National Registration Authority
For Agricultural & Veterinary Chemicals

THE NRA REVIEW OF

CHLORFENVINPHOS
Interim Report

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

Telephone: (02) 6272 3213
Facsimile: (02) 6272 3551

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 co-operation with advisory agencies including the Department of Health and Aged Care (Chemicals and Non-Prescription Drug Branch), Environment Australia (Risk Assessment and Policy Section), National Occupational Health and Safety Commission (Agricultural and Veterinary Chemicals Section) 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 chlorfenvinphos 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 chlorfenvinphos, 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 completing the order form in the back of this book.

Comments on the review program can be addressed to Manager, Chemical Review, National Registration Authority for Agricultural and Veterinary Chemicals, PO Box E240 Kingston ACT 2604, Australia.

CONTENTS

ABBREVIATIONS AND ACRONYMS

µg	microgram	mg/kg bw/day	milligram per kilogram of bodyweight per day
m	metre	min	minute
ai	active ingredient	mg	milligram
h	hour	mL	millilitre
ha	hectare	d	day
kg	kilogram	IM	intramuscular
L	litre	IV	intravenous
bw	bodyweight	PO	oral
m^2	square metre	SC	subcutaneous
sec	second	ppm	parts per million

AAVCC	Australian Agricultural and Veterinary Chemicals Council	**LD_{50}**	dosage of chemical that kills 50% of the test population of organisms
ACPH	Advisory Committee on Pesticides and Health	**LOEL**	lowest observable effect level
ADI	acceptable daily intake (for humans)	**MAFF**	Ministry of Agriculture, Fisheries and Food
ChE	cholinesterase	**MATC**	mean acceptable toxicant concentration
DHAC	Department of Health and Aged Care	**MCH**	mean corpuscular haemoglobin
EC	emulsifiable concentrate	**MCHC**	mean corpuscular haemoglobin concentration
EC_{50}	concentration at which 50% of the test population are affected	**MCV**	mean corpuscular volume
ECRP	Existing Chemicals Review Program	**ME**	micro-encapsulated
EEC	estimated environmental concentration	**POEM**	predicted operator exposure model
EUP	end use product	**PPE**	personal protective equipment
GAP	good agricultural practice	**PQ**	performance questionnaire
GLP	good laboratory practice	**TGAC**	technical grade active constituent
HPLC	high performance liquid chromatography	**USEPA**	US Environmental Protection Agency
IPM	integrated pest management	**WHP**	withholding period
LC_{50}	concentration that kills 50% of the test population of organisms		

EXECUTIVE SUMMARY

Chlorfenvinphos was reviewed as part of the NRA's Existing Chemical Review Program, which covered all aspects related to chlorfenvinphos, including approvals of labels and active constituents and registration of products. Assessments conducted as part of the review considered the existing use patterns of chlorfenvinphos in terms of their impact on public health, occupational health and safety (OHS), the environment and trade. Summarised below are the main review findings. Specific details of the regulatory approach and risk-mitigating measures are provided in Section 10 at the end of this document.

Current Uses

Chlorfenvinphos is an organophosphorus insecticide and acaracide registered in Australia for insect control under both agricultural and veterinary situations.

The current uses of chlorfenvinphos are highlighted in the agricultural assessment and were obtained from consultation with growers, commodity organisations, State and Territory agricultural regulators, and the chemical industry. Information was gained regarding the present use of the chemical and whether the use is the same as when it was first registered and if the present label directions are still applicable.

Chlorfenvinphos is commonly used against a variety of insects which infest pastures, lucerne, mushrooms and potato crops and is also used for fly control in and around buildings. However the major use of chlorfenvinphos is as an ectoparasiticide treatment for cattle, sheep, horses and to a lesser extent deer, goats and working dogs.

Toxicology and Public Health

Chlorfenvinphos, like other organophosphorus compounds, kills insects by inhibiting the enzyme cholinesterase. As with experimental animals the main effects of chlorfenvinphos in humans are clinical signs of poisoning associated with inhibition of cholinesterase activity. In mammals, exposure to chlorfenvinphos by ingestion, contact with skin or by inhalation can lead to signs of poisoning which may include excessive saliva production, rapid breathing, loss of co-ordination, coarse generalised body tremors, convulsions, respiratory failure and even death.

Chlorfenvinphos is rapidly absorbed however studies showed that it did not persist for long periods in the tissues or organs of animals, passing relatively quickly from the body. Chlorfenvinphos did not interact with genetic material and long-term studies in animals gave no indication that it would be likely to cause cancer in humans.

Based on the current uses of chlorfenvinphos, it is considered that there should be no adverse effects on public health from the continued use of chlorfenvinphos in Australia. However in light of information presented for this review it is recommended that the Acceptable Daily Intake (ADI) for chlorfenvinphos be changed from 0.002 mg/kg bw/day to 0.0005 mg/kg bw/day, based on the dose that caused no effects in a rat study (0.05 mg/kg bw/day) and

applying a 100-fold safety factor to account for variation between species and variation between individuals of the same species. The likely human exposure to chlorfenvinphos through the diet is expected to be much lower than the ADI for this compound.

Occupational Health and Safety

The occupational risk assessment takes into consideration the toxicological hazard of chlorfenvinphos and worker exposure associated with its use patterns in Australia.

The main potential route of occupational exposure to chlorfenvinphos is dermal. The main adverse effect following acute or repeated chlorfenvinphos exposure is inhibition of cholinesterase, which can be readily measured in blood samples.

No measured worker exposure data were submitted for this review. Quantitative estimation of exposure was conducted using the UK Predictive Operator Exposure Model (POEM). For some uses where no data existed nor was there a suitable model within POEM to assess the use pattern, a qualitative risk assessment was conducted. As a result the risk assessment relied on a number of conservative assumptions, with certain methods and applications found to be unacceptable.

The following end uses were considered to provide acceptable margins of exposure, provided the existing exposure mitigation methods, label instructions and safe work practices are followed:

- Use of chlorfenvinphos applied as a broadcast spray to potatoes, pastures and lucerne.
- Use in mushrooms when incorporated into mushroom casing.
- Chlorfenvinphos when used as an aerosol for wound dressing.

The following end uses can continue provided that changes are made to the packaging of the product thus reducing exposure to the concentrate:

- Plunge dipping and automatic spray race application to cattle and sheep

A number of chlorfenvinphos uses were of OHS concern with specific measured exposure data required. Without a commitment to generate appropriate OHS data the following uses cannot continue:

- Fly control in and around farm buildings using hand held equipment
- Application to livestock using hand held equipment (hand jetting, overspraying of cattle)
- Formulations of chlorfenvinphos containing 1000g ai/L

Environmental Impact

Aquatic invertebrates are most at risk from exposure to chlorfenvinphos, especially through the direct application in agricultural situations. Spray drift and run-off under these

circumstances is also of concern due to the impact that chlorfenvinphos may have on non-target aquatic and terrestrial invertebrates. Insufficient information was available on this for a conclusion to be drawn. As such additional information is required.

The overall hazard to birds from the spraying of chlorfenvinphos in pastures and the subsequent feeding by birds on insects in these areas is unable to be determined. Additional information on this situation is required.

The above comments relate to the agricultural product only. The registrant is not willing to maintain the registration of this product following this review and will not generate any data.

In addition to the above, studies showed that direct application to livestock may pose an unacceptable risk to birds that feed on insects that live in close association with the treated animals; however this could not be confirmed under Australian conditions. A watching brief on this is to be maintained.

In order to minimise the impact of chlorfenvinphos in the environment appropriate warning statements are to be added to product labels.

Residue Limits

In spite of the fact that resistance in some pest populations exists for chlorfenvinphos, it continues to be important in the control strategies for ectoparasites in Australia's livestock industries.

The residue data package presented did not contain sufficient Australian residue data to confirm the present Maximum Residue Limits (MRLs) for all agricultural commodities noted in the MRL Standard. The only chlorfenvinphos MRLs for agricultural commodities supported by appropriate residue data were for mushrooms and potatoes. Consequently temporary Australian MRLs have been recommended for all other agricultural commodities with their retention depending on the presentation of satisfactory Australian residue data or, where appropriate, scientific argument.

The meat withholding periods (WHP) specified on current labels essentially remain unchanged. However those for the two jetting fluids have been extended to 14 days, negating the need for additional residue data.

Milk residues resulting from plunge and spray dip applications are of concern and are likely to violate the **milks [in the fat]** MRL**.** Use by these application methods in lactating animals cannot be supported and appropriate restraint statements are to be added to labels.

Overspray application of chlorfenvinphos to lactating dairy cattle is not likely to violate the **milks[in the fat]** MRL. However no data exists to support treatment of lactating animals other than cattle with chlorfenvinphos. As such the **milks[in the fat]** MRL is to be revoked with the addition of a **cattle milk[in the fat]** MRL of 0.2 mg/kg.

Residue storage stability studies were not provided for any animal commodities for the purpose of setting MRLs and therefore commodity stability studies are requested.

1. INTRODUCTION

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

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 product labels at any time. The basis for a reconsideration is whether the NRA is satisfied that the requirements prescribed by the Agricultural and Veterinary Chemicals Code (scheduled to the *Agricultural and Veterinary Chemicals Act 1994*) for continued approval are being met. These requirements are that the use of an active constituent or product, in accordance with the recommendations for its use:

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

Obligations to submit data and other information on chemicals under review

On initiating a review, the NRA 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 through national and local newspapers, inviting them to make submissions.

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

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

Outcomes of reviews

There are three possible outcomes to an ECRP review:

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

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

1.2 Data Protection

To 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 registration information' for a 'protection period' of two to seven years if the information:

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

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

1.3 Reasons for the Chlorfenvinphos Review

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

- high avian and aquatic invertebrate toxicity; and
- high worker exposure potential, especially associated with veterinary applications.

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

1.4 International Status of Chlorfenvinphos

CODEX MRLs for all commodities except brussel sprouts, cabbages head, carrot and cauliflower were withdrawn in April 1999.

Registration of chlorfenvinphos in the United States was cancelled in 1991. The United States Environmental Protection Agency (USEPA) had proposed chlorfenvinphos for review under its Re-registration Eligibility Decision (RED) program. The registrant was not willing to support chlorfenvinphos through this process.

The UK Ministry of Agriculture, Fisheries and Forestry (MAFF) is currently undertaking a review of organophosphates (OPs), including chlorfenvinphos. Data for the review was initially requested from registrants in September 1998. At this time there were only two chlorfenvinphos pesticide products approved by MAFF in the UK (Sapecron 240 EC and Birlane 24, (both agricultural products). Sapecron 240 EC was not supported by the approval holder at phase II of the review (notification of support). The product was therefore revoked and is not approved for use in the UK after 31 August 2000. Support for Birlane 24 was withdrawn by the approval holder at phase III of the review (data submission) in September 1999. The product was therefore revoked and is not approved for use in the UK after 31 December 2001.

The Canadian Pest Management Regulatory Agency (PMRA) is also undertaking a review of OPs however chlorfenvinphos has not been given a priority for review. The review of 29 organophosphates currently underway should be completed by 31 December 2000. There are currently four products registered for use in Canada. In lieu of a re-evaluation decision, these products could potentially be renewed for use on a year to year basis only until such time as a re-evaluation decision is made on this active, or if the registrants choose not to renew registration.

2. CONSIDERATION OF PUBLIC SUBMISSIONS (December 1996)

2.1 Introduction

Consistent with the NRA's policy of consulting with all parties interested in the review process, the NRA published notices in the Australian rural and metropolitan press calling for written submission addressing the announcement of the review of the chemical chlorfenvinphos. This resulted in twelve submissions being received from members of the public, environmental, government and commodity groups.

These submissions expressed views discussing the use of chlorfenvinphos in particular industries. These were generally positive towards having chlorfenvinphos remain available for use. Other submissions made comments on the detrimental effects that the use of this chemical is thought to have on the environment, public health and occupational safety. The majority of support for the continued availability of this chemical was from grower groups.

While all views expressed as a result of public consultation were considered in the review of chlorfenvinphos, these remain the view of the authors of these public submissions, and not the view of the NRA. The primary purpose of this section is to highlight the range of views resulting from public consultation. Any issues raised that have been supported with data are further considered in the relevant sections of the ECRP report.

For the ease of presentation, all views and concerns raised on chlorfenvinphos have been categorised as follows.

- Those submissions that discuss any public health, environmental or occupational safety issues relating to this chemical are presented under the heading 'Risk Identification'. The way in which the level of risk associated with the use of chlorfenvinphos can be minimised by particular user groups is also discussed here.

- The final section is where general views on chlorfenvinphos are expressed. This information can be found under the heading 'General Views on Chlorfenvinphos'. This details some of the benefits of chlorfenvinphos over other chemicals in particular industries.

Most views expressed in the public submissions have been summarised in the following sections, and where views expressed in several submissions are similar or related, these have been consolidated.

2.2 Risk Identification

Health

Chlorfenvinphos is well known as being a cholinesterase inhibitor. It is highly toxic to humans and is thus classified as a Schedule 7 poison.

A representative from the Qld Conservation Council and Qld Consumers Association, provided general details on the toxicological effects associated with exposure to the organophosphate group of chemicals. Some of these symptoms included, nausea, vomiting, diarrhoea, abdominal cramps, headache, dizziness, eye pain, blurred vision, sweating and confusion. Although other effects were noted, they were not reported here, as a full toxicity assessment of chlorfenvinphos is presented elsewhere in the report.

One respondent recognised that although this chemical is considered harmful when applied incorrectly, there is a perception amongst industry that the beneficial nature of this chemical outweighs the possible harm to human health.

Occupational safety

It was noted by a number of respondents that there are training courses available within various industries, to ensure that users are appropriately trained in the use of chemicals. It was the view of the respondents that these courses make users aware of the importance of adhering to the safety requirements for the particular product, and thus are important in reducing chemical abuse. There was also comment by one respondent that to prevent or reduce chemical exposure, the appropriate safety equipment should be used.

It was noted by two respondents, that when any product containing chlorfenvinphos is used as directed, there would be no hazards to the user or the target species.

No other public submissions were received dealing with occupational safety issues associated with the use of chlorfenvinphos.

Environment

It was noted by one respondent, that when the containers in which the product is presented are disposed of according to the directions, there should be no hazard to the environment, plants or animals. It was also considered that the likelihood of ground water contamination was minimal when the product was used in accordance with the labelling directions.

Within the mushroom industry, it was thought that this chemical has no detrimental effects on the environment due to its confined method of application. It is registered as a casing treatment and is applied indoors. The respondent noted that this application method would limit exposure to non-target species or the surrounding environment. The product is mixed with water and is applied to dry peat moss. This ensures that there is no run-off into surrounding waterways.

It was recognised however, that this chemical is dangerous to bees, fish, and native fauna. Care should be taken when using it to avoid contamination of waterways.

No other submissions were received dealing with the possible environmental effects that the use of chlorfenvinphos may have.

2.3 General Views on Chlorfenvinphos

A number of respondents discussed the importance of maintaining chlorfenvinphos as part of integrated pest management programs. Success of integrated pest management (IPM) depends on the well managed and controlled use of chemicals that have minimal impact on biological control techniques. The success of these programs is dependent on chemical rotation, together with the timely introduction of biological controls. With the limited number of chemicals that are available for use, any further reduction would lead to more resistance pressures being placed on the remainder of the chemicals.

In Tasmania this chemical is used in the potato industry. Routine spraying for control of potato moth is not undertaken but chlorfenvinphos is used when required. This is usually when the use of irrigation to prevent tuber cracking, and thus infestation by potato moth, is ineffective. This occurs especially in good seasons where potato moth populations are large. Chlorfenvinphos is also the only alternative to fenitrothion for 'corbie' control in pastures.

In the mushroom industry chlorfenvinphos is useful in the management of low level infestations of phorids. The only alternative to chlorfenvinphos is fipronil, but this is more expensive and only worthwhile using when the levels of infestations are high.

Chlorfenvinphos is an important chemical to the grazing industry. It is found in a wide range of products used on cattle and sheep for ectoparasite control.

