UNITED NATIONS

PIC

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

Distr.
GENERAL

UNEP/FAO/PIC/INC.9/10
11 March 2002

ORIGINAL: ENGLISH

INTERGOVERNMENTAL NEGOTIATING COMMITTEE FOR AN INTERNATIONAL LEGALLY BINDING INSTRUMENT FOR THE APPLICATION OF THE PRIOR INFORMED CONSENT PROCEDURE FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES IN INTERNATIONAL TRADE
Ninth session
Bonn, 30 September-4 October 2002

IMPLEMENTATION OF THE INTERIM PRIOR INFORMED CONSENT PROCEDURE

INCLUSION OF THE CHEMICAL MONOCROTOPHOS, AND ADOPTION OF ITS DECISION GUIDANCE DOCUMENT

Note by the secretariat

A. Introduction

1. In paragraph 8 of its resolution on interim arrangements[1], the Conference of Plenipotentiaries decided that the Intergovernmental Negotiating Committee shall decide, between the date on which the Convention is opened for signature and the date of its entry into force, on the inclusion of any additional chemicals under the interim prior informed consent procedure in accordance with the provisions of Articles 5, 6, 7 and 22 of the Convention.

2. Paragraph 5 (a) of Article 22 provides that amendments to Annex III shall be proposed and adopted according to the procedure laid down in Articles 5 to 9 and paragraph 2 of Article 21. Paragraph 2 of Article 21 provides that amendments to the Convention shall be adopted at a meeting of the Conference of the Parties and that the text of any proposed amendment shall be communicated to the Parties by the Secretariat at least six months before the meeting at which it is proposed for adoption.

3. At its second session, the Interim Chemical Review Committee reviewed two notifications of final regulatory action from two PIC regions to ban or severely restrict the chemical monocrotophos and, taking into account the criteria set out in annex II of the Convention, concluded that the requirements of that annex had been met. Accordingly, the Interim Chemical Review Committee recommended to the eighth session of

[1] Contained in the Final Act of the Conference of Plenipotentiaries on the Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (UNEP/FAO/PIC/CONF/5, annex I, resolution 1).

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the Intergovernmental Negotiating Committee that monocrotophos should become subject to the interim PIC procedure, noting that the Interim Chemical Review Committee would develop a draft decision guidance document and forward it to the Intergovernmental Negotiating Committee in accordance with Article 7 of the Convention (UNEP/FAO/PIC/ICRC.2/11, annex I).

4. At its third session, the Interim Chemical Review Committee finalized the draft decision guidance document and decided to forward it and the recommendation for inclusion of monocrotophos in the interim Prior Informed Consent Procedure to the Intergovernmental Negotiating Committee. The text of that recommendation, a summary of the deliberations of the Committee including a rationale for the inclusion of monocrotophos based on the criteria listed in Annex II of the Convention, and a tabular summary of comments received and how they had been addressed, are attached as annex I.[2] The draft decision guidance document is attached as annex II[3] to the present note.

5. In accordance with decision INC-7/6, which sets out the process for drafting decision guidance documents, and in line with the time frame specified in paragraph 2 of Article 21, the secretariat circulated the present document to all Parties and observers on 25 March 2002.

B. Suggested action by the Committee

6. The Committee may wish to decide to make the chemical monocrotophos subject to the interim prior informed consent procedure, as defined in paragraph 2 of the resolution on interim arrangements, and to approve the draft decision guidance document.

[2] Circulated in document UNEP/FAO/PIC/ICRC.3/19/Add.1.

[3] Reproduces annex V of the report to the third session of the Interim Chemical Review Committee, document UNEP/FAO/PIC/ICRC.3/19.

