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The NRA Review of

CHLORPYRIFOS

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FOREWORD

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

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

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

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

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

This report covers the review of chlorpyrifos 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 chlorpyrifos, 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.affa.gov.au/nra.html* or obtained by completing the order form in the back of this book.

Other publications explaining the NRA's requirements for registration can also be purchased or obtained by contacting the NRA. Among these are: *Ag Requirements Series;* and the *Vet Requirements Series.*

ABBREVIATIONS AND ACRONYMS

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

EXECUTIVE SUMMARY

Introduction

The NRA released the draft chlorpyrifos review report for public comment in January 2000. The draft review report was placed on the NRA Internet Website and printed copies were available on request. Consistent with the established practice, the draft review report emphasised the areas of concerns and data gaps identified from the assessments conducted during the review of chlorpyrifos.

The draft review attracted wide-ranging comment from the public. All responses received from the public have been considered by the NRA. A summary describing the main issues raised in the public submissions and the NRA response to those issues is at Attachment 2.

As foreshadowed in the draft report the NRA now proposes to implement a series of interim regulatory measures to mitigate potential risks to the environment and public health and to fill the data gaps that have been identified.

Certain interim review recommendations require the development of residue data. Where appropriate this data will be eligible for data protection in accordance with part 3 of the Agvet Code. Those conducting new studies are required to provide appropriate protocols and study designs to the NRA within specific time limits for approval prior to commencing studies.

The following summaries of assessments are intended to provide the reader with a brief background to the review findings. As the assessment conclusions have remained largely unchanged from those in the draft report, the summaries are repeated from the draft report with minimal amendment where necessary.

Uses of chlorpyrifos

Uses of chlorpyrifos in a wide range of crop protection and pest control applications are highlighted in the efficacy assessment. These uses were also acknowledged by State authorities. The most often quoted reason for the importance of chlorpyrifos in crop protection uses is the particular suitability of chlorpyrifos to integrated pest management (IPM) in having a relatively less harmful effect on beneficial insects and its use as a rotational tool in resistance management programs associated with these crops.

Toxicology and Public Health

Chlorpyrifos is a broad-spectrum organophosphate insecticide that has been used in Australia for over 30 years. Like other organophosphorus compounds, chlorpyrifos kills insects by interfering with the activity of an enzyme (acetylcholinesterase) in the nervous system. This interference causes over-stimulation of the nervous system, and results in rapid twitching and paralysis of muscles. If chlorpyrifos is swallowed, applied to the skin or breathed in by mammals, the effects of poisoning are typical of those seen with other organophosphorus insecticide. Such effects include excessive saliva, rapid

breathing, coarse generalised body tremors, secretion of tears, urination, defecation, convulsions, respiratory failure, and death. The severity of signs increases with the amount of exposure but there is an effective antidotal treatment for acute poisoning of chlorpyrifos.

In studies in laboratory animals, chlorpyrifos was rapidly absorbed when swallowed, but did not persist for long periods in the tissues or organs of animals, and passed relatively quickly from the body. Absorption through the skin was relatively poor. Long-term exposure to a low concentration of chlorpyrifos in the diet was without serious consequences in animal studies, although high concentrations resulted in symptoms consistent with those listed above. Chlorpyrifos did not interact with genetic material, and long-term exposure studies in animals provided no evidence that chlorpyrifos can cause cancers in humans. Similarly, exposure to chlorpyrifos had no adverse effects on reproduction. The data on effects of chlorpyrifos in young or developing animals have been reviewed and infants and children are not considered to be at an increased risk from chlorpyrifos products that are used according to label instructions.

In Australia, chlorpyrifos is registered for use in many products including those used in or around the home and garden including termiticide use. These uses may give rise to some exposure of the public, but studies indicate that such exposures do not pose a public health risk. Based on the current uses of chlorpyrifos and with the removal of home garden products containing more than 50g/L chlorpyrifos, and restrictions on indoor spray treatments, it is considered that there should be no adverse effects on public health from the continued use of chlorpyrifos in Australia.

The Australian Market Basket Survey estimates the daily intake of a range of pesticides based on food consumption. In the 1996 survey, the highest exposure to chlorpyrifos in the groups studied, (based on the 95th percentile energy intake,) was in infants aged 9 months, and was estimated to be 3% of the Acceptable Daily Intake (ADI). The lowest dietary exposure was seen in girls aged 12, with an intake estimated to be 1% of the ADI. The ADI is derived from toxicological data obtained from humans, and using a 10-fold safety factor to account for inter-individual variation. This indicates that chlorpyrifos exposure from residues in the Australian diet is very low and does not pose a public health risk.

Occupational Health and Safety Issues

The occupational risk assessment considered the hazard of chlorpyrifos as determined by toxicology testing, and worker exposure associated with its use pattern in Australia.

In order to determine the risks associated with the use of the chemical, margins of exposure (MOE) were calculated by comparing the most appropriate toxicity end point with exposure data obtained from measured worker exposure data or predicted exposure modeling. A qualitative risk assessment was conducted where a suitable model was not 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. However, it should

be noted that the use of exposure data from predictive models using default assumptions, is likely to overestimate risk.

The main adverse health effect of chlorpyrifos exposure is acetylcholinesterase inhibition. This toxicity end point was compared with the standardised exposure estimates or the predicted exposure estimates to give MOE for each Australian use scenario. As a human toxicity end point was used, MOE of approximately 10 or more were considered to be acceptable to account for intra-species variation. It is recognised that in cases where the use of chlorpyrifos is infrequent, the above toxicity end point may be conservative and result in an overestimation of risk.

Chlorpyrifos is a slight skin irritant and slight to moderate eye irritant in experimental animals. These topical effects may be manifested in workers who come in contact with chlorpyrifos products.

The overall risk for occupational groups associated with the use of chlorpyrifos according to label in crop protection and pest control was considered acceptable under conditions specified in the OHS assessment. As a precautionary measure, further improved warnings for re-entry exposure have been specified for inclusion on the product labels.

Environmental Issues

Chlorpyrifos binds strongly to soil or disperses to the atmosphere following application. Limited quantities may enter aquatic environments with spray drift or run-off, and will mainly partition to sediment where slow to moderate degradation occurs. Atmospheric persistence appears limited, while residues in soil are degraded at a moderate rate by chemical and microbial processes.

Consistent with its properties, chlorpyrifos is very much an occasional contaminant of surface waters, but can reach high levels on occasion. The use pattern of main concern with respect to high level surface water contamination is termite protection, which involves generally higher rates of application than agricultural treatments. Chlorpyrifos is also a common contaminant of sewage in the Sydney region, probably reflecting ingress into the sewer system from diffuse sources. Similar contamination is likely in other urban areas.

Levels of contamination arising from agricultural uses of chlorpyrifos are considerably lower, generally (below 1 µg/L) and are detected in Australian surface waters on rare occasions. Chlorpyrifos has been detected in cotton areas of northern- and the irrigation areas in southern NSW. These appear to be isolated occurrences because of the limited aquatic persistence of chlorpyrifos. In some cases, non-agricultural uses such as termite protection of bridge timbers may have contributed.

As a broad spectrum insecticide, chlorpyrifos is very highly toxic to a range of insects, including beneficials. A very high toxicity is also evident to aquatic arthropods, in both laboratory and field situations. Chlorpyrifos is also very highly toxic to fish, but less so than to aquatic invertebrates. Fish kills have been reported where aquatic contamination is high, with termiticide treatments a common cause, particularly if followed by heavy rain. Kills of aquatic fauna in the field appear to be infrequent, notwithstanding very

high laboratory toxicity, because of the limited persistence of chlorpyrifos in the water column.

Chlorpyrifos is toxic to mammals under conditions of acute exposure, and has relatively low mammalian toxicity compared with other organophosphorus insecticides. Birds are more sensitive, as demonstrated by laboratory trials conducted on certain species of birds which are broadly accepted as being representative of the Australian bird life. By comparison, field studies reported on bird toxicity of chlorpyrifos appear inconclusive.

The environmental assessment has identified a need to strengthen labels to include measures to minimise spray drift and environmental contamination. Users, particularly in urban areas, need to be better educated in order to minimise the frequency of surface water contamination and incidents involving aquatic and terrestrial wildlife.

Residue Limits

Crop protection uses of chlorpyrifos were the primary focus of the residues evaluation. Non-food uses, plus a recently-registered direct veterinary treatment, were considered; however no changes to existing animal commodity MRLs resulted from the assessment of these products.

In the majority of crop situations, existing MRLs were established on minimal Australian data or on overseas data in support of an Australian use pattern. Where appropriate residue data was inadequate or missing, it was considered that such use patterns were not supported by contemporary regulatory standards. The existing MRLs for certain commodities (such as asparagus, bananas, brassica vegetables, cereals, citrus fruits, grapes, oilseeds (except cotton), pineapples, pome fruits, stone fruits, sugar cane, tomatoes, tree nuts and vegetables (excluding those mentioned above) will become temporary until appropriate data are submitted and evaluated).

There are several crops and processed crop commodities for which residues data are either deficient or lacking (*eg*. cereal grains, legume animal feeds, pastures, grapes [pomace and marc] and sugar cane). In view of the data deficiencies, the existing animal commodity MRLs will become temporary until data are provided in support of the feed commodities, which have been identified.

Given the wide range of registered uses for vegetables, the current entry for vegetables (MRL of *0.01 mg/kg) is recommended to be deleted and replaced with entries for specific vegetable crops. However, until specific uses on product labels are supported and the appropriate data generated and assessed, the vegetable MRL will remain temporary.

Interim restrictions and data requirements

As outlined above, the assessments conducted as part of the review point to possible public health and environmental concerns associated with the use of chlorpyrifos. The NRA aims to address these concerns using the proposed regulatory actions for chlorpyrifos.

The toxicology assessment indicated that some formulations of chlorpyrifos currently accessible to householders may pose an unacceptable risk to these users. These concerns arise from the fact that the toxicity of these products exceed the relevant guideline levels for pesticides used by householders. Accordingly, a series of restrictions and risk mitigating measures for these products will be implemented as soon as practicable. Several new and improved warnings will be employed on chlorpyrifos product labels to mitigate further potential risks to the public occupational groups and the environment. Further details of these restrictions and label statements are provided in Section 7 of this report.

New or additional data on chemical residues will be obtained from parties who have indicated a commitment to provide such data. These data are required to establish/maintain the appropriate residue standards for some use patterns. Where satisfactory data is not submitted in time or the assessment of data leaves the NRA unsatisfied about the underpinning of a use, such uses might face deletion from the label and/or cancellation of the associated product(s). Any data specified as required in Section 7 should be provided within set time lines.

The review outcomes and use conditions outlined in this report are only of an interim nature while the required studies are conducted and the resulting data evaluated by the NRA. At the end of the period required to generate the necessary data, (expected to be 3 years from the date of gazettal of the interim recommendations or such other period that the NRA deems appropriate) the NRA will re-examine the use of chlorpyrifos, assessing both the data provided to fill the identified gaps, including any new information becoming available and the effectiveness of the proposed conditions of registration and use practices in mitigating risk.

PLEASE NOTE:
Further details of the proposed interim regulatory approach are presented in Section 7 of this report.

1. INTRODUCTION

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

1.1 Regulatory Information

Initiating a review

The NRA has statutory powers to reconsider the approval of active constituents, the registration of chemical products or the approval of labels for containers at any time. The basis for a reconsideration is whether the NRA is satisfied that the requirements prescribed by the regulations 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 its handling or people using anything containing its residues;
- would not be likely to have an effect that is harmful to human beings;
- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

Obligations to submit data and other information on chemicals under review

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

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

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

Outcomes of review

There are three possible outcomes to an ECRP review:

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

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

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 Protected Information

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

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

In general, the NRA designates information as 'protected information' 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 the 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 Chlorpyrifos Review

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

- its very high toxicity to birds;
- water pollution potential and US restrictions imposed to reduce hazards to fish, birds and other wildlife;
- demonstrated potential for adverse effects in users; and
- high potential chronic and moderate potential acute toxicity risk.

Whilst the selection process ranked chlorpyrifos highly due to certain issues, the review was not confined only to those issues, but covered **all aspects** of registration and approval of chlorpyrifos. The review included registrations of products containing chlorpyrifos and associated label and active constituent approvals.

1.4 Consultation Activities

Consistent with the NRA's policy of consulting with all parties interested in the review process, the NRA published notices in the rural and metropolitan press calling for written submissions for the review of the chemical chlorpyrifos. This attracted **32** submissions from members of the public, environmental, government and commodity groups.

The majority of submissions expressed views supporting the continued use of chlorpyrifos. There were a number of submissions, which dealt with the detrimental effects that the use of this chemical has on the environment, public health and occupational safety. Comment supporting the continued availability of chlorpyrifos in the market was primarily from commodity groups who find this chemical a useful tool in the management of insect pests.

2. CHEMISTRY ASSESSMENT

2.1 Overview

Chlorpyrifos is an organophosphorus insecticide used for the control of *Coleoptera*, *Diptera*, *Homoptera* and *Lepidoptera* in soil or on foliage in a wide range of crops. Crops include fruit (pome, stone and citrus fruit, strawberries, figs, and bananas), nuts, vines, vegetables (potatoes, asparagus), grains (rice, cereals, maize, sorghum), cotton, mushrooms and ornamentals. The mode of chlorpyrifos action is non-systemic, and exposure of insects to the active (via contact, ingestion and/or inhalation) affects the nervous system by inhibiting the activity of acetyl cholinesterase.

Chlorpyrifos is included in Schedule 6 of the SUSDP, although formulations containing chlorpyrifos concentrations of 5 % or less are included in Schedule 5.

There are 13 chlorpyrifos TGAC manufacturers currently approved in Australia. The chemistry aspects (synthetic process, quality control procedures, batch analysis results and analytical methods) were evaluated previously and found acceptable.

2.2 Declaration of Composition (DoC) for Chlorpyrifos TGAC

Details of the 13 chlorpyrifos TGAC manufacturers are tabulated below. Also included in the table are details of: (i) the purity of chlorpyrifos; (ii) the specification limit for the toxic micro-contaminant sulfotep (*O,O,O,O*-tetraethyldithiopyrophosphate); and (iii) an indication of whether all impurities which could be present at a concentration of 1 g/kg or more are listed in the DoC.

Licensed Chlorpyrifos Manufacturer	TGAC Approval N	Chlorpyrifos purity	Sulfotep levels	Other Impuriti listed in DoC
Dow Chemical Company, Michigan, USA	P44112	NLT 990 g/kg	NMT 0.3 g/k	✓
	P44113	NLT 990 g/kg	NMT0.3 g/kg	✓
	P44160	NLT 970 g/kg	NMT 2 g/kg	✓
Dow AgroSciences Ltd, Norfolk UK	P44111	NLT 970 g/kg	NMT 2 g/kg	✓
	P49340	NLT 180 g/kg	*	N/A
Luxembourg Industries (Pamol) Ltd, Tel-Aviv, Israel	P46670	NLT 940 g/kg	NMT 2 g/kg	✓
	P48643	NLT 990 g/kg	NMT 0.3 g/k	✓
Lupin Agrochemicals Inc, India	P46796	NLT 940 g/kg	NMT 2 g/kg	✓
Makhteshim Chemical Works Ltd, Israel	P44005	NLT 970 g/kg	**	✓
Ficom Organics Ltd, India	P46642	NLT 940 g/kg	NMT 2 g/kg	✓
Gharda Chemicals Ltd, India	P46888	NLT 980 g/kg	NMT 2 g/kg	✓
Hubei Sanonda Company Ltd, China	P47254	NLT 940 g/kg	Not detectab	✓
Aimco Pesticides Ltd, India	P48459	NLT 940 g/kg	NMT 2 g/kg	✓
3M Canada Inc, Ontario	P49124	NLT 190 g/kg	*	N/A
Excel Industries Ltd, Bombay, India	P47155	NLT 960 g/kg (965 g/kg)	NMT 2 g/kg	✓
Mitsu Industries Ltd, India	P48077	NLT 940 g/kg	NMT 2 g/kg	✓
Cheminova Agro A/S, Denmark	P48521	NLT 960 g/kg	NMT 2 g/kg	✓

NLT: Not Less Than; NMT: Not More Than; N/A: Not Applicable

*The manufacturing concentrate is prepared using chlorpyrifos TGAC that has a maximum sulfotep concentration of 2 g/kg. Hence, the levels of impurities in the manufacturing concentrate will not exceed those present in the technical material.

**Sulfotep was not listed on the DoC. However, the manufacturer tested for the presence of the impurity, and determined that it was not detected.

Chlorpyrifos purity: The FAO Specification Limit for chlorpyrifos technical is 940 g/kg minimum. The NRA approved sources of chlorpyrifos TGAC have minimum chlorpyrifos limits of between 940 g/kg and 990 g/kg.

Impurities: All impurities that could be present in the chlorpyrifos TGAC (at concentrations of 1 g/kg or more) were listed in the DoCs. The specification limit for *O,O,O,O*-tetraethyldithiopyrophosphate (sulfotep) was 2 g/kg maximum, with the highest purity (99%) chlorpyrifos TGACs specifying a sulfotep limit of 0.3 g/kg maximum.

Toxic Impurities: It is considered that other compounds of toxicological significance (N-nitrosamines, halogenated dibenzo-pi-dioxins, or halogenated dibenzofurans and PCBs) are not expected in chlorpyrifos TGAC due to the raw materials and synthetic route used.

Manufacturing concentrates: There are two approved sources of chlorpyrifos manufacturing concentrates, containing a minimum of 180 to 190 g/kg chlorpyrifos. In manufacturing concentrates, the chlorpyrifos is present in a micro-encapsulated form (0.5 µm polyurea coating) that is suspended in an aqueous mixture. The capsule wall protects the chlorpyrifos from any physical damage, enabling the concentrate formula to withstand the effects of strong acids and bases. Since the manufacturing concentrate is prepared using the chlorpyrifos TGAC, any impurities present will not exceed those present in the technical material.

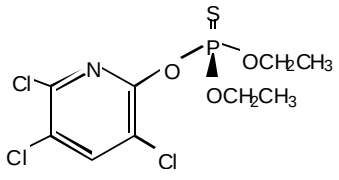
2.3 Active Constituent

2.3.1 Chemical Identity

Chlorpyrifos is a broad-spectrum organophosphorus pesticide, displaying insecticidal activity against a wide range of insect and arthropod pests. Technical chlorpyrifos has a minimum purity of between 940 and 990 g/kg. Manufacturing concentrates contain a minimum of 180 to 190 g/kg chlorpyrifos.

Common name:	Chlorpyrifos	
IUPAC Name:	*O,O*-diethyl	*O*-3,5,6-trichloro-2-pyridyl phosphorothioate
CA Name:	*O,O*-diethyl	*O*-(3,5,6-trichloro-2-pyridinyl) phosphorothioate
CAS Registry No.:	2921-88-2	
Empirical formula:	$C_9H_{11}Cl_3NO_3PS$	
Molecular weight:	350.6	

Structural formula:



2.3.2 Physical and Chemical Properties

Physical and chemical properties of the pure active constituent

Colour	white/colourless crystalline solid
Odour	odourless
Physical state	crystalline solid
Melting point	41 to 43.5 ^{o}C

Octanol/water partition coefficient (Log P)	4.70 (McDonald *et al*., 1985)
Vapour pressure	1.87×10^{-5} mm Hg (2.5 mPa) at 25 ^{o}C (Brust, 1964)
Density/specific gravity	1.38 g/cm^3 at 46 ^{o}C
Dissociation constant	Chlorpyrifos does not contain any readily dissociable groups
Solubility in water	2 mg/L at 23 ^{o}C (Hummel and Crummet, 1964); 1.39 mg/L at 25 ^{o}C (Drummond, 1986)
Solvent solubility	Benzene - 7900 g/kg; acetone – 6500 g/kg; chloroform – 6300 g/kg; carbon disulfide – 5900 g/kg; carbon tetrachloride – 3100 g/kg; chloroform – 6300 g/kg; diethyl ether – 5100 g/kg; ethanol – 630 g/kg; ethyl acetate - >2000 g/kg; isooctane – 790 g/kg; methanol – 450 g/kg; methylene chloride – 4000 g/kg; propylene glycol – 40 g/kg; toluene – 1500 g/kg; trichloroethane – 4000 g/kg; triethylene glycol – 50 g/kg; xylene – 4000 g/kg (Drummond, 1986; Hummel and Crummet, 1964);
Stability	Chlorpyrifos is stable in air (non-volatile) and is not sensitive to UV radiation. It is stable to neutral and weakly acidic solutions, but is hydrolysed by strong bases. Chlorpyrifos is thermally sensitive to temperatures over 50 ^{o}C, and undergoes violent exothermic decomposition above 130 ^{o}C. The half-life of the aqueous methanolic solution at pH 6.0 is 1930 days.
Hydrolysis	The rate of chlorpyrifos hydrolysis increases with both pH and temperature. At 25 ^{o}C, pH 8 $t_{½}$ = 23 days pH 7 $t_{½}$ = 35 days pH 5 $t_{½}$ = 63 days At pH 7.0, 35 ^{o}C $t_{½}$ = 12 days 25 ^{o}C $t_{½}$ = 35 days 15 ^{o}C $t_{½}$ = 100 days
Corrosiveness	corrosive to copper and brass
Hazchem code	2WE
Fire and explosion hazard	Unknown
Extinguishing media	Dry chemical, water spray or regular foam
Hazardous combustion products	Thermal decomposition may release toxic and/or hazardous gases

Physical and chemical properties of the TGAC

Colour	White to light yellowish-brown crystalline solid
Odour	mild mercaptan odour

Other characteristics are as listed above for the pure active constituent.

2.4 Chemistry Aspects

The chemistry aspects (manufacturing process, quality control procedures, batch analysis results, and analytical methods) of chlorpyrifos TGACs were evaluated and found acceptable.

2.5 Formulation of end-use products

Chlorpyrifos is used in a formulated form as a broad spectrum insecticide for the control of *Coleoptera*, *Diptera*, *Homoptera* and *Lepidoptera* in soil or on foliage in a wide range of crops. Crops include fruit (pome, stone and citrus fruit, strawberries, figs, bananas), nuts, vines, vegetables (potatoes, asparagus), grains (rice, cereals, maize, sorghum), cotton, mushrooms and ornamentals. The chlorpyrifos formulations are available as emulsifiable concentrates (EC), baits, granules, ultra-low volumes (ULV), liquid concentrates (LC), wettable powders (WP) and dusts. The mode of chlorpyrifos action is non-systemic, and exposure of insects to the active (via contact, ingestion and/or inhalation) affects the nervous system by inhibiting the activity of acetyl cholinesterase.

2.6 Declaration of Composition

The FAO monograph specifications for the Technical chlorpyrifos are listed below:

Chlorpyrifos content:	not less than 940 g/kg
Impurities:	Water: 1 g/kg maximum
	Acetone insolubles: 5 g/kg maximum

Chlorpyrifos TGACs from 13 approved sources comply with the FAO specifications for the content of the active constituent (the minimum chlorpyrifos limits are between 940 g/kg and 990 g/kg).

2.7 Toxic Impurities

The specification limit for the toxic impurity sulfotep (*O,O,O,O*-tetraethyldithiopyrophoshate) is 2 g/kg maximum. All of the approved chlorpyrifos TGAC sources comply with this sulfotep specification, and the highest purity chlorpyrifos TGACs (99%) specify a sulfotep limit of 0.3 g/kg maximum. The levels of sulfotep in the Manufacturing Concentrates do not exceed those present in the technical material, since the Manufacturing Concentrates are prepared using the chlorpyrifos TGAC.

Other compounds of toxicological significance (N-nitrosamines, halogenated dibenzo-pi-dioxins, or halogenated dibenzofurans and PCBs) are not expected in chlorpyrifos TGAC due to the raw materials and synthetic route used.

2.8 Conclusion

The NRA will introduce a compositional standard for all chlorpyrifos TGACs which is based on the latest FAO specifications for this chemical. In addition, the level of sulfotep should be ≤ 2 g/kg.

3. AGRICULTURAL ASSESSMENT

3.1 Introduction

One aspect of the contemporary assessment standards with which chemicals must comply to maintain registration is that use of products containing the chemical must be effective according to criteria determined by the NRA for the product.

Growers, commodity organisations, State departments of agriculture and the chemical industry have been surveyed for information on the performance of the chemical in the field, addressing aspects such as management strategies, methods of application and chemical failures. In particular, information has been sought on whether the present use of the chemical is the same as when it was first registered and whether the present label directions are still applicable.

3.2 Current Usage

Chlorpyrifos, an organophosphorus insecticide dating from the mid 1960s, has gained wide use in agriculture, at industrial and building sites and in domestic applications.

There are 164 products containing chlorpyrifos registered in Australia (as at 03/08/00).

In agricultural applications, chlorpyrifos is registered to control a broad range of insect pests across many crops including cotton, sugarcane, vegetables, pome and stone fruit, turf and ornamental crops. In the home and commercial sites it is registered for the control of pests such as cockroaches, termites and fleas. It is also registered for use in dog and cat flea collars and shampoos and in flea sprays for dogs.

Chlorpyrifos is used throughout Australia for the control of soil associated insects such as cutworms, crickets, earwigs, wireworms, false wireworms and cockroaches. It is an important weapon against the root feeding larvae of bloodworm on rice and is also used in most states to control red-legged earth mite, lucerne flea, blackheaded cockchafer and pasture webworm, southern armyworm, common armyworm.

Many vegetable crops such as onion, carrot, bean and sweetcorn require protection from cutworms as seedlings or transplants. It is also widely used in early spray programs in brassica because it achieves a broad spectrum of activity against cutworm, aphid, cabbage moth and cabbage white butterfly with a single application.

