The NRA Review of

MONOCROTOPHOS

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

Telephone: (02) 6272 5158
Facsimile: (02) 6272 3551

FOREWORD

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

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

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

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.

The summary provides a brief overview of the review of monocrotophos 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.

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.*

CONTENTS

ABBREVIATIONS AND ACRONYMS

µg	microgram
µm	micrometer or micron
2-PAM	Pyridine-2-aldoxime methiodide
ACGIH	American Conference of Governmental Industrial Hygienists
ACPH	Advisory Committee on Pesticides and Health
ADI	Acceptable Daily Intake (for humans)
ai	active ingredient
ALT	Alanine aminotransferase (SGPT)
AP	Alkaline phosphatase
AST	Aspartate aminotransferase (SGOT)
BEI	Biological exposure index
BUN	Blood urea nitrogen
ChE	Cholinesterase
CPK	Creatinine phosphokinase
d	Day
DDM	4,4'-Diaminodiphenylmethane
DMSO	Dimethyl sulfoxide
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
GI	Gastrointestinal
GLP	Good Laboratory Practice
h	Hour
ha	hectare
Hb	Haemoglobin
Hct	Haematocrit
IM	Intramuscular
in vitro	outside the living body and in an artificial environment
in vivo	inside the living body of a plant or animal
IP	Intraperitoneal
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
LDH	Lactate dehydrogenase
LH	Luteinising hormone
LOEL	Lowest Observable Effect Level
LV	Low volume
m	Metre
M/L/A	Mixer/Loader/Applicator
MCH	Mean corpuscular haemoglobin
MCHC	Mean corpuscular haemoglobin concentration
MCV	Mean corpuscular volume
ME	microencapsulated
mg	Milligram
mg/kg bw/day	mg/kg bodyweight/day
mL	Millilitre
mM	Millimolar
MOE	margin of exposure
MRL	maximum residue limit
NDPSC	National Drugs and Poisons Schedule Committee
ng	Nanogram
NHMRC	National Health and Medical Research Council
nM	Nanomolar
NOEL	No Observed Effect Level
NOHSC	National Occupational Health and Safety Commission
OP	organophosphate
P-2-S	2-pyridine-aldoxime methyl methanesulfonate
PNP	p-nitrophenol
PO	Oral
POEM	Predicted Operator Exposure Model
ppb	parts per billion
PPE	personal protective equipment
ppm	Parts per million
RBC	Red blood cells/erythrocyte
SC	Subcutaneous
sec	Second
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGAC	technical grade active constituent
ULV	Ultra Low Volume
USEPA	US Environmental Protection Agency
vmd	vapour median diameter
WHP	withholding period
WSA	Worksafe Australia

EXECUTIVE SUMMARY

Monocrotophos, an organophosphate, was first registered in Australia in 1968 and has played a useful role in agriculture as a broad spectrum, systemic insecticide and acaricide in crops such as sorghum, sunflowers, tomatoes and tobacco.

Monocrotophos was proposed for review in 1996 as part of the second group of chemicals reviewed by the National Registration Authority under the Chemical Review Program (CRP).

At the initiation of the review of monocrotophos comments from the public were invited and twelve submissions were received in response to the NRA's published invitation to participate in the review process. These were from members of the public, and from environmental, government, commodity and user groups. These have been discussed in greater detail in Attachment 2.

Evaluation of all available information relating to the review of monocrotophos was completed in 1998 and a proposed regulatory approach developed following extensive consultation with registrants, users and the States. The draft report, incorporating the proposed approach was released for public comment in July 1999.

During the public consultation period of the review undertaken in July 1999 letters were sent to all groups with an interest in monocrotophos. In the letter it was emphasised that the registrants were unlikely to support this chemical and it was stated that if they wished to retain this chemical for their industry they would have to consider providing data to satisfy the data requirements. No user groups were either willing or able to generate the necessary data to retain the use for their group. There were also several submissions received from environmental and bird observer groups arguing against the retention of this chemical. These comments were used to finalise the most appropriate regulatory action to be taken. The submissions received are discussed in further detail in Attachment 3.

The review found that although it would appear that the level of efficacy required to meet current registration standards has been maintained, there has been a steady decline in the use of monocrotophos. Cheaper, more effective and less hazardous chemicals have come onto the market and the general trend towards integrated pest management has mitigated against use of this chemical because of its damaging effect on beneficial insects and mites. In addition, there has been increasing resistance in pest populations to OPs in general and monocrotophos in particular (eg. two spotted mites and western flower thrips).

The most probable source of difficulties in relation to trade was found to be some incompatibilities between Australian and trading partner Maximum Residue Limits (MRLs), although there has been no record of these resulting in trade difficulties between Australia and other countries to date. In particular, there were differences between Australian and Codex MRLs and it was likely that differences would be heightened by the removal of general cereal, fruit and vegetable MRLs by Codex over time.

SUMMARY OF KEY FINDINGS

The key findings of the review are summarised below.

Uses of monocrotophos in agriculture

There were a number of uses considered important by some sectors of agriculture in Australia. For example, the grain industry supported locust uses in broadacre situations (not supported by the Australian Plague Locust Commission or State locust control authorities); West Australia (WA) supported use in cotton and potatoes (not supported by other States or industry bodies) and Victoria supported use in tobacco and tomatoes.

Toxicology and Public Health

A comprehensive toxicology package, including human data, was reviewed and current health standards for monocrotophos confirmed. However, an additional health standard, an acute reference dose, was proposed (0.0003 mg/kg bw, based on plasma ChE inhibition seen in a 28-day human oral dosing study). The current Acceptable Daily Intake (ADI) was confirmed, as was current scheduling and first aid and safety directions.

The most likely route of exposure to monocrotophos for the public is via residues in food. From the 1994 Australian Market Basket Survey, the estimated intake in the group with the highest consumption of monocrotophos residues (toddlers aged two), based on average energy intake, was 0.0000072 mg/kg bw/day. This makes up less than 3% of the ADI.

Occupational Health and Safety

No measured worker exposure studies conducted under conditions comparable with Australian use patterns and conditions for mixer/loader/applicators (M/L/A) of monocrotophos were submitted. The UK Predictive Operator Exposure Model (POEM) was therefore used to estimate exposure and MOE (margins of exposure) for the Australian use pattern wherever possible.

Using this model, predicted exposure was high and unacceptable in all usual ground application situations. Although the POEM model does not apply to aerial application, it was considered that aerial application was likely to be acceptable because of the different parameters which apply in this industry situation. These include more regulated equipment specifications and training requirements.

If similar levels of equipment and training requirements prevailed in the ground spraying situation, particularly if the rate of use were to be reduced, it is possible that the level of exposure during ground spraying would also be acceptable. However, data was required for all registered uses for ground application as shown in Tables 1 & 2 (pg xi & xii).

Environmental Impact

The concerns from the environmental assessment are that monocrotophos is very toxic to aquatic invertebrates, birds and mammals and is not compatible with IPM programs. There is a high hazard to birds from current uses of monocrotophos when avian food items are sprayed. Spray drift from aerial and orchard air blast spraying is a significant hazard to aquatic invertebrates. Runoff from recently treated areas was identified as being hazardous to aquatic invertebrates from both acute and chronic toxic effects.

Much of the data presented was from older, overseas studies, many of which do not comply with current National Registration Authority (NRA) Guidelines. In addition, evidence for bird mortalities in Australia was anecdotal (although consistent with overseas studies) and no actual incidents of aquatic mortalities associated with use of monocrotophos have been recorded in Australia. Extensive data requirements are necessary if continued use of monocrotophos in Australia is to be permitted as shown in Tables 1 & 2.

Residues

The residues evaluation highlighted a number of anomalies and deficiencies in relation to registered use patterns, existing MRLs and withholding periods. There were uses on previously registered labels for which there are no MRLs, such as soya beans and sunflowers. There are uses for which the grazing withholding periods are in question such as lucerne, pastures and cereals. In some instances, such as bananas and soya beans, the harvest withholding periods are questionable. For broad beans and sunflowers, Australian studies were not conducted. With regard to some locust uses, some crop withholding periods are not compatible with existing MRLs. As a result extensive residue studies are required for most uses on the then registered labels as is illustrated in Tables 1 & 2.

CONCLUSION

From these assessments it can be seen that the NRA is faced with addressing significant concerns associated with worker and environmental safety related to the existing use patterns for monocrotophos, as well as gaps in residue data. There was a small data package provided to support this chemical and there are major data gaps for all registered use patterns. Details of the data requirements are in Tables 1 & 2.

Registrants and the main user groups were asked if they would provide data to support this review. Advice was received from all areas consulted stating that this chemical was not critical to their industry and they were not willing or able to generate the data that had been requested.

DETAILS OF DATA REQUIREMENTS

Table 1: Summary of data requirements

Crop	**Data Requirements (Under Australian use patterns and conditions+)**		
	Environmental	Worker Exposure	Residue**
Apples, pears	YES	YES	YES
Bananas*	YES	YES	NO
Barley	YES	YES	YES
Beans, french	YES	YES	YES
Cotton	YES	YES	YES
Lucerne	YES	YES	YES
Lucerne, pasture	YES	YES	YES
Maize, millet, (panicum), wheat	YES	YES	YES
Pastures	YES	YES	YES
Potatoes	YES	YES	NO
Sorghum*	YES	YES	YES
Soyabeans	YES	YES	YES
Sunflowers	YES	YES	YES
Sweet corn	YES	YES	YES

Crop	Data Requirements (Under Australian use patterns and conditions+)		
	Environmental	Worker Exposure	Residue**
Tobacco	YES	YES	NO
Tomatoes	YES	YES	NO
Wheat, triticale	YES	YES	YES

Notes:

* Advice received during the review is that this chemical is no longer used on bananas and that this use could be deleted

**Animal feeding studies will be required on crop residue

\+ All trial work will need to be carried out in accordance with protocols and guidelines negotiated with the NRA and the relevant assessing agency. Note that where equipment and/or rates are similar, one study may be sufficient to cover several crops. This would also need to be negotiated with the relevant assessing agencies and the NRA.

Table 2: Requirements for further data

	Occupational Health & Safety
1	Determination of Dermal and Inhalational Exposure to Monocrotophos to Professional Pesticide Mixer/Loader/Applicators for all registered use patterns and crops (see Table 1)
	Environment
2	Aerobic Metabolism Study
3	Aquatic Invertebrate toxicity Study including daphnia and other invertebrates
	Residues
4	Animal Feeding Studies required on crop residues for apples, pears, french beans, cotton, lucerne, pasture, sunflowers and cereal grains
5	Trials that reflect modern resistance management practices (ie number of applications normally applied) and confirm appropriate withholding periods for cotton use.
6	For use on sweet corn data will be required to support a multiple application use pattern as suggested by current labels. A single treatment at the recommended rate is supported by existing data.
7	Australian confirmatory trial data are required to set MRLs for any uses remaining on the label with the exception of bananas, potatoes, tobacco and tomatoes.
	Efficacy
8	Any rates that were to be reduced from current label levels would require appropriate data to demonstrate that monocrotophos is efficacious at the proposed reduced rates.

In determining an appropriate course of action, the NRA took into consideration the following factors relating to the use of monocrotophos in Australia.

- Significant data deficiencies have been identified during the individual assessments.
- Neither registrants nor industry were willing or able to generate the required data.

The NRA cannot be satisfied, as set out in s.34(1) of the Agvet Code, that the approval or any other dealings with the constituent, monocrotophos, or registration of any product containing monocrotophos would not:

(i) be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
(ii) be likely to have an effect that is harmful to human beings; and
(iii) be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
(iv) unduly prejudice trade or commerce between Australia and places outside Australia.

It is considered that, of itself, the long standing use of monocrotophos without reported adverse incidents of occupational and/or environmental damage in Australia is not a sufficient basis for the NRA to be satisfied of the matters set out in s.34(1) of the Agvet Code. If the required data were produced, then the NRA might be in a position to conclude that it is satisfied of those matters.

In the absence of the required data, the environmental and occupational exposure concerns identified during the assessment phase of the review remain untested. It is considered that on the available information, it is open to the Board to decide that it is not satisfied that the continued use of monocrotophos products and the related approvals, in accordance with their conditions and recommendations for use:

(i) would not be an undue hazard to the safety of people exposed to it during its handling; and
(ii) would not be likely to have an unintended effect that is harmful to the environment;
(iii) would not unduly prejudice trade or commerce between Australia and places outside Australia.

The second matter for consideration was whether the NRA was satisfied that the conditions to which the monocrotophos registrations and related approvals are subject, could be varied in such a way that the requirements set out in s.34(1) of the Agvet Code would be complied with. In the absence of further and relevant data, varying the conditions of registration to which monocrotophos is currently subject is not considered to be a viable regulatory option.

The third matter for consideration was whether to cancel or suspend the registrations and approvals for monocrotophos. Before exercising its power to cancel or suspend, the NRA had to decide that it is not satisfied that the conditions of the approval or registration can be varied in such a way that the requirements for continued approval or registration will be complied with.

It is considered that on the available information and in the absence of a commitment to provide the required data, there are reasonable grounds for cancelling the registrations and approvals for monocrotophos. If the required data were provided and the NRA were to become satisfied of the matters set out in s.34(1) of the Agvet Code, the NRA could revoke any cancellation.

Upon cancelling the registrations and approvals, the NRA has issued instructions to the interested registrants on how to use or otherwise deal with monocrotophos. It is this mechanism that enables the NRA to "phase-out" the use of monocrotophos products and in determining the dates and the length of the phase-out period.

Therefore the NRA has:

1. DETERMINED that under s.34(1) of the Agvet Code, the NRA is not satisfied that the continued use of monocrotophos products in accordance with the recommendations for its use as approved by the NRA:

   (i) would not be an undue hazard to the safety of people exposed to it during its handling; and
   (ii) would not be likely to have an unintended effect that is harmful to the environment.
   (iii) would not unduly prejudice trade or commerce between Australia and places outside Australia.

2. DETERMINED that under s.34(5) of the Agvet Code, the NRA is not satisfied that the conditions to which registrations and approvals for monocrotophos can be varied in such a way that the requirements for continued registration and approval will be complied with.

3. Under s.40 of the Agvet Code, CANCELS the registrations and all relevant approvals (including the active constituent approval) for monocrotophos.

4. For the purposes of s.45(3)(b) of the Agvet Code, the following instructions were approved in respect of monocrotophos products:

   (i) the active constituent approval and its importation was cancelled on the date of the board's decision (9th December 1999);
   (ii) that registrations and label approvals were cancelled immediately;
   (iii) that MRLs are cancelled as of 30 June 2002.

5. An instruction under s.55 of the Agvet Codes allows:
   (i) supply by wholesale until 30 June 2000;
   (ii) sale by retail until 31 December 2000; and

6. For the purposes of s.14(5)(f) of the Agvet Code, APPROVES the MRLs for monocrotophos subject to the condition that these approvals will remain in force only until 30 June 2002.

1. INTRODUCTION

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

1.1 Regulatory Information

Initiating a review

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

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

Obligations to submit data and other information on chemicals under review

On initiating a review, the NRA 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 reviews

There are three possible outcomes to an ECRP review:

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

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

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

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

1.2 Protected Information

To grant protection to providers of certain information relating to agricultural and veterinary chemicals, the NRA introduced a program of data protection. The objectives of this program are:

- to provide an incentive for the development of products and data applicable to Australian or local conditions;

- to encourage the availability of overseas products and data; and

- to provide reciprocal protection for Australian products and data under overseas' data protection systems.

In general, the NRA designates information as 'protected registration information' for a 'protection period' of two to seven years if the information:

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

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

1.3 Reasons for the Monocrotophos Review

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

- its very high toxicity to bees;
- its association with worker poisonings overseas, during end use and upon re-entry;
- high worker exposure scenarios; and
- high potential acute and chronic risk.

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

1.4 Consultation Activities

1.4.1 Public Comment requested at initiation of review of monocrotophos

Consistent with the NRA's policy of consulting with all parties interested in the review process, the NRA published notices in the Australian rural and metropolitan press calling for written submissions regarding the review of the chemical monocrotophos. Twelve submissions were received from members of the public, and from environmental, government, commodity and user groups. These comments have been given in more detail in Attachment 2.

There was some support for the retention of monocrotophos in the market and was from grower groups who would like to retain this chemical as an alternative to other registered chemicals for the management of pests relevant to the particular commodities produced by their members.

Responses from growers

In general, there was some support for monocrotophos, in some specific areas of agriculture. The role of monocrotophos in resistance management was also mentioned. It was stated that alternative chemicals are usually used in preference to monocrotophos as part of a rotation program. However, users expressed the necessity of retaining monocrotophos because it is important to have a selection of pesticides to lower risks of pesticide resistance developing.

There are a limited number of crops where monocrotophos is considered a most effective product against certain sucking and chewing insect pests. It is used by growers of tomatoes, tobacco, cotton and potatoes in WA, and in some areas of ornamental horticulture with other chemicals in rotation for resistance management.

Responses from the community

Comments from the community focused on generalised symptoms of organophosphate poisoning and the concern that the effects of chronic exposure may not be recognised by workers and their general practitioners. It was also stated that monocrotophos is particularly toxic to humans and is no longer registered for use in the USA and other countries.

Responses on the Environment

There was concern that monocrotophos was highly toxic to aquatic organisms.

1.4.2 Public comments on draft review report

The draft review report was released for public comment in July 1999. The release was advertised on the NRA website and in the media for comment from the public on the draft report and the recommendations contain therein. Groups known to have an interest in the outcome of the review were also sent a copy of the summary report and specifically asked for their comment.

The NRA received submissions from State Agricultural authorities representing grower groups in their state, from individual grower groups and from environmental groups.

A summary of the comments can be found at Attachment 3.

1.5 Chemical and Product Details

1.5.1 History of registration

Monocrotophos is an organophosphorothioate used in agriculture to control a range of insect pests in a range of horticultural and agricultural crops.

Monocrotophos was developed by Shell Chemical Co. and Ciba Geigy Ltd in 1965. It was first registered in Australia for control of various insect pests in cotton and pome fruit, with residue limits set for apples, pears and cotton seed in 1968. Uses were extended into potatoes, tomatoes, sweet corn, bananas, beans and cereals throughout the 1970s and 1980s. Some of the main insect pests are locusts, various aphids, mites and thrips, green vegetable bug and budworms.

In Australia, there is currently one TGAC approval and three product registrations for monocrotophos, and it has been classified as Schedule 7 in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Monocrotophos TGAC manufactured by United Phosphorus, India (applicant: United Phosphorus. Australia) is approved in Australia.