Annex I

Monocrotophos

The Interim Chemical Review Committee,

Noting that at its second session it had reviewed the notifications of final regulatory actions by Australia and Hungary on monocrotophos and, taking into account the requirements set forth in Annex II of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, and had come to the conclusion that the requirements of that Annex had been met,

Recalling that, in line with paragraph 6 of Article 5 of the Convention, at its second session it had accordingly recommended to the Intergovernmental Negotiating Committee that monocrotophos should become subject to the interim prior informed consent procedure and noting (recommendation B of its report of its second session (UNEP/FAO/PIC/ICRC.2/11)) that it was to develop a draft decision guidance document and forward it to the Intergovernmental Negotiating Committee in accordance with Article 7 of the Convention,

Recalling also that, in accordance with the operational procedures for the Interim Chemical Review Committee, set forth in decision INC-7/6 of the Intergovernmental Negotiating Committee on the process for drafting decision guidance documents, it had established a task group to draft a decision guidance document on monocrotophos and that that task group, upon fulfilling the requirements of the operational procedures and in accordance with paragraph 1 of Article 7 of the Convention, had developed a draft decision guidance document on monocrotophos (UNEP/FAO/PIC/ICRC.3/18) and had submitted it to the Committee at its third session for further action,

Noting that the draft decision guidance document was based on the information specified in Annex I of the Convention, as required by paragraph 1 of Article 7 of the Convention,

Recalling that in accordance with step 7 of the process for drafting decision guidance documents, final documentation forwarded by the Secretariat to all Parties and observers in advance of Intergovernmental Negotiating Committee sessions must include a draft decision guidance document, a recommendation by the Interim Chemical Review Committee for inclusion in the prior informed consent procedure, a summary of the deliberations of the Interim Chemical Review Committee including a rationale for inclusion based on the criteria listed in Annex II to the Convention, and a tabular summary of comments received by the Secretariat and how they had been addressed,

Adopts the following recommendation to the Intergovernmental Negotiating Committee:

Recommendation ICRC-3/1: Inclusion of monocrotophos in the interim prior informed consent procedure

The Interim Chemical Review Committee

Recommends, in line with paragraph 5 of Article 5 of the Convention, that the Intergovernmental Negotiating Committee should make monocrotophos subject to the interim prior informed consent procedure;

Forwards, in line with paragraph 2 of Article 7 of the Convention, this recommendation, together with the draft decision guidance document on monocrotophos, to the Intergovernmental Negotiating Committee for a decision on the inclusion of monocrotophos in the interim prior informed consent procedure.

Appendix I

Rationale and summary deliberation for the inclusion of monocrotophos in the prior informed consent procedure based on the criteria set forth in Annex II to the Convention

In reviewing the notifications of final regulatory actions by Australia and Hungary on monocrotophos, the Interim Chemical Review Committee was able to confirm that those actions had been taken in order to protect human health or the environment.

The Committee established that the final regulatory actions had been taken consequent on risk evaluations and that those evaluations had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognized methods, that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures, and that the final regulatory actions had been based on risk evaluations taking into account the conditions prevailing within Australia and Hungary.

The Committee concluded that there was ongoing trade in monocrotophos and the final regulatory actions notified to it provided a sufficiently broad basis to merit including monocrotophos in the interim PIC procedure.

Appendix II

Task Group on monocrotophos

Second-round comments on the draft internal working document for monocrotophos

China	The trade name and formulation type in DGD should be current in international trade. It's very difficult in collecting all the trade names and formulation types including the product used domestically and no necessary for the PIC procedure	Noted - Issue to be discussed in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
China	In part 2 of Annex 1 "Toxicological properties" we need detail information on the item which is the basis for the final regulatory action. Other toxicity information can be a conclusion	Agree. We consider that the DGD summary adequately covers the key end-points underpinning the national actions.
China	About alternatives and regulatory measures to reduce exposure, as much information as possible should be provided. The Secretariat can get the information from other countries through Website after the draft DGD distributed.	Noted - Issue to be discussed in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
Samoa	P1: CAS-No.(s) omits Hungary's …ICRC.2/INF.6?Add.2 page 3 2157-98/4 (mixture of isomers)	Only common form of the chemical captured by the two notifications is the E-ISO form. There is an issue of consistency in using CAS numbers. This will be discussed in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
Samoa	P2: Risk evaluation could be combined with p.4 (Classification of) Hazards and risks…).	The current layout is consistent with that agreed at ICRC3.
Samoa	P2: Environmental Impact should be moved to p.3	The current layout is consistent with that agreed at ICRC3.
Samoa	P3: Other measures to reduce exposure could be combined with p.4 Exposure limits.	The current layout is consistent with that agreed at ICRC3.
Samoa	P4: Hazards… hazard class 11 could be 2 or II	Editorial – done
Samoa	P4: Exposure limits for Air and soil not established as for drinking water?	Not relevant to the national decisions.
Samoa	P5: Packaging could include storage stability as per …ICRC.2/11 paragraph (para.) 21 Annex III 8 suggestion by Amb. El Zarka et al. [N.B. your (15 Aug. 2001 fax) ICRC3 TG2 D.G.D. format S.H.P.F. 9. Physico-chemical bullet 7 …dissolution properties (p.10) & p.12 Annex II S.D.S. 9. Stability and reactivity}	Noted. Stability information may be included where is it appropriate. In this case, stability is not relevant to the national decision(s).