In Queensland, chlorpyrifos is the only chemical registered for use on citrus, mangoes, avocado and banana to control a variety of pests such as the green tree ant, citrus rust thrips, fruit eating weevil, avocado leaf roller, light brown apple moth, pink wax scale and cluster caterpillars. Chlorpyrifos is the only chemical registered for pineapples against ants, canegrubs and white grubs and along with diazinon against mealybugs and pineapple scale.

In pome and stone fruit orchards, chlorpyrifos is used to control high infestations of light brown apple moth, looper, mealy bug and woolly aphid. It is also used in the control of light brown apple moth in grapes.

Kiwi fruit producers in Victoria stress its effectiveness and importance for control of light brown apple moth and scale in kiwi fruit.

Chlorpyrifos is considered by growers of subtropical fruits to be the best product registered for use as a fruit fly bait spray. Chlorpyrifos is the most important insecticide available to canegrowers. It is the only registered insecticide against symphylans and the most widely used chemical against wireworms, armyworms and locusts.

Chlorpyrifos is applied during the construction of domestic and commercial buildings to prevent termite infestation. It is also used in and around existing buildings to control termites, cockroaches, spiders, ants, beetles and mosquitos.

Chlorpyrifos is used in both residential and commercial environments, especially in turf and landscape gardens, to control problem pests such as lawn beetles, lawn armyworms, ants, earwigs, and African black beetles. For use with residential applications on lawns and in home gardens, some formulations are packed in child-proof containers and are usually about 10% or less as concentrated as formulations typical of agricultural applications.

3.3 Review of Chlorpyrifos in the Context of International Regulatory Activity

As was outlined in the draft report, chlorpyrifos has also been recently reviewed by the US Environmental Protection Agency (US EPA) and by the World Health Organisation (WHO) and Food and Agriculture Organisation (FAO) Joint Meeting on Pesticide Residues (JMPR), and is currently under review by Health authorities in the UK and Canada. Most notably, the US EPA recently released its revised risk assessment for chlorpyrifos. In agreement with registrants, the US EPA is to cancell and phase-out certain uses.

- Residential uses to be cancelled:
    - post-construction termiticide use by December 2001;
    - pre-construction termiticide use by December 2005;
    - home lawn, outdoor uses and certain other indoor uses by December 2001.

- Agricultural uses to be modified:
    - apples: post-bloom use discontinued; tolerance (equivalent to MRL) lowered ;
    - tomatoes: use cancelled from December 2000;
    - grapes: tolerance (equivalent to MRL) lowered.

New health standards established by the US EPA following its review of chlorpyrifos have not caused the Australian health authorities and international regulatory bodies to change their approach to chemicals assessment at this stage. Some differences remain in the public health standards that were established by the US EPA as compared to Australia. While occupational exposure and environmental conclusions also varied to some extent across the two countries, the most notable differences appear to be on the assessment and management of public health risk. For this reason, the following discussion will deal primarily with the public health regulatory aspects.

A number of technical and scientific policy issues were considered during the public health risk assessment and risk management phases of the ECRP review of chlorpyrifos. Some of these were specific to chlorpyrifos, while others were issues that are routinely considered when reviewing agricultural and veterinary chemicals. For chlorpyrifos, the Australian approach to several issues does not necessarily mirror that of the US EPA. The following are amongst the main aspects where differences arose.

- **The use of human data to derive public health standards such as the ADI**

To establish the Acceptable Daily Intake value for chlorpyrifos, the TGA and the JMPR used doses of chlorpyrifos that caused no toxicological effects in humans. In the USA on the other hand, the EPA has used data from animal studies to establish their chronic reference dose (or RfD, which is analogous to an ADI). This means that the US EPA have used an additional 10-fold factor in their RfD calculations, due to the extra uncertainty inherent in extrapolating data from animal species to humans.

- **The use of the most sensitive toxicological endpoint for regulating chlorpyrifos**

The TGA and the US EPA have regulated chlorpyrifos on the basis of its inhibition of plasma cholinesterase activity, which is the most sensitive measure of toxicity for chlorpyrifos and for a number of related organophosphorus compounds. The JMPR derived their ADI based on effects of chlorpyrifos on brain cholinesterase activity in animal studies, and erythrocyte cholinesterase inhibition in human subjects. Both of these measures of toxicity are less sensitive than the inhibition of plasma cholinesterase activity, and hence the JMPR ADI is higher than that recommended by Australian authorities.

- **The sensitivity of children to the toxicological effects of chlorpyrifos**

There was some evidence that neonatal rats were more sensitive to the lethal effects of high doses of chlorpyrifos, but the TGA did not consider that young animals were more sensitive to repeated exposure to lower levels of chlorpyrifos than adult animals. There was no evidence that significant developmental or neurological effects were caused by

chlorpyrifos in young animals at doses below those that inhibited plasma cholinesterase activity. The US EPA has operated under the Food Quality Protection Act (FQPA) since 1996, which requires the use of an extra ten-fold safety factor in setting an intake standard for pesticide residues to allow for the presumed extra sensitivity of children (unless, for a particular chemical, there was unequivocal evidence that this was not the case). For chlorpyrifos, the EPA has decided to impose an extra 10-fold uncertainty factor to satisfy FQPA requirements, and this contributes to the EPA Population Adjusted Dose (PAD) for infants, children and females aged 13-50 years being an extra 10-fold lower than the US RfD (and 100-fold lower then the Australian ADI).

- **The identification of high-risk public uses of chlorpyrifos**

In Australia, the majority of chlorpyrifos usage (greater than 60%) is for agricultural purposes, with most of the remainder used in termite control. A small amount is used by householders in lawn and other home garden applications. Data indicate that exposure to chlorpyrifos in the air is low in homes that have been treated for termites. The ECRP review identified that some concentrated chlorpyrifos products (up to 50% w/v) were available for use by both pest control operators (PCOs) and householders; however the use of these products by householders is considered to pose an unacceptable public health risk, and risk mitigation strategies have been proposed for these products by the NRA to remove the risk of such products to householders. Other chlorpyrifos products available to the public must be formulated to meet NRA Guidelines for the use of chemicals by householders and be packaged in a manner to ensure that they do not present a significant public health risk. The US EPA has also identified residential uses of chlorpyrifos as posing public health risks. As a consequence, registrants in the USA are withdrawing and/or phasing-out residential uses, while most agricultural uses of chlorpyrifos will remain in the USA.

- **The determination of possible exposure to chemicals from food residues**

An estimate of chlorpyrifos intake was derived from the Australian Total Diet Survey (formerly the Australian Market Basket Survey), based on actual food consumption in Australia, and using National Dietary Survey information. The ingestion of chlorpyrifos as food residues is calculated to be very low, and not to pose a public health risk. For example, in the 1996 survey (the most recent), the highest dietary exposure to chlorpyrifos was in infants aged 9 months, and was estimated to be 3% of the Acceptable Daily Intake (ADI). The lowest dietary exposure was in girls aged 12 and was estimated to be 1% of the ADI. Similar findings were reported in the USA, that is, the long-term dietary risk from chlorpyrifos residues in food did not exceed the level of concern for any population groups.

Furthermore, an assessment conducted using the available Australian consumption data for apples indicated that the acute dietary intake of chlorpyrifos in apples was low in relation to the applicable Australian public health standard - the acute reference dose (ARfD) of 0.01 mg/kg bw/day. The intake of chlorpyrifos at 97.5 percentile food intake level expressed as a percentage of the ARfD, was less than half for 2-6 years old children; and less than one-fifth for the general population (7 years and above) and is not considered to pose a public health risk.

- **Regulatory Action from Other Reviews of Chlorpyrifos**

Canada has also recently reviewed chlorpyrifos, and while the outcomes of this review have not yet been announced, it is likely that Canada will adopt similar regulatory restrictions as the USA, due to the relationship between these countries under the North American Free Trade Agreement (NAFTA). Following the review of chlorpyrifos in the United Kingdom (UK), authorities have proposed restrictions that are comparable to what is flowing from the ECRP review. The UK authorities have not proposed restrictions on agricultural uses of chlorpyrifos, but have required further information on pattern of usage and work rates for farmers and contract applicators and a 4-week study in dogs measuring cholinesterase in peripheral tissues, erythrocytes and the brain. The UK authorities have recommended that all amateur home-garden uses be revoked because sufficient data on exposures to users had not been provided.

Some US EPA conclusions differ from those of the WHO/FAO Joint Meeting on Pesticide Residues (JMPR) which reviewed chlorpyrifos in 1999.

3.4 Efficacy

Chlorpyrifos controls insects primarily by contact and also ingestion and vapour action. Chlorpyrifos has generally exhibited short residual activity on plant foliage with a half-life of one to two days, but it is effective for several weeks in turf thatch, in soil and on surfaces not exposed to direct sunlight.

Information contained in the performance questionnaires from user industries indicated that it was still efficacious for the purposes claimed.

Registrants indicated that they did not have any information on any reduction in efficacy and had not received any complaints from users in relation to failure to control nominated pests using this chemical.

One point that was emphasised is that its residual activity in soil made it especially useful for controlling the many soil inhabiting insects for which it is registered.

Another aspect of chlorpyrifos which was frequently stressed in the survey was its importance in integrated pest management (IPM) programs.

3.5 Phytotoxicity and Resistance

Although chlorpyrifos is not phytotoxic to most plant species when used as recommended, certain species have shown signs of phytotoxicity to the chemical.

Phytotoxic reactions in the floriculture industry with varieties of azalea, camellia, ficus, ivy, hibiscus, nephrolephis, poinsettia and rose have been known to occur. Queensland authorities state that high volume sprays of EC formulations are phytotoxic to immature banana fruit.

Although chlorpyrifos has held its efficacy well, isolated cases of resistance have been observed. For instance, some resistance to chlorpyrifos in the banana weevil borer was recently reported in localised areas of Queensland.

3.6 Trade

It is anticipated that trade difficulties could arise in cases where residue violations occur. Because there are some incompatibilities between Australian MRLs and overseas countries' MRLs for chlorpyrifos there is some scope for residue violations to occur even in crops which are produced according to good agricultural practice.

A number of Australia's trading partners accepts Codex MRLs for chlorpyrifos. The Codex MRLs in a number of cases are lower than Australian MRLs (eg 0.3 mg/kg compared to 0.5 mg/kg for citrus fruit). It is therefore possible that, where Codex MRLs have been adopted, Australian produce could contain residues above an importing country's MRL. This is also true for the MRLs that are set by individual countries. The removal of the Codex general fruit and vegetable MRL means that the crop/MRL combination on Australian registered labels based on Codex general fruit or vegetable MRLs will no longer be supported when these general MRLs are removed.

3.7 Residues

In the majority of crop situations, existing chlorpyrifos MRLs were established on minimal Australian data or on overseas data in support of an Australian use pattern. In consideration of current registration standards, such use patterns were not supported by appropriate residue data. The existing MRLs for crops such as asparagus, bananas, brassica vegetables, cereals, citrus fruits, grapes, oilseeds (except cotton), pineapples, pome fruits, stone fruits, sugar cane, tomatoes, tree nuts and vegetables (excluding those mentioned above) will become temporary until appropriate data are submitted for consideration. Of the two use patterns in sugarcane, the soil application of controlled release granular product at planting does not lead to residues above the existing MRL for sugarcane. Residue data is required for foliar applications of chlorpyrifos. Coffee, hops, custard apple and loquats have been identified as commodities for which there is a use pattern, but no corresponding MRL. Residues data must be submitted to allow the uses on these commodities to remain.

Temporary MRLs have been recommended for animal commodities such as meat (mammalian) and edible offal (mammalian). This is an amendment to the existing specific entries for cattle, pigs and sheep, as direct veterinary treatments in cattle are no longer being supported. This is the basis of the discrepant cattle meat and cattle offal MRLs. The consolidated animal commodity MRLs are now representative of exposure from treated feed commodities, not direct veterinary treatments. As further data are requested for certain feed commodities and crops, the MRLs remain temporary until such data have been received and evaluated.

MRLs have also been amended for oilseeds (except cotton) and pome fruits. These changes are based on contemporary information on methodology for oilseeds, and monitoring data for pome fruits where violations of the existing MRLs were reported. Further data to confirm the temporary MRLs are required, as outlined in the draft residues assessment report.

3.7.1 Non food uses

Termite treatment of timber posts in and around cattle yards was raised as a possible residues issue. It has been determined that a greater exposure to cattle would be through feeding of treated commodities and that the existing animal commodity MRLs would adequately cover such a situation.

3.7.2 Recommendations

The following changes to the chlorpyrifos entries in Table 1 of the MRL Standard are recommended:

Codex Commodity classification	MRL
Chlorpyrifos	
DELETE:	
VS0621 Asparagus	0.5
VB0040 Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.5
MO0812 Cattle, Edible offal of	2
MM0812 Cattle meat [in the fat]	2
GC0080 Cereal grains [except sorghum]	0.1
FC0001 Citrus fruits	0.5
DF0167 Dried fruits	2
FB0269 Grapes	1
SO0088 Oilseed	0.01
MO0888 Pig, Edible offal of	0.1
MM0888 Pig meat [in the fat]	0.1
FI0353 Pineapple	0.5
FP0009 Pome fruits	0.2
MO0822 Sheep, Edible offal of	0.1
MM0822 Sheep meat [in the fat]	0.1
GC0651 Sorghum	3
FS0012 Stone fruits	1
GS0659 Sugar cane	0.1
VO0448 Tomato	0.5
TN0085 Tree nuts	0.2
Vegetables [except asparagus; brassica, cassava; celery; potato; tomato, sweet potato]	*0.01
ADD:	
VS0621 Asparagus	T0.5
VB0040 Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	T0.5
GC0080 Cereal grains [except sorghum]	T0.1
FC0001 Citrus fruits	T0.5
DF0167 Dried grapes (currants, raisins, and sultanas)	2

MO0105 Edible offal (mammalian)	T0.1
FB0269 Grapes	T1
MM0095 Meat [mammalian] [in the fat]	T0.5
SO0088 Oilseed (except cottonseed)	T0.05
FI0353 Pineapple	T0.5
FP0009 Pome fruits	T0.5
GC0651 Sorghum	T3
FS0012 Stone fruits	T1
GS0659 Sugar cane	T0.1
VO0448 Tomato	T0.5
TN0085 Tree nuts	T0.2
Vegetables [except asparagus; brassicas; cassava; celery; potato; tomato; sweet potato]	T*0.01

Notes:
The residue definition for all chlorpyrifos MRLs remains unchanged as **"Chlorpyrifos".**

Retention of temporary MRLs will depend on supply of relevant and appropriate, preferably Australian, residue data or argument.

It is recommended that the following MRLs in the NRA's MRL Standard remain unchanged:

Table 1 entries:

Avocado	0.5 mg/kg
Banana	T0.5mg/kg
Cassava	*0.02 mg/kg
Celery	T5 mg/kg
Cottonseed	0.05 mg/kg
Cottonseed oil, crude	0.2 mg/kg
Eggs	T0.01 mg/kg
Ginger, root	*0.01 mg/kg
Kiwi fruit	2 mg/kg
Mango	*0.05 mg/kg
Milks [in the fat]	T0.2 mg/kg
Passionfruit	*0.05 mg/kg
Potato	0.05 mg/kg
Poultry, Edible offal of	T0.1 mg/kg
Poultry meat [in the fat]	T0.1 mg/kg
Strawberry	0.05 mg/kg

Table 4 entries:

Cotton fodder, dry	30 mg/kg
Cotton meal and hulls	0.05 mg/kg

4. TOXICOLOGY ASSESSMENT

The extensive toxicological database for chlorpyrifos consists primarily of toxicity tests conducted using laboratory animals and some experiments using human volunteers, and a number of reports of accidental, occupational or deliberate human exposure. In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared to likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observed-Effect-Level (NOEL) are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

4.1 Metabolism and Toxicokinetics

Chlorpyrifos is moderately fat-soluble, and was readily absorbed by oral and inhalation routes but dermal absorption was relatively low (about 2% in humans). Studies in rats, rabbits, chickens, goats, pigs, cows and humans indicated that chlorpyrifos which entered the general circulation was widely distributed throughout the body but was excreted very rapidly in the urine and faeces. In animals, only low concentrations of residues remained in tissues such as fat, lung, liver and brain several days after administration of chlorpyrifos.

4.2 Acute Studies

There is a substantial database of studies on the acute toxicity of chlorpyrifos. The lowest oral median lethal dose (LD50) value in rats was 96 mg/kg, in mice 102 mg/kg and in rabbits 1580 mg/kg. In the rat the worst dermal LD50 was greater than 2000 mg/kg and the worst 4-hour inhalation median lethal concentration (LC50) was greater than 230 mg/m3. Following chlorpyrifos exposure by all major routes of administration, clinical signs were typical of cholinesterase inhibition and included increased swallowing, excessive saliva, rapid breathing, twitching of the ears, pinpoint pupils, tail lashing, loss of coordination, excitement, twitching and rapid contractions of the neck and jowl muscles, coarse generalised body tremors, secretion of tears, urination, defecation, depression, prostration, epileptoid tremors, convulsions, respiratory failure, and death. In rats, signs of poisoning commenced generally within 0.5 h of treatment and peaked at 6-7 h. In surviving animals, recovery was usually evident within one week of dosing. Young rats were more sensitive to the acute lethal effects of chlorpyrifos than adult rats, but recovered more quickly. Chlorpyrifos was a slight eye and skin irritant in rabbits, and was not sensitising to the skin of guinea pigs.

4.3 Short-Term, Repeat-Dose studies

In a number of two and four-week dietary studies in mice and rats, the spectrum of observations recorded after doses of 80 mg/kg/d or above ranged from death, clinical signs of toxicity and reductions in body weight and food consumption. Doses as low as 3.0 mg/kg/d were associated with cholinesterase (ChE) inhibition and reduced body weight gain. A 3-day gavage study in Rhesus monkeys at 2 mg/kg/d showed significant inhibition of plasma and red blood cell (RBC) cholinesterase. A 4-week oral study in beagle dogs recorded significant inhibition of plasma cholinesterase at 0.5 mg/kg/d and

RBC and brain cholinesterase at 5.0 mg/kg/d, without evident clinical signs. In a 20-day dermal study there were no effects in rats at 5 mg/kg/d, but significant plasma and RBC cholinesterase inhibition was seen at 10 mg/kg/d. Significant plasma and RBC cholinesterase inhibition was also seen in rabbits after 20 daily doses at 5 mg/kg or one dose at 50 mg/kg.

In an inhalational study in which rats were exposed for 6 h/day over one or two weeks there were no effects at 0.71 mg/m3, but plasma cholinesterase activity was inhibited in females at 0.34 mg/m3 in a 5-day study. In other 2-week rat studies, plasma cholinesterase inhibition was observed at 0.072 mg/m3 (no effects at 0.01 mg/m3) and plasma, RBC and brain cholinesterase activity was inhibited at doses of 10 mg/m3 and higher. Cholinesterase activity was generally inhibited in the order plasma > RBC > brain in these studies.

4.4 Sub Chronic studies

A number of 13-week or 26-week dietary studies were conducted in rats and mice. The NOEL for brain cholinesterase inhibition was consistently around 1.0 mg/kg/d, and the NOEL for plasma and RBC cholinesterase inhibition was 0.1 mg/kg/d. In 13-week studies in beagle dogs, plasma cholinesterase was more sensitive (LOEL 0.01-0.03 mg/kg/d) to the effects of chlorpyrifos administration than either RBC (NOEL 0.01-0.03 mg/kg/d) or brain cholinesterase (NOEL 0.2-1.0 mg/kg/d). Inhalational studies over 13 weeks in rats recorded NOELs of 0.14-0.3 mg/m3 for inhibition of any cholinesterase activity but no other adverse effects were observed. Dietary studies (13 weeks) conducted with the major chlorpyrifos metabolite, 3,5,6-trichloro-2-pyridinol (TCP) in rats found little significant toxicity at doses up to 50 mg/kg/d, whereas similar studies in beagle dogs found liver toxicity at doses of 10 mg/kg/d and above.

4.5 Chronic studies

The dietary administration of technical chlorpyrifos to mice for 78 or 105 weeks at doses up to 250 ppm in the feed (about 32 mg/kg/d) did not reduce survival or increase the incidence of cancers. Plasma cholinesterase activity was inhibited at dietary levels of 5 ppm (0.7 mg/kg bw/d) and above, while the NOEL for brain and erythrocyte cholinesterase activities was 5 ppm (0.7 mg/kg/d).

In a poorly-reported study, rats were fed chlorpyrifos at up to 3.0 mg/kg/d in their diet for 2 years. The NOEL for plasma and RBC cholinesterase inhibition was 0.1 mg/kg/d and the NOEL for brain cholinesterase inhibition was 1.0 mg/kg/d based on significant inhibition in both sexes at 3.0 mg/kg/d. Rats were also exposed to chlorpyrifos in the diet at up to 100 ppm (6 mg/kg/d) for two years, with no effect on mortality or neoplastic findings. The NOEL for plasma cholinesterase activity was 0.012 mg/kg/d and the NOEL for inhibition of brain cholinesterase was 0.3 mg/kg/d. When rats were exposed to chlorpyrifos in the diet at up to 10 mg/kg/d for up to 2 years, effects at the high dose were more severe in males than females and included lower body weight gain, depression of plasma, RBC and brain cholinesterase activities, and an increase in the weight of adrenal glands. There was no increase in tumour incidence of any type in any organ or tissue at any of the dose levels tested. The NOEL for this study, based on inhibition of plasma ChE activity in both sexes at 1.0 mg/kg/d, was 0.1 mg/kg/d. The NOEL for erythrocyte ChE was 1.0 mg/kg/d and for brain ChE was 1.0 mg/kg/d.

In a poorly-reported study, beagle dogs were administered chlorpyrifos in the diet at up to 3.0 mg/kg/d for up to 2 years. In both sexes the NOEL for plasma cholinesterase inhibition was 0.01 mg/kg/d, while for RBC cholinesterase inhibition the NOEL was 0.03 mg/kg/d, and for inhibition of brain cholinesterase activity it was 1.0 mg/kg/d. In another study, beagle dogs were fed the chlorpyrifos metabolite TCP (3,5,6-trichloro-2-pyridinol) at doses of up to 48 mg/kg/d for one year. At the high dose, body weights were decreased and some clinical chemistry values indicative of liver toxicity were elevated. Based on the biologically significant increased levels of serum ALP and ALT values at 12 mg/kg/d, the NOEL for dietary intake of TCP in male and female dogs was 3 mg/kg/d.

Female chickens were fed chlorpyrifos in the diet at up to 200 ppm (approximately 20 mg/kg/d) for 52 weeks. Hen mortality was unaffected by treatment, but inhibition of plasma cholinesterase activity was rapid and dose-related, and persisted throughout the study before returning to control levels during the recovery period. Significant plasma cholinesterase activity inhibition was seen all doses (LOEL 2.5 mg/kg/d or 25 ppm).

4.6 Reproduction studies

In a dietary study, rats were fed chlorpyrifos at doses up to 0.3 mg/kg/d for the first generation, and up to 1.0 mg/kg/d for the second and third generations. Clinical signs of toxicity were not seen in any parents or offspring. The fertility, gestation and lactation indices were comparable between groups and generations. There was a reduction in pup viability in each generation at 0.3 and 1.0 mg/kg/d, decreased plasma and RBC cholinesterase activity at 1.0 mg/kg/d in males and females, and decreased RBC cholinesterase activity in 0.3 mg/kg/d in females. The NOEL for this study was 0.1 mg/kg/d. In a supplemental study at doses up to 1.2 mg/kg/d for two generations, no adverse effects were demonstrated at the highest dose.

In a 2-generation dietary study, rats were fed chlorpyrifos at dietary concentrations up to 50 ppm for two generations (up to 8.1 mg/kg/d). Body weights were unaffected by treatment, and the fertility, gestation and lactation indices were comparable between groups and generations. No adverse, treatment-related effects were observed at any dose, up to and including 50 ppm. In another 2-generation rat dietary reproduction study, at doses up to 5.0 mg/kg/d, no significant effects on clinical signs, food intake or body weight were observed. Treatment had no effect upon fertility, length of gestation, gestation survival, time to mating, sex ratio or litter size in either generation. The NOEL for maternal toxicity was based on plasma cholinesterase inhibition seen in adult animals at 0.1 mg/kg/d. The NOEL for RBC cholinesterase inhibition in adults was 0.1 mg/kg/d and for brain cholinesterase inhibition was 1.0 mg/kg/d, with reduced maternal weight gain during lactation seen at this dose also. The NOEL for neonatal effects was 1.0 mg/kg/d based on decreased body weight gain and survival at 5 mg/kg/d and the NOEL for fertility and reproductive effects was 5 mg/kg/d.

4.7 Developmental Studies

A dose-ranging developmental study in mice found severe cholinergic signs and consequent reproductive failure at doses of 30 mg/kg/d and above, but in two developmental studies (doses up to 25 mg/kg/d) no teratogenicity was seen at any dose. Foetal toxicity was seen at 25 mg/kg/d (reduced pup weight, crown-rump length and delayed ossification), and foetal homogenate cholinesterase activity was depressed at 10 mg/kg/d in both studies. The NOEL for foetal toxicity was 1 mg/kg/d. Based on

erythrocyte cholinesterase inhibition and cholinergic signs at 1 mg/kg/d the NOEL for maternal toxicity was 0.1 mg/kg/d.

In a range-finding developmental study in rats, foetal toxicity (increased resorptions) was seen at the high dose of 30 mg/kg/d only, but in a subsequent developmental study in rats at doses up to 15 mg/kg/d no foetal toxicity was observed at any dose. Cholinergic signs and decreased body weight gain were observed in the 15 mg/kg/d group only. No adverse effects were observed on reproductive parameters, and no teratogenicity was observed. The NOEL for maternal toxicity was 0.1 mg/kg/d, based on plasma and RBC cholinesterase inhibition seen in all adult animals at 3.0 mg/kg/d and above.

