currently registered aldicarb products are formulated as granular preparations. In addition, the containers in which the products are available allows a closed system for loading of the granules and there is no hand held application. These factors virtually eliminate exposure during loading and application of the chemical.

Granules are covered with soil following application and workers who do enter the fields will not be exposed directly unless they come into contact with moist soil. Should workers re-enter treated areas the use of additional protective equipment will result in minimal worker exposure, provided safe work practices are observed and products are used in accordance with label instructions.

Environmental Impact

The environmental assessment found that aldicarb that aldicarb has the potential to contaminate surface and groundwater. In Australia aldicarb is only available in granular form which is incorporated into the soil and therefore the risk of run off or drift is low. However, aldicarb can be persistent and has the potential to leach through the soil profile. Groundwater contamination is an issue of concern in the US and is most likely in areas of higher rainfall, shallow water tables and acidic soils. There is a greater risk of contamination when applied at high rates to sandy soil during the cool rainy seasons as happens in the citrus growing areas of Australia. However, there is very little use of aldicarb in citrus as opposed to cotton where the low rates, single application per season combined with the neutral to alkaline clays and relatively deep water tables suggest a reduced potential for contamination.

Review reports

The following information is a summary of the assessment carried out for aldicarb. Copies of the final technical reports can be accessed electronically on the NRA website http://www.nra.gov.au/

1. Introduction

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

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

1.1 Regulatory Information

Initiating a review

The NRA has statutory powers to reconsider the approval of active constituents, the registration of chemical products or the approval of labels for containers at any time. The basis for a reconsideration is whether the NRA is satisfied that the requirements prescribed by the Agricultural and Veterinary Chemicals Codes (scheduled to the Ag and Vet Chemicals Act 1994), for continued approval are being met. These requirements are that the use of an active constituent or product, in accordance with the recommendations for its use:

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

Obligations to submit data and other information on chemicals under review

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

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

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

Outcomes of review

There are three possible outcomes to an ECRP review:

- The NRA is satisfied that the chemical under review continues to meet the prescribed requirements for the initial approval or registration and confirms the approval or registration.

- The NRA is satisfied that the conditions to which the approval or registration is currently subject can be varied in such a way that the requirements for continued approval or registration will be complied with.

- The NRA is not satisfied that the conditions continue to be met and suspends or cancels the approval or registration.

1.2 Protected Information

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

- to grant protection to providers of certain information relating to agricultural and veterinary chemicals to provide an incentive for the development of products and data applicable to Australian or local conditions;
- to encourage the availability of overseas products and data; and
- to provide reciprocal protection for Australian products and data under overseas' data protection systems.

In general, the NRA designates information as 'protected information' if the information:

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

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

1.3 Reasons for Aldicarb Review

Aldicarb was selected by the NRA Board for review in the NRA's third cycle of chemicals after scoring highly against the agreed selection criteria for public health, occupational health and safety, and environment. In summary, the concerns over the chemical were:

- high acute toxicity risk;
- reports of bird deaths;
- demonstrated adverse effects in humans following consumption of treated produce;
- concern over persistence and mobility in sandy soils leading to water contamination

Whilst the selection process ranked aldicarb highly due to certain issues, the review was not confined only to those issues, but covered **all aspects** of registration and approval of aldicarb including registrations of products and approvals of labels and active constituents.

1.4 Consultation Activities

Consistent with the NRA's policy of consulting with all parties interested in the review process, the NRA published notices in the rural and metropolitan press calling for written submissions for the review of the chemical aldicarb. This aims to attract submissions from members of the public, environmental, government and commodity groups.

At the initiation of the review of aldicarb, only 3 submissions from the public were received on the review of aldicarb and these were all from commodity groups representing aldicarb use in sugarcane. These submissions indicated that aldicarb was important for the control of nematode pests in this crop which is increasing. Although there are alternative control chemicals available, aldicarb remains the most effective against nematodes in sugarcane.

The draft report was released in April 2000 and comments from the public were requested. Prior to this release, extensive consultation was undertaken with state authorities, registrants and user groups. As a result minimal comments were received during the public comment period.

This final report has taken all comments into consideration when preparing this final report.

1.6 International activities

The presence of aldicarb residues in groundwater raises particular sensitivities because of its very high mammalian toxicity. Groundwater contamination and crop residue concerns led to restrictions on the use of aldicarb in the USA. Aldicarb is listed as a restricted use pesticide in the USA because of acute oral toxicity and groundwater concerns. The US EPA is addressing groundwater concerns through the special review process with a report expected 2001.

Aldicarb restrictions in the US included voluntary cessation of use on potatoes in 1990 because of crop residue concerns. Similarly, restrictions were introduced in Florida citrus in 1991, and use on bananas was voluntarily cancelled in 1992. In

September 1995 the US EPA approved reintroduction of the potato use in some geographic regions where the groundwater contamination risk was believed to be low, and where more controlled application techniques were used to reduce crop residues.

Use of aldicarb has also been restricted in Canada because of the above crop residue concerns. Aldicarb was voluntarily withdrawn from the potato market in 1990, and a registration submission for greenhouse ornamentals was also withdrawn in Canada.

2. CHEMISTRY ASSESSMENT

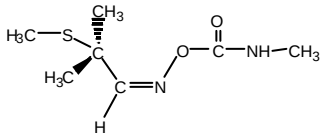
2.1 Chemical Identity

Aldicarb is an oxime carbamate insecticide. It structurally resembles acetycholine and is a potent cholinesterase inhibitor. It is a systemic pesticide that is applied to soil to control certain insects, mites and nematodes. It is currently registered for use in Australia on cotton, citrus (mandarin, orange and non-bearing citrus trees) and sugar cane.

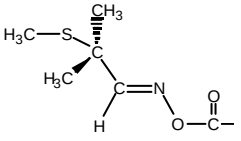
The mode of aldicarb action is systemic (contact and stomach action), and exposure of pests to this active constituent affects the nervous system by inhibiting the activity of acetyl cholinesterase. Aldicarb is metabolically transformed to aldicarb sulfoxide and aldicarb sulfone. Aldicarb sulfoxide has similar toxicity to aldicarb; aldicarb sulfone (also known as aldoxycarb) is considerably less toxic (approximately 4% of that of aldicarb).

Aldicarb is an acutely toxic pesticide and is included in Schedule 7 of the SUSDP.

Common name	Aldicarb (BSI, E-ISO, ANSI, SA)
IUPAC Name	2-methyl-2-(methylthio)propionaldehyde *O*-methylcarbamoyloxime
CA Name	2-methyl-2-(methylthio)propanal *O*-[(methylamino)carbonyl]oxime
CAS Registry Number	116-06-3
Empirical formula	$C_7H_{14}N_2O_2S$
Molecular weight	190.25 daltons
Development code/official codes	UC 21 149; OMS 771; ENT 27 093; AI3-27 093
Principal tradename	'Temik' (Rhone-Poulenc)
Structural formula	Since the carbon – nitrogen double bond prevents both rotation and ammonia like inversion, two geometrical isomers of aldicarb are possible. The commercial product is a mixture of these two isomers. It is not certain which isomer is the more biologically active form.



Anti-aldicarb



Syn-aldicarb

Chemical family	Aldicarb is a systemic pesticide belonging to the carbamate ester family

2.2 Physical and Chemical Properties

2.2.1 Physical and chemical properties of the pure active constituent

Colour	White/colourless crystals	
Odour	Odourless, or slight sulphurous smell	
Physical state	Crystalline solid	
Melting point	98 to 100 ^{o}C	
Boiling point	Unknown; decomposes above 100 ^{o}C	
Vapour pressure	1×10^{-5} mm Hg at 0 ^{o}C 1×10^{-4} mm Hg (13 mPa) at 25 ^{o}C 7×10^{-4} mm Hg at 50 ^{o}C 4×10^{-3} mm Hg at 75 ^{o}C	
Relative density/Specific gravity	1.195 at 25 ^{o}C	
Octanol/water partition coefficient	Log P = 0.053	
Solubility in water	Moderately soluble in water; 6 g/L at 20 ^{o}C (WHO, 1991); 4.93 g/L (pH 7, 20 ^{o}C) (The Pesticide Manual, 1994)	
pH (1% aqueous suspension)	5 to 8	
Solvent solubility (at 20 to 25 ^{o}C)	Acetone	350 g/L
	Benzene	150 g/L
	Chlorobenzene	150 g/L
	Chloroform	350 g/L
	Dichloromethane	300 g/L
	DMSO	= 100 g/L
	Ethanol (95%)	= 100 g/L
	Ether	200 g/L
	Heptane	Insoluble
	Isopropane	200 g/L
	Methylene chloride	300 g/L
	Mineral oils	Insoluble
	Toluene	100 g/L
	Xylene	50 g/L
Stability	Pure crystalline aldicarb is stable when stored under ambient temperature. Aldicarb decomposes above 100 ^{o}C. It is stable in neutral, acidic and weakly alkaline media, but is rapidly hydrolysed by concentrated alkali. Hydrolysis of the carbamate ester group, which inactivates the pesticide, is pH dependent, half-lives in distilled water varies from a few minutes at a pH > 12 to 560 days at pH of 6.0. In the presence of oxidising agents, aldicarb is rapidly converted to the sulfoxide, which is then (more slowly) oxidised to the sulfone.	
Corrosiveness	Aldicarb is non-corrosive to metals.	
Flash point	Non-flammable	

2.2.2 Physical and chemical properties of the TGAC

The physical properties of aldicarb TGAC are identical to the pure active constituent.

