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INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED  
CONSENT PROCEDURE: CONSIDERATION OF DRAFT  
DECISION GUIDANCE DOCUMENTS

MONOCROTOPHOS

Note by the secretariat

1. At its second session, the Interim Chemical Review Committee reviewed the notifications of final regulatory actions from Australia and Hungary, including the supporting documentation referenced therein, and, taking into account each of the specific requirements set out in annex II of the Convention, concluded that the requirements of that annex had been met.
2. Accordingly, the Committee agreed to recommend to the Intergovernmental Negotiating Committee that monocrotophos should become subject to the interim prior informed consent (PIC) procedure, and agreed to establish an intersessional drafting group with the mandate to produce a draft decision guidance document for that chemical. A report of the work of the drafting group may be found in the annex to document UNEP/FAO/PIC/ICRC.3/11
3. Annexed to the present note is the draft decision guidance document submitted to the secretariat by the drafting group.

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\* UNEP/FAO/PIC/ICRC.3/1.

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Operation of the interim Prior Informed Consent procedure  
for banned or severely restricted chemicals in international trade

Decision Guidance Document

Monocrotophos

DRAFT



Interim Secretariat for the Rotterdam Convention  
on the Prior Informed Consent Procedure for  
Certain Hazardous Chemicals and Pesticides in  
International Trade

## **Mandate**

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was adopted at the Conference of Plenipotentiaries held in Rotterdam on 10 and 11 of September 1998. The same Conference also adopted a resolution on interim arrangements in order to operate an interim PIC procedure between the time of the adoption of the Convention and its entry into force, and to prepare for its effective operation once it enters into force.

At its ninth session, held in Geneva on [insert date] the INC thus adopted the decision guidance document for Monocrotophos [Insert decision number] with the effect that this chemical became subject to the interim PIC procedure.

[This decision guidance document replaces the one dated June 1997 which was limited to Soluble liquid (SL) formulations of the substance which exceed 600 g a.i./l.]

*The present decision guidance document for Monocrotophos was communicated to the Designated National Authorities on [Insert date] with the request that they submit a response concerning the future import of the chemical to the Secretariat in line with Article 10, paragraph 2 of the Rotterdam Convention.*

## **Disclaimer**

The use of trade names in this document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in this document.

While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) disclaim any responsibility for omissions or any consequences that may flow therefrom. Neither FAO or UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

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**ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT**

(N.B. Chemical elements and pesticides are not included in this list)

<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
>>	much greater than
µg	microgram
AgDRIFT	Spray Drift Task Force model
ARfD	acute reference dose
a.i.	active ingredient
ACGIH	American Conference of Governmental Industrial Hygienists
ADI	acceptable daily intake
ADP	adenosine diphosphate
ATP	adenosine triphosphate
BBA	Biologische Bundesanstalt für Land- und Forstwirtschaft
b.p.	boiling point
BSI	British Standards Institution
bw	body weight
°C	degree Celsius (centigrade)
CA	Chemicals Association
CCPR	Codex Committee on Pesticide Residues
CHO	Chinese hamster ovary
D	dust
E.C.	European Community
EC	emulsifiable concentrates
EC <sub>50</sub>	effect concentration, 50%
ED <sub>50</sub>	effect dose, 50%
EHC	Environmental Health Criteria
ISO	International Organization for Standardization
ERL	extraneous residue limit
FAO	Food and Agriculture Organization of the United Nations
g	gram
GAP	good agricultural practice
GL	guideline level
GR	granules
H	hour
ha	hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC <sub>50</sub>	inhibition concentration, 50%;
IPCS	WHO/ILO/UNEP/International Programme on Chemical Safety
IPM	integrated pest management
IRPTC	International Register of Potentially Toxic Chemicals

**ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT**

IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
kg	kilogram
K <sub>oc</sub>	organic carbon/water partition coefficient
l	litre
LC <sub>50</sub>	lethal concentration, 50%
LD <sub>50</sub>	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LD <sub>Lo</sub>	lowest lethal dose
LOEL	lowest observed effect level
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
mPa	milliPascal
MRL	maximum residue limit
MTD	maximum tolerated dose
NCI	National Cancer Institute
ng	nanogram
NIOSH	National Institute for Occupational Safety and Health
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
OP	organophosphorus pesticide
PHI	pre-harvest interval
PIC	prior informed consent
Pow	octanol/water partition coefficient
POP	persistent organic pollutant
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).
RfD	reference dose for chronic oral exposure (comparable to ADI)
SBC	Secretariat of the Basel Convention
SC	soluble concentrate
SG	Water-soluble granules
SL	soluble concentrate
SMR	standardized mortality ratio
STEL	short-term exposure limit
TADI	temporary acceptable daily intake
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRL	temporary maximum residue limit
TWA	time-weighted average

**ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT**

ULV	ultra-low volume
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
vmd	vapour median diameter
VOC	volatile organic compound
WHO	World Health Organization
WP	wettable powder
wt	weight

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**PIC – Decision guidance document for a banned or severely restricted chemical**

Monocrotophos

Published: *Draft – October 2001***Identification and uses (see annex I)**

<b>Common name</b>	Monocrotophos (BSI, E-ISO)
<b>Chemical name</b>	Dimethyl (E)-1-methyl-2-(methylcarbamoyl)vinyl phosphate (IUPAC)
<b>Other names/ synonyms</b>	
<b>CAS-No.(s)</b>	6923-22-4 (formerly 919-44-8)
<b>Harmonized System</b>	2924.10.00 (technical grade active constituent)
<b>Customs Code</b>	3808.10.90 (formulated product)
<b>Category</b>	Pesticide
<b>Regulated Category</b>	Pesticide
<b>Use(s) in regulated category</b>	An organophosphorus contact and systemic insecticide and acaricide used to control a broad spectrum of pests, including sucking, chewing and boring insects and spider mites on cotton, citrus, olives, rice, maize, sorghum, soybeans and tobacco.
<b>Trade names</b>	Azodrin, Bilobrin, Crisodrin, Crotos, Glore Phos36, Harcros Nuvacron, More-Phos, Monocil, Monocron, Monocrotophos 60 WSC, Nuvacron 600 SCW, Plantdrin, Red Star Monocrotophos, Susvin, Phoskil 400.
<b>Formulation types</b>	Available in a variety of soluble, liquid and emulsifiable concentrate formulations including 200, 400, and 600 g a.i./l concentrates, 400, 500, and 600 g a.i./l water-soluble concentrates, and 250 g a.i./litre ULV formulations. Monocrotophos is also available in mixtures with other pesticides.
<b>Uses in other categories</b>	No reported uses as an industrial chemical.
<b>Basic manufacturers</b>	Agrolinz, Inc; Bharat Pulverizing Mills Ltd (India), Cia-Shen Co. Ltd. (China), Comlets Chemical Industrial Co. Ltd. (Taiwan), Cyanamid (Brasil), Hindustan Ciba Geigy Ltd (India), Lupin (India), Nantong Pesticides Factory (China), Hui Kwang (China), National Organic Chemical Industries Ltd. (India), Quimica Estrella SACI eI (Argentina), Qingdao Pesticides Factory (China), Sudarshan (India), United Phosphorus (India), Sundat (S) Pte Ltd. (Singapore).