In another rat developmental study at doses up to 15 mg/kg/d, there was no mortality and clinical signs were confined to the high dose. Plasma cholinesterase activity was inhibited of at all doses compared to controls. The NOEL for frank maternal toxicity was 2.5 mg/kg/d, based on reduced body weights, tremors and transient reductions in food consumption at 15 mg/kg/d. The NOEL for foetal toxicity was 2.5 mg/kg/d, based on a slight increase in post-implantation loss at 15 mg/kg/d, probably associated with maternal toxicity at this dose level. No evidence of major malformations was observed at any dose.

In a developmental study in rabbits at doses up to 140 mg/kg/d, no treatment-related mortality or clinical signs were observed, but inhibition of plasma cholinesterase activity was seen at all doses (1 mg/kg/d and above). The NOEL for frank maternal toxicity was 81 mg/kg/d, based on decreased body weight gain at 140 mg/kg/d. The NOEL for foetal toxicity was 81 mg/kg/d, based on a slight decrease in mean foetal crown-rump length, a decrease in mean foetal weight, and an increased incidence of foetuses with fifth sternebra and/or xiphisternum unossified, at 140 mg/kg/d. No major treatment-related malformations were observed in this study.

Rats were given the chlorpyrifos metabolite TCP at doses up to 150 mg/kg/d in a developmental study, but no clinical signs of toxicity were seen in any group. There was no significant influence of treatment on reproductive parameters nor on foetal observations. Based on decreased body weight gain during treatment, the NOEL for maternal effects was 50 mg/kg/d. The NOEL for foetal toxicity and teratogenic effects was 150 mg/kg/d, the highest dose tested.

Rabbits were given TCP in a developmental study at doses up to 250 mg/kg/d; there was no statistically-significant influence of treatment on reproductive parameters or foetal observations, but an increased incidence of CNS malformations at doses of 100 mg/kg/d and above was noted. There was no strong dose relationship for these findings, which included severe dilation of the cerebral ventricles and hydrocephaly, and the incidence was not statistically significantly different to controls. As these effects were only reported at high doses, and there was no change in the incidence of minor alterations observed externally, viscerally or upon skeletal examination, TCP was not considered to pose a teratogenic risk to humans. Based on decreased body weight gain during treatment, the NOEL for maternal effects was 100 mg/kg/d. The NOEL for foetal toxicity and teratogenic effects was 25 mg/kg/d, based on increased incidence of malformations at 100 mg/kg/d and above.

4.8 Genotoxicity Studies

Chlorpyrifos does not interact with genetic material and has been shown not to cause genetic damage in a variety of genotoxicity tests.

4.9 Neurotoxicity

Several neurotoxicological studies were conducted in hens with chlorpyrifos given in the diet or by single or multiple oral doses. These studies did not reveal any increases in histopathological lesions of the nerve tissues which are characteristic of delayed neuropathy. Doses were up to 5 times the oral LD50 in hens (up to 150 mg/kg) and extensive and aggressive antidote treatment, both prior to and throughout the treatment and recovery periods, was often required for the birds' survival.
Studies were also conducted in rats to evaluate the neurotoxicity of chlopyrifos. No neuropathological lesions of inhibition of neuropathy target esterase (NTE) activity were reported in animals receiving single doses of chlorpyrifos at up to 100 mg/kg. No clear treatment-related effects on cognitive function were observed in rats dosed orally with chlorpyrifos at doses up to 10 mg/kg/d for 4 weeks. In a 13-week neurotoxicity study in rats at doses up to 15 mg/kg/d, no neuropathological findings related to treatment were observed at any dose.

A number of studies were conducted to assess the toxicity of chlorpyrifos to neonatal rats. Results were variable, with brain region weights decreased in one study at 5 and 25 mg/kg/d, but not affected in another study at up to 5 mg/kg/d, even in the presence of cholinesterase activity inhibition. In general, the usefulness of these studies for regulatory purposes has been restricted by the study design and protocols employed. For example, many of these studies have used routes of administration such as subcutaneous injection, and/or at high doses that cause clinical signs and/or extensive inhibition of cholinesterase activity. As such, the relevance of findings in these studies in determining the public health risks associated with exposure to chlorpyrifos from food residues and/or non-agricultural uses is limited. The reliability and validity of the results obtained from such studies is not clear.

In several studies designed to investigate treatment-related effects on brain DNA synthesis, neonatal rats were exposed to chlorpyrifos by intra-cisternal and/or subcutaneous injection. In these studies, the study authors reported inhibition of DNA synthesis and reductions in DNA amounts in brain regions. However, the usefulness of these studies for regulatory purposes was limited by the routes of administration (which are not relevant for assessing public risks for chlorpyrifos uses in agricultural and/or residential uses), study protocol deficiencies (including the lack of information on animal numbers used), and the use of high doses (1 to 2 orders of magnitude higher than the NOELs for inhibition of plasma and/or erythrocyte cholinesterase activity).

When pregnant rats were given chlorpyrifos at doses up to 5 mg/kg/d from days 6-11 or 6-20 of gestation, chlorpyrifos treatment induced toxicity (decreased viability index, relative brain weight and delayed sexual maturity) at the high dose only (in the presence of frank maternotoxicity). Cognitive functions in the pups (learning, memory and habituation) were not affected by treatment. When pregnant rats were injected subcutaneously with a single 200 mg/kg dose of chlorpyrifos on gestation day 12 (GD12) and then sacrificed on either GD16, GD20, or postnatal day 3 (PND3) for measurement of maternal and developmental indicators of toxicity, most treated dams

exhibited no overt signs, and there no treatment-effect on foetal body weights or brain weights. The results of this study suggested that acute chlorpyrifos exposure of dams during gestation produced more extensive neurotoxicological effects in the dam than in the developing foetus.

4.10 Effects in Humans

A number of reports addressed the potential exposure and/or risks associated with the use of chlorpyrifos insecticides in domestic and/or urban settings. These studies contained a range of monitoring data, and estimates of dermal and or inhalational exposure varied widely depending on the methods used for application and sample collection. Similarly, estimates of risk to humans were largely dependent upon the default assumptions and uncertainty factors used in the exposure models.
In a review of chlorpyrifos poisoning data by the US EPA, the main concern was associated with the use of chlorpyrifos liquid formulations used by householders or Pest Control Operators (PCOs) indoors or outdoors, termite treatments, and liquid sprays and dips applied to domestic animals. Most of the more serious poisonings were associated with misuse or inappropriate use (spills, inadvertent contamination) by a PCO. A critique of this review was provided by the sponsor. This critique stated that there were deficiencies in the EPA report which invalidated its use for reaching any conclusions about the safety of chlorpyrifos and concluded that there has been a misinterpretation of Poison Control Centre data, and that data from state and national poison control centres supported the relative safety of products containing chlorpyrifos.

A variety of human case studies presented extensive and sometimes contradictory symptomology after chlorpyrifos exposure, including the usual signs of organophosphate poisoning, such as lacrimation, salivation, respiratory paralysis, or muscle fasciculation. Some case reports also indicated the onset of polyneuropathy in exposed humans. Four incidents of birth defects allegedly associated with exposure to chlorpyrifos were reported. However on the basis of the findings in this report, and the poor characterisation of exposure, it is not possible to determine whether the reported effects were associated with chlorpyrifos exposure.

Groups of four healthy adult male volunteers received chlorpyrifos in tablet form at doses up to 0.10 mg/kg/day for up to 28 days. Rapid and marked depression of plasma cholinesterase activity was observed in subjects at the high dose of 0.1 mg/kg/day chlorpyrifos, but no other treatment-related effects were noted. The NOEL for this study was 0.03 mg/kg/d, based on the inhibition of plasma cholinesterase activity at 0.1 mg/kg/d .

Six male Caucasian volunteers were given a dermal dose of 5.0 mg/kg chlorpyrifos four weeks after the administration of a single oral dose (0.5 mg/kg) of chlorpyrifos. The oral dose significantly inhibited plasma cholinesterase within 12-24 h after treatment, but this recovered after 30-days. The mean predicted absorption following oral administration was 72 + 11%, and following dermal administration was 1.35 + 1.0 %.

In a recent study of the effects of a single oral dose of chlorpyrifos at 0, 0.5, 1.0 or 2.0 mg/kg bw on fasted human males and females, the NOEL for clinical signs or symptoms in this study was 2.0 mg/kg, the highest dose tested. The NOEL for RBC cholinesterase inhibition was 1.0 mg/kg based on significant inhibition in 1/12 subjects exposed at 2.0 mg/kg. Plasma cholinesterase activity was not measured. There were no

effects of treatment at any dose level on general health measures during the study or on clinical chemistry parameters measured at 7 days after dosing.

In a paper in which the authors reported 8 case studies where chlorpyrifos exposure was claimed to cause sensory neuropathy, the cases each presented with a range of symptoms, and exposure characterisation was poor. The lack of immediate electrodiagnostic testing, the poor exposure characterisation, and the variability in the reported clinical findings makes interpretation of these case studies difficult.

4.11 Public Health Standards

Poisons Scheduling and Safety Directions

Chlorpyrifos is currently in Schedule 6 of the Standard for the Scheduling of Drugs and Poisons (SUSDP), with products in either Schedule 6 or Schedule 5. There are provisions for appropriate safety directions on the product labels aimed at limiting exposure, and first aid instructions in the event of poisoning.

The use of products that contain more than 50 g/L chlorpyrifos by the householder are not supported, due to the toxicity of such products and the need for personal protective equipment when using such products.

No Observed Effect Level / Acceptable Daily Intake

In Australia, the current Acceptable Daily Intake (ADI) for chlorpyrifos is 0.003 mg/kg/day, based on the NOEL for plasma cholinesterase inhibition of 0.03 mg/kg/day in a 28-day human volunteer study (Coulston et al, 1972), and using a 10-fold safety factor for individual variability.

Following the considerations of the Advisory Committee on Pesticides and Health (ACPH) and the Scientific Director of the Chemicals and Non-Prescription Medicines Branch (CNPMB) of the Therapeutic Goods Administration (TGA), the current ADI for chlorpyrifos was affirmed.

Acute Reference Dose

The recommended acute RfD for chlorpyrifos is 0.01 mg/kg, derived from an NOEL of 0.1 mg/kg/d in a human volunteer 28-day study (in which plasma and erythrocyte ChE activities were not inhibited at one or three days at any dose in the study), and using a 10-fold safety factor for individual variability.

5. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

5.1 Toxicity relevant to occupational exposure

Technical chlorpyrifos is of moderate acute oral, dermal and inhalation toxicity. It is a slight skin irritant and slight to moderate eye irritant but not a skin sensitiser in experimental species.

A number of chlorpyrifos formulations have been tested for acute and repeat dose toxicity. The acute toxicity of chlorpyrifos formulations was related to the level of the active ingredient.

Female animals were generally more sensitive to the acute effects of chlorpyrifos exposure than male animals. Depression of cholinesterase (ChE) activity appears to be the most sensitive toxicological endpoint for chlorpyrifos with plasma ChE more sensitive than red blood cell (RBC) or brain ChE.

The most suitable No-Observable-Effect Level (NOEL) for use in the occupational health and safety (OHS) risk assessment is 0.03 mg/kg/day, established in a human short-term repeated dose study.

Dermal absorption

Dermal absorption was not measured in animals. The relative toxicity of chlorpyrifos to animals via the oral and dermal routes suggests a low dermal absorption.

Dermal absorption measured in human volunteers was 1.35 ± 1.0%. Based on the available information a conservative estimate of 3% absorption was used in the OHS risk assessment, however it is noted that this value may be an overestimate.

Health effects resulting from occupational exposure

Insufficient information was available to quantify the extent of occupational health effects associated with the use of chlorpyrifos in Australia.

A review of chlorpyrifos poisoning data concluded that chlorpyrifos was one of the leading causes of acute insecticide poisoning incidents in the United States. Certain types of usage were considered of greater risk. The greatest concerns were for use of liquid formulations by homeowners and pest control operators (PCOs) indoors or outdoors, termite treatments, and the use of sprays and dips on domestic animals. Most of the more serious poisonings were associated with misuse or inappropriate use.

In a study in the USA, the prevalence of selected illnesses and symptoms were compared between chemical industry workers potentially exposed to chlorpyrifos and matched controls, over an 8 ½ year period. Exposed workers were involved in chlorpyrifos manufacture and/or formulation of liquid and granular products containing chlorpyrifos. These workers showed significant depression of mean plasma ChE compared to controls. A greater proportion of the exposed group than the controls reported symptoms of dizziness, malaise and fatigue, however there were no statistically significant differences in illness or prevalence of symptoms.

5.2 Use profile

Prior to end use

There are a large number of registered products containing chlorpyrifos. The usage pattern can be broadly grouped into crop protection, pest control and other (such as treatment of hides and skin), as well as home garden/home veterinary use (pest control and pet care products). Some products are imported ready for use, whilst others are formulated locally from imported active ingredient. Product formulations currently registered include emulsifiable concentrates (500 EC), wettable powders (500 WP, 250 WP), Ultra Low Volume formulations (300 ULV, 500 ULV), granules (140 GR) and baits (home garden use only).

Manufacturing and formulation workers may be exposed to chlorpyrifos 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.

Commonwealth/State/Territory regulatory controls for OHS.

End use

End use parameters used in the assessment are based on label rates and survey information excluding any off-label uses identified by users. This review considers only the end uses which have potential for occupational exposure.

Chlorpyrifos is used predominantly for crop protection and pest control. It is also registered for use in hides and skins, however this is expected to be minor in relation to total chlorpyrifos.

Chlorpyrifos use for crop protection is extensive covering a wide variety of horticultural and field crops, including: broadacre crops (eg cereals and pasture), cotton, sugarcane, tropical fruit, berry fruit, pome and stone fruit, citrus, vines, vegetables and lawn/turf. It is applied as a spray to foliage, the ground surrounding the crop or to bare ground at the time of sowing. Application methods include vehicle mounted equipment, hand-held equipment and aircraft.

Pest control is also a significant end use of chlorpyrifos. Chlorpyrifos is used in pre- and post-construction for termite control in all Australian states and Territories, with most regarding termiticide use of chlorpyrifos as essential. Approximately 29% of all chlorpyrifos used in Australia are for termite control.

For pre-construction use, one spray treatment is applied to soil just before the waterproofing membrane is positioned and just prior to pouring of the concrete slab. Application methods for termite treatment of existing buildings include hand held pneumatic sprayers or bucket/watering cans, soil injection using rodding equipment with high pressure, hand lance with low pressure high volume sprayer (rose head nozzle), and under slab reticulation systems. Pole treatment for termite control is

achieved by rodding or trenching and puddle treating as a continuous barrier. For general pest control of buildings (such as cockroach control) application is usually by handheld spray.

All chlorpyrifos 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 in representative crop protection and pest control situations is summarised in Tables 1 and 2, respectively. Other minor uses of chlorpyrifos are identified in Table 3.

Due to the large number of end use situations/crops the review considered exposure and risk by application method.

Table 1: Use pattern parameters used in exposure assessment - Crop protection

Application method **Crop groups**	**Application parameters** **kg ai applied/ha ha treated/day L spray/ha**	**Frequency of use** **applications per season**	Comments
Airblast			
Tropical & berry fruit	0.5 kg ai/ha 6 ha/day 1000 L/ha	2-4 (average)	application rate within label rates; work rate is maximum on PQs; spray volume based on label and PQs
Pome & stone fruit	1 kg ai/ha 15 ha/day 2000 L/ha	2-4 (average)	application rate and spray volume as per labels; work rate within range on PQs
Vines	0.25 kg ai/ha 15 ha/day 1000 L/ha	2-4 (average)	application rate as per label; work rate within range on PQs; spray volume as per label and PQs
Oscillating Boom			
Citrus	0.25 kg ai/ha 24 ha/day >1000 L/ha	2-4 (average)	label application rate; work rate as per PQs; spray volume estimated to be greater than PQ rate
Boom			
Tropical fruit, berry fruit, vegetables	0.75 kg ai/ha 6 ha/day 2000 L/ha	up to 5	average label application rate; work rate consistent with airblast work rate; spray volume within label and PQs ranges
Cereal, pasture, forage crops, sugarcane	0.45 kg ai/ha 50 ha/day 1000 L/ha	up to 5	application rate within label range; work rate within range on PQs; representative spray volume
Lawn/Turf	2 kg ai/ha 20 ha/day 400 L/ha	up to 2	application rate within label rates; work rate not expected to be more than 20 ha and spraying time ~2-3 h; spray volume as per label
Aerial			
Bananas, cereals (including rice), cotton, sugarcane, lawn/turf	0.5 kg ai/ha 1200 ha/day ≥10 L/ha	contractors operate regularly	application rate within label range; work rate within range on PQs for cotton; spray volume as per label
Aerial ULV			
Cereals, pasture, forage crops, cotton	0.5 kg ai/ha 1200 ha/day applied undiluted	contractors operate regularly	application rate within label rates; work rate within label rates; no spray volume information available, expected to be applied undiluted in most cases
Handspray			
Berry fruit & vegetables	0.4 kg ai/ha 1 ha/day (vehicle mounted), 0.25 ha/day (knapsack) 1600 L/ha	infrequent (2 per season) to frequent (every 3 weeks)	application rate within label rates; work rate for vehicle mounted equipment based on PQs, work rate for knapsack application based on POEM default maximum of 400 L spray/day; spray volume as per label

PQ - performance questionnaire
POEM – Predictive Operator Exposure Model

Table 1: Use pattern parameters used in exposure assessment - Crop protection (continued)

Application method **Crop groups**	**Application parameters** **kg ai applied/ha ha treated/day L spray/ha**	**Frequency of use** **applications per season**	Comments
Basal application (tree base or surrounding soil)			
Custard apple, passion fruit, bananas, pome & stone fruit, citrus, cabbage, cauliflower, tomatoes, potted plants	10 kg ai/ha 0.01 ha/day 1000 L/ha	1 per season for bananas frequent (every 7 days) for other crops	application rates as per labels; work rates expected to be low based on PQs with small areas treated (~100 m^2/day) and work intermittent; spray volumes varied with maximum spray concentration 1%
Seed treatment			
Vegetables, cereals and oil seed crops	quantitative risk assessment for mixing/loading only	once at sowing	0.2-2.5 kg ai/100 kg seed, applied undiluted through seed dressing equipment; no work rate information available, expected to be ~30 ha/day based on work rates for other ground application methods
Soil baits			
Strawberries, stone fruit, vegetables, cotton, legumes, cereals, oil crops, turf	qualitative risk assessment only	infrequent by ground regular by air (contractors)	50 g ai/10 kg bran/ha, 50 g ai/2.5 kg wheat/sorghum per ha (or 100 g ai/5 kg/ha) mixed in bait, applied aerially, by fertilizer spreader or by hand
Bandspray at sowing (in furrow)			
Vegetables, cotton, cereals and oil crops	0.75 kg ai/ha 30 ha/day 20 L/ha 0.75 kg ai/ha 60 ha/day (ULV) 2.5 L/ha (ULV) quantitative risk assessment for mixing/loading only	once at sowing	application rate within label rates; work rate as per PQs for cotton, spray volume as per label for ULV product (30% ULV) work rate is expected to be higher and product applied undiluted
Gravity feed at sowing			
sugarcane	quantitative risk assessment for mixing/loading only	once at sowing	14% granular product or 50% EC product loaded into drum and gravity fed onto plant sett and immediately covered by soil
Bell injection and irrigation			
bananas, potatoes	no label uses		inadequate information

PQ - performance questionnaire

Table 2: Use pattern parameters used in exposure assessment - Pest control

Pest **Situation**	**Maximum application rate**	**Maximum work rate (per day)**	**Spray volume**	**Comments**
Termites				
Buildings (pre- and post-construction)	100 or 200 g ai/10L	390-450 m^2 (3 sites, 130-150 m^2 each)	horizontal: 5 L/m^2 vertical: 100 L/m^3	application rate and spray volume as per label; work rate based on PQs
Termite nests or colonies	200 g ai/10L	various	not provided	application rate as per label
Pole treatment	100 g ai/10 L water or creosote	various	100 L/m^3	application rate and spray volume as per label
General household pests (including. ants, cockroaches, spiders, fleas, silverfish))				
Buildings	50 g ai/10 L	780-900 m^2 (6 sites, 130-150 m^2 each)	1L/m^2	application rate and spray volume as per label; work rate expected to be at least twice the rate for termite control based on relative application rates and volumes
Mosquitoes				
Vegetation	0.015-0.06 kg ai/ha	various	not provided	application rate and spray volume as per label (maximum); work rate dependant on application method
Water impoundments	10 g ai/ 100 m^3	various	no dilution	application rate and spray volume as per label; work rate dependant on application method.

PQ – performance questionnaire

Table 3: Use pattern parameters used in exposure assessment - Other uses

Situation	**Maximum application rate**	**Maximum work rate (per day)**	**Spray volume**	**Comments**
Handspray of hides and skins	200 mL product/100 L (0.1% ai)	various	30 mL/hide or until saturated	inadequate information

5.3 End use exposure

Australian workers may be exposed to chlorpyrifos during product handling, product application (mainly spray) and during clean-up activities.

The potential routes of occupational exposure to chlorpyrifos will be dermal and inhalation. Inhalation exposure may occur to product dust when using wettable

powders or granular formulations and/or spray mist when using emulsifiable concentrates, wettable powders or ultra low volume formulations. Exposure to active constituent vapour is not likely to be significant as the vapour pressure of chlorpyrifos is low (2.5×10^{-3} Pa). Workers may however inhale solvent vapour when using liquid formulations which contain hydrocarbon solvents.

Individual farmers generally conduct crop protection; therefore the frequency of worker exposure will depend on the crop type, the pest targeted and the method of application. The frequency of exposure during pest control is dependent on the individual work load of the pest control contractor, as the same worker may be involved in treating multiple sites for a variety of pests.

A large number of measured exposure studies were provided to estimate worker exposure during crop protection and pest control applications. Some of these studies could not be used in the risk assessment due to data and/or study design deficiencies. Crop situations covered by suitable measured exposure data included airblast application of orchards and citrus, boom application to low crops and handspray of greenhouse ornamentals. Pest control situations with adequate measured exposure data were pre- and post-construction termiticide application.

Predictive exposure modelling (using the UK Predictive Operator Exposure Model, POEM) was used where necessary, to support the measured data and to gauge exposure during individual tasks where measured data was not available.

5.4 Post-application exposure

Crop protection

There is potential for re-entry exposure for workers who enter treated crops to check, irrigate, thin or harvest crops.

Cotton chippers have a high potential for foliar contact when pulling or chipping out weeds. These workers are usually contract workers who work on a regular basis depending on the season.

Post-application exposure data were available for orchards, corn fields and low crops treated with chlorpyrifos. Dislodgeable residue data were available for cotton.

There are no label re-entry/re-handling statements for chlorpyrifos products registered for crop protection.

Pest control

Re-entry exposure may occur after pest treatment of existing buildings or buildings under construction. Occupational exposure will be limited to construction workers re-entering treated areas or office workers re-entering treated work sites.

Products used for pre-construction termite control should carry the following re-entry/re-handling statement:

Suspended floors: allow treated areas to completely dry (normally 3-4 hours) and ventilate buildings before re-occupying

Concrete slabs: cover immediately after treatment with a moisture membrane

Products used for post-construction termite control and general pest control should carry the following re-entry/re-handling statement:

Re-entry to treated areas: allow treated areas to completely dry (normally 3-4 hours) and ventilate buildings before re-occupying

5.5 Occupational risk assessment and conclusions – end use

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.

In order to determine the risks associated with the use of the chemical, Margins of Exposure (MOE) were calculated by comparing the most appropriate NOEL with exposure data obtained from measured worker exposure data or predicted modeling, where possible. A qualitative risk assessment was conducted where a suitable model was not 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.

The main adverse health effect of chlorpyrifos exposure is ChE inhibition. The most appropriate NOEL for the occupational health and safety risk assessment was 0.03 mg/kg/day, based on plasma ChE inhibition observed over 20 days in a human study. This NOEL was compared with the standardised exposure estimates or the predicted exposure estimates to give MOE for each Australian use scenario. As a human NOEL was used, MOE of approximately 10 or more were considered to be acceptable to account for intra-species variation. It is recognised that in cases where the use of chlorpyrifos is infrequent, the above NOEL may be conservative and result in an overestimation of risk.

A dermal absorption adjustment of 3% was used in the risk assessment. No correction was made for inhalation absorption, as 100% absorption was assumed.

Chlorpyrifos is a slight skin irritant and slight to moderate eye irritant in experimental animals. These topical effects may be manifested in workers who come in contact with chlorpyrifos 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 chlorpyrifos products, it is assumed that workers wear appropriate PPE, as specified on product labels.

Crop protection

Airblast application

chlorpyrifos is applied by airblast in a range of crop situations. The use pattern parameters used in the exposure and risk assessment for airblast application represent a reasonable worst-case scenario for this application method.

Exposure data were available for airblast application using two formulations of chlorpyrifos, WP and EC. Exposure modelling was used to fill data gaps, in particular to estimate exposure to workers handling WP formulations in water-soluble packaging and liquid formulations packaged in wide neck containers. Measured data and model data indicated unacceptable risk during open mixing/loading and airblast application in open cabs. However MOE estimated from measured and model data may overestimate the risk in some cases, because airblast applications are expected 2-4 times per season in most cases and some measured exposure data were conducted with workers wearing less PPE than Australian workers.