2.4 Chlorfenvinphos Public Submission Contributors

- Wholesale Indoor Foliage
- United Graziers Association of Qld
- Qld Conservation Council
- Qld Consumers Association
- Western Australian Farmers Federation
- Grains Council of Australia
- Qld Nursery Industry Association
- Bombala Rural Lands Protection Board
- Australian Mushroom Growers Association Ltd
- Tasmanian Farmers & Graziers Association
- Blackman Consultancies Pty Ltd
- Qld Cotton
- Australian Vegetable & Potato Growers Federation

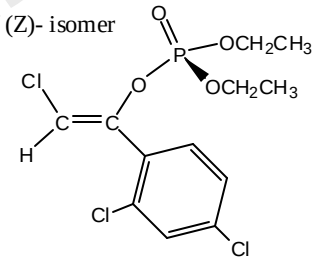
3. CHEMISTRY ASSESSMENT (September 1999)

3.1 Chemical Identity

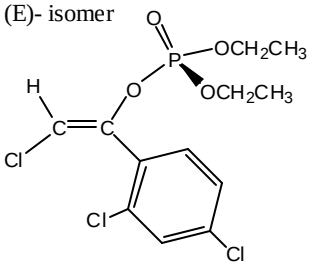
Technical chlorfenvinphos (comprised of the sum of E- and Z- isomers) has a minimum purity of 900 g/L. Typically, the ratio of isomers Z:E is 8.6:1 in the technical material, with both the cis and the trans isomers having insecticidal activity. Whilst the potency of the isomers varies from species to species, the trans isomer is usually the more active one.

Common name:	Chlorfenvinphos
IUPAC Name:	2-chloro-1-(2,4-dichlorophenyl)vinyl diethyl phosphate
CA Name:	2-chloro-1-(2,4-dichlorophenyl)ethenyl diethyl phosphate
CAS Registry Numbers:	
(Z)- and (E)- isomers	2701-86-2
(Z)- isomer	18708-87-7
(E)- isomer	18708-86-6
Empirical Formula:	$C_{12}H_{14}Cl_3O_4P$
Molecular weight:	359.57
Manufacturers' code no.:	SD 7859; C 8949 (Ciba-Geigy) GC 4072 (Allied); CGA 26351 ENOLOFOS®; OMS 166; OMS 1328; ENT 24 969
Synonyms:	"Birlane", "Supona", CL 58,085; SD 7859; GLC 4072
Structural formula:	

(Z)- isomer



(E)- isomer



3.2 Physical and Chemical Properties

3.2.1 Physical and chemical properties of the pure active constituent and the TGAC

Colour	pure active - clear, colourless TGAC – amber to brown
Odour	mild specific odour
Physical State	liquid at 25 ^{o}C
Melting point	-23 to –19 ^{o}C
Boiling point	167 to 170 ^{o}C (at 0.5 mm Hg) 110 ^{o}C (at 0.001 mm Hg)
Octanol/water partition coefficient (log K_{ow})	
(Z)- and (E)- isomers	3.85
(Z)- isomer	4.22
(E)- isomer	3.81
Specific gravity/density	1.36 at 15/20 ^{o}C
Refractive Index	1.5272 (N_D^{25})
Vapour pressure (volatility)	2.2 x 10^{-7} mbar at 25 ^{o}C
Water solubility (at 23 ^{o}C)	145 mg/L (at 23 ^{o}C)
Solvent solubility	Miscible with most common organic solvents e.g. ethanol, acetone, dichloromethane, hexane, xylem, propylene glycol, and kerosene
pH Stability	Hydrolysed slowly in neutral, acidic and slightly alkaline aqueous solutions; Hydrolysed rapidly in strongly alkaline solutions.
Thermal stability	Extremely stable at high temperature. Rapid decomposition only at temperatures above 150 ^{o}C. Non-flammable.
Hydrolysis	Decomposes very slowly in water with $t_{½}$ >400 hours (pH 9.1, temp 38 ^{o}C), and at pH 1.1, $t_{½}$ >700 hours. Hydrolysis half-life in water at 20-30 ^{o}C: pH 3-5, $t_{½}$ = 200 days pH 6, $t_{½}$ = 170 days pH 9, $t_{½}$ = 80 days pH 11, $t_{½}$ = 5 days
Henry's Law (K): (various sources)	1.55 X 10^{-3} Pa.m^3/mol 2.5 X 10^{-3} Pa.m^3/mol at 20^{o}C 2.80 X 10^{-4} Pa.m^3/mol

3.3 Comments on Physio-chemical Properties

The vapour pressure and Henry's Law Constant indicate that chlorfenvinphos has a low volatility and is unlikely to volatilise from water or moist soil surfaces. It is moderately to very soluble in water at common environmental temperature ranges. The log K_{ow} indicates a moderate bioconcentration potential in aquatic organisms. The Mackay level 1 fagacity model predicts 55%

partitioning into water with 22% in soil, 20% in sediment and 2% in air at equilibrium (US EPA 1998) using a vapour pressure of 2.95 X 10^{-2} Pa and Henry's Law constant of 1.13 X 10^{-1} $Pa.m^3/mol$ which indicate greater volatility.

3.4 Chemistry Aspects

The chemistry aspects (manufacturing process, quality control procedures, batch analysis results, and analytical methods) of chlorfenvinphos TGAC were evaluated and found acceptable. The chlorfenvinphos content of the TGAC is determined by GLC with flame ionisation detection.

3.5 Declaration of Composition (DoC)

The Australian minimum compositional standard for chlorfenvinphos TGAC requires that the sum of the isomers (Z and E) comprise not less than 900 g/L of the technical material. The NRA-approved source of technical chlorfenvinphos meets this standard. All impurities that are present in the chlorfenvinphos TGAC at concentrations of 1 g/L or more are listed in the DoC.

There is no FAO monograph specification for technical chlorfenvinphos.

3.6 Toxic Impurities

The toxicologically significant compounds (sulfotepp, N-nitrosamines, halogenated dibenzo-pi-dioxins, halogenated dibenzofurans and PCBs) are not expected to occur in the chlorfenvinphos TGAC due to the raw materials and synthetic route used in the manufacture of the material.

3.7 Conclusion

The NRA minimum compositional standard for chlorfenvinphos TGAC requires that the sum of the isomers (Z and E) comprise not less than 900 g/L of the technical material. This standard is to be retained.

4. AGRICULTURAL ASSESSMENT (September 1999)

4.1 Introduction

In order to ascertain whether chlorfenvinphos complies with contemporary assessment standards for efficacy, the NRA surveyed groups in the community who supply, use, or provide technical advice on chlorfenvinphos. Questionnaires were distributed to both large and small scale users of the chemicals, commodity organisations, State departments of agriculture and the chemical industry.

4.2 Use Patterns

Chlorfenvinphos is an important chemical for insect control in a number of key areas of Australian agriculture, the most important of these being control of ectoparasites in livestock industries. There are currently 9 registered products (8 veterinary, 1 agricultural) containing chlorfenvinphos and two approved technical grade active constituents (TGACs).

Ectoparasite Control - Cattle

In spite of the fact that there is resistance in the Parkhurst and Ultimo strains of cattle tick, chlorfenvinphos remains an important tickicide especially with increasing resistance to the synthetic pyrethroid chemicals. In addition, it is an important chemical for control of buffalo fly, which has demonstrated little, if any, resistance to chlorfenvinphos.

Ectoparasite Control – Sheep

The use of chlorfenvinphos in sheep has been significantly affected by the occurrence of resistance to organophosphate chemicals in sheep blowfly. Chlorfenvinphos is not one of the major sheep ectoparasite treatments in Australia, with chlorfenvinphos and propetamphos together accounting for less than 10% of all organophosphate usage. Nevertheless, it is still considered a cost-effective remedy under some circumstances.

Agricultural application - Pastures

Chlorfenvinphos is one of two chemicals registered (the other being fenitrothion) for control of a number of pasture pest species including underground grass grub, pasture webworm (Tas &Qld) and corbies. Corbies are of particular concern to Tasmanian pasture production. All of Tasmania's 900,000 ha of pasture is subject to attack annually, but only a comparatively small percentage requires treatment, depending on seasonal conditions.

Advice from Tasmanian agricultural authorities indicates that there are probably other chemicals that would be effective in this situation, but unless the respective chemical companies are prepared to undertake the necessary trial work, approval of alternative chemicals will not be possible. The Tasmanian Department of Primary Industry and Fisheries is not in a position to carry out chemical trial work in relation to this situation.

Chlorfenvinphos is also registered in Victoria, South Australia and Tasmania for control of red legged earth mite (*Halotydeus destructor)* and lucerne flea (*Sminthurus viridis).* However, insufficient information was available to determine the extent of importance of this use.

Agricultural application – Mushrooms

Enhanced microbial degradation has now shortened the useful life of chlorfenvinphos as well as other organophosphate chemicals for use in mushroom production. However, despite its shortened period of protection, chlorfenvinphos, when incorporated into the mushroom casing layer, still provides protection against phorid infestation for two weeks after casing application. This initial period is important since it has been shown that infestation later than this does not reduce yield.

Agricultural application – Potatoes

Use of chlorfenvinphos for the control of potato moth has been declining over the past ten years with other management measures being widely used to prevent the access of potato moth to potato tubers. It is now mainly used where these management techniques fail and during seasons in which potato moth pressure is high.

4.3 Residues

This review of residue issues associated with chlorfenvinphos is based primarily on data submitted for the ECRP but also considered other relevant information from overseas regulatory authorities and Codex.

4.3.1 Metabolism of chlorfenvinphos

Animals

Metabolism studies performed in rats, cattle and dogs demonstrated that chlorfenvinphos is rapidly absorbed and completely metabolised after both oral and dermal administration. The metabolites are eliminated mainly in urine and to a lesser degree in faeces within several days of administration. The majority of radioactive residues were in omental or renal fat with little or no measurable residues in liver, kidney, muscle and other tissues. These findings are consistent with chlorfenvinphos being fat-soluble.

The studies also indicated that neither chlorfenvinphos nor its metabolites are stored in significant amounts in body tissues. Following multiple treatments with chlorfenvinphos at either weekly or biweekly intervals, residues in fat depleted to undetectable levels before 28 days. No important differences in chlorfenvinphos metabolism between ruminants and rats were observed.

Plants

Plant metabolism following soil and foliar application was reported however the full metabolism pathway in plants was not fully elucidated. Nevertheless, the results clearly demonstrated that there is no evidence of translocation of any radioactivity from treated leaves to untreated parts of the plant.

4.3.2 Analytical Methodology

The analytical methods used for the determination of chlorfenvinphos in animal tissues, milk and crops are based on GC with electron-capture detection. Acceptable recoveries were obtained in crops and milk at fortification levels of 0.05 and 0.01 mg/kg, respectively. The limit of quantitation for tissue samples (based on acceptable recovery data) was 0.01 mg/kg.

4.3.3 Residue Definition

The current Australian residue definition for chlorfenvinphos is the sum of E- and Z-isomers. This is considered appropriate and is consistent with the Codex definition.

4.3.4 Residue trials

Veterinary uses

Two Australian residue trials by plunge dipping at the recommended application rate on cattle were presented. Residue data supported the current MRL of 0.2 mg/kg for both **Cattle meat [in the fat]** and **Cattle, Edible offal** at re-treatment intervals of 10 days and a slaughter withholding period of 8 days.

Four residue trials by plunge dipping on sheep were presented. Residue data indicated that chlorfenvinphos residues were unlikely to exceed the current MRL of 0.2 mg/kg for both **Sheep meat [in the fat]** and **Sheep, Edible offal** under the current use pattern.

A residue trial involving the use of backrubbers on cattle was also conducted. The results indicated that this use pattern would not result in chlorfenvinphos residues in fat tissues exceeding the current **Cattle meat [in the fat]** MRL.

In response to the residue violation for beef destined for the USA, two Australian residue trials involving plunge dipping and backrubber application were conducted. Fat residue data for the current label use pattern from both trials were in compliance with the current **Cattle meat [in the fat]** MRL.

Two milk residue trials to support the current use patterns for plunge dipping and overspraying were provided. The milk residue data submitted did not support the plunge dipping use pattern at the current milk (in the fat) MRL of 0.2 mg/kg. Raising the Australian milk MRL for chlorfenvinphos from 0.2 mg/kg to 2 mg/kg would

accommodate the plunge and spray dip use patterns in lactating dairy cattle is not an option because of dietary intake considerations. The following restraint must be added to the products intended for use via plunge or spray dip application: *DO NOT use in lactating cattle or within 42 days of calving where milk or milk products will be used for human consumption.*

By contrast, dairy cows could be oversprayed without violations of the current **milks[in the fat]** MRL of 0.2 mg/kg. When used as an overspray for lactating dairy cattle a NIL milk withholding period is considered appropriate.

Considering the scarcity of residue data for sheep and goats and the different gestation, lactation and dry periods, the findings of the cattle studies cannot be used to extrapolate to sheep and goats. Therefore chlorfenvinphos products should not be used in dairy sheep and goats. Product labels should include the following statement: *DO NOT USE on female sheep or goats that are producing or may in the future product milk or milk products for human consumption.* In addition the milk MRL of 0.2 mg/kg currently listed as **milks[in the fat]**, will be deleted and replaced with a **cattle milk [in the fat]** MRL of 0.2 mg/kg.

Agricultural uses

Two Australian residue trials on potatoes were conducted at the recommended label rates and at re-treatment intervals of 1-2 weeks. The results indicated that chlorfenvinphos residues were unlikely to exceed the current MRL of *0.05 mg/kg for potatoes.

An Australian residue trial involving the spraying of grass and hay at the recommended dose rate was conducted. The residue levels in grass depleted to about 0.01 mg/kg after 6 weeks. Animal feeding studies indicated that animals fed on pasture 2 days following treatment had non-detectable milk residues at 4 days and 1, 2 and 3 weeks after feeding of the treated pasture. The contribution of chlorfenvinphos residues in animal commodities arising from the grazing of treated pasture is considered negligible.

In response to the public comment phase, additional residue data was provided for the use of chlorfenvinphos in mushrooms. The data was sufficient to allow the continued use of chlorfenvinphos in mushrooms however the data showed that residues above the current MRL of 0.05 mg/kg were likely to occur when used as directed. It was recommended that the MRL be increased to 0.2 mg/kg with a withholding period of 21 days.

4.3.5 Residue Detections

In terms of actual residue detections of chlorfenvinphos in export commodities, the only residues that have been reported through the National Residue Survey (NRS) have been in horse fat and these have been well below the MRL.

However, in early November, after public submissions to the Review had closed, import testing by the US Food Safety Inspection Service (FSIS) detected chlorfenvinphos in

Australian beef at a level of 0.26 mg/kg. The US does not have an import tolerance for chlorfenvinphos and the level detected was above the Australian MRL of 0.2 mg/kg.

Ten years of National Residue Survey (NRS) data, in which no detections of chlorfenvinphos were report, was used to demonstrate this was an isolated incident linked to the inappropriate use of the chemical by a single producer.

The FSIS lifted test and hold restrictions on produce derived from the implicated establishment following negative test results from 15 additional samples. Korea was the only country to react adversely to the advice provided in reaction to the US residue finding.

Pesticide residues in milk are monitored through the Australian Milk Residues Analysis (AMRA) Survey. In the period January 1995 to June 2000 chlorfenvinphos was not detected in any of the milk samples taken (1356). These samples were collected from regions of dairy production throughout Australia relative to level of production.

4.3.6 Current labels

The current registered label for *Coopers Blockade S Cattle Dip and Spray (46815*) does not specify a milk withholding period. Instead it has a label restraint which prevents use of chlorfenvinphos in lactating animals which are producing or may in the future produce milk or milk products for human consumption.

The milk residue data submitted does not support the use of *Barricade S Cattle Dip and Spray (45211)* or *Coopers Blockade S Cattle Dip and Spray (46815)* as plunge dips for lactating cows. A label restraint against use in lactating animals as noted above is to be added to the *Barricade* label. *Coopers Blockade S Cattle Dip and Spray (46815*) is to also include a restraint against the use of cattle as stirrers.

Supona Buffalo Fly Insecticide (45594) restricts use to lactating animals if treated via backrubber application only.

Although currently registered labels exist for *Coopers Suprex 100 Jetting Fluid*, *David Grays Aerosol Sheep Dressing, WSD Aerosol Sheep Dressing* and *WSD Jetting Fluid 100 Jetting Fluid for Control of Flystrike on Sheep*, residue data were not submitted in support of the use of these products.

4.3.7 Maximum Daily Intake

The TMDI (based on Supervised Trial Median Residues [STMR] of the animal commodities) is 15% of the Acceptable Daily Intake (ADI) for chlorfenvinphos of 0.0005 mg/kg bw/day. Therefore, the chronic dietary exposure is small and the risk is acceptable. This conclusion is consistent with 1996 monitoring data and the finding of the 1994 Australian Market Basket Survey that no detectable residues of chlorfenvinphos were found in food commodities (excluding milk).

If use in lactating animals is not deleted then the risk associated with acute dietary intake is estimated by the estimated short term intake (ESTI) calculation. The ESTI (based on

the current MRL of 0.2 mg/kg for **Cattle milk [in the fat]**) for 9.11 kg infants is 35% of the acute reference dose (ARD) of 0.002 mg/kg bw/day for chlorfenvinphos. It was concluded that the acute dietary exposure is small and the risk is acceptable.