**Reasons for inclusion in the PIC procedure**

Monocrotophos is included in the PIC procedure as a pesticide. It is listed on the basis of the final regulatory actions to ban all uses of Monocrotophos reported by Australia and Hungary.

Initially, only formulations of monocrotophos exceeding 600 g a.i./l were included in the PIC procedure as severely hazardous pesticide formulations based on the recommendation of the fifth meeting of the FAO/UNEP Joint Expert Group (October 1992). The action was taken because of their acute hazard classification and concern as to their impact on human health under conditions of use in developing countries.

**Final regulatory action:** (see annex II for details)**Australia**

Registration of all monocrotophos products was cancelled from 9 December 1999 with all uses phased out over a year to allow existing stocks to be exhausted. This was seen as the lowest-risk option for disposing of existing stock of monocrotophos in the light of risks associated with product recall, storage and disposal. It also allowed users time to change over to other pesticides.

Reason: Occupational<sup>1</sup> health and environmental concerns.

**Hungary**

The registration for monocrotophos was withdrawn in 1996 as the reduction of application rates and the restriction of its uses did not reduce the level of adverse impact on wild life to an acceptable level.

Reason : Environmental concerns.

**Risk evaluation****Australia**

Monocrotophos was applied in Australia using aerial, ground-rig and directed sprays to sorghum, sunflowers, tomatoes, cotton, potato, lucerne, soybean and tobacco to control *Helicoverpa* species, locusts, sorghum midge, western flower thrips, aphids, green vegetable bug, mites, stem borer and potato tuber moth.

On the basis of concerns arising from its risk evaluation and in the absence of a commitment by stakeholders to provide the data necessary to allay these concerns, Australia's National Registration Authority (NRA) for Agricultural and Veterinary Chemicals concluded that there were reasonable grounds to cancel the registration and approvals for Monocrotophos. The key aspects of this evaluation are detailed below.

**Occupational safety and health**

In the absence of measured worker exposure studies for conditions comparable with those for Australian use patterns and conditions for mixer/loader/applicators (M/L/A), the United Kingdom Predictive Operator Exposure Model (POEM) was used, where possible, in the assessment of risk, i.e. exposure and MOE (margins of exposure).

Exposure was predicted to be high and therefore unacceptable in all usual ground application situations.

*On this basis, it was concluded that data would be required for all registered uses for ground application in Australia, including information on the functional efficacy of lower dose rates, if continued use of Monocrotophos were permitted.*

**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 integrated pest management (IPM) programmes. There is a high hazard to birds from 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 hazardous to aquatic invertebrates from both acute and chronic toxic effects.

**Hungary**

Monocrotophos in Hungary was registered for use on sugarbeet, sunflower, *Solanum nigrum*, maize, soybean, and alfalfa to control *Bothynoderes punctiventris*, *Psalidium maxillosum*, *Tanymecus dilaticollis* and *Tanymecus palliatus*.

Monocrotophos was first registered in Hungary in 1971, and the registration was extended in 1975. Registrations for the use of monocrotophos were modified in 1982, because of its observed adverse

<sup>1</sup> In the Australian context, 'occupational exposure' would include exposure to workers involved in:

- \* Manufacture;
- \* Formulation and re-packaging
- \* Mixing/loading
- \* Application
- \* Post-application activities such as cleaning of equipment;and
- \* Re-entry following application for trimming/maintenance, bug-checking etc.

Occupational exposure may even go so far as to take into account exposure to "bystanders" such as fellow workers not directly involved in using the chemical. However, by definition, occupational exposure would not include members of the public. This would be included under public health.

impacts on wildlife. Further reduction of application rates and restriction of its uses did not reduce the level of adverse impact upon wildlife to an acceptable level, leading to the withdrawal of all registrations in 1996. The key aspects of this evaluation are detailed below.

#### **Environmental impact**

The wildlife toxicity studies carried out at pilot and large-scale farms clearly confirmed that the use of Azodrin 40 WSC significantly damaged wildlife, first of all birds. Independently of the age and body weight of the animals and the growth stage of the treated crops, the use of the product caused death to some of the animals and prolonged poisoning in others (6–12 days). The Poisoned animals did not respond to stimulus and would not flee, therefore it is probable that most were killed by predators. Additional losses were caused by the fact that the recommended use of the product was at the time of reproduction, thus poisoned animals which survived did not feed for several days did not return to their nests and so on. In Hungary, in addition to pheasants, field hares (*Lepus europeus*) are the most important small game. In the wildlife toxicity studies carried out in large-scale farms, no hare death was observed, though slightly poisoned adults could be seen (3–4 kg). It is therefore probable that Azodrin 40 WSC caused death of young hares of low body weight. Azodrin 40 WSC had been used in Hungary since 1971. The annually treated acreage was 50 000–150 000 ha. Considering the very low populations of the daed animals and their unborn progeny, the estimated loss in Hungary amounted to 5 to 10 million pheasants since the beginning of the use of Azodrin 40 WSC (25 years). Losses of other songbirds and granivorous birds of low body weight may be much greater than this figure. No other pesticide has caused damage of this extent in Hungary to the natural wild bird population, and the use of Azodrin 40 WSC has played a significant role in the current very low populations of small game birds and animals in Hungary.

### **Protective measures that have been applied concerning the chemical**

#### **Regulatory measures to reduce exposure**

- |                  |   |
|------------------|---|
| <b>Australia</b> | Under the conditions of use in Australia, protective measures, including prohibition of application by back-mounted knapsack sprayers, the use of closed cabins for ground spraying and closed systems for mixer loaders, were not considered sufficient to reduce exposure to an acceptable level. As a result, registration for all Monocrotophos products was cancelled. |
| <b>Hungary</b>   | <i>Protective measures were taken to reduce exposure, including a reduction in application rates and restriction of uses. They were not considered sufficient to reduce the adverse impacts of Monocrotophos on wildlife and the compound was banned.</i>   |

#### **Other measures to reduce exposure**

*This section should be completed only where a chemical has been subjected to severe restriction and the notifying countries have allowed continued use of the chemical and associated products.*

#### **Alternatives**

Monocrotophos is a broad-spectrum contact and systemic insecticide and acaracide used in a wide range of crops. There are a number of alternative products available depending on the individual crop-pest complex under consideration. Limited information on alternatives that have been identified by Australia and Hungary may be found in annex II.

*It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs and the anticipated local conditions of use.*

**Socio-economic effects**

No detailed assessment of socioeconomic effects was undertaken by the notifying countries.