Noting: (i) the frequency of use and intermittent nature of chlorpyrifos use in orchards, (ii) that the risk assessment was based on a reasonable worst case scenario for airblast application, and (iii) the possible overestimation of risk from exposure estimates obtained from exposure studies and predictive modelling, it is concluded that the overall risk to workers during airblast applications of chlorpyrifos is likely to be acceptable under the following conditions:

(a) that exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice and label instructions.

Oscillating boom

It is anticipated that oscillating booms will be used to apply chlorpyrifos predominantly in citrus, 2-4 times per season. The use pattern parameters used in the risk assessment are considered to be a reasonable representation of actual use of the chemical in citrus. No exposure data are available for this application method and exposure modelling cannot be used.

Exposure estimates generated for airblast application were used as an indication of exposure during the use of oscillating boom. The overall risk to workers during application by oscillating boom is expected to be similar to airblast application, as less product is applied and the spray is more dilute, even though more spray volume is applied. Although oscillating boomsprayers are known to result in greater worker contamination than airblast sprayers, these vehicles are usually equipped with closed cabs.

Noting: (i) the frequency of use and intermittent nature of application over the growing season, and (ii) that potential mixer/loader and applicator exposure during oscillating boom spraying is expected to be comparable to airblast spraying, it is concluded that the overall risk to workers during application by oscillating boom is likely to be acceptable under the following conditions:

(a) that exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice and label instructions.

Boom application

Workers are expected to apply chlorpyrifos to crops up to five times per season and turf up to two times per season. Although the application rate is higher in turf than broadacre crops, the areas treated are small in comparison.

The use pattern parameters used in the exposure and risk assessment represent: (i) a reasonable worst case scenario (lawn and turf) and (ii) the major use situation (broadacre crops).

Exposure data were available for boom application using WP and EC formulations of chlorpyrifos, using normal and high clearance boom sprayers. These data were normalised for the major use scenario (broadacre crops), therefore the degree of risk will be greater for maximum exposure scenarios which utilise more concentrated sprays (for example lawn/turf).

Exposure modelling was used to estimate exposure for scenarios which had data gaps, for example water-soluble packs for WP formulations and wide neck containers for EC formulations, and also to compare potential exposure and risk associated with major uses (broadacre crops) with relatively minor uses (lawn/turf).

The risk to workers was dependant on packaging and formulation type, mixing/loading method, presence of cab on vehicle, application rate and area treated. A greater risk was shown for lawn and turf treatment than for broadacre crops.

Noting: (i) the frequency of use and intermittent nature of chlorpyrifos use in field crops and amenity turf, (ii) that the risk assessment was based on a reasonable worst case scenario for amenity turf, and (iii) the possible overestimation of risk from exposure estimates obtained from exposure studies and predictive modelling, it is concluded that the overall risk to workers during boom applications of chlorpyrifos is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice and label instructions.

Aerial application

Aerial spraying is likely to be conducted by trained aerial spraying crew. These workers may handle large quantities of chlorpyrifos.

The use pattern parameters used in the exposure and risk assessment are considered to be representative across all possible crops treated by aerial application.

No suitable exposure data were available for aerial applicators. Model data were used to estimate exposure to mixer/loaders for aerial operations. There were no suitable models within POEM to estimate exposure to aerial applicators or human markers (flaggers).

Open mixing and loading methods will result in unacceptable risk however most workers are expected to use closed systems. Applicator exposure is not expected to pose unacceptable risk as pilots are in enclosed cockpits and fly against the direction of the spray drift. Flaggers may be used in limited situations and are expected to be adequately protected provided they follow best practice guidelines e.g. those developed by the Aerial Agricultural Association of Australia (AAAA).

Aerial crew have potential for exposure to large volumes of product, however noting that: (i) most aerial spraying crews use closed mixing systems (dry coupling and closed filling systems), (ii) aerial applicator exposure is expected to be minimal, (iii) aerial spray operators are required to undergo appropriate training and accreditation, and (iv) flaggers are used only for night spraying when GPS is not available, it is concluded that the overall risk to workers during aerial applications of chlorpyrifos is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with best practice guidelines and label instructions.

Handspray

Hand spraying of chlorpyrifos will take place on field crops and greenhouse plants. Applications are expected to range from a small number of applications per season to frequent applications (such as every 3 weeks).

Chlorpyrifos formulations applied by handspray are EC and WP. Some exposure data were available for handspraying in greenhouses using microencapsulated (ME) and WP formulations. As this review does not consider ME formulations, the data from the ME studies were used as a guide to assess worker exposure to the formulations under review.

Model data were used to estimate worker exposure for scenarios where suitable measured exposure data were not available.

The risk during all handheld applications (except overhead plants in greenhouses) was acceptable provided exposure was minimised during mixing and loading.

For handspray application to low level greenhouse plants or field crops, noting that: (i) the use pattern parameters used in the exposure and risk assessments represent a reasonable worst-case scenario for this application method, (ii) the frequency of use and intermittent nature of chlorpyrifos use in field crops and greenhouse crops, and (iii) extrapolations from study results using ME formulations to WP and EC formulations are used as a guide only, it is concluded that the overall risk to workers applying chlorpyrifos by handspray to low level greenhouse plants or field crops is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice and label instructions.

For handspray application overhead greenhouse plants, noting that: (i) this is likely to be a high exposure scenario, and (ii) available measured data indicated unacceptable exposure and risk when treating overhanging plants for workers wearing PPE additional to Australian requirements, the use of chlorpyrifos products in this manner is not acceptable. However, as handspray of greenhouse ornamentals is an off-label use, the treatment of overhead plants is not expected to occur under normal use situations.

Basal application

Chlorpyrifos products registered for this use are EC and WP. Liquid and dry formulations are applied by spray or trunk injection to the base of trees or the surrounding soil. In addition, dry formulation is applied as a dry mixture with sand to bananas only. Exposure data were not available for basal application. Theoretical calculations and exposure modelling were used where possible to estimate potential exposure.

The use pattern parameters used in the risk assessment are based on information obtained from the performance questionnaires.

The risk during basal spray application or trunk injection was acceptable provided exposure was minimised during mixing and loading. The risk to workers applying WP formulation as a dry mixture could not be quantified. It is noted that application will be infrequent in bananas and an alternative method of application (spray) is available for this crop.

For workers applying chlorpyrifos as a liquid mixture to the base of trees, or the ground around them, noting that: (i) the information available on extent of use is limited, (ii) the use pattern parameters used in the exposure and risk assessments represent a reasonable worst-case scenario for this application method and workers may treat smaller areas, (iii) no suitable exposure data are available for this end use with modelling information used only as a rough guide, and (iv) model data is likely to overestimate risk during basal application, it is concluded that the overall risk is likely to be acceptable under the following conditions:

(a) that exposure mitigation methods specified below are instituted, where applicable; and

(b) the product is used in accordance with good agricultural practice and label instructions.

For workers applying chlorpyrifos as a dry mixture with sand, noting that: (i) the potential for dermal and inhalation exposure is high, and (ii) no suitable exposure data are available for this end use with modelling information used only as a rough guide, however: (i) this method of application is used only on bananas and applications in this crop are conducted once per season, and (ii) alternative application methods (spray application) are available and currently used by Australian workers, it is concluded that the overall risk is likely to be acceptable under the following conditions:

(a) that exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice and label instructions.

For use on bananas it is preferable that chlorpyrifos products be applied as a liquid rather than a dry mixture.

Seed treatment

Seed treatment and sowing is conducted together as a single operation. Chlorpyrifos products used as seed treatments are EC and WP formulations. The WP products are marketed specifically for seed treatment and are packaged in a different manner to other WP products. Both EC and WP are open mixed in a seed planter. Potential exposure scenarios during seed treatment were identified as being during mixing and loading only. No worker exposure is expected during transfer of seed and planting, as this is a mechanised process.

No exposure data were available to estimate worker exposure during seed treatment and no appropriate model was available to estimate worker exposure for a full work cycle during seed treatment. Model data were used to estimate exposure during mixing and loading only. This data included hand exposure only and therefore was interpreted with caution and used as a rough guide estimate of exposure.

Use pattern parameters and information regarding work practices used in the risk assessment were obtained from regular users of chlorpyrifos products from the performance questionnaires. Work rates were estimated based on work rates for other ground application methods.

The risk to workers using EC formulation was acceptable provided exposure is minimised during mixing and loading. The risk to workers using WP formulation was unacceptable due to the high potential for exposure during open mixing techniques.

For workers using WP formulations, noting that: (i) open pouring has a high potential for dermal and inhalation exposure, (ii) manual mixing of product with seed is also expected to result in dermal and inhalation exposure, however the extent of exposure cannot be quantified, (iii) label safety directions do not recommend the use of a respirator or dust mask, and (iv) modelling information was used only as a rough guide and is expected to be an underestimate of risk, however considering chlorpyrifos will be

used at sowing only, it is concluded that the overall risk to workers applying WP chlorpyrifos as a seed dressing will be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice.

For workers using EC formulations, noting that: (i) seed treatments will be conducted at sowing only, (ii) inhalation exposure to EC formulations is not expected to be significant during open mixing/loading, and (iii) the risk assessment assumes workers wear PPE as recommended on product labels, it is concluded that the overall risk to workers applying EC chlorpyrifos as a seed dressing is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice.

Soil baits

Application of chlorpyrifos in soil baits is not expected to be a major use in Australia and only EC formulations are registered for this use. No more than two applications per season are expected by this method.

Potential exposure scenarios identified for this use were during mixing and loading for both ground (including fertilizer spreader and hand application for small areas) and aerial application (for large areas) of bait. Worker exposure during application of bait is not anticipated.

No exposure data or appropriate models were available to estimate exposure for this application method.

Use pattern parameters and work practice details used in the risk assessment were obtained from limited survey information, however the risk to workers during soil bait preparation and application could not be adequately quantified.

During ground applications, the risk for mixer/loaders is expected to be acceptable due to small volumes of product being handled, low final concentration of active ingredient in the bait and the mixture being loaded as a solid. No significant exposure is anticipated during application as this method is mechanical.

For ground applications, noting that: (i) two applications are anticipated per season with an exposure free period between them, (ii) the risk assessment is based on maximum work rates for other ground based applications, (iii) small quantities of chlorpyrifos are handled, and (iv) exposure is limited to mixing/loading, it is concluded that the overall risk to workers applying soil baits is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice and label instructions.

For aerial applications, manual mixing operations are not likely to be used given the large amounts of product handled. With the use of closed loading systems, the risk to loaders should be acceptable. No exposure is anticipated for aerial applicators.

For aerial applications, noting that: (i) mixer loader potential is limited due to use of automatic mixing and closed loading systems, and (ii) aerial applicator exposure is expected to be minimal, it is concluded that the overall risk to workers applying soil baits is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice and label instructions.

Applications at sowing (bandspray or gravity feed)

EC and ULV formulations are applied by bandspray, while gravity feed applications are conducted using either EC or granular products in sugarcane only. Overall, applications at sowing are expected to be a minor use of chlorpyrifos.

No exposure data were available to assess risk during bandspray or gravity feed.

Open mixing and loading has potential for significant exposure and risk. Model data were used to assess exposure during mixing and loading using EC and granular formulations, and are considered only as a rough guide.

The risk to workers mixing/loading and applying chlorpyrifos products by bandspray and gravity feed will be mainly dependant on the formulation type and product packaging. Applicator exposure and risk is not expected to be significant, as applications will be conducted low to the ground and treated areas will be covered immediately by soil.

Noting that: (i) applications are infrequent (only at sowing), (ii) slow-release granulated formulations limit the amount of chlorpyrifos available for inhalation or dermal contact, (iii) liquid formulations are used undiluted, requiring no mixing, (iv) closed transfer systems are used when handling bulk containers of liquid products, and (v) applicator exposure is not expected to be significant, it is concluded that the overall risk to workers applying chlorpyrifos by bandspray or gravity feed is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with good agricultural practice and label instructions.

Pest control

The risk assessment considers exposure and risk during each of the individual types of pest control separately. In practice however, some tasks may be conducted by the same worker.

All workers involved in termite control (such as pre- and post-construction termiticide application, as well as spot treatments of poles and termite nests) are grouped together. PCOs conducting general pest control (eg control of ants, cockroaches and fleas) and mosquito control, may also be the same workers, however they have lesser PPE requirements and less potential for exposure, and so are considered separately.

Termite control

Chlorpyrifos is applied as a dilute solution (1-2% depending on geographic location).

The frequency and extent of chlorpyrifos usage may vary significantly for these workers. At the low end of the scale, some operators may use a variety of pesticides and may combine chemical applications with other activities which do not result in chemical exposure (such as providing quotes, conducting pest inspections and writing reports). At the other end of the scale, large operators may contract work out to termite specialists who may use chlorpyrifos for most of their applications.

PCOs are usually trained and accredited and have access to better facilities (such as PPE, washing up equipment and emergency facilities).

Risk during pre-construction termiticide application was acceptable provided exposure is minimised during mixing/loading, appropriate PPE is worn and safe work practices are in place. The risk during post-construction termiticide application is expected to be comparable to pre-construction application for the following reasons: both roles are conducted by trained PCOs with access to specialised equipment; application rates, work rates, final active concentrations and mixing/loading methods are similar.

In the absence of exposure studies and based on use pattern information, the exposure and risk during treatment of termite nests/colonies or during pole treatment, was determined in relation to post-construction application.

Noting that: (i) PCOs may apply chlorpyrifos either pre-construction, post-construction or as a spot spray (to treat termite nests or for pole treatment) depending on the job requirement, (ii) most workers are not expected to treat sites daily, however some have potential for frequent and extensive usage of chlorpyrifos all year round, (iii) modelling data showed a concern for workers during mixing and loading when using containers of standard design, (iv) literature studies have shown overseas pest controllers to have significant ChE inhibition following a full termite control season, however given that PCOs: (i) are required to have access to health surveillance facilities in accordance with the NOHSC Control of Workplace Hazardous Substances, (ii) are adequately trained and accredited and have access to more sophisticated equipment and facilities than other categories of workers, and (iii) are required to wear extensive PPE, it is concluded that the overall risk to workers applying chlorpyrifos termiticide by any approved method is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with safe work practices and label instructions.

It is preferable that alternative methods of termite control (eg physical barriers) be employed where possible.

Control of general household pests

The risk assessment relied in the main on the relative exposure potential (as determined using POEM) of this end use method compared to post-construction termite control.

Based on the relative exposure estimates using modelling, the risk during general pest control is expected to be similar to the risk during post-construction termite control. It is noted however that these workers are required to wear less PPE than termiticide applicators.

Noting that: (i) the use pattern parameters used to estimate exposure and risk represent a reasonable worst case situation, and (ii) no suitable exposure data are available for this end use with modelling information used only as a rough guide, however PCOs: (i) are required to have access to health surveillance facilities in accordance with the NOHSC Control of Workplace Hazardous Substances, and (ii) are adequately trained and accredited and have access to more sophisticated equipment and facilities than other categories of workers, it is concluded that the overall risk to workers applying chlorpyrifos for general pest control is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with safe work practices and label instructions.

Mosquito control

Mosquito control is a minor use in Australia. Council workers or PCOs will treat vegetation or water impoundments using spray or direct product incorporation. Products available for this end use are the same as those available for general pest control.

A number of exposure studies were provided, however they were not suitable for use in the risk assessment. Model data were therefore used to estimate worker exposure for mixer/loaders and applicators by this method.

The risk to workers using chlorpyrifos for the control of mosquitoes is considered acceptable when used in accordance with label directions.

Noting: (i) that the frequency of application by this method is low for some workers (council workers), (ii) that the end use parameters used in the exposure and risk assessment represent a reasonable worst case scenario, (iii) insufficient end use

information resulted in the use of default estimates, and (iv) the possible overestimation of risk from exposure estimates obtained from predictive modelling, it is concluded that the overall risk to workers applying chlorpyrifos for mosquito control is likely to be acceptable under the following conditions:

(a) exposure mitigation methods specified below are instituted, where applicable; and
(b) the product is used in accordance with safe work practices and label instructions.

5.6 Existing regulatory controls for occupational health and safety

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

Risk phrases

3%	R21	Harmful in contact with skin
	R22	Harmful if swallowed
	R50	Very toxic to aquatic organisms
	R53	May cause long term effects in the aquatic environment.
25%	R24	Toxic in contact with skin
	R25	Toxic if swallowed
	R50	Very toxic to aquatic organisms
	R53	May cause long term effects in the aquatic environment.

Safety phrases

S1/2	Keep locked up and out of reach of children
S28	After contact with skin wash immediately with plenty of (to be specified by manufacturer).
S36/37	Wear suitable protective clothing and suitable gloves
S45	In case of accident or if you feel unwell, contact a doctor or Poisons Information Centre 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

These risk and safety phrases should be present on the label for technical chlorpyrifos.

All chlorpyrifos formulations registered in Australia are determined to be hazardous substances, as they contain greater than 3% active constituent.

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.

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

It is recommended that appropriate training courses (eg. Farm Chemical User Course or recognised equivalent) be identified for all workers involved in the use of chlorpyrifos products.

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

3. 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 preferable that the following engineering controls be adopted where possible:

(a) mixer/loaders;
  (i) container/pack designed to minimise spillage, eg. water-soluble packs for WP formulations and wide neck or any other "no-glug" container design for liquid formulations;
  (ii) use of closed mixing/loading (mechanical transfer) systems, eg. closed filling/loading systems or dry coupling; and
  (iii) use of closed mixing techniques for dry mixing of dry formulations (eg WP).

(b) ground applicators;
  (i) use of closed cab tractors – inclusion of air-conditioning and pesticide filters will provide added protection as well as worker comfort.

(c) flaggers in aerial operations;
  (i) use of closed cab vehicles.

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.

4. Health surveillance – Organophosphates including chlorpyrifos 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.

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

5.7 Occupational risk assessment and conclusion – post application

Crop protection

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 following restricted entry period must be included on the product label:

> **Restricted-entry period - field crops:** Do not allow entry into treated fields until spray deposits have dried. If prior entry is required, limit duration of entry and wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.
>
> **Restricted-entry period - greenhouses:** Do not allow entry into greenhouses until spray deposits have dried and treated areas are adequately ventilated. If prior entry is required, limit duration of entry and wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), chemical resistant gloves and half-facepiece respirator. Clothing must be laundered after each day's use.

Cotton chippers may be at risk of unacceptable exposure during repeated and prolonged re-entry activity. These workers should follow recommended guidelines. To protect cotton chippers, the following REP must be included on the product label:

> **Cotton chippers:** Do not allow entry into treated areas until spray deposits have dried. After this time, wear shoes, or boots, socks, long trousers, long sleeved shirt, gloves and hat.

Pest control

The review identified the main sources of re-entry exposure to be (a) during the application of the moisture membrane following pre-construction termite control or (b) during the re-entry of treated buildings by office staff.

The review indicated that the risk to these workers is likely to be acceptable, provided the chemical is used in accordance with safe work practices and label instructions.

The current restricted entry periods (refer earlier) are adequate for chlorpyrifos pest control products. All chlorpyrifos pest control product labels must include these statements.

6. ENVIRONMENTAL ASSESSMENT

6.1 Introduction

The organophosphate insecticide chlorpyrifos is included in the second round of chemicals selected for review under the National Registration Authority's Existing Chemicals Review Program. From the environmental perspective, chlorpyrifos was accorded high priority for review because of its toxicity to birds and aquatic organisms.

Chlorpyrifos is an organophosphorus insecticide widely used for urban and domestic pest control, including turf maintenance, and as a termiticidal barrier in, around or under buildings. Agricultural uses include cotton, sugarcane, vegetables, cereals, canola, rice, pome fruit, stone fruit, citrus, tropical fruit and grapes.

6.2 Chemical Identity and Properties

Chlorpyrifos belongs to a group of organophosphorus compounds known as the phosphorothioates that do not inhibit acetylcholinesterase directly. They rely for their effect on metabolic transformation in target tissue to their oxon form, which is intrinsically less stable and has greater activity, generally by several orders of magnitude. Water solubility (1.4 mg/L) and vapour pressure (2.7 mPa) are both low, but environmentally significant. Chlorpyrifos is a lipophilic chemical with a high octanol-water partition coefficient.

6.3 Environmental Exposure

Release

Chlorpyrifos is widely used in Australia, with current annual consumption of about 1000 tonnes. It is sold as emulsifiable concentrate (used in agriculture, for turf maintenance and termite protection), wettable powder (favoured for orchard use to avoid phytotoxicity problems with solvents in emulsifiable concentrate formulations), ultra low volume (mainly for cotton), microencapsulate (general urban pest control), seed dressing, granule (home garden use against pests such as ants and beetles), prepared bait (for control of cockroaches in the home; note that user prepared baits are also used to control certain surface feeding soil insects in agriculture) and sustained release (for multi season grub control in sugarcane) formulations. There are also some animal health products (collars and sprays) for use on companion animals.

Occurrence

Chlorpyrifos is very much an occasional contaminant of surface waters, but can reach high levels on occasion. The use pattern of main concern with respect to high level surface water contamination is termite protection, which involves much higher rates of application than agricultural treatments. Several fish kills have been reported in association with this use pattern in Australia, with levels in water reaching several hundred ppb.

Levels of contamination arising from agricultural uses are much lower, generally below 1 µg/L on the rare occasions that chlorpyrifos is detected in Australian surface waters. Extensive monitoring has been conducted in the cotton areas of northern NSW and the irrigation areas in southern NSW. There are a few high outliers, reaching 26 µg/L in northern rivers and 25 µg/L in irrigation drainage adjacent to rice bays in southern NSW, but these appear to be isolated occurrences which are seldom detected because of the limited aquatic persistence of chlorpyrifos. In some cases, non-agricultural uses such as termite protection of bridges may contribute.

Monitoring programs provide indicative data on levels of pesticide contamination prevailing in waterways, but not a complete picture, particularly for chemicals such as chlorpyrifos that tend not to persist in the water column. For example, monitoring in the cotton areas of NSW involves the taking of weekly surface water samples during the summer cropping season, mainly from the major rivers in the region but also from smaller waterways. Such sampling is able to detect widespread contaminants such as endosulfan. However, localised contamination events immediately adjacent to areas of production will probably not be detected, although they may cause localised damage to biological communities. The occurrence of such events is supported by exploratory studies in February and March 1997 using solvent filled polyethylene bags to obtain continuous samples from Carole Creek, a site with a history of high level agrochemical detections. Continuous sampling did find chlorpyrifos, but the data could not be verified. Routine weekly samples failed to detect chlorpyrifos at this site in the 1995/96 and 1996/97 seasons, although two low-level detections occurred at the end of the 1994/95 season. Continuous samplers found chlorpyrifos at two other sites where grab samples remained consistently negative during the 1997-98 spray season. These detections could reflect accumulation from background levels, or from occasional high pulses entering the river. The latter appears more likely given that such pulses are detected in spot samples from time to time.

Similar results are available from monitoring in other jurisdictions. For example, levels in the San Joaquin River have been reported to reach 0.22 µg/L on occasion. The San Joaquin River drains areas of intensive agriculture where chlorpyrifos is used in high volumes (more than 500 tonnes per annum). Diazinon and methidathion, two more hydrophilic organophosphorus insecticides, are found much more frequently, and at much higher levels. Detections above 1 µg/L in North American surface waters are extremely rare, and the majority of detections are below 0.1 µg/L.

Chlorpyrifos also occurs in surface waters at some distance from agricultural uses, such as Lake Tahoe or Chesapeake Bay, but at very low levels (in the low ppt range). In the former case, atmospheric transport is implicated, as chlorpyrifos has also been found in samples of air, vegetation and precipitation. The more toxic metabolite, chlorpyrifos oxon, can be detected in air samples because of greater atmospheric stability, although both parent and metabolite have low atmospheric persistence (a few hours). Chlorpyrifos can also be found in remote locations, with ppq levels recorded in Arctic seawater.

Chemistry and fate

Chlorpyrifos partitions to soil or disperses to the atmosphere following application. Limited quantities may enter aquatic environments with runoff, and will mainly partition to sediment where slow to moderate degradation occurs. Atmospheric

persistence appears limited, while residues in soil are degraded at a moderate rate by the following processes.

Hydrolysis

Chlorpyrifos hydrolyses in sterile neutral to acidic solution with a half-life in the order of 1-2 months, forming TCP and desethyl chlorpyrifos (DEC) as main metabolites. The variability in reported half-lives reflects the behaviour of chlorpyrifos, which tends to partition from solution by sorption to glass surfaces or by volatilisation from open systems. Hydrolysis proceeds more rapidly at alkaline pH to form TCP. Hydrolysis in solution is catalysed by cupric ions, and microbial influences also intervene in non-sterile systems to accelerate degradation. The toxic metabolite, chlorpyrifos oxon, hydrolyses much more rapidly than chlorpyrifos.

Hydrolysis in sterile soils forms the same metabolites but generally proceeds more slowly than in solution. The exception is air-dried soils, where clay catalysed hydrolysis may proceed very rapidly. Half-lives in the range 92-341 days have been recorded in neutral to acid soils, decreasing to 11-200 days in alkaline soils. The faster rates are thought to reflect catalysis by metal ions or soil enzymes. Degradation slows at elevated soil concentrations, apparently because most of the chlorpyrifos remains in the undissolved phase where it is not readily available for hydrolysis.

Photolysis

Chlorpyrifos is susceptible to photolytic degradation in aqueous solution, with typical summer half-lives in the order of a month in sunlit surface waters. Photolysis forms TCP which appears generally to be more photolabile than chlorpyrifos, undergoing dechlorination and ring cleavage on further irradiation. Direct and photosensitised reactions are possible, and model studies using acetone found the latter to be faster. However, studies in natural river water found no significant rate increases compared with buffered solution, suggesting that the humic substances generally present in natural surface waters are inefficient photosensitisers for chlorpyrifos. Strong sorptive properties are also likely to reduce the importance of solution photolysis as a breakdown pathway in the environment by removing chlorpyrifos from solution, particularly in the turbid waters characteristic of Australian cropping areas.