4.4 Trade

Although chlorfenvinphos is an important chemical for control of pasture pests in Tasmania and control of pests in the mushroom industry, these uses have little, if any, impact on trade. Mushrooms are not exported, and although pasture production may affect animal industries, no evidence was produced during the review of any transfer of residues into animal products via pasture.

Similarly, although chlorfenvinphos is registered for use on potatoes, it is clear that use of this chemical in the potato industry has declined to the extent that it is only used in circumstances where other management strategies have broken down, and even in this event there are a number of alternative chemicals available. It is therefore extremely unlikely that use of chlorfenvinphos will affect Australia's minor trade in potatoes.

However, in spite of the fact that there is resistance to the chemical in some pest populations, chlorfenvinphos continues to be an important component of ectoparasite control strategies used in Australia's largest rural export industries, meat and wool.

The US EPA has withdrawn the chlorfenvinphos tolerances for cattle fat; eggs; goats, fat; horses, fat; milk, fat; poultry fat; and sheep fat (see the Code of Federal Registry [60 FR 49799]). This may have significant trade implications because chlorfenvinphos residues in animal commodities would need to be undetectable in order to comply with the US requirements. However, adherence to the Export Slaughter Interval (ESI) of 21 days established by Meat and Livestock Australia (MLA) should achieve non-detectable tissue residues (provided cattle are not used to stir the dip) and avert any adverse impact on trade with the USA.

Moreover, the US EPA has revoked tolerances for chlorfenvinphos while the Codex Committee on Pesticide Residues (CCPR) at its April 1999 meeting, deleted all Codex MRLs for chlorfenvinphos with the exception of MRLs for brussel sprouts, cabbages head and cauliflower.

Meat

In response to the residues found in Australian beef in the USA, the Meat Research Corporation funded trials to examine the residues resulting in beef following typical farm treatments for tick and buffalo fly.

Wool

In order to forestall any possible deleterious effects on the industry, the issue of ectoparasiticide residues in wool has been thoroughly examined in a comprehensive report of sheep ectoparasiticides carried out by the NRA at the request of the Australian Wool Industry Residue Council. This looked at the residue implications of sheep ectoparasiticides used in Australia. As a result of this report, the NRA is currently undertaking a review of selected sheep ectoparasiticides addressing the issue of pesticide residues in wool.

The industry is now confident that steps can be taken to ensure that current and future trade in Australian wool will not be affected by the presence of residues of ectoparasiticides in wool.

Milk

Codex maximum residue limits for chlorfenvinphos were revoked in April 1999. An MRL for milk had been set at 0.008mg/kg prior to revocation. Although there is the potential for a trade concern due to lack of international tolerances for chlorfenvinphos, the likelihood of rejection of Australian produce solely on this basis is unlikely.

Taking into consideration that:

- Plunge dipping of lactating cattle will be discontinued (this use pattern results in residue levels that greatly exceed the MRL);
- The residue data support the overspray use pattern for lactating cattle without residues that exceed the MRL;
- Residue data confirmed the milk MRL as appropriate;
- There have been no violations in the AMRA survey attributed to chlorfenvinphos; and
- Use of the product in lactating cattle is not in an area which exports significant amounts of dairy products;

the NRA consider that the risk to Australia's trade of dairy products is minimal.

4.5 Conclusion

Based on the current use patterns and the residue data provided for this review, it is concluded that the critical good veterinary practice of the product *Barricade 'S' Cattle Dip and Spray (45211), Coopers Blockade S Cattle Dip and Spray (46815) and Supona Buffalo Fly Insecticide (45594)* determines the chlorfenvinphos MRLs for animal commodities for sheep and cattle.

Milk residues resulting from plunge and spray dipping are of particular concern with respect to dietary exposure and trade. The application of chlorfenvinphos to lactating animals via plunge and spray dipping cannot be supported and appropriate label restraint statements should be added to product labels for *Barricade 'S' Cattle Dip and Spray (45211), Coopers Blockade S Cattle Dip and Spray (46815).*

MRLs for numerous agricultural commodities appear in the *MRL Standard* which are not linked to registered uses. The deletion of these MRLs is recommended.

Birlane 500 Insecticide is the only chlorfenvinphos-based product currently registered for use on potatoes and pastures. An MRL of *0.05 mg/kg for potatoes and an MRL of 0.2 mg/kg for mushrooms combined with a 21 day withholding period is recommended.

Because of its low usage on pasture, the residue concerns arising as a result of animals consuming treated pastures is considered negligible provided a grazing restraint of 7 days is observed.

DETAILS OF THE REGULATORY APPROACH CAN BE FOUND IN SECTION 10

5. TOXICOLOGICAL ASSESSMENT (September 1999)

5.1 Public Health Aspects

Chlorfenvinphos is a broad-spectrum organophosphate insecticide that has been registered for use in Australia for over 30 years. Like other organophosphate pesticides, chlorfenvinphos kills insects by interfering with the activity of an enzyme (acetylcholinesterase) in the nervous system. This interference causes overstimulation of the nervous system, and results in rapid twitching and paralysis of muscles. The paralysis of muscles used for breathing eventually causes death in insects.

Chlorfenvinphos is also highly toxic to other animals and humans, and poisoning can occur if a toxic level of chlorfenvinphos is swallowed, breathed in, or absorbed through the skin. Signs of poisoning may include nausea, vomiting, abdominal cramps, diarrhoea, excessive salivation, headache, dizziness, blurred vision, eye pain, pinpoint pupils, breathing difficulty due to excessive secretions and bronchoconstriction, random jerky movements, convulsions, respiratory failure and death. There is an effective antidote treatment for the immediate poisoning effects of chlorfenvinphos if medial assistance is prompt.

When laboratory animals were exposed to chlorfenvinphos, the compound was absorbed quickly, but did not persist for long periods in the tissues or organs of animals, and passed relatively quickly from the body. Long-term exposure to a low concentration of chlorfenvinphos in the diet was associated with some inhibition of cholinesterase activity in animals. Chlorfenvinphos did not interact with genetic material, and long-term studies in animals gave no indication that it would be likely to cause cancer in humans. Some studies indicated that there was decreased fertility in rats at relatively high doses of chlorfenvinphos. There was no evidence that chlorfenvinphos caused permanent effects on nerves when fed to laboratory animals.

The most likely exposure to chlorfenvinphos for the public is via residues in food, as there are currently no registered domestic uses for chlorfenvinphos. Registered uses for chlorfenvinphos include application to animals for control of external pests, and some uses on vegetables. No chlorfenvinphos residues were detected in foods in recent Market Basket Surveys and, based on current use-patterns, the likely human consumption of chlorfenvinphos is expected to be much lower than the Acceptable Daily Intake (ADI) for this compound.

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

It should be noted that toxicity tests generally use doses that are high relative to likely human exposure. The use of a range of doses enables toxic effects to be identified so that 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.

5.2 Kinetics and Metabolism

Chlorfenvinphos was relatively rapidly excreted in the urine following oral intake in all species, with 86 – 89% of the administered dose excreted over 4 days in rats and dogs, and 94% of the administered dose excreted in a human volunteer over 26 hours. In all species, the majority of the excretion occurred via the urine, with small amounts excreted in the faeces. In a study using a lactating cow, very low levels were found in the milk. *In vitro*, chlorfenvinphos metabolism was more rapid in dogs than rats, and dog plasma also bound chlorfenvinphos more strongly than did rat plasma. Metabolic rates in the liver showed species variation, with relative reaction rates in the order: rats<mice< rabbit< dog. Liver metabolism in rats was shown to be increased by pre-treatment with either dieldrin or phenobarbital, chemicals which cause an increase in enzymes which metabolise exogenous compounds. Rat brain cholinesterase (ChE) activity was found to be 10-times more sensitive to chlorfenvinphos than was dog brain. Tissue residues were low in sheep three days after dermal application of chlorfenvinphos.

5.3 Acute Toxicity

A large number of acute toxicity studies have been performed on chlorfenvinphos and some of its formulated products. There were obvious species difference in the oral toxicity of chlorfenvinphos, with rats being the most sensitive species tested. The oral LD50 values were lowest in rat (ranging from 9.7-39 mg/kg bw) then mouse (117 mg/kg bw), guinea pig (125 - 500 mg/kg bw), rabbit (300 mg/kg bw), and dog (>5000 mg/kg bw). The differences in species sensitivity may have been related to differences in metabolism. Signs of poisoning were typical of organophosphorous poisoning, and included salivation, lacrimation, diarrhoea, tremors and convulsions. Chlorfenvinphos formulations had similar toxicity to technical chlorfenvinphos, based on the content of the active ingredient. Chlorfenvinphos was very toxic in the rat following dermal (LD50 30 mg/kg bw) or inhalational (133 mg/m^3) exposure. Technical grade chlorfenvinphos was not irritating to eyes, although a formulation left in contact with rabbit eyes over an extended period caused severe irritation. Chlorfenvinphos was a weak skin sensitiser. Atropine sulphate alone, or in combination with oximes such as pyridine-2-aldoxime methiodide, was a useful antidote for acute chlorfenvinphos poisoning.

5.4 Short-Term Repeat-Dose Studies

Dietary studies in mice revealed that chlorfenvinphos at doses of up to 3000 ppm in the diet (for 2 weeks) or 1000 ppm in the diet (for 4 weeks) did not result in any deaths or treatment-related clinical signs. Plasma ChE activity was inhibited from 10 ppm and erythrocyte ChE was inhibited from 100 ppm in both studies. In the two-week study, brain ChE was inhibited from 1000 ppm, while in the four-week study brain ChE was inhibited at all doses. No treatment-related effects were seen at 1 ppm (0.2 mg/kg bw/day) in the two-week study.

In one study, rats were fed chlorfenvinphos for four weeks at dietary concentrations of up to 30 ppm with no mortalities or abnormal clinical signs, but plasma, erythrocyte and brain ChE were inhibited at the highest dose. Cholinesterase activity in plasma and liver was inhibited from 3 ppm but not at 1 ppm (0.05 mg/kg bw/day). In another rat dietary study conducted over 31 days, plasma ChE inhibition was observed at dietary concentrations of 5 ppm (0.25 mg/kg bw/day) and above.

In a number of dog dietary studies, there were no deaths or treatment-related clinical signs at the doses used. In a four-week study plasma ChE activity was inhibited from 100 ppm in the diet, erythrocyte ChE activity was inhibited at 3000 ppm in the diet (the highest dose tested), while brain ChE activity was not affected by treatment. No effects were seen at 3 ppm (0.12 mg/kg bw/day).

In a dermal study in guinea pigs, there was inhibition of plasma ChE activity from doses of 1 mg/kg bw/day after 4 days of application. After 14 days there was some recovery of plasma ChE activity. In another dermal study, there was no plasma ChE inhibition at 0.1 mg/kg bw/day. In repeat-dose dermal studies over five weeks, only mild irritation was detected in guinea-pig skin in the second week, while no irritation was seen in rabbit skin. When dogs were fitted with chlorfenvinphos-containing collars for a 14-day period, inhibition of plasma ChE activity was seen during the test period and for up to 17 days after the collars were removed.

Chlorfenvinphos given by daily subcutaneous injection to female rats at 1.85 mg/kg bw/day for 28 days produced a decrease in body weight and decreased ChE activity in the liver. Following intraperitoneal injection of chlorfenvinphos to male rats, body weight was not affected. There was a decrease in locomotor activity in high-dose rats on days 1 to 5. Following a challenge dose given 7 days after the last day of dosing there was a decrease in locomotor activity in low-dose and control rats, but no observed change in the high-dose rats. Plasma and erythrocyte ChE was inhibited at all tested doses, with inhibition of 45 - 65% in plasma and 45% in erythrocyte ChE activity. Plasma ChE activity in the low-dose group returned to normal over a recovery phase, while erythrocyte and brain ChE remained significantly inhibited in all treated rats.

5.5 Subchronic Studies

When rats were fed diets containing chlorfenvinphos at up to 1000 ppm for 12 weeks in one study, mortality and food consumption were unaffected, but growth was depressed at the high dose. Plasma and erythrocyte ChE activities were consistently inhibited from 30 ppm, and sporadic decreases were also seen at 10 ppm. In another 12-week study in rats at dietary concentrations of up to 1000 ppm, muscle fasciculations, tremors and bloody discharge from the nose and eyes were seen in high-dose rats. Body weight was decreased in animals from 100 ppm. Plasma ChE activity was inhibited from 10 ppm, with erythrocyte ChE activity inhibited from 30 ppm in both sexes, and in females on 10 ppm. The NOEL for both studies was 3 ppm in the diet, equivalent to a chlorfenvinphos intake of 0.15 mg/kg bw/day.

In another dietary study in rats at 0, 1 or 3 ppm for 12 weeks, there were no treatment-related effects on mortality, body weight or food consumption. Plasma ChE activity was decreased at 3 ppm throughout the study but no inhibition of plasma ChE activity was seen at 1 ppm. Erythrocyte ChE activity was not inhibited at either dose. The NOEL was 1 ppm in the diet, equivalent to an intake of 0.05 mg/kg bw/day.

In a dietary study in Beagle dogs at doses of 0, 0.5, 1 or 3 ppm for 16 weeks, no abnormal signs were reported. The NOEL for the study was 3 ppm in the diet, equivalent to an intake of 0.075 mg/kg bw/day, the highest dose tested in the study.

5.6 Long Term Studies

In long-term studies ranging from 18 months to 2 years, chlorfenvinphos was administered in the food at concentrations of up to 625 ppm in mice, 300 ppm in rats, and 1000 ppm in dogs. The effect of long-term administration was mainly the inhibition of ChE activity. In mice, focal hypertrophy and nodular hyperplasia were seen in the adrenal cortex of high-dose males. There was no evidence of an increase in the rate or severity of fibre degeneration in the sciatic nerve of rats. The NOEL for mice was 0.15 mg/kg bw/day and for rats was 0.05 mg/kg bw/day, based on plasma ChE inhibition. No NOEL could be established for dogs, given plasma ChE inhibition at the lowest dose. The LOEL for dogs was 0.75 mg/kg bw/day.

5.7 Reproduction Studies

In a 3-generation reproduction study in Wistar rats (2 litters/generation) at dietary concentrations up to 300 ppm, plasma and erythrocyte ChE activities were reduced at 30 and 100 ppm. The fertility index (rats pregnant/rats mated) was decreased at 100 ppm and above in the second generation and at 30 ppm and above in the third generation. F2b animals at 30 ppm were also cross-mated with control animals. The fertility indices from these matings were significantly reduced. Surviving F2b females showed normal follicle formulation, corpora lutea and ova formation. In males, the testes showed normal development and there was no explanation for the decreased fertility seen in animals in the test or cross-mated animals. The ratio of pups surviving to 5 days to pups born alive was decreased in F1a animals at 300 ppm, and in F1b animals from 100 ppm. In the F2 animals at 300 ppm, no pups survived to 5 days. No NOEL could be established, as the decreased fertility index and plasma and erythrocyte ChE inhibition were seen at all dietary concentrations. The LOEL was 30 ppm (1.5 mg/kg bw/day).

There were no changes in appearance or behaviour in a 3-generation study in Long-Evans rats at dietary concentrations of up to 15 ppm, and no effect was seen on the litter sizes or mean survival of litters. The fertility index was slightly reduced with chlorfenvinphos treatment at the two highest doses with the mean fertility index being 98%, 98%, 93% and 92%, but this was not considered to be biologically significant. The mean survival of pups was not affected by treatment, nor was the mean weight of weanlings. Based on the absence of effects on reproduction, the NOEL for this study was 15 ppm in the diet (0.75 mg/kg bw/day).

When Wistar rats were given dietary doses of chlorfenvinphos at up to 125 ppm for one generation, no abnormal clinical signs or deaths were noted. Mating parameters (mating index, time to conception, conception rate, or gestation indices) were not significantly affected. There was significant plasma ChE inhibition in females from 25 ppm, but no inhibition of plasma ChE was seen in males at any dose. Erythrocyte ChE was inhibited in males from 25 ppm, and in females at all doses ($p<0.01$). Brain ChE activity was inhibited in males from 125 ppm and in females from 5 ppm. No NOEL was established in this study; the LOEL based on ChE inhibition was 5 ppm (0.4 mg/kg/day).

In a 2-generation reproduction study, chlorfenvinphos was fed to Wistar rats at 0, 1, 10 or 100 ppm in the diet. In the second generation, there was an increase in the mean pre-coital interval in the high-dose group. The fertility index was slightly decreased at the high dose, while the birth index (pups born/implantations) was decreased in both the mid- and high-dose in the first generation. The weaning index (pups alive on day 21/pups alive on day 4) was lower in the mid- and high-dose groups in the first generation, and in the high-dose group in the second generation. There was inhibition of plasma ChE in both males and females from 10 ppm. Erythrocyte ChE was inhibited at 100 ppm, while brain ChE was statistically significantly inhibited in females from 10 ppm. The NOEL for was 1 ppm (0.05 mg/kg bw/day), based on reduced food consumption, reduced plasma and brain ChE activity and increased post-implantation losses at 10 ppm.