Monocrotophos has been evaluated by the Joint FAO/WHO Expert Committee on Pesticide Residues (JMPR) in 1972, 1975, 1991, 1993 and 1995. An ADI of 0.0006 mg/kg bw/day was allocated by JMPR in 1993, and confirmed in 1995.

This ADI was based on the following levels causing no toxicological effects.

Mouse: <1 ppm in the diet, equivalent to <0.15 mg/kg bw/day (2 year study)
Rat: 0.1 ppm in the diet, equivalent to 0.005 mg/kg bw/day (2 year study)
Human: 0.006 mg/kg bw/day (30 day study)

In Australia, the PACC established an acceptable daily intake (ADI) of 0.0003 mg/kg bw/day (December 1990). This ADI was set on a No Observable Effect Level (NOEL) of 0.003 mg/kg bw/day based on plasma ChE inhibition in a human study.

1.5.2 Use pattern

Monocrotophos is a plant systemic insecticide and acaricide with contact and stomach activity. It is registered for use on a wide range of crops as listed below.

In general, it appears that monocrotophos use may be in decline as reflected by the limited response to the performance questionnaires.

Major Uses

Monocrotophos is registered for agricultural use only (no veterinary or public health uses) and according to the current labels and the performance questionnaires, the major uses are in cotton, lucerne, potato, sorghum, soybean, tobacco, tomatoes and commercial flower crops.

Pome fruit	Bananas
Beans: french	Cotton
Lucerne	Maize
Millet	Panicum
Wheat	Potatoes
Sorghum	Soybeans
Sunflowers	Sweet corn
Tobacco	Non-fruit bearing trees
Non-crop areas	

*Note: Some labels specify "Pome Fruit" while others specify individual pome fruit crops (apples and pears)
**Note: Some labels specify "vegetable crops" in addition to listing individual vegetable crops such as carrots and potatoes.

Monocrotophos was considered to be of strategic importance for the following applications by the respondents to the questionnaires.

Queensland:
- for the control of stem borer and *Helicoverpa* spp. on tobacco
- a fall back option for cotton tipworm during heavy infestations
- for the control of budworms in flower species that are monocrotophos tolerant

Victoria:
- a useful insecticide/miticide which is used for the control of pests in cereals and pastures
- monocrotophos is reputedly the most effective of the remaining registered chemicals which provide adequate control of sucking insects on tobacco

Western Australia:
- for the control of potato tuber moth on potatoes
- one of the few organophosphates which kill *Helicoverpa armigera* and is used in the Ord River Irrigation area for resistance management of this pest.
- perhaps important for locusts

Application methods
Growers indicated that farming practices had changed to include regular monitoring of pests to assist in determining which chemicals to use in a spray program. Growers also advised that improvements in spray equipment enable even application providing greater control of pests.

Information from the label indicates that monocrotophos is to be applied by directed spray, aircraft or ground rigs except for Victoria, Tasmania and potatoes in NSW where aerial spraying is prohibited. Bananas can only be sprayed aerially at a maximum application rate of 800 g ai/ha in a minimum of 20 litres of water per hectare, every 7 to 14 days depending on pest activity. However, although bananas still appear on product labels, information received during the review

indicates that monocrotophos is no longer used in this crop. The label warns that monocrotophos is not to be applied by fogging machines or back mounted knapsacks.

For aerial application an ultra low volume (ULV) or low volume spray is used with suitable equipment to provide a droplet size of approximately 100 to 200 microns (low volume application) or 90 to 120 microns (ULV). When applying as a low volume spray, the total spray volume should not be less than 10 L/ha.

Application by ground-rig requires a minimum of 250 L of water per hectare using cone nozzles or in a minimum of 150 L of water per hectare using fan-assisted rotary atomisers. Fan nozzles are not recommended.

The use of wetting agents is included in the label directions and varies between products for various crops or situations.

Monocrotophos is also used for non-fruit tree injection. Holes that are 5 cm deep, 1 to 5 cm in diameter and slanted downwards at 45^{o}, are drilled around the tree at 30 cm intervals. These holes must be at least 1.5 metres below the lowest branch. Monocrotophos is placed in the holes with an eyedropper and then the next day the holes are plugged with putty or mastic. The plugs and surrounding area are painted over with bitumen emulsion sealer.

1.6 Overseas Regulatory Status

Monocrotophos is registered in many countries in the world including those listed in the following table:

Brazil	Bulgaria	Chile
Colombia	Costa Rica	Dominican Republic
Ecuador	Egypt	France
Greece	Guatemala	Honduras
India	Jordan	Italy
Japan	Mexico	Kenya
Malaysia	Nicaragua	Mozambique
Myanbar	Paraguay	Pakistan
Panama	South Africa	Peru
Philippines	Thailand	Spain
Sudan	Zimbabwe	Turkey
Zambia		

It is registered for use in crops such as fruit, vegetables, olives, hops, cotton, tobacco, sorghum, sugar beets, rice and ornamentals for control of mites, budworms, loopers and a number of other pests.

Australian agriculture covers a wide range of geographical regions and climate types and a correspondingly wide range of agricultural and horticultural crops. The registered uses and limitations applied in Australia compare with those countries with corresponding crops.

1.7 Overseas Regulatory Action

- Products containing monocrotophos are not registered in USA, the UK, Indonesia, Sri Lanka, Argentina and the Philippines and is severely restricted in Kuwait, Malaysia and Germany.
- There are no MRLs set for monocrotophos by Argentina, China, Germany, Ireland, New Zealand or UK.

In 1997 Monocrotophos was added to an existing watch list, the PIC (Prior Informed Consent), so that its trade can be better monitored and managed in future. Chemicals are added to this list because they are considered dangerous substances and participating countries in the PIC procedure do not allow the chemical to be exported without the agreement of the importing country.

Toxicology Reviews

Monocrotophos has been evaluated by the Joint FAO/WHO Expert Committee on Pesticide Residues (JMPR) in 1972, 1975, 1991, 1993 and 1995. An ADI of 0.0006 mg/kg bw/day was allocated by JMPR in 1993, and confirmed in 1995.

Environmental Reviews

Monocrotophos has been voluntarily withdrawn from sale in the US in 1989 following concern on its toxicity to non-target species, especially birds (Anonymous, 1997 A). It is also banned in Indonesia, Sri Lanka and Philippines, severely restricted in Kuwait (for use on plants to flowering stage only), Malaysia (for use on coconut and oil palm by truck injection) and Germany (not to be handled by adolescents and pregnant and nursing women).

Recently, in 1996, the companies selling monocrotophos in Argentina have voluntarily agreed to withdraw the product from the market and bought back all existing supplies following concerns over bird deaths from its use in grasshopper control (Pesticide Action Network North America Updates Services, 4 November 1996—for further details see p 36).

Residues Reviews

A periodic review Monocrotophos was undertaken by JMPR in 1991. It was a comprehensive review and some Australian use patterns have been included in the residues component of the review.

2. CHEMISTRY ASSESSMENT

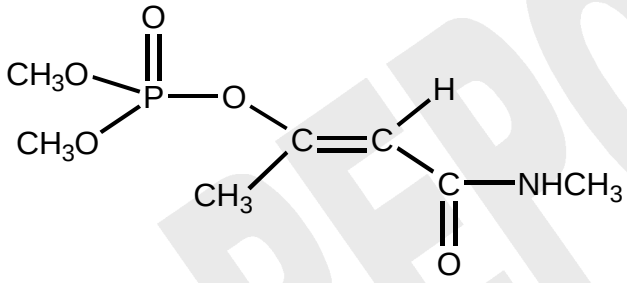
2.1 Chemical identity

Common Name: Monocrotophos

IUPAC: Dimethyl (E)-1-methyl-2-(methyl-carbamoyl)vinyl phosphate

C.A.: (E)-dimethyl 1-methyl-3-(methylamino)-3-oxo-1-propenyl phosphate

Structural Formula:



Purity: Monocrotophos content: not less than 750 g/kg; trimethyl phosphate (impurity): 20 g/kg maximum

Monocrotophos TGAC from the approved source complies with FAO specifications in respect of monocrotophos content and trimethyl phosphate.

Other toxic impurities (N-nitrosamines, halogenated dibenzo-p-dioxins or halogenated dibenzofurans and PCBs etc) are not expected in monocrotophos TGAC due to raw materials and synthetic chemistry used.

Stability: Decomposes above 38^0C, thermal runaway reaction can occur above 55^0C. To minimise any degradation, monocrotophos TGAC should be stored out of direct sunlight and under cool and dry conditions

Molecular formula: $C_7H_{14}NO_5P$

Molecular weight: 223.2

2.2 Chemistry Aspects

The chemistry aspects (manufacturing process, quality control procedures, specifications applied to the active ingredient, batch analysis results and analytical methods) of monocrotophos TGAC were evaluated previously and found acceptable.

3. AGRICULTURAL ASSESSMENT

3.1 Efficacy

Limited information was received regarding the efficacy of this chemical in the field. Generally, growers, commodity groups and registrants had observed no problems with the efficacy of monocrotophos in the field.

Information from the Queensland Department of Primary Industries indicated that monocrotophos efficacy was questionable in field crops and bananas (no longer used in this crop although still registered). In Victoria, it is considered that monocrotophos is not effective on mature grubs and there appear to be more effective alternatives.

Queensland, SA and NSW respondents indicated that resistance to monocrotophos appears to have developed in two-spotted mite. Resistance to monocrotophos in some populations of aphids and mites is also noted on some product labels.

Monocrotophos appears to be effective for the purposes indicated on product labels with only a few examples of chemical resistance being identified. The decline in use of monocrotophos seems to be related to other factors such as:

- Concerns about operator safety and toxicity to birds and other non-target species.
- Incompatibility with the use of Integrated Pest Management strategies.
- The long withholding period for some crops.
- The availability of other effective, less hazardous and more cost effective alternatives.
- Phytotoxicity in some varieties of sorghum.
- The development of lucerne varieties resistant to aphids.

There are some uses where monocrotophos seems to have an important current role to play. These are principally in relation to:

- Insecticide resistance management strategies in horticulture and the Victorian tobacco industry.
- Locust control, especially as a perimeter spray as part of a strategic preventative control program.
- Control of some specific pests in tobacco, potatoes, cotton, ornamental horticulture and cereals.

From the information available to the NRA, the efficacy of monocrotophos does not appear to be in question.

3.2 Trade

It is anticipated that if trade difficulties arise, the most likely source will be from residue issues. Because there are some incompatibilities between Australian MRLs and overseas countries' MRLs, it is possible for residue violations to occur in importing countries in commodities which are produced according to Australian Good Agricultural Practice (GAP) and which comply with Australian MRLs.

The maximum residue limit (MRL) is defined as the maximum concentration of a residue, resulting from the officially authorised safe use of an agricultural or veterinary chemical, that is

recommended to be legally permitted or recognised as acceptable in or on a food, agricultural commodity, or animals feed.

Australian MRLs are set by Commonwealth government authorities and are then adopted by the State governments for inclusion into their legislation. No agricultural chemical is registered for use unless MRLs have been set for that use of the chemical or has been exempted from the need to set an MRL (where the chemical would not occur in food or the level of residue is considered to be of no toxicological significance).

The monocrotophos MRLs which have been established in Australia for various crops, are detailed below in Table 1.

Table 1: Australian MRLs for monocrotophos [9]

Crop	**MRL mg/kg**	**Crop**	**MRL mg/kg**
Apple	0.5	Banana	0.5
Beans, except broad bean & soya bean	0.2	Broad Beans (green pods and immature seeds)	0.2
Cereal grains	*0.02	Cotton Seed	0.1
Edible offal (mammalian)	*0.02	Eggs	*0.02
Meat (mammalian)	*0.02	Milks	*0.002
Pear	0.5	Potato	0.1
Poultry, Edible offal of	*0.02	Poultry meat	*0.02
Sweet corn	*0.01	Tomato	0.5
Vegetable oils, edible	*0.05		

***The MRL is set at or about the limit of analytical quantitation**

A number of Australia's trading partners accept Codex MRLs for monocrotophos. In a number of cases Australian MRLs have been set for commodities where there are no Codex MRLs (see Table 2). It is therefore possible that, where Codex MRLs have been adopted, there could be residues above an importing country's MRL following normal use in Australian agricultural or horticultural production due to varying use patterns and pest pressures. This is also true for the MRLs that are set by individual countries.

The following table provides examples of where Australian, Codex and other countries MRLs differ and therefore the possibility of residue violations affecting Australia's trade may occur.

Table 2: Comparison of Codex [10], Australian [9] and other trading partners [11] MRLs in mg/kg:

Commodity	Codex	Australia	Korea	USA	Malaysia	Japan	Thailand	Italy
Apple	1	0.5	1	-	1	-	-	0.05
Cattle, pigs, sheep (meat)	*0.02	*0.02	0.02	-		-	0.02	-
Cottonseed	0.1	0.1	0.1	0.1	-	-	-	-
Cottonseed oil	*0.05	*0.05	-	-	-	-	-	-
maize	*0.05	*0.02	0.05	-	0.05	-	-	0.05
Pears	1	0.5	1	-	1	-	-	0.05
Potatoes	*0.05	0.1	0.05	0.1	-	0.05	0.05	0.05
sorghum	-	*0.02	-	-	-	-	0.02	-
soybean (immature)	*0.05	-	0.05	-	0.05	-	0.05	-
Vegetable oil	-	*0.05	-	-	0.05	-	-	-
Sweet corn	-	*0.01	0.05	-	-	0.05	0.05	-
Tomato	1	0.5	1	0.5	1	0.05	1	0.05
triticale	-	*0.02	-	-	-	-	-	-
wheat	*0.02	*0.02	-	-	-	-	-	-

***The MRL is set at or about the limit of analytical quantitation**

An associated difficulty with MRLs is that the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) has recommended the removal of the Codex general fruit and vegetable MRLs for all chemicals, replacing them with individual fruit and vegetable MRLs provided that these are supported by appropriate data. This inevitably 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. However, monocrotophos only has a crop/MRL combination for vegetable oils.

The information in Table 2 clearly shows that many of our export markets have few MRLs for monocrotophos. The two crops with most support for MRLs across the countries are potatoes and tomatoes. There are also few Codex MRLs for monocrotophos. Countries that have not set MRLs tend to use the Codex MRLs or accept MRLs set at or about the limit of analytical quantitation.

Other comments

When comparing MRLs for crops between different countries, a number of issues, other than the MRL assigned for a particular crop, need to be considered.

(1) The residue definition for monocrotophos in one country may not be identical to that used in another country. Monocrotophos could be defined as either the parent compound, or may include a number of the metabolites. In this situation, just comparing the MRL value would not be an accurate comparison between countries.

(2) The listing of individual crops under a generic group may also cause inaccuracies when comparing MRLs. An example is the definitions that are used in Taiwan. The fruits classified under the pome fruit category include not only apples and pears, but also peaches, apricots and a number of other fruits which Australia would classify under a

different category. Their stone fruit category includes fruit such as mangoes, loquats and kiwifruit. However, Australian group entries are applied as described by the Codex classification scheme which is a recognised standard. Fruits and other products which are considered unusual in Australia and may not have data, still will have recognised groupings.

Harmonisation of Australian MRLs with those of Codex and other countries for groupings of crops, MRLs and residue definitions, would be a way to reduce the potential for residue violations in export crops.

Residue Detections

Where chemicals are used according to label directions, residues above the Australian MRL are unlikely to occur. If growers use chemicals contrary to label instructions, there is a risk of residues occurring in produce at a level above the Australian MRL. Examples of misuse include: failure to observe the withholding period; applying too much chemical; repeating a treatment too soon after a previous treatment; and using a chemical on a crop or commodity for which there is no registered use. In some states, off-label use regulations may allow use on crop for which MRLs have not been set and this could result in trade problems.

Another source of residues is unintended exposure of plants and animals to chemicals. This can occur, for example through spray drift from treatment of an adjacent crop, or poor animal and chemical management.

The National Residue Survey results in 1996 indicated that Australian produce is of a high standard, as few of the samples contained violative chemical residues. Test results from a total of 46482 samples showed that only 140 residues above the MRL for all chemicals were detected. [(5)]

Organophosphate residues are becoming less frequent in meat species with less than 1% of the samples having residues. The organophosphates detected in 1996 were diazinon (5 residues), ethion (5 residues), fenthion (4 residues), chlorpyrifos (1 residue). There have been no residues above the MRL since 1992 and all of the organophosphate residues detected in the past 2 years have been less than the MRL.[(5)]

Inconsistencies between the Australian and Codex MRLs for various commodities may be a source of difficulty in relation to trade with those countries.

Several grower organisations and State departments of agriculture have commented on the usefulness of this chemical in preparing produce for market.

These advantages may be listed as follows:

- it provides another chemical group rotation option in resistance management strategies eg thrips in horticultural crops
- according to growers, it is comparatively much cheaper than alternatives
- it is considered important in the horticultural industry because it has a broad spectrum activity and is effective against a wide range of pests
- access to a wide range of chemicals in the horticultural industry is considered necessary to avoid problems of phytotoxicity
- concerns that the ornamental horticultural industry as a minor user of chemicals will lose one of an already small range of chemicals.
- monocrotophos has been listed as a strategic component of pest control strategies for ornamentals, tobacco and potatoes

3.3 Residues

Plant Metabolism

The metabolism of radiolabelled monocrotophos on cotton, maize, cabbage and apples trees was reviewed. For cotton, various treatments such as a seed dressing, a foliar spray, stem treatment and petiole injection were investigated. Identical metabolites were found following each treatment, although the proportions of each compound varied with crop growth. Monocrotophos was identified as the major component of the applied radioactivity (up to 85%), with dimethyl phosphate, phosphoric acid and *O*-demethyl monocrotophos present in the range of 1 to 30%.

^{14}C monocrotophos was applied to the leaves and husks of maize, to the leaves of cabbage and to the leaves and fruit of apple trees. Samples of foliage, fruit and husk were taken at various intervals after application. The results showed that a similar distribution pattern of monocrotophos and metabolites was found in all three crops. A large proportion of the radioactivity (up to 68%) was recovered as monocrotophos. *O*-demethyl monocrotophos and dimethyl phosphate were present at up to 17% of the applied radioactivity, and *N*-hydroxymethyl monocrotophos and *N*-demethyl monocrotophos were present at less than 5% of the applied radioactivity. The data also showed that monocrotophos levels in treated foliage decline with time.