Impurities	Dimethylamine; 2-methyl-2-(methylthio)propionitrile; 2-methyl-2-(2-methylthiopropylenaminoxy)-propionaldehyde *O*-(methylcarbamoyl)oxime; 2-methyl-2-(methylthio)propionaldehyde oxime
Flammability	The flashpoint is over 170 ^{o}C by open cup
Ignition temperature	360 ^{o}C
Suitable extinguishing agent	Powder, foam, CO_2, or water spray (do not use direct jet of water). Combustion products are toxic and/or irritant.
Hazard rating	Explosiveness – not explosive Health hazard – high Occupational toxicity – high Fire hazard – fumes would be expected to be moderately to highly toxic

2.3 Chemistry Aspects

The chemistry aspects (manufacturing process, quality control procedures, batch analysis results, and analytical methods) of aldicarb TGAC were evaluated and found acceptable. The levels of aldicarb and its impurities are quantified using reverse-phase HPLC with UV detection.

3. AGRICULTURAL ASSESSMENT

In order to assess the use of aldicarb in the field, the NRA obtained information from users, commodity organisations, chemical companies, state authorities and other representative groups on the performance of aldicarb. This information, together with an evaluation of the current use pattens of aldicarb are noted below.

3.1 Use Patterns

In Australia there are two registered products containing aldicarb (*Temik 150G Insecticide/nematicide 48937* and *Farmoz Touche 150G Insecticide/nematicide 48089*) and they both contain aldicarb at 150g ai/kg. The label use patterns for aldicarb are for application to cotton, plant and ratoon cane, non-bearing citrus, mandarins and oranges. All use patterns involve application of aldicarb granules to the soil followed by incorporation into the soil. Aldicarb is normally applied at planting (cotton), at an early stage of growth (cane) during the spring flush of growth (citrus) or as required to non-bearing citrus.

Aldicarb disperses through the soil with soil moisture on release from the granule, is taken up by plant roots and translocated through the plant to provide protection against chewing and sucking insects and nematode damage.

All respondents to the review indicated that aldicarb is still effective for insect/nematode control. The only new use highlighted in the review was that for control of bulb mite in freesias (a permit use) however the permit for freesias is no longer current.

Under Victoria's Control of Use Legislation aldicarb has been used for nematode control in vineyards, however before it could be used a permit was required from Victorian State Authorities. This use pattern has never been assessed by the NRA but recent advice indicates that it is no longer used because of resistance issues.

Cotton

As noted above aldicarb is applied in cotton to the seed furrow at planting and buried with the seed. Aldicarb is applied at a rate of 3 to 7 kg/ha. It is recommended that aldicarb only be applied when there is sufficient soil moisture as this is important for rapid aldicarb distribution into the cotton seedling. In cotton aldicarb is used to control aphids, jassids, wireworm, mites, thrips, false wireworm, and green mirids. Control of these pests is effective for around 6 to 10 weeks.

Aldicarb itself plays an important role in early season pest protection of cotton. It currently offers the longest early season in furrow protection for a number of key pests. Its use in integrated pest management system allows greater retention of early season beneficial insects as well as preventing early broad spectrum insecticide applications that may be responsible for flaring of secondary pests.

Citrus

In citrus aldicarb is applied as either a band or broadcast application. For non-bearing citrus rates for area treatments are 7 g/m^2 or 30g/tree for band treatment (20 to 50mm wide, 150 to 300mm long incorporated at a depth of 50-80mm). For oranges and mandarins aldicarb is applied at 14 to 77 kg/ha. Again it is recommended that sufficient moisture is available before applying aldicarb however excess moisture will result in off-target movement of the chemical particularly due to the soil types on which citrus is grown (sandy soils). In non-bearing citrus, aldicarb is used for control of citrus leaf miner. In oranges (non trifoliata rootstock only) and mandarins it is used for control of citrus nematode, soft brown scale and mealybug. It is applied to oranges and mandarins only after the crop has been harvested.

Sugarcane

Aldicarb is applied to plant and ratoon cane for control of root-knot, root lesion, burrowing and spiral nematodes. It is applied no later than the 3 to 5 leaf stage at rates of 17 kg/ha or 24 g/10m row. It is incorporated into the soil and irrigated with 12 to 25 mm of water within 24 hours of application. Aldicarb is applied only once in the life of the crop and is the most cost effective chemical for control of nematodes in sugar. Nematodes represent a significant commercial pest to sugarcane growers especially in the Bundaberg and Proserpine districts of Queensland.

3.2 Product Stewardship Program

Aventis Crop Science has established a comprehensive training and accreditation program for the distribution and use of their aldicarb product (Temik 150G). The focus of the field component of the program is the education, training and accreditation of distributors and end-users. The main principles of this program are:

(a) All distributors of *Temik* must be Agsafe accredited and complete the training course and exam for accreditation by Aventis.
(b) All product users must complete the training course and successfully complete the exam prior to purchase and use of the products
(c) Specialised application equipment is recommended.

For use of Temik 150G in both cotton and sugarcane the above training and accreditation conditions apply. There are approximately 150 trained and accredited cotton growers and 20 sugarcane growers who purchase and use this product annually.

The conditions for Temik 150G use in citrus are slightly different to that in cotton and sugarcane due to the unique differences in the crop to be treated. Application is only carried out by contract applicators who have been trained and accredited through the Aventis course. No product is stored on farm or sold directly for use by growers. There are approximately 5 accredited contract applicators in this market. Specialised application equipment has also been purpose built for application of Temik 150G in citrus.

3.3 Efficacy

The effectiveness of any granular application is affected by soil conditions (moisture, temperature and soil type) and by the preparation and placement methods used. Respondents to the review of aldicarb indicated that aldicarb still continues to be efficacious when used as directed. Aldicarb is fast acting with effects noticeable in 48 hours.

Aldicarb in sugarcane and cotton is still effective for the intended purposes. Advice from Canegrowers indicates that use in sugar is likely to increase in Queensland. Research in progress is showing that nematodes are far more widespread than previously recognised.

3.4 Alternatives

In cotton alternative soil applied insecticides are available (phorate, carbofuran, imidacloprid) as well as seed dressings (thiodicarb, imdacloprid, furathiocarb). Aldicarb is the preferred chemical as alternatives are not as effective either in performance or cost, with seed dressings having a limited duration of protection.

Alternatives to aldicarb in citrus do exist and in some cases are preferred because of their lower toxicity. Consideration is being given to application of alternative nematicides by repeat, broadcast application under trees (as opposed to band applications). However the practicality of this will depend on whether or not the alternative chemical/method is comparable to the current band application recommendation for use of aldicarb in terms of economic benefit.

Although a number of alternatives exist for nematode and insect control in sugarcane, the effectiveness of alternatives(including chlorpyrifos and ethoprophos) are not comparable to that achieved from aldicarb application.

3.5 Other information

Aldicarb is a component of a number of treatment programs recommended by State Agricultural Authorities. These programs include IPM in cotton (WA), nematode control in citrus (VIC, SA) and nematode control in sugarcane (QLD).

Advice from Qld DPI indicates that they have experienced disruption to IPM programs in oranges from the use of aldicarb. Beneficial insects have been affected both at initial application and on the leaves through systemic activity.

4. RESIDUE ASSESSMENT

The residue assessment was based mainly on data provided by Rhone-Poulenc Rural Australia (now known as Aventis CropScience following a merger of Rhone-Poulenc and AgrEvo) to support the review of aldicarb. Data submitted for the registration of aldicarb on mandarins have also been reviewed (minor extension of use). Aldicarb was reviewed by the JMPR in 1994 as part of the Periodic Review Program and data reviewed by JMPR have been included where relevant.

4.1 Plant Metabolism

In potato, cotton, sugar beet and peanuts aldicarb was extensively metabolised. The parent compound was only detected in immature cotton foliage up to 37 days after treatment. In all plants aldicarb was rapidly metabolised to the sulfoxide which is in turn further oxidised to the sulfone. Aldicarb and its sulfoxide and sulfone analogues are converted to the corresponding nitriles and oximes which in turn may be converted to aldehyde, amide, alcohol and acid metabolites. Besides aldicarb sulfone and aldicarb sulfoxide, no other metabolites with an intact carbamate moiety were identified.

4.2 Animal Metabolism

In animals urinary excretion typically accounted for over 80% of the totally administered radioactive dose. Parent compound was not detected in any animal product including blood, urine, faeces, meat, offal, fat, milk and eggs. Aldicarb sulfoxide and aldicarb sulfone were present at low levels in some tissues. Aldicarb nitrile sulfone was the major tissue and milk residue in lactating goats. In the studies reviewed no other metabolites with an intact carbamate moiety (besides aldicarb sulfone and sulfoxide) were identified as being present, although the presence of minute amounts of N-hydroxymethyl aldicarb sulfone has been reported.