Photochemical reactions do not appear to represent a significant mode of degradation for chlorpyrifos on the surface of soils, although the metabolite TCP is photolabile under such conditions.

Photodegradation occurs in the vapour phase, with at least two unidentified reaction products formed in addition to TCP. Chlorpyrifos is photostable in dry air, consistent with indirect photodegradation through hydroxyl radical attack. Monitoring studies indicate that chlorpyrifos vapours are oxidised to chlorpyrifos oxon as they are transported through the sunlit atmosphere.

Metabolism

A principal mode of degradation for chlorpyrifos in the environment is metabolism in soils. Chlorpyrifos degrades to TCP in microbially active and sterile soils, but mineralisation only occurs where microbes are active. Based on results from numerous and diverse soils, typical soil half lives for chlorpyrifos at normal agricultural concentrations are in the order of a month, but may range from less than a week to more than 4 months. At elevated concentrations (1000 mg/kg) half lives for chlorpyrifos degradation extend to between 4 and 12 months, and further to more than 4 years in one sandy soil.

The primary metabolite TCP is more resistant to metabolism than chlorpyrifos, with an average half-life at 1 mg/kg of about 2 months but wide variation between soils, from about a week to 9 months. Again, higher concentrations retard metabolism, with a half-life of more than 2 years in one soil spiked at 10 mg/kg.

Degradation of TCP forms trichloromethoxypyridine and $^{14}CO_2$. TMP appears persistent in some laboratory soils as it increased in concentration throughout a 300 day study in two soils, but this should not cause problems in the field given the volatility of this metabolite. Degradation of TMP occurs in other soils, forming $^{14}CO_2$ and TCP, and half-lives in the order of 1-2 months have been recorded.

Chlorpyrifos partitions rapidly from water to sediment following entry to aquatic systems, and also volatilises to the atmosphere, particularly following spray application. Concentrations of chlorpyrifos in the water column decline sharply in the few hours after entry, and then more gradually with dissipation half-lives of a few days generally prevailing in natural surface waters. Dissipation from sediment is slower. Limited data suggest half-lives in the order of a month but possibly extending up to 4 months.

Mobility

With a mean soil organic carbon sorption coefficient of 8500 from around thirty different soils, chlorpyrifos has a strong tendency to partition from aqueous into organic phases. Sorption is rapid and largely reversible over short timeframes. In contrast to the immobility of the parent, the metabolite TCP is moderately to highly mobile, with soil organic carbon partition coefficients across 29 different soils ranging from 27 to 389. Mobility of this weakly acidic metabolite tends to increase in alkaline soils. Column leaching studies on four soils confirm that chlorpyrifos is immobile in soils, but significant leaching of TCP from aged samples has been demonstrated in one soil.

Chlorpyrifos is also mobile in the environment by virtue of its volatility. Volatilisation from foliage is particularly pronounced, with around 80% lost within 24-48 hours, compared with up to 25% from soil surfaces. The Henry's law constant is high enough that volatilisation should also occur from water. There is some experimental support for this in that rapid losses have been observed from open or aerated solutions, with unchanged chlorpyrifos recovered from resin plugs in one instance. However, the significance of volatilisation as a dissipation pathway for chlorpyrifos from surface waters remains unclear. Recent modelling studies suggest that mass transfer from the surface microlayer to underlying water is more important than volatilisation.

Spray drift also transports chlorpyrifos into non-target areas. Available data indicate that aerial application generates the highest levels of drift, with buffers of 300 m needed to reduce off-target deposition below 0.5% of the application rate. Nozzle selection is critical. With solid stream nozzles delivering very coarse droplets, aerial applications generate comparable levels of drift to ground based treatments. The other key factor that gives rise to excessive drift is atmospheric stability and associated inversions.

Field dissipation

Chlorpyrifos would not be expected to persist in the field based on the laboratory results, and this prediction is supported by results from field trials.

Three separate studies on turfgrass plots indicated a rapid initial degradation with half-lives of about a week, followed after a month by a more gradual decline with half-lives in the order of a month. Residues remained at the site of application because of good retention by the organic rich thatch layer, with less than 0.1% lost with runoff water.

Studies in citrus orchards found a rapid dissipation of surface soil residues, which declined by at least an order of magnitude in the month after application.

Studies in cotton found that as much as 4.5% can be lost in runoff water when heavy rains occur. Studies were conducted on heavy clay and lighter silt loam soils, with chlorpyrifos applied at 0.56 or 1.12 kg/ha. Most of the chlorpyrifos leaving the field in runoff was in the dissolved phase, suggesting foliar wash off as the main source. Losses were lower after canopy closure, notwithstanding increased foliage, because the larger plants depleted soil moisture under the prevailing dry conditions and allowed greater infiltration before runoff occurred. The main factor determining the magnitude of runoff losses was the time between application and precipitation, during which foliar deposits are lost to volatilisation.

Pond studies indicate that volatilisation also occurs from water, particularly soon after spray contact while the bulk remains near the surface. Volatilisation is the main process for dissipation of chlorpyrifos from water, with a half-life of 3.5 days estimated by modelling. The half-life in sediment was 200 days.

Studies on corn receiving various treatments in consecutive seasons found seasonal losses to an adjacent pond of about 0.2-0.4% of applied. In contrast to the cotton study where a mature crop was treated, most losses occurred in runoff as sorbed residues. Foliar washoff provided minor dissolved contributions as foliar interception was generally low due to small plant size, and delays between application and runoff events allowed volatilisation to occur. Peak concentrations in an adjacent receiving pond approached 10 µg/L in the second year when heavy rains fell, with peak residues approaching 1 mg/kg in sediment. Simulated storms soon after application at the time of planting when soil was bare removed some 2-3% of applied chlorpyrifos from the field in runoff. The half-life of chlorpyrifos in the soil appeared to be about 3 weeks. No residues were detected below 25 cm in the soil, or in tile drainage.

Bare soil studies in Germany found half-lives in the order of 2 months. Similar persistence was recorded after application at 3.4 kg/ha to bare soil in Illinois, Michigan and California, with no residues of chlorpyrifos or metabolites (TCP/TMP) found below

30 cm in the year following treatment. Canadian studies found half-lives of 2 weeks in a sandy soil and 2 months in a muck soil seeded with carrots and radish.

Bioaccumulation

Chlorpyrifos bioconcentrates to moderate to high levels in fish and other aquatic life. A bioconcentration factor of about 1400 has been recorded in rainbow trout, and 745 in oysters. Steady state is soon achieved, and residues depurate rapidly in clean water, with typical half-lives of about 2 days. Bioconcentration of TCP in mosquito fish is insignificant.

6.4 Environmental Effects

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

Birds

Detailed test reports on acute oral toxicity were submitted for the standard test organisms, bobwhite quail and mallard duck. A comprehensive literature review including data for a much wider variety of species was also submitted. Chlorpyrifos has been shown to be highly to very highly toxic (LD50s below 20 mg/kg) to several species (house sparrow, red-winged blackbird, Japanese quail, ring-necked pheasant, common pigeon and mallard duck) when administered as an acute oral dose, although there are other results available for some species indicating lower toxicity. Acute oral testing is compromised by the tendency of some birds, notably mallards, to regurgitate the test material. Testing with quail indicated the metabolite TCP to be practically nontoxic by the acute oral route.

Detailed dietary toxicity test reports were submitted for bobwhite quail and mallards. Dietary toxicity is moderate to high, with mallards becoming anorexic when dietary concentrations exceed 100 ppm. Choice tests with young mallards offered the option of food contaminated with 112-1124 mg/kg chlorpyrifos revealed an ability to discriminate in favour of clean feed. Earlier studies indicated that some other birds share this ability, with the onset of repellency between 1000 and 10000 mg/kg chlorpyrifos. However, pheasants, which are highly sensitive to chlorpyrifos, suffered mortality following consumption of food contaminated with 10000 mg/kg chlorpyrifos, with no sign of any repellency. The metabolite TCP was found to be practically nontoxic to mallards.

Chlorpyrifos does not appear to have significant reproductive toxicity based on testing in bobwhite quail and mallards. Reproductive performance was compromised in mallards at elevated dietary concentrations (above 100 ppm) as the birds stopped eating and lost condition, but this appears to reflect nutritional deficiencies rather than true reproductive toxicity. Reproductive parameters remained unaffected in bobwhite quail fed at 125 ppm.

Overseas studies have found little evidence for avian impact. Geese grazing on pasture sprayed at 0.72 kg/ha were clearly exposed to chlorpyrifos as residues were found in excreta, but suffered no ill effect. No dead birds were found when golf courses in Florida were closely monitored after treatment at relatively high rates (4.5 kg/ha) for grubs and crickets. Studies in Iowa corn at lower rates (1.1-3.4 kg/ha) found only two

American robins as possible chlorpyrifos casualties, despite abundant bird life and significant residues in vegetation and insects. Similar studies in California citrus found some changes in abundance following a high rate treatment (6.7 kg/ha) but these were thought to reflect avoidance rather than mortality. Field studies in Senegal found a few avian casualties following application of chlorpyrifos at 280 or 387 g/ha for grasshopper control. Post-treatment reductions in avian populations appeared to reflect reduced food resources. In general, field studies in which birds were abundant provided little indication of chlorpyrifos related effects on birds. The notable exception is a study in freshwater ponds in California in which significant mortality of mallard ducklings was recorded following application of chlorpyrifos to the water at rates of 11-1120 g/ha. Birds apparently died as a result of consuming contaminated water boatmen, but the study is old and causal factors can not be firmly established.

There are some reports of adverse avian impact from use of chlorpyrifos in Australia. Again, these appear to involve the consumption of contaminated invertebrates. Occasional bird kills (scavenging species such as crows and butcher birds) have been reported in association with the use of chlorpyrifos baits to control surface feeding insects in cotton, sorghum, sunflowers and maize. There is a report of dead magpies that were found following treatment of power poles to treat termites, with contaminated worms apparently responsible. A granular ant control product was recently reported to have killed a number of pigeons at a Darwin residence. Chlorpyrifos may have been the cause of a major incident at an ibis rookery in the Macquarie Marshes in early 1995 in which large numbers of nestlings died, apparently from consumption of contaminated invertebrates brought back to the nest by parents.

Isolated avian incidents have also been reported from overseas, with chlorpyrifos specifically identified as the causal factor in some. Abnormally high levels of chlorpyrifos and other organophosphates were found in dead shorebirds following relatively large incidents in Florida in 1997.

Reported avian incidents, while relatively few, appear inconsistent with the generally favourable outcomes from field studies. One explanation may be the much higher toxicity of chlorpyrifos oxon, which may reach significant levels in contaminated invertebrates. This does not appear to have been specifically investigated, and may have been overlooked. Chlorpyrifos oxon would probably remain undetected using standard analytical procedures because of its instability.

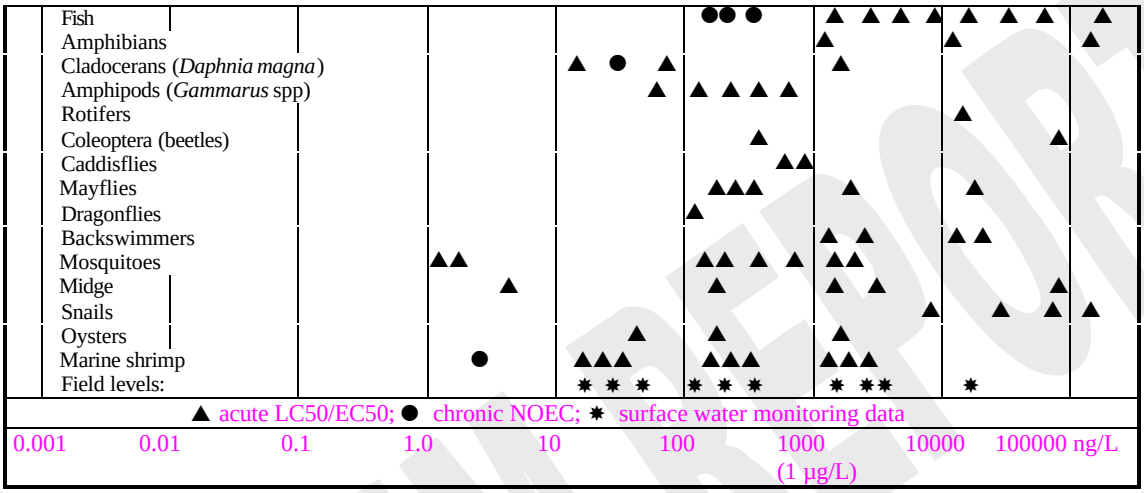
Aquatic organisms

Extensive testing shows chlorpyrifos to be highly to very highly toxic to fish, aquatic arthropods, oysters and algae. Limited data suggest that some amphibians may share similar sensitivity. Acute LC50s for freshwater and marine fish are typically below 100 µg/L, with bluegill sunfish sensitive at around 2 µg/L. For invertebrates, acute LC50s are typically in the 0.1-10 µg/L range. Algal endpoints are typically above 100 µg/L, but with one well reported result of 64 µg/L for the sensitive freshwater species, *Selenastrum capricornutum*. Testing with fish and invertebrates shows the metabolite TCP to be slightly to moderately toxic, consistent with its hydrophilic character.

Chronic exposure of rainbow trout resulted in complete mortality at low concentrations (2-3 µg/L). The NOEC was 0.5 µg/L. Life-cycle testing with fathead minnows

returned a similar NOEC, with larval mortality observed at concentrations in the order of 1 µg/L. Semi-static reproductive testing with *Daphnia magna* found a no effect concentration of 0.056 µg/L. Complete mortality occurred within 21 days at the next highest test concentration, nominally 0.1 µg/L. Reproductive testing with mysid shrimp, a sensitive marine invertebrate, found mortality and growth impairment at concentrations above 10 ng/L, with a NOEC of 4.6 ng/L.

Aquatic toxicity data for chlorpyrifos are summarised below. Available Australian surface water monitoring data are included for comparison. It should be noted that most water samples test negative for chlorpyrifos, and would therefore contain less than the detection limit of 0.01 or 0.1 µg/L, but that any detections will be toxic to sensitive species.



Differences in toxicity to fish, invertebrates and vegetation are readily apparent from multi-species testing in microcosms and ponds. As a general rule, aquatic arthropods suffer dose-responsive impacts following acute (pulse) exposure at 0.1-1 µg/L, while only minor fish impacts occur at such doses, consistent with the summary depiction above. Algae are not affected directly by such exposures, but indirect effects of increased algal and periphyton growth may arise due to suppression of planktonic grazers. Some gastropods may also increase in number with increased food resources. The threshold for acute effects at species and community levels in such studies appears to be about 0.1 µg/L. Invertebrate communities generally recover from acute exposures within 6 months, depending on the magnitude of the disturbance and the responses of less sensitive species, which may occupy ecological niches vacated by sensitive organisms before they can recover.

A static microcosm study in fibreglass tanks examined spray drift and runoff simulations delivering target concentrations between 0.03 and 3 µg/L. Nominal concentrations were achieved soon after drift simulation and declined with a half life of about 3days. Aquatic concentrations after slurry application reached about half of nominal but remained fairly constant for some days as further material desorbed. Rotifers remained unaffected by treatment, but arthropod populations suffered sharp reductions at target concentrations of 0.3-3 µg/L and needed 2-4 weeks to recover. Bluegill sunfish were reduced by about a third by drift simulation at the highest rate, and almost eliminated by the corresponding slurry treatment, repeated three times at fortnightly intervals. Drift simulation at 10 µg/L eradicated bluegill populations. Various alternating spray and slurry sequences were also investigated. Measured

concentrations suggested biphasic dissipation kinetics, with rapid losses (half-lives of a day or two) in the initial 24 hours after spray treatment followed by a more gradual decline (half-life about a week). Initial losses were thought to reflect volatilisation. Sorption to sediment was a relatively minor dissipation pathway, with levels recorded in sediment remaining generally below 10% of applied. Results indicate that repeat exposure to concentrations in the order of 1 µg/L should not affect bluegill survival or growth, and will cause only temporary reductions in invertebrate populations, provided that chronic exposures remain below 1 µg/L.

The maximum concentration of 4.7 µg/L detected in samples taken from 15-20 cm below the surface of shallow Minnesota ponds following spray application was about 25% of nominal. All other recordings were below 1.5 µg/L, or 10% of nominal. Effects seen in the pond were consistent with laboratory data. Substantial numbers of bluegill sunfish, for which laboratory LC50s in the order of 2 µg/L are typical, were killed. Arthropod populations, particularly water fleas, were reduced.

Similar trends were evident in deeper Minnesota ponds sprayed at three different rates. Bluegill mortality at target concentrations of 5 and 20 µg/L reached 38 and 99%, respectively. Minimal mortality occurred at a target concentration of 0.5 µg/L. Arthropod populations were reduced, and cladocerans were again most sensitive with major reductions at all treatment levels. Analyses of water samples indicated that nominal concentrations at mid-depth were exceeded 1 hour after treatment. However, some doubt is attached to this observation because of contradictory results from vertical mixing studies, which found less than 10% of applied chlorpyrifos at mid-depth during the initial 2 hours after treatment. An initial rapid drop in chlorpyrifos concentrations in the water column (half-life 4-18 hours, with greater persistence at higher dose) was followed after about 12 hours by a more gradual decline.

Actual concentrations in artificial drainage ditches containing standing water were estimated by measuring the stratification and by taking depth-integrated water samples. Nominal target concentrations exceeded actual concentrations by a factor of about two following surface spray treatment. Stratification was evident for about a day in open water and 2-4 days where aquatic vegetation was present. The nominal NOEC at species and community levels was 0.1 µg/L under this acute dosing regime.

Australian studies in flowing water dosed continuously for 6 hours at a nominal 0.1 µg/L found no effect on artificial stream communities. Significant reductions in invertebrate density occurred at higher dose (nominally 5 µg/L). Continuous dosing over 21 days reduced numbers of chironomids, copepods and cladocerans at low and high doses. Periphyton density increased with reduced grazing pressure, as did one species of gastropod mollusc.

Artificial stream studies in Minnesota examined continuous dosing for 100 days at nominal concentrations of 0.2-1.01 µg/L, or 24 hour pulses at a nominal 3.1-11.5 µg/L every fortnight. The number of invertebrate taxa and number of organisms sampled declined under pulse dosing. Amphipod bioassays found no effect under continuous dosing but 50% mortality under pulse dosing. Symptoms of intoxication were seen in caged bluegills, but only under pulse dosing. Unstocked white suckers were found dead or dying following pulse dosing.

Non-target terrestrial invertebrates

Acute oral and contact testing using technical material and an emulsifiable concentrate found chlorpyrifos to be highly to very highly toxic to honey bees. Semi-field studies using a microencapsulated formulation applied at 800 g/ha to flowering ground cover confirmed that chlorpyrifos is harmful to bees, with peak mortality after a few days, presumably reflecting delayed release from the microcapsules.

Artificial soil tests in three laboratories found chlorpyrifos to be slightly toxic to the earthworm *Eisenia foetida*, but with weight loss at sub-lethal concentrations. Reviews indicate other species to have similar acute sensitivity, and to suffer reproductive impairment at concentrations above 100 ppm.

Testing with short-winged beetles found chlorpyrifos (1 kg/ha) to be very harmful to their parasitisation capacity. Sevenspotted lady beetles were completely killed by chlorpyrifos at relatively low rates (180-400 g/ha) with mortality remaining above 50% at 7 days after treatment. Testing in an apple orchard found chlorpyrifos (1 kg/ha) to be highly toxic to all beneficial arthropod groups, but limited residual activity meant that impacts were relatively short-lived with recovery apparent after 10 days. Impacts to beetles, spiders and collembola were also evident in pasture sprayed at 750 g/ha, with some weeks needed for recovery.

Chlorpyrifos residues appear to impair microbial processes in some soils, even at normal application rates, but to exert no adverse influences in other soils, even at elevated rates (5-8 kg/ha). Some microbial species, particularly fungi, appear to be highly susceptible, and the metabolite TCP is reported to have some microbial toxicity.

Plants

Laboratory tests indicate that chlorpyrifos can be phytotoxic to some sensitive plants at elevated doses, and this has been confirmed by field reports of phytotoxicity, particularly in the floriculture industry. There are no reports of off-target damage to native vegetation.

Reptiles

Widespread mortality (> 100/ha) of two lizard species was observed 8 hours after application of chlorpyrifos at 240 g/ha to control immature desert and mature tree locusts in Mauritania. A large monitor was found moribund from acute poisoning 24 hours after treatment at 387 g/ha to control acridid nymphs and adults in Senegal. Its stomach was filled with contaminated beetles, grasshoppers and other invertebrates.

Overview

As a broad spectrum insecticide, chlorpyrifos is very highly toxic to a broad range of insects, including beneficial species. Very high toxicity is also evident to aquatic arthropods, in both laboratory and field situations. Chlorpyrifos is also very highly toxic to fish, but less so than to aquatic invertebrates. Fish kills have been reported where aquatic contamination is high, with termiticide treatments a common cause, particularly if followed by heavy rain. Fish kills from agricultural uses are also possible in misuse situations such as direct overspray, but none appear to have been reported in Australia. Kills of aquatic fauna in the field appear to be infrequent, notwithstanding

very high laboratory toxicity, because of the limited persistence of chlorpyrifos in the water column. Toxicity profiles observed during prolonged, constant concentration exposure in the laboratory may not accurately reflect toxicological responses to pulsed and rapidly declining concentrations in water under field conditions.

Chlorpyrifos is slightly to moderately toxic to mammals under conditions of acute exposure, and has relatively low mammalian toxicity compared with other organophosphorous insecticides. Birds are more sensitive, with high to very high toxicity recorded in the laboratory. Chlorpyrifos has been implicated in a number of bird kills in Australia, most notably a major die off at an ibis rookery in the Macquarie Marshes in 1995. While conclusive proof of causation is lacking for most of these incidents, the weight of evidence indicates that chlorpyrifos will give rise to occasional bird kills, particularly in predatory and scavenging species feeding on contaminated invertebrates. Abnormally high levels of chlorpyrifos and other organophosphates were found in dead shorebirds following a recent incident in Florida, but the route of exposure remains unclear. Overseas evidence suggests that similar impacts may occur with reptiles.

6.5 Prediction of Environmental Hazard

Hazard assessment compares estimated levels of exposure with toxicity data in order to predict whether adverse impacts will occur. The initial approach is conservative, allowing the screening out of compounds for which hazard is low and no further work is needed. Exposure predictions are then refined, for example using more detailed models or field derived data.

The hazard assessment for chlorpyrifos is summarised below. Only the main arguments are presented here. Readers should consult the full technical report for further detail.

Terrestrial organisms

Initial deterministic predictions indicate that residues on vegetation and small insects may be high enough soon after application to cause adverse impacts on birds that eat these items as a major proportion of the diet. For example, application at 1.5 kg/ha would leave estimated residues of 400 ppm on short grass and 230 ppm on small insects. Acute dietary LC50s for birds may be as low as 200 ppm.

Volatilisation from foliage would rapidly reduce the hazard in the field, and few birds feed on foliage. Insectivorous birds may experience the highest exposures, and metabolic activation to the oxon in insects would lead to increases in the avian toxicity of residues.

Field studies support the conclusion that chlorpyrifos can be hazardous to birds, but suggest that risks are relatively low as few casualties were recovered notwithstanding the presence of a rich and varied avifauna. Similarly, incident reports are not numerous, although some events are worrisome. Foremost among these is the Macquarie Marshes incident, in which large numbers of ibis nestlings died. This was apparently a consequence of being brought contaminated food by the parents, but no firm cause was established. The incident is reminiscent of early observations in California of high duck mortality after feeding on contaminated water boatmen in a treated pond. Chlorpyrifos was one of a number of organophosphates found at abnormally high levels in dead shorebirds in a recent Florida incident that remains unexplained. Occasional incidents of birds deaths as a result of feeding on contaminated soil insects are reported from agricultural areas, and from urban areas where chlorpyrifos is used for termite protection. Direct consumption of granules used for ant control has also reportedly killed birds in the home garden situation.

Hazard to mammals appears relatively low, but reptiles may share similar or higher sensitivity than birds, based on limited information.

In summary, chlorpyrifos appears hazardous to birds and reptiles, although pathways of exposure are not well understood. A watching brief needs to be kept on this issue, and registrants should keep the NRA informed of any further incidents in Australia or overseas. Label restraints appear warranted.

Aquatic organisms

- **Initial assessment**

Initial deterministic predictions indicate that drifting chlorpyrifos represents a high acute hazard to aquatic fauna, and that further work is necessary to refine the hazard. Predicted residues from application at 150-1500 g/ha are 5-200 µg/L in shallow (15 cm) water, and 0.4-15 µg/L in deeper (2 m) water, assuming drift of 5-20%. Acute LC50s for fish range generally from 10-250 µg/L, but some species are sensitive at lower concentrations (around 2 µg/L). Invertebrates are more sensitive. The most sensitive acute LC50 is 15 ng/L for *Daphnia magna*.

- **Mitigating factors**

The hazard will be mitigated by environmental factors that reduce exposure. Volatilisation appears to be the main mitigating factor, but is not well understood. There is evidence to support the importance of volatilisation, but some of it is conflicting. Analytical data obtained following dosing of still and flowing water indicate that concentrations to which fish are exposed should not exceed 20% of the estimated concentration that would arise from complete dissolution through the water column. However, further clarification is needed and will be sought from registrants.

Assumption of a fivefold mitigation factor due to volatilisation and other processes reduces predicted deeper water exposures to 0.04-1.5 µg/L. Shallow water predictions reduce to 0.5-20 µg/L. Acute hazard remains high for invertebrates, and for fish in shallow water, but reduces to acceptable levels for fish in deeper water.