5.8 Developmental Studies

No developmental effects were observed in the multi-generational studies, or in a developmental study in rats at oral doses of up to 3 mg/kg bw/day. In a developmental study in rabbits using oral doses of 25 to 100 mg/kg bw/day, the incidence of hydrocephalus was higher in treated groups than controls. However, there was no dose relationship with this finding, and the high doses used in this study made the relevance of this effect unclear.

5.9 Genotoxicity

Chlorfenvinphos did not produce any genetic changes in a number of studies using *Escherichia coli*, *Salmonella typhimurium* or *Saccharomyces cerevisiae*, either with or without metabolic activation. No chromosomal damage was produced in a study using bone marrow cells of Chinese hamsters, and there was no effect in a dominant lethal assay in male mice. Based on these findings chlorfenvinphos was not considered to be genotoxic.

5.10 Neurotoxicity and behavioural studies

Specialised test in hens to assess organophosphate-induced delayed neuropathy (OPIDN) showed that chlorfenvinphos did not cause any neural degeneration changes typically associated with this syndrome.

Rats given chlorfenvinphos at 2 mg/kg bw orally showed disturbances in sleep patterns for two days following dosing. Atropine treatment 2 h after exposure resulted in an earlier return to normal sleep patterns. In a one-year feeding study, in which chlorfenvinphos was given at 150 ppm in the diet to rats, changes in muscle action potential, including prolonged negative potentials and repetitive activity were noted. Rats treated on a hot-plate 18 or 19 days after a single oral dose of chlorfenvinphos showed altered reactions to pain and stress in comparison to controls. Rats treated with chlorfenvinphos also showed an altered response to the introduction of a new object in an open field trial. The hippocampal EEG of rats exposed to an acoustic stimulus was altered in treated rats, particularly after the stimulus was associated with an electric shock. This effect was seen at times when brain ChE had returned to normal levels.

5.11 Effects in Humans

As with experimental animals, the main effects of chlorfenvinphos in humans are clinical signs of poisoning associated with inhibition of cholinesterase activity. Several reports of chlorfenvinphos poisoning indicated that clinical signs were the same as those seen in laboratory animal studies. Symptoms include nausea, vomiting and abdominal cramps. Antidotes were effective in treating chlorfenvinphos poisoning. Studies in human volunteers indicated that a daily oral dose of 3 mg chlorfenvinphos over 53 days did not produce abnormal clinical signs, but ChE activity was not determined. A single oral dose of 1 mg/kg bw chlorfenvinphos did not produce any abnormal clinical signs, but resulted in plasma and erythrocyte ChE inhibition. A single dermal dose of 5 mg/kg bw produced inhibition of plasma ChE activity.

Exposure studies indicated that workers applying chlorfenvinphos without protective clothing showed inhibition of plasma ChE activity although without abnormal clinical signs. More inhibition was seen following the use of liquid formulations than following granular formulation use. In epidemiological studies of workers exposed to chlorfenvinphos, there were changes in electromyographic voltages measured in the ulnar nerve region. The effects appeared to be reversible, with improvement following improvements in industrial hygiene or removal of affected workers from the workplace.

5.12 Public health standards

Acceptable Daily Intake

At the time of this review, the current acceptable daily intake (ADI) was set at 0.002 mg/kg bw/day. This ADI was derived from a NOEL of 0.15 mg/kg bw/day for plasma ChE inhibition in a 2-year rat dietary study. In the current review, a number of lower NOELs have been identified, including 0.075 mg/kg bw/day in a 16-week dog dietary study (highest dose tested), 0.05 mg/kg bw/day in a 4-week (plasma ChE inhibition), 2-year dietary study (plasma ChE inhibition) and a 2-generation reproduction study (plasma and brain ChE

inhibition) in the rat, and approximately 0.04 mg/kg bw/day in a 53-day oral dosing in humans.

The human study was not adequate to establish an ADI, as there was no monitoring of plasma or erythrocyte ChE, and it was not possible to accurately determine the dose delivered in mg/kg bw/day, as all volunteers received 3 mg of chlorfenvinphos daily with no reporting of the weight of each volunteer.

Based on the NOEL of 0.05 mg/kg bw/day obtained in a number of rat studies and applying a 100-fold safety factor (10-fold each for interspecies extrapolation and for variability in human sensitivity) the ADI for chlorfenvinphos has been amended to 0.0005 mg/kg bw/day.

Poisons Scheduling

No change to the current Schedule 7 of the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP) is proposed for chlorfenvinphos.

DETAILS OF THE REGULATORY APPROACH CAN BE FOUND IN SECTION 10

6. OCCUPATIONAL HEALTH AND SAFETY (September 1999)

6.1 Introduction

Toxicity relevant to occupational exposure

Technical chlorfenvinphos was of high acute oral, dermal and inhalation toxicity. It was a slight skin and eye irritant but not a skin sensitiser in experimental species.

Chlorfenvinphos formulations were as toxic as the active constituent, and in some cases more toxic. The oral toxicity was the same between formulations, however, the dermal toxicity varied according to the formulation type with granules or wettable powders (WP) having a lower dermal toxicity than emulsifiable concentrates (EC).

Animal studies demonstrated wide inter-species variation, but no sex related differences in sensitivity to chlorfenvinphos. Depression of cholinesterase (ChE) activity appears to be the most sensitive toxicological endpoint for chlorfenvinphos, with both plasma and brain ChE having a similar level of sensitivity in the rat.

A human No-Observable-Effect Level (NOEL) suitable for use in the occupational health and safety (OHS) risk assessment was not identified. Therefore, the NOEL of 0.15 mg/kg/d, based on plasma and red blood cell (RBC) ChE inhibition, established in repeat-dose rodent dietary studies was used in the OHS risk assessment.

Dermal absorption

No animal studies directly measuring the skin absorption of chlorfenvinphos were available. ChE depression was demonstrated in animals and humans dermally exposed to chlorfenvinphos, indicating uptake of the chemical via the skin. In the absence of specific skin penetration data, a default of 10% is used in the OHS risk assessment.

Insufficient data exists to describe the dermal penetration process in terms of percentage absorption. The amount penetrating will depend on the area of skin involved, the amount of pesticide present on the skin, the duration of presence on the skin, as well as on many other aspects related to the worker (skin) and the work situation.

6.2 Health effects resulting from occupational exposure

Insufficient information was available to quantify the extent of occupational health effects associated with the use of chlorfenvinphos in Australia. Surveys conducted overseas suggest that workers may suffer adverse health effects from occupational exposure to

chlorfenvinphos, particularly from sheep dips, with primary effects being ChE depression and possible neurobehavioural effects.

Influenza-like symptoms and alterations in ChE levels were noted in workers exposed to organophosphates (OPs) including chlorfenvinphos, while working with sheep, or in some cases during accidental exposure. It has been shown that factors influencing ChE activity are the degree of exposure, type of formulation and its concentration, route of exposure, and environmental conditions such as heat and humidity. Exposure studies indicated that the degree of ChE inhibition correlates poorly with clinical symptoms of illness.

Studies conducted in workers exposed to OP pesticides highlighted possible alterations in neuromuscular activity. In follow-up studies, there was a correlation between exposure to OP compounds and changes in electromyographic (EMG) voltages measured in the ulnar nerve. The results improved after a 3-week discontinuation of exposure or implementation of effective industrial hygiene practices.

6.3 Use profile

Prior to end use

Chlorfenvinphos products are available for agricultural and veterinary use. Some products are imported ready for use, whilst others are formulated locally from imported active ingredient. A considerable portion of the imported technical grade chlorfenvinphos is used in the manufacture of ectoparasiticide products. Veterinary products containing chlorfenvinphos either alone or in combination with another chemical such as cypermethrin are available mainly as EC formulations and as aerosol formulations. The one agricultural product is an EC formulation.

Manufacturing and formulation workers may be exposed to chlorfenvinphos and products, where sufficient controls are not in place. Individual premises, manufacturing/formulation processes and exposure control measures may vary within workplaces. However, they are expected to follow good manufacturing practices and have adequate quality control and monitoring facilities.

End use

Chlorfenvinphos is currently registered for agricultural use in broadacre crops, potatoes, mushrooms and for pest control in farm buildings. It is applied using ground based broadcast sprayers, hand-held equipment or by aircraft. Information obtained from users indicated that the most extensive use of the chemical in agriculture is in pastures.

For veterinary use, chlorfenvinphos is considered to be an important chemical in the control of ectoparasites in livestock. Chlorfenvinphos products are used as backrubber or overspray for the control of buffalo fly in cattle. Plunge dipping and hand-spraying are used for the

control of ticks in cattle (major use), horses, deer, sheep and goats (minor uses). Chlorfenvinphos is also registered as a treatment for superficial wounds in cattle and sheep and for the control and treatment of fly strike in sheep.

All chlorfenvinphos product labels recommend the use of protective clothing during mixing/loading and spray/solution application. The personal protective equipment (PPE) specified varies depending on product and work activity.

Use pattern information on agricultural and veterinary situations is summarised in the tables below together with the parameters used in the occupational exposure assessment.

Table 1: Use pattern of chlorfenvinphos product (EC 500 g/L) in agricultural situations

Crop/Situation	Application rate/dilution (concentration of ai in spray)	Work rate	Spray Volume	Application frequency
Pastures and lucerne	**Broadcast spray**: 550 mL/ha to 1 L/ha	50 ha/day	100 L/ha	usually only 1 application (occasionally 2 applications) is required
	Directed spray: 50 mL/100 L (0.05% ai)	Short duration	-	-
	Aerial spray: 550 mL/ha to 1 L/ha	200 ha/day	20L/ha	-
Mushroom casing	**Incorporation**: 100 mL/1000 L water per cubic metre of casing	Intermittent activity of short duration	-	Casing is generally applied weekly on commercial farms if pest pressure is high enough
Farm buildings (fly control)	**Directed spray**: 500 mL/10 L (2.5% ai)	Expected to be of short duration	400mL/10m^2	Seasonal and intermittent
Potatoes	**Broadcast spray**: 550 mL/ha	30 h/day	400L	Not regularly used
	Directed spray: 50 mL/100 L (0.05% ai)	Short duration	-	-

(1) The following Restricted Entry Statement is included on the product label: "workers should not handle sprayed crop for 5 days unless wearing protective clothing".

Table 2: Use pattern of chlorfenvinphos products (EC 138 g/L, 200 g/L and 2.5 g/L) in veterinary situations (cattle)

Application method/concentration of ai in product	Application rate/dilution	Work rate	Spray Volume	Frequency of application
Backrubber (200 g/L)	1 L/20 L sump oil		charged at a rate of 20 mL prepared mixture per animal	Every 3 weeks
Plunge dip (138 g/L)	1 part product to 250 parts of water (initial dilution) 4L/11000L water	500 cattle/day	standard size dip for a herd of 500 cattle is 11000 L (range 9000 L to 18000 L).	10-21 day intervals. Maximum of 10 treatments per year
	1 part product to 185 parts of water (topping up) 8L/1500L water		Top up required when the level of the dip falls by 1000 L – 1500 L.	
Spray race (138 g/L)	1 part product to 250 parts of water (initial dilution)	500 cattle/day	Spray races operate at low pressure(140 kPa) and deliver 90000 L per hour.	10-21 day intervals. Maximum of 10 treatments per year
	1 part product to 185 parts of water (topping up)		Pump and manuals paddles used to ensure thorough mixing	
Overspray (200 g/L)	20 mL /1 L water (0.4L/20L water)	100 cattle/day	Apply 200 mL per animal Ensure thorough coverage with 4 passes of the spray along the dorsal midline of each animal	Treatment interval is 21 days, minimum 10 days Maximum of 18 treatments per year
Hand spray and non-recirculating spray races (138 g/L)	1 part product to 250 parts of water (0.08L/20L water)	100 cattle/day	200mL/animal	Assumed to be used as for overspray
Wound dressing (2.5 g/L)	Apply undiluted, 0.5-1 mL/5 kg liveweight (not to exceed 1 mL/5 kg)		As required	Apply when necessary. Do not reapply at less than 10 day intervals and not more than 5 times/year

Note: The WHP specified on chlorfenvinphos product labels range from "nil" to 8 days for cattle.
The product labels prohibit concurrent use with other OPs and application within 10 days of treatment with other OPs.

Table 2: Use pattern of chlorfenvinphos products (EC 1 kg/L, 2.5 g/L, and aerosol 0.64 g/kg) in veterinary situations (sheep)

Application method, formulation and concentration of ai	Application rate/dilution	Spray Volume	Frequency of application
Jetting (EC 1 kg/L)	100 mL product per 200 L water 500 sheeop/day	Allow up to 4 L of wash depending on length of wool when jetting against body strike Crutch jetting requires at least 1 L of wash per sheep. Up to 900 kPa pressure for dense-woolled sheep with 9-12 months wool growth; and 550-600 kPa for sheep with 6 months wool	When necessary
Hand dressing (EC 1 kg/L)	10 mL product/12 L water	-	When necessary
Lamb marking (EC 1 kg/L)	5 mL product/10 L water	-	When necessary
Wound dressing (EC 2.5 g/L)	2-5 mL/kg bw (depending on size of affected area)	Maximum 5 mL/kg bw Applied undiluted	Apply when necessary. Minimum re-treatment interval 10 day Maximum of 5 applications/year
Mulesing/marking wounds (EC 2.5 g/L)	5-8 mL/kg bw Applied undiluted	Minimum volume 55 mL/sheep	Apply at the time of marking or mulesing Minimum re-treatment interval 10 day Maximum of 5 applications/year
Wound dressing (Aerosol 0.64 g/kg)	As required	-	Apply and repeat as necessary Re-treatment interval and maximum applications not specified

6.4 Occupational Exposure Assessment

End use exposure

Under routine conditions of use, the main route of occupational exposure for all use patterns is expected to be by skin contamination. Chlorfenvinphos is of low volatility, however, workers handling undiluted solvent-based product can be potentially exposed to solvent vapour. Inhalation of spray mist may occur during spray application, particularly when using hand-held equipment.

Cattle treatment is expected to occur mainly by plunge dipping and automatic spraying. Workers involved in these application methods will handle large volumes of chemical. Mixer/loader exposure will be mainly by skin contamination and inhalation of solvent vapour. Worker exposure during dipping and operation of spray races is expected to be by skin contamination as well as inhalation of spray mist, particularly when using automatic spray races.

Hand spraying of cattle involves smaller amounts of product. The main routes of exposure during this method of cattle treatment will be dermal contact and inhalation of spray mist, due to the close proximity of the operator to spray equipment.

A large proportion of sheep treatment is expected to occur by automatic or hand jetting. Large numbers of animals are treated by jetting, therefore, workers will handle large quantities of jetting fluid. Mixer/loader exposure can occur mainly by skin contamination and to some extent by inhalation of solvent vapour. Worker exposure during actual jetting operations is likely to occur by skin contamination and inhalation of spray mist.

The main route of occupational exposure during wound dressing of cattle and sheep is expected to be through dermal contact. Inhalation of spray mist may occur, particularly when using pressure sprayers.

Instead of considering each individual exposure/use separately, exposure scenarios were developed, coded and grouped where possible, in order to facilitate the exposure assessment and risk assessment. This allows maximisation of available data and simplifies the assessment. Representative application/dilution rates, spray/dip volumes, work rates and application frequencies were obtained from product labels and information available from users.

No suitable measured exposure data were available to estimate worker exposure during the agricultural and veterinary uses of chlorfenvinphos products. Predictive exposure modelling (using the UK Predictive Operator Exposure Model, POEM) was used where possible, in an attempt to estimate potential worker exposure for the various exposure scenarios identified.

The use of exposure values derived from predictive models, using conservative assumptions for unknowns and a range of values for a particular method of spraying, is internationally accepted as the first step in a tiered risk assessment (Tier 1). However, it should be noted that the use of exposure data from predictive models using default assumptions, is likely to overestimate risk.

A qualitative risk assessment was conducted for scenarios where predictive modelling was not used.

Post-application exposure

Agricultural uses

There is a potential for post-application exposure for persons entering treated areas after application is complete, particularly following aerial and ground broadcast spraying. No post-application exposure data or dislodgeable residue data were available for chlorfenvinphos.

The current chlorfenvinphos label carries the following re-entry/re-handling statement: "workers should not handle sprayed crop for five days unless wearing protective clothing".