**Hazards and risks to human health and/or the environment**

<b>WHO</b>	Technical product.: 1b (highly hazardous), classification based on oral toxicity (WHO 1999)				
	<i>Classification of formulations</i>				
		<b>oral toxicity</b> LD <sub>50</sub> : 14 mg/kg bw		<b>dermal toxicity</b> LD <sub>50</sub> : 112 mg/kg bw	
	<b>formulation</b>	a.i. (%)	hazard class	a.i. (%)	hazard class
	liquid	>70	1a	>25	1b
	>5	1b	>1	11	
	>1	11			
solid	>30	1b	>90	1b	
	>3	11	>10	11	
<b>E.C.</b>	Classification of the active substance (E.C. 1998) is: Mutagenic category 3 ; R 40: possible risks of irreversible effects; T+; R 26/28: very toxic by inhalation and if swallowed; T; R 24: toxic in contact with skin; N; R 50-53: dangerous to the environment, very toxic to aquatic organisms, may cause long-term effects in the aquatic environment.				
<b>US EPA</b>	Category 1 (highly toxic) (EPA 1985)				
<b>IARC</b>	Not classified				

**Notifying countries**

**Australia** – Monocrotophos is listed in the Australian National Occupational Health and Safety Commission (NOHSC) List of Designated Hazardous Substances. All Monocrotophos products that were part of the Australian review are determined to be hazardous substances because they contain Monocrotophos at 40% (w/v), exceeding the NOHSC cut-off concentration for hazardous substances. It is included in Schedule 7 (Dangerous Poisons) of Australia's Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

**Hungary** - In compliance with annex II to Ministerial Decree 6/2001, Monocrotophos is on the list of banned active ingredients.

**Exposure limits****Food**

The Codex Alimentarius Commission has published maximum residue limits for a range of fruits and vegetables, animal products, grains and edible oils. Maximum residue limits (MRLs) for these commodities range between the limit of analytical quantitation (0.02 to 0.05 mg/kg) and 1.0 mg/kg. These MRLs were recommended by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in 1991 and 1994.

JMPR established an acceptable daily intake (ADI) of 0.0006 mg/kg bw in 1993. This value was confirmed in 1995. An acute reference dose of 0.002 mg/kg bw/d was established in 1995.

**Drinking water**

WHO has not established a drinking water guideline for Monocrotophos.

**Packaging and labelling**

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

<b>Hazard Class</b>	6.1, poisonous substance;
<b>Packing:</b>	UN Pack Group: II; substances and preparations presenting a serious risk of poisoning, formulations containing 25–100% Monocrotophos.
	Unbreakable packaging; put breakable packaging into closed unbreakable container. Do not transport with food and feedstuffs.
<b>International Maritime Dangerous Goods (IMDG) Code</b>	Monocrotophos is classified as a marine pollutant.

*For specific guidance on appropriate symbols and label statements regarding formulations of monocrotophos, countries should consult the [FAO Guidelines on Good Labelling Practice for Pesticides \(1995\)](#).*

<b>First aid</b>
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***NOTE: The following advice is based on information available from the World Health Organization and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.***

The signs and symptoms of acute organophosphate poisoning may occur in various combinations and can manifest at different times. According to the degree of severity of poisoning, the following signs and symptoms may occur: anorexia, headache, dizziness, weakness, anxiety, miosis, blurred vision, slurred speech, nausea, hypersalivation, stomach pains, diarrhoea, vomiting and excessive sweating. In severe cases, respiratory depression and convulsions may also occur. In the case of Monocrotophos "intermediate syndrome" has been reported: this occurs after initial improvement, approximately one to eight days after poisoning. Muscle weakness leading to paralysis and sudden respiratory arrest occur (IPCS 1999).

First aid personnel should wear rubber or plastic gloves to avoid contamination. Contaminated clothing and contact lenses should be removed as quickly as possible to prevent further absorption. If skin contact occurs, the area should be washed with soap and water; wash eyes for 15–20 minutes with running water. In the case of ingestion, the stomach should be emptied as soon as possible by careful gastric lavage, preferably within one hour of ingestion. Do not induce vomiting if the formulation contained hydrocarbon solvents. Activated charcoal may be effective. In massive overdoses, acute respiratory failure may occur. It is important to keep the airway open and to prevent aspiration if nausea and vomiting occur (IPCS 1999).

Persons who have been poisoned, accidentally or otherwise, must be transported immediately to a hospital and placed under the surveillance of properly trained medical staff. Where possible, show the label of the Monocrotophos container when the patient/affected person is presented for medical attention. Antidotes are atropine sulphate and pralidoxime chloride.

***Depending on the degree of exposure, periodic medical examination is indicated, particularly since Monocrotophos has been known to cause "intermediate syndrome", which may become manifest some time after acute poisoning effects have worn off. Specific treatment is necessary in the event of poisoning with this substance; the appropriate means with instructions must be available.***

***If the substance is formulated with solvent(s), also consult the ICSC cards for the solvent(s). Carrier solvents used in commercial formulations may affect the toxicity of the active ingredient by altering the extent of absorption from the gastrointestinal tract or through the skin.***

**Waste management**

**Regulatory actions to ban a chemical should not result in creation of a stockpile requiring waste disposal. For guidance on how to avoid creating stockpiles of obsolete pesticide stocks, the following FAO publications are available: Provisional guidelines on the prevention of accumulation of obsolete pesticide stocks (1995); Pesticide storage and stock control manual (1996); and Guidelines for the management of small quantities of unwanted and obsolete pesticides (1999).**

**In all cases, wastes should be disposed of in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, any technical guidelines thereunder and any other relevant regional agreements.**

**It should be noted that the disposal/destruction methods recommended in literature such as high-temperature incineration, are often not available in, or suitable for, all countries. Consideration should be given to the use of alternative destruction technologies. Further information on possible approaches may be found in the FAO/WHO/UNEP provisional technical guidelines for the disposal of bulk quantities of obsolete pesticides in developing countries (1996).**

**Australia and Hungary avoided creating a stockpile of Monocrotophos by taking a step-by-step approach to the phase-out of permitted uses (See annex II). It was considered that the risk was manageable for this phase-out period.**

**Annexes**

- Annex I **Further information on the substance**
- Annex II **Details on final regulatory action**
- Annex III **Address of designated national authorities**
- Annex IV **References**

**Introductory text to annex I**

The information presented in this annex reflects the conclusions of the two notifying countries, Australia and Hungary. This information is contained in the documents referenced in the notification of regulatory action as supporting their national regulatory actions banning Monocrotophos. These notifications of regulatory action were first reported in the PIC Circular of December 2000.

The FAO/WHO Joint Meeting on Pesticide Residues reviewed monocrotophos in 1972, 1975, 1991, 1993 and 1994. The conclusions of JMPR were not substantially different from those reported here. Section 2.7 includes a brief comparative summary of the conclusions of the two toxicological evaluations.