- **Modelling studies**

Regional models underscore the importance of buffer zones in reducing aquatic contamination. For example, studies predict that drift from aerial treatment of cotton reduces tenfold at 150 m downwind, and is further halved at 300 m. A twenty fold reduction in predicted concentrations would reduce shallow water predictions for Australia to 1 µg/L. This represents the lower threshold for prediction of high acute hazard to sensitive fish. It remains well above acute LC50s for many invertebrates, however.

A spray drift model being developed for possible regulatory use by the US EPA predicts that aquatic exposures can be maintained below 1 µg/L by observing appropriate buffers as outlined below. The 1 µg/L target concentration is based on microcosm results that showed no long term damage to fish and invertebrate populations from acute exposures.

- **High rate aerial application to cotton**

Based on the assumption that measured residues in water do not exceed 20% of nominal, the model predicts that 90% of shallow water exposures from aerial application to cotton at 1.5 kg/ha will remain below 1 µg/L, provided that coarse droplets (vmd 353 µm) are used and a 300 m buffer is observed. Use of medium droplets (vmd 226 µm) roughly triples drift, and raises concerns for sensitive fish and invertebrates in shallow wetlands. However, adequate protection remains for less sensitive fish species. Environmental hazard from this use pattern appears acceptable provided that coarse droplets are used and a 300 m buffer is observed.

- **Low rate ground based treatment**

The model predicts that ground based and medium volume aerial treatments at rates below 0.5 kg/ha do not present an unreasonable environmental hazard. Buffer zones do not appear necessary.

- **High rate ground based and aerial treatments**

Again, the model predicts that ground based treatment at higher rates (1 kg/ha) does not present an unreasonable hazard to fish, even without buffer zones, although some hazard remains for sensitive species in shallow wetlands. For aerial treatments, a buffer of 100 m appears essential. Even this precaution may not adequately protect the most sensitive fish species, and the model suggests that some impacts may occur unless buffers are increased to at least 300 m. This may not be practical.

- **Orchards**

For orchard spraying, a 50 m buffer appears adequate for protection of sensitive fish in shallow water from treatment of dormant and densely foliated orchards. The buffer should be increased to 100 m if rates rise above 2 kg/ha chlorpyrifos. Buffer zones do not appear necessary for normal orchard spraying.

- **European approaches to spray drift**

Spray drift data from Europe indicate that buffers for pasture and cereals can be reduced to 5 m when ground based application is used. For orchard spraying, buffers can be reduced to 30 m (increasing to 40 m above 2 kg/ha, and to 50 m above 4 kg/ha). These buffers do not offer sufficient protection in isolation, and must be used as part of a spray drift management strategy, including use of lower drift nozzles, when chlorpyrifos is applied near sensitive areas.

- **Ecological considerations**

Concentrations that kill individual organisms in laboratory testing do not necessarily elicit the same consequences in the field. For example, avoidance responses can reduce exposure under field conditions, and populations of invertebrates can recover rapidly from acute stressors. Microcosm studies indicate that lasting ecological damage to bluegill sunfish or invertebrate populations should not occur from acute exposures to 1 µg/L, provided that chronic exposures remain below this threshold.

Accordingly, the buffers outlined above, with use of coarse droplets in cotton, should help to avoid aquatic effects from use of chlorpyrifos in agriculture. For general medium volume aerial applications at 1 kg/ha, the buffer should ideally be extended to at least 300 m, but this may not be practical.

Note that some aquatic impacts, particularly to invertebrates, can be expected even with these restrictions. The ANZECC water quality guideline for protection of aquatic life is 1 ng/L. Restricting exposures to 1 µg/L will not protect against all non-target effects, but should be adequate to maintain longer term ecosystem function. A 1 µg/L target is considered achievable, provided practical restrictions are implemented. A 1 ng/L target would be impractical because of the very large buffers that would be needed, and could not readily be enforced as it is below analytical detection limits.

- **Chronic and multiple exposures**

Australian exposure data suggest that aquatic exposures are primarily acute. Chlorpyrifos dissipates rapidly from the water column, and inputs are discrete rather than continuous.

The effects of sequential exposures to chlorpyrifos are likely to be more significant, and it would appear essential to avoid repeat applications for an appropriate period. An interval of 10 days is suggested based on the recovery of invertebrate populations in microcosms from fortnightly spray drift exposures (each followed after 4 days by a runoff simulation) but not from weekly exposures.

There is also the question of simultaneous exposures to other toxic chemicals, particularly where chemicals are used heavily, as in cotton production. Heavy use of other toxic insecticides in crops such as cotton may compromise the ability of populations to recover from acute chlorpyrifos impacts, just as chlorpyrifos exposures will delay recovery from other chemical insults. It is unrealistic to consider the ecological effects of chlorpyrifos in isolation.

- **The current situation, and the termiticide problem**

Current Australian aquatic exposures in agricultural areas are isolated and generally below 1 µg/L. Exposures of this magnitude are not expected to cause lasting damage to invertebrate populations or kill fish, but are well above the ANZECC guideline for protection of aquatic life (1 ng/L). There are some higher level detections probably attributable to higher rate termite treatments, reaching several hundred ppb on occasion in urban areas. These incidents reflect runoff rather than drift. Simple calculations indicate that even very low levels of runoff can give rise to toxic concentrations in nearby water, because of the very high termiticide application rates.

Summary of aquatic hazard

In summary, chlorpyrifos is highly hazardous to aquatic life, but occurs only occasionally at toxic concentrations in Australian surface waters. Strict observance of buffer zones as outlined above can be expected to reduce such occurrences. Incidents in urban areas indicate a strong need for users to be educated about the hazards associated with termite treatments and the options available for minimising the risks of aquatic exposure.

6.6 Conclusions

Chlorpyrifos is widely used as an agricultural insecticide and for general urban pest control, including lawn maintenance and termite protection. A large volume of environmental data is available for this substance.

Quality of the studies submitted

A comprehensive data package has been submitted, and no specific additional studies are identified to complete the assessment, with two exceptions. Dow studies on surface

water contamination incidents associated with termite treatments in the USA and impacts on fish and invertebrates from alternating exposure in microcosms to spray and runoff simulations will be requested from the data owner.

Questions remain in relation to some of the studies submitted. In particular, clarification is also sought regarding techniques used to obtain depth integrated water samples in the microcosm study. For the Minnesota pond studies in littoral enclosures an explanation is sought for some apparently contradictory data. Samples taken from mid-depth one hour after application at a nominal 20 µg/L contained 32 µg/L chlorpyrifos, yet stratified samples taken during the first two hours after treatment contained less than 10% of the applied chlorpyrifos at mid-depth. The data owner is requested to comment on these matters, and to provide any further information that may be available to clarify the relationship between reliably measured and calculated concentrations in water. Any discussion of volatilisation as a dissipation pathway from water should address recent findings that mass transfer to the water column appears more important than volatilisation.

Avian issues

Simple screening methods identify a high acute hazard to birds from use of chlorpyrifos. Incident reports confirm the existence of avian impacts, which have been reported to attend the use of chlorpyrifos granules in the home garden and chlorpyrifos termiticides in urban situations. Use of baits to control surface feeding soil insects in agricultural situations also reportedly gives rise to avian mortality on occasion when pest pressure from larger invertebrates is heavy. Recent significant but unexplained avian incidents in the Macquarie Marshes and in Florida suggest that chlorpyrifos can present particular hazards to birds in some circumstances. Use of chlorpyrifos does not appear to incur widespread avian impacts, but isolated incidents are likely to be occurring where birds ingest granules or invertebrates containing significant levels of chlorpyrifos. Limited observations suggest the occurrence of similar and possibly more widespread incidents in reptiles that feed on contaminated invertebrates. A watching brief needs to be maintained on these issues. Specific monitoring of some products (home garden ant control granules and baits for surface feeding insects in agriculture) appears warranted. Registrants should keep the NRA informed of any further incidents that may occur in Australia or overseas. Label warnings appear warranted.

Aquatic issues

Chlorpyrifos dissipates from water through hydrophobic mechanisms such as volatilisation and sorption to sediment. Environmental monitoring finds only occasional detections, notwithstanding widespread use. When detected, chlorpyrifos generally occurs at concentrations in the order of 0.1 µg/L, a concentration likely to be lethal to sensitive aquatic invertebrates although it should not impact on populations. Occasional higher detections in agricultural areas, at concentrations between 1 and 30 µg/L, may reflect spray drift incidents or high rate non-agricultural uses such as termite protection of bridges. Aquatic contamination may extend into the hundreds of µg/L in urban areas, apparently as a result of high rate underslab treatments for termite protection, with insufficient precautions taken to avoid surface runoff from the treated area. Overseas evidence indicates that such problems may also occur with post-construction treatments if termiticide emulsion is injected into sub-surface drainage

channels. State authorities need to be mindful of such possibilities when investigating fish kills associated with use of chlorpyrifos in urban areas.

Artificial stream studies indicate that chronic exposure to 0.1 µg/L is likely to lead to reduced diversity, number of taxa and abundance or aquatic arthropods, but that pulse exposures of this magnitude should have no effect on invertebrates at species or community level. Fish are less sensitive, but may suffer impacts from some of the higher pulse exposures that have been documented to occur, as would some invertebrates.

Current environmental exposures to chlorpyrifos in Australian surface waters appear unlikely to exert broadscale environmental impact, but isolated incidents of fish and invertebrate mortality are likely to be occurring.

Modelling studies suggest that aquatic hazards from spray drift can be mitigated to acceptable levels by observing appropriate buffers upwind from aquatic areas, depending on application method and rate. For aerial application to cotton, a buffer of at least 300 m is recommended, together with use of coarse droplets. Buffers do not appear necessary for lower rate ground based treatments or the use of soil incorporated slow release formulations such as used in sugar.

The modelling studies also suggest that surface run-off may give rise to aquatic hazard, particularly if application rates are high, as for cotton. Vegetated filter strips are one option for mitigating this hazard. Field studies show that concentrations in surface runoff decline markedly in the 24-48 hours after treatment, largely because of foliar volatilisation. Avoidance of treatment when heavy rains are expected would be expected to significantly reduce risks from surface runoff. On-farm retention of at least the first flush of stormwater will also significantly reduce aquatic contamination from surface runoff.

Labelling issues

Risks from use of chlorpyrifos can be reduced by modifying labels to alert users to the hazards and ways of minimising them. Hazards are particularly acute for the high rate termiticide products. Warning statements could be expressed as follows:

For termiticide products:

1. VERY HIGHLY TOXIC TO FISH AND AQUATIC INVERTEBRATES. Rinse waters, and run-off from treated areas MUST NOT enter drains or waterways. For under-slab treatments, the moisture membrane MUST be installed immediately after treatment. Do NOT apply to waterlogged soils. Do NOT apply if heavy rains are expected to occur within 48 hours of application.

2. HIGHLY TOXIC TO BIRDS. Do NOT treat fill unless it has been placed back in the trench to form the chemical soil barrier.

For agricultural products:

For general agricultural uses, risks could be reduced by upgrading labels to warn users to avoid runoff and drift after application. Warnings could be expressed as follows:

3. HIGHLY TOXIC TO BIRDS AND REPTILES. VERY HIGHLY TOXIC TO AQUATIC INVERTEBRATES.

4. DO NOT re-apply to the same crop within 7 days (unless specifically recommended in the directions for use)

5. Spray drift may occur under adverse meteorological conditions or from certain spray equipment. Do NOT allow spray to drift onto sensitive areas including, but not limited to, natural streams, rivers or waterways and human dwellings. A spray drift management strategy such as those in the 'Best Management Practices Manual for Cotton Growers' or the 'Pilots and Operators Manual' should be applied.

   Options for minimising drift to sensitive areas include not spraying within a certain distance of sensitive areas when the wind is blowing towards them (see table for guidance) or ensuring that drifting spray will be intercepted by a catching surface such as a row of shelter trees, an unsprayed row of orchard trees, or hail netting.

Situation	Rate (kg/ha)	Recommended buffer distance (m)
Orchard (dormant trees, citrus, large trees)	< 2	30
	> 2	40
	> 4	50
Cotton (aerial application)		300
Other crops (aerial application)		100

   NRA Note: This table has been further simplified. Please see p.71 of this report.

6. DO NOT apply if heavy rains or storms that are likely to cause surface runoff are forecast in the immediate area within two days of application.

7. DO NOT apply when irrigating, or to waterlogged soil, or while water remains on the surface or in furrows, unless tailwater is captured on farm.

8. DO NOT allow contaminated runoff water from treated paddocks to enter adjacent areas or water bodies. Runoff contaminated by irrigation events (tailwater) and a 25 mm rain storm should be captured on farm for two days after application.

9. All labels of chlorpyrifos granular ant control products registered for use in the home garden should carry the following statements:

   Do NOT heap granules.
   These granules may kill birds if ingested.
   Do NOT feed granules or otherwise expose to wild or domestic birds.

The grain bait products used to control surface feeding insects in agricultural situations warrant specific statements in view of their avian hazard and the avian incidents

reported, for example: “Birds may be killed if they feed in areas where granules have been laid”.

Label upgrades also appear warranted for household products. Several products are registered for lawn maintenance by the homeowner. In general, users are advised to dispose of empty containers by wrapping in paper and placing in garbage, but it appears that at least one product label carries instructions to wash out the container thoroughly before disposal. Such advice is likely to introduce chlorpyrifos residues into sewers, and should be replaced by the standard statement: “Dispose of empty container by wrapping in paper, placing in plastic bag and putting in garbage”. Similar attention should be given to household insecticide and companion animal products, to ensure that rinsing does not form part of the container disposal instructions.

Home garden ant control product are of particular concern with respect to avian toxicity. Label statements need to be included to warn of the risk to birds, for example as follows: “DO NOT heap granules. Birds may be killed if they eat granules. DO NOT feed granules or otherwise expose to wild or domestic birds.”

Continuation of certain use patterns

Discontinued use patterns, such as for rice in Queensland, should be deleted from labels.

Use in cotton raises particular concerns as the application rate is high and the preferred ULV method of application is especially prone to aerial drift. Application to cotton using large droplet placement spraying needs to be actively encouraged.

The home garden granular ant control products appear problematic as they are likely to be used at high rates and contain sufficient toxicant to kill birds that ingest them. Mortality of pigeons that ingested granules has recently been reported from the Northern Territory. Environment Australia is unable to support granular home garden products for ant control, given the hazard identified and the evidence that bird kills can occur. Provision of further information such as obtained from careful monitoring to better determine the likelihood of avian consumption , may allow reconsideration of this position. Such monitoring would aim in the first instance to determine through careful observation whether birds consume granules in the home garden situation. If such exposure occurs, further work will be necessary to determine whether adverse impacts occur. Protocols should be agreed between registrants, the NRA and Environment Australia before monitoring occurs.

The suitability of such products for home garden use appears questionable.

NRA Note: While field studies on avian toxicity of chlorpyrifos reported in the environmental assessment appear inconclusive, laboratory studies indicate that chlorpyrifos is highly to very highly toxic to certain bird species. On the basis of laboratory studies the NRA considers that the use of chlorpyrifos granular products for control of ants in the home garden in accordance with the existing recommendations is likely to pose a hazard to birds, without having to call for further monitoring data. Accordingly, the NRA proposes to incorporate specific label statements so that the use of granular chlorpyrifos ant control products in the home garden in accordance with

their proposed recommendations for use would not be likely to have an unintended effect that is harmful to birds.

The following statements are proposed for all granular products of chlorpyrifos registered for ant control in the home garden:

"DO NOT heap granules. Birds may be killed if they eat granules. DO NOT feed granules or otherwise expose to wild or domestic birds."

Education of users

Particular concerns arise in urban areas. High application rates mean that the termiticide use, particularly pre-construction across new housing estates, presents a high hazard to aquatic life if surface run-off occurs. Use of companion animal products appears to give rise to excessive concentrations in sewage effluent in the Sydney region and probably in other cities. This illustrates the importance of following label warnings. Responsible registrants will educate users regarding these hazards, and ensure that labels contain appropriate warnings, so that risks can be minimised.

Conclusion

Registrants are requested to comment on the above proposals, and to suggest other measures that could be taken to reduce the risks that chlorpyrifos poses to the environment.

7. INTERIM REGULATORY MEASURES FOR CHLORPYRIFOS

7.1 Introduction

As was stated in the draft report released previously for public comment, the review of chlorpyrifos covered all aspects related to its registration, including approvals of labels and active constituents. Assessments conducted as part of the review considered the existing use pattern of chlorpyrifos in terms of its impact on public health, occupational health and safety (OHS), the environment and trade.

In addition to the above, the NRA considered all public comments that have been received on the draft report and the review of chlorpyrifos. The public consultation process resulted in a re-examination of certain aspects of the draft review report. This re-examination led to a strengthening of the assessment of aggregate exposure, restatement of the environmental warnings on labels, and a further elaboration of the Australian regulatory approach to chlorpyrifos. A summary of the main comments from the public and the NRA responses to these comments is at Attachment 2.

The NRA now proposes to implement a series of interim regulatory measures to manage public health, occupational and environmental risks and to fill the residue data gaps that have been identified.

Certain interim review recommendations require the generation of residue data. Where appropriate this data will be eligible for data protection in accordance with part 3 of the Agvet Code. Those conducting new studies are required to provide appropriate protocols and study designs to the NRA for approval prior to commencing studies.

The following summaries of assessments are intended to provide the reader with a brief overview of the review findings. As the assessment conclusions have remained largely unchanged from those in the draft report, the summaries are repeated from the draft report released previously for public comment with minimal amendment where necessary.

7.2 Main Review Findings

Toxicology and Public Health

Chlorpyrifos is a broad-spectrum organophosphate insecticide that has been used in Australia for over 30 years. Like other organophosphorus compounds, chlorpyrifos kills insects by interfering with the activity of an enzyme (acetylcholinesterase) in the nervous system. This interference causes over-stimulation of the nervous system, and results in rapid twitching and paralysis of muscles. If chlorpyrifos is swallowed, applied to the skin or breathed in by mammals, the effects of poisoning are typical of those seen with other organophosphorus insecticide. Such effects include excessive saliva, rapid breathing, coarse generalised body tremors, secretion of tears, urination, defecation, convulsions, respiratory failure, and death. The severity of signs increases with the amount of exposure but there is an effective antidotal treatment for acute poisoning of chlorpyrifos.

In studies in laboratory animals, chlorpyrifos was rapidly absorbed when swallowed, but did not persist for long periods in the tissues or organs of animals, and passed relatively quickly from the body. Absorption through the skin was relatively poor. Long-term exposure to a low concentration of chlorpyrifos in the diet was without serious consequences in animal studies, although high concentrations resulted in symptoms consistent with those listed above. Chlorpyrifos did not interact with genetic material, and long-term exposure studies in animals provided no evidence that chlorpyrifos can cause cancers in humans. Similarly, exposure to chlorpyrifos had no adverse effects on reproduction. The data on effects of chlorpyrifos in young or developing animals have been reviewed and infants and children are not considered to be at an increased risk from chlorpyrifos products that are used according to label instructions.

In Australia, chlorpyrifos is registered for use in many products including those used in or around the home and garden including termiticide use. These uses may give rise to some exposure of the public, but studies indicate that such exposures do not pose a public health risk. Based on the current uses of chlorpyrifos and with the removal of home garden products containing more than 50g/L chlorpyrifos, and restrictions on indoor spray treatments, it is considered that there should be no adverse effects on public health from the continued use of chlorpyrifos in Australia.

The Australian Market Basket Survey estimates the daily intake of a range of pesticides based on food consumption. In the 1996 survey, the highest exposure to chlorpyrifos in

the groups studied, (based on the 95th percentile energy intake,) was in infants aged 9 months, and was estimated to be 3% of the Acceptable Daily Intake (ADI). The lowest dietary exposure was seen in girls aged 12, with an intake estimated to be 1% of the ADI. The ADI is derived from toxicological data obtained from humans, and using a 10-fold safety factor to account for inter-individual variation. This indicates that chlorpyrifos exposure from residues in the Australian diet is very low and does not pose a public health risk.

Occupational Health and Safety

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.

In order to determine the risks associated with the use of the chemical, Margins of Exposure (MOE) were calculated by comparing the most appropriate NOEL (No-Observable-Effect Level: the highest dose level of a substance that, in a given toxicity test, causes no observable effect in the test animal/subject) with exposure data obtained from measured worker exposure data or predicted modeling, where possible. A qualitative risk assessment was conducted where a suitable model was not 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. However, it should be noted that the use of exposure data from predictive models using default assumptions, is likely to overestimate risk.

The main adverse health effect of chlorpyrifos exposure is acetylcholinesterase inhibition. The most appropriate NOEL for the occupational health and safety risk assessment based on plasma cholinesterase inhibition observed over 20 days in a human study. This NOEL was compared with the standardised measured exposure estimates or the predicted exposure estimates to give MOE for each Australian use scenario. As a human NOEL was used, MOE of approximately 10 or more were considered to be acceptable to account for intra-species variation. It is recognised that in cases where the use of chlorpyrifos is infrequent, the above NOEL may be conservative and result in an overestimation of risk.

Chlorpyrifos is a slight skin irritant and slight to moderate eye irritant in experimental animals. These topical effects may be manifested in workers who come in contact with chlorpyrifos products.

The overall risk for occupational groups using chlorpyrifos according to label instructions for crop protection and pest control was considered acceptable under conditions specified in the OHS assessment. As a precautionary measure, further improved warnings for re-entry exposure have been specified for inclusion on the product labels.

Environmental issues

Chlorpyrifos sorbs strongly to soil or disperses to the atmosphere following application. Limited quantities may enter aquatic environments with spray drift or run-off, and will mainly partition to sediment where slow to moderate degradation occurs. Atmospheric persistence appears limited, while residues in soil are degraded at a moderate rate by chemical and microbial processes.

Consistent with its properties, chlorpyrifos is very much an occasional contaminant of surface waters, but can reach high levels on occasion. The use pattern of main concern with respect to high level surface water contamination is termite protection, which involves much higher rates of application than agricultural treatments. Chlorpyrifos is also a common contaminant of sewage in the Sydney region, probably reflecting ingress into the sewer system from diffuse sources. Similar contamination is likely in other urban areas.

Levels of contamination arising from agricultural uses are much lower, generally below 1 µg/L on the rare occasions that chlorpyrifos is detected in Australian surface waters. Extensive monitoring has been conducted in the cotton areas of northern NSW and the irrigation areas in southern NSW, using grab samples. There are a few high outliers, reaching 26 µg/L in northern rivers and 25 µg/L in irrigation drainage adjacent to rice bays in southern NSW, but these appear to be isolated occurrences which are seldom detected because of the limited aquatic persistence of chlorpyrifos. In some cases, non-agricultural uses such as termite protection of bridges may contribute. Although detections in grab samples are infrequent, continuous samplers found chlorpyrifos at two sites in northern NSW where grab samples remained consistently negative during the 1997-98 spray season. The rate of detection of chlorpyrifos in water samples remained low during the 1998-99 season, but sediment sampling detected chlorpyrifos at five locations among the eighteen sampled.

As a broad spectrum insecticide, chlorpyrifos is very highly toxic to a broad range of insects, including beneficial species. Very high toxicity is also evident to aquatic arthropods, in both laboratory and field situations. Chlorpyrifos is also very highly toxic to fish, but less so than to aquatic invertebrates. Fish kills have been reported where aquatic contamination is high, with termiticide treatments a common cause, particularly if followed by heavy rain (concentrations of several hundred µg/L have been recorded). Fish kills from agricultural uses are also possible in misuse situations such as direct overspray, but none appear to have been reported in Australia. Kills of aquatic fauna in the field appear to be infrequent, notwithstanding very high laboratory toxicity, because of the limited persistence of chlorpyrifos in the water column.

Chlorpyrifos is slightly to moderately toxic to mammals under conditions of acute exposure, and has relatively low mammalian toxicity compared with other organophosphorus insecticides. Birds are more sensitive, with high to very high toxicity recorded in the laboratory. Chlorpyrifos has been implicated in a number of bird kills in Australia, most notably a major die off at an ibis rookery in the Macquarie Marshes in 1995. While conclusive proof of causation is lacking for most of these incidents, the weight of evidence indicates that chlorpyrifos will give rise to occasional bird kills, particularly in predatory and scavenging species feeding on contaminated invertebrates. Overseas evidence suggests that reptiles have similar sensitivity.

Label restraints need to be strengthened by incorporating statements that are designed to minimise spray drift and environmental contamination. Users, particularly in urban areas, should be better educated in order to minimise the frequency of surface water contamination and incidents involving aquatic and terrestrial wildlife.

Residue Limits

Crop protection uses of chlorpyrifos were the primary focus of the residues evaluation. Non-food uses, plus a recently-registered direct veterinary treatment were considered, however no changes to existing animal commodity MRLs resulted from the assessment of these products.

In the majority of crop situations, existing MRLs were established on minimal Australian data or on overseas data in support of an Australian use pattern. Where appropriate residue data was inadequate or missing, it was considered that such use patterns were not supported by contemporary regulatory standards. The existing MRLs for certain commodities (such as asparagus, bananas, brassica vegetables, cereals, citrus fruits, grapes, oilseeds (except cotton), pineapples, pome fruits, stone fruits, sugar cane, tomatoes, tree nuts and vegetables (excluding those mentioned above) will become temporary until appropriate data are submitted and evaluated).

There are several crops and processed crop commodities for which residues data are either deficient or lacking (*e.g.* cereal grains, legume animal feeds, pastures, grapes [pomace and marc] and sugar cane). In view of the data deficiencies, the existing animal commodity MRLs will become temporary until data are provided in support of the feed commodities which have been identified.