Samoa	P10 @ S2.2.7: Australia (2001) "volunteers received daily oral doses…" - The latter is also to be queried about paraquat with or without earth (Fullers) and efficacy of emetic.	Noted.
Samoa	P11 @ S3.3: Water - Not relevant?	Not relevant to the national decision(s).
Samoa	P14 @ S4.2.5: Soil microorganisms - No toxicity data… recalls note that one page SDS do not contain ecotoxicology information.	No data provided.
Samoa	P17 @ S5 Alternatives Moderately…Slightly hazardous by WHO and/ or Australian classification?	WHO is the standard adopted in this Draft DGD. Issue to be discussed in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
Sudan	**List of Abbreviations:** Add >> greater than; Replace ec with EC for emulsifiable concentrates, without dots, it is distinguish able from European Community; Replace EC50, ED50 and IC50 with EC_{50}, ED_{50} and IC_{50} respectively.	 Editorial – done Editorial – done Editorial – done
Sudan	**Final Regulator action:** Page 2 under subtitle Hungary, line 5 delete the extra **T**.	 Editorial - done
Sudan	**Risk Evaluation:** Crops and pests are sometime written with Latin names and sometimes written with common names. I guess it is better to be consistent in using names. If the list of crops and pest is not too long it is better to give the Latin name for proper identification. Thus it may be appropriate to always use Latin names specially for citing pests and disease causing organisms throughout the DGD	 Editorial. Requirement for uniformity agreed in principle. Standards to be adopted to be discussed in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
Sudan	P3, line 4, end of the line, replace **is** killed with **were** killed.	Editorial - done
US	Under Reasons for inclusion in the PIC procedure', include in addition to the impact on human health, the concerns for its effect on birds, mammals and invertebrates	The reference made in the opening paragraph is to the original listing of monocrotophos as a severely hazardous pesticide formulation. The reason for the original listing was on human health grounds only. The two references to national action are correctly reported.
US	Under 4.2.1 mammals, indicate whether the single dose at 80 to 100 mg/kg bw was an oral or dermal dose	Clarification – Editorial - done

US	Under 4.2.1 birds --- last sentence, it is Swainson's hawks (with an 'I') The ecological incidents associated with the use of this chemical reported on the Internet are very significant. We would suggest that this information get more emphasis and earlier in the birds section (e.g., nearly 6,000 Swainson's hawks were killed on the Pampas of Argentina between 1995 and 96 ---- the Internet piece on this called this incident "unrivalled in recent history due to the large numbers of animals affected and the speed with which international interests responded") Apparently, raptors are >10 times more sensitive to this pesticide than other bird species and it is "highly toxic" to the other species based on LD50s.	Editorial. No particular emphasis contained in the material supporting the national decision(s). Two issues are raised by the second group of comments. (i) whether the DGD should include comprehensive references to original source material or whether to omit them but refer the reader to the overarching national papers which were produced in support of the national actions ((i.e. probably the focused summary in most cases). • The strategy adopted in the draft DGD has been to not include detailed referencing to source material, but leave the reader to pursue particular source references by referral to the national overarching documentation. (ii) whether supporting material which may not have been used directly by the responsible national authority in taking a final regulatory action should be introduced. Both of these issues have been identified for discussion in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
US	S5.1 – Birds. Again emphasize that raptors are particularly sensitive.	As above.
US	S5.2 - Fish/aquatic invertebrates. Add the concept that invertebrates are the food source for higher aquatic organisms and their diminution ultimately affects fish at a slower rate.	As above
Saudi Arabia	No comments requiring changes	No action required.