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## Annex I – Further information on the substance (Tomlin, 2000)

<b>1.</b>	<b>Physico-chemical properties</b>	
<b>1.1</b>	<b>Identity</b>	Monocrotophos
<b>1.2</b>	<b>Formula</b>	C <sub>7</sub> H <sub>14</sub> N <sub>05</sub> P
<b>1.3</b>	<b>Chemical name (IUPAC)</b>	dimethyl (E)-1-methyl-2-(methylcarbamoyl) vinyl phosphate
<b>1.4</b>	<b>Chemical type</b>	organophosphate
	<b>Form</b>	pure Monocrotophos: colourless hygroscopic crystals technical Monocrotophos: reddish-brown semi-solid, is at least 75% pure
<b>1.5</b>	<b>Solubility</b>	At 20°C - in water 100%, methanol 100%, acetone 70%, n-octanol 25%, toluene 6%
	<b>K<sub>ow</sub>logP</b>	-0.22 (calculated)
<b>1.6</b>	<b>Vapour pressure</b>	2.9 x 10 <sup>-4</sup> Pa at 20°C
<b>1.7</b>	<b>Melting point</b>	54–55°C
<b>1.8</b>	<b>Reactivity</b>	Hydrolysis – half life at 20°C calculated from Arrhenius parameters: 96 days at pH 5, 66 days at pH 7 and 17 days at pH 9. Corrosive to black iron, drum steel and stainless steel
<b>1.9</b>	<b>Stability</b>	Decomposes above 38°C, thermal runaway reaction can occur above 55°C. Unstable in short-chain alcohols, decomposes on some inert materials. Decomposes on heating or burning, producing toxic and irritating fumes including nitrogen oxides, phosphorous oxides. Attacks iron, steel, brass. Storage – Monocrotophos Technical Grade Active Constituent should be stored out of direct sunlight and under cool and dry conditions to minimize any degradation.
<b>1.10</b>	<b>Molecular Weight</b>	223.2
<b>2</b>	<b>Toxicological properties</b>	
<b>2.1</b>		<b>General</b>
<b>2.1.1</b>	<b>Mode of action</b>	Monocrotophos affects the nervous system by inhibiting acetylcholinesterase, an enzyme essential for normal nerve impulse transmission. The toxicological profile of monocrotophos is typical of organophosphorus compounds, with cholinergic signs (including tremors, convulsions, salivation and trismus) being similar in experimental mammals and humans.
<b>2.1.2</b>	<b>Symptoms of poisoning</b>	Symptoms of Monocrotophos poisoning are typical of cholinergic signs seen after exposure to other organophosphorus insecticides and include excess salivation and lachrymation, tremors, convulsions, and miosis (see also Section 4.5).
<b>2.1.3</b>	<b>Absorption, distribution, excretion, and metabolism in mammals</b>	Monocrotophos is systemically absorbed if it is swallowed, inhaled or comes in contact with the skin. Dermal absorption of <sup>14</sup> C-labelled monocrotophos in humans was about 22% of a single dose applied (in acetone) to the forearm for 24 h. Oral absorption in experimental animals was effectively 100% of the administered dose. Monocrotophos was rapidly absorbed and excreted, mainly in the urine, within 24 hours after oral dosing in rodents. Very little residual tissue accumulation of monocrotophos or its metabolites occurred. Unchanged monocrotophos was found in the urine of rats at greater than 30% of the administered dose. After oral administration of monocrotophos to rats and goats, parent compound, N-methyl acetoacetamide and 3-hydroxy-N-methyl butyramide were detected in the urine.

There were variations in the rates of absorption, metabolism and elimination but overall the metabolic path for monocrotophos appeared to be similar between species. The metabolic pathway in mammals was determined to be mainly a detoxification route involving ester cleavage of monocrotophos.

## 2.2 Toxicology Studies

### 2.2.1 Acute toxicity

#### Oral

Monocrotophos was extremely toxic by oral route for rats and mice, with LD<sub>50</sub> values of approximately 8 and 10 mg/kg bw respectively.

#### Dermal

The acute dermal toxicity of monocrotophos was solvent-dependent: it was of low to high toxicity in rats (LD<sub>50</sub> values ranging from 119 to >2000 mg/kg) and of moderate to high toxicity in rabbits (LD<sub>50</sub> values ranging from 130 to 709 mg/kg).

#### Inhalation

Monocrotophos had high inhalation toxicity in rats, with an LC<sub>50</sub> (4 h) of 80 mg/m<sup>3</sup>.

#### Irritation

In rabbits, monocrotophos was slightly irritating to the eyes and skin but it was not a skin sensitizer in guinea pigs.

#### ARfD

No inhibition of erythrocyte cholinesterase activity or other signs of toxicity were seen in volunteers exposed to single oral doses of monocrotophos at up to 0.0059 mg/kg bw in a 28-day study. Based on this No-Observed-Effect Level (NOEL), and using a 10-fold safety factor, the acute reference dose (ARfD) for monocrotophos in Australia was established at 0.0006 mg/kg bw.

### 2.2.2 Short-term toxicity

In short-term studies, the inhibition of cholinesterase activity was the main toxicological effect in experimental animals. When rats were given monocrotophos (technical) in the diet for up to 13 weeks, cholinesterase activity was significantly inhibited, but a 5-week recovery phase following feeding allowed some recovery of cholinesterase activity. In repeat-dose dermal studies, the inhibition of cholinesterase activity was also the main toxicological finding. Even at doses that resulted in clinical signs of intoxication, no significant treatment-related gross or histopathological findings were generally observed.

There did not appear to be any clear difference between monocrotophos binding affinity with plasma (or pseudo- or butyryl-) cholinesterase and with erythrocyte or brain cholinesterase (acetyl- or true cholinesterase). There was considerable variability in responses to monocrotophos between studies, with brain cholinesterase on occasions being the most sensitive to effects of monocrotophos, while in other studies plasma and/or erythrocyte cholinesterase activities were most sensitive to inhibition by Monocrotophos. The anticipated clinical signs associated with organophosphorus compounds and attributable to an excessive interaction of acetylcholinesterase with muscarinic and nicotinic cholinergic receptors were common to all animal studies using Monocrotophos. Measurements of plasma, erythrocyte and brain cholinesterase activity in a variety of studies did not reveal a clear hierarchy of inhibition.

It is Australia's policy to use human data in preference to animal data where human studies are considered to be adequately conducted and reported according to ethical principles of human experimentation. In two different human studies, volunteers received daily oral doses of monocrotophos at up to 0.0059 mg/kg bw for 28 days. No adverse clinical signs were observed. Erythrocyte acetylcholinesterase activity was not affected at any dose level. Plasma cholinesterase activity was significantly decreased at higher doses but not at the low dose of 0.0036 mg/kg bw/d (Verberk 1977). The acceptable daily intake (ADI) for monocrotophos in Australia was established as 0.0003 mg/kg bw/d, based on the NOEL of 0.0036 mg/kg bw/d for plasma