Significant post-application activity (scouting, irrigation, manual harvesting) is not expected shortly after spraying of pastures, lucerne and potatoes. Considering the work practices in the mushroom industry and protective clothing specified on product labels, post-application exposure of mushroom-house workers is not likely to be extensive. Farm workers are not expected to re-enter treated buildings or handle treated surfaces, shortly after spray application.

Veterinary uses

Normal animal husbandry practices are not likely to require significant contact with treated animals shortly after treatment. In addition, the degree of post-application exposure is likely to be substantially lower than end use exposure. Considering the WHP for slaughter and work practices within abattoirs, exposure of workers during slaughter and subsequent handling of carcasses is not expected to be significant.

Post application exposure is likely for persons handling treated sheep, particularly following jetting of long woolled sheep, due to retention of chemical in the wool staple. Animal husbandry practices such as wound dressing require workers to handle treated sheep. Workers are expected to adhere to safe work practices and not handle treated animals shortly after jetting. Therefore, overall exposure during such activities is expected to be less than worker exposure during mixing/loading and jetting of sheep.

Chlorfenvinphos products are registered in Australia as long wool treatments. Product labels do not carry a WHP for shearing. Therefore, it is reasonable to assume that sheep may be shorn within days/weeks of treatment with the chemical (this issue is being addressed as part of the NRA's review of selected sheep ectoparasiticides).

6.5 Occupational risk assessment and conclusions

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.

No suitable measured exposure data were available for the agricultural or veterinary uses of chlorfenvinphos. In order to determine the risks associated with the use of the chemical, Margins of Exposure (MOE) were calculated by comparing the most appropriate No Observable Effect Level (NOEL) with exposure data obtained from predicted modelling, where possible. A qualitative risk assessment was conducted where a suitable model was not identified.

The main adverse health effect of chlorfenvinphos exposure is ChE inhibition. The most appropriate NOEL to assess the occupational risk to workers was determined to be 0.15 mg/kg/d, established in repeat-dose dietary studies in rodents, for plasma and RBC ChE depression. A dermal absorption adjustment of 10% was used in the risk assessment. No correction was made for inhalation absorption, as 100% absorption was assumed.

Considering that the NOEL used in the OHS risk assessment was established in experimental species, MOE of approximately 100 or more were considered acceptable, to account for possible intra- (10x) and inter-species (10x) variability.

Chlorfenvinphos is a slight skin and eye irritant in experimental animals. These topical effects may be manifest in workers who come in contact with chlorfenvinphos products. The potential for topical effects when in contact with the working strength solutions is likely to be governed by the concentration of the product in the spray/solution in each case.

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

End use

Pastures and lucerne

Noting the infrequent use of the chemical over the growing season (generally once), the likely overestimation of risk during broadcast spraying, from use of predictive exposure models, and the use pattern, frequency and potential for directed spraying of pastures and lucerne, it is concluded that the risk to workers involved in broadcast application (ground and aerial) and directed spraying of chlorfenvinphos in pastures and lucerne is likely to be acceptable.

Potatoes

Noting the infrequent and relatively minor use of the chemical, the likely overestimation of risk from use of predictive models and the use frequency of use (only as a backup chemical), it is concluded that the risk to workers during broadcast application and directed spraying of chlorfenvinphos in potatoes is likely to be acceptable.

Fly control in and around farm buildings

Considering the potential for significant operator exposure during hand spraying, the lack of Australian use pattern information, possible regular (seasonal) use of the chemical on farms and the lack of measured exposure data, it is concluded that the risk to workers during hand-

held application of chlorfenvinphos for fly control in farm buildings is unacceptable on occupational health and safety grounds. Additional worker exposure data and use pattern information are required.

Fly control in mushrooms

A suitable model does not exist within POEM to estimate operator exposure for this use. Considering the probable frequency of use, dilution of the product in the working strength solution (0.005% ai), work practices within the mushroom industry and protective equipment specified on product labels, the risk to mushroom house workers is not expected to be of concern.

Cattle: Backrubber

Available information did not indicate the extent of use of chlorfenvinphos as back rubber treatment in Australia. Cattle farmers are expected to prepare backrubbers, using a 1% solution of chlorfenvinphos, at approximately 3-week intervals during the buffalo fly season (November to April).

A suitable model does not exist to provide surrogate exposure data. However, worker exposure during backrubber preparation is expected to be neither frequent nor extensive and therefore it is concluded that the risk to workers during preparation of cattle backrubbers is likely to be acceptable.

Cattle: Plunge dip and spray race operations

Plunge dipping is the preferred method for controlling cattle tick in Australia with large numbers of cattle treated by these methods. Worker exposure is anticipated during initial charging of dip/spray race as well as top up operations.

The label recommends that chlorfenvinphos be applied by these methods at 10 –21 day intervals, with a maximum of 10 treatments per year therefore, intermittent worker exposure is anticipated.

Predictive modelling was used to obtain an estimate of mixer/loader exposure only. The risk to workers involved in open mixing/loading was determined to be unacceptable.

A suitable model was not available for estimating worker exposure during plunge dipping or spray race operation. Splashing is quite common during plunge dipping of cattle, whilst the large quantity of spray mist generated during automatic spray race operations may result in significant worker exposure.

The risk to workers involved in plunge dipping and automatic spraying of cattle could not be adequately quantified. Additional data are required in order to assess this use of chlorfenvinphos with any degree of confidence.

Cattle: Hand spraying

Chlorfenvinphos is used during the fly season, from November to April, at intervals of 10 –21 days, with a maximum of 18 treatments per year applied by hand held methods. Therefore, worker exposure is expected to be intermittent and seasonal.

POEM was used to provide a rough estimate of worker exposure during hand spraying of cattle. The risk to workers during mixing/loading from currently registered containers and during spray application was determined to be unacceptable.

Potential exposure (and risk) during hand spraying of cattle is of OHS concern due to the potential for significant operator exposure during hand-held applications, the relatively large volumes of solution handled and the lack of measured exposure data. Additional worker exposure data are required.

Cattle: Wound dressing

Wound treatment is carried out as required, and herd treatment is not anticipated by this method. A minimum re-application interval of 10 days and a maximum of 5 applications per animal are specified on the product label. Considering the frequency of use, number of animals likely to be treated and work practices, worker exposure during wound dressing of cattle is not expected to be of OHS concern.

Sheep: Jetting

Jetting is the preferred method of fly control on Australian sheep farms. Jetting may be carried out using automatic jetting races or hand-held spray equipment however hand jetting is more labour intensive yet more effective against fly strike and thus the preferred method of treatment.

Farmers are not expected to jet long woolled sheep more than a few times per year and therefore, intermittent worker exposure is anticipated.

Considering work practices frequency and extent of use and concentration in the working solution (0.005%), applicator exposure during hand-jetting was unacceptable.

Sheep: Wound dressing/lamb marking

Workers are likely to treat a varying number of animals, depending on the extent of flystrike or husbandry practice requiring protective wound dressing. It is expected that worker exposure during wound dressing would be either regular (for short periods of time) or intermittent.

Considering the concentration of chlorfenvinphos in solution/aerosol is low, the areas requiring dressing are not expected to be extensive, and outdoor application will provide a dilution effect and mitigate inhalation of spray/aerosol, the risk to workers during wound dressing is likely to be acceptable:

6.6 Occupational risk assessment and conclusion – post application

Agricultural uses

The review indicated that the risk to re-entry workers is likely to be acceptable, provided the chemical is used in accordance with good agricultural practices and label instructions.

The current REP of 5 days is adequate for chlorfenvinphos products.

Veterinary uses - Cattle

The risk to workers re-handling treated cattle and sheep is not expected to be significant provided workers do not come in direct contact with treated animals immediately after treatment and good animal husbandry practices are observed.

Sheep shearing and wool handling

The main risk for shearers and wool handlers is exposure to residues in the wool wax through dermal absorption. No withholding period is specified on product labels for shearing.

Assuming a single application of chlorfenvinphos and using conservative assumptions where data was unavailable, the risk to shearers and other wool handlers was determined to be unacceptable. Additional data are required to more accurately assess the post-application risk during shearing and subsequent handling of wool. This issue will be dealt with as part of the NRA's Special Review of Selected Sheep Ectoparasiticides.

6.7 Existing regulatory controls for occupational health and safety

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

R24	Toxic in contact with skin
R28	Very toxic if swallowed
R50	Very toxic to aquatic organisms
R53	May cause long term effects in the aquatic environment
S1/2	Keep locked up and out of reach of children
S28	After contact with skin, wash immediately with plenty of (material to be specified by the manufacturer)
S36/37	Wear suitable protective clothing and gloves
S45	In case of accident or if you feel unwell, contact a doctor or Poisons Information Center immediately (show the label where possible).
S60	This material and its container must be disposed of as hazardous waste
S61	Avoid release to the environment. Refer to special instructions/safety data sheets

All formulations of chlorfenvinphos registered in Australia containing 2.5 g/L to 1000 g/L of the active constituent are determined to be hazardous substances. The aerosol product for sheep treatment containing 0.64 g/kg is not determined to be hazardous.

The NOHSC National Model Regulations and National Code of Practice for the Control of Workplace Hazardous Substances apply to all hazardous substances, and extend to all workplaces in which hazardous substances are used or produced and to all persons with potential for exposure to hazardous substances in those workplaces.

In accordance with Commonwealth/State/Territory legislation, the following control measures must be instituted, where applicable.

- **Induction and training** - Appropriate induction and on-going training of all workers with the potential for exposure to chlorfenvinphos products, in relation to those substances in the workplace and commensurate with the risk identified by the workplace assessment process.

- **Workplace assessment** - A suitable and sufficient assessment of the risks to health created by work involving potential exposure to chlorfenvinphos.

- **Control** - As far as practicable, the prevention or adequate control of exposure of workers to hazardous substances should be secured by measures other than the provision of PPE. Control measures should be implemented in accordance with the hierarchy of controls.

  It is recommended that industry-based standard operating procedures (including safe work practices) be developed, where appropriate.

  The use of PPE for exposure mitigation should be limited to situations where other control measures are not practical or where PPE is used in conjunction with other measures to increase protection. Where PPE is used, it should be selected and used in accordance with the relevant Australian Standards. Protective equipment should be properly selected for the individual and task, be readily available, clean and functional, correctly used and maintained.

- **Health surveillance** – OPs including chlorfenvinphos are listed on the Schedule for Health Surveillance. Therefore, workers should have access to health surveillance facilities in accordance with the NOHSC Control of Workplace Hazardous Substances. The employer is responsible for providing health surveillance where estimates of workplace risk indicate surveillance.

- **Record keeping** – Records should be maintained in accordance with the NOHSC Control of Workplace Hazardous Substances.

DETAILS OF THE REGULATORY APPROACH CAN BE FOUND IN SECTION 10

7. ENVIRONMENTAL ASSESSMENT (September 1999)

7.1 Environmental Chemistry and Fate

7.1.1 Abiotic transformation

Chlorfenvinphos only slowly hydrolyses at environmentally relevant pH values (ie. pH 5-9) and this is not expected to be a major degradation pathway. No studies were submitted on the phototransformation of chlorfenvinphos although a US review considered this to be a minor pathway as the maximum wavelength for absorption is filtered out by the atmosphere. However, transformation due to hydroxyl radical reaction in the atmosphere is estimated to be rapid with a half-life of about 7 h.

7.1.2 Biotic transformation

When an aerobic sandy loam was treated at 10 mg a.i./kg soil dry weight, incubation temperatures of 28, 15 and 3°C gave DT50 values of about 16, 42 and 98 d, respectively. Degradation in an organic muck was slower with DT50 values of 21 and 80 d at 28 and 15°C, respectively, and 63% remaining at 168 DAT in the 3°C treatment. The DT50 was uniform at about 11 d (nonpersistent) in the sandy loam at 20-60% MHC at 28°C, but was slower at about 63 d (moderately persistent) in air-dried sandy loam. Degradation in muck soil was more dependent on moisture with a DT50 of 13-58 d (nonpersistent-moderate) at 20-60% MHC; air-dried muck had a moderately persistent DT50 of about 91 d. The main soil metabolite was 2,4-dichloro-1-(1-hydroxyethyl)benzene which peaked at 11.2 and 27.7% of the originally applied amount at 63 DAT in a further experiment on four soils.

A US review reported that neither this nor any other metabolite retained any pesticidal characteristics and that adsorption to organic matter decreased the rate of degradation. A UK MAFF review reported the conflicting results of several studies: soil concentrations of chlorfenvinphos hardly declined over 126 d in carrots grown in a glasshouse; DT50 values in Belgian soils previously treated with chlorfenvinphos were 25-30 d but 50-56 d in "unadapted" soils; a natural sandy loam and an organic soil had DT50 values of <7 and 7 d, respectively, when incubated at 28°C and 60% FCM; 50-80% of the applied dose remained in eight soils incubated at 15°C and FCM for 56 d. No studies on anaerobic soil metabolism were submitted.

When natural sediment and pond water at 10°C were treated with ^{14}C-chlorfenvinphos, radioactivity slowly moved from the aqueous phase into the sediment with a half-life in water of about 70 d and in the whole system of 90.5 d. The major metabolite was 2,4-dichloro-1-(1-hydroxyethyl)benzene which peaked at 11.2 and 27.7% in the sediment and water, respectively, 63 DAT. At 25°C however, the half-life in water was about 7 d, reflecting more rapid movement to the sediment, with a whole system half-life of 27.0 d. At this temperature, no metabolites were found at >10%. In two other natural stream sediment-water systems held at 20°C, the half-life of parent compound was 38.0 and 40.3 d with the same major metabolite as in the previous study peaking at 17.4% of the originally applied amount at 61 DAT. Nonextractable radioactivity and evolved $^{14}CO_2$ peaked at 28.6 and 10.0% at 103 DAT. When a natural pond was treated at 74 kg a.i./ha in a field study, chlorfenvinphos dissipated

from the water column with a half-life of 8.3 d while the concentration in sediment peaked at 0.32 mg a.i./kg sediment at 4.8 DAT and declined to 0.15 mg a.i./kg sediment by 33.9 DAT.

The submitted studies are summarised in the following Table.

Media	Half-life or DT50	
Soil		
-aerobic sandy loam	16 d at 28°C 42 d at 15°C 98 d at 3°C (all at 60% MHC)	11 d at 20-60% MHC 63 d in air dried soil (all at 28°C)
-organic muck	21 d at 28°C 80 d at 15°C >168 d at 3°C (all at 60% MHC)	13 d at 20% MHC 41 d at 40% MHC 58 d at 60% MHC 91 d in air dried soil (all at 28°C)
-carrots in a glasshouse	soil concentrations hardly declined over 18 weeks	
-previously treated Belgian soils -not previously treated	25-30 d 50-56 d	
-sandy loam -organic soil	<7 d at 28°C and 60% FCM 7 d at 28°C and 60% FCM	
-eight soils	50-80% of the applied dose remained at 56 DAT at 15°C and FCM	
Natural water/sediment systems		
-pond water -whole system	70 d (both at 10°C) 90.5 d	7 d (both at 25°C) 27.0 d
-stream water/sediment	38.0-40.3 d at 20°C	
-pond water -sediment	8.3 d peak concentration of 0.32 mg a.i./kg sediment at 4.8 DAT declining to 0.15 mg a.i./kg sediment by 33.9 DAT	

7.1.3 Mobility

The K_{OM} value for chlorfenvinphos of 170 with the equivalent K_{OC} of 293 indicates medium mobility. When chlorfenvinphos was applied to a sloping silty clay loam (about 8 m up slope from a pond) seeded with spring barley at 22 kg a.i./ha in the emulsifiable concentrate formulation, the highest concentration (8.7 mg a.i./kg soil 1 DAT) was found in the treated strip which dissipated with a half-life of about 28 d. Only at 28 DAT were detections of 0.03 mg a.i./kg soil found near the edge of the pond while all other samples (soil and water) were below the limits of detection. On a clay loam treated in a similar manner, the low mobility was confirmed as detections were only made in the treated strip to 25 cm depth and the adjacent strip (1.8 m down slope) to 15 cm; however, the DT50 was longer at >98 d. Another experiment was conducted with a sloping trough filled with silt loam and partitioned so that horizontal and vertical movement could be distinguished. When chlorfenvinphos was applied at 37 mg a.i./kg soil in the top compartment and the trough left outdoors for 140 d, 78% of all parent found in the leachate (20.1 L) occurred in the first 63 DAT and from the originally treated uppermost compartment; this confirmed the low surface run-off potential of chlorfenvinphos.

A US review reported low soil mobility with only 1-1.5% of the applied amount (formulation unspecified) leached to a depth of 7.5-15 cm in one study and no detections below 10 and 15 cm with a granular formulation in two other studies. Surface run-off was not significant as only 0.3-0.6% of the applied amount was found in run-off water after rain. Monitoring of surface waters over 8 yr in areas where chlorfenvinphos had been used also found no

detections. As well, water and sediments in farm ditches did not contain chlorfenvinphos despite its detection in some soil samples.