EC	Identification and uses BSI, E-ISO, ULV should be defined in the abbreviations list (*p. ii-iv*) (or for ULV full name to be included). **Basic manufacturers:** The name of the country where the firm Comlets Chemical Industrial is established (ROC) should be spelt out.	 Editorial - done Editorial – done Note Pesticide Manual gives: Aimco, BASF, CAC, Comlets, Crystal, DE_NOCIL, Hindustan, Hui Kwang, India Pesticides, Cheminova, Makhteshim-Agan, Nagarjuna Agrichme, Parry, Q.W.A. C.A., Rallis, Sabero, Shenzhen Jiangshan, Sinon, Sudarshan, Sundat, Taiwan Tainan Giant, Tantech, United Phosphorus
EC	Final regulatory action: **Australia:** According to the footnote, "occupational" includes workers involved in manufacture and re-packaging. However, it appears that the final regulatory action was taken only because of concerns for operators and environmental protection during the use of this insecticide. We wonder therefore whether to avoid any possible confusion or misunderstanding it may be appropriate to replace the word "occupational" by "operators" and to delete the footnote.	 The current text reflects Australia's OH&S terminology in the national risk assessment. The footnote clarifies the basis for the regulatory action. These definitions cover the different worker activities considered in the Australian OH&S risk assessment and the proposed amendment may lead to confusion particularly where the terms are loosely used to refer to certain activities (e.g. operating machinery and not mixing and loading).
EC	Risk Evaluation: **Australia**: The sentence "The ADI was used as the point of reference." might be usefully be added for clarification to the end of the first paragraph in the section on occupational health and safety. In the section on environmental impact, IPM should be defined in the abbreviations table. **Hungary**: "our country" should be replaced by "Hungary"	 NOHSC does not commonly use the ADI, which is the point of reference for dietary intake studies. Editorial - done Editorial - done

EC	Hazards and Risks to human health and/or the environment: **WHO:** In the table columns for oral and dermal toxicity, the words "see annex 1" should be deleted as the given LD_{50} values are not consistent with the values found in annex 1. **EC:** In the second column EC is unnecessary and can be deleted.	Editorial - done Editorial – done
EC	Food: For the Codex, dates should be included where possible.	Editorial - done. Note to be included in the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
EC	Physico-Chemical properties *(Pesticides Manual – 12th Ed. 2000* K_{ow}logP should be replaced by logP_{ow}.	Reference taken directly from the *Pesticides Manual – 12th Ed. 2000*
	S2.2.1. Acute toxicity A sub-heading for the last paragraph should be added to distinguish it from the paragraph titled "Irritation". This sub-heading might be "ARfD".	Editorial - done

	2.2.7. Summary and overall evaluation In the penultimate sentence of the second paragraph, the reference should be to skin and eye irritant "in rabbits". In the third paragraph, considering the metabolites present in urine (§2.1.3), the route of administration should be specified as dimethyl phosphate is detected after dermal exposure, whereas N-methyl acetoacetamide and 3-hydroxy-N-methyl butyramide are found after oral exposure. The text should therefore read "The major metabolite following dermal application ……"	Clarification – Editorial - done Clarification – Agree, the text is not optimal! – note that N-methyl acetoacetamide and 3-hydroxy-N-methyl butyramide metabolites come from the other end of the monocrotophos molecule than the part which forms dimethyl phosphate and methyl phosphate i.e. these metabolites are not mutually exclusive. We have dealt with this in the following manner:- 1. at Section 2.1.3, to delete the sentence "Following dermal exposure to monocrotophos in humans and intra-peritoneal exposure in rats, dimethyl phosphate was the most common urinary metabolite detected."; and 2. at Section 2.2.7 (paragraph 3) to replace the sentence "The major metabolite is dimethyl phosphate (DMP)." with the following:- "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."
	In the 6th paragraph, "genotoxic" should be replaced by "mutagenic".	Clarification: should be 'genotoxic' since this is the general term for effects on nuclear material, 'mutagenic' refers solely to the induction of mutations in genes i.e. effecting a specific measured gene output. Gross chromosome damage (gaps, breaks, etc) and induction of unscheduled DNA synthesis are genotoxic actions, not necessarily mutagenic. Sentence amended.
	In the eighth paragraph RBC ChE should be defined in the abbreviations table or put in plain words in the text.	Editorial - done
	More generally, it seems to us that much of the information in this section is very detailed and is not strictly a summary of the evaluation. Much of it would be more appropriate to the preceding individual sections (e.g. the last sentence of paragraph 7 might be better placed in section 2.2.4; the material in the Australian section on ADI and ARfD is much more detailed than the corresponding passages in sections 2.2.1 and 2.2.2 and might be more appropriately reported there etc).	Noted. Our preference is to have a summary addressing all the key end-points expected of a toxicological analysis.