- cholinesterase inhibition and using a 10-fold safety factor.
- 2.2.3 Genotoxicity (including Mutagenicity)** Extensive genotoxicity testing has been conducted with monocrotophos ranging in purity from 36% to 99%. Some *in vitro* mutagenicity tests in bacteria and in yeast, fungi and mammalian cell cultures showed that monocrotophos and its formulations had weak mutagenic potential, both with and without metabolic activation. Similarly, monocrotophos showed potential to damage chromosomes of human lymphocytes, Chinese hamster ovary cells, and rat tracheal epithelial cells, and to induce unscheduled DNA synthesis in human fibroblasts. *In vivo* genotoxicity tests showed predominantly negative results, although a weakly positive result was obtained in a mouse micronucleus assay. Monocrotophos did not induce dominant lethal mutations in mice. The doses at which genotoxic effects were observed in *in vivo* studies were several orders of magnitude greater than the doses at which cholinesterase inhibition was seen in previous studies.
- 2.2.4 Long-term toxicity and carcinogenicity** The inhibition of cholinesterase activity was the main toxicological effect in long-term animal studies. A 2-year rat study investigated histopathological changes in peripheral and central nerves, and found no evidence for a dose-related increase in abnormalities. Progressive examinations through the 2-year period did not provide evidence for any acceleration of normal age-related changes. No other significant pathological findings were observed in long-term studies, even when treatment resulted in clinical signs of intoxication. There were no carcinogenic effects seen over 2 years of dosing with monocrotophos at the highest dose tested in CD mice (approximately 1.5 mg/kg bw/d), Charles River rats (approximately 5 mg/kg bw/d), Wistar rats (approximately 0.5 mg/kg bw/d) and Beagle dogs (approximately 0.4 mg/kg bw/d).
- 2.2.5 Effects on reproduction** In multi-generational reproduction studies in rodents, effects on pups (including reduced survival and bodyweights) and maternal animals (including reduced bodyweights) were observed at doses which did not cause clinical signs of acute monocrotophos intoxication. A development study using Sprague Dawley rats showed a dose-related decrease in the percentage of male foetuses. However, this effect was not seen in a developmental study using Charles River rats, or in a number of multi-generation reproduction studies in Wistar or Long-Evans rats. In New Zealand rabbits, there was an increase in the incidence of premature deliveries in one study, but this effect was not seen in a second study using another strain of rabbits. Delayed foetal development, including effects on ossification, were attributed to the maternal toxicity of monocrotophos. Overall, development signs were seen only at doses at or near maternotoxic doses, and there were no significant treatment-related teratogenic findings.
- 2.2.6 Neurotoxicity/ Delayed neurotoxicity** There was no evidence for delayed neurotoxicity effects in a range of studies using hens, varying from single oral administration to a 78-day study.
- 2.2.7 Summary and overall evaluation** Studies in experimental animals indicate that cholinesterase (ChE) inhibition is the major toxic effect of Monocrotophos. In experimental animals, monocrotophos is of high acute toxicity. The lowest oral LD<sub>50</sub> is 8.4 mg/kg bw in rats (10 mg/kg bw in mice) and lowest inhalation LC<sub>50</sub> is 80 mg/m<sup>3</sup> (4h) in rats. The acute dermal toxicity of monocrotophos is variable and dependent on the solvent; the lowest dermal LD<sub>50</sub> is 123 mg/kg (rats). Monocrotophos is a slight skin and eye irritant in rabbits. It is not a skin sensitizer in guinea pigs. In animal studies, monocrotophos is rapidly excreted mainly in the urine, without evidence of significant accumulation in the body. The metabolic pathway is a detoxification route ultimately involving the ester cleavage of

Monocrotophos with the formation of N-methyl acetoacetamide and 3-hydroxy-N-methyl butyramide as well as dimethyl phosphate and/or monomethyl phosphate.

Single or repeat dose studies (up to 78 days) in hens did not demonstrate delayed neurotoxicity.

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 mutagenic effects of Monocrotophos.

Monocrotophos was not found to be carcinogenic. 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. Red blood cell cholinesterase was not affected. The NOELs established in short-term human studies are similar to the NOEL for long term animal studies (0.004 mg/kg bw/d).

Acceptable daily intake (ADI) was established at 0.0003 mg/kg bw/d.

The ADI is based on human studies in which volunteers received daily oral doses of monocrotophos at up to 0.0059 mg/kg bw for 28 days. No adverse clinical signs were observed. Erythrocyte acetylcholinesterase activity was not affected at any dose level. Plasma ChE activity was significantly decreased at higher doses but not at the low dose of 0.0036 mg/kg bw/d. The ADI was established as 0.0003 mg/kg bw/d, based on the NOEL of 0.0036 mg/kg bw/d for plasma cholinesterase inhibition and using a 10-fold safety factor.

Acute reference dose (ARfD) was established at 0.0006 mg/kg bw.

The ARfD is based on human studies in which volunteers were exposed to single oral doses of Monocrotophos at up to 0.0059 mg/kg bw in a 28-day study and no inhibition of erythrocyte cholinesterase activity or other signs of toxicity were seen. The ARfD was established based on this no-observed-effect level (NOEL) of 0.0059 mg/kg bw and using a 10-fold safety factor.

**FAO/WHO Joint Meeting on Pesticide Residues (JMPR) evaluated monocrotophos in 1972, 1975, 1991, 1993 and 1995.** Monocrotophos was not found to be carcinogenic or teratogenic and caused no toxicity other than the cholinergic syndrome.

An acceptable daily intake (ADI) of 0.0006 mg/kg bw was allocated in 1993 and confirmed in 1995.

This ADI was established on the basis of a 28-day human volunteer study with an NOAEL for erythrocyte acetylcholinesterase of 0.006 mg/kg bw/d and using a 10-fold safety factor.

An acute reference dose (ARfD) of 0.002 mg/kg bw was established [by JMPR] in 1995.

It was concluded that the available toxicological data in humans allowed the establishment of an acute reference dose on the basis of erythrocyte acetyl cholinesterase inhibition and using a 10-fold safety factor.

**Australia  
(2001)**

**FAO/WHO  
JMPR (1995)**

### 3 Human exposure/Risk evaluation

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3.1	<b>Food</b>	<p>Australia</p> <p>An estimate of monocrotophos intake was derived from the Australian Market Basket Survey. This procedure is based on measured monocrotophos residues found in food surveys rather than assuming that the pesticide is present at the MRL. In 1994, the estimated intake in the group with the highest consumption of monocrotophos residues (toddlers aged two) was 7.2 nanograms/kg bw/d. This intake accounts for less than 3% of the ADI.</p>
3.2	<b>Air</b>	Not relevant.
3.3	<b>Water</b>	Not relevant
3.4	<b>Occupational</b>	<p>Australia</p> <p>In accordance with internationally accepted practice, the occupational risk assessment was based on hazard characterization and worker exposure. The latter took into consideration the mixing, loading and application activities involved in the use of the pesticide.</p> <p><b>End-Use Applications</b></p> <p>There were no measured worker exposure studies for mixing, loading or application of Monocrotophos. Therefore, the UK POEM was used to estimate exposure from which margins of exposure (MOE) for the Australian use pattern were determined wherever possible.</p> <p>As a result of the occupational risk assessment, the following conclusions were reached.</p> <p><b>Acceptable and Supported Uses of Monocrotophos</b></p> <p><b>Broadacre Crops, Potatoes &amp; Bananas</b></p> <p>Broadacre crops including tobacco, cereals, wheat, oilseeds and cotton are mainly treated with monocrotophos by aerial spraying, which was the only application method used to treat bananas with this pesticide in Australia. Aerial spraying of monocrotophos may also be used for potatoes. Based on the qualitative risk assessment, continued use of aerial spraying for these crops would be acceptable as long as it remains available only to licensed and authorized personnel.</p> <p>As the risk could not be quantified, the following control measures are needed for aerial spraying on these crops:</p> <ul style="list-style-type: none"> <li>▪ Essential uses only;</li> <li>▪ Development of enclosed mixing/loading systems;</li> <li>▪ Farm chemical user training for workers handling monocrotophos;</li> <li>▪ Health surveillance to be conducted, when appropriate, for workers handling monocrotophos;</li> <li>▪ Human flagging in aerial operations is not acceptable, unless flaggers are protected by engineering controls such as cabs.</li> </ul> <p><b>Unacceptable and Not-Supported Uses of Monocrotophos</b></p> <p><u>Fruit trees &amp; Vegetables</u></p> <p>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. Other uses for pome fruit (apples and pears) are not supported as the risk is unacceptable. Measured worker exposure data is needed to quantify risk for these uses.</p> <p>Monocrotophos use by high-volume or low-volume boom-spraying on tomatoes, French beans and sweet corn is not supported as the risk is unacceptable. Measured worker exposure data is needed to quantify risk for these uses.</p> <p>Groundspraying on broadacre crops is not supported as the risk is also unacceptable. Measured worker exposure data is needed to quantify risk for this use.</p> <p><u>Flowers - control of budworms</u></p>