In summary, the plant metabolism studies indicate that the predominant residue from application of monocrotophos to varying crops is the parent compound. Hence the existing residue definition of parent compound is appropriate. The major metabolites formed include *O*-demethyl monocrotophos, dimethyl phosphate and phosphoric acid. The formation of the metabolites clearly indicates cleavage of monocrotophos at the vinyl phosphate bond and demethylation at the phosphate end of the molecule.

Animal Metabolism

Metabolism studies in lactating goats using ^{14}C and ^{32}P monocrotophos were reviewed. A single oral dose of 1 mg/kg bodyweight ^{32}P monocrotophos was administered to goats. Within 72 hours of treatment, a total of 1.4% of the administered dose was recovered in milk. Parent monocrotophos comprised up to 67% of the total extractable residue in milk and *N*-hydroxymethyl monocrotophos was present at up to 26%. The data show that monocrotophos is the major component of the residue present in milk.

^{14}C monocrotophos was administered to goats at 10 mg/kg in the diet (approximately 0.4 mg/kg bodyweight) for three days. The animals were slaughtered within 24 hours of the final dose. Total excretion over three days accounted for 80% of the total administered dose. Total radioactive residues in milk reached a maximum level of 0.2 mg/kg monocrotophos equivalents. Total radioactive residues in liver, kidneys, muscle and fat were 0.13, 0.16, 0.07 and 0.03 mg/kg monocrotophos equivalents, respectively. The data showed that the majority of the administered dose is excreted and finite residues are present in edible tissues, although characterisation of the total radioactivity in tissues was not reported.

In summary, the available animal metabolism data suggest that the existing residue definition of parent compound is appropriate.

Analytical Methods

Methodology for the determination of monocrotophos in cereals, soya beans, tomatoes, sweet corn and vegetable oils was provided. Monocrotophos residues were quantified using Gas Liquid Chromatography with a phosphorus specific thermionic detector. Limits of detection were reported at 0.01 mg/kg; limits of determination were reported at 0.02 mg/kg, with acceptable

recoveries in the range 70 – 110%. Recoveries were often reported at levels greater than the limit of determination, *eg.* 0.1 mg/kg compared to 0.02 mg/kg.

Methods for the determination of monocrotophos in milk and animal tissues were cited, however details were not provided.

Animal Transfer Studies

Studies in dairy cattle were conducted using ^{32}P monocrotophos. Cows were fed hay treated with monocrotophos, resulting in intake levels equivalent to 45 mg/kg in the feed for 14 days. During the period of the study, milk was collected twice daily. The animals were slaughtered on day 15. Monocrotophos levels in milk reached a maximum of 0.02 mg/kg within 3 to 6 days of feeding. Residues in muscle and liver were 0.03 and 0.12 mg/kg, respectively. From the nature of the study, it is not possible to make an accurate estimate of the Daily Dietary Intake for Livestock on which the current mammalian MRLs are based.

Animal Feed Commodities

There is one entry for monocrotophos in Table 4 of the MRL Standard:

Straw and fodder of cereal grains	*0.02 mg/kg

As the MRLs for cereal grains, cereal straw and fodder are 'at or about' the limit of determination, the corresponding animal MRLs are also set 'at or about' the limit of determination in animal tissues, milk and eggs. Other commodities which would also have feed implications are apple/pear pomaces, bean vines/hay, cotton seed/meal and soya bean forage/fodder and meal. However, data were not available for any of these feed items. Until decisions are made on the continued use of monocrotophos on these crops, changes to the existing animal MRLs are not recommended.

Animal feed commodities for which additional data would be required are lucerne and pastures. For each commodity there is a 7 day grazing withholding period. It would seem that in the absence of data which can demonstrate adequate depletion of monocrotophos over the 7 day period, the existing withholding period may be questionable. Such data would allow a valid judgement to be made in terms of the adequacy of the existing animal (mammalian) MRLs.

Summary and Conclusions

The residues evaluation has highlighted a number of anomalies and deficiencies in relation to registered use patterns, existing MRLs and withholding periods. There are uses on registered labels for which there are no MRLs, such as soya beans and sunflowers. There are uses for which the grazing withholding periods are in question such as lucerne, pastures and cereals. In some instances, such as bananas and soya beans, the harvest withholding periods are questionable. For broad beans and sunflowers, Australian studies were not conducted. With regard to plague locust uses, some crop withholding periods are not compatible with existing MRLs.

In relation to the overseas situation, Codex has recommended the deletion of certain MRLs. These include apples, pears and tomatoes. Monocrotophos was listed as a banned chemical by the USEPA in 1992, and many uses have been progressively deleted. Tolerances were listed in 1997 for cotton seed, peanuts, potatoes, sugar cane and tomatoes.

4. TOXICOLOGY ASSESSMENT

The current Australian ADI for monocrotophos is 0.0003 mg/kg bw/d, based on a NOEL of 0.0036 mg/kg bw/day for plasma ChE inhibition in a human study. Monocrotophos is in Schedule 7 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

4.1 Kinetics and Metabolism

Radiolabelled monocrotophos was administered to Wistar rats by oral gavage at 2 mg/kg bw, and the levels of radioactivity determined in the urine, faeces, expired carbon dioxide and in selected tissues. Signs of organophosphate poisoning were seen for up to 3 h after dosing. Urinary excretion was the main excretory route, with 76% of the administered dose excreted after 12 h, and 82% after 96 h. Faeces and expired air accounted for 3% and 6% of radioactive dose respectively. Low levels of radioactivity were found in tissues after 96 h, with the highest levels of 0.08 ppm found in adipose tissue. Unchanged monocrotophos was found in the urine at up to 33% of the administered dose. The major urinary metabolites were N-methyl acetoacetamide (SD 9112) and 3-hydroxy-N-methyl butyramide (SD 11734). The metabolic pathway was determined to mainly be a detoxification route, involving ester cleavage of monocrotophos (Lee, 1987).

Monocrotophos was incubated with tissue samples from previously untreated animals, and the metabolites found included phosphoric acid, monomethyl phosphate, dimethyl phosphate, O-demethyl monocrotophos, monocrotophos acid and hydroxymethyl monocrotophos. The proportions of metabolites were not quantified. Additionally, radiolabelled monocrotophos was administered by IP injection to Wistar rats at 5 mg/kg bw. Over the following 48 h, 61% of the administered radioactivity was recovered in the urine, with 6% recovered in the faeces. Initially, 50% of the material excreted was unchanged monocrotophos, while at 24 h dimethyl phosphate made up 50% of the excreted material, with monocrotophos contributing 10% at this stage. Over the 48 h monitored excretion phase, dimethyl phosphate contributed 40% of the total excretion, monocrotophos 28%, hydroxymethyl monocrotophos 19%, O-demethyl monocrotophos 10%, and phosphoric acid 3% (Bull & Lindquist, 1966).

Radiolabelled monocrotophos (^{32}P, N-methyl-^{14}C, or O-methyl ^{14}C-labelled) was used to investigate metabolism. Monocrotophos was found to undergo N-methyl oxidation to form hydroxy methyl compounds, which underwent subsequent dehydroxymethylation. Monocrotophos was also excreted unchanged into urine or milk. Studies in rats indicated that most of the administered compound was excreted in urine within 24 h of administration. There were variations in the rates of absorption, metabolism and elimination, however the overall metabolic path appeared to be similar between species. (Menzer & Casida, 1965).

Radiolabelled monocrotophos was administered to goats at approximately 0.2 mg/kg bw/day for 3 days. Excreted radioactivity in urine, faeces and milk was quantified over the observation period, and animals were killed 24 h after the final dose for quantification of tissue levels. No adverse clinical signs were seen. 66% of the administered dose was recovered in the urine, and 13% in the faeces. Less than 2% of the administered dose was recovered in the milk. Major metabolites were N-methyl acetoacetamide and 3-hydroxy-N-methyl butyramide. Monocrotophos equivalent levels in the kidney were 0.17 ppm, and in the liver 0.13 ppm (Hall, Jameson & Shaffer, 1987).

Two cows were fed a monocrotophos metabolite found in plants at 360 mg/day. There were no adverse clinical affects, and milk production was not decreased. Residues of a number of monocrotophos metabolites were not detectable (Modesto Technical Report, undated).

Radiolabelled monocrotophos was fed to cattle at approximately 1 mg/kg bw/day in 2 divided doses for 14 days. There were no adverse clinical signs during this period. Monocrotophos levels in milk ranged between 0.0061 - 0.022 ppm, while metabolite levels were less than 0.005 ppm at all times. Higher levels were excreted in the urine, with monocrotophos detected at 0.32 - 1.02 ppm and N-hydroxy monocrotophos at 0.083 - 0.63 ppm. Liver levels of monocrotophos were 0.11 - 0.13 ppm, while muscle levels were 0.023 - 0.041 ppm. Therefore there was more excretion in urine than in milk, with little evidence of accumulation in tissues (Potter, 1965).

4.2 Acute Toxicity

Monocrotophos was of extreme oral toxicity in rats and mice with LD50 values of approximately 8 and 10 mg/kg bw, respectively. The acute dermal toxicity of monocrotophos was solvent dependent, and it was of low to high toxicity in the rat (LD50 values ranging from 119 to >2000 mg/kg) and of moderate to high toxicity in the rabbit (LD50 values ranging from 130 to 709 mg/kg). Signs were typical of organophosphate poisoning; including piloerection, abnormal body positions, reduced locomotor activity, exophthalmos, dyspnoea, tremor and convulsions, and trismus. Monocrotophos was of high inhalational toxicity in rats with an LC50 of 80 mg/m^3. In mice, the IV LD50 was 11.5 mg/kg. In rabbits, monocrotophos was slightly irritating to the eyes and skin. Monocrotophos was not a skin sensitiser in guinea pigs.

Atropine sulfate alone, or in combination with oximes was a useful antidote against acute monocrotophos poisoning.

Acute studies conducted with the trans isomer of monocrotophos indicated that it was of moderate oral toxicity in rats (LD50; 207 mg/kg), mice (LD50; 118 mg/kg) and rabbits (LD50; 485 mg/kg), of low dermal toxicity in rats (LD50; > 3100 mg/kg) and of moderate inhalational toxicity in rats (LC50; 805 mg/m^3). In rabbits, it was a slight skin irritant, but was not irritating to the eyes. The trans isomer also caused skin sensitisation in guinea pigs. The amide metabolite was found to be more toxic than monocrotophos, and the H-hydroxymethyl metabolite slightly less toxic than monocrotophos. The oral LD50 in rats for the major metabolite N-hydroxymethyl monocrotophos was 27 mg/kg.

4.3 Short-Term Repeat-Dose Studies

Monocrotophos technical was fed to CD mice at doses of 0, 0.1, 0.5, 1, 10 or 100 ppm in the diet (equivalent to 0, 0.015, 0.075, 0.15, 1.5 or 15 mg/kg bw/d) for five weeks. Body weight decreases were seen in animals at the highest dose; in females the weight loss was transitory. No significant haematological effects were seen, and an increase in AP levels in high-dose males was not correlated with any histopathological findings. Significant plasma ChE inhibition was seen in males at all doses and in females from 1 ppm. Erythrocyte ChE was inhibited in males at all doses and in females from 10 ppm. Brain ChE was inhibited from 10 ppm in both sexes. Based on the plasma and erythrocyte ChE inhibition in males at the lowest dose, no NOEL was established in this study: the LOEL was 0.1 ppm, equivalent to 0.015 mg/kg bw/d (Hend & Gellatly, 1979).

Monocrotophos technical was administered by gavage to Carworth Farm E rats at doses of 0, 1.68, 3.36 or 6.72 mg/kg bw/d for 5 days. All high-dose rats died on day 2 of the study. Rats on 3.36 mg/kg bw/d showed severe symptoms following the first dose; these persisted until 5

days after the final dose. At the lowest dose, slight cholinergic signs were seen after the first dose. These signs persisted until 4 days after the final dose. Given the clinical signs seen at the lowest dose, no NOEL could be established for this study (Brown & Muir, 1970).

Monocrotophos technical was administered by IP injection to male mice at 0.8 mg/kg bw once weekly for 6 weeks. Mice were examined for effects on haematological and erythropoietic systems. Clotting times increased approximately 3-fold following monocrotophos administration. Erythrocyte and platelet counts were decreased, and bone marrow was mildly depressed. The splenic weight was unchanged, however the number of cells present increased by a factor of 4. This may be a reaction to the bone marrow depression (Gupta et al, 1982)

Monocrotophos technical was administered by IP injection to male mice at 0.8 mg/kg bw once weekly for 6 weeks. At the end of this time, mice were killed by immersion in liquid air and brain ChE and other enzymes were analysed. Acetylcholine concentration in the brain was increased. ChE activity in the brain was significantly decreased. The concentration of adrenaline, noradrenaline and dopamine were significantly decreased, while the concentration of GABA was unchanged (Gupta et al, 1984).

Monocrotophos technical was administered to Wistar rats in an 8-week feeding study, a 13-week feeding study, and an 8-week feeding study with a 5-week recovery period. The doses in each study were 0, 0.1, 0.25, 0.5, 2.0 or 8.0 ppm in the diet (equivalent to 0, 0.005, 0.0125, 0.025, 0.1 or 0.4 mg/kg bw/d). There were no treatment related clinical signs or mortalities observed during the study. No body weight decreases of biological significance were observed, although statistically significant decreases were seen in male rats in the high dose group in the first few weeks of feeding. ChE inhibition was most evident in the 13-week feeding study. Plasma ChE was significantly inhibited in females in the 13-week feeding study at 0.1 ppm. Erythrocyte ChE was significantly inhibited in both males and females at 0.5 ppm in the 13-week feeding study: in the 8-week study, males were inhibited from this dose, while in females, inhibition was seen from 2.0 ppm. Brain ChE was significantly inhibited in both studies and in both sexes at 2.0 ppm. The 5-week recovery phase following 8-weeks feeding allowed recovery of plasma and brain ChE levels; erythrocyte ChE was still inhibited at 2.0 ppm in males and 8.0 ppm in females. No NOEL can be set for this study, based on the effects seen on plasma ChE in females: the LOEL is 0.1 ppm, equivalent to 0.005 mg/kg bw/d (Hend & Brown, 1981).

Monocrotophos technical was fed to Wistar rats in the diet for 5 weeks at doses of 0, 0.1, 0.5, 1.0, 10 or 100 ppm (equivalent to 0, 0.005, 0.025, 0.05, 0.5 or 5 mg/kg bw/d). There were no treatment related mortalities during the study. Clinical signs were seen in the 100 ppm rats, including tremors and poor condition. Body weight was significantly reduced in the high dose animals, and food intake was also lower. Decreased plasma protein, and an increase in AP, AST and ALT was noted in the high-dose animals; it was suggested that this may be related to decreased food intake, rather than being a directly compound related effect. Plasma ChE was significantly inhibited in females from 0.5 ppm in the diet, and in males from 10 ppm. Erythrocyte ChE was significantly inhibited in females from 0.5 ppm, and in males from 1 ppm. Brain ChE was significantly inhibited in both sexes from 1 ppm. On gross pathological examination corneal opacity was noted in high dose animals. Histopathologically, these animals had subacute keratitis, with corneal oedema and pannus formation. Pigment depletion in the Harderian glands was found in control, 10 ppm and 100 ppm animals, and it was suggested that this may be related to hypersecretion. Overall, the NOEL for the study was 0.1 ppm in the diet, equivalent to 0.005 mg/kg bw/d, based on the inhibition of plasma and erythrocyte ChE seen in females at 0.5 ppm (McAusland & Gellatly, 1979)

Monocrotophos technical was applied to the shorn dorso-lumbar skin of Tif RAIf rats once daily for 28 days at doses of 0, 0.2, 1, 10 or 100 mg/kg bw/d. There were no mortalities. Clinical signs were seen in the 2 highest dose groups, with tremors and clonic-tonic muscle spasms seen only at 100 mg/kg bw/d. No skin irritation was observed. Plasma ChE was significantly inhibited at 10 mg/kg bw/d in both sexes. Erythrocyte ChE was significantly inhibited at 10 mg/kg bw/d in males and 100 mg/kg bw/d in females. Brain ChE was significantly inhibited at 10 mg/kg bw/d. There were no treatment related abnormalities found on gross or histopathological examination. Overall, the NOEL can be established at 1 mg/kg bw/d, based on ChE inhibition seen at 10 mg/kg bw/d (Hageman, 1992).

The trans-isomer of monocrotophos was applied to the shorn dorso-lumbar skin of Himalayan rabbits once daily for 5 days using 5 mL of the material. Within 2 days of commencing treatment, rabbits showed salivation, trismus, convulsions, ataxia and sedation. Signs increased in severity over time, and all animals died between days 5 and 7. Irritation scores of the application site over the course of treatment indicated that the trans-isomer was a mild skin irritant (Sachsse & Ullman, 1976a)

The trans-isomer of monocrotophos was applied to the left eye of 6 rabbits, with rinsing in 3 animals. 0.1 mL of the material was used for each rabbit. There were no adverse clinical signs, and no loss of body weight. Monocrotophos trans-isomer was considered to be a slight irritant to the rabbit eye (Sachsse & Ullman, 1976b)

A 40% formulation of monocrotophos in acetone was applied in aqueous solution to the intact or abraded skin of New Zealand White rabbits 5 days per week for 3 weeks at 0, 42 or 84 mg/kg bw/d. Clinical signs were seen in both treatment groups, with increased severity at the higher dose. Mortalities were increased in the high dose group. There were no treatment related histopathological findings. No NOEL could be established for this study, given the clinical signs seen at 42 mg/kg bw/d (Newell & Shellenberger, 1964; Newell, 1965).

A 60% solution of monocrotophos (no formulation details specified) was applied to the intact and abraded skin of albino rabbits at 0, 36 or 72 mg formulation/kg bw/d. Applications were made on 5 d/week for 3 weeks. There were no treatment related abnormal clinical signs observed in this trial. Mild skin irritation was seen in treated animals, particularly in those with abraded skin. Kidney congestion and splenic enlargement was seen at the high dose on gross examination. There were no histopathological findings. Based on the skin and gross histopathological effects seen at 72 mg formulation/kg bw/d, the NOEL was established at 36 mg formulation/kg bw/d (equivalent to 22 mg active/kg bw/d) (Doyle and Elsea, 1965).