	S4.2.1 - Terrestrial vertebrates **Mammals:**	
	In the first paragraph " mammals" should be replaced by "rats" and LC_{50} should be changed to LD_{50}.	Clarification & Correction – Editorial - done
	Furthermore there is an inconsistency in the figures quoted. The LD_{50} values previously given for terrestrial mammals (rats, §2.2.1) were 8 mg/kg, not 18 mg/kg, for the oral route and 119 mg/kg, not 354 mg/kg, for the dermal route. In the last paragraph "EC" should be deleted.	Clarification – Editorial - done This Section should refer back to Section 2.2.1. When Australia has done a detailed toxicology evaluation, it is not appropriate to refer to the US EPA figures.
	Birds:	
	In the first sentence exposure duration (5-10 days) should be given for dietary route studies to allow comparisons with other data.	Standard protocols are implied in the draft DGD. Issue identified for discussion in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
	Office of Pesticide Program: the abbreviation OPP appears further on in the text and should be defined here and/or in the abbreviations table.	Editorial - done
	Literature toxicity values as set out in the Australian NRA Review should be added at the end of the last sentence of the first paragraph, which should read as follows: "Results in the literature for toxicity also indicate very high toxicity to birds- acute toxicity:1.0-4.21 mg/kg, chronic toxicity: NOEC 0.5mg/kg/d (Japanese quail, 21d.)	Editorial - done

	Environmental Exposure/Risk Evaluation Throughout this whole section the word "hazard" should in our view be replaced by "risk". **Birds** We suggest that the LC_{50} duration of exposure (10 days) be added. **Fish/Aquatic invertebrates** AgDRIFT, vmd, IPM should be defined in the abbreviations.	Standard language adopted – Editorial – done As per S4.2.1 above. Editorial – Latter two done. First will be included later
	Annex 2, S7 – Other The stated Health Value of 0.0001 mg/l is a little puzzling. If this is normally set at 10% of the ADI, as the text states, one might have expected a health value of 0.00003 mg/l given that the ADI is 0.0003. Perhaps some clarification/explanation should be provided.	Clarification Health value (mg/l) = (ADI x bodyweight x 10%)/volume water drunk per day = (0.0003 x 70 x 0.1)/2 = 0.0001
	Annex 4 – Regulatory control actions **Regulatory control actions** Hungary: Appropriate references should be added. **Documentation used for Accident reporting and poison management** In the fifth entry referring to the Basel Convention the date in brackets is repetitive and can be deleted. Likewise the date in brackets at the end of the sixth entry is unnecessary. The seventh entry appears to be referring to the same document as the fourth entry. If so, the reference can be deleted.	Editorial - done Editorial - done Editorial - done

Annex II

Operation of the interim prior informed consent procedure
for banned or severely restricted chemicals in international trade

Decision Guidance Document

Monocrotophos

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 September 1998. The same Conference also adopted a resolution on interim arrangements 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 does enter into force.