The risk for workers applying Monocrotophos by high-volume or low-volume boom-spraying based on predicted exposure was high and unacceptable, even if mixer/loader exposure was eliminated in each case, and thus its use was not supported.

#### **Re-entry**

Overseas studies on dislodgeable foliar residues indicated low levels of residues at 96 hours post-application. The degradation of Monocrotophos under aerobic conditions in soil was rapid, with a half-life of between 1 and 7 days, and thus it is unlikely to persist beyond one week following application in soil. It is not expected to bioaccumulate. Based on currently available data, a re-entry period of 5 days is acceptable.

#### **Regulatory advice**

It is recommended that appropriate training courses be identified for all workers involved in the use of monocrotophos.

Aerial spraying is the only application method which is supported due to the comparatively minimal exposure likely to users. In general, the use of monocrotophos products should be restricted to emergency-permit use only. In Australia, organophosphorus pesticides are placed on the National Occupational Health and Safety Commission's Schedule for Health Surveillance.

- 3.5 Medical data** Several 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 cholinesterase activity has begun to return to normal. Thus, its onset may be delayed after apparent recovery from the acute effects characteristic of muscarinic, nicotinic and CNS nerve overstimulation.

## **4 Environmental fate and effects**

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### **4.1 Fate**

#### **4.1.2 Soil**

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 mineralization.

No studies were presented that determined a half-life or examined whether Monocrotophos degrades under anaerobic conditions. The photolysis half-life of monocrotophos on soil was less than 7 days.

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.

#### **4.1.3 Water**

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, i.e. with soil/sediment, degradation could be rapid. The lack of a suitable aerobic aquatic metabolism study is a significant data gap.

Hydrolysis is unlikely to be a significant contributor to the overall degradation of Monocrotophos within the normal environmental pH range.

Direct photolysis in water is not expected but indirect photolysis is possible. Volatilization from soil, or water, is not expected to be a significant route for

#### **4.1.4 Air**

- dissipation, but volatilization from other non-adsorbing surfaces cannot be ruled out. Significant concentrations in air are not expected.
- 4.1.5 Bioconcentration** Based on water solubility, low  $K_{oc}$  and ready soil degradation, significant bioaccumulation in the aquatic environment is not expected.
- 4.1.6 Persistence** Does not accumulate in soil because it is biodegradable and photoabile. Its half-life is less than 7 days in soil exposed to natural sunlight. Monocrotophos has a half-life of 1.3 to 3.4 days on plant foliage.
- 4.2 Ecotoxicity – Effects on non-target organisms**
- 4.2.1 Terrestrial vertebrates**
- Mammals** Monocrotophos is extremely toxic to laboratory rodents by the oral route of exposure, with  $LD_{50}$ s around 10 mg/kg (see Section 2.2.1). The acute dermal toxicity is somewhat less (Section 2.2.1). In Australia, tests on the native marsupial *Sminthopsis macroura* showed that a single dietary dose at 80–100 mg/kg bw 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 alexis* 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. In the Hungarian wildlife toxicity studies carried out at large-scale farms using Azodrin 40 WSC at 1.5 l/ha (maximum label rate), no hare deaths were observed, though slightly poisoned adults could be seen. Therefore it is probable that Azodrin 40 WSC causes death of young hares of low body-weight.
- Birds** Monocrotophos is rated (according to US EPA) as very highly toxic to birds by both the acute oral (reports for 13 species,  $LD_{50}$  of 0.19 to 6.49 mg/kg), and dietary routes of exposure (3 species,  $LC_{50}$  range 2.4–32 ppm). Multi-generation tests (approximately 20 weeks exposure) on Japanese quail and Mallard duck showed that effects occurred at low levels, 0.1 and 3.0 mg/kg in feed respectively. [Source: database compiled by the US EPA (Ecological Fate and Effects Division, Office of Pesticide Programs) of studies reviewed by them and judged to meet US EPA Guidelines.] Results in the literature for toxicity also indicates very high toxicity to birds – acute toxicity: 1.0–4.21 mg/kg; chronic toxicity: NOEC 0.5 mg/kg/d (Japanese quail, 21d). Field reports indicate that Monocrotophos has been associated with several incidents of bird kill in the United States of America. These old field studies suggest that where there was either food, i.e. wild seeds, or standing water which attracted birds to either drink or feed in the 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 led to high mortalities. There are anecdotal Australian reports of bird kills from label use of Monocrotophos EC, but no reliable reports. There are well-documented reports of Monocrotophos causing significant mortalities of Swainson's hawks in Argentina following use to control grasshoppers. In Hungary, wildlife toxicity studies at pilot and at large-scale farms clearly confirmed that the use of Azodrin 40 WSC significantly damaged wildlife, mainly birds. Independently of the age and body weight of the animals and the growth stage of the treated crops, the use of the product caused death to some birds and, prolonged poisoning to others (6–12 days). The poisoned birds did not respond to stimulus and were unable to flee, therefore it is probable that most were killed by predators. Additional losses were caused by the fact that the recommended use of the product in Hungary was at the time of bird reproduction, thus poisoned birds which survived did not feed

for several days and return to their nests, and so on.