A UK MAFF review calculated a GUS of 1.72 using a K_{OC} and soil half-life of 680 and 30 d, respectively, which classifies chlorfenvinphos as a non-leacher.

7.1.4 Volatility

The US review considered chlorfenvinphos to volatilise slowly from water and therefore to be essentially nonvolatile. The vapour pressure and Henry's Law Constant indicate that chlorfenvinphos has a low volatility and is unlikely to volatilise significantly from water or moist soil surfaces.

7.1.5 Field dissipation

When chlorfenvinphos was applied to cabbage foliage in the laboratory, the initial half-life was 2-3 d but decreased after this time and >50% was said to have volatilised within 4-7 DAT. There was some suggestion that phototransformation had isomerised the Z-isomer to the E-isomer. This was similar to potato and cabbage foliage in dry outdoor conditions. No translocation of residues from treated leaves was found and the major degradation product was a conjugate of 2,4-dichloro-1-(1-hydroxyethyl)benzene.

Half-lives of chlorfenvinphos were 1.5-2.4 times longer in three soils (13-53 d) which had been amended with organic compost and planted with cauliflower, compared to control soils which had not been fertilised (9-23 d). The dissipation rate in control soils would classify chlorfenvinphos as non-persistent to slightly persistent. No parent compound or metabolites were detected in the cauliflower flower or soil deeper than 10 cm. In three sandy loams and a silty loam planted with cauliflower, the half-lives were 8.8-35.9 d and 23.0 d, respectively. Main metabolites were 2,4-dichloro-chloromethyl ketone, 2,4-dichlorobenzoic acid and 2-hydroxy-4-chlorobenzoic acid whose maximum concentrations were 3.3, 7.9 and 5.0 mg a.i./kg soil at 36, 18 and 36 DAT, respectively. When cauliflower, brussel sprouts and chinese cabbage were planted in the same soils and treated in the same manner, half-lives in the soils of the three crops were 13.5-27.9, 23.2 and 20.8-25.8 d, respectively. It was suggested the history of 1-18 years of previous treatment may have selected for a microbial population adapted to decomposing chlorfenvinphos and therefore account for the sometimes shorter half-lives. This was supported by half-lives of chlorfenvinphos in other cauliflower and brussel sprout plots of 27.2 d in soils with 1 yr previous chlorfenvinphos history, to 20.1-25.7 d for soils with 2 yr history, to 10.8-18.7 d in a soil with 8 yr history. Half-lives for the collective dissipation of parent and five metabolites was relatively constant at 52.4-68.6 d in all these soils. Residue analyses indicated that chlorfenvinphos was absorbed from the soil and translocated into the foliage.

In a sandy loam and peat loam treated with chlorfenvinphos granules and planted with carrots, dissipation was quicker from the sandy loam than peat loam with about 21 and 41% of the originally applied amount remaining at 238 DAT, respectively. At 182 DAT, only about 1% of the chlorfenvinphos had leached to the 10-15 cm layer in both soils and only traces were detectable below this. There was some suggestion that high organic matter content of the peat loam increased the adsorption of chlorfenvinphos to soil and reduced the rate of dissipation. On soils in the UK, the initial half-life was usually in the wide range of 28-210 d, probably

due to a slowing of degradation when temperatures fell below 6-7°C. Other data showed annual carryovers of 2.5-12.5% in field trials.

These studies are summarised in the Table below.

Media	Half-life or DT50
Cabbage foliage	initially 2-3 d but decreased after this time with >50% volatilisation in 4-7 DAT
Three soils -controls (no compost) -with organic compost	 9-23 d (non-persistent to slightly persistent) 13-53 d
Three sandy loams Silty loam	8.8-35.9 d All soils planted with cauliflower 23.0 d
Three sandy loams and a silty loam	Planted with -cauliflower 13.5-27.9 d -brussel sprouts 23.2 d -chinese cabbage 20.8-25.8 d
Cauliflower and brussel sprout plots with different chlorfenvin-phos histories	-1 yr history 27.2 d -2 yr history 20.1-25.7 d -8 yr history 10.8-18.7 d -parent + 5 metabolites 52.4-68.6 d in all soils
Sandy loam Peat loam	21% remaining at 238 DAT 41% remaining at 238 DAT
UK soils	28-210 d initial half-life possibly due to low temperatures over winter, annual carryovers of 2.5-12.5%
MAFF (1994)	
Four soils	12-45 d All soils planted with cauliflower and brussel sprouts
Field crops	27% of the applied amount detected in the soil at 161 DAT, traces of both isomers found 4 yr after treatment
Sandy loam	granules 41% remaining in the top 15 cm 84 DAT fluid gel 65-76% remaining in the top 15 cm 84 DAT
Sandy loam	granules no significant decrease in soil concentration after 62 d liquid 20% decrease 62 DAT
Peat blocks	85-100% remaining 56 DAT when stored in a glasshouse
Onion plots	variable residue concentrations (up to 11.1 mg a.i./kg soil) but no overall accumulation after treatment for 3 yr
Sorghum plots	30-45 d, no residues at 120 DAT
Fallow field	33 d, no residues at 120 DAT
Sand Silt loam	70-140 d 40-70 d
Four sand soils Peat	2-60 d 70% remained 150 DAT

7.1.6 Uptake and metabolism in plants

Carrots, onions (treated at 3.4 and 4.5 kg a.i./ha, respectively) and cabbages (treated at 4 mg a.i./plant) were harvested at maturity after 12-18 weeks. In carrot plots, the majority of the radioactivity was identified as parent at 2.2 mg a.i./kg soil with 0.33 mg a.i./kg tissue in the leaf. In the onion plots, the greatest residues of parent were in the soil at 2.4 mg a.i./kg soil; residues in the leaf and bulb were =0.08 mg a.i./kg tissue. The majority of the applied radioactivity (mostly as parent compound) to cabbage was found in the soil at 0.32-0.36 mg a.i./kg soil with equal amounts (0.26 mg a.i./kg plant) in the acetone extractable and unextractable portions of the cabbage stump and root.

The leaves of potato, cabbage and maize plants grown in a glasshouse were treated with 30 mg a.i./kg plant. The half-life for parent compound in potatoes was 5.9 d over the entire 28 d

sampling period despite an initially rapid degradation with a half-life of 1.9 d during the first week. Half-lives in cabbage and maize were 10.6 and 6.8 d, respectively and no translocation from treated to untreated leaves occurred. The main metabolite was 2,4-dichloro-1-(1-hydroxyethyl)benzene in the soil and as a conjugate in the crops.

Carrot seedlings grown in treated soil were transferred to an untreated sandy loam or peat after 19 d and transferred 75% of the chlorfenvinphos in carrot seedlings to the untreated soil.

7.1.7 Bioconcentration

The relatively low bioconcentration factors of 37-460 (reported in other reviews) and 332 (estimated) for fathead minnow indicate that bioconcentration is likely to be low. This was confirmed by BCFs of 66-103 with depuration half-lives of 25-26 h in whole rainbow trout.

7.1.8 Residues in wool

Pesticide residues generally dissipate in fleece over time due to volatilisation and oxidation. A half-life for chlorfenvinphos in greasy wool of 56.6 d, including accounting for dilution by wool growth, was found in an Australian study when merino sheep were handjetted. Other studies indicate that dissipation of residues located near the surface of the fleece and on coarse open fleeces is faster and organophosphates generally degrade relatively quickly with half-lives of 28-35 d under Australian conditions.

Little degradation occurs when wool is baled; however, scouring removes about 95% of residues, >28.5% of which is recovered in the grease to be processed into various lanolin products. The remainder of the grease (containing residues) is usually treated before discharge to the environment in the liquid effluent and sludge. As chlorfenvinphos has a moderate solubility in water of 95 mg/L and a log K_{OW} of 3.1-4.2, it will partition mostly into the grease but still be found in the aqueous phase of the scour. Dye house effluents may also contain residues after processing the wool.

CSIRO's new Sirolan CF process can extract up to 80% of lipophilic pesticide residues from the effluent; however, not all scouring plants use this method. The SimpleTreat model predicts 37% of the chlorfenvinphos in treatment plant wastewater will partition to sludge and 32% to water with 31% degraded if it were inherently biodegradable.

7.2 Environmental Toxicology

7.2.1 Birds

The toxicity of chlorfenvinphos to several species of birds was examined in submitted studies, including those published in the scientific literature. Chlorfenvinphos was very highly toxic to starlings with an acute LD50 < 10 mg a.i./kg bodywt, highly toxic to pigeons and blackbirds (LD50 of 10-50 mg a.i./kg bodywt) and moderately toxic to mallard ducks, chickens, pheasants and quail (LD50 of 50-500 mg a.i./kg bodywt) in acute exposures. The 28-d LOEC to pigeon, pheasant and Japanese quail was 100 mg a.i./kg food for depressed brain esterase activity and/or liver and kidney esterases. Feeding by various bird species on

treated wheat seeds in recently planted fields resulted in no overt symptoms until after a second sowing 12 d later when 12 pigeon and dove carcasses were found. The 8-h NOEC and LOEC for adult starlings was 3 and 6 mg a.i./kg bodywt, respectively, based on adverse brain AChE levels.

Studies reviewed in MAFF (1994) confirmed the very high toxicity of chlorfenvinphos to starlings and high toxicity to red-wing blackbirds, house sparrows, common pigeons, brown-headed cowbirds, common grackles, house finches and quail and moderate toxicity to golden-crowned sparrows and pheasants. The 21-d NOEC and LOEC to Japanese quail were 0 and 74 mg a.i./kg bodywt, respectively, based on plasma and brain AChE inhibition.

7.2.2 Fish

Toxicity studies from the company and scientific literature on a range of fish species were assessed. Chlorfenvinphos, in various formulations, was found to be very highly toxic to *Tilapia nilotica* and common carp (LC50 < 0.1 mg/L) and highly toxic to rainbow trout (LC50 of 0.1-1 mg/L) in acute exposures. It was moderately (LC50 of 1-10 mg/L) to highly toxic to the guppy in two experiments but highly to very highly toxic to the guppy and Harlequin fish in another. Juvenile carp placed in cages in a rice paddy showed 97% mortality within 7 d after treatment with 1.2 kg a.i./ha of a granular formulation. Many dead perch and roach were reported anecdotally when a pond was treated at 74 kg a.i./ha. Unfortunately, details on methodology were lacking in several of these studies and the results should be treated with caution.

The review by MAFF (1994) found some differences in the acute toxicity of chlorfenvinphos to fish. It was listed as only highly toxic to carp, goldfish, *Orizias latipes* and guppy, and moderately toxicity to rainbow trout. The very high toxicity of chlorfenvinphos to *Tilapia nilotica* and carp was confirmed in one study, but another found only moderate toxicity to carp. The chronic 7-d NOEC and LOEC to rainbow trout were 10 and 100 µg a.i./L, respectively, based on brain acetylcholinesterase inhibition. For reproductive physiology endpoints in the striped catfish, the 84-d NOEC and LOEC were 0 and 3.02 µg a.i./L respectively. Chlorfenvinphos applied at 0.9 kg a.i./ha to a pond still caused 30% mortality to mosquito fish when introduced 15 DAT. It is apparent that there is a range of toxicity among and within a species possibly dependent upon differences in methodology.

7.2.3 Aquatic invertebrates

A number of submitted studies and those summarised from MAFF (1994) on the freshwater invertebrate *Daphnia magna* showed conflicting results ranging from moderate (LC50 of 1-10 mg/L) to very high (LC50 <0.1 mg/L) acute toxicity. Chlorfenvinphos was highly toxic to another species of water flea (*Ceriodaphnia dubia*) and the eastern oyster but moderately toxic to the scud. Only slight toxicity was found to protozoa. As experimental details were lacking in several of these studies, these results should be treated with caution. The 21-d LOEC to *D. magna* was the lowest dose tested of 0.3 µg a.i./L based on statistically significant reduced numbers of live young and young per adult.

7.2.4 Aquatic plants

One toxicity study was submitted on a freshwater alga while other studies on algae and macrophytes were summarised from MAFF (1994). Chlorfenvinphos was moderately toxic (IC50 of 1-10 mg/L) to *Selenastrum capricornutum, Scenedesmus subspicatus*, and moderately to slightly (LC50 of 10-100 mg/L) toxic to *S. quadricauda*. Concentrations as low as 600 µg a.i./L reduced the biomass and chlorophyll content of *Lemna minor* at an unspecified exposure duration. The bacteria *Sphaerotilus natans* showed decreased growth at 1.0-100 mg/L but increased growth at 10,000 mg/L.

7.2.5 Terrestrial invertebrates

Several studies were submitted which showed chlorfenvinphos was generally nontoxic to most terrestrial invertebrates at the maximum rate registered in Australia of 500 g a.i./ha. Earthworms were generally unaffected by chlorfenvinphos with 14-d LC50, NOEC and LOEC values of 204, 123 and 234 mg a.i./kg soil, respectively, in a laboratory experiment, and no mortality claimed in a 21-week field study (although up to half the worms were not recovered). Various studies reported a wide range of responses with chlorfenvinphos relatively nontoxic (oral LD50 = 14.9 µg a.i./bee) to highly toxic (topical LD50 = 0.41 µg a.i./bee) to bees although a midvalue of 4.1 µg a.i./bee (moderately toxic) for contact toxicity seems fairly reliable. Mortality of larval and adult ladybird beetles appears high at 76 and 88% 72 h after being sprayed with 500 mg/L, however, no EC50 could be calculated from the data provided. Rove beetles showed contrasting results with initially reduced parasitisation efficiency to eventual greater efficiency compared to controls when treated with =4 kg a.i./ha but only adverse effects at 16 kg a.i./ha. More carabid beetles were caught in traps in spring wheat plots treated at 9-22 kg a.i./ha than in controls possibly due to increased activity. In this report, the 48-h LC50 was reported as 2.3 mg/L in topical exposures while another reported 24-h LD50 values of 600-2000 mg a.i./kg soil for three different species of carabids.

Summaries reported high doses of 100 kg a.i./ha significantly decreased nematode numbers; 4.5 and 9.0 kg a.i./ha greatly decreased predatory mites and temporarily increased oribatid mites, respectively; and slugs and beetles concentrated chlorfenvinphos to 280 and 1.33 mg a.i./kg bodywt, respectively. Spiders and natural predators of rice pests were not affected by 0.75 kg a.i./ha applied three times at 10-15 d intervals. Mortality was higher to springtails at 24°C than at 13°C when other factors were constant with a 24-h LC50 of 0.5-1.0 mg a.i./kg soil. Predatory beetles and earthworms were reduced by up to 32 and 50%, respectively, at 1.8-2.2 kg a.i./ha.

The numbers of carabids caught in the field was slightly higher than controls when treated at the equivalent of up to 15 kg a.i./ha, although the statistical significance is unknown. In the laboratory, beetles were relatively resistant to treatments of 40 mg a.i./kg soil after 7 d. Complex interactions were found in another field study with springtails greatly diminished initially but recovering within 4-7 months of treatment with up to 9.0 kg a.i./ha. However, one family of springtails and oribatid mites were increased even at 6 MAT possibly due to reduced predators. Wireworms experienced up to 70% reductions although the authors regarded this as not very lethal. Fly larvae decreased by 50-80% initially but recovered as chlorfenvinphos dissipated while microarthropods (eg predatory mites) were decreased even after residues had almost disappeared.

The MAFF (1994) review reported 100% mortality to honey bees when treated at 0.56 kg a.i./ha when caged in clover and lucerne fields. When exposed to foliar residues, 41% were killed when leaves had been sprayed 3 h previously, but only 1% when residues were 24 h old. The maximum LD50 risk zone was estimated as within 1 m of a spray nozzle based on an LD50 of 4.1 µg a.i./bee and a surface area of 1 cm^2. Chlorfenvinphos was not harmful to a carabid beetle at up to 40 mg a.i./kg soil.

This wide variety of studies shows most terrestrial invertebrates were unaffected at the maximum single application rate of chlorfenvinphos of 500 g a.i./ha.

7.2.6 Terrestrial plants and soil micro-organisms

No studies were submitted on the toxicity of chlorfenvinphos to terrestrial plants.

Studies generally showed chlorfenvinphos to be nontoxic to soil microbial processes at the maximum application rate in Australia of 500 g a.i./ha. However, the processes of respiration, ammonification and denitrification are not good indicators of toxicity to individual species. These processes can be maintained in the face of significant toxic impacts as resistant microbes increase their populations at the expense of sensitive species.