Monocrotophos (either with or without 5% chloromonocrotophos) was applied to the skin of New Zealand White rabbits at 3 mg/kg bw/d for 5 consecutive d. Significant plasma and erythrocyte ChE inhibition was seen in both males and females up to and including day 10 of the trial. Erythrocyte ChE was inhibited until days 14 - 17 of the trial. There were no major differences in the degree or length of inhibition seen with monocrotophos or with monocrotophos containing 5% chloromonocrotophos (Coombs, 1977).

4.4 Subchronic Toxicity

Monocrotophos technical was fed in the diet to Long Evans rats at doses of 0, 0.5, 1.5, 15, 45 or 135 ppm in the diet for 12 weeks. At 135 ppm, tremors were seen in all rats. Body weight gains were decreased in the high dose group, despite normal food consumption. Three high-dose females died during the 3rd week of the study. Haematology values were normal, and no gross or histopathological changes were seen. ChE inhibition was seen in both blood and brain

at 1.5 ppm. Thus, the NOEL for the study was established at 0.5 ppm (equivalent to 0.03 mg/kg bw/d) (Shellenberger & Newell, 1964e).

A monocrotophos metabolite, the beta-D-glycosyl conjugate of N-hydroxymethyl monocrotophos, was fed in the diet to Long Evans rats at doses of 0, 1 and 18, 3, 9 or 90 ppm for 12 weeks. The lowest-dose group was fed at 1 ppm for 7 weeks, then at 18 ppm for the final 5 weeks. Bodyweights were decreased in the 90 ppm group from week 7 until the end of the study. ChE inhibition was seen in whole blood from 9 ppm, and in brain from 18 ppm. ChE inhibition resolved following 4-weeks recovery, except in animals in the high-dose group. There were no treatment related findings on either gross or histopathological examination. Based on the inhibition of whole blood ChE at 9 ppm, the NOEL can be established at 3 ppm (equivalent to 0.3 mg/kg bw/day) (Shellenberger, 1966; Newell, 1966).

Monocrotophos technical was fed to dogs for 13 weeks at 0, 0.5, 1.5, 4.5, 15 or 45 ppm in the diet. Dogs were also fed monocrotophos 135 ppm for 8 weeks, then 270 ppm for 2 weeks, then 540 ppm for 2 weeks and finally 1080 ppm for one week. The highest dose group showed tremors on handling after the first 3 weeks at 135 ppm. There were no gross or histopathological abnormalities observed. There was significant plasma, erythrocyte and brain ChE inhibition from 15 ppm. ChE inhibition was not measured at 4.5 ppm, and therefore the NOEL was established at 1.5 ppm in the diet, equivalent to 0.038 mg/kg bw/d (Shellenberger & Newell, 1964e).

Monocrotophos technical was fed in the diet to Beagle dogs at doses of 0, 0.5, 45 or 135 ppm for 12 weeks. Tremors were seen in the high-dose group after 3 - 4 weeks; no clinical signs were seen in other groups. No treatment related effects were seen on gross or histopathological examination (Shellenberger, 1965d).

4.5 Chronic Toxicity

Monocrotophos technical was fed to CD mice in the diet for 2 years at doses of 0, 1, 2, 5 or 10 ppm. Dose related increases in the incidence of stress related convulsions was seen; these spontaneous convulsions had previously been observed in mice of this strain in this laboratory. There was no treatment related change in body weight, food consumption, haematological findings or organ weights. Ophthalmological examination did not reveal any treatment related abnormalities. Retinopathies were present in all groups of mice; this was considered to be related to the light intensity some mice were exposed to due to cage location. Plasma ChE was inhibited at the lowest dose tested in both sexes. Erythrocyte ChE was inhibited in females from 1 ppm, and in males from 2 ppm. Inhibition of brain ChE was seen in males from 1 ppm and in females from 2 ppm. There were no treatment related gross or histopathological findings. Based on inhibition of plasma, erythrocyte and brain ChE seen in one or both sexes at 1 ppm, the lowest dose tested, no NOEL could be established for this study. The LOEL was established at 1 ppm, equivalent to 0.15 mg/kg bw/d (Brown, 1982).

Monocrotophos technical was fed to Charles River rats at 0, 1, 10 or 100 ppm in the diet for 2 years. Tremors and diarrhoea were observed in rats on 100 ppm. Bodyweight gain was reduced in these animals throughout the study, while males on 100 ppm showed a decreased food intake. There were no abnormal haematological findings, or any abnormal macroscopic changes. There was a dose related increase in chronic inflammatory changes in one or both eyes at 100 ppm. Plasma ChE was significantly inhibited in males from 1 ppm while females showed inhibition from 10 ppm. Erythrocyte ChE was significantly inhibited from 10 ppm, while brain ChE was inhibited from 1 ppm. No NOEL could be established for this study: the

LOEL could be set at 1 ppm (equivalent to 0.05 mg/kg bw/d) based on brain and plasma ChE inhibition (Johnston, 1966; Johnston, Howard & Donoso, 1967b).

Monocrotophos technical was administered to Wistar rats at 0, 0.01, 0.03, 0.1, 1 or 10 ppm in the diet for 2 years. There were no treatment related clinical signs seen during the study; incidental findings included poor condition, piloerection, sore hocks and abnormal gaits. Haematology, urinalysis and ophthalmological examination revealed no abnormalities. Plasma, erythrocyte and brain ChE was inhibited from 1 ppm in both sexes. There were no significant treatment related findings on gross or histopathological examination. Overall, the NOEL for the study was established at 0.1 ppm in the diet, equivalent to 0.005 mg/kg bw/d (Brown, 1983).

Monocrotophos technical was fed to Beagle dogs at doses of 0, 0.16, 1.6 or 16 ppm for 2 years; an additional group was fed 100 ppm for 1 year. Tremors, salivation and constricted pupils were seen in dogs on 100 ppm during the first 8 weeks of treatment. There were no treatment related abnormalities in haematology, clinical chemistry (except ChE), urinalysis or ophthalmoscopic examination. Gross and histopathological examination revealed no abnormalities. Plasma and erythrocyte ChE were inhibited from 16 ppm. Brain ChE in females was inhibited from 1.6 ppm. Overall, the NOEL was 0.16 ppm, equivalent to 0.004 mg/kg bw/d, based on the inhibition of brain ChE in females (Johnston, 1966; Johnston, Thompson & Donoso 1967b).

4.6 Reproductive Toxicity

Monocrotophos was fed at 0, 0.1, 1, 3 or 10 ppm in the diet to Wistar rats for 2 generations. Body weight of all adults at the highest dose was reduced. Teat development in females at 3 and 10 ppm in the first generation was impaired. Pup survival in the F2 generation was decreased at 3 and 10 ppm, and the mean litter sizes at 10 ppm were decreased in both the F1 and F2 generations. Therefore the NOEL for the study is 1 ppm (equivalent to 0.05 mg/kg bw/d), based on the signs seen at 3 ppm (Dix, 1981).

Monocrotophos technical was fed in the diet at 0, 2, 5, 12 or 30 ppm to Long-Evans rats for three generations (F0, F1a, F2a). No treatment related clinical signs were seen at any dose. Body weight was decreased in F1 males at 12 and 30 ppm and in F1 females at 30 ppm. No significant differences were found in F2 animals, in which the top dose was 12 ppm. Pup mortality at 30 ppm in the first two generations was significantly increased; this dose was discontinued after these generations as there were insufficient numbers to continue to the next generation. Litter sizes in the F2 generation were significantly decreased in all treatment groups, however there was no clear dose relationship. Pup survival was decreased at 12 and 30 ppm in all generations, and was decreased at 5 ppm in the second and third generations. Pup weights were decreased at 30 ppm. There were no abnormal macro- or microscopic findings in the F0 adults or F3 weanlings. The NOEL for maternal effects was 5 ppm (equivalent to 0.25 mg/kg bw/d), while the NOEL for reproductive effects was 2 ppm (equivalent to 0.1 mg/kg bw/d), based on decreased pup survival seen at 5 ppm in the second and third generation (Eisenlord & Loquvam, 1965).

Monocrotophos technical was fed at 0, 2, 5, 12 or 30 ppm in the diet to Long-Evans rats for three generations, with the second litter from each group of adults used to produce the next generation. Body weights were significantly reduced in F2b males at 12 ppm; other body weight decreases were seen, but were not considered of biological significance. The 30 ppm dose was discontinued after the first generation, as pup mortality was so high. Litter sizes were significantly decreased in the 5 and 12 ppm groups in the F2a generation. Pup mortality was

increased at 12 ppm in the F1b, F2a and F2b litters, and at 5 ppm in the F3b litter. Pup weights were reduced at 12 ppm in the F3a weanlings. There were no histopathological or gross abnormalities seen in F3b weanlings. Thus the NOEL for maternal effects was 5 ppm in the diet (equivalent to 0.25 mg/kg bw/d) and for reproductive effects, 2 ppm (equivalent to 0.10 mg/kg bw/d) (Eisenlord & Loquvam, 1966).

Monocrotophos administered by gavage at doses up to 1.2 mg/kg bw/d did not cause any impairment in the reproductive performance of female Wistar rats in a 1-generation study. However, maternotoxicity was evident as reduced bodyweight apparently in proportion to dose (data was not given). Reduced pup birthweight, size, viability, and survival throughout lactation were similarly dose related. Reduced survival during lactation suggests monocrotophos and/or its metabolites are secreted into milk. However, as there is insufficient detail reported in this study, it is considered to be unsuitable for regulatory purposes (Adilaxmamma et al, 1994).

Male Swiss albino mice, given monocrotophos by gavage at 0, 0.9, 1.8 or 3.6 mg/kg bw on day 1 and then reduced to 0, 0.18, 36 or 0.72 mg/kg bw/d over the next 5 days, were found to have a dose-related increase in abnormal sperm forms (ie. from 2.1% in controls to 2.1%, 3.6% and 5.4% for the low-, mid- and high-dose treatments), 35 days after the first dose. The investigators of this published report asserted these abnormal sperm forms were evidence for *in vivo* mutagenic potential, but no evidence was provided to implicate any change in sperm DNA integrity (Vijaya Kumar & Janardhan, 1988).

4.7 Developmental Toxicity

Monocrotophos technical was administered by gavage to Sprague Dawley rats at doses of 0, 0.1, 0.3, 1.0 or 2 mg/kg bw/d from days 6 to 15 of gestation. There were no maternal deaths during the study. The two highest dose groups showed an increased incidence of tremors; the high-dose group also had an increased startle reflex. Food consumption was markedly decreased in the high-dose group. Pre- and post-implantation losses were not affected by treatment. No effects on the number of foetuses, early and late resorption, or foetal bodyweights were attributable to treatment. A significant decrease in the proportion of male foetuses was seen at 2.0 mg/kg bw/d, and a non-significant decrease at the next lower dose. There were no external or visceral abnormalities related to treatment. An increased incidence (both foetal and litter) of delayed ossification was seen at the highest dose. Therefore the NOEL for maternotoxicity was 0.3 mg/kg bw/d, based on clinical signs at 1 mg/kg bw/d, and the NOEL for foetotoxicity was 1 mg/kg bw/d, based on delayed ossification at 2 mg/kg bw/d (Fuchs, 1992).

Monocrotophos technical was administered by gavage to pregnant female Charles River Crl:Cd SD (BR) rats at doses of 0.3, 1.0 or 2.0 mg/kg bw/d during days 6 to 15 of gestation. Clinical signs of toxicity were seen at 2.0 mg/kg bw/day, including muscle tremors, twitching, staggering gait, salivation and listlessness. Maternal body weight was decreased in the high dose group from day 15. There were no treatment related effects on the number of corpora lutea, implantation sites, resorption or viable foetuses. Mean foetal body weight and crown-rump length were decreased in the high-dose group. Foetal sex ratios were not affected by treatment. Delayed ossification of sternebrae was seen at 2 mg/kg bw/d, however the incidence was within the range of historical controls. There were no external or visceral abnormalities detected. The NOEL was established at 1 mg/kg bw/d for both maternotoxic and foetotoxic effects (Lu, 1984).

Monocrotophos technical was administered by gavage to pregnant New Zealand White rabbits at 0, 0.1, 1, 3 or 6 mg/kg bw/d on days 6 to 18 of gestation. Mortalities were seen at the high and mid dose, (13/29 and 1/20 respectively). Clinical signs were seen in the two highest dose groups, including excitation or depression, diarrhoea, weight loss and decreased food consumption. Ataxia was also seen for 5 h after dosing. Abortions were seen in some treatment groups, however the incidence was within the range of historical control values. Premature deliveries were seen at 3 mg/kg bw/d at a rate higher than that seen in historical controls. This was considered to be treatment related; however, due to the high mortality in the high dose group, this parameter could not be adequately evaluated. High-dose animals had decreased live foetal bodyweights, and an increase in the mean percent of dead or resorbed conceptuses per litter. An increase in the incidence of agenesis of the intermediate lobe of the lungs which was greater than historical controls was seen at the 2 highest doses. There were also increased incidences of irregular ossification of the parietal bones of the skull at 2 mg/kg bw/day, which may be related to delayed development due to maternotoxicity. The NOEL for both maternal and foetal toxicity were 1 mg/kg bw/d, based on maternal death and clinical signs seen at 3 mg/kg bw/d, and the increased incidence of agenesis of the intermediate lobe of the lung at 3 mg/kg bw/d (Christian, Hoberman & Dearlove, 1987).

A 40% formulation of monocrotophos in hexylene glycol was administered to pregnant female Dutch banded rabbits at 0, 0.7 or 2 mg formulation/kg bw/d from days 6 to 18 of gestation inclusive. No treatment related clinical signs were observed. Survival of foetuses over the first 24 h was not affected by treatment. There was an increase in the number of foetuses with an extra rib in monocrotophos treated animals, however this was within the range of historical controls. The NOEL for maternal and foetal effects was established at 2 mg formulation/kg bw/d, equivalent to 0.8 mg active/kg bw/d (Dix & Wilson, 1972).

4.8 Genotoxicity

Extensive genotoxicity testing has been conducted with monocrotophos (ranging in purity from 36% to 99%). *In-vitro* mutagenicity tests in bacteria, yeast, fungi and mammalian cell cultures (mouse, hamster and human) showed that monocrotophos and its formulations had mutagenic potential. In *in vitro* assays monocrotophos showed potential to damage chromosomes of human lymphocytes, Chinese hamster ovary cells, and rat tracheal epithelial cells. *In vivo* genotoxicity tests showed predominantly negative results, although a weakly positive result was obtained in a mouse micronucleus assay. Monocrotophos induced UDS in human fibroblasts. Monocrotophos did not induce dominant lethal mutations in mice. Results from the different studies submitted indicated that metabolic activation was not required for expression of genotoxicity. The doses at which genotoxic effects were observed in *in vivo* studies were several orders of magnitude greater than the doses at which ChE inhibition had been seen in previous studies.

4.9 Neurotoxicity

Monocrotophos was administered by IP injection to male albino mice at doses of 0, 2, 3 or 4 mg/kg bw, and neurological assessments performed. These included awareness tests, evaluation of reflexes, motor activity and a somersault test. Doses of 2 mg/kg bw monocrotophos and higher significantly decreased awareness. Performance in the somersault test was unaffected by monocrotophos. Motor activity was not affected in a dose-related manner, however mice treated with monocrotophos were inactive for 30 - 60 minutes after dosing, with behaviour returning to normal over 4 h. The pinna reflex was absent in all treated groups, and there was a dose-related decrease in gripping time. Monocrotophos appears to have short term effects on

the neurological system in mice, over a time frame consistent with ChE inhibition (Gupta & Bagchi 1982).

Monocrotophos in combination with an unspecified pyrethroid was assessed for neurotoxic potential in Wistar rats. A formulation containing 50 g/L pyrethroid and 200 g/L monocrotophos was tested, using blank formulation as a negative control and a dose of pyrethroid known to be neurotoxic as a positive control. Mortalities were seen in all groups receiving monocrotophos, either with or without pyrethroid, as well as in the positive control group. Clinical signs were seen in animals receiving monocrotophos, either alone or in combination, and in the positive control group. Changes in glucuronidase and galactosidase levels in sciatic nerves were similar in animals receiving monocrotophos and in positive controls. No histopathological examination was performed. The effects of monocrotophos on the enzyme activity in nervous tissue appear to be similar to the effects of a known neurotoxic agent; these effects were seen at a high dose of monocrotophos which produced obvious clinical signs and mortalities (Rose & Dewar, 1970).

Monocrotophos was administered by IP injection to male Wistar rats at a dose calculated to be twice the LD50, and a number of neurological effects examined. This dose produced respiratory arrest within 30 min; neuromuscular transmission was significantly inhibited. Pretreatment with atropine increased the dose required to produce respiratory arrest to 15 times the LD50. Neuromuscular transmission was significantly inhibited at this time. A diaphragm strip was prepared from a rat dying from monocrotophos administration. Neuromuscular transmission in this strip was restored to normal following washing out of the pesticide; monocrotophos is presumed to have primarily a peripheral action. Behavioural trials including a runway performance test and open field tests were performed. The runway trial indicated that monocrotophos did not affect this behaviour. In the open field test, doses of 1.2 or 1.8 mg/kg bw decreased the distance moved and areas entered 30 min after treatment, indicating that the activity and exploratory behaviour of the rats was reduced. ChE inhibition was significant at these doses. Following treatment with 0.18 mg/kg bw on 5 days/week for 3 weeks, open field behaviour was unaffected, however significant plasma, blood and brain ChE inhibition was seen (Wolthius, Hoodendijk & Vanwersch, 1982).

Monocrotophos technical was administered orally to White Leghorn hens at 0, 0.03, 0.1, 0.3 or 1.0 mg/kg bw/d for 14 days. A negative control and 2 positive control groups were used. Hens in the high dose group were euthanised on day 3 as they were either unable to stand or unable to walk, presumably due to acute compound related effects. Body weight decreased were observed in the 0.3 mg/kg bw/d group, and egg production was decreased in all treatment groups except the lowest dose. Plasma ChE activity was inhibited from 0.1 mg/kg bw/d, while brain ChE activity was inhibited at 1.0 mg/kg bw/d. There was no evidence of delayed neuropathy related to monocrotophos administration (Jenkins, 1981a).

Warren Studdler hens were premedicated with IM atropine and pralidoxime chloride 1 h prior to oral administration of monocrotophos at the LD50 for hens. Positive and negative control groups were used. Hens surviving the first monocrotophos dose were given a second dose 3 weeks later, and were euthanised either 3 weeks after this or when they showed a persistent progressive ataxia. There were significant mortalities in the group receiving monocrotophos. Additional birds were included in the study, however few survived 2 doses of monocrotophos. These birds showed no signs of persistent ataxia, or histopathological nervous system lesions. Positive control animals had foci of axonal and myelin degeneration in the spinal cord and sciatic nerves (Owen & Butterworth, 1978).