- 4.2.2 Aquatic Species**
- Fish** Fish are the least sensitive, with LC<sub>50</sub>s ranging from 1.9 to 180 mg ai/l, based on 9 species. Monocrotophos is rated as moderately to slightly toxic to fish, again according to US EPA criteria. Several of these values are old, nominal and not considered reliable, but they have been used by NRA in the absence of other data. The USEPA Office of Pesticide Programs database entries show similar sensitivities for fish with, LC<sub>50</sub>s between 5.2 and 50 mg/l.
- Aquatic invertebrates** 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.
- Algae** Monocrotophos is rated as moderately toxic to one species of green alga, *Chlorella vulgaris*, with EC<sub>50</sub>s of 6.8 mg/l (nominal) but non-toxic to *Scenedesmus subspicatus*, another greenalga, where the EC<sub>50</sub> was >100 mg/l and NOEC = 100 mg/l. The US EPA considers both as insensitive species.
- 4.2.3 Honey bees & other arthropods** 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. Residues on foliage were very highly toxic to bees 24 hours after application (100% mortality). Some reports show that monocrotophos is more toxic to beneficial insects than to pests
- 4.2.4 Earthworms** The toxicity to earthworms was 196 mg/kg of soil for one test and 35 mg/kg for another. Tests were stated to be based on OECD Guideline 207. These tests rate monocrotophos as either slightly or moderately toxic to earthworms.
- 4.2.5 Soil microorganisms** **No toxicity data were available for these organisms.**
- 4.2.6 Terrestrial plants** Direct application to desirable terrestrial plants and vegetation is not expected and monocrotophos is non-phytotoxic when used as directed, although some apple, pear, peach, cherry and sorghum varieties may suffer slight injury. Significant effects on desirable plants are therefore considered unlikely.
- 5 Environmental Exposure/Risk Evaluation**
- 5.1 Terrestrial Vertebrates**
- Birds** Australia's environmental assessment calculations using standard methodology show that the overall risk to birds appears high and unacceptable, especially to birds that consume insects, seeds and so on or are directly oversprayed by the chemical. Use of Monocrotophos to control locusts at the higher rate is likely to represent a very high risk to avian predators of locusts and is unacceptable. This risk 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 (LC<sub>50</sub> = 2.4ppm, 50% of feed contaminated) for small insects indicate a high risk and for large insects a moderate risk.
- 5.2 Aquatic Species**
- Fish/aquatic invertebrates** For aerial application, apart from direct overspray, the risk to fish is considered to be acceptable. No risk is expected to algae. However, the risk to sensitive aquatic invertebrates was determined to be unacceptable to beyond 300 metres from spray drift at all aerial application rates, based on AgDRIFT (from the US EPA) and literature reports, when used according

to current label directions. At the lowest rate examined, 140 g ai/ha, the risk to less sensitive aquatic invertebrates was acceptable at 300 metres but only with placement spraying (coarse droplets, vmd 350 µm). It should be noted that a high risk exists from runoff at high rates as well.

For orchard applications, AgDRIFT showed that for apple and stone-fruit orchards the risk to aquatic invertebrates from orchard air-blast sprayers was moderate at 50 metres and may be acceptable with additional label restrictions. For larger trees and dormant spraying, the risk 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 on degradation, the level of risk and also that use of monocrotophos is declining in favour of chemicals more suitable for IPM, Australia's assessment favoured the removal of pome fruit use from the label.

The spray-drift risk from boom sprayers (given by AgDRIFT) to aquatic invertebrates was high at 30 metres, especially at the application rate tested, 800g ai/ha (2 l/ha), and just acceptable at 100 metres. At the lowest rate, 140 g ai/ha (350 ml/ha), the risk at 30 metres was just acceptable. Runoff remained a potential problem for rates  $\geq 280$  g ai/ha. Australia nor could support the use of Monocrotophos by boom spray unless the application rate was significantly reduced.

In the aquatic environment, monocrotophos is not expected to persist for an extended period, but, based on very limited data, the degradation rate is considered dependent on the level of microbial activity. The field studies showed the degradation was fast in rice paddies but slow in natural water. There were 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 application 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.

### 5.3 Honey bees and other arthropods

At the application rate of 720 g ai/ha (1.5 l/ha, the rate for sunflowers, sorghum, and orchards), the risk to bees was determined to be high. The risk 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, 280 g ai/ha at 100 metres. 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.

### 5.4 Earth Worms

The risk to earthworms from use of Monocrotophos is expected to be low.

### 5.5 Soil microorganisms

For other soil invertebrates there may be expected to be a high risk but there are no toxicity data for these organisms.

### Summary

Using standard methodology it was concluded that there was a high risk to birds from the current use of monocrotophos when avian food items were sprayed. There was also a high aquatic risk to sensitive invertebrates from spray drift at 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 risk is moderate. The risk to bees and other non-target insects was high. There is also a potentially high risk to aquatic organisms from runoff if rain occurs within days of application.

## Annex II – Details on final regulatory actions reported

## Country Name: Australia

1	<b>*Effective date(s) of entry into force of actions</b>	From 9 December 1999; registration of monocrotophos cancelled, further imports prohibited. Use phased out according to the following schedule: <b>Wholesale supply:</b> to cease by 30 June 2000; <b>Retail sale:</b> to cease by 31 December 2000; and <b>MRLs withdrawn:</b> from 30 June 2002
	<b>*Reference to the regulatory document</b>	(a) The NRA review of monocrotophos, January 2000. NRA Review Series 00.1. National Registration Authority for Agricultural and Veterinary Chemicals. (b) National Registration Authority for Agricultural and Veterinary Chemicals (NRA) Board Resolution 793, Action 99-77a, 9 December 1999.
2	<b>Succinct details of the final regulatory action(s)</b>	The decision cancels the registrations and all relevant approvals for monocrotophos, halts further imports and phases out its use over a one year period. The Australian MRL for monocrotophos to be withdrawn on the 30 June 2002.
3	<b>Reasons for action</b>	Unacceptable occupational health and safety risks.
4	<b>Basis for inclusion into annex III</b>	Decision follows a review of monocrotophos under the Australian National Registration Authority's (NRA) Existing Chemical Review Programme, which failed to satisfy the NRA that continued use of monocrotophos products, in accordance with the recommendations for its use, would not harm people or the environment. Importantly, there was no commitment by stakeholders to generate the required data to allay concerns about environmental, occupational health and residue impacts. The review identified several areas of concern about the use of monocrotophos relating to environmental and worker exposure, residues, and to its particular toxicity to birds.
4.1	<b>Risk evaluation</b>	The review concluded that continued use of monocrotophos would pose an unacceptably high risk to workers, wildlife and trade.
4.2	<b>Criteria used</b>	Risks to the environmental, occupational health and safety (OHS), public health and trade.
	<b>Relevance to other States and Region</b>	Of special concern to developing countries because of the high risk associated with ground spraying of monocrotophos, even when rigorous OHS practices are employed.
5	<b>Alternatives</b>	The following alternatives are considered to pose lower risks to workers and the environment. WHO hazard classifications are provided as an aid to consideration of relative risks. These classifications are for active constituents. Actual hazard depends on formulations. This list is not exhaustive and other alternatives are available. <b>Moderately hazardous:</b> ▪ Chlorpyrifos, diazinon; dimethoate; fenitrothion <b>Slightly hazardous:</b> • Azamethiphos; malathion.
		It is recommended that if any of the above chemicals are to be considered as alternatives, advice should be sought from product manufacturers concerning suitability for the proposed use and for local conditions.
6	<b>Waste management</b>	Halting imports followed by phase-out of existing stocks
7	<b>Other</b>	Australia has established a Health Value of 0.001 mg/l for monocrotophos in drinking water. (The "Health Value" is the concentration of contaminant

which is not expected to result in any significant health risk to consumers, assuming a lifetime intake of 2L water/day. The derivation of this value assumes a bodyweight of 70 kg and that intake from drinking water will constitute 10% of the ADI.)