4.3 Residue Definition

The current residue definition for aldicarb is:

Aldicarb: *Sum of aldicarb, its sulfoxide and its sulfone, expressed as aldicarb*

The Australian residue definition is the same as the CODEX residue definition and is considered adequate based on the review of aldicarb metabolism in plants and animals.

4.4 Residue Trials and MRLs

Adequate Australian residue data were provided to support all currently registered use patterns of aldicarb. No changes to the citrus and cotton MRLs will be recommended. The sugar cane MRL will be amended to a value “at or about the limit of analytical quantitation” (*0.02 mg/kg compared to the current value of 0.02 mg/kg).

Residue data were submitted in support of uses on cereals, grape vines, potatoes and strawberries however, there are no registered uses in these crops. NRA records

indicate that uses on cereals and grapevines were previously cleared but have not been listed on the approved product labels since at least 1994. Residue data for potatoes and strawberries were submitted, however, there is no history of registered uses in these crops. As such the MRLs for all of these commodities will be deleted from the MRL Standard.

The risk of detectable residues of aldicarb occurring in animal commodities is small provided cotton forage is not used as a feed item. It is recommended that current grazing restraints remain in place and that MRLs be established at or about the limit of quantitation for meat, milk and edible offal (standard NRA practice). Residue analytical methods capable of determining aldicarb residues in animal commodities down to 0.01 mg/kg are available.

4.5 Fate of Residues in Storage

Aldicarb residues in oranges, bananas and potato products are sufficiently stable when stored frozen. There is some indication that residues in liver may be rapidly depleted during frozen storage.

4.6 Bioaccumulation Potential in Animals

Aldicarb has a log Kow of 0.053 indicating that it is unlikely to concentrate in fat deposits. Metabolism studies indicated that aldicarb is rapidly excreted and does not concentrate in the tissues, milk or eggs of animals.

4.7 Dietary Risk Assessment

The chronic dietary risk is estimated by the National Estimated Daily Intake calculation encompassing all registered/temporary uses of the chemical and dietary intake data from the 1995 National nutrition Survey of Australia. The NEDI calculation is made in accordance with accepted guidelines.

The NEDI for aldicarb is equivalent to 13% of the ADI . it is concluded that the chronic dietary exposure is small and the risk is acceptable.

Using the currently adapted deterministic methodology the acute dietary risk is estimated by the National Estimated Short Term Intake calculation (NESTI).

The use on citrus was the only use considered relevant in assessing the acute dietary risk of aldicarb. The NESTI for aldicarb in oranges and mandarins is equivalent to 17% and 6% of the acute reference dose respectively (whole population). The NESTI for children 2-6 years old is 56% and 20% of the acute reference dose for oranges and mandarins.

4.8 Conclusions

In respect of residues aspects the continued registration of aldicarb is supported. Existing MRLs will be deleted from the MRL Standard where there is no

corresponding registered use. New MRLs will be established for animal commodities and the sugarcane MRL will be amended.

	Food	MRL (mg/kg)
Delete	GC0080 Cereal Grains	*0.02
	FB0269 Grapes	0.05
	VR0589 Potatoes	0.2
	FB0275 Strawberry	0.2
	GS0659 Sugarcane	0.02
Add	ML0106 Milks	*0.01
	GS0659 Sugarcane	*0.02
	MM095 Meat [mammalian]	*0.01
	MO 0105 Edible Offal [mammalian]	*0.01
No change	FC 0001 Citrus fruits	0.05
	SO 0691 Cotton seed	*0.05

Additional label statements regarding harvest withholding periods for plant and ratoon cane and an additional feeding restraint are to be added to the product label.

4.9 Trade

Taking into consideration the early application of aldicarb in the growth of the crop, the use of aldicarb is not expected to result in residues in the 3 major exports from Australia – sugar, cotton and citrus. Codex MRLs are either the same of higher than those set in Australia, therefore adherence to label directions regarding withholding periods will not result in residues that exceed the Australian and Codex MRLs.

All major importers of Australian oranges have tolerances for aldicarb and these are above the Australian MRL. Compliance with good agricultural practice will ensure no residues in exported produce.

There has only been 1 incident where residues have occurred, thought to be as a result of failure to adhere to label withholding periods when applied to oranges. It is noted that Australian MRLs are set at or very close to the limits of analytical quantitation and violative residues of aldicarb have not been detected in Australia in any of the commodities traded.

No tolerance exist overseas for sugar but there have been no incidents where trading partners have raised concerns over the use of aldicarb in sugar. The Queensland Sugar Corporation sample raw sugar from each bulk sugar terminal to test for residues. Aldicarb has not been detected in any of the samples taken nor have any residues been detected by an importing country.

5. TOXICOLOGY ASSESSMENT

The extensive toxicological database for aldicarb consists primarily of toxicity tests conducted using laboratory animals, some experiments using human volunteers, and a number of reports of accidental or occupational exposure.

Toxicity tests in animals generally use doses that are high relative to human exposure, so that the toxic effects induced by the compound can be identified and dose levels at which these effects are unlikely to occur can be determined. These dose levels are known as the No-Observed-Effect-Level (NOEL) and are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

5.1 Kinetics and Metabolism

Studies in rats, dogs, goats and cows showed that aldicarb, given orally, was readily absorbed from the gastrointestinal tract, widely distributed to tissues, and rapidly excreted (primarily via the urine). Approximately 65-95% of aldicarb was excreted in the urine in the first 24 hours, with smaller amounts excreted in the faeces (1-3%). No dermal absorption studies were available, however from the high acute toxicity of aldicarb by the dermal route, it may be assumed that dermal absorption is substantial.

Similarities exist between the metabolic pathways of aldicarb in plants and animals. The parent compound is primarily converted to aldicarb sulfoxide, some of which is subsequently converted to aldicarb sulfone. These metabolites retain their insecticidal activity and are of high acute toxicity by the oral route. Hydrolysis and dehydration of aldicarb and its sulfoxide and sulfone metabolites results in a loss of insecticidal activity.

5.2 Acute studies

There is a substantial database of studies on the acute toxicity of aldicarb, its oxidative metabolites aldicarb sulfoxide and aldicarb sulfone, and some end-use products. Aldicarb was of high acute toxicity to rats by the oral (LD50 0.487-1.3 mg/kg bw), dermal (LD50 3.2 mg/kg bw) and inhalational (LC50 3.8 mg/m^3) routes. The compound was a slight eye irritant, but was not a skin irritant and was not sensitising to the skin of guinea pigs. Clinical signs of intoxication were indicative of anticholinesterase poisoning and included tremors, convulsions, salivation, lacrimation, muzzle and abdominal staining and/or wetness.

The time-course of cholinesterase inhibition induced by oral administration of aldicarb was investigated in rats dosed by gavage at doses of 0, 0.25 and 0.5 mg/kg bw. Clinical signs were evident in all aldicarb-treated animals 1 hour following dosing and persisted in high-dose animals 4 hours after dosing. Significant inhibition of blood and brain cholinesterase activity was observed at 1 hour post-dose and some recovery had occurred by 4 hours. Inhibition of plasma cholinesterase activity was observed in males at 0.25 and 0.5 mg/kg bw at 8 hours, but in general cholinesterase activity had recovered by this time.

In a study in which pregnant rats were given a single dose of aldicarb on day 18 of gestation, inhibition of cholinesterase activity in foetal blood, brain and liver was reported at a dose of 0.001 mg/kg bw. This dose is the current acceptable daily intake (ADI). The authors claimed that the results in this study indicated that the foetus was more sensitive to cholinesterase inhibition than maternal animals, as no inhibition of maternal blood or brain cholinesterase activity was observed at this dose. However, these findings were inconsistent with the pattern of cholinesterase inhibition observed in other studies. The cholinesterase inhibition caused by aldicarb exposure in a number of other studies was rapidly reversible, with maximum inhibition observed within one hour, and recovery usually seen within a few hours after dosing. In this particular study, maximum inhibition of cholinesterase activity was observed at 5 hours for maternal blood, and significant effects were still observed at 24 hours. There were a number of aspects of the experimental protocol that were considered to differ from current practices, including the use of two control groups, the storage of unfrozen blood samples overnight prior to cholinesterase activity determinations, and the dilution of blood samples to achieve haemolysis. There was large variability between day 18 and day 19 control values for foetal blood, maternal liver, foetal brain and foetal liver cholinesterase activity, no consistent dose-response relationship for cholinesterase inhibition, and an unexpected time-response for cholinesterase inhibition. These findings were considered to be an artefact of the study's analytical design and methodology. As such, the data did not support the conclusion that foetal rats were more susceptible to the effects of aldicarb on cholinesterase activity than adult animals.

Aldicarb sulfoxide had an oral LD50 value of 0.49 to 1.13 mg/kg bw in male rats, while aldicarb sulfone was less acutely toxic with oral LD50 values ranging from 20-38 mg/kg bw. Both compounds had dermal LD50 values of greater than 20 mg/kg bw. Rats treated with aldicarb sulfoxide by gavage at 0.25 and 0.5 mg/kg bw showed clinical signs and significant inhibition of plasma, erythrocyte, whole blood and brain cholinesterase activities at 1 hour post-dose. As observed for aldicarb treated rats, some recovery was observed by 4 hours. At 8 hours, plasma cholinesterase activity was inhibited by 48% and 37% in males and females, respectively.