Monocrotophos was fed in the diet at levels of 0, 1, 10 or 100 ppm to White Leghorn hens for 4 weeks. At this time, half the birds were euthanised and the others maintained on untreated diets for 4 weeks. Body weights and egg production were decreased in the two higher dose groups. Abnormal clinical signs, including tremors, were observed at 100 ppm, however the birds were still able to walk. The positive control group showed significant neurotoxic signs after 16 - 17 days, including an inability to stand. On histopathological examination, control animals had demyelination at a relatively high frequency. This was also seen at a similar frequency in birds receiving monocrotophos. Demyelination was more consistent and severe in the positive controls. Monocrotophos did not produce any signs of nervous system lesions (Shellenberger, 1965c).

Monocrotophos was administered orally at doses of 0, 0.03, 0.1 or 0.3 mg/kg bw/d to White Leghorn hens for 78 days, with the high-dose group then increasing to 0.5 mg/kg bw/d from day 79. There were no treatment related effects on bodyweight. Egg production was decreased in hens on the high dose from days 14 - 41, however had returned to normal by the end of the study. There were no clinical signs of neuropathy observed in monocrotophos treated animals; some positive control animals showed gait deficits. Plasma ChE activity was inhibited in the mid- and high-dose groups, while erythrocyte ChE activity was only inhibited in the high-dose group. There were no histopathological signs of delayed neurotoxicity seen in the monocrotophos treated group; the positive controls had swollen axons (Jenkins, 1981b).

4.10 Human Studies

Male students received daily oral doses of monocrotophos at either 0.0036 or 0.0057 mg/kg bw for 28 days. No adverse clinical signs were observed. Erythrocyte ChE activity was not altered by doses of 0.0036 or 0.0057 mg/kg bw/d. Plasma ChE activity was significantly decreased by 0.0057 mg/kg bw/day; a decrease was seen with 0.0036 mg/kg bw/d, however this was not significant. The NOEL may be established at 0.0036 mg/kg bw/d (Verberk 1977).

Monocrotophos was administered orally to young male volunteers in a number of trials. In the first trial, 0.015 mg/kg bw/d was administered: plasma ChE activity had decreased to 65% of pre-test levels within 7 d of commencing treatment. In the second trial, 0.0036 mg/kg bw/d was administered. Plasma ChE activity decreased to 85% of pre-test levels, and stabilised with this 15% inhibition. In the third trial, volunteers received 0, 0.0036 or 0.0059 mg/kg bw/d by gelatine capsules. In the high-dose group, plasma ChE activity was inhibited, with levels decreasing by 28% (from pre-test values) from day 18 to day 28 of the trial. Levels had returned to normal by day 9 after the end of dosing. Erythrocyte ChE activity was not affected in either dose group, and plasma ChE was not significantly decreased in the low dose group. The NOEL may be established at 0.0036 mg/kg bw/d (Verberk 1972).

Radiolabelled monocrotophos was initially administered by IV injection to young male volunteers. Urinary excretion was measured over a five day period, and the percentage of administered dose excreted was calculated. Over this period, 68% of the administered dose was excreted in urine, with the half life for urinary excretion determined to be 20 h. The IV study was followed by a dermal application study. The dose was applied to either one or both forearms and the skin allowed to air dry. Subjects were asked not to wash the skin for 24 h following application. Urinary excretion was measured as for the IV dose. Over the 5-day period, 15% of the administered dose was excreted in the urine. It was calculated that 22% of the applied dermal dose was absorbed (Feldman & Maibach, 1974).

A swamper, 2 flagmen and 2 field checkers were monitored for dermal exposure (gauze patches) and plasma and RBC ChE levels during aerial spraying of a cotton field in California

with a 60% formulation of monocrotophos in acetone (Azodrin-5) applied at 1.2 L/ha. No protective clothing was worn. Greatest dermal exposure was encountered by the field checkers, although one of the flagmen showed significant exposure on one wrist. Plasma and RBC ChE levels of the field workers were not altered (Shell Development Company, 1968).

Five workers applying a 0.06% solution of monocrotophos to rice fields in India for 7 h/day on 6 consecutive days had plasma and erythrocyte ChE levels monitored. There did not appear to be any marked difference in levels in comparison to workers not involved in pesticide application. However there were concerns that the testing method used produced variable results, and may not have given consistent ChE activity (Blok & Mann, 1977).

Volunteers were exposed to monocrotophos during aerial spraying of cotton. The quantity of monocrotophos applied was not specified. No protective clothing was used, and workers wore only light clothing (men removed their shirts). Workers remained in the cotton field for 1 h after spraying. No abnormal clinical signs were observed, and no significant variation in ChE activity was detected (Rao, Marathe & Gangoli, 1979).

Volunteers were exposed to monocrotophos during aerial spraying of cotton and adjoining grazing area. A number of animals were also exposed. No abnormalities were observed following exposure, and ChE activity was normal (Rao et al, 1980).

Workers and animals were exposed to monocrotophos during aerial spraying of a small plot. Approximately 2 kg of monocrotophos was applied over a 10-acre area. Workers wore only light clothing; no protective equipment was used. No adverse clinical signs were observed, and ChE activity remained unchanged following spraying (Nayak et al, 1975).

All personnel involved in spraying activities in the Sudan were monitored, including pilots, aircraft engineers, ground personnel and entomologists. No baseline values could be determined for any of the groups, as all had been previously working with pesticides. Protective equipment was supplied, which workers were encouraged to wear although the hot conditions made the equipment unpopular. Initial tests of ground personnel revealed many had inhibitions of whole blood ChE activity of >60% in comparison to control populations. This improved in later checks, however the percentage of ground personnel with inhibitions in excess of 20% did not improve. Inhibition in other groups of workers (pilots, aircraft engineers and entomologists) was significantly less. Few of these workers had inhibitions in excess of 60%, while a number of engineering staff had inhibitions of more than 20% (Ullmann, Phillips & Sachsse, 1979).

Monocrotophos (60% EC, diluted with water to 0.25%) was applied by 2 groups of workers to either immature or mature plants. No protective clothing was worn, and clothes were not washed daily. One individual showed signs of intoxication during the study. A number of workers on the plantation who were not involved in the study required hospitalisation. Plasma and erythrocyte ChE activity had significantly decreased on the first day after spraying, and had not returned to normal after 31 days (Gaeta, Puga & Mello, 1975).

Monocrotophos and DDT mixtures were applied to cotton by hand-held ULV applicators. Sprayers were not involved in mixing, loading or filling activities; any exposure they received was the result of spraying activities. Protective clothing was minimal, consisting of long sleeved overalls, boots and hats. Face masks, face shields, respirators, goggles or gloves were not used. No adverse clinical signs were observed. Urinary excretion of dimethyl phosphate, a monocrotophos metabolite, was higher in workers using a formulation containing Shellsol AB than those using a formulation containing ethyl dioxitol. This probably indicates a greater dermal penetrance of the formulation containing Shellsol AB. ChE activities were significantly

inhibited in both spraying groups, with some cases showing 80% inhibition on the morning following spraying. Due to the significant inhibition, the study did not proceed for the 5 days of its initial design. The study designers recommended that ULV formulations not be used for hand-held application (Sittert & Tordoir, 1981, Sitter; Tordoir & Kummer, 1985).

Monocrotophos was handsprayed to cotton, using 5 groups of workers with a variety of exposures. In some groups, workers were specifically designated as fillers or spraymen; in other groups, spraymen filled their own drums. The recommended protective equipment for spraying was trousers and a long-sleeved shirt; some workers chose to wear shorts and short-sleeved shirts. Overalls, masks, rubber boots and gloves were provided only to designated fillers; this equipment was not worn when spraymen filled their own drums. Observations indicated fillers occasionally touched contaminated equipment with ungloved hands. Sprayers were occasionally contaminated following a change in wind velocity or direction, and were exposed while filling and cleaning their containers. No adverse clinical signs were noted during the trial. Levels of the urinary metabolite of monocrotophos were higher when sprayers acted as fillers and cleaners. Whole blood ChE activity was inhibited 19 and 36% after the first and second applications, respectively across all groups (Kummer & van Sittert, 1985).

Workers entered a cotton field 24 h after spraying with 1.3 kg monocrotophos/ha. Foliar residues were approximately 4.7 mg/m^2. Residues extracted from hands and clothing ranged from 3 mg on hands to 71 mg on trousers. A respiratory dose of 27 µg/5 h was estimated. No adverse clinical signs were observed. Plasma ChE activity was not altered, while erythrocyte ChE activities were decreased by 15 -30% (Ware et al, 1974).

Workers entered a cotton field either 48 or 72 h after spraying with 1 kg monocrotophos/ha. Foliar residues decreased from 12.8 mg/m^2 immediately after application to 4.3 mg/m^2 after 72 h. Monocrotophos residues after 48 h were 2 mg on hands, 13.5 mg on shirt and 20 mg on trousers. After 72 h, the residues were 2 mg on hands, 13.4 on shirt of 29 on trousers. No adverse clinical signs were observed during the trial. ChE activities were not decreased more than 20% in comparison to controls (Ware et al, 1975).

Workers entered a tobacco plantation 48, 72 or 96 h after spraying with monocrotophos at 450 g/ha. The mean ChE inhibition following exposure 48 h after spraying was 9% for both plasma and erythrocyte ChE activity. There was less inhibition following entry at 72 or 96 h after spraying (Guthrie et al, 1976).

In a field study in the Phillippines using hand-held sprayers, 21 volunteer spraymen with no prior exposure for at least 3 weeks sprayed 1-15 ha/day with 0.09-0.18% (w/v) monocrotophos for 3 days. Only one sprayman reported a daily episode of blurred vision (duration not reported) following spraying. Excretion of urinary dimethyl phosphate (expressed as monocrotophos equivalents) increased with successive daily exposure, from a median of 0.07 mg/24 h (range, <0.04 to 0.58) on the day before spraying to 0.64 (range, <0.04 to 1.9), 0.74 (range, <0.04 to 5.1) and 1.9 (range, 0.09 to 6.3) mg/24 h respectively on the 3 spraying days. Even on the day following exposure, a median of 0.76 mg/24 h (range 0.07 to 3.5) was observed indicating a relatively long half life in plasma. A mean half life of 18 h was calculated from excreted dimethyl phosphate. Mean plasma ChE inhibition increased progressively from 0% after day 1 to 14% on day 2 and 60% on day 3. A day after spraying, plasma ChE activity was still reduced by 54% relative to controls. By contrast, erythrocyte ChE activity was reduced by only 8% on day 2 and remained unchanged on day 3 and day 4 (Van Sittert & Dumas, 1990).

Reports of occupational exposure to monocrotophos describe clinical signs, ChE inhibition in blood and excretion of the major metabolite (dimethyl phosphate) among rural residents and workers. A study reported by Guthrie et al (1976) found that rainfall substantially reduced the extent of plasma and erythrocyte ChE inhibition of workers engaged in tobacco fields previously sprayed with monocrotophos at 0.5 pounds/acre.

Following dermal exposure to approximately 600 mL of an EC formulation of monocrotophos (formulation details unknown) a young male showed clinical signs including muscle weakness, blurred vision and blackouts approximately 28 h after exposure. Following repeated doses of atropine and 2-PAM, recovery from the acute signs occurred after 3 days. On examination 11 days later, numbness of arms and hands was reported. Whole blood ChE activity decreased to 10% of reference values 1.5 days after exposure, and returned to normal after 8 weeks (Simson et al, 1969).

Following ingestion of approximately 2.5 mL monocrotophos, a man was admitted into hospital showing symptoms of organophosphorus poisoning. Consciousness returned on the fourth day and recovery was reported as complete after 33 days (Przezdziak & Wisniewsa, 1975).

A woman was found dead following presumed ingestion of a combination of monocrotophos, dodine and dinocap. Her blood alcohol level was 0.12%. The only abnormal finding detected at autopsy was congestion in the abdominal organs. Monocrotophos was detected in the stomach at 350 ppm and in the liver and blood. Dodine and dinocap were not detected. The cause of death was presumed to be monocrotophos, as the estimated ingested dose of 23 mg/kg bw exceeded the LD50 in rats, whereas dodine and dinocap have low acute oral toxicity (Gelbke & Schlicht, 1978).

At least 3 published clinical case studies involving accidental exposure or suicide attempts with monocrotophos have reported the development of "intermediate syndrome". This condition owes its name to the onset of reversible paralysis of cranial nerves, weakness of thorax muscles and respiratory difficulties occurring after exposure. generally after ChE activity has begun to return to normal. Thus, its onset is after early signs characteristic of muscarinic, nicotinic and CNS nerve overstimulation, and before delayed and irreversible neuropathy. Although not all OPs are able to induce intermediate syndrome, Senanayake & Karalliedde (1987) reported an association with monocrotophos exposure after reviewing several case histories. Two other more recent case reports have supported this finding (Mani et al, 1992; Peiris et al, 1988).

4.11 Conclusions For Public Health Standards

Acceptable Daily Intake

The current acceptable daily intake (ADI) for monocrotophos is 0.0003 mg/kg bw/day. This ADI was derived from a NOEL of 0.0036 mg/kg bw/day, based on plasma ChE inhibition seen in a 28-day human oral dosing study.

No change to the current ADI of 0.0003 mg/kg bw/day is recommended.

Acute Reference Dose

An acute RfD for monocrotophos may be set as 0.0003 mg/kg bw, based on plasma ChE inhibition seen in a 28-day human oral dosing study.

Poisons Scheduling

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

First Aid and Safety Directions

No changes to the current safety directions are recommended.

Note: Safety Directions recommendations relating to the use of personal protective equipment are to be provided by National Occupation Health and Safety Commission.

No changes to the current first aid directions (monocrotophos: a, h) and T-value (currently 0.8) are recommended.

4.12 Summary Of Acute Toxicology Hazard

Date of Preparation:	November, 1997
Chemical name:	Monocrotophos
Worst oral LD50 in rats:	8.4 mg/kg bw
Worst oral LD 50 in other species:	10 mg/kg bw, in mice
Worst dermal LD50, rat:	123 mg/kg bw
Worst inhalation LC50, rat:	80 mg/m^3
Skin irritation:	Slight
Eye irritation:	Slight
Skin sensitisation:	Negative
T-value:	0.8
NOEL: human)	0.0036 mg/kg bw/day (28-day

5. OCCUPATIONAL HEALTH & SAFETY ASSESSMENT

5.1 Existing regulatory controls for occupational health and safety

Hazardous substances

Monocrotophos is listed in the National Occupational Health and Safety Commission (NOHSC) List of Designated Hazardous Substances. Concentration cut-offs for monocrotophos are:

0.1%	Harmful
1.0%	Toxic
7.0%	Very toxic

The following risk and safety phrases have been allocated to monocrotophos:

R24	Toxic in contact with skin
R28	Very toxic if swallowed
S1/2	Keep locked up and out of reach of children
S23	Do not breathe gas/fumes/vapour/spray *[appropriate wording to be specified by the manufacturer]*.
S36/37	Wear suitable protective clothing and gloves
S45	In case of accident or if you feel unwell, contact a doctor or Poisons Information Centre immediately (show the label where possible)

All monocrotophos products which were part of the review are determined to be hazardous substances because they contain monocrotophos at 40% (w/v), exceeding the cut-off concentrations for hazardous substances.

5.2 Atmospheric monitoring

There is a NOHSC Exposure Standard for monocrotophos of 0.25 mg/m^3 time weighted average (TWA).

5.3 Health Surveillance

NOHSC has placed organophosphate (OP) pesticides (including monocrotophos) on the Schedule for Health Surveillance. The employer is responsible for providing health surveillance where a requirement has been established as a result of a workplace assessment process.

5.3.1 Toxicity relevant to occupational exposure

In experimental animals, monocrotophos is of high acute toxicity. The lowest oral LD_{50} is 8.4 mg/kg bw in rats (10 mg/kg bw in mice) and lowest inhalation LC_{50} is 80 mg/m^3 (4h) in rats. The acute dermal toxicity of monocrotophos is variable and dependent on the solvent; the lowest dermal LD_{50} is 123 mg/kg (rats). Monocrotophos is a slight skin and eye irritant in rabbits. It is not a skin sensitiser in guinea pigs.

In animal studies, monocrotophos is excreted mainly in the urine and the major metabolite is dimethyl phosphate (DMP).

Studies in experimental animals indicate that cholinesterase (ChE) inhibition is the major toxic effect of monocrotophos. The chemical did not demonstrate a clear difference in binding affinity between plasma, red blood cell (RBC) and brain ChE. Some animal studies indicated no difference in sensitivity between different ChE activities.

Monocrotophos was not found to be carcinogenic. It did not have an adverse effect in reproductive parameters in rodent studies. Developmental toxicity was noted only at or near maternotoxic doses in rats and rabbits, however, no teratogenic findings were observed.

Monocrotophos appears to be a weak mutagen at high doses. Metabolic activation was not required for genotoxic effects of monocrotophos.

Single or repeat dose studies (up to 78 days) in hens did not demonstrate delayed neurotoxicity. Two year dietary administration of the chemical in rats did not indicate nerve damage or acceleration of normal age related changes.

The most conservative no-observed effect level (NOEL) for monocrotophos established for animal studies was 0.004 mg/kg/d in 1 and 2 year dog dietary studies for brain ChE depression.

In a number of trials (monocrotophos given in capsule form for 28 days) in human volunteers, a NOEL of 0.0036 mg/kg/d was established based on plasma ChE depression at the next high dose. RBC ChE was not affected.

The NOELs established in short-term human studies (0.0036 mg/kg bw/d) are similar to the NOEL for long term animal studies (0.004 mg/kg bw/d).

In reports of human poisonings, there were three cases, having muscular weakness and paralysis which was manifested 1-4 days after exposure (short-term effects). It was concluded that monocrotophos does not produce chronic neurological changes.

In a study in male volunteers, it was calculated that a maximum of 22% of the applied dose on skin was absorbed. This value is used in the risk assessment.

5.3.2 Reported health effects and urinary excretion involving agricultural workers using monocrotophos

In Australia, reports of ChE measurements during routine use of monocrotophos (aerial spraying) along with other organophosphate pesticides indicated that ChE inhibition could occur in some individuals without clinical symptoms. In the first report, protective clothing was not provided and washing facilities were poor. In a follow up survey when protective clothing and washing facilities were provided, fewer workers demonstrated ChE depression.