Given the wide range of registered uses for vegetables, the current entry for vegetables (MRL of *0.01 mg/kg) is recommended to be deleted and replaced with entries for specific vegetable crops. However, until specific uses on product labels are supported and the appropriate data generated and assessed, the vegetable MRL will remain temporary.

7.3 Proposed Regulatory Action

As outlined above, the assessments conducted as part of the review point to possible public health and environmental concerns associated with the use of chlorpyrifos. The NRA aims to address these concerns using the proposed regulatory actions for chlorpyrifos.

The toxicology assessment indicated that some formulations of chlorpyrifos, currently accessible to householders may pose an unacceptable risk to these users. Accordingly, a series of restrictions and risk mitigating measures for these products have been recommended. The re-examination of the aggregate exposure to chlorpyrifos, revealed that the current labels do not specifically preclude indoor broadcast applications. The labels have been strengthened to provide clear directions to users/applicators to prevent indoor broadcast applications of chlorpyrifos. Environmental concerns warrant new and improved warnings on chlorpyrifos product labels. The residues assessment has identified that for some use patterns there are little or no data on which to establish/maintain residue standards.

The public consultation process enabled the NRA to obtain detailed comment on the proposed regulatory action for chlorpyrifos and commitments to generate the required data from stakeholders. In the light of stakeholder comments, the NRA also made further refinements to its regulatory approach for chlorpyrifos. Commitments to provide the required residue data have been accepted on the understanding that these will be submitted within a mutually acceptable time frame. These initial commitments notwithstanding, failure to provide data for whatever reason would mean that the NRA will have insufficient information to satisfy itself of the absence of an undue hazard associated with the continued use of chlorpyrifos. The NRA would therefore be obliged to take further regulatory measures that could include the cancellation of registrations of products containing this chemical.

7.4 Changes to Labels and Conditions of Registration

The following changes will apply as appropriate to the labels and registered details of products containing chlorpyrifos.

Recommendation 1: First Aid and Safety Directions

First Aid Instructions

No changes to First Aid Instructions have been proposed for chlorpyrifos or products containing chlorpyrifos.

Safety Directions (SD)

Table 1. Current FAISD Handbook entries
*(Including recommended amendments in **bold** text)*

Current entry	TGA recommendation	NOHSC recommendation
HG BA 5 g/kg or less in a plastic labyrinth	No changes to existing SD	No changes to existing SD
BL 500 g/L or less	No changes to existing SD	**Remove** entry from FAISD Handbook
DU 30-50 g/kg	No changes to existing SD	No changes to existing SD
EC for termiticide application except as otherwise specified	No changes to existing SD	**Remove** entry from FAISD Handbook
EC 500 g/L or less EC ME 500 g/L or less (termiticide application by hand spray)	No changes to existing SD	**Replace 295** (elbow-length (nominate other specific material) gloves) with **294** (elbow-length PVC gloves) **Remove "by hand spray"**
EC ME 200 g/L or less	No changes to existing SD	No changes to existing SD
EC greater than 200 g/L, 500 g/L or less EC ME greater than 200 g/L, 500 g/L or less ULV 500 g/L or less WP 500 g/L or less	**Add 161, 162** **Will irritate the eyes and skin**	**Add LC greater than 200 g/L, 500 g/L or less** No changes to existing SD

GR 100 g/kg or less, in controlled slow release form	No changes to existing SD	No changes to existing SD
HG GR 50 g/kg or less	No changes to existing SD	No changes to existing SD
HV ME 50 g/L or less	No changes to existing SD	No changes to existing SD
LD 10-20 g/L	**Add** **AC 10-20 g/L** No changes to existing SD	No changes to existing SD
SR 10 g/kg or less	No changes to existing SD	No changes to existing SD
SR (impregnated paper)	No changes to existing SD	No changes to existing SD
SR (pet collar)	No changes to existing SD	No changes to existing SD
SR 140 g/kg	No changes to existing SD	**Replace 300** (half face respirator) with **292b 294** (cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length PVC gloves); **Replace 364** (respirator …) with **361 366** (gloves and contaminated clothing)
WG 750 g/kg or less	No changes to existing SD	No changes to existing SD
WG ST 750 g/kg or less when packed in sealed water soluble bags	No changes to existing SD	No changes to existing SD

Table 2. New FAISD handbook entries

New entry	**TGA recommendation**	**NOHSC recommendation**
ME gel 16 g/L (microencapsulated compound in a gel formulation)	160 161 210 211 351 May irritate the eyes and skin. Avoid contact with eyes and skin. Wash hands after use.	No additional PPE required
HG ME PA 16 g/L (microencapsulated compound in a paste formulation)	160 161 210 211 351 May irritate the eyes and skin. Avoid contact with eyes and skin. Wash hands after use.	No NOHSC advice required
BA 20 g/kg	160 161 210 211 351 May irritate the eyes and skin. Avoid contact with eyes and skin. Wash hands after use.	When using the product wear chemical-resistant gloves (*).
EC 225 g/L or less with dichlorvos 250 g/L or less in liquid hydrocarbon		To be finalised during dichlorvos ECRP review

Note: Bold text in Table 1 above indicates amendments to current First Aid Instructions and Safety Directions Handbook entries for these formulation types. For complete Safety Directions for the respective formulation type, refer to the current edition of the Handbook.

(*) NOHSC advice for PPE was (279, 283, 290, 294, 360, 361, 366) "When using the product wear elbow-length PVC gloves. After each day's use wash gloves and contaminated clothing". The PPE specified in the table above is considered appropriate for this product.

Recommendation 2: Home Garden and Indoor Use of Certain Chlorpyrifos Products - Public Health Implications

The toxicology assessment has identified that there are a number of emulsifiable concentrate (EC) and/or liquid concentrate (LC) formulations registered for use in

domestic, home garden and/or lawn areas. Most of these formulations contain chlorpyrifos at concentrations between 240 and 500 g/L, and are available in home garden pack sizes (1 litre or less). The toxicity of these formulations is such that they do not comply with NRA Guidelines for pesticides used by householders.

The NRA guidelines "Guidelines for pesticides used by householders, Ag Requirements Series, Part 3, Toxicology, Appendix 3-1" indicate that pesticides for household, home garden or domestic use should be relatively harmless or capable of causing only mild illness if poisoning occurs. They should not cause irreversible toxicity on repeated exposure, nor require the use of safety/personal protective equipment that is not readily available to householders. It is generally regarded that liquid formulations containing chlorpyrifos at 50g/L or less are acceptable in terms of their compliance with the NRA guidelines.

The following risk-mitigation measures are to reduce public health risks from the use of these products:

1. Registrations and label approvals of all EC and LC products based on the Code of Practice for Labelling Home Garden and Domestic Pest Control Products (Home Garden Labelling Code) and that contain chlorpyrifos in amounts greater than 50 g/L shall be cancelled.

2. Labels of all emulsifiable concentrate (EC) and liquid concentrate (LC) products containing chlorpyrifos in amounts greater than 50 g/L and in pack sizes of 1 Litre or less must include statements *"This product is too hazardous for use by householders. Householders must not use this product in or around the home."*

3. Registrations and label approvals of all EC and LC products containing chlorpyrifos in amounts greater than 50 g/L and in pack sizes of 1 Litre or less that do not include the label statements *"This product is too hazardous for use by householders. Householders must not use this product in or around the home."* shall be cancelled.

Indoor use of chlorpyrifos

It has become apparent in the course of re-examination of the aggregate exposures to chlorpyrifos, that the current labels do not specifically preclude indoor broadcast applications. While the product labels supported crack and crevice treatments, they did not contain statements to prevent indoor broadcast use. In order to provide clear instructions to users/applicators, specific statements will be placed on labels of certain products as follows:

4. Label of any product containing chlorpyrifos at concentrations above 5% that can be applied inside buildings as a spray, must contain the statements *"DO NOT apply inside buildings except as a crack and crevice treatment. DO NOT apply to surface areas such as interior floors or walls."*

Recommendation 3: Label Warnings for Occupational Health and Safety

The following re-entry period statements must be included on product labels as appropriate:

(a) Field crops, tree crops and vines: Do not allow entry into treated crops until spray deposits have dried. If prior entry is required, limit duration of entry and wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.

***(b) Greenhouses*:** Do not allow entry into greenhouses until spray deposits have dried and treated areas are adequately ventilated. If prior entry is required, limit duration of entry and wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), chemical resistant gloves and half-facepiece respirator. Clothing must be laundered after each day's use.

(c) Cotton chippers: Do not allow entry into treated areas until spray deposits have dried. After this time, wear shoes, or boots, socks, long trousers, long sleeved shirt, gloves and hat.

(d) Pre-construction termite control

Suspended floors: DO NOT allow entry until treated areas are completely dry (normally 3-4 hours)

Concrete slabs: cover immediately after treatment with a moisture membrane

(e) Post-construction termite control and general pest control

Re-entry to treated areas: DO NOT permit re-occupation of any premises until treated areas are completely dry (normally 3-4 hours) and adequately ventilated.

Recommendation 4: Label Warnings for Environmental Protection

In order to avoid run-off and drift after application as well as reduce other risks to the environment from the use of chlorpyrifos, the following statements must be incorporated on product labels as appropriate:

For termiticide products:

10. VERY HIGHLY TOXIC TO FISH AND AQUATIC INVERTEBRATES. Rinse waters, and run-off from treated areas MUST NOT enter drains or waterways. For under-slab treatments, the moisture membrane MUST be installed immediately after treatment. Do NOT apply to waterlogged soils. Do NOT apply if heavy rains are expected to occur within 48 hours of application.

11. HIGHLY TOXIC TO BIRDS. Do NOT treat fill unless it has been placed back in the trench to form the chemical soil barrier.

For agricultural products:

12. HIGHLY TOXIC TO BIRDS AND REPTILES. VERY HIGHLY TOXIC TO FISH AND AQUATIC INVERTEBRATES.

13. DO NOT re-apply to the same crop within 7 days (unless specifically recommended in the directions for use)

14. Spray drift may occur under adverse meteorological conditions or from certain spray equipment. Do NOT allow spray to drift onto sensitive areas including, but not limited to, natural streams, rivers or waterways and human dwellings. A spray drift management strategy such as those in the 'Best Management Practices Manual for Cotton Growers' or the 'Pilots and Operators Manual' should be applied.

    Options for minimising drift to sensitive areas include not spraying within a certain distance of sensitive areas when the wind is blowing towards them (see table for guidance) or ensuring that drifting spray will be intercepted by a catching surface such as a row of shelter trees, an unsprayed row of orchard trees, or hail netting.

Situation	Recommended buffer distance (m)
Orchard (dormant trees, citrus, large trees)	30
Cotton (aerial application)	300
Other crops (aerial application)	100

15. DO NOT apply if heavy rains or storms that are likely to cause surface runoff are forecast in the immediate area within two days of application.

16. DO NOT apply when irrigating, or to waterlogged soil, or while water remains on the surface or in furrows, unless tailwater is captured on farm.

17. DO NOT allow contaminated runoff water from treated paddocks to enter adjacent areas or water bodies. Runoff contaminated by irrigation events (tailwater) and a 25 mm rain storm should be captured on farm for two days after application.

18. All labels of chlorpyrifos granular ant control products registered for use in the home garden should carry the following statements:

    Do NOT heap granules.
    These granules may kill birds if ingested.
    Do NOT feed granules or otherwise expose to wild or domestic birds.

Recommendation 5: Label Statements Associated with Residues and Maximum Residue Limits

The following statements apply to product labels as appropriate.

1. The prohibition for human consumption of chlorpyrifos treated grapevine leaves should be removed from labels.

2. For **cotton** the following withholding periods are required:

(i) DO NOT harvest for 4 weeks after application
(ii) DO NOT graze or cut for stockfood for 4 weeks after application
3. For major animal feeds (cereal grains, legume animal feeds, grasses, grass-like plants, pastures and other forages/forage crops) the following grazing restraint applies:

(i) DO NOT graze or cut for stockfood for 2 days after application

Recommendation 6: Changes to the MRL Standard

Table 7X: Chlorpyrifos MRLs: Proposed Changes from Review

Commodity	MRL Prior to review	Amended MRL	Comment
Asparagus	0.5	T0.5	**HRDC to provide indication of interest**
Avocado	0.5	0.5	No change to the current MRL and no additional data required.
Banana	T0.5	T0.5	Data required for bunch spray use pattern
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.5	T 0.5	Further data being evaluated. Commitment obtained from registrant to conduct new studies.
Cassava	*0.02	T*0.02	Proposed to be grouped under 'Root vegetables' classification. Further data being evaluated.
Celery	T5	T5	Further data to be evaluated. MRL will remain as temporary pending evaluation of data.
Cottonseed	0.05	0.05	No change to the current MRL and no additional data required.
Cottonseed oil, crude	0.2	0.2	No change to the current MRL and no additional data required.
Cattle, Edible offal of	2		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. Temporary MRL for Edible offal (mammalian)
Cattle meat [in the fat]	2		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. Temporary MRL for meat (mammalian) [in the fat].
Edible offal (mammalian)		T0.1	Further data to be evaluated. MRL will remain as temporary pending evaluation of data.
Meat [mammalian] [in the fat]		T0.5	Further data to be evaluated. MRL will remain as temporary pending evaluation of data.
Cereal grains [except sorghum]	0.1	T0.1	New data to be evaluated. Registrant commitment to conduct new studies obtained.
Citrus fruits	0.5	T0.5	Further data to be evaluated. MRL will remain as temporary pending evaluation of data.
Dried fruits	2		MRL to be deleted and replaced by Temporary MRL for appropriate Codex Commodity classification, i.e. Dried Grapes
Grapes	1	T1	Existing MRL proposed to be deleted and replaced by Temporary MRL. Registrant commitment to conduct new studies obtained.

Commodity	MRL Prior to review	Amended MRL	Comment
Dried grapes (currants, raisins, and sultanas)		T2	Temporary MRL established for appropriate Codex Commodity classification, i.e. Dried Grapes.
Eggs	0.01	T0.01	Further data to be evaluated. MRL will remain as Temporary pending evaluation of data.
Kiwi fruit	2	2	No change to the current MRL and no additional data required.
Mango	*0.05	*0.05	No change to the current MRL and no additional data required.
Milks [in the fat]	T0.2	T0.2	No change to the current MRL and no additional data required.
Oilseed	0.01	T0.01	Existing MRL to be deleted and replaced by Temporary MRL for Oilseed (except cotton seed) while new data are assessed.
Oilseed (except cotton seed)	T0.05	T0.05	Temporary MRL T0.05 established for Codex Commodity classification. Commitment to generate new data has been obtained from registrant.
Passionfruit	*0.05	*0.05	No change to the current MRL and no additional data required.
Pig, Edible offal of	0.1		MRL proposed to be deleted and replaced by appropriate Codex Commodity classification, i.e. Edible offal (mammalian).
Pig meat [in the fat]	0.1		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. Edible offal (mammalian) [in the fat].
Pineapple	0.5	T0.5	Existing MRL to be deleted and replaced by Temporary MRL while data is being generated.
Pome fruits	0.2	T0.5	Further data to be assessed. Existing MRL to be deleted and replaced by Temporary MRL while new data is assessed.
Poultry, Edible offal of	0.1	T0.1	MRL to remain as temporary pending assessment of new data.
Poultry meat [in the fat]	0.1	T0.1	MRL to remain as temporary pending assessment of new data.
Sheep, Edible offal of	0.1		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. Temporary MRL for Edible offal (mammalian)
Sheep meat [in the fat]	0.1		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. meat (mammalian) [in the fat].
Sorghum	3	T3	Existing MRL to be deleted and replaced by Temporary MRL while data are being generated.
Stone fruits	1	T1	Existing MRL to be deleted and replaced by Temporary MRL pending assessment of new data.
Strawberry	0.05	0.05	No change to the current MRL and no additional data required.
Sugar cane	0.1	T0.1	Existing MRL to be deleted and replaced by Temporary MRL pending assessment of new data.
Tomato	0.5	T0.5	Existing MRL to be deleted and replaced by Temporary MRL pending assessment of new data.

Commodity	MRL Prior to review	Amended MRL	Comment
Vegetables [except asparagus; brassica, cassava; celery; potato; tomato, sweet potato]	*0.01	T*0.01	Existing MRL to be deleted and replaced by Temporary MRL. Separation of generic vegetable entry into single commodity entries or group entries expected.
Cotton fodder, dry	30	30	No change to the current MRL and no additional data required.
Cotton meal and hulls	0.05	0.05	No change to the current MRL and no additional data required.

The residue definition for all chlorpyrifos MRLs remains unchanged as **"Chlorpyrifos".**

7.5 Notes on MRLs and Residue Data Requirements

1. Retention of MRLs (temporary use or otherwise) will depend on the provision of relevant and appropriate (preferably Australian) residue data or argument.

2. Establishment of a re-entry period for animals entering areas treated with chlorpyrifos for mosquito control (the re-entry period on labels will remain as 24 hours during the interim period while data is being generated).

3. Further data requirements for ginger root, and potatoes are not considered in the above table as these data requirements pertain to off-label uses under permit. Persons wishing to support these uses with further data should liaise with the Permits Section of the NRA.

4. As indicated in Table 7X, there are specific uses and commodities for which data are available and yet to be assessed or uses for which new data are being generated. This is on the basis of commitments that have already been made by various stakeholders.

5. If for whatever reason the studies are not proceeded with or if the assessment of data does not satisfy the NRA, any associated uses that remain unsupported will be deleted from labels.

ATTACHMENT 1 – LIST OF REGISTERED PRODUCTS AND APPROVED ACTIVE CONSTITUENTS (as at 3 August 2000)

NCRIS	PRODUCT NAME	COMPANY NAME
32220	Rentokil Chek-Pest 'C' Domestic Insecticide	Rentokil Initial Pty Ltd
32879	Campbell Pyrinex 500 EC Insecticide	Colin Campbell (Chemicals) Pty Ltd
32881	Campbell Pyrinex 250 WP Insecticide	Colin Campbell (Chemicals) Pty Ltd
32882	CRG Grass-Gard Lawn Insecticide	Chemical Recovery Co Pty Ltd
32883	Chemspray Ant, Spider & Cockroach Killer Insecticide	Garden King Products Pty Ltd
32884	Chemspray Chlorban Insecticide	Garden King Products Pty Ltd
32887	Lorsban 500 EC Insecticide	Dow Agrosciences Australia Ltd
32889	Dursban Micro-Lo Termiticide And Insecticide	Dow Agrosciences Australia Ltd
32890	Dursban PC Termiticide And Insecticide	Dow Agrosciences Australia Ltd
32891	Dursban Turf-500 Insecticide	Dow Agrosciences Australia Ltd
32894	Lorsban 500 WG Insecticide	Dow Agrosciences Australia Ltd
32897	David Grays Chlorpyrifos 200 Termite Spray	David Gray & Co. Pty Limited
32902	Nufarm Chlorpyrifos 500 EC Insecticide	Nufarm Australia Limited
32903	Nufarm Chlorpyrifos ULV500 Insecticide	Nufarm Australia Limited
32904	Garden King Antkil Granular Insecticide	Garden King Products Pty Ltd
32905	Garden King Peskil C Insecticide	Garden King Products Pty Ltd
32908	Deter Insecticide	Aventis Cropscience Pty Ltd
32909	Chlorfos Insecticide	Aventis Cropscience Pty Ltd
33198	CRG Ban Ant	Chemical Recovery Co Pty Ltd
33589	Watch Cat 8 Month Flea Collar	Friskies Pet Care Pty Ltd
33605	Zodiac Long Life Flea Cat Collar	Novartis Animal Health Australasia Pty Ltd
36396	Watchdog 9 Month Flea Collar	Friskies Pet Care Pty Ltd
36918	Exelpet No Fleas Flea And Paralysis Tick Spray For Dogs	Exelpet Products (A Division Of Effem Foods Pty Ltd)
36919	Exelpet Red 5 Month Flea Collar For Dogs	Exelpet Products (A Division Of Effem Foods Pty Ltd)
36920	Exelpet Red 8 Month Flea Collar For Cats	Exelpet Products (A Division Of Effem Foods Pty Ltd)
38930	Vet-Kem Long Life Flea Cat Collar	Novartis Animal Health Australasia Pty Ltd
38933	Zodiac Long Life Flea & Tick Dog Collar	Novartis Animal Health Australasia Pty Ltd
39222	David Grays Antex Granules	David Gray & Co. Pty Limited
39267	Pyrinex 250 WP Insecticide	Makhteshim-Agan (Australia) Pty Limited
39268	Pyrinex 500 EC Insecticide	Makhteshim-Agan (Australia) Pty Limited
39885	Nufarm Chlorpyrifos PCO Insecticide	Nufarm Australia Limited
39910	Nufarm Chlorpyrifos PCO Micro-Emulsion Insecticide	Nufarm Australia Limited
40117	Vet-Kem Long Life Flea And Tick Dog Collar	Novartis Animal Health Australasia Pty Ltd
40812	Campbell Pyrinex 500 WP Insecticide	Colin Campbell (Chemicals) Pty Ltd
41073	CRG Terminant Plus Ant And Termite Killer	Chemical Recovery Co Pty Ltd
41396	Hygrain Beetle Bait - Pellets	Hygrain Pty Ltd

41781	Pyrinex 300 ULV Insecticide	Makhteshim-Agan (Australia) Pty Limited
41818	Addimix Chlorpyrifos Insecticide 500 EC	Addimix Pty Ltd
42032	David Grays Lawn Beetle Granules	David Gray & Co. Pty Limited
42033	David Grays Lawn Beetle Spray	David Gray & Co. Pty Limited
42039	David Grays PCO Chlorpyrifos 500	David Gray & Co. Pty Limited
42062	Hygrain Beetle Baits	Hygrain Pty Ltd
42081	Monsan Beetle Bait	Monsan Pty. Ltd.
42284	David Grays Chlorpyrifos 500	David Gray & Co. Pty Limited
44005	Chlorpyrifos TGAC	Makhteshim-Agan (Australia) Pty Limited
45068	Brunnings Lawn Beetle Destroyer	Brunnings Garden Products Pty Ltd
45227	Ant-Out Granular Insecticide	Pest Control Technologies International Pty Ltd
45449	Brunnings Lawn Grub Destroyer	Brunnings Garden Products Pty Ltd
45486	Farmoz Strike-Out 500 EC Insecticide	Farmoz Pty Ltd
45518	Country Chlorpyrifos 500 Insecticide	A & C Rural Pty Ltd
46154	Mortein Plus 6 Superbaits	Reckitt & Colman Pty Ltd
46435	Mortein Plus 12 Superbaits	Reckitt & Colman Pty Ltd
46677	Baygon Mothpaper	Bayer Australia Limited (Consumer Care)
47022	Richgro Garden Products Ant Killer	A Richards Pty Ltd
47023	Richgro Garden Products Lawn Beetle Killer	Richgro Garden Products
47528	Crg Lawn Beetle Blitz Insecticide	Chemical Recovery Co Pty Ltd
47538	Suscon Blue Soil Insecticide	Crop Care Australasia Pty Ltd
47760	Master 250 CS Insecticide	Makhteshim-Agan (Australia) Pty Limited
47991	SC Johnson Wax Raid Max 12 Roach Terminators Plus 3 Egg Stoppers	S.C. Johnson & Son Pty Ltd
47992	SC Johnson Wax Raid 6 Ultra Baits	S.C. Johnson & Son Pty Ltd
47993	SC Johnson Wax Raid 18 Ultra Baits	S.C. Johnson & Son Pty Ltd
48029	Dursban Pre-Construction Termiticide	Dow Agrosciences Australia Ltd
48051	David Grays Micro-Lo Chlorpyrifos Termiticide And Insecticide	David Gray & Co. Pty Limited
48069	Davison Chlorpyrifos 500 EC Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
48146	David Grays Pre-Construction Chlorpyrifos Termiticide	David Gray & Co. Pty Limited
48448	Agchem Chlorpyrifos 500 EC Insecticide	Chemag Pty Ltd
48624	Blattanex (Bayer) Cockroach Baits	Bayer Australia Limited (Animal Health)
48625	Cyren PC Insecticide	Cheminova Australia Pty Limited
48662	Richgro Garden Products Slater Killer	A Richards Pty Ltd
48764	Iban 500 EC Insecticide	United Phosphorus Ltd
48770	Farmoz Strike-Out PC Termiticide And Insecticide	Farmoz Pty Ltd
48774	Lief Chlorpyrifos Insecticide	Lief Resources Pty Ltd
48795	Oztec Chlorpyrifos 500 EC Insecticide	Oztec Rural Pty Ltd
48911	Mortein Plus Nest Kill 12 Superbaits	Reckitt & Colman Pty Ltd
48958	Richgro Garden Products Ant, Spider & Cockroach Killer Insecticide	A Richards Pty Ltd
48998	Cyren 500 EC Insecticide	Cheminova Australia Pty Limited
49008	Permakill Insecticide	Flamestar Pty Ltd
49055	Predator 300 Insecticide	Dow Agrosciences Australia Ltd
49165	Summit Chlorpyrifos Insecticide	Sumitomo Australia Ltd