Nitrogen fixation (as measured by nitrogenase activity of the rhizosphere soil around rice plant roots) was somewhat slowed by application of 0.5 kg a.i./ha but this effect was inconsistent throughout the sampling period. When this process was measured by acetylene reduction, treatments of up to 10 mg a.i./kg soil (equivalent to 15 kg a.i./ha presuming 10 cm soil depth) decreased reduction after 2 d but not 6 d. The activity of some microbial enzymes was different from controls when treated at 10 mg a.i./kg soil, however the environmental significance is unknown. Entomopathogenic fungi were affected with a LOEC of 5 mg/L but showed inconclusive results at the field rate of 100 mg a.i./kg soil when soil amended with chlorfenvinphos-exposed fungi caused somewhat increased toxicity of Colorado potato beetle pupae in the winter but not summer. Total soil biomass, consisting of bacterial and fungal counts, were not affected by treatments up to 1.52 kg a.i./ha. Chlorfenvinphos treatment at 2 kg a.i./ha increased the number of spores (by 41%) of a beneficial fungi. Preliminary work has shown that composting under favourable conditions can biodegrade chlorfenvinphos in dip sludges.

7.2.7 Mammals

The UK review reported inhibition of brain acetylcholinesterase in the wood mouse up to 10 d after treatment with 2,500 mg a.i./kg food. In a field drilled with treated wheat seed, trapped wood mice had variable residue concentrations in their gut correlated with significant inhibition of plasma cholinesterases in the first 10 d after treatment. However, the rapid disappearance of surface grain and residues in grain limited the transitory exposure to wildlife.

7.3 Environmental Hazard

Of all the various use patterns, chlorfenvinphos is likely to have the greatest environmental exposure through the spraying of Birlane 500 Insecticide on pasture, lucerne and potato. The treatment of sheep, cattle and other animals may also result in exposure. However, the potential for off-site movement during these uses is expected to be lower. The disposal of wool scouring effluent containing residues may also result in some exposure while the uses on cattle by backrubbers and coarse overspray, localised treatment of animal wounds, farm buildings and mushroom casings are not expected to result in any significant exposure.

7.3.1 Hazard to Terrestrial Organisms

A preliminary worst case assessment shows that the application of Birlane 500 Insecticide at the maximum rate of 500 g a.i./ha in Tasmania is a potential hazard to birds through dietary exposure. However, a more detailed assessment indicates any adverse effects on birds from applications to potatoes and lucerne are likely to be isolated with populations remaining unaffected due to the more likely reduced exposure through spray drift, the mobility of birds and the broadacre application instead of the concentrated seed dressings which have resulted in poisoning reports. However, use in pastures may cause dosed pests (underground grass grubs, pasture webworms and corbies) to become easy prey for birds resulting in an unacceptable hazard; therefore, the continued registration of this use pattern cannot be supported without further information, such as results of monitoring to determine whether birds are present during or visit shortly after application to feed. In the use pattern of the other products containing chlorfenvinphos on cattle, sheep and other animals, soil contamination is unlikely to result in significant exposure to birds. However, the hazard to birds which associate with cattle is unknown as poisonings have occurred in this manner with another organophosphate insecticide. The establishment of a watching brief would be appropriate in this case. The irrigation of land with wool scouring effluent containing residues is not expected to be a hazard to birds.

No chronic hazard to earthworms is expected from any of the registered products containing chlorfenvinphos. Of all the products and all the beneficial arthropods, only Birlane 500 Insecticide poses an unacceptable hazard to bees; its application to any plants in flower is prohibited on the label which is expected to reduce the hazard to an acceptable level. The hazard to dung beetles is expected to be low given the EEC in cattle faeces relative to the toxicity to related beetles. Soil microorganisms may be adversely affected by dripping solution from treated sheep but this will be mostly limited to fenced holding yards and expected to be transitory as residue concentrations decline due to biodegradation.

7.3.2 Hazard to Aquatic Organisms

The direct overspray of Birlane 500 Insecticide of a 15 cm deep body of water at the maximum rate in Tasmania, and also at the lower maximum rates in other States, would result in an unacceptable hazard to fish, aquatic invertebrates and plants. As ground spraying is the more likely application method and aerial application is prohibited in Tasmania, exposure by spray drift or run-off is more likely. In the worst case of 10% drift, fish and invertebrates are still at risk. In the more realistic case of 1% drift at 5 m suggested by the literature, a 62 m buffer would be sufficient to reduce the drift and the EEC sufficiently to protect daphnids. As it is not expected that these restrictive conditions are likely to be met in many of the pasture, lucerne and potato growing areas where Birlane 500 Insecticide is used, this clearly indicates a potentially unacceptable hazard to aquatic invertebrates that may be associated with spray

drift from ground based equipment.

Computer modelling of aerial spraying with coarse droplets at 385 g a.i./ha (aerial application is prohibited in Tasmania) predicts that a buffer zone of 281 m is required to be protective of daphnids in a water body 17 m deep. To protect fish would require a 106 m buffer in 15 cm deep water. Even at the lower application rate of 275 g a.i./ha, a buffer of 285 m is required for daphnids in a 12 m deep water body, and 82 m buffer for fish in 15 cm deep water. These conditions are clearly unlikely to be met which indicates the unacceptable hazard. Therefore it is recommended that aerial application should be prohibited in all States.

If 0.6% of the amount applied reached water as run-off (as reported in field studies), the hazard would be unacceptable only for invertebrates. Given half-lives of chlorfenvinphos in natural water studies of 7-70 d, the estimated initial concentration would take 53-532 d to decline to a non-hazardous level, indicating the hazard would persist. Further, the hazard to benthic organisms from chlorfenvinphos partitioned to sediment is unknown as no toxicity studies were submitted on this subject.

Given the potential hazard to aquatic invertebrates from spray drift and run-off, further information is needed before the continuation of this high rate use pattern could be supported. This information should be in the form of monitoring of chlorfenvinphos residues in receiving waters, particularly shallow ponds, and/or sediments caused by drift and/or run-off to surface waters from pastures, and monitoring of concentrations in receiving waters, particularly shallow ponds, and/or sediments.

Effluent from wool scouring containing chlorfenvinphos residues would be further treated at sewage treatment plants before discharge to the environment. In the worst case of the sewage outfall at Geelong, the predicted hazard to invertebrates is unacceptable and these organisms near the outfall may be adversely affected. However, after accounting for the dilution effect in the ocean of at least 20:1 within 50 m of the outfall, the hazard is expected to be acceptably low. When effluent containing residues is used for irrigation, the weekly equivalent application rate is low enough to be an insignificant hazard considering that chlorfenvinphos is non-persistent and effluent is retained in settling ponds before irrigation allowing dissipation. The EECs for chlorfenvinphos in UK rivers are below both the average annual Environment Quality Standard and the short term Maximum Allowable Concentration, thus indicating an acceptable hazard. However, it is recommended that the environmental impact be re-examined should the market share for chlorfenvinphos increase as the hazard could rise significantly.

7.3.3 Terrestrial Plants

Although no studies were submitted on the toxicity of chlorfenvinphos to terrestrial plants, Environment Australia expects that the hazard to terrestrial plants from the registered products is insignificant as they are used to protect plants from insect attack, chlorfenvinphos is a neurotoxin and there is an acceptable hazard to the most sensitive aquatic plant (duckweed).

7.4 Conclusions

The greatest hazard from the use of chlorfenvinphos is to aquatic invertebrates (due to their

high sensitivity) from the spraying of Birlane 500 Insecticide in pasture, lucerne (at the maximum application rates of 500 g a.i./ha in Tasmania, 385 g a.i./ha in Victoria and South Australia and 275 g a.i./ha Queensland) and potatoes (at 275 g a.i./ha). Even at the lower exposure rates from spray drift and run-off, the hazard is still unacceptable and may require from about eight weeks to 1.5 years to dissipate to an acceptable concentration in natural waters, depending on temperature. The hazard to benthic organisms is unknown as no toxicity studies were submitted on this subject. Monitoring data on chlorfenvinphos residues in drift and/or run-off waters from treated areas, and concentrations in receiving waters and/or sediments are required before these use patterns can continue.

Aquatic invertebrates within 50 m of the ocean outfalls of sewage plants treating effluent from wool scours containing chlorfenvinphos residues may be adversely affected. However, after accounting for the dilution effect in the ocean of at least 20:1 within 50 m of the outfall, the hazard is expected to be acceptably low. The use of wool scouring effluent for irrigation is considered a low hazard given that the equivalent weekly application rate is low, chlorfenvinphos is relatively non-persistent and effluent is retained in settling ponds before irrigation allowing dissipation. As well, the EECs in the UK riverine environment are below the annual average Environmental Quality Standard of 10 ng a.i./L and the short-term Maximum Allowable Concentration of 100 ng a.i./L for organophosphate insecticides; this indicates an acceptable hazard.

There is also a hazard to honey bees, however, the label of Birlane 500 Insecticide prohibits spraying on any plants in flower which is expected to reduce the hazard to an acceptable level.

Soil microorganisms may be adversely affected by dripping solution from treated sheep but this will be mostly limited to fenced holding yards and is expected to be transitory as residue concentrations decline due to biodegradation.

The hazard to terrestrial plants from the registered products is insignificant as they are used to protect plants from insect attack, chlorfenvinphos is a neurotoxin and there is an acceptable hazard to the most sensitive aquatic plant (duckweed).

To alert users of the toxicity to aquatic organisms, reduce the potential for offsite movement of chlorfenvinphos to non-target water bodies and reduce the potential adverse effect any spray drift or run-off may have to aquatic invertebrate communities, the following recommendations are made.

- The use of Birlane 500 Insecticide in pasture, lucerne and potatoes presents an unacceptable hazard to aquatic invertebrates, which may be adversely affected by direct overspray, spray drift and/or run-off, and an unknown hazard to benthic organisms for which no toxicity data were submitted. Monitoring data on chlorfenvinphos residues in drift and/or run-off waters from treated areas, and concentrations in receiving waters and/or sediments are required before these use patterns can continue. Until these data indicate an acceptable hazard, aerial application should be prohibited in all States. Application by ground spray only once per year is recommended.

- There is concern over the continued registration of *Birlane 500 Insecticide* in pastures without further information. The hazard to birds from the use of *Birlane 500 Insecticide* in pastures is potentially unacceptable and the continued registration cannot be supported without further information, such as results of monitoring of birds feeding in or visiting

sprayed pastures.

- Similarly, the hazard to birds from chlorfenvinphos use on cattle is unknown as poisonings have occurred in this manner with another organophosphate insecticide; the establishment of a watching brief would be appropriate in this case.

- There is a potential hazard to aquatic organisms associated with high residues in wool and therefore it is recommended that the environmental impact be re-examined should the market share for chlorfenvinphos increase.

- All other registered use patterns present a low hazard to the environment and can be supported based on this initial review.

DETAILS OF THE REGULATORY APPROACH CAN BE FOUND IN SECTION 10

8. RESPONSE TO THE PUBLIC RELEASE OF THE DRAFT REPORT

In September 1999, the draft chlorfenvinphos ECRP review report was released for public comment. Prior to its release consultation with stakeholders in Commonwealth and State authorities and industry was undertaken. The release of this report was widely publicised and notices were sent to all who had expressed interest in or who had participated in the review thus far. The report was available to all parties either via the NRA Website or in hard copy format available from the NRA on request. The public comment phase lasted two months during which comments and submissions from the public were obtained on the proposed regulatory approach for this chemical.

The response from the public on this report was minimal. Comment on the proposed regulatory approach was received from a number of State Departments particularly relating to the applicability of the proposed recommendations for the use patterns in their State. This chapter describes the main issues raised in response to the release of the draft review report.

Key stakeholders were requested to provide a commitment to undertake the necessary studies required for the NRA to be satisfied that the continued use of chlorfenvinphos does not pose any risk to the environment, worker safety, public health or trade.

General comments

Water contamination

A submission was received from Sydney Water regarding the detection of chlorfenvinphos in the sewer system. Sydney Water has been conducting a toxicity assessment program at sewage treatment plants (STPs) discharging into the Hawkesbury-Nepean River since April 1998. The results of the program have shown chlorfenvinphos to be consistently causing toxicity at only one site – St Marys STP. Due to the primarily urban characteristics of that sewerage system it was unusual to find chlorfenvinphos in sewage effluent as it is not registered for use on domestic animals. A sewer survey study was recently completed to locate the source of chlorfenvinphos. The source of the discharge was subsequently identified as a pet grooming establishment that had been using a jetting fluid for many years to control flea outbreaks on large dogs.

The dog groomer was informed that the way in which they had been using chlorfenvinphos was illegal. Not only was the use illegal but the way in which the chemical had been disposed of was also illegal.

Sydney Water is conducting a comprehensive education program aimed to increase the awareness of home owners regarding the disposal of used household chemicals.

The NRA noted these concerns however consider that the action taken by Sydney Water in this case was appropriate. A watching brief will be maintained and the NRA will be informed if similar incidents occur in the future.

Beef residues

In early November 1999, after the public submissions to the review had closed, import testing by the US Food Safety Inspection Service (FSIS) detected chlorfenvinphos in Australian beef at a level of 0.26 mg/kg. The US does not have an import tolerance for chlorfenvinphos and the level detected was above the Australian MRL 0.2 mg/kg.

Ten years of National Residue Survey (NRS) data, in which no detections for chlorfevninphos were reported, was used to demonstrate that this was an isolated incident linked to the inappropriate use of the chemical by a single producer.

The FSIS lifted test and hold restrictions on produce derived from the implicated establishment following negative test results from additional samples. Korea was the only other country to react adversely to the advice provided in relation to the US residue finding.

Updating of product labels

It was highlighted by a number of respondents that many of the chlorfenvinphos product labels do not comply with the current NRA labelling requirements for agricultural and veterinary chemicals.

As part of the implementation of review recommendations, all product labels will need to be updated to incorporate the recommended label statements discussed in Section 10. At this time the NRA will require labels to also incorporate all of the current label requirements specified in the Code of Practice for Labelling Veterinary/Agricultural products.

Training/record keeping

As chlorfenvinphos is a schedule 7 product, one respondent suggested that chlorfenvinphos be restricted so that only those who have at a minimum, successfully completed a Farm Chemical User Training Program Course can use the chemical. In addition it was suggested that it be made mandatory that for the agricultural product, users maintain spray records.

The following statement was suggested to appear on the labels of chlorfenvinphos products: "NRA recommends that a person using, keeping or disposing of this product should have successfully completed an appropriate course of training such as the Farm Chemicals Users Course or similar course qualification".

The NRA acknowledges these concerns however unless chlorfenvinphos is declared a restricted chemical product, this requirement cannot be enforced. The NRA do not consider it appropriate at this time to proceed down the path of making chlorfenvinphos a restricted chemical. However a watching brief should be maintained on this issue and should the need arise, the above actions may be taken.

Cattle uses

A respondent from the Department of Primary Industries (Qld) noted the implications that the withdrawal of chlorfenvinphos would have to the Queensland cattle industry.

Currently as part of the tick control program there are only 3 dip sites in the whole of Queensland that are charged with chlorfenvinphos. Changing the chemical in these dips

would be no problem. However it was also noted that it would be difficult to have the necessary worker exposure data generated in Queensland as *'Barricade S Cattle Dip and Spray'* is no longer officially used for spraying of stock. Obtaining the required OH&S data when this product is not used would be very difficult.

The restriction of this product to not allow use on lactating animals would have a big impact on the Queensland dairy industry. Currently chlorfenvinphos is used in the control of ticks when there is the emergence of resistance amongst ticks to amitraz. Therefore it is essential that this chemical be maintained for this use.

Sheep uses

It was noted that in general the withdrawal of chlorfenvinphos for use on sheep would have very little impact. There is a trend in the industry towards the use of insect growth regulators rather than the chlorfenvinphos/organophosphate type compounds. However chlorfenvinphos and other organophosphates, although they provide a relatively short period of protection, they are very effective when sheep blowfly numbers are high. Chlorfenvinphos and another organophosphate propetamphos, account for less than 10% of all OP usage in sheep.

Agricultural use

Chlorfenvinphos is used as a mushroom casing layer treatment, and is incorporated into casing during the preparation of the casing material. The draft recommendations noted that there was insufficient information to support the use of chlorfenvinphos in mushrooms from a residue point of view.

In response, data was submitted on behalf of the mushroom industry to support the MRL for mushrooms. The submitted data was evaluated from a residue perspective. The resulting conclusion was that the use of chlorfenvinphos in mushrooms was accepted however to ensure no residues would be found in the harvested product it was recommended that the MRL be increased from 0.05 mg/kg to 0.2 mg/kg combined with a 21 day withholding period.

No other comments were received.

DETAILS OF THE REGULATORY APPROACH CAN BE FOUND IN SECTION 10

9. THE EXPERT PANEL REPORT TO THE NRA (June 2000)

In July 1999, the UK Institute of Occupational Medicine (IOM) released a report titled *Epidemiological study of the relationship between exposure to organophosphate pesticides and indices of chronic peripheral neuropathy, and neuropsycological abnormalities in sheep farmers and dippers*.