Ten cases of neurotoxic effects of OP insecticides were reported in a research publication. One of them was related to contamination after spraying monocrotophos. The muscular weakness lasted for 16-18 days. The person did not develop delayed polyneuropathy.

Many studies were conducted in developing countries using knapsack (on rice) or hand held equipment and an ultra low volume (ULV) formulation (on cotton). ULV formulations are not registered in Australia and hand held uses in field crop are not anticipated. Back mounted knapsack application is prohibited on registered Australian labels for monocrotophos products. Only the findings applicable to the Australian use of monocrotophos are summarised below.

- Recovery of whole blood and plasma ChE was not seen up to 40-hrs post-exposure.
- Hand contamination was noted during open mixing/loading operations which included the use of a 1 L container with a special dispenser. One mixer/loader demonstrated a 47% ChE depression (from individual baseline level) despite wearing gloves.
- During hand-held spraying operations, greatest exposure was noted on the forearms and hands.
- Cleaning up application equipment without gloves resulted in worker exposure and depression of ChE. Clean up activities are not covered by the safety directions on Australian labels.
- Urinary DMP excretion corresponded with handling and application practices. DMP excretion was incomplete 20 hrs after last exposure.
- The degree of ChE depression correlated well with urinary DMP levels. Greater absorption was noted when using monocrotophos products containing aromatic hydrocarbon solvents than glycol ether solvents, as indicated by urinary DMP levels and blood ChE depression.

5.4 Use pattern for monocrotophos in Australia

5.4.1 Handling prior to end use

Technical grade monocrotophos is imported from India. All the products are formulated in Australia. Chemical industry workers will be potentially exposed to monocrotophos and monocrotophos products. Retail, transport and storage workers will handle the packaged active constituent or products. There is no exposure information available on formulation workers.

The products are available in 5L and 200L size containers.

5.4.2 Handling by end users

Monocrotophos is used as a broad spectrum insecticide/miticide on various crops including fruit (apples, pears and bananas) and vegetables (tomatoes sweetcorn, potatoes and beans), cotton, tobacco, cereals, oilseeds, and for treatment of non-fruit bearing tree trunks by local injection.

The use patterns of all registered monocrotophos products are similar. Both ground and aerial spraying is possible. The products are not registered for home garden use.

Application rates are specified on product labels as mL product/100 L water or L product/ha. The ranges are 85 mL-300 mL/100 L (0.03-0.12% monocrotophos) and 250 mL - 4.0 L/ha (100 g-1600 g monocrotophos/ha). Information on the Australian use pattern of monocrotophos is derived from the product labels, NRA Performance Questionnaires and NRA Agricultural Assessment Report. The information is used to estimate worker exposure under Australian conditions and is summarised in Table 1.

Workers may be exposed to monocrotophos when mixing/loading, applying spray, cleaning up spills and maintaining equipment. In addition, re-entry workers may come in contact monocrotophos residues on treated foliage. Re-entry tasks would include crop checking and maintenance, manual weeding (eg in cotton crops) and harvesting. In aerial operations, flaggers may be exposed to monocrotophos.

The main route of occupational exposure will be through skin contamination while performing any routine tasks. Sprayers may inhale spray mist. Workers may handle monocrotophos repeatedly throughout the season(s).

5.4.3 Estimation of worker exposure

There were no measured worker exposure studies from use under conditions comparable with Australian use patterns and conditions for mixer/loader/applicators (M/L/A) of monocrotophos products. Estimations of worker exposure relied on a predictive modelling. Estimates of exposure (and risk) covered a range of application rates (kg ai handled/day) and work rates as specified in Table 1.

Table 1 End use parameters used to estimate worker exposure and risk to monocrotophos by crop groups

Crop	Application rate (range) kg ai/day	Work rate (range) (ha/day)	POEM Estimates
Apples & pears	1.6 - 24	2 - 30	high volume air-blast
Bananas	-*	-*	None (only aerial spraying)
French beans	6.24 - 8.16	24	high volume and low volume boomspray
Potatoes	20	50	low volume boomspray
Tomatoes	30	24 - 30	high and low volume boomspray
Sweet corn	12 - 15	30	low volume boomspray high volume boomspray
Tobacco (broadacre)	6.72	24	high volume boomspray
Broadacre including cereals, wheat, oilseeds and cotton	5 - 80	50	low volume boomspray

* Qualitative assessment only

5.4.4 Predicted end use exposure

The UK Predictive Operator Exposure Model (POEM) was used to estimate monocrotophos exposure for the Australian use pattern in orchard and field crops. Two application methods were chosen:

- Vehicle mounted with cab (boomspray) with hydraulic nozzles (V-nozzle);
- Vehicle mounted (without cab) Air-Assisted (Air-Blast) both high (V-500) and low volume (V-100).

POEM could not be used to estimate worker exposure during aerial spraying.

5.4.6 Re-entry exposure

No Australian re-entry exposure data or field residue data were available. Overseas measured worker re-entry exposure data were available from the published literature. Overseas residue data were available in cotton, from spray application to 15 days post-application.

5.4.7 Assessment of health risk to workers

In estimating health risk to workers from predicted exposure data, an average body weight of 60 kg per worker and skin penetration of 22% for monocrotophos, were used.

- ***Single exposure*** - A fatal case of human poisoning after ingestion of monocrotophos at dose equivalent to 23 mg/kg bw was reported in the published literature. Assuming 60-kg body weight and 22% dermal absorption, this equates to a dermal dose of 6.3g monocrotophos or 15.8 mL of Azodrin Insecticide at 40%.
- Monocrotophos is a slight eye and skin irritant in experimental animals and may cause these effects in exposed workers.

- ***Repeated exposure*** - The human oral NOEL of 0.0036 mg/kg/d for significant decrease of plasma ChE is selected for the occupational health and safety risk assessment. In order to exceed this dose, skin would need to be contaminated with more than 0.98 mg monocrotophos or 0.002 mL of 40% formulation for an average 60-kg worker with a 22% dermal absorption. This calculation does not include a safety factor. Assessment of risk was based on calculations of margins of exposure (MOE). MOE for Australian use patterns were calculated by comparing the NOEL with predicted worker exposure. An MOE of 10 or more was considered acceptable for monocrotophos.

5.5 Assessment – Ground application

There are no measured worker exposure studies from use under conditions comparable with Australian use patterns and conditions for M/L/A of monocrotophos. The UK POEM was used to estimate exposure and MOE for the Australian use pattern wherever possible.

5.5.1 Fruit trees (apple and pears)

Predicted exposure for M/L/A from POEM (open M/L) for high volume airblast spraying without cabs at 2000 L/ha spraying for 2 hours (2 ha) or 6 hours (30 ha) resulted in low and unacceptable MOE for workers wearing gloves and overalls. Elimination of mixer/loader exposure will not substantially reduce the risk. An additional layer of protective clothing will not substantially reduce the risk.

5.5.2 Vegetables including potatoes, French beans, tomatoes and sweet corn

Predicted exposure using POEM for both high and low volume applications resulted in low and unacceptable MOE for mixer/loader and applicators wearing gloves and overalls. The elimination of worker exposure during mixing is unlikely to substantially influence the MOE. The addition of respiratory protection is unlikely to substantially influence the MOE.

5.5.3 Broadacre (tobacco, cereals, wheat, oilseeds and cotton)

Predicted exposure using POEM results in low and unacceptable MOE for workers wearing gloves and overalls. The elimination of worker exposure during mixing is unlikely to substantially influence the MOE. The addition of respiratory protection is unlikely to substantially influence the MOE.

5.5.4 Non-fruit bearing trees

There are no measured exposure studies available for workers involved in treating trees by standard syringe or eyedropper and it is not possible to predict exposure using POEM. Details of work practices are not available for this registered use. Exposure and risk for these workers could not be quantified.

5.5.5 Flowers-control of budworms (permit use in Queensland)

The assessment of monocrotophos use found an unacceptable level of risk during ground spraying for control of budworms.

5.6 Assessment - Aerial spraying

There are no measured exposure studies available for workers involved in the aerial spraying of monocrotophos and it is not possible to predict exposure using POEM. Aerial spraying is the common method of applying monocrotophos in various broadacre crops including cotton, potatoes, non-crop areas (locust control) and tobacco.

The operators would be involved in multiple applications. The container sizes available are 5 L or 200 L. However considering the large amounts of monocrotophos needed, the 200 L bulk handling containers would be most frequently used. Mixer/loaders using bulk containers are likely to receive special training in chemical handling and should be able to exercise more effective control over exposure. On balance, the risk to mixer/loaders and spray pilots is considered acceptable.

Flaggers involved in aerial spraying would become contaminated with spray mist. The likelihood of exposure is high and cannot be quantified. Therefore the potential risk to human flaggers is considered unacceptable, unless they are protected by engineering controls such as cabs.

5.7 Tank mixing

The risk assessment indicated unacceptable risk to workers handling monocrotophos alone. Therefore, the additional (unquantified) risk of mixing monocrotophos and other anticholinesterase chemicals is not acceptable on occupational health and safety grounds.

5.8 Re-entry Assessment

There is a re-entry period of 5 days on the registered label for Azodrin 400 Systemic Insecticide/Miticide cautioning workers not to handle treated crops after spraying unless wearing protective clothing.

The overseas studies on dislodgeable foliar residues indicated low levels of residues at 96 hours.

The degradation of monocrotophos under aerobic conditions in soil was rapid, with a half-life of between 1 and 7 days. It is unlikely to persist beyond one week following application in soil. Bioaccumulation is not expected.

Based on currently available data a re-entry period of 5 days is acceptable.

5.9 Conclusions

5.9.1 Worker exposure during end use

Aerial application
The risk could not be quantified for aerial applications. However, this method of application is considered to be relatively safe in comparison with other application methods due to its minimal exposure to sures and more demanding training requirements for operators. Therefore, aerial application was considered acceptable as long as the following control measures were observed if aerial spraying was to be undertaken.

- Development of enclosed mixing/loading systems;
- Farm chemical user training for workers handling monocrotophos (addressed below);
- Health surveillance to be conducted when appropriate, for workers handling monocrotophos;
- Human flagging in aerial operations is not acceptable, unless flaggers are protected by engineering controls such as cabs.

Fruit trees (apple, pears and bananas)
The risk for workers applying monocrotophos by high volume airblast spraying based on predicted exposure was high and unacceptable, even if mixer/loader exposure was eliminated.

Vegetables including potatoes, French beans, tomatoes and sweet corn
The risk for workers applying monocrotophos by high volume or low volume boomspraying, based on predicted exposure was high and unacceptable, even if mixer/loader exposure was eliminated.

Monocrotophos may be applied by aerial spraying on potatoes. Based on the qualitative risk assessment, continued use of aerial spraying for potatoes is acceptable, as long as it remains available only to licensed and authorised personnel.

Monocrotophos use on tomatoes, French beans and sweet corn could not be supported as the risk is predicted as unacceptable. Measured worker exposure data are needed to quantify risk for these uses.

Broadacre (tobacco, cereals, wheat, oilseeds and cotton)
The risk for workers applying monocrotophos for high volume and low volume boomspraying based on predicted exposure was high and unacceptable, even if mixer/loader exposure was eliminated.

Monocrotophos was applied mainly by aerial spraying on broadacre crops. Based on the qualitative risk assessment, continued use of aerial spraying for cotton, lucerne, maize, non-crop areas (locust control), sorghum, wheat, soybeans and sunflower is acceptable, as long as it remains available only to licensed and authorised personnel.

Groundspraying on broadacre crops is not supported as the risk is predicted to be unacceptable. Measured worker exposure data is needed to quantify risk for this use.

Non-fruit bearing trees
This use could not be assessed. Use could not be supported unless worker exposure data was provided for assessment.

Flowers-control of budworms (permit use in Queensland)

This is very similar to high volume boomspraying of tomatoes and application rates are the same. The risk for workers applying monocrotophos for high volume or low volume boomspraying, based on predicted exposure was high and unacceptable, even if mixer/loader exposures were eliminated. The permit use of monocrotophos for control of budworms is not supported as the risk is unacceptable.

6. ENVIRONMENTAL ASSESSMENT

6.1 Introduction

Monocrotophos was registered for use on cotton, beans (French), granny smith apples and some varieties of pears, bananas, sunflowers, maize, millet, sorghum, soybeans, sweet corn, wheat, triticale, panicum, potatoes, tobacco, tomatoes and for non-fruit bearing trees by injection, with the major use in sorghum and sunflowers for control of locusts. It was used to control a wide range of chewing, sucking and boring pests (aphids, caterpillars, *Helicoverpa spp*, mites, moths, jassids, budworm, scale and stem borer) as well as locusts. Application is normally by air for cotton, sorghum and sunflower. Ground based equipment was used for other crops. It seemed to be used mainly as a back-up spray when insect pressure and resistance levels were high, eg tomatoes 1997-98 or for control of locusts by landholders.

The maximum use rate stated on the, now unregistered, label is 4.0 L/ha, corresponding to 1.6 kg ai/ha for *Helicoverpa* in cotton, with lower rates for other pests. For orchards the maximum use rate is 2 L/ha for bananas and for Granny Smith apples and pears a spray rate of 100 mL/100 L of spray. For vegetable crops the maximum rate is 250 mL/100 L or 2 L/ha, corresponding to 800 g ai/ha. There are other uses on the label at different rates, grains at 700 mL/ha (280 g ai/ha) for locusts, tobacco at 300 mL/100 L for budworm, sunflowers at 1.8 L/ha (720 g ai/ha) and tomatoes at 2 L/ha, both for *Helicoverpa spp.*

The current major usages are for sorghum and sunflowers, with tomatoes and cotton the other significant uses. On the label there are unlimited number of repeats allowed for most applications, apart from tomatoes in Victoria with a maximum of four applications per season. It should be noted that in the season 1997-98, monocrotophos was applied to approximately 20% of the tomatoes processing crop in Australia at least once or twice which represents a significant increase in use over the 1996-97 season.

Several of the rates in the, now unregistered, label are as dilutions and these do not readily convert to rates per hectare, eg L/ha. As it is normal practice to spray to runoff, in field crops (tomatoes, sorghum etc) this normally requires 200 to 1000 L/ha of spray solution, depending on the size of the plants, but could be higher, ie 1500 L/ha. Using the figure of 1000 L of spray per hectare, the rate for tomatoes and tobacco is 2.5 L/ha (1 kg ai/ha) and 1.6 L/ha (640 g ai/ha) respectively.

The use pattern, as stated on the, now unregistered, labels, is as indicated by crop monitoring for cotton or 4 days with heavy infestations on one label or 10 days between sprays (other labels), on a weekly program basis for beans; every 7-10 days for potatoes and tobacco crops, 2 to 3 times per week during silking for sweet corn and for other crops as indicated by pest activity. It should be noted that tomatoes could have three crops per year in the tropics.

Monocrotophos is applied to crops by aircraft and tractor powered sprayers, either as a mist or a spray. Application by fogging machines and back mounted knapsacks is forbidden on two labels but not on others. The labels ban aerial spraying in Tasmania (without specific approval of the Registrar of Pesticides).

6.2 Chemistry And Fate

All studies presented are old, pre 1980, and were not performed to modern Guidelines or laboratory standards. Several are from the scientific literature and again have not been performed according to current Guidelines. Despite this, the results are relatively consistent and give a reasonable profile of the environmental fate of monocrotophos.

Hydrolysis
From three experiments it was concluded that in acidic conditions, pH between 3 and 8, hydrolysis is slow, 66-150 days, and is classified as slightly hydrolysing (Netherlands classification). At higher pHs hydrolysis is quicker, the half-life was 17 and 26 days at pH 9.0 in two studies, and is classified as moderately hydrolysing. Hydrolysis is unlikely to be a significant contributor to the overall degradation of monocrotophos at the normal environmental pH range (5-9).

Photolysis

—Aquatic
Based on the single study presented there is no evidence that monocrotophos photolyses in water.

—Soil
In the study presented, there was evidence that sensitised photolysis had occurred, with a significant increase in the rate of degradation between the sample exposed to sunlight and the dark control, with a half life of 3 days compared to 30 days.

It is concluded that there is no evidence in the studies presented by the registrants that direct photolysis will be a degradation pathway in the environment but indirect photolysis could increase the degradation rate in the environment.

Metabolism

—Aerobic Soil Metabolism
The degradation of monocrotophos under aerobic conditions in soil is fast, with a half-life of between <1 and 7 days, based on 5 different soils. The major products were carbon dioxide and non-extractable residues. Some minor metabolites were identified in some soils, with the highest at 3.5% of the applied dose. The major degradation pathway appears to be direct metabolism to carbon dioxide or incorporation into the organic fraction of the soil followed by mineralisation.

—Aerobic Aquatic Metabolism
No studies were presented that determined a half-life. However, monocrotophos was shown to degrade rapidly under aquatic aerobic conditions (a rice paddy in the tropics) but by contrast there was no degradation in natural river water at room temperature, consistent with the hydrolysis experiments. It is concluded that the limited studies show that in aquatic systems with high microbial activity, ie with soil/sediment, degradation could be rapid. The lack of a suitable aerobic aquatic metabolism study is a significant data gap that should be correct if any registrations are retained.

—Anaerobic Aquatic Metabolism
No studies were presented that determined a half-life or examined whether monocrotophos degrades under anaerobic conditions.

Mobility

—Soil adsorption/desorption
The soil adsorption/desorption of monocrotophos was determined in four soils by the standard batch flask method. It was concluded that monocrotophos is only weakly adsorbed to most soils and is rated as being mobile in soils. There was significant desorption which confirms that binding is weak.

—Leaching
In a column leaching study on the same four soils used in the adsorption/desorption study, most of the applied monocrotophos was found in the leachate and it was concluded that monocrotophos is mobile. However, using treated soil that was aerobically aged for 30 days, there were no monocrotophos or metabolites in the leachate, thus indicating that the rapid degradation will limit the extent of leaching that is likely to occur under field conditions.

—Volatility from Soil
It has been calculated in the literature that monocrotophos is not volatile from soil, based on Henry's law constant, modified for adsorption to soil.

—Conclusion
It is concluded that monocrotophos is mobile in soil and that leaching is possible. However, the rapid degradation will limit the extent of leaching that is likely to occur under field conditions. Volatilisation from soil is not expected to be a significant route for the dissipation but volatilisation from other non-adsorbing surfaces cannot be ruled out.