Rats similarly treated with 10 and 20 mg/kg bw aldicarb sulfone showed clinical signs and significant blood and brain cholinesterase inhibition that persisted for 8 hours in one study, and inhibition of plasma and erythrocyte cholinesterase activity that persisted for up to 48 hours in another study.

The observed LD50 values for end-use products containing aldicarb were representative of the percentage of active ingredient in the formulation.

5.3 Short-Term Repeat-Dose Studies

Several short-term studies have been conducted with aldicarb and its oxidative metabolites (the sulfoxide and sulfone) both alone and in combination. Mice, rats and dogs given aldicarb showed clinical signs indicative of anticholinesterase poisoning, as well as decreases in body weight and changes in organ weights. Cholinesterase activity was not always measured in these studies, but in studies where cholinesterase activity was determined 24 hours following removal from the test diet, no treatment-related effects were observed. Rats given a 1:1 mixture of aldicarb

sulfoxide and aldicarb sulfone in the drinking water showed decreased body weight gains and food and water consumption. Significant inhibition of plasma, erythrocyte and brain cholinesterase activity was also observed.

In studies with the aldicarb metabolites, aldicarb oxime and 2-methyl-2-(methylsulfinyl) propanol-1, decreased body weight gains and changes in organ weight were observed.

Dermal studies with end-use products showed that when formulations containing about 10% of the active ingredient were applied to the scarified skin of rabbits at up to 200 mg/kg bw/day for 15 days, limited mortality, clinical signs and decreased body weight gain were observed. There were no effects in animals with intact skin.

5.4 Subchronic studies

In dogs fed diets containing up to 2 ppm aldicarb for 14 weeks, the only significant sign of toxicity was depression of plasma ChE at the high dose.

Aldicarb sulfoxide and aldicarb sulfone were given to rats and dogs in the feed for 3-6 months in several studies and effects typical of those observed in short-term studies, including reduced body weight gain, decreased feed consumption, and plasma, erythrocyte and brain cholinesterase inhibition, were observed. Treatment-related plasma and erythrocyte cholinesterase inhibition was observed in rats from doses of 0.25 mg/kg bw/day for aldicarb sulfoxide, while aldicarb sulfone significantly inhibited plasma, erythrocyte and brain cholinesterase activity from doses of 1.8 mg/kg bw/day.

5.5 Chronic/Carcinogenicity assays

There were no carcinogenic effects related to administration of aldicarb in the feed to mice for 18 months at up to 0.7 mg/kg bw/day, or to rats for two years at up to 1.87 mg/kg bw/day. The most sensitive marker of exposure to aldicarb is cholinesterase inhibition. In a 2-year rat study, plasma cholinesterase inhibition was observed at doses above 0.05 mg/kg bw/day, and in a 1-year study in dogs, plasma cholinesterase inhibition was seen at doses of 0.024 mg/kg bw/day and above. Beagle dogs given aldicarb sulfone for 1 year showed plasma cholinesterase inhibition at all doses (0.11-2.30 mg/kg bw/day).

5.6 Reproduction Studies

Reduced pup weight and pup viability were observed at the high-dose (1.3-3.4 mg/kg bw/day) in a rat reproduction study. Parental toxicity was observed at the same dose. Neonatal toxicity was evident as weak, thin and dehydrated pups at doses of 0.6-1.6 and 1.3-3.4 mg/kg bw/day, with no effects at 0.3 mg/kg bw/day.

No developmental toxicity was seen in rats at 0.125 mg/kg bw/day, but maternal toxicity and foetoxicity were seen at higher doses. No foetal toxicity or teratogenicity were observed at doses of up to 0.5 mg/kg bw/day in rabbits.

5.7 Genotoxicity

Aldicarb was not genotoxic in a range of bacterial and mammalian cells, *in vitro*. Weak positive responses only were observed in two sister chromatid exchange assays in human lymphocyte cultures and the results were considered equivocal in at least one of the assays. *In vivo*, aldicarb did not cause chromosome aberrations in a mouse bone marrow cytogenetic assay, an increase in the rate of micronuclei in polychromatic erythrocytes, or dominant lethal effects. The weight of evidence suggests that aldicarb is not genotoxic.

5.8 Neurotoxicity

Aldicarb was investigated for neurotoxicity in acute studies, a 91-day study, and a developmental neurotoxicity study in rats. Cholinergic signs, changes in forelimb and hindlimb grip strength, gait abnormalities, changes in landing foot splay, changes in response to sensory stimuli, and decreased activity levels in figure-eight maze tests were observed. The time of maximal effect was generally from about 0.5 to 2 hours after dosing, and the effects were mainly transient in nature. Inhibited pupil response appeared to be the most sensitive indicator in the neurobehavioural assay in rats treated with both aldicarb and its metabolites (aldicarb sulfoxide and aldicarb sulfone). No neuropathological effects were observed at doses of up to 0.5 mg/kg bw in an acute study and 0.4 mg/kg bw/day in the 91 day study. In a developmental neurotoxicity study, reduced grip strength, decreased rearing in the arena, reduced faecal boli and delayed analgesic reflex in response to heat stimulus were seen in rats given aldicarb at 0.3 mg/kg bw/day. The NOEL for developmental neurotoxicity was 0.1 mg/kg bw/day.

5.9 Immunotoxicity

In a published series of four experiments, the authors asserted that there was evidence for an inverse relationship between exposure to aldicarb (1 and 10 ppb) and suppression of antibody response in female Swiss Webster or CF1 mice. In response to these results another study using a similar protocol was conducted in female outbred Swiss Webster and hybrid B6C3F1 mice. The animals received aldicarb in the drinking water at 0, 0.1, 1, 10, 100 or 1000 ppb for 34 days, but no evidence of significant ($p>0.05$) immunosuppression was observed at any of the doses tested.

In 1986 it was reported that women drinking water from shallow wells that contained detectable levels of aldicarb had an increased number of $CD8^+$ cytotoxic suppressor cells and an increased percentage of total lymphocytes that resulted in a decreased T4/T8 ratio. It was considered that the study provided little evidence of immunotoxicity as a result of ingestion of aldicarb given the small sample size, the lack of a calculation of dose with respect to body weight and the failure to determine other toxicants that may have been present in the water. In the follow up study in 1990 conducted on 14 volunteers from the previous cohort, it was found that 3 had a 50% reduction in $CD8^+$ cytotoxic suppressor T-cell count whereas 11 others recorded no change. The women had not been exposed to aldicarb in drinking water since 1985, and the lack of reversibility for the reported effect appears to further weaken the original hypothesis.

5.10 Human Studies

In human studies, clinical signs including sweating, nausea and vomiting, pinpoint non-reactive pupils, malaise, weakness, epigastric pain, yawning, salivation and slurred speech were observed from doses of 0.075 to 0.1 mg/kg bw. Whole blood cholinesterase activity was significantly inhibited at doses of 0.025 to 0.1 mg/kg bw in a 1970 study. In a more recent study conducted according to EU Good Clinical Research Practice, plasma and erythrocyte cholinesterase activities were significantly inhibited at 0.025-0.075 mg/kg bw in males and 0.025-0.05 mg/kg bw in females. The NOEL for plasma and erythrocyte cholinesterase inhibition was 0.01 mg/kg bw.

5.11 Human Poisonings

Several human poisoning incidents resulting from the ingestion of aldicarb contaminated cucumbers and watermelons have been reported in the literature. In 1990, a published report endeavoured to estimate aldicarb dosages from four separate poisonings that occurred in the US between 1978 and 1988. The poisonings (some with clinical signs) occurred at estimated doses of 0.001 to 0.06 mg/kg bw based on self reports of the amount of fruit consumed, averaged weights of the consumable portions, estimates of body weights by age and sex, and estimates of aldicarb sulfoxide determined in the fruit. In a paper published in 1987, after 140 people had become ill from eating cucumbers adulterated with a pesticide, the estimate of the dose of aldicarb ingested for 13 cases ranged between 0.01 and 0.03 mg/kg bw/day.

While these dose estimates were lower than those that caused effects in controlled studies, it was considered that the description of many of these cases was limited in terms of onset, duration of clinical signs or final outcome. Many of the clinical signs reported were non-specific (abdominal cramping and vomiting), and the use of estimates of body weight and self-reported food consumption may have influenced dosage estimates.

5.12 Public Health Standards

Acceptable Daily Intake

The current Australian acceptable daily intake is 0.001 mg/kg bw/day, derived from a NOEL of 0.01 mg/kg bw, based on plasma and erythrocyte cholinesterase inhibition observed at higher doses in a single-dose human study. A 10-fold safety factor was used to account for inter-individual variability. No change is recommended to the current ADI [refer to 4.7 in the residue assessment for dietary risk assessment information].

Acute Reference Dose

The recommended acute reference dose for aldicarb is 0.001 mg/kg bw derived from a NOEL of 0.01 mg/kg bw in a single dose human study and applying a 10-fold safety factor.

Poisons Scheduling

No change to the current schedule of Schedule 7 of the SUSDP is proposed for aldicarb.

6. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

6.1 Toxicity

Technical aldicarb is of high acute toxicity by oral, dermal and inhalational routes. It is a slight eye irritant but not a skin irritant or dermal sensitiser. Oral studies conducted in rats, dogs, goats and cows revealed that aldicarb was readily absorbed from the gastrointestinal tract, widely distributed, and excreted in the urine, faeces, and expired CO_2 within 24 hours. Following this initial rapid elimination, smaller amounts were slowly eliminated in the urine for several days thereafter.

The metabolite aldicarb sulfoxide is of similar acute oral toxicity to the parent compound but is of lower toxicity by the dermal route. Aldicarb sulfone, while still of high acute oral toxicity, is substantially less toxic than the parent compound.

6.2 Absorption characteristics

The main potential routes of occupational exposure to aldicarb are dermal and inhalational. Aldicarb does not vaporise extensively at ambient temperatures, thus while extremely toxic when inhaled the inhalation hazard of aldicarb is not considered a major concern.

It has been noted that dermal toxicity is greatly reduced for granular formulations of aldicarb. However, if the granular material containing aldicarb is moistened, the dermal toxicity is significantly increased and this could potentially lead to acute poisoning upon dermal contact.

There is no known dermal absorption data available for aldicarb. In the absence of dermal penetration studies for aldicarb, a dermal absorption estimate of 100% is assumed for (wet granules).

6.3 Health effects

Reported health effects following exposure to aldicarb varied from skin or eye irritation to systemic illnesses. These health effects were either from direct exposure to the granules or exposure to aldicarb residues. Direct exposure was either by dermal or inhalational exposure, or to partially eroded granules, or exposure to dissolved granules. Common symptoms included dizziness, nausea, headache and abdominal pain. These effects were resolved by either withdrawing the worker from the exposure scene or if severe enough, hospitalisation or treatment with atropine.

Three outbreaks of food poisoning involving the ingestion of cucumbers and melons contaminated with aldicarb residues were reported overseas. Signs and symptoms of poisoning included diarrhoea, vomiting, lacrimation, salivation, miosis, convulsions and death. The health effects were due to exposure to aldicarb sulfoxide, one of the toxic metabolites of aldicarb.

Acute haemorrhagic necrotic pancreatitis has been reported in a patient after ingestion of Temik granules. Serum cholinesterase levels were low while red blood cholinesterase was within normal range. The diagnosis of pancreatitis was confirmed by various biochemical and radiological investigations.

6.4 Occupational Exposure Assessment

6.4.1 Exposure prior to end use

The granular formulation of aldicarb is the only type of product currently registered in Australia. Exposure of Australian workers during manufacture/formulation is unlikely as the two registered products containing aldicarb at 150 g/kg are manufactured/formulated overseas. Both products are imported in 20 kg packages. Exposure during routine transport, storage and retail may occur, however this is expected to be minimal.

6.4.2 End use exposure

Aldicarb is currently registered for a variety of crops including plant and ratoon cane (stages in sugarcane growth), cotton, non-bearing citrus, oranges and mandarins.

Loading of aldicarb into application equipment for all crops is carried out using an enclosed transfer system. Protective clothing is recommended during both loading and application of the aldicarb granules.

Apart from ratoon cane and citrus, aldicarb is applied at planting. In plant and ratoon cane and citrus, the granules must be applied to growing plants. When applied to growing crops, they are distributed along the side of the rows of plants (band treatments) rather than in the row itself. Both methods of application require the granules to be incorporated into the soil and this is carried out by machinery designed for this use.

6.4.3 Post application exposure

There is a potential for post-application exposure for persons entering treated areas after application is complete. Although aldicarb does not exhibit significant volatility due to its incorporation beneath the soil surface, contact with moist soil after application can result in exposure to aldicarb. No post-application exposure data or dislodgeable residue data were available for aldicarb. Current labels do not carry any re-entry period statement.

6.4.4 Parameters used in exposure assessment

To facilitate the exposure and risk assessment, exposure scenarios for aldicarb use for the various crops/situations were identified. These scenarios are identified below:

Exposure scenarios identified for aldicarb are:

Scenario (1)	Loading and application for treatment of plant and ratoon cane
Scenario (2)	Loading and application for treatment of cotton
Scenario (3)	Loading and application for treatment of non-bearing citrus
Scenario (4)	Loading and application for treatment of oranges/mandarins

6.4.5 Use patterns

Plant and ratoon cane

It is estimated that in a day (6-8 hours) 8 to 10 ha can be treated. In plant and ratoon cane aldicarb is applied as a soil treatment only once to the crop and not later than the 3-5 leaf stage. Application is carried out using tractor-mounted applicators which can feed granules directly into a microfeed applicator which applies the product across the width of the drill. The product is then incorporated with rakes discs or tynes and the area irrigated. The product is only applied once to the crop. No worker exposure is expected during application as the process is fully automated. Protective equipment is worn during loading and application. It is anticipated that in most instances loading and application will be carried out by the farmer or farm employee.

Cotton

Workers treating cotton for various pests are expected to treat 30-50 ha of cotton per day. Application in cotton requires accurately calibrated tractor mounted equipment which does not grind the granules. Granule applicators attached to the cultivation bar distribute granules to the seed furrow or bed. There is usually a single operator per tractor. Exposure during application is unlikely as the process is fully automated and protective equipment is worn during loading and application.

Non-bearing citrus

A broadcast (area) or band treatment is recommended for control of citrus leaf-miner in non-bearing citrus. Workers will treat 3 ha/day. Aldicarb is applied to growing crops, prior to, or as pests appear using a granule applicator attached to a tractor. Application is carried out with applicators which do not grind the granules. The granules are incorporated to a depth of 30-50 mm and covered with soil. No exposure is expected as application is automated. Repeat applications may be required if pests return.

Oranges/Mandarins

Aldicarb is registered for the treatment of citrus nematode in oranges/mandarins. No exposure is expected during loading as the process is fully enclosed. The product is applied once per year after crop harvesting and pruning of the second crop as a band application and incorporated into the soil to a depth of 30-80 mm. Worker exposure

is not anticipated as application is automated. Workers are expected to wear PPE during loading and application.

6.5 Occupational risk assessment

6.5.1 Introduction

The occupational risk assessment takes into consideration the hazard of the chemical as determined by toxicology testing, its use pattern in Australia, and worker exposure for each exposure scenario.

The main adverse health effect of aldicarb exposure is cholinesterase (ChE) inhibition. The most appropriate No Observable Effect Level (NOEL) to assess occupational risk to workers was determined to be 0.01 mg/kg/day, established in a human study, for ChE inhibition. A dermal absorption of 100% for wet granules was used in the risk assessment. No correction was made for inhalation absorption, as 100% absorption was assumed.

A human NOEL is used to estimate risk. Therefore, Margins of Exposure (MOE) of approximately 10 or more are considered to be acceptable, to account for intra-species (10x) variability.

In estimating the risk to workers handling aldicarb products, it is assumed that workers wear appropriate PPE, as specified on product labels.

6.5.2 Risk assessment

Predictive exposure modeling (using the UK Predictive Operator Exposure Model, POEM) was not used to asses occupational health and safety exposure to aldicarb. This model does not contain suitable scenarios to estimate worker exposure to granular applications.

Risk from end use exposure was estimated using surrogate data. The surrogate study used was a worker exposure study conducted on pecans with exposure of workers during loading and application of aldicarb measured. This study could be considered a worst case scenario as granules were loaded manually as opposed to enclosed loading as is the standard practice in Australia. Application rates and the total amount of aldicarb handled per day were also higher in the study than the rates and amount of aldicarb handled by workers under Australian conditions. This is shown in the table below. Worker exposure (dermal and inhalational) to aldicarb during application to pecans is considered acceptable for both loaders and applicators as MOEs were >10.

Surrogate study vs Australian use patterns

Work parameters/ Exposure values	Measured worker exposure study on Pecans (Study No. 94388, 1995)	Scenario 1: Plant and ratoon cane	Scenario 2: Cotton	Scenario 3: Non-bearing citrus	Scenario 4: Oranges/ mandarins
Application method		Mechanical (microfeed applictor)	Mechanical (granule applicatior attached to a cultivation bar)	Mechanical (granule application attached to tractor)	Mechanical (granule application attached to tractor)
Concentration of ai in product	1.5%	15%	15%	15%	15%
Application rate	6.7 kg ai/ha	2.55 kg ai/ha or 0.0036 kg ai/10 m row	0.45 kg ai/ha to 1.05 kg ai/ha	0.00105 kg/m^2 or 0.0045 kg ai/tree	2.1 kg ai/ha to 11.55 kg ai/ha
Work rate		8-10 ha/day	30-50 ha/day	3 ha/day	3 ha/day
Total ai handled/day	61.4 kg –101 kg	20.4 kg – 25.5 kg	13.5 kg– 31.5 kg (30 ha) 22.5 kg – 52.5 kg (50 ha)	Varies with area size or number of trees	6.3 kg – 34.65 kg
PPE	Shorts and short sleeved shirts under cotton-polyester long-sleeved coveralls, dust/mist filtering respirator, nitrile gloves, rubber boots, goggles, hard hats, and a chemical-resistant apron (loader only)	Cotton overalls buttoned to the neck and wrist, washable hat, elbow-length PVC gloves and half-face respirator with dust cartridge or canister			

Exposure calculations from Pecan Study

	Loader	Applicator
Mean dermal exposure	0.000234 mg/kg ai (9.72 µg/hr)	0.0000584 mg/kg ai (1.18 µg/hr)
Mean inhalation exposure (@ 28L/min)	0.0000421 mg/kg ai (1.74 µg/hr)	0.0000099 mg/kg ai (0.201 µg/hr)
MOE – dermal exposure	43	171
MOE – inhalation exposure	237	1010

- MOE – margin of exposure
- A MOE of 10 or more is considered acceptable
- MOE = NOEL (0.01 mg/kg) ÷ daily absorbed dose (mg/kg/day)
- one day = 6-8 hours exposure

6.6 Health Surveillance

Carbamates (including aldicarb) are not listed on the NOHSC Schedule for Health Surveillance (Schedule 3)[NOHSC 1994a]. Aldicarb has been assessed as being of high acute toxicity, with cholinesterase inhibition (reversible) identified as the critical effect in animals and humans. However under the current conditions of use in Australia the risk of adverse effects in workers has been assessed as low. As such health surveillance is not recommended as a mandatory requirement for aldicarb. However should conditions/patterns of use for aldicarb change, with a concomitant increase in potential exposure to workers, then the requirements for health surveillance should be re-assessed according to existing NOHSC guidelines [NOHSC 1994; NOHSC 1998].