The NRA established an independent Expert Panel to review the findings of the IOM report, assess its implications for Australia, and develop recommendations to the NRA in light of this report and other recent reports. This Panel reviewed the UK IOM report and other relevant literature published since 1995. During this time the ECRP review of chlorfenvinphos was put on hold pending the findings from this evaluation.

The Expert Panel Report was presented to the NRA in February 2000 and released for public comment after consideration by the Board at its meeting in March 2000 (a copy of this report is available from the NRA on request or can be accessed electronically through the NRA website at http://www.nra.gov.au/nra).

The NRA Expert Panel considered that the main findings from of the IOM Report were that:

- The main source of exposure to organophosphate (OP) sheep dip chemicals is associated with handling the concentrate (a significant difference in extent of worker exposure was found between exposure to concentrate and diluted solution). As such, all practical measures should be taken to minimise worker exposure to the concentrate.

- A definitive link between OP exposure and chronic health effects could not be established.

In addition it was noted that diluted products pose lower risk to workers than the concentrate and when used according to label directions and good hygiene then existing controls should minimise exposure.

The NRA Expert Panel considered it prudent that the NRA should continue to take measures to minimise user exposure to organophosphates in sheep dip concentrates and thus recommendations to this effect were made to the NRA.

The NRA endorsed the findings of the Expert Panel and as a consequence, the NRA has decided to implement relevant changes to components of the original draft occupational health and safety recommendations for chlorfenvinphos. These are discussed below.

Container design

The Predictive Operator Exposure Model (POEM) estimates undertaken in the initial Occupational Health and Safety (OHS) assessment for mixing and loading of the concentrate were carried out on both non-specific and 'wide neck' containers. Predictive modelling showed that the margin of exposure could be substantially increased and the exposure risk correspondingly reduced by the use of wide-necked containers. However no specific recommendation had been made in the draft report regarding the design of containers.

In addition the Expert Panel highlighted that worker exposure to the concentrate could be significantly reduced if modifications to the packaging and/or delivery systems for products were made.

When a wide neck container scenario was used in the assessment for mixing and loading for plunge dipping and automatic spray race application of chlorfenvinphos, as per instructions on the product labels of *Coopers Blockade S Cattle Dip and Spray (46815), Barricade S Cattle dip and Spray (45211) and Supona Buffalo Fly Insecticide (45594),* the margins of exposure were substantially increased with the risk to workers considered acceptable.

As such the packaging of these products are to be amended to 'wide neck' (see Section 10 Recommendations for further detail).

A 2.5g/L ready to use formulation is available for treatment of flystrike and for dressing of wounds. During the public comment phase for the Expert Panel Report it was highlighted that often products intended for this use are applied to the affected area and then massaged in with the hands. Although this product is a dilute preparation there is still the potential for workers to be exposed if they are applied in this manner. As such it is recommended that the container for the product *Defiance S Insecticidal flystrike, Mules and Wound Dressing (45736)* include a brush or another appropriate delivery system for application of this product (see section 10 recommendations for further detail).

Concentrate vs ready-to-use products

Another area of concern highlighted by the Expert Panel was the frequency of exposure to the concentrate. Although the IOM study was not conclusive it did show that exposure to concentrated forms of organophosphates above a certain frequency and on a repeated basis, over even a relatively short time scale may be associated with increased long-term health effects.

The study found that the most important source of exposure to OP's was contact with concentrate, which occurred almost always on the hands and usually as a result of handling the concentrate container. Levels of urinary metabolites were found to increase with the frequency of handling the concentrate.

There are two chlorfenvinphos products to which the above comments are relevant, *WSD Jetting Fluid (39576)* and *Coopers Suprex 100 Jetting Fluid (33428)*. These both contain chlorfenvinphos at 1kg active ingredient per litre. The products are then diluted at a rate of 10mL/12L for application to the animal as a flystrike treatment, a dilution rate of 5mL/10L for lamb marking and 100mL/200L for jetting. The availability of such a highly concentrated Schedule 7 product poses a significantly greater risk to the worker than does a ready-to-use product. In addition, the small quantities of concentrate needed at one time, often on a regular basis may lead to significant exposure for the worker to these particularly concentrated products.

In line with the recommendations from the Expert Panel that the primary source of exposure is that to the concentrate, the NRA has concluded that these concentrated products should not be available for use when more dilute products as well as ready to use formulations are available (see Section 10 Recommendations for further detail).

Therefore the recommendation is made to cancel the registration of these products.

Worker exposure during chlorfenvinphos application (plunge dipping and automatic spray race application)

The initial OHS assessment completed in September 1999 noted that the application of chlorfenvinphos through plunge dipping and automatic spray races was unable to be quantified either through predictive modelling or qualitative assessment and thus not supported.

The occupational health and safety assessment found that plunge dipping has the potential to result in splashing during the actual dipping operation. Although during plunge dipping splashing is not uncommon, there is no need for close contact between the applicators and the animals in comparison to hand held application methods. Many dips are also mechanically mixed and not expected to result in worker exposure during mixing of the dip. In addition the concentration of the active in the dip solution for chlorfenvinphos products is significantly less than that in the formulated product (138 g/L then diluted at a rate of 1:250 for charging and 1:185 for topping up).

It was noted in the OHS draft assessment that exposure from automatic spray equipment is less than that for hand held equipment. As the spray is directed downward there is little opportunity for the applicator to inhale the spray mist and thus inhalational exposure is expected to be minimal. While automatic spray races do generate a certain amount of spray mist, the operator is usually not in proximity to the jets and therefore at lower risk of exposure.

The IOM study found that the most significant source of exposure to dip wash was splashing. The point where exposure from splashing occurred at the greatest level was as sheep entered the dip and were submerged in the dip wash. Proximity of workers to this area and design of dips are important factors in determining the level of exposure. This study only addressed use in sheep and since sheep are more reluctant to enter water than cattle, they often require manual pushing into the dip. This would be a worst case scenario as opposed to dipping of cattle.

Taking into consideration the UK IOM report findings and the Expert Panel deliberations it is again highlighted that the greatest exposure during dipping operations is the handling of the concentrate in comparison to the dilute preparation. Although splashing during application is not a ‘nil risk’ situation it is expected that adherence to label PPE and hygiene information as well as additional occupational health and safety warning statements proposed for product labels, the NRA consider that a case exists for the retention of the use of chlorfenvinphos via automatic spray race and plunge dipping application methods without the need for additional worker exposure data.

Taking into consideration all of the above, some of the draft recommendations have been revised. In addition label warning statements have been recommended in order to reduce the risk associated with the remaining uses. Further detail on these can be found in Section 10.

10. REGULATORY APPROACH FOR CHLORFENVINPHOS

10.1 Introduction

As stated earlier, this review covered all aspects related to the registration and approvals of chlorfenvinphos. Assessments conducted as part of the review process considered the impact that chlorfenvinphos would have on public health, occupational health and safety (OHS), residues, trade and the environment. On the basis of the available data and theoretical modelling the OHS and environmental assessments in particular, pointed to significant concerns relating to the current chlorfenvinphos use patterns. The draft report also highlighted that for some use patterns there were insufficient Australian data on which to base regulatory decisions with any reasonable degree of confidence.

The review of chlorfenvinphos was released for public comment in September 1999 but was put on hold in November 1999 while the NRA Expert Panel on Organophosphate sheep dips had undertaken their evaluation. The implications of the UK IOM report on organophosphate use in Australia were to be investigated and recommendations made to the NRA.

The NRA has considered all public comments obtained on the draft report (chapter 8) and adopted recommendations made in the NRA's Expert Panel report on worker exposure to OP sheep dips (as discussed in chapter 9). Commitments to generate the necessary data have also been taken into consideration in development of the following recommendations.

10.2 Recommendations

Recommendation 1: Acceptable daily intake

It is recommended that the ADI be lowered to 0.0005 mg/kg bw/day from the current ADI of 0.002 mg/kg/day.

Recommendation 2: First Aid and safety directions

No changes to the current first aid or safety directions are recommended.

Recommendation 3: Label warnings for environmental protection

To alert users of the toxicity to aquatic organisms, under 'Protection of Wildlife, Fish, Crustaceans and the Environment' the following statement should be added to all product labels:

DO NOT use this product in a manner which causes the product or used container to enter streams, rivers or waterways

Recommendation 4: Label warnings for occupational health and safety

The following occupational health and safety warning about minimising exposure to the concentrate is to be added to all labels.

All efforts should be made to minimise your exposure to chlorfenvinphos, particularly the concentrate

Recommendation 5: Label statements associated with PPE

Concern over the practicality of and compliance with label PPE especially during periods of hot weather have been highlighted in the review and reinforced in the public comment phase of the Expert Panel Report. As such labels are to include the following restraint statement:

DO NOT use this product if it is too hot to wear the recommended PPE.

Recommendation 6: Container design

Improvements in container design to reduce exposure during the mixing/loading of organophosphate chemicals are recommended.

Wide neck containers or other containers demonstrated to decrease user exposure to the concentrate are to be adopted for all chlorfenvinphos liquid formulations.*

** a wide neck container is one where neck diameter is >45mm*

Implementation date: 31 December 2002

For the product Defiance S Insecticidal flystrike, Mules and Wound Dressing (45736) the following recommendation applies:

Modify ready to use flystrike products to include a delivery nozzle, brush or equivalent to distribute the product.

Implementation date: 31 December 2002

Recommendation 7: Deletion of certain use patterns

Currently the directions on the products Barricade S Cattle Dip and Spray (45211) and Coopers Blockade S Cattle Dip and Spray (46815) refer to hand spraying and non-recirculating spray races. The only hand spraying application permitted in the interim period is that for cattle (as data is being generated for this use).

As such the label direction on these products for hand spraying is to be reinforced to be for cattle only as per the following wording.

Hand sprays and non-recirculating spray races CATTLE ONLY

Recommendation 8: Label statements associated with residues and maximum residue limits

- For Barricade S Cattle Dip and Spray (45211) and Coopers Blockade S Cattle Dip Spray (46815) add:

  DO NOT use on lactating cows or within 42 days of calving, where milk or milk products may be used for human consumption.

  DO NOT use on female sheep or goats that are producing or may in the future produce milk for human consumption.

- In addition for Coopers Blockade S Cattle Dip and Spray (46815*)* add:

  DO NOT mix the dipping solution by using cattle as stirrers

- For Supona Buffalo Fly Insecticide (45594) the following withholding period statement is to be added:

  Milk withholding period: NIL

Recommendation 9: Consultation with Meat and Livestock Association (MLA)

All registrants must consult with the MLA concerning trade issues regarding the establishment of appropriate export slaughter intervals (ESI's).

(This is an NRA requirement for all veterinary products intended for use on animals intended for export).

Recommendation 10: Maximum Residue Limits

Residue definition

- The residue definition for chlorfenvinphos remains unchanged as *'chlorfenvinphos'*.

Veterinary purposes

- The following MRLs are to be maintained:

Commodity	MRL
MO 0812 Cattle, Edible offal of	T*0.2 mg/kg
MM 0812 Cattle meat [in the fat]	T 0.2 mg/kg
MO 0814 Goat, Edible offal of	T*0.2 mg/kg
MM 0814 Goat meat [in the fat]	T0.2 mg/kg
MO 0822 Sheep, Edible offal of	T*0.2 mg/kg
MM 0822 Sheep meat [in the fat]	T0.2 mg/kg
Deer Meat [in the fat]	T0.2 mg/kg

Note: Retention of temporary MRLs will depend on supply of relevant and appropriate storage stability data.

- The following MRL is to be deleted:

Milks [in the fat] 0.2 mg/kg

And replaced with:

Cattle milk [in the fat] T0.2 mg/kg

Agricultural purposes

All MRLs in the MRL Standard that relate to agricultural applications of chlorfenvinphos are to be deleted as the agricultural use will not continue (see recommendation 12 below). These will be deleted effective **30th December 2002**.

Commodity	MRL (mg/kg)
VB 0400 Broccoli	0.05
VB 0402 Brussel sprouts	0.05
VB 0041 Cabbages, head	0.05
VR 0577 Carrot	0.4
VB 0404 Cauliflower	0.1
VS 0624 Celery	0.4
SO 0691 Cotton seed	0.05
VO 0440 Egg Plant [aubergine]	0.05
VR 0583 Horseradish	0.1
VA 0384 Leek	0.05
GC 0645 Maize	0.05
VO 0450 Mushrooms	0.05
VA 0385 Onion, bulb	0.05
SO 0697 Peanut	0.05
VR 0589 Potato	0.05
VR 0494 Radish	0.1
GC 0649 Rice	0.05
VR 0497 Swede	0.05
VR 0508 Sweet potato	0.05

Commodity	MRL (mg/kg)
VO 0448 Tomato	0.1
VR 0506 Turnip, garden	0.05
GC 0654 Wheat	0.05

Recommendation 11: Storage stability data

The residue assessment highlighted the need for the following:

Storage stability data for residues in animal commodities

(A commitment has been given to generate this data and should be provided to the NRA by 31 December 2003).

Recommendation 12: Bird poisoning incidents

The hazard to birds from chlorfenvinphos use on cattle is unknown as poisonings have occurred in this manner with another organophosphate insecticide. A watching brief should be maintained and any incidents reported to the NRA.

Recommendation 13: Registration – Birlane 500 Insecticide (47478)

The registrant for the agricultural product *Birlane 500 Insecticide (47478)* was not willing to undertake any of the necessary studies (environmental monitoring and OHS) in order to maintain the registration of this product.

As such the registration of Birlane 500 Insecticide (47478) will be cancelled effective **11th December 2000.** The phase out of this product will be in accordance with the timeframes below:

Sale at retail level: 31st December 2001
Cancellation of MRLs and use: 31st December 2002

Recommendation 14: Registration – Jetting Fluids (1000g/L)

The continued registration of the products and *Coopers Suprex 100 Jetting Fluid (33428)* containing 1000 g ai/kg, are not supported on occupational health and safety grounds.

As such the registration of these two products will be cancelled on **11th December 2000**. The phase out of these products will be in accordance with the timeframes below:

Sale at retail level: 31st December 2001
Cancellation of product use: 31st December 2002

The product *WSD Jetting Fluid 100 (39576)* was also recommended for cancellation as per recommendation 14. However the registrant of this product requested the NRA to cancel the registration of this product. This was effected 8th November 2000.

Recommendation 15: Occupational Health and Safety data

Taking into consideration the above, the following OHS data is required:

> *Dermal and inhalational exposure data for mixers, loaders and applicators of chlorfenvinphos products using hand-held equipment.*

A commitment has been given to undertake the necessary OHS studies to support the use of chlorfenvinphos when applied by hand-held equipment in cattle. Data should be received within 3 years (December 2003).

ATTACHMENT 1: PRODUCTS AND ACTIVE CONSTITUENTS AFFECTED BY THIS REVIEW

Products

NCRIS	Product Name	Registrant
47478	Birlane 500 Insecticide	Cyanamid Agriculture Pty Ltd
42259	David Grays Aerosol Sheep Dressing	David Gray & Co Pty Ltd
45211	Barricade 'S' Cattle Dip and Spray	Fort Dodge Australia Pty Ltd
45736	Defiance S Insecticidal Flystrike, Mules and Wound Dressing	Fort Dodge Australia Pty Ltd
45594	Supona Buffalo Fly Insecticide	Fort Dodge Australia Pty Ltd
39575	WSD Aerosol Sheep Dressing	Rebop Holdings Pty Ltd T/as Western Stock Distributors
46815	Coopers Blockade 'S' Cattle Dip and Spray	Schering-Plough Animal Health Ltd
33428	Coopers Suprex 100 Jetting Fluid	Schering-Plough Animal Health Ltd
39576	WSD Jetting Fluid 100 Jetting Fluid For Control of Flystrike On Sheep **(registration cancelled 8/11/00)**	Rebop Holdings Pty Ltd T/as Western Stock Distributors

*Note: this list does not include those products which have not been renewed by applicants but which are still permitted to be sold in order to clear remaining stocks

Active Constituents

NCRIS	Active Constituent	Approval Holder
44031	Chlorfenvinphos	Cyanamid Agriculture Pty Ltd
46687	Chlorfenvinphos	Australian Generics Pty Ltd

NRA ORDER FORM

To receive a copy of the full technical report for the NRA's evaluation of chlorfenvinphos, please complete this form and send it, along with payment of $100 to:

Administrative Officer
Chemical Review Section
National Registration Authority
PO Box E240
Kingston ACT 2604

Alternatively, fax this form, along with your credit card details, to Administrative Officer on (02) 6272 3551.

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