Spray Drift
Recent literature studies on aerial spray drift from a number of experiments showed that the 95th percentile gave spray drift results of 0.35% of the application rate at approximately 300 metres. Thus one in twenty aerial applications result in >0.35% of the application rate as spray drift at 300 metres from the edge of the field being sprayed. Under adverse conditions, ie inversion layers, the 95th percentile for spray drift increases to 1% of the application rate.

In another study in an orange grove four different application methods were compared, fixed wing and rotary wing (helicopter) aircraft as well as high volume and low volume ground applications. This data showed that fixed wing aircraft gave the highest spray drift close to the last sprayed trees, with the other three methods giving similar spray drift and at 200 metres the aerial (fixed and rotary wing) and ground based low volume were similar and the high volume gave the lowest spray drift.

Field Dissipation Studies
Six of the seven field studies presented were older than the current standards and none of the studies meet the current requirements for details of reporting, methods used or analysis of application rates. However, all the older studies showed a consistent pattern, in that monocrotophos was degraded quickly, with half-lives <7 days, and that there are no significant metabolites formed. In one study where soil was sampled at depth, no leaching was noted.

In a more recent literature study in rice paddies, the half-lives were <1 and 9.7 days in water and soil respectively after 3 applications.

Bioaccumulation
The bioaccumulation study presented was found unsuitable as a bioaccumulation study for monocrotophos due to the lack of any monocrotophos present after aging of the soil used. However, based on water solubility, low K_{oc} and ready soil degradation, significant bioaccumulation in the aquatic environment is not expected.

6.3 Ecotoxicity

Monocrotophos is a highly toxic organophosphate insecticide. It is toxic to most organisms and in particular to birds.

Avian
A database from the US EPA (Ecological Fate and Effects Division of the Office of Pesticide Programs, to which Environment Australia has access, contains the presently known ecotoxicity endpoints for registered pesticides used in the US (referred to as OPP database). The database is compiled from studies reviewed by EPA in conjunction with pesticide registration or reregistration and judged to meet US EPA Guidelines. The database for avian species show that monocrotophos can be rated (according to US EPA) as very highly toxic to birds by both the acute oral, based on reports for 13 species (LD50 of 0.19 to 6.49 mg/kg), and dietary routes of exposure, 3 species (LC50 range 2.4-32 ppm). Multi-generation tests (approximately 20 weeks exposure) on Mallard and Japanese quail, accepted as supplemental studies by the US EPA, showed that effects occurred at low levels, at 0.1 mg/kg in feed for Japanese quail. However, as Environment Australia does not have access to the study, the effects observed are not known.

Results in the literature for toxicity to also indicate very highly toxic to birds by acute oral route, based on reports for 9 species (LD50 of 1.0 to 6.7 mg/kg). For mallards in chronic (30 days) exposure, the "empirical minimum lethal dose", ie when first mortalities were noted in chronic 30 exposure, was very low, 0.25 ppm in the feed but for quail a 21 day dietary test showed that the LOEC was 5 ppm in the feed.

Field reports indicate that monocrotophos has been associated with several incidents of bird kills in the USA and has been used as an avicide. The table below summarises all the field studies presented. This table does not include one very complex semi-field study on quail which examined a range of different exposures when monocrotophos was aerially applied at 450 or 900 g ai/ha to caged birds (quail and pheasants) leading to contaminated feed, water, soil, plants etc but the results were very variable and confusing. A similar but smaller study on pheasants at 450 g ai/ha showed limited toxicity.

The old field studies presented in the Table suggest that in areas where there was either food, ie wild seeds, or standing water which attract birds to either drink or feed in treated fields significant mortalities occurred at rates of 1 kg ai/ha and above, except for one study that showed mortalities at 0.32 kg ai/ha. Birds entering recently sprayed fields were not affected, provided they did not feed or drink in the field. Feeding on sprayed locusts or rodents also leads to high mortalities. However, there is no evidence from the field studies that dermal exposure is a significant route of mortality. Importantly, data from the literature suggests that monocrotophos is palatable to birds above the lethal dosage.

There are anecdotal Australian reports of bird kills from label use of the EC, especially where birds are actively feeding on sprayed crops. Many growers consider it as causing significant

birds kills. There are well documented reports of monocrotophos causing significant mortalities of Swainson's hawks in Argentina following use to control grasshoppers.

Trial	rate used, kg ai/ha	Effects/Observations
Germany Site A Site B	1.0 1.0	>40 dead birds after 3 days in field with weeds seeding (>50% weed cover, site A). <10 dead if field relatively weed free (<10%, site B)
Arizona	0.14-0.18	Minimal effect on local population of birds (quail and doves)
California Site 1 Site 2	1-1.4 0.32	25 blackbirds killed. Standing water and weeds in fields. 120 horned larks died. Again standing water and weeds in fields.
Aust. Caged zebra finches and caged magpies	1.26	6 of 36 finches dead and 7 of 24 magpies dead after 3 days, all finches were directly exposure only and the magpies were direct exposure and fed contaminated grain.
Bearing No. 1 first treatment	1.07	21 Hatchlings dead. No controls used.
Second treatment	3.4	11 feather piles, 3 mammals dead. Leaking pipes noted in orchard. Possibility that birds drunk contaminated water from puddles near the leaking pipes.
Bearing No. 2	1.7	25 birds dead, 8 sick. Dead and dying birds had monocrotophos in their crops. Authors considered that birds had drunk contaminated water from leaves or shallow ponds, possibly due to hot weather.
7 non-bearing citrus groves	0.22-0.28	No dead birds but few expected to be exposed.
2 non-bearing	0.225 and 0.5	No dead or intoxicated birds but few expected to be exposed.
Israel Vole plague	1.6-2.8	Large no. of pipits and wagtails killed by direct application. 150 birds of prey (kites, eagles, owls etc.) found dead and 69 paralysed. Total of 300-400 birds affected by one application.
Louisiana rice fields	0.65 to 110 ppm in seed	100 ducks and geese died from deliberate poisoning of rice seed
Argentina	not known	Up to 20,000 hawks died when monocrotophos was misused to control grasshoppers in Argentina.

Summary of the field studies presented for avian toxicity. One very complex semi-field study has not been included.

Aquatic

Only a few modern test results are available but these are consistent with those from the older tests, both company and literature, and the toxicity (LC50 or EC50) to aquatic organisms ranges from 0.24 µg/L to 180 mg/L. Monocrotophos is rated according to US EPA classifications as very highly to slightly toxic, with invertebrates being the most sensitive class of organisms. The reported acute toxicity to daphnia is given as between 0.24-20 µg/L but no study meets current requirements and this is a significant data gap. Fish are the least sensitive, with a range of LC50s from 1.9 to 180 mg ai/L, based on 9 species, and monocrotophos is rated as moderately to slightly toxic to fish, again according to US EPA criteria. Several of these values are old, nominal and are considered not reliable but in the absence of other data, they will have to be used. The OPP database entries show similar sensitivities for fish, LC50 between 5.2-50 mg/L, and invertebrates as more sensitive based on a single study for scud, LC50 of 0.26 mg/L.

Monocrotophos is rated as moderately toxic to one species of green algae, *Chlorella vulgaris* with EC50s of 6.8 mg/L (nominal) but non-toxic to *Scenedesmus subspicatus,* another green alga, where the EC50 was >100 mg/L and NOEC = 100 mg/L. The US EPA considers both as insensitive species.

Frogs seem to be insensitive to effects of monocrotophos.

Non-Target Invertebrates
Monocrotophos is extremely toxic to bees by all routes of exposure, based on 7 different literature reports. The only modern study used an Indian Guideline but it was not possible to determine the dose received by the bees. Residues on foliage were very highly toxic to bees 24 hours after application (100% mortality).

The toxicity to earthworms was 196 mg/kg of soil for one test and 35 mg/kg of soil, reported in the company literature to which Environment Australia does not have access. Both tests are stated to be based on OECD Guideline 207. These tests rate monocrotophos as either slightly or moderately toxic to earthworms (Netherlands classification).

Based on the results of 15 reports, monocrotophos is very toxic to all the non-target invertebrates tested, in particular bees, lacewing and a range of other predatory insects. Some reports show that monocrotophos is more toxic to the beneficial insects than the pests. Again the only modern results are from 3 studies performed to Indian requirements and are difficult to relate or compare to results from other studies.

Monocrotophos has minimal effects on a range of soil micro-organisms and their biological activities at the concentrations expected in the soil following application at the maximum label rate.

Mammals
Monocrotophos is extremely toxic to mammals by the oral route of exposure and is classified by the US EPA in Toxicity Category I, with LC50 of 18 mg/kg. The dermal toxicity is less, with an LD50 of 354 mg/kg.

In Australia tests on the native marsupial *Sminthopsis macroua* showed that a single dose at 80-100 mg/kg body weight caused death. A lower dose at 2 mg/kg bw at intervals over 18 days did not cause any deaths. The Australian native rodents *Notomys alexic* and *Notomys mitchelli* when fed monocrotophos at 668 mg/kg for 5 consecutive days showed reduced body weight and all animals were off their feed by the end of the testing period.

Phytotoxicity
Monocrotophos is non-phytotoxic when used at the recommended rates although some varieties of apples, pears, cherry, peach and sorghum may show some injury.

6.4 Predicted Environmental Hazard

6.4.1 Terrestrial organisms

Mammals

Terrestrial animals are at risk from monocrotophos when application of the chemical is in progress or afterwards by contact with sprayed surfaces or from consuming residues of the insecticide in feed and water. Aerial applications could overspray larger non-target organisms, such as marsupials but this is not considered a common occurrence due to the low height of the spray aircraft at application, ie close to crop height, and it is expected that these animals will move some distance from the area where spray operations are occurring, while smaller mammals will be undercover. Similarly, overspray by tractor powered equipment is considered unlikely.

It is difficult to assess the risk to larger terrestrial organisms that enter sprayed areas and are orally and dermally exposed to residues. Residues on short grass are estimated at 340 ppm from direct application at the highest rate for cotton (1.6 kg/ha). As this is half the dosage used for an acute dietary study on native mammals with minimal effects noted, and as direct overspray of grass for locusts is at a greatly reduced rate, the hazards is considered low. However, animals that enter recently sprayed areas are at some risk of exposure but as there are few, if any, reports of dead or dying animals from use in Australia, it is considered likely that the risk is relatively low at the rates used in Australia.

Birds

According to available literature reports and press reports, there have been a number of incidents of monocrotophos poisoning of birds in Australia and overseas when used according to label directions. Most of these reports involved birds either eating sprayed feed or drinking from water that has been oversprayed. The older field data examined clearly indicates that the birds that died were observed or had been feeding in treated areas or had drunk from water in fields following application.

Environment Australia's calculations of the hazard using standard methodology shows that the overall hazard to birds appears high and unacceptable, especially to birds that consume insects, seeds etc that are directly oversprayed by the chemical. Use of monocrotophos to control locusts at the higher rate is likely to represent a very high hazard to avian predators of locusts and is unacceptable. This hazard has occurred in Argentina, where large numbers of Swainson's Hawks died following application of monocrotophos to control grasshoppers and led to use of the chemical being restricted/banned. At the lowest label rate for small locusts, 350 mL/ha, calculations for acute dietary exposure for quail (LC50 = 2.4 ppm, 50% of feed contaminated) for small insects indicate a high hazard and large insects a moderate hazard. Given the possible increased sensitivity of the raptors, a significant hazard to these birds cannot be ruled out, even for large insects. Anecdotal evidence also suggests significant mortality after use in cotton and for locust control in Australia.

An endangered bird at risk from use of monocrotophos is the Plains-wanderer (*Pedionomus torquatus*), which lives in areas of sparse native grassland and similar vegetation. A recovery plan has been developed for the Plains-wanderer, which listed the main threats as habitat clearance for agriculture and overgrazing by stock and rabbits, with locust spraying a suspected additional factor. Use of monocrotophos in non-cropping areas, likely habitat for the Plains-wanderer, could potentially impact the survival of the Plains-wanderer and is of concern.

The weight of evidence indicates use of monocrotophos poses a high hazard to birds, and it is difficult to defend its continued use. Unfortunately most of the evidence is old and from overseas, with local reports of bird mortality largely anecdotal though consistent and derived from a number of sources. If any uses are to be retained, these should be at the lower rate (140 g ai/ha) and closely controlled, eg. under permit, with conditions that require close monitoring of hazard to birds so that the hazard posed by use these crops may be better defined. As noted above, this is of particular importance to use for control of locusts and other pests in sorghum, sunflowers and pasture/rangelands.

Invertebrates

The hazard to bees and to other terrestrial invertebrates is high, particularly from aerial application. Using the application rate of 720 g ai/ha (rate for sunflowers, sorghum, and orchards) and the method of Urban and Cook, the hazard was determined to be high. The hazard from aerial spray drift to bees is high at the higher rates and likewise for other non-target insects but is acceptable at rates used for locust control, ²280 g ai/ha, at 100 metres or greater for bees and the less sensitive insects. However, spray drift from the lowest rate, 140 g ai/ha, is expected to be toxic to *Apanteles spp*, the most sensitive insect to topical applications of monocrotophos.

The hazard to earthworms from use of monocrotophos is expected to be low. For other soil invertebrates there may be expected to be a high hazard but there are no toxicity data for these organisms.

If use of the chemical is to be retained, the current label warning with regard to bees should be strengthened and modified to read:

> Do not spray any plants in flower or if flowering expected within 7 days, including ground covers, or while bees are present. Spray drift is also highly toxic to bees and at hundred of metres distance.

6.4.2 Aquatic organisms

Overall, using standard methodology it is concluded there is a high hazard aquatic hazard to sensitive invertebrates from spray drift for all application rates, except for boom spray applications at 140 g ai/ha, where provided suitable measures to reduce spray drift are in place, the hazard is moderate. There is also a potentially high hazard from runoff if rain occurs within days of application.

Aerial Application

Apart from direct overspray, the hazard to fish is considered to be acceptable. No hazard is expected to algae. However, the hazard to sensitive aquatic invertebrates was determined to be unacceptable to beyond 300 metres for all aerial application rates from spray drift, based on AgDRIFT and literature reports, when used according to current label directions. At the lowest rate examined, 140 g ai/ha, the hazard to less sensitive aquatic invertebrates was acceptable at 300 metres but only with placement spraying (vmd 350 μm). It should be noted that a high hazard exists from runoff at high rates as well.

The newly proposed Best Practices Manual for Cotton Growers has a guideline for a buffer of 300 metres downwind for all aerial applications. While adoption of this would reduce the hazard to environmentally sensitive areas, additional measures such as reduced applications rates and placement spraying are required to reduce the hazard to more acceptable levels. As it is unlikely that the rates in cotton can be reduced sufficiently, aerial application of

monocrotophos to cotton is likely to cause significant impacts on aquatic invertebrates 300 metres and beyond from the application site and is therefore unacceptable.

As most other crops do not have a best practices guideline and the condition of use is up to the individual grower, current aerial application to other crops is considered unacceptable for all rates. However, if the rates could be lowered to 140 g ai/ha and placement spraying is used, then the hazard is moderated and considered just acceptable.

In conclusion Environment Australia considers that an unacceptable hazard exists through aerial application of monocrotophos, due to both spray drift and runoff, when use according to the current label. While we are not aware of any actual aquatic mortality incidents due to monocrotophos, continued regular use of monocrotophos according to the current label is difficult to defend, based on the hazard assessment. Environment Australia cannot support its continued use by aerial application, except at the lowest rate together with other mitigating factors such as large droplets and buffer zones (>300 metres).

Orchard Air Blast Equipment

The analysis using the AgDRIFT for spray drift from the US EPA showed that for apple and stone fruit orchards, the hazard to aquatic invertebrates from orchard air blast sprayers may be acceptable. For larger trees and dormant spraying the hazard was high and extended to beyond 100 metres from the orchard. Information from the agricultural assessment and other sources show that use on pome fruit orchards is declining with the introduction of IPM. Considering the lack of data for degradation, the level of hazard and that use of monocrotophos is declining in favour of chemicals more suitable for IPM, Environment Australia would favour the removal of pome fruit use from the label. Environment Australia notes that this is already the case with some labels.

Boom Sprayer

Calculations clearly showed that the spray drift hazard from boom sprayers to aquatic invertebrates from boom sprayers is high at 30 metres distances, especially at the application rate tested 800 g ai/ha (2 L/ha), and just acceptable at 100 metres. At the lowest rate of 140 g ai/ha (350 mL/ha) the hazard at 30 metres is just acceptable. However, as it is expected that in the vast majority of cases that crops are unlikely to be within 30 metres of waterways, use monocrotophos by boom sprayers may be acceptable provided that the rates are reduced to 140 g ai/ha. In addition, the growers should not use monocrotophos near or under conditions that allow for drift onto waterways or other sensitive areas. Runoff remains a potential problem for rates ≥ 280 g ai/ha and Environment Australia cannot support the use of monocrotophos by boomspray unless the rate is reduced.

Chronic Effects

Once in the aquatic environment, monocrotophos is not expected to persist for an extended period, but the degradation rate was considered dependent on the level of microbial activity, based on very limited data. The field studies showed the degradation was fast in rice paddies, but slow in natural water. There was no data for more typical agricultural sediment/water systems in temperate conditions. Assuming a half-life of 2 days, calculations showed that chronic and subchronic effects on aquatic invertebrates were possible from aerial spray drift but less likely from other applications technologies. Although there are no chronic effects data, it was assumed that chronic effects are approximately one tenth of the acute effect, a common ‘rule of thumb’. Chronic effects on aquatic organisms could not be ruled out.

Runoff and Leaching
Runoff from areas where monocrotophos has been applied could be significantly contaminated. The K_{oc} indicates weak binding to soil particles. The hazard for sensitive aquatic invertebrates was calculated as high at all rates and was only acceptable at the lowest rate for locusts control (140 g ai/ha) for the less sensitive organisms. Despite the rapid degradation in soil, which will limit the time when runoff will be problematical, runoff from areas treated with monocrotophos is likely to be hazardous to aquatic invertebrates.

Multiple applications
The above analysis is for a single application but in practice there are expected to be multiple applications. It is expected that in most situations there would be at least 7 days between sprays. As there is a high hazard from spray drift for a single application and further applications would increase that hazard, noting the degradation rate in water is not known, the hazard from multiple applications appears unacceptable.