6.7 Conclusions

Application rates and the amounts of active ingredient handled in the treatment of plant and ratoon cane, cotton, non-bearing citrus and oranges/mandarins were far less than that stated in the worker study. As the margins of safety in the surrogate study were acceptable, margins of safety are expected to be acceptable for workers using aldicarb in the treatment of the above crops.

The above conclusions are made on the basis that:

- an enclosed transfer system is used for loading the granules into the applicator;
- the application process is automated and no handling of granules occurs; and
- the products are used in accordance with label instructions.

An additional label statement is recommended for labels in order to protect workers who re-enter treated areas. The statement is as follows:

> DO NOT enter, or allow any other person to enter treated area without protective footwear. Persons coming into direct contact with treated soil after the initial irrigation or rainfall following treatment must wear overalls, rubber or neoprene boots and gloves.

7. ENVIRONMENTAL ASSESSMENT

7.1 Introduction

The carbamate insecticide/nematicide aldicarb scored highly against selection criteria for the existing chemicals review program, particularly in light of overseas incidents and regulatory action (bird kills and groundwater contamination in the US).

Aldicarb has high water solubility and is formulated as granules for incorporation beneath the soil. It disperses through the soil with soil moisture on release from the granules, and is taken up by plant roots and translocated through the plant to provide systemic protection against chewing and sucking insect and nematode damage.

7.2 Environmental exposure

The total use of aldicarb in Australia does not exceed 100 tonnes per annum. Only small amounts (less than 10 tonnes combined) are used in sugarcane and citrus. The main use is in cotton in NSW and central and southern Qld only.

Aldicarb is not included among the analytes monitored in broadscale Australian monitoring programs such as the Central and North West Regions Water Quality Program. Inclusion in this program seems attractive but would be difficult as a separate and expensive assay would need to be conducted since aldicarb would not picked up in their current screen. Further, it is unclear whether it would routinely detect aldicarb under its present structure (mainly weekly or fortnightly sampling of surface waters) given the low rates, single application per season and soil incorporation.

7.2.1 Environmental Chemistry and Fate

Testing has been conducted in the following areas to determine the environmental fate of aldicarb.

Hydrolysis

Studies submitted indicate that hydrolysis of aldicarb is slow under laboratory conditions. The toxic metabolites aldicarb sulfoxide and aldicarb sulfone also resist hydrolysis unless conditions are alkaline. Under environmental conditions, hydrolysis of the carbamate linkage occurs more readily (half-lives in the order of a week) because of catalysis by sediment.

Photolysis

The photostability of aldicarb in aqueous solution was determined from summary data contained in reviews. A report on soil surface photolysis was also submitted. Photolysis is unlikely to be a significant pathway for dissipation of aldicarb in the environment as it will be applied beneath the soil and appears resistant to photolysis in aqueous solution.

Metabolism

Several aerobic metabolism studies conducted in a variety of soils were submitted, including detailed studies of the persistence of aldicarb and its toxic sulfoxide and sulfone metabolites in Dutch topsoils and subsoils. The focus of these studies was the persistence of toxic residues. Only limited investigations were conducted into the identities of detoxified metabolites. A single aerobic/anaerobic soil study was also submitted, together with aquatic metabolism studies under aerobic and anaerobic conditions, including simulated aquifer conditions. Many of the studies were conducted at lower temperatures than would prevail in Australian soils, making the results conservative predictors of persistence under Australian conditions.

Aldicarb is rapidly oxidised to aldicarb sulfoxide, thought to be the main active material in soil, and more slowly to aldicarb sulfone. These oxidative reactions occur concurrently with hydrolysis to oximes, which are further transformed to other compounds (amides, nitriles, alcohols and carboxylates). Only the sulfoxide and sulfone metabolites retain the high toxicity of aldicarb, which is lost upon hydrolysis of the carbamate linkage.

Detoxification half-lives in topsoils are typically a few months but exhibit considerable variability. The controlling factors are not well understood. The detoxification reaction can be very slow in some aerobic or partially aerobic subsoils. For example, aldicarb sulfone has been found to be essentially stable over periods of a year under such conditions, including in subsoils taken from three Dutch sites with documented groundwater contamination. In contrast, detoxification can occur surprisingly rapidly (half-life a few days or weeks) in anaerobic soils.

The initial detoxification reaction (cleavage of the carbamate linkage) appears to be abiotic in nature. Oxidation of aldicarb may occur abiotically or with microbial involvement. Mineralisation of the detoxified metabolites appears to depend on microbial activity.

Detoxification reactions appear to proceed much more readily in aquatic systems, with half-lives of a few days in tests conducted under aerobic or anaerobic conditions. However, the occurrence of aldicarb residues in groundwater indicates that detoxification reactions do not occur readily in all aquatic environments, and persistence in samples of shallow groundwater has been confirmed in the laboratory under partially anaerobic conditions.

Mobility

Several standard batch adsorption studies were conducted in a variety of soils in order to determine the partitioning behaviour of aldicarb and its toxic sulfoxide and sulfone metabolites. These studies were supported by standard column leaching studies, again with aldicarb and its toxic metabolites, and by a specialised leaching study designed to demonstrate upward movement under drying conditions. Movement of aldicarb through the soil profile was modelled at three canefield sites with sandy soils in the Bundaberg district.

Standard batch equilibrium studies indicate that aldicarb is only weakly adsorbed by soils, and its oxidation products even less so. Aldicarb and its toxic metabolites share significant water solubility and tend to move with soil moisture through the soil. Low adsorption coefficients indicate that mobility in soils is high, and this has been confirmed in leaching experiments with soil columns. Simple model calculations identify aldicarb as a probable leacher. More sophisticated computer models found relatively low mobility, with residues confined to the surface 200-400 cm, but assumed a relatively rapid degradation (15 day half-life) which is appropriate for the site studied (Bundaberg) but would not be representative of areas where groundwater contamination by the more persistent sulfoxide and sulfone metabolites has occurred.

Field dissipation

Reports of field investigations in the UK, US and Australia were submitted. Results confirm the laboratory predictions of high mobility for aldicarb, and highlight the importance of soil properties in determining the degree of off-target movement.

Soil residue studies on UK grassland found oxidation to be a significant metabolic pathway, together with hydrolytic degradation pathways that left only 2% toxic residues after 2 months.

Investigations of persistence and mobility beneath California vineyards illustrate the importance of meteorology to the dissipation and movement of aldicarb. Half-lives were much longer after winter treatment (3.5 months) than when aldicarb was applied in spring (2 months) because of colder soil temperature. Leaching to deeper groundwater (below 10 m) from winter treatments became noticeable when late winter and early spring rains carried aldicarb down through the soil profile. Contamination in the order of 10 µg/L was detected over the following two seasons, together with higher contamination (93 µg/L) remote from the treated area because of preferential lateral flow through a perched water table. Higher residues (a spring peak of 135 µg/L) were seen in shallow groundwater (< 2 m) and recurred over the following two seasons (77 and 113 µg/L, respectively).

Aldicarb dissipated more rapidly during the summer growing season in Georgia, with half-lives in the order of 2-3 weeks for total carbamate residues. Field dissipation rates were around three times faster than those observed in the laboratory. Leaching did not appear to be a problem with these more rapid degradation rates, notwithstanding application to well drained sandy soils. No residues were detected below 1.2 m during 4 consecutive years of study.

Studies in citrus groves on sandy soils in SA found residues in shallow tile drainage, at about 10 µg/L at one site and 50 µg/L at another, following application of aldicarb at about 10 kg/ha. Contamination of tile drainage proved persistent following these high rates of application to sandy soils, remaining at about 50 µg/L with little sign of dissipation after a year at one location. Aldicarb sulfoxide was the main contaminant.