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<b>Country Name: Hungary</b>
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| 1   | <b>*Effective date(s) of entry into force of actions</b><br><b>*Reference to the regulatory document</b> | Registration of monocrotophos containing insecticides withdrawn in 1996. The registration of products with monocrotophos as their active ingredients was reviewed in compliance with Ministerial communiqué 1994/20 by the Plant Protection and Agro-environmental Department of the Ministry of Agriculture and Food, published in the Official Journal of the Ministry. In compliance with annex II to Ministerial Decree 6/2001 FVM, monocrotophos is on the list of banned active ingredients.<br>9032/1992; 21175/1996.   |
| 2   | <b>Succinct details of the final regulatory action(s)</b>  | Banned for all agricultural uses.  |
| 3   | Reasons for action   | Unacceptably high adverse impact on wildlife.  |
| 4   | <b>Basis for inclusion into Annex III</b>  | A review based on field observations and studies which showed that Monocrotophos has an unacceptably high adverse impact on the environment.   |
| 4.1 | <b>Risk evaluation</b>   | Scientific studies carried out at small-scale and large farms indicated extremely high risk to birds and bees during and following the application of Monocrotophos-containing products.<br><br>The review identified concern about environmental impacts resulting from the extreme adverse impacts on wildlife observed under conditions of commercial use, confirmed by toxicity tests at pilot farms and large-scale farms at the Nature and Wildlife Conservation Station (Fácánkert, Hungary) between 1976 and 1980, and reported by users, hunters, and environmentalists. Restrictions on uses and times of application, and of the quantity to be applied per unit area (limited to 0.75-1.0 l/ha to control seedling pests of sugar-beet and maize grown in blocks, and crops with poorer wildlife populations) did not reduce the impact on wildlife to an acceptable level.  |
| 4.2 | <b>Criteria used</b><br><b>Relevance to other States and Region</b>                                      | Assessment of impact upon wildlife.<br>Because of the similar ecological parameters (climate, crops and pests), the action by Hungary is highly relevant to neighbouring States.   |
| 5   | <b>Alternatives</b>  | The product can be replaced with other organophosphorus compounds and other types of products with lower acute toxicities and lower risk to humans and environment.  |
| 6   | <b>Waste management</b>  | As Monocrotophos has not been used in Hungary since 1996, there are no waste management problems.  |
| 7   | <b>Other</b>   | Monocrotophos was registered for use in Hungary, in the form of Azodrin 40 WSC (Shell, UK; Agrokémia Szövetkezet, Hungary) at a rate of 0.75–1.0 l/ha to control <i>Bothynoderes punctiventris</i> , <i>Psalidium maxillosum</i> , <i>Tanyemecus dilaticollis</i> and <i>Tanyemecus palliatus</i> in emerging sugar beet and maize grown in blocks if applied within 30 days of the sowing date. Nuvacron 40 WSC (Ciba-Geigy AG, Switzerland; Nitrokémia Ipartelep, Hungary), with the same active ingredient, was registered for use on sugar beet against <i>Aphis fabae</i> , <i>Bothynoderes punctiventris</i> , <i>Chaetocnema tibialis</i> , <i>Pegomya betae</i> and <i>Lixus scabricollis</i> (rate: 0.75–1.25 l/ha); <i>Psalidium maxillosum</i> (rate: 1.0–1.25l/ha); <i>Scrobipalpa ocelatella</i> (rate: 1.5l/ha); <i>Mamestra brassicae</i> (rate: 1.5–2.5l/ha); and spider mites ( <i>Tetranychus urticae</i> ) (rate: 1.5–2.0 l/ha). For maize it was registered at rates of 0.75–1.25 l/ha and 1.5 l/ha against <i>Tanyemecus dilaticollis</i> and <i>Oscinella frit</i> respectively. In maize and soya, the following rates were registered to control various pests: noctuid larvae, 1.5- |

2.0 l/ha and spider mites 1.5-2.0 l/ha. In sunflower and soya 1.75–1.25 l/ha was the registered rate against *Tanymecus spp.*, *Psolidium maxillosum* and *Sitona spp.* For the control of *Leptinotarsa decemlineata*, 2.4–2.8 l/ha was registered in *Solanum nigrum*. Both products were authorized for large-scale farm use only. Biological efficacy of the products was good against the above pests.

Monocrotophos-containing insecticides were registered for use in Hungary from 1971 until 1996. With their withdrawal, no gaps in the pest management programmes for the concerned crops (sugar beet, maize, sunflower, soya and *Solanum nigrum*) appeared. For their major uses (to control *Bothynoderes punctiventris*, *Chaetocnema tibialis* and *Tanymecus dilaticollis*), several registered organophosphate insecticides, such as Danatox 50 EC, Dimecron 50, Nurelle D 50/500 EC, Pyrinex 48 EC, Ultracid 40 WP organochlorine insecticides (such as Thiodan 35 EC and, Thionex 35 EC), and insecticides containing other active ingredients (such as Bancol 50 WP and Padan 50) are available. Regent 80 WG will soon have its registration document, including a very efficient solution for pest management programmes. For sugar beet, maize and sunflower, seed-dressing agents containing chloronicotinyl have recently been registered which can be successfully applied against pests of young plants *Bothynoderes punctiventris*, *Psolidium maxillosum*, *Tanymecus dilaticollis*, *Tanymecus palliatus* and *Chaetocnema tibialis*. Other pests such as *Aphis fabae*, *Pegomya betae*, *noital* and *Scrobipalpa ocelatella* can be well controlled using several registered organophosphates and synthetic pyrethroids with less mammalian toxicity. The replacement of Azodrin 40 WSC has therefore caused no problems in this area either.

**Annex III – Addresses of designated national authorities****AUSTRALIA**

<p><b>P</b>  Manager  Agricultural &amp; Veterinary Chemicals  Agriculture Fisheries Forestry – Australia  GPO Box 858  CANBERRA ACT 2601  <i>Mr. André Mayne</i></p>	<p><b>Phone</b> +61 2 6272 5391  <b>Fax</b> +61 2 6272 5697  <b>Telex</b>  <b>e-mail</b> andre.mayne@affa.gov.au</p>
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<p><b>CP</b>  Assistant Secretary  Environment Quality Division  Environment Australia  GPO Box 787  CANBERRA ACT 2601  <i>Mr. Peter Burnett</i></p>	<p><b>Phone</b> +61 2 6250 0270  <b>Fax</b> +61 2 6250 7554  <b>Telex</b>  <b>e-mail</b> Peter.Burnett@ea.gov.au</p>
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**HUNGARY**

<p><b>P</b>  Director  Plant Protection Department  Ministry of Agriculture  Budapest, 1055  Kossuth Lajos tér 11  <i>Mr. Zoltán Ocskó</i></p>	<p><b>Phone</b> +36 1 3014248  <b>Fax</b> +36 1 3014644  <b>Telex</b> 22-5445  <b>e-mail</b> zoltan.ocsko@fmv.hu</p>
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<p><b>CP</b>  Director-General  National Centre of Public Health  Budapest, H-1450  PO Box 22</p>	<p><b>Phone</b> +36 1 2155491  <b>Fax</b> +36 1 2156891  <b>Telex</b>  <b>e-mail</b></p>
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**C** Industrial and consumer product chemicals

**CP** Pesticides

**P** Pesticides, industrial and consumer product chemicals

## Annex IV – References

### Regulatory control action

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