Desirable terrestrial vegetation
As direct application to desirable terrestrial plants and vegetation is not expected and monocrotophos is non-phytotoxic when used as directed, although some varieties of apples, pears, peach, cherry and sorghum may suffer slight injury, significant effects on desirable plants are considered unlikely.

6.5 Conclusion

Monocrotophos is an organophosphate and is extremely toxic to aquatic invertebrates, birds and mammals. It is used to control a wide range of chewing, sucking and boring pests (aphids, caterpillars, *Helicoverpa spp*, mites, moths jassids, budworm, scale and stem borer) as well as locusts. Monocrotophos is not compatible with IPM programs.

Monocrotophos is readily degradable in soil and could degraded in aquatic environments but this appears to be dependent on the level of biological activity. It is unlikely to persist beyond 1 week following application in soil. Bioaccumulation is not expected. Due to the very rapid degradation in soil, leaching is not expected despite laboratory studies suggesting high mobility.

The chemical is extremely toxic to birds, mammals and aquatic invertebrates. Its toxicity to birds when it is incorporated into the diet is very high. There are a number of reports from overseas and anecdotal Australian reports on large numbers of bird kills having occurred from use of this chemical. The overall hazard to birds appears high and unacceptable, especially to birds that consume insects, seeds etc that are directly oversprayed by the chemical. Use of monocrotophos to control locusts at the higher rate (280 g ai/ha) is likely to represent a very high hazard to avian predators of locusts and is unacceptable. At the lowest label rate for small locusts (140 g ai/ha) a high to moderate hazard was indicated based on the toxicity testing. However, as there was some indication of an increased sensitivity of the raptors, a significant hazard cannot be ruled out when used for locusts control, despite the low rate. Anecdotal evidence also suggests significant bird mortalities occur after use in cotton and for locust control in Australia.

The weight of evidence indicates use of monocrotophos poses a high hazard to birds, and it is difficult to defend its continued use. Unfortunately, most of the evidence is old and from overseas, with local reports of consistent bird mortality largely anecdotal though derived from a number of sources.

Mammals are not expected to be significantly exposed to the chemical unless they enter an area recently sprayed. However, the direct application of monocrotophos to aquatic systems is expected to significantly effect aquatic invertebrates.

Apart from direct overspray, the hazard to fish is considered to be acceptable. However, the hazard to aquatic invertebrates is unacceptable to beyond 300 metres for all aerial application rates when used according to the, now unregistered, label directions. At the lowest rate examined, 140 g ai/ha, the hazard to less sensitive aquatic invertebrates was acceptable at 300 metres but only with placement spraying (vmd 350 μm). It should be noted that a high hazard exists from runoff at rates ≥ 280 g ai/ha.

The newly proposed Best Practices Manual for Cotton Growers has a guideline for a buffer of 300 metres downwind for all aerial applications. While adoption of this would reduce the hazard to environmentally sensitive areas, additional measures such as reduced applications rates (140 g ai/ha and below) and placement spraying would be required to reduce the hazard to more acceptable levels. As most other crops do not have a best practices guideline and the conditions of use are up to the individual grower, current aerial application to other crops is considered unacceptable for all rates.

Calculation for the spray drift from conventional high volume orchard air blast equipment shows there is a high hazard to daphnia up to 200 metres away in shallow water at the highest rate (800 g ai/ha) and only decreases to acceptable levels at 300 metres away. For less sensitive aquatic invertebrates, there is a high hazard at 50 metres, which decreases to an acceptable hazard at 200 metres away. It should be noted that this is based on citrus orchard spray drift data and a lower hazard is expected for orchards with less dense foliage, ie pome fruit trees.

Using the US EPA AgDRIFT model shows that the spray drift from conventional air blast spraying of pome and stone orchards is acceptable at 25 metres for most aquatic invertebrates and for the most sensitive invertebrate at 100 metres away. For other orchards crops, ie tall trees and citrus, the spray drift was high and the hazard unacceptable up to 200 metres away for a number of aquatic invertebrates. In addition, the AgDRIFT model showed that dormant spraying of apples gives a similar level of drift as for tall trees and citrus and is therefore considered unacceptable. It should be noted that this model is fitted to experimental data from a range of orchards and is therefore considered to be of high quality. However, the orchard results are for the average situation, not worst case, and therefore the results from the model may not be fully protective of the environment.

Given that there is a broad range of locations where pome fruit orchards are situated and that a number are expected to be close to waterways, the hazard from spray drift on the aquatic environment is considered to be moderate for modern style orchards with smaller trees and close planting. However, for other orchards crops, especially those with tall trees, and for dormant spraying hazard is high and unacceptable. While the degradation of monocrotophos is expected to be rapid, there was no reliable data on the rate of aquatic degradation and it is unknown how long the toxicity will last.

The spray drift hazard from boom sprayers is less that from orchard air blasters under the same conditions but a significant hazard to aquatic invertebrates remains. The AgDRIFT model for boom sprayers showed that at the higher application rates (800 g ai/ha), there was a hazard to aquatic invertebrates within 100 metres of the boomsprayer. The spray drift hazard to the sensitive aquatic invertebrates species extends to beyond 100 metres. However, at 280 g ai/ha the model showed that the hazard is acceptable at 100 metres and just acceptable at 30 metres.

Runoff is a potential problem and calculations showed that runoff from treated areas could cause acute toxic effects to sensitive aquatic invertebrates. As there were no chronic aquatic studies, default values were used in calculations which showed that chronic effects to a wide range of aquatic invertebrates were possible. The hazard due to runoff from areas treated with monocrotophos according to the current labels is high and considered unacceptable at rates ≥ 280 g ai/ha.

In conclusion, there is a high hazard to birds from the current use of monocrotophos when avian food items are sprayed. Spray drift from aerial and orchards air blast spraying represents a significant hazard to aquatic invertebrates. Runoff from recently treated areas was identified in the hazard assessment as being hazardous to aquatic invertebrates from both acute and chronic toxic effects. While there are no actual aquatic mortality incidents that the NRA is aware of, anecdotal reports of wide spread bird deaths are a clear indication that unacceptable birds mortalities do occur. The weight of evidence indicates use of monocrotophos poses a high hazard to birds, and it is difficult to defend its continued use.

During the assessment several data gaps where identified, in particular the lack of an aerobic aquatic metabolism study. If any uses are retained an aerobic aquatic metabolism study using the current US EPA Guideline should be conducted. Also, no daphnia or other aquatic invertebrate toxicity studies were available that met current Guidelines. This should be addressed, as both studies would considerably help clarify the aquatic hazard.

7. PROTECTION STATUS OF SUBMITTED DATA

Many of the studies contained in the bibliographies of the full review report have been judged by the NRA as being protected registration information in accordance with Part 3 of the Agvet Code. A full list of those studies identified as protected can be obtained separately from the NRA. Requests for this list should be addressed to:

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

ATTACHMENT 1: Products And Active Constituents Which Have Been Cancelled By This Review

NCRIS	Product Name	Applicant
47518	Azodrin 400 Systemic Insecticide/Miticide	Cyanamid Agriculture Pty Ltd
49412	Farmoz Monocron 400 systemic Insecticide	Farmoz Pty Ltd
50000	Phoskill 400 Systemic and Contact Insecticide	United Phosphorus Ltd

NCRIS	Active Constituents	Approval Holder
44523	Monocrotophos	United Phosphorus Ltd

ATTACHMENT 2: Consideration of Public Submissions

Introduction

Consistent with the NRA's policy of consulting with all parties interested in the review process, the NRA published notices in the Australian rural and metropolitan press calling for written submissions regarding the review of the chemical monocrotophos. Twelve submissions were received from members of the public, and from environmental, government, commodity and user groups.

Submissions primarily expressed views supporting the continued use of monocrotophos. One submission addressed the detrimental effects that the use of this chemical has on the environment, public health and safety to the user. Support for the continued availability of monocrotophos in the market was from grower groups who would like to retain this chemical as an alternative to other registered chemicals for the management of pests relevant to the particular commodities produced by their members.

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

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

- Submissions regarding any public health, environmental or safety issues are presented under the heading 'Risk Identification'. Practices for minimisation of risk associated with the use of monocrotophos employed by particular user groups, are also discussed here.

- Submissions discussing the importance of monocrotophos in integrated pest management systems in various sectors, are dealt with under the second section labelled 'Agronomic practice'.

- The third section contains views on the fate of this chemical. This information can be found under the heading 'Public Opinion on the Fate of Monocrotophos'.

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

RISK IDENTIFICATION

Public Health

The issue of possible health effects arising from the use of this chemical was discussed by several respondents.

One submission commented on generalised symptoms of organophosphate poisoning, that monocrotophos is particularly toxic to humans and is no longer registered for use in the USA and other countries. The submission states that although the effects of organophosphate poisoning are widely recognised and mostly avoided, there is concern that many workers and

their general practitioners may not be aware of, or diagnose the effects of chronic exposure, and that these effects may be more widespread than is realised.

Comment was also made that no adverse effects had been recorded amongst the members of the growers group when proper care and label directions were followed.

A submission fully endorsed the training of staff in the field of chemical application and storage and commented on the benefits of undergoing training in courses such as Farm Chemical Users Course, CHEMSAFE, which covers areas such as safety, and re-entry periods.

Environment
There was only one submission regarding the effects of this chemical on the surrounding environment. This submission indicated that monocrotophos was highly toxic to aquatic organisms.

AGRONOMIC PRACTICE

8 submissions from industry groups and individuals from the farming, horticultural, and fruit and vegetable growing sectors supported the continued use of monocrotophos, particularly for horticultural uses, as it has a wide spectrum of activity and usefulness in spray management programs.

Resistance Management
The importance of maintaining access to a range of chemicals for effective management of pest resistance through chemical rotation was stressed by several contributors. IPM strategies are also considered a critical element in overall reductions in pesticide use.

It was claimed that if chemicals from an already small choice of chemicals were removed from use, more resistance pressure would be placed on remaining chemicals thus weakening resistance management programs. Industry would be forced to increase chemical rates and frequency of applications of the available products, possibly leading to increased insect resistance.

It was stated that alternative chemicals are usually used in preference to monocrotophos as part of a rotation program. However, users expressed the necessity of retaining monocrotophos because it is important to have a selection of pesticides to lower risks of pesticide resistance developing.

Fruit and Vegetables
Fruit and vegetables are minor use areas with few registrations. Monocrotophos is considered a most effective product against green vegetable bug in various crops. If used according to label instructions monocrotophos is considered to be cost effective and reduces the number of applications usually needed with other products. It is used by growers of tomatoes, apples, beans and sweetcorn with other chemicals in rotation for resistance management.

Two submissions commented that there are alternatives to monocrotophos for various uses. User groups stated that in Tasmania and other states alternatives were generally selected instead of monocrotophos for use on sweet corn and tomatoes for control of aphids, mites and budworm and neither submission made a request to retain this chemical.

Ornamental Horticulture
Ornamental horticulture is comprised of a great diversity of plant species and varieties. This wide range of plants and varieties requires a larger choice of chemicals to avoid phytotoxic effects shown by different plant varieties to the same chemical.

There were several reasons given for maintaining registration of monocrotophos in the ornamental horticulture industry:

a) Monocrotophos is a broad spectrum insecticide effective against a wide range of pests.
b) There are difficulties in getting manufacturers to register chemicals for use in this field due to the high costs of registration and the relatively small use by this industry.
c) Build-up of chemical resistances is becoming a major concern. This is combated by rotation of as large a selection of chemical groups as possible when treating the same pests.
d) There is a lack of potential substitutes to replace the loss of monocrotophos.

Forage crops
Used to prevent insect attack in forage crops, monocrotophos is considered a strategic element for the production of high quality feed for grazing establishments. This is an important consideration where resistance is a contributing factor to failure of other chemical groups.

Locust control
Monocrotophos is registered for spur-throated and migratory locust control in Qld, NSW, WA, and plague locusts in NSW, Vic and WA. There is strong support in Qld and NSW for use against spur-throated locusts as residual life gives protection over a period of time when used as a perimeter spray. However, the respondents commented that fenitrothion is the pesticide of choice amongst various State Government Departments and the Australian Plague Locust Commission. The submission stated the need for alternatives as part of a strategic preventative control program.

Cotton
Although monocrotophos in cotton crops is not conducive to IPM programs and is an irregularly used option, it has proved a useful backstop when options become limited.

Other
There is a 42 day withholding period in cereal crops which limits use of monocrotophos.

It is phytotoxic on some varieties of sorghum. It is sometimes used as an alternative for control of sorghum midge.

PUBLIC OPINION ON THE FATE OF MONOCROTOPHOS

Comments from respondents on the possible outcome of the current review of monocrotophos ranged as follows:

- it is important to maintain as broad a base as possible of chemicals for control of insect pests for resistance management

- a broad-based selection of chemicals is important for management of phytotoxicity on horticultural ornamental plants

- if registration is to be discontinued, a suitable timeframe should be granted to allow the industry to make necessary adjustments and for identification of possible alternatives

- if registration is to be maintained, use should be restricted to prevent any overspray, run-off or other contamination of waterways

- to ensure the retention of this chemical (as part of an important chemical group) it may be necessary to rethink the way chemicals are sold, distributed and applied and give further education in these areas and to help promote awareness of the hazards.

It is important to continue training (eg under Farm Chemical Users Courses) and to develop particular modules to target specific user groups.

MONOCROTOPHOS PUBLIC SUBMISSION CONTRIBUTORS

R.G. Grainger	Qld Fruit And Vegetable Growers
	Australian Vegie And Potato Growers Federation Inc.
Wayne Bacchi	Wholesale Indoor Foliage
Col Schiller	Walsh's Seeds
Sean Blair	RMSA Chemical Committee
Marie O'Dea	West Australian Farmers Federation - no information on Monocrotophos.
Dick Copeman	Qld Conservation Council And Qld Consumers Association
Marcus Holdsworth	Bombala Rural Lands Protection Board
Neil Fisher	Grains Council Of Australia
John McDonald	Qld Nursery Industry Association
	Tasmanian Farmers Federation
Scott Shepherd	Qld Cotton

ATTACHMENT 3: Summary Of Comments From Public

Following consultation with the stakeholders in Commonwealth and State authorities and industry, the NRA released a draft monocrotophos review report on 6 July 1999 for public comment. This release was widely publicised and notices were sent to all who had expressed interest in or who had participated in the review thus far.

A more targeted approach was also adopted for this review with contacts for consultation obtained from the State Departments of Agriculture for industries where monocrotophos was considered of importance. These industry representatives were contacted by letter plus a copy of the Review Summary of the monocrotophos review.

The draft review report was placed on the NRA Website and printed copies were available on request. The monocrotophos draft incorporated an approach to public consultation where the emphasis was on identifying concerns and data gaps flowing from the review of fenitrothion. The public comments phase lasted two months during which comments and submissions from the public were obtained on the draft report.

Six submissions were received, which came from State authorities, grower groups and other organisations as listed below:

- Queensland Fruit and Vegetable Growers Association (QFVG)
- Queensland Department of Primary Industry (QDPI)
- Victoria Department of Natural Resources and Environment (Vic DNRE) and Ovens Research Centre on behalf of Tobacco growers, Victoria
- New South Wales Environment Protection Agency (NSW EPA)
- Birds Australia/RAOU
- Birds Observers Club of Australia (BOCA)

The submissions supplied both support for the continued registration of monocrotophos and vigorous support for the immediate deregistration of the chemical.

Fruit and Vegetables

The Qld Fruit and Vegetable Growers would generally like to keep monocrotophos to include in a list of chemicals for use in resistance management. However, the main industries either do not currently use this chemical or use it infrequently.

Comments from QDPI, QFVG, Vic DNRE and the Ovens Research Centre were received on specific crops as stated below:

- Tomatoes – in Qld monocrotophos was used infrequently. However, growers wanted it kept as an option for resistance management.

- Sweet corn – this industry has very few chemicals registered for use on their crops. There was concern that organophosphate chemicals in general were being lost and they would like to keep monocrotophos available as part of chemical rotation for resistance management.

- Potatoes – monocrotophos is not used in Bundaberg, Queensland (Qld) as there is leaf minor resistance – spraying causes flair up and entire crops can be lost.

- Citrus – this chemical is not registered in citrus but there was concern over its loss in case a pest from Asia (variety of cillid) were to infiltrate Australia. This pest is controlled in Asia with monocrotophos. If this pest were to occur in Australia the belief was that monocrotophos would be vital for its control.

- Bananas – monocrotophos is no longer used on bananas and its removal from registration is welcomed.

- Tobacco – Victoria DNRE and Qld DPI both argued strongly in favour of retaining the use of monocrotophos on tobacco. Advice from Qld was that the industry has a real need for this product. It is effective against the tobacco bud worm and is the only effective chemical against green vegetable bug. Acephate is the alternative and is suspected of tainting. If acephate is lost then monocrotophos is all that is left and would be an integral part of a resistance management strategy. The Victorian tobacco industry was also keen to retain the use of the chemical with similar arguments for its retention.

While there was argument in favour of retaining monocrotophos the only industry that appears likely to suffer from it's loss in the short term is the tobacco industry. Other industries have stated that they don't use monocrotophos except as part of a resistance management strategy.

Only the tobacco industry were prepared to discuss possible generation of data. However, it was determined that generating the data could not be justified due to cost, likely poor long-term availability of the product, and the 'risk' of not being able to retain the product despite generating the data.

Registrants have also determined that the cost of the data does not justify the future possible sales and have chosen not to generate data to support monocrotophos.

Against

NSW EPA supports the NRA's decision to place additional restrictions on the use of monocrotophos in light of the serious environmental concerns.

Birds

There were several submissions relating to the effects of monocrotophos on birds. NSW EPA submitted a paper by Dr Michael Hooper, an avian toxicologist from Texas Technical University, USA, detailing investigations into deaths of Swainson's hawks exposed to monocrotophos in Argentina over the period 1995-1997. His work also indicates other bird species are affected.

The Research Committee of Birds Australia (previously the Royal Australasian Ornithologists Union, RAOU) sent in a submission which argues that the toxicity of monocrotophos to birds (as well as invertebrates, fish and mammals) justifies deregistering this chemical in Australia. The organisation presents evidence of monocrotophos's toxicity to birds and puts forward a strong argument for the deregistration of this chemical.

The Bird Observers Club of Australia (BOCA) sent in a letter stating their concern over the impacts of monocrotophos on wildlife in Australia. BOCA supported the restrictions pending data generation and strongly argued in favour of the deregistration of this chemical.