Little off-site movement was apparent when aldicarb granules were used at lower rates (< 1 kg/ha) in Australian cotton planted on clay soils. The half-life appeared from limited data to be about a week near the soil surface. Analysis of surface and groundwater samples generally failed to detect aldicarb. The highest detections

occurred in inter-row tailwater (116 µg/L) and tile drainage (37 µg/L) when samples were taken a day after treatments that coincided with significant rainfall.

Bioaccumulation

As hydrophilic compounds, aldicarb and its toxic sulfoxide and sulfone metabolites would be expected to have a very low capacity for bioaccumulation, and this has been confirmed experimentally in bluegill sunfish.

7.3 Environmental effects

Toxicity tests with aldicarb have been conducted in the following organisms.

7.3.1 Birds

Reports were submitted on acute oral testing in five species and acute dietary testing in one species. Palatability of aldicarb granules was studied in cage trials with five species under laboratory or field conditions. Reports of detailed wildlife monitoring studies were also submitted.

Aldicarb is highly to very highly toxic to birds on an acute basis, with most LD50s below 5 mg/kg. Cage studies with 6 species show that birds can consume lethal quantities of aldicarb granules, particularly when food is in short supply, but that at least some individuals seem to reject the granules completely. Surveillance in the field in both the UK and the US confirmed that a limited number of birds are likely to be killed by use of aldicarb, but without affecting populations. Carcases were recovered in low numbers (generally less than ten specimens) from individual field study sites. Residue analysis confirmed exposure to aldicarb in around half of the specimens examined. Granules left exposed on the surface appeared to be the main source of exposure, but other sources such as contaminated earthworms were also identified.

7.3.2 Aquatic organisms

A basic aquatic toxicity package for aldicarb was submitted, consisting of acute tests with rainbow trout and bluegill sunfish, chronic tests with rainbow trout, acute tests with daphnids and mysids, reproductive testing with daphnids, and algal growth inhibition tests with a green alga. Limited data for sulfoxide and sulfone metabolites were also submitted. Laboratory results were supplemented by limited field data.

Available test results indicate that aldicarb is highly toxic to most fish under conditions of acute exposure. Threshold concentrations for toxic effects are similar for acute and chronic exposures, and chronic toxicity to fish is slight. Crustaceans share similar acute sensivity, but are affected by lower concentrations when chronically exposed. Maternal mortality rather than reproductive impairment is the main indicator of chronic effects in daphnids. Aldicarb is slightly to moderately toxic to a green alga. Laboratory effects on aquatic fauna have been confirmed in the field, with mortality of fish and frogs reported from exposures in the low mg/L range but few further details available.

Aldicarb sulfoxide and aldicarb sulfone share the high toxicity of aldicarb when tested with daphnids. The three toxicants also appear to share similar toxicity towards green algae. However, fish toxicity of metabolites is markedly reduced, being moderate for the sulfoxide and no more than slight for the sulfone.

7.3.3 Non-target terrestrial invertebrates

A limited package of data was submitted to address toxicity to non-target terrestrial invertebrates. Reports of laboratory testing with bees were not provided, but high toxicity is documented in the literature. However, bees are unlikely to receive high exposure to this soil applied insecticide. Because of its systemic properties, limited exposure of bees to aldicarb may occur through consumption of nectar containing residues. A study was submitted confirming that bees in citrus groves can be killed through this exposure route, but in relatively low numbers and only for a limited period.

Earthworm toxicity studies were also not submitted. Published results indicate that aldicarb is moderately toxic to toxic to earthworms.

Carabid beetles also appeared susceptible to aldicarb, suffering complete mortality soon after exposure to heavily treated sand.

Field studies indicate no long term damage to non-target insect populations from use of aldicarb.

Laboratory tests with bacteria and fungi indicate that effects on microbial populations in the field are unlikely.

7.3.4 Mammals

Rodent data indicate that mammals are likely to be at least as sensitive to aldicarb as are birds.

7.3.5 Plants

Aldicarb does not appear to affect the germination and growth of plants, apart from improvements to plant vigour as a result of insect and nematode control.

7.4 Prediction Of Environmental Hazard

Aldicarb is mobile in most soils to which it is applied, but particularly in sandy soils (sands, loamy sands and sandy loams) where any water input tends to recharge rapidly through the profile, carrying aldicarb with it. Aquifer contamination, particularly shallow groundwater, is most likely to occur when aldicarb is applied at high rates to acidic sandy soils when soil temperatures are low and heavy rain or irrigation occurs. Under Australian use patterns, this combination of circumstance is most likely to arise in citrus grown in southern States, where high rates of application coincide with spring rains.

Aldicarb has high to very high toxicity to birds, mammals, aquatic organisms and non-target invertebrates. These toxic properties indicate a potential hazard to birds, mammals and non-target invertebrates exposed to aldicarb at the site of application, and to aquatic fauna exposed to residues in water draining treated areas. Again, hazard is highest in citrus because of the high rates used.

7.4.1 Terrestrial hazard

Birds may ingest granular pesticide formulations when foraging for food or grit. They also may be exposed by other routes, such as walking on exposed granules, drinking water contaminated by granules, or consuming contaminated prey.

The US EPA has adopted a level of concern of 1 LD50 per square foot (roughly equivalent to 10 LD50s/m^2) as a screening tool to identify low risk granular pesticides for which no further work is needed. Again, this procedure assesses hazard rather than risk, as it measures only the number of granules potentially available to birds, with no information on the likelihood of consumption. Exposures are tabulated below, based on an avian LD50 of 1 mg/kg for a small bird weighing 20g.

Crop	Application rate	Exposure (LD50s/m^2)
Sugarcane	2550 g/ha	12750
Cotton	450-1050 g/ha	2250-5250
Citrus	2100-11550 g/ha	10500-57750

The above procedure greatly overestimates risk when applied to aldicarb as granules are incorporated beneath the soil. If 0.1% of granules remain exposed at the surface, exposure levels in cotton fall below the US EPA's level of concern, but remain significantly above 10 LD50s/m^2 for sugarcane and citrus. For these more heavily treated crops, granule incorporation levels need to exceed 99.99% in order to reduce exposure of small birds below the US EPA's level of concern.

Avian exposure in treated areas will not be uniform as application in bands or in-furrow will leave most of the paddock untreated. Birds may forage preferentially within treated areas where soil has been disturbed.

A granule incorporation study used inert gypsum granules coated with a fluorescent dye to qualitatively determine the efficiency of granule incorporation using photographic methods. Granules were applied to citrus at 37 kg/ha by soil injection and at 75 kg/ha as broadcast in-furrow treatment, and to cotton at 22.4 kg/ha as side dressing by soil injection and at 7.8 kg/ha in-furrow at planting. Incorporation using these methods, with care taken to disengage application equipment before row ends, was said to be excellent. Discing of row ends was effective in incorporating any granules spilt in these situations. Wildlife impact is predicted to be minimal where granules are incorporated beneath the soil as required.

Predictions of minimal wildlife impact need to be substantiated by surveillance activities when products enter the market. Such activities form an integral part of the product stewardship programs operated by most agricultural chemical registrants.

For mammals, a similar analysis can be carried out as for birds. Risks to mammals appear low provided that granules are efficiently incorporated beneath the soil. Few mammals other than pest rodents would be expected to be present in Australian cotton fields, canefields or citrus groves.

Estimated soil residues of aldicarb, assuming even dispersion through 30 cm soil (density 1.2) overlap with the more sensitive results from earthworm toxicity testing, suggesting the likelihood of a hazard to earthworms in the field. This conclusion is supported by field observations of earthworm mortality in aldicarb treated areas, particularly when soils are wet.

The broad spectrum of insecticidal and nematocidal activity suggests that aldicarb will be hazardous to many soil dwelling arthropods in treated areas. This is illustrated by the early onset of toxicity in laboratory testing with carabid beetles.

Hazard to surface dwelling arthropods is likely to be relatively low for exposure reasons. Aldicarb is incorporated in soil and taken up into plants. Sucking and chewing insects are likely to suffer adverse impacts if they feed on plants containing aldicarb residues. Field observations indicate that this hazard even extends to bees because of residues in nectar and/or pollen, but for a limited period only. Predatory insects may be exposed to aldicarb residues in prey or from limited feeding on plant material. As noted in the agricultural assessment, disruptions to integrated pest management programs in citrus have been experienced with use of aldicarb.

7.4.2 Aquatic hazard

Aquatic exposure to aldicarb and its toxic metabolites may arise when drainage water enters natural bodies of water. Contamination by aerial drift should not arise as aldicarb is applied to the soil in granular form and incorporated. Similarly, residues are unlikely to be washed off the soil surface by erosive rainfall in the sediment phase of runoff because they will remain for the most part below the soil surface. Rather, residues will mainly be confined to subsurface drainage. The persistence of aldicarb residues in soil means that drainage water is likely to remain contaminated for extended periods, particularly in acidic subsoils where degradation is slower. Residues may leach to groundwater or move laterally with tile drainage into irrigation drainage systems, and subsequently to natural surface water.

The standard runoff scenario used for risk assessment by the US EPA entails a treated area of 10 acres draining into a 1 acre pond with a depth of 6 feet (Urban and Cook, 1986). A generalised maximum runoff figure of 1.5% is used, based on earlier findings that runoff losses of water soluble pesticides range from less than 0.5% to a maximum of 1.5% if a large, early runoff event occurs. Predicted concentrations of aldicarb in a 2 m pond, based on this model, are tabulated below.