49315	Richgro Garden Products Lawn Beetle And Grub Killer	A Richards Pty Ltd
49399	Hortico Lawn Beetle & Slater Killer Granules	Hortico (Aust) Pty Ltd
49454	Garden King Fix Ant Insecticide	Garden King Products Pty Ltd
49473	Creofos Pre-Construction Termiticide	Gainsleek Pty Ltd
49551	Farmoz Strike-Out 250 WP Insecticide	Farmoz Pty Ltd
49666	Barmac Chlorpyrifos G Granular Insecticide	Barmac Industries Pty Ltd
49760	Garden King Lawn Beetle Bomb	Garden King Products Pty Ltd
49766	Baygon (Bayer) Cockroach Stopper	Bayer Australia Limited (Consumer Care)
49809	Empire Insecticide	Dow Agrosciences Australia Ltd
49816	Barmac Chlorpyrifos Insecticide	Barmac Industries Pty Ltd
49869	4 Farmers Chlorpyrifos 500 Insecticide	4farmers Pty Ltd
49944	Proficid (Bayer) Cockroach Paste	Bayer Australia Limited (Animal Health)
50002	Proficid (Bayer) Cockroach Baits	Bayer Australia Limited (Animal Health)
50232	Farmoz Instinct 300 Cotton Insecticide	Farmoz Pty Ltd
50246	Garden King Fix Ant Granular	Garden King Products Pty Ltd
50283	Termfos Termiticide And Insecticide	Pest Management Solutions (A Division Of Nambla Pty Ltd)
50318	Garden King Grubkil Insecticide	Garden King Products Pty Ltd
50335	Richgro Garden Products Lawn Grub And Beetle Killer Insecticide	A Richards Pty Ltd
50384	Scientific Professional Formulation Insecticide	David Gray & Co. Pty Limited
50387	Qm Profos 500 Termiticide And Insecticide	Quadron Manufacturing Pty Ltd
50388	Qm Chlorpyrifos 500 Insecticide	Quadron Manufacturing Pty Ltd
50416	Suscon Green Soil Insecticide	Crop Care Australasia Pty Ltd
50452	Qm Profos 450 Termiticide And Insecticide	Quadron Manufacturing Pty Ltd
50459	Pest One Termiticide And Insecticide	Pest One Pest Control Products Pty Ltd
50566	David Grays Grubkiller Insecticide	David Gray & Co. Pty Limited
50581	Chlorpyrimax 500 Insecticide	Artfern Pty Ltd
50644	S.C. Johnson Wax Raid Maxkill. The Total Cockroach System	S.C. Johnson & Son Pty Ltd
50740	Baygon (Bayer) Cockroach Stopper Killing Gel	Bayer Australia Limited (Consumer Care)
50751	Bar 500ec Insecticide	Sanonda (Australia) Pty Ltd
50753	Optem Pre-Construction Termiticide	Pest Control Technologies International Pty Ltd
50754	Optem 500 Termiticide And Insecticide	Pest Control Technologies International Pty Ltd
50845	Exelpet Fleaban Red 8 Month Flea Collar For Cats	Exelpet Products (A Division Of Effem Foods Pty Ltd)
50931	Protector 500 EC Insecticide	P M Young (Nsw) Pty Ltd
50956	Creofos Pre-Construction - Post-Construction Termiticide & Insecticide	Gainsleek Pty Ltd
51044	Protector 450 Termiticide And Insecticide	P M Young (Nsw) Pty Ltd
51053	Chemturf Argenstem Turf Insecticide	Chemturf Pty Ltd
51107	Suscon Ultra Soil Insecticide	Crop Care Australasia Pty Ltd
51140	Exelpet Fleaban No Fleas Flea & Paralysis Tick Spray For Dogs	Exelpet Products (A Division Of Effem Foods Pty Ltd)
51151	Country Pre-Construction/Post-Construction Termiticide And Insecticide	A & C Chemicals Pty Ltd
51180	Qm Prefos Pre-Construction Termiticide	Quadron Manufacturing Pty Ltd
51190	Chemag Chlorpyrifos 500 Insecticide	Chemag Pty Ltd
51211	Lorsban 750 WG Insecticide	Dow Agrosciences Australia Ltd

51258	Davison Low Odour Chlorpyrifos 500 EC Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
51286	Snare Termiticide	Dow Agrosciences Australia Ltd
51306	Davison Chlorpyrifos 300 ULV Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
51372	Australian Fine Chemicals Pro-Tek Pre-Construction Termiticide	Jenny Richardson T/As Australian Fine Chemicals
51404	Cropro Optem EC 500 Insecticide	Pest Control Technologies International Pty Ltd
51448	Superfos Termiticide And Insecticide	R.V. Pidgeon
51473	Chlorfos ULVInsecticide	Aventis Cropscience Pty Ltd
51513	Cyren 500 WP Insecticide	Cheminova Australia Pty Limited
51524	Y-Tex Warrior Insecticidal Cattle Ear Tags	Flycam Pty Ltd
51558	Pif Paf Nest Kill Cockroach Baits	Reckitt & Colman Pty Ltd
51563	Generifos 300 Ec/ULV Insecticide	Grow Choice Pty Limited
51566	O'briens Beetle Bait	O'briens Trading Pty Ltd
51567	Optem Pt 45 Termiticide And Insecticide	Pest Control Technologies International Pty Ltd
51592	Prefos Termiticide	Chemag Pty Ltd
51624	Prowler 300 Insecticide	Chemag Pty Ltd
51626	Generex Chlorpyrifos 500 EC Insecticide	Generex Australia Pty Ltd
51727	Pest One Agricultural Insecticide	Pest One Pest Control Products Pty Ltd
51769	Garrards Ant Killer 50	Garrard's Pesticides Pty Ltd
51792	Jwk Chlorpyrifos 450 Termiticide And Insecticide	Jwk Services Pty Ltd
51840	Voodoo 500 Insecticide	Sipcam Pacific Australia Pty Ltd
51875	Pidgeon's Pest Controller 500 Termiticide And Insecticide	R.V. Pidgeon
51897	Cropro Eclipse 300 Insecticide	Pest Control Technologies International Pty Ltd
51963	Protem Termiticide And Insecticide	Pest Control Technologies International Pty Ltd
51965	Pro-Tek Termiticide & Insecticide	Jenny Richardson T/As Australian Fine Chemicals
51983	Chlorpyrifos Tgac	Unisun Chemicals Pty Ltd
52023	Davison Banshee 300 Duo Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
52037	Nomix Chlorpyrifos 500EC Insecticide	Nomix Australia Pty Ltd
52038	Kensban 500ec Insecticide	Chin-Huat Teo For Kenso Corporation (M) Sdn Bhd
52045	Cyren 300 ULV/EC Instecticide	Cheminova Australia Pty Limited
52046	Promex Pco Termiticide & Insecticide	Lawlor Chemical Industries Pty Ltd
52049	Nufarm Pirate 300 Insecticide	Nufarm Australia Limited
52167	Munns Lawn Grubs, Lawn Beetle Grubs & Slater Killer With Long Life Organically Advanced Weta-Lawn	Munns Lawn Co Pty Ltd
52235	Farmoz Cyren 500 WP Insecticide	Farmoz Pty Ltd
52289	Exelpet Fleaban 8 Month Flea Collar For Cats	Exelpet Products (A Division Of Effem Foods Pty Ltd)
52344	Cropro Zigma 300 Insecticide	Pest Control Technologies International Pty Ltd
52564	David Grays Antex 50 Granular Professional Insecticide	David Gray & Co. Pty Limited
52585	Termispray 500 Insecticide And Termiticide	Termiproducts Pty Ltd

52596	United Farmers Chlorpyrifos 500 Insecticide And Termiticide	United Farmers Cooperative Company Ltd
52746	Voodoo 300 Insecticide	Sipcam Pacific Australia Pty Ltd
52766	Generex Distribution Generifos 500 EC Insecticide	Grow Choice Pty Limited
52822	Davison Battleaxe 300 Duo Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
52870	Snare Termiticide And Insecticide	Dow Agrosciences Australia Ltd
52976	Crop Care Chlorpyrifos 500 EC Insecticide	Crop Care Australasia Pty Ltd

44005	Chlorpyrifos TGAC	Makhteshim-Agan (Australia) Pty Limited
44111	Chlorpyrifos TGAC	Dow Agrosciences Australia Ltd
44112	Chlorpyrifos TGAC	Dow Agrosciences Australia Ltd
44113	Chlorpyrifos TGAC	Dow Agrosciences Australia Ltd
44160	Chlorpyrifos TGAC	Dow Agrosciences Australia Ltd
46670	Chlorpyrifos TGAC	David Gray & Co. Pty Limited
46796	Chlorpyrifos TGAC	Australian Generics Pty Ltd
46888	Chlorpyrifos TGAC	Gharda Australia Pty Ltd
47155	Chlorpyrifos TGAC	Excel Industries (Australia) Pty Ltd
47254	Chlorpyrifos TGAC	Sanonda (Australia) Pty Ltd
48077	Chlorpyrifos TGAC	Lief Resources Pty Ltd
48459	Chlorpyrifos TGAC	Davison Industries An Activity Of Joyce Rural Pty Ltd
48521	Chlorpyrifos TGAC	Cheminova Australia Pty Limited
48643	Chlorpyrifos TGAC	David Gray & Co. Pty Limited
49124	Chlorpyrifos TGAC	Dow Agrosciences Australia Ltd
49340	Chlorpyrifos TGAC	Dow Agrosciences Australia Ltd
50886	Chlorpyrifos TGAC	Becot Pty Ltd T/As Imtrade
51235	Chlorpyrifos TGAC	Gharda Australia Pty Ltd
51239	Chlorpyrifos TGAC	Unisun Chemicals Pty Ltd
51983	Chlorpyrifos TGAC	Unisun Chemicals Pty Ltd

ATTACHMENT 2: SUMMARY OF RESPONSES TO THE PUBLIC RELEASE OF DRAFT REVIEW REPORT

In January 2000, the draft report from chlorpyrifos ECRP review was released for public comment. Consistent with the established practice, extensive consultation was conducted with stakeholders in Commonwealth and State authorities and industry prior to the release of the draft report.

The release of the draft report was widely publicised and written notices were sent to all who had expressed interest in or who had participated in the review thus far. The report was available to the public either via the Internet or as a printed copy upon request from the NRA. The public comment phase was originally intended for two months. However due to sustained public and media interest in chlorpyrifos, comments were received and considered beyond the two-month period.

In addition to calling for comments on the actual report, stakeholders were also requested to provide a commitment to undertake trial work to generate the necessary residues data. Residues data are required for the NRA to be satisfied that the continued use of chlorpyrifos does not pose an unacceptable risk to the people using anything containing its residues and that it does not unduly prejudice trade.

In response to the release of the draft report some 40 responses were received from individual members of the public, activist and user groups, chemical & other industry, environmental associations and Commonwealth and State government and overseas regulatory agencies. Submissions also included those from organisations producing, processing or associated with the following commodities: avocado, tropical fruits, vegetables, cotton, tobacco, pineapple, sugarcane, pome and stone fruit, citrus, longans, custard apple, ginger, hops and olives.

As expected, most comments centred on the proposed restrictions and the identified residue data gaps. Significant comments were also received on the subjects of exposure to chemicals in general and to chlorpyrifos in particular. The recent United States Environmental Protection Agency (USEPA) actions on chlorpyrifos triggered substantial public and media interest in the review. The NRA has acknowledged this interest by re-examining the relevant components of its review to ensure that the continuing use of chlorpyrifos in Australia meets the legislative criteria for safety and performance.

The following summary describes the main issues raised and concerns expressed by the respondents to the ECRP review of chlorpyrifos. Where several respondents have similar comments and concerns these have been grouped together for the ease of presentation. Views and opinions expressed remain those of the respondents and not those of the NRA or the assessing agencies. Wherever possible any assessable data accompanying public submissions has been assessed by the relevant agency advising the NRA. In the following summary, public comments and concerns are presented in normal font while the NRA responses to those concerns or the NRA proposals to address those concerns are in *italics.*

User industry views on chlorpyrifos

Most respondents from grower associations highlighted the important role that chlorpyrifos plays in their total pest management strategies.

Chlorpyrifos is a valuable insecticide in the stone fruit industry. In stone fruit, 70% of growers use chlorpyrifos in IPM programs to control such pests as light brown apple moth, thrips, dimple bug, bryobia mite, earwig, rose weevil, oriental fruit moth, garden weevil and white ants. Chlorpyrifos is particularly important in this industry for the control of San Jose Scale. In the tobacco industry chlorpyrifos is the only pre-plant insecticide currently registered for the control of certain soil borne insects.

The importance of chlorpyrifos in insect control in bananas in both NSW and QLD was highlighted. The most common application method is for bunch spraying of bananas. The control of bunch pests such as bud moth, flower thrips and rust thrips is critical to producing a marketable product. Alternative chemicals do exist, however, chlorpyrifos is preferred as it provides long-term broad spectrum control of all main bunch pests.

Chlorpyrifos is critical for the control of cutworms and crickets in vegetables as well as scale and ant control in mangoes.

Chlorpyrifos is widely used for ant control since the phasing out of organochlorine pesticides. It is known to provide efficacious ant control in longans, citrus, cucurbits, mangoes, custard apples and pineapples. It has both good contact action and a degree of residual action against a range of ant species. There appears to be no satisfactory alternatives to chlorpyrifos for ant control in fruit trees.

According to the Department of Natural Resources and Environment in Victoria, canola growers have increased their use of chlorpyrifos for control of false wireworm, used mainly prior to sowing.

The Avocado Growers Association of Western Australia states that they are a minor user of chlorpyrifos. While alternatives to chlorpyrifos exist for control against latania scale and ivy leafroller in avocados the alternatives have concerns. Oil sprays are moderately effective but can be phyto-toxic to trees in hot weather. The association further states that methidathion is used as an alternative however this is highly toxic and damaging to beneficial insects. Although alternatives are being investigated, these will probably need to be used in rotation with chlorpyrifos to obtain optimal control.

A respondent from the custard apple industry stated that chlorpyrifos is used as a trunk spray in custard apples for control of ants. The alternative to chlorpyrifos is methidathion which is disruptive to IPM control programs.

The NRA would consider the continued use of chlorpyrifos in any crop/use situation on the current label subject to the filling of data gaps and the implementation of restrictions designed to mitigate risks identified during the assessment phase. If uses are not supported by data and concerns remain, then such uses will not be retained. The longer term decisions on the use of chlorpyrifos are expected to be made when additional data has been submitted and assessed.

Domestic uses of chlorpyrifos - public health issues

Several respondents commenting on the domestic uses of chlorpyrifos question the apparent lack of attention to the exposure and effects on children and other sensitive individuals. Some respondents identified domestic use of chlorpyrifos as a risk to children and still others were of the view that chlorpyrifos is a principal contributor to multiple chemical sensitivity in certain individuals. One respondent claimed flea collars containing chlorpyrifos as being inherently dangerous and that children would be at risk if they chew or suck the collar.

Some respondents argued that the sensitive individuals would suffer greater damage from environmental and domestic exposure to chlorpyrifos and the absence of a pesticide illness reporting program in Australia would constrain the introduction of the appropriate regulatory responses.

The NSW EPA commented that the proposed statement to limiting householder use of chlorpyrifos should focus on the restriction of its use by householders, and not just the home garden applications.

The NRA does not share the view that the attention devoted to public safety in this review is lacking in any respect. Following its review of chlorpyrifos, the NRA has instituted a range of risk-mitigating measures aimed at safeguarding public health. These measures focus on areas of probable risk of public exposure and are consistent with the accepted standards of public safety.

For instance, specific regulatory action is pending on products that are identified as being non-compliant with the NHMRC/NRA guidelines relating to public health. Further labelling restrictions have been introduced to curtail residential uses of chlorpyrifos that are identified as potential sources of risk to the public.

- *All liquid products whose concentration of chlorpyrifos exceeds 5% that are supplied in home garden pack sizes (1 Litre and below) are slated for withdrawal from householder use.*

- *A warning to the effect that "This product is too hazardous for use by householders. Householders must not use this product in or around the home." will appear on labels of chlorpyrifos products of concentration greater than 5%. This restriction is intended to prevent concentrated chlorpyrifos products intended for PCO use, from being used by householders.*

- *A further statement will strengthen the regulation of indoor spray applications of chlorpyrifos.*

- *Safety directions have been reconsidered for all chlorpyrifos products and have been strengthened for the most.*

- *The review has required adequate ventilation (until complete dryness of treated areas) before reoccupying or entering treated areas. This applies to pre- and post construction termiticides and general pest control treatments.*

- *The actual data on food intake contained in the Australian Market Basket Survey of 1996 (the latest available) indicate that the intake of chlorpyrifos remains low and not considered to pose a risk to public health .*

Based on the available information on the toxicity and release properties of flea collars, the TGA considered that the risk associated with the use of chlorpyrifos flea collars was not significant for both children and adults.

On the comment regarding sensitive individuals; it is not possible to determine the role of chlorpyrifos in causing complex clinical effects in sensitive individuals incidentally exposed to indeterminate amounts of this compound. However it is recognised that long-term neurological effects have been reported in workers repeatedly exposed to organophosphate compounds. While the role of chemical exposure in the aetiology of these clinical effects has not been conclusively determined the NRA adopts a conservative approach to the regulation of organophosphate pesticides, in the interests of maintaining public and occupational health and safety. The use of plasma chloinesterase inhibition, the most sensitive indicator of toxicity to set public health standards for chlorpyrifos, is a case in point.

The issues raised on the exposure to chlorpyrifos via food, environmental and household exposures appeared in some instances to concern the use patterns in the USA. However, under Australian use conditions, the Australian Market Basket Survey has found very low chlorpyrifos food residues in the average diet. Other routes of exposure arising from the use of chlorpyrifos according to labels is considered by the appropriate authorities not to pose an unacceptable risk to the public.

Some respondents noted the lack of an adverse effects reporting register for pesticide exposures in Australia. Such data, were they available, would be very useful in recording poisoning incidents that arise from the use of chlorpyrifos, and to determine the nature of such exposures.

In view of the NSW EPA comment, an appropriate statement will be incorporated on product labels to include both home garden and other domestic uses of chlorpyrifos.

In conclusion, following a comprehensive review the public health aspects of chlorpyrifos the appropriate authorities concluded that based on the current uses of this compound, with the removal of home garden products containing more than 5% chlorpyrifos, and restrictions on indoor spray applications, it is considered that there should be no adverse effects on public health from the continued use of chlorpyrifos in Australia.

The Australian review of chlorpyrifos vis-a-vis the US EPA regulatory actions

A major issue raised during the public comments phase has been the regulatory actions of the United States Environmental Protection Agency (US EPA) on chlorpyrifos. Significant public comment revolved around the differences of Australian regulatory approaches for chlorpyrifos in comparison to those of the US EPA.

There are a number of technical and policy approaches to the regulation of pesticides that vary between different national authorities, and these have contributed to some differences in risk assessment and management strategies for chlorpyrifos in the USA as compared with Australia.

For chlorpyrifos, Australian regulators have reviewed the extensive database of toxicology studies conducted in animals and human volunteers. The public health standards in Australia have been established using the most sensitive biological effects of chlorpyrifos and based on results from studies in human subjects, and this removes the added uncertainty that comes from the use of data from animal studies. The Australian Acceptable Daily Intake (ADI) value is lower than the international equivalent established by the World Health Organisation in 1999. The data on effects of chlorpyrifos in young or developing animals have been reviewed and infants and children are not considered to be at an increased risk from chlorpyrifos products that are used according to label instructions. Chlorpyrifos residues in the Australian diet are very low and do not pose a public health risk. Household products that contain chlorpyrifos must meet strict guidelines on packaging and formulation to ensure that the risk to the public from such products continues to be low. For more hazardous chlorpyrifos products such as those used by licensed pest control operators, changes have been recommended in availability, packaging and labelling. As a result products whose toxicity makes them inappropriate for use by householders (products that contain greater than 50 g/L chlorpyrifos) will be restricted to reduce any public health risks.

The US EPA have applied extra uncertainty factors when establishing public health standards due to their use of animal studies and as mandated by the Food Quality Protection Act (FQPA). As a result, the health standards established by the US EPA (including the Reference Dose and the Population Adjusted Dose) are lower than the Australian ADI. One of the outcomes of the US EPA review is that registrants in the USA have arrived at a negotiated position that includes the withdrawal of most residential and a few agricultural uses of chlorpyrifos products over the next five years.

Short-term dietary risk considerations

A comment was made about the US restrictions regarding chlorpyrifos use on agricultural uses such as apples, tomatoes and grapes. The US EPA are discontinuing the use of chlorpyrifos on tomatoes, restricting use on apples, and reducing the tolerance (MRL) on grapes. These actions appear to have been motivated solely by short-term dietary intake considerations.

In the USA, the chronic dietary food risk did not exceed the EPA's level of concern for any of the population groups. The risks identified arose from acute dietary intake and resulted from the use of chlorpyrifos on apples (residues resulting from post-bloom uses), grapes (residues primarily on imported crops) and fresh tomatoes. The NRA has also noted that the dietary estimates for these commodities were reached using probabilistic modelling methods (Monte Carlo) at the 99.9th percentile for the most highly exposed population sub-group.

An assessment conducted using the available Australian consumption data for apples indicated that the acute dietary intake of chlorpyrifos in apples was low in relation to the applicable Australian public health standard - the acute reference dose (ARfD) of 0.01

mg/kg bw/day. The intake of chlorpyrifos at the 97.5 percentile food intake level when expressed as a fraction of the ARfD was less than half for 2-6 years old children; and less than one-fifth for the general population (7 years and above) and was not considered to pose a public health risk.

Environmental Warnings

A number of respondents raised concern over the proposed environmental warning statements. Concerns were raised by a number of State agencies noting that the wording of some of these statements would need to be amended in order for them to be enforceable. Others noted that certain statements required re-wording in order to clarify the purpose of these statements.

Amongst the key issues raised by the State authorities relate to enforceability of proposed label warnings and the need for a clear distinction between mandatory requirements and advisory information. These comments were referred to Environment Australia for consideration.

In conjunction with Environment Australia, the NRA has refined the environmental warnings wherever possible by making a clearer distinction between the advisory and mandatory statements. Where appropriate alternative risk management/mitigation measures have also been incorporated, with emphasis on environmental safety outcomes.

Buffer Zones

Many respondents expressed concern over the practicality of mandatory physical distances as buffer zones in certain use situations. Some of the issues raised were as follows:

- No allowances have been given for orchard areas situated close to human dwellings;
- New practices are being undertaken in certain industries to reduce spray drift. Studies have shown that a single row of trees can reduce up to 80% of spray drift, as an alternative to establishing particular physical distances or no-spray zones;
- The apple and pear industry stated that they recommend a row of trees or hail net curtains as having the same effect of capturing potential drift, thereby providing the protection necessary for sensitive areas;
- A clearer definition was required for droplet sizes, as well as definitions for upwind and downwind buffers and including what constitutes a sensitive area.

Having considered the above, the label statements have been modified to include additional advisory information with respect to drift reduction in addition to references to industry best practice manuals. It is recognised that alternative solutions such as tree rows or hail netting have the same effect on spray drift reduction as mandatory distances and label language has been incorporated to reflect this.

Capture of irrigation tail-water

Sugar industry representatives have expressed concern over the requirement for capturing of irrigation tailwater. They have pointed out that many sugarcane growers are unable to capture tail-water and hence could not meet this requirement.

The NRA is of the view that irrigation run-off containing chlorpyrifos residues should not be allowed to pollute adjacent areas. If tail-water cannot be captured, other methods such as improved irrigation practices should be adopted so that off-site contamination by tail-water containing chlorpyrifos residues does not occur.

The statements relating to this issue have been modified to indicate that contaminated run-off water must not be allowed to pollute adjacent areas. The on-farm retention, which is but one option for achieving this is now provided as advisory information on the label.

Mosquito Control Use

One respondent pointed out that the existing label advice on mosquito control use of chlorpyrifos as having scope for contradicting the proposed statements on environmental protection and could give rise 'blanket' sprays over mosquito refuges in residential areas, especially in the sub-tropical regions. For these reasons, it was argued that the mosquito control use should be discontinued. The NRA having considered these comments obtained further advice from Environment Australia on the mosquito control use–pattern as specified on existing labels.

Given the possibility of fine sprays being applied over vegetated aquatic areas with resultant disruptions to aquatic life, and uncertainty over varying applicator interpretations of what constitutes a 'polluted' water impoundment, Environment Australia is of the view that the mosquito control use does not meet requirements for continued registration as it is likely to be disruptive to aquatic communities. The NRA is considering the modalities for further regulation of this use including the feasibility of a phase out for the mosquito control use of chlorpyrifos. Further action is expected on this issue in the course of the interim phase for chlorpyrifos.

Data Requirements

The main area where data was required is to address residue issues associated with the use of chlorpyrifos. Additional data have been submitted in support of some use patterns, along with a commitment that further residue data will be generated to support other uses.

While data is being generated, the MRLs will remain temporary for these uses until their status can be confirmed following assessment of the appropriate data. At that time any uses which remain unsupported or where the assessment of data submitted in support of a particular use or use pattern fails to satisfy the NRA then these uses or use patterns will be deleted from labels.

Other

One respondent was of the view that all users of chlorpyrifos should undergo some formal training in the handling and application of the chemical.

The NRA shares the view that all users of pesticides should be aware of the attendant risks and exercise appropriate caution in handling and application of pesticides.

In the case of chlorpyrifos products, they are used in many different situations ranging from agricultural, professional pest control, to residential settings where they are applied in a range of different working-strengths, formulation and packaging types. Given this wide diversity, it is impractical to device a training program that would suit all users of chlorpyrifos.

Pre-construction termiticide use is identified as one where user education is seen as being essential due to high concentration of working-strength solution and the enhanced need for correct treatment and coverage. Pre-construction termiticides containing chlorpyrifos are Restricted Chemical Products by proclamation under the AgVet codes. This being so, certain mandatory requirements including those for training are applicable to the supply and use of pre-construction termiticides containing chlorpyrifos.

All State licensing schemes for pest control operators (PCO) require a level of competency in the application of pesticides. While this tends to cover the use of specialised applications of chemicals by PCOs, the residential-use chemicals used by householders also require due care and caution in their application. As a general principle, the NRA encourages the participation of all chemical users in appropriate training.