Crop	Application rate	Predicted concentration
Sugarcane	2550 g/ha	19 µg/L
Cotton	450-1050 g/ha	3.4-8 µg/L
Citrus	2100-11550 g/ha	16-87 µg/L

The most sensitive acute LC50s for fish are 560 µg/L in cold water (rainbow trout) and 63 µg/L in warm water (bluegill sunfish). Predicted concentrations remain below 56 µg/L (10% of the LC50 for rainbow trout) except towards the upper end of the citrus range. However, these predictions would appear conservative in light of results from field studies in Australian citrus, which found that maximum residues in tile drainage did not exceed 50 µg/L. Given dilution in receiving waters, it appears unlikely that runoff from Australian citrus would give rise to concentrations in adjacent waterways that would be toxic to cold water fish such as rainbow trout.

Predicted concentrations exceed 6.3 µg/L (10% of the LC50 for bluegill sunfish) for sugarcane, citrus, and higher rate applications to cotton. This simple screening evaluation suggests that a hazard may exist for more sensitive fish such as bluegills, particularly in shallow water (note that the above predictions assume a water depth of 2 m which is likely to be deeper than commonly found in Australian cropping situations). Additional concerns are raised by the likely repetitive nature of the exposures. Local field studies show that runoff from citrus can remain contaminated for up to a year with little evidence of declining concentrations.

For invertebrates, the usual indicator organism is *Daphnia magna*. The most sensitive acute EC50 is 411 µg/L, disregarding the more sensitive result obtained under conditions of temperature stress. Predicted concentrations remain below 10% of this concentration, except at the upper end of the citrus range. The preceding comments regarding the conservative nature of these predictions, and the low likelihood that toxic concentrations would arise in practice, remain valid.

Other invertebrates such as chironomids and mysid shrimp exhibit greater sensitivity, with LC50s around 10 µg/L. Aldicarb contaminated runoff appears more likely to exert adverse impacts on sensitive invertebrate organisms such as these.

7.5 Conclusions

Aldicarb is a moderately persistent and highly mobile, hydrophilic carbamate nematicide/insecticide which is mostly used in cotton but also has relatively small but important uses in sugarcane and citrus. It is applied to soil at relatively high rates in granular form and incorporated beneath the soil surface. Soil moisture liberates aldicarb from the granules and distributes it through the root zone, where it helps control damaging nematode populations. Uptake by plant roots offers systemic protection against sucking and chewing insect attack for several weeks.

A recent international evaluation of aldicarb concluded that it would not cause effects on organisms in the environment at the population level. Incidents of kills of individual birds and mammals will occur where granules are not fully incorporated into the soil. Aquatic organisms are not at risk from aldicarb. The report recommends that exposure of terrestrial vertebrates be minimised by fully incorporating aldicarb granules into soil to a depth of 5 cm, as recommended by the manufacturer.

Aldicarb granules represent a primary poisoning hazard to any mammals and birds that may eat them, particularly if they have relatively low body weight. Incorporation beneath the soil as required by the label minimises this hazard. It is important that

label instructions are closely followed in this regard if wildlife impacts are to be avoided.

Risks to most terrestrial invertebrates are also relatively low because aldicarb remains below the soil surface. Short term impacts to earthworms have been recorded, and some transient effects on pollinators visiting citrus as well as disruption to integrated pest management programs in this crop.

The mobility and persistence of aldicarb and its toxic sulfoxide and sulfone metabolites raise concern for groundwater contamination. Overseas experience suggests that such problems are less likely in cotton and sugarcane because of the warm soils which facilitate breakdown. Contamination appears more likely in citrus grown in southern States, because of high application rates, sandy soils, cool temperatures at the time of application, and the likelihood of heavy spring rains. However, only small amounts of aldicarb are used in Australian citrus, and significant contamination therefore appears unlikely.

Contamination of surface water also merits consideration, given the mobility and toxicity of aldicarb. Simple screening methods indicate a potential hazard to more sensitive fish species. Hazard to more sensitive invertebrate species such as shrimps is also apparent. However, effects are likely to be transient as aldicarb does not persist in surface waters, and longer term invertebrate impacts would not be expected given the high reproductive capacity characteristic of such organisms.

In order to monitor the load of aldicarb in the environment following use in citrus, the registrant will be required to provide information on amounts aldicarb applied and the areas in which it is used for a 3 year period.

8. REGULATORY APPROACH FOR ALDICARB

8.1 Introduction

In developing the following regulatory approach for aldicarb, the NRA consulted with State authorities, reviewers of each component part of the review, user and commodity groups.

This information shows that although a highly toxic chemical, aldicarb use in Australia is not expected to result in any adverse impacts on the environment, public health, worker safety or trade. Therefore the NRA is satisfied that the approvals and registrations of aldicarb in Australia can be affirmed. Minor modifications to currently approved labels are required, as well as modification to the current aldicarb entries in the MRL Standard.

8.2 Recommendations

The following recommendations will apply to the labels and registered details of products containing aldicarb.

TOXICOLOGY

Recommendation 1: Acceptable daily intake

- The acceptable daily intake (ADI) is 0.001 mg/kg

Recommendation 2: Acute Reference Dose

- The acute reference dose if 0.001 mg/kg bw

Recommendation 3: Poison scheduling

- The poison scheduling of aldicarb is schedule 7 (S7)

Recommendation 4: First aid directions

- The first aid directions for aldicarb are as follows:

If poisoning occurs contact a doctor or Poisons Information Centre (131 126)	a
If swallowed give one atropine tablet every 5 minutes until dryness of the mouth occurs. If poisoned by skin absorption or through lungs, remove contaminated clothing, wash skin thoroughly and give atropine tablets as above. Get to a doctor or hospital quickly.	h

RESIDUES

Recommendation 5: Changes to the MRL Standard

The following changes will be made to the MRL Standard for aldicarb .

Compound		Food	MRL (mg/kg)
Delete:	GC 0080	Cereal grains	*0.02
	FB 0269	Grapes	0.05
	VR 0589	Potatoes	0.2
	FB 0275	Strawberry	0.2
	GS 0659	Sugar cane	0.02
Add:	ML 0106	Milks	*0.01
	MM 095	Meat [mammalian]	*0.01
	MO 0105	Edible offal [mammalian]	*0.01
	GS 0659	Sugar cane	*0.02
No change:	FC 0001	Citrus fruits	0.05
	SO 0691	Cotton seed	*0.05

* at or about the limit of analytical quantitation

Recommendation 6: Withholding periods/feeding restrictions

The harvest withholding period for plant and ratoon cane must be amended to:

Plant and Ratoon Cane: Not required when used as directed.

The following additional feeding restriction must be added:

DO NOT feed cotton trash to animals

OCCUPATIONAL HEALTH AND SAFETY

Recommendation 7: Safety directions

- The changes recommended for aldicarb safety directions are highlighted below in bold.

Aldicarb GR 150g/kg or less

Very dangerous, product is poisonous if absorbed by skin contact, inhaled or swallowed	100, 120, 130, 131, 132, 133
Avoid contact with eyes and skin	210, 211
Do not inhale dust	220, 221
Do not touch or rub eyes, nose or mouth with hand when handling granules	**140, 141**
When using the product wear cotton overall buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves, half facepiece respirator with dust cartridge or canister	279, 283, 290, 292, 294, 300, 302
If product on skin, immediately wash area with soap and water	340, 342
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, contaminated clothing, respirator and if rubber wash with detergent and warm water	360, 361, 364, 366
Obtain an emergency supply of atropine tables 0.6 mg	373

Recommendation 8: Container Design

An enclosed transfer system for loading the granules into the applicator must be adopted for all aldicarb granular formulations. In addition the application process must be automated with no handling of the granules occurring.

Recommendation 9: Re-entry protective equipment

The following statement is required on labels:

> *DO NOT enter, or allow any other person to enter treated area without protective footwear. Persons coming in direct contact with wet treated soil after the initial irrigation or initial rainfall following treatment must wear coveralls, rubber or neoprene boots and gloves.*

ENVIRONMENT

The following label statements must be added:

Recommendation 10: Protection of wildlife, fish, crustaceans and environment

"Dangerous to fish and aquatic invertebrates"

"DO NOT use aldicarb in such a manner that would allow aldicarb to enter groundwater supplies. Application, washing, loading or emptying of application equipment must not occur within 15m of any drinking water well. This distance must be increased to 150m where soils are sandy and water tables are shallow".

Recommendation 11: Reporting Requirements

Over the next 3 years, registrants must provide the NRA with figures on an annual basis, on the amount of aldicarb applied to citrus, broken down by area.

ATTACHMENT 1: products and active constituents affected by this review

[effective June 2001]

Products

NCRIS	Product Name	Registrant
48937	Temik 150G Insecticide/Nematicide	Aventis CropScience Pty Ltd
48089	Farmoz Touche 150G Systemic Insecticide/Nematicide	Farmoz Pty Ltd

Active constituents

NCRIS	Active constituent	Approval Holder
44025	Aldicarb	Aventis CropScience Pty Ltd
44450	Aldicarb	Aventis CropScience Pty Ltd