At its ninth session, held in Geneva on [insert date] the Intergovernmental Negotiating Committee (INC) 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 future imports of the chemical to the Secretariat in accordance 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.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

I. 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
a.i.	active ingredient
AchE	Acetylcholinesterase
ADI	Acceptable daily intake
ADP	Adenosine diphosphate
ArfD	acute reference dose
ATP	Adenosine triphosphate
b.p.	boiling point
BSI	British Standards Institution
Bw	body weight
°C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticide Residues
ChE	Cholinesterase
CHO	Chinese hamster ovary
D	Day
D	Dust
E.C.	European Community
EC	Emulsifiable concentrate
EC_{50}	effect concentration, 50% (median effective concentration)
ED_{50}	effect dose, 50% (median effective dose)
EHC	Environmental Health Criteria
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
IARC	International Agency for Research on Cancer
IC_{50}	Inhibition concentration, 50 % (median inhibitory concentration)
ICSC	International Chemical Safety Card
i.m.	Intramuscular
i.p.	Intraperitoneal
IPCS	International Programme on Chemical Safety
IPM	Integrated pest management
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry

I. ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT (N.B. Chemical elements and pesticides are not included in this list)	
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- (× 1,000)
Kg	Kilogram
K_{oc}	organic carbon/water partition coefficient
K_{ow}	octanol/water partition coefficient
K_{ow}logP	Logarithm of the octanol/water partition coefficient
L	Litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, 50%
LD_{LO}	lowest lethal dose
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
M	Metre
Mg	Milligram
Ml	Millilitre
m.p.	melting point
MPa	MilliPascal
MRL	Maximum residue limit
MTD	Maximum tolerated dose
NCI	National Cancer Institute (United States of America)
Ng	Nanogram
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOHSC	National Occupational Health and Safety Commission (Australia)
NRA	National Registration Authority for Agricultural and Veterinary Chemicals (Australia)
OECD	Organisation for Economic Co-operation and Development
OHS	Occupational health and safety
OP	Organophosphorus pesticide
Pa	Pascal
PHI	pre-harvest interval
PIC	prior informed consent
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)
SC	soluble concentrate
SG	soluble granules
SL	soluble liquid
SMR	Standardized mortality ratio
STEL	short-term exposure limit
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons (Australia)
TLV	Threshold limit value
TMDI	Theoretical maximum daily intake
TWA	time-weighted average

I. ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT (N.B. Chemical elements and pesticides are not included in this list)	
UKPOEM	United Kingdom Prediction Operator Exposure Model
ULV	ultra-low volume
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
Vmd	volume median diameter
VOC	volatile organic compound
WHO	World Health Organization
WP	wettable powder
Wt	Weight

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

Identification and uses (see annex I)

Common name	Monocrotophos (BSI, E-ISO)
Chemical name Other names/ synonyms	Dimethyl (E)-1-methyl-2-(methylcarbamoyl)vinyl phosphate (IUPAC)
CAS-No.(s)	6923-22-4 (formerly 919-44-8)
Harmonized System Customs Code	2924.10.00 (technical grade active constituent) 3808.10.90 (formulated product)
Category	Pesticide
Regulated Category	Pesticide
Use(s) in regulated category	An organosphosphorus 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.
Trade names	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.
Formulation types	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.
Uses in other categories	No reported uses as an industrial chemical.
Basic manufacturers	Agrolinz, Inc.; Bharat Pulverizing Mills Ltd. (India); Cia-Shen Co. Ltd. (China); Comlets Chemical Industrial Co. Ltd. (Taiwan); Cyanamid (Brazil); Hindustan CibaGeigy Ltd. (India); Lupin (India); Nantong Pesticides Factory (China); Hui Kwang (China); National Organic Chemical Industries Ltd. (India); Quimica Estrella SACI eI (Argentina); Quingdao Pesticides Factory (China); Sudarshan (India); United Phosphorus (India); Sundat (S) Pte Ltd. (Singapore). *This is a representative list of current and former manufacturers of monocrotophos. It is not intended to be exhaustive.*

Reasons for inclusion in the interim PIC procedure

Monocrotophos is included in the interim 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 interim 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 stocks of monocrotophos in the light of the risks associated with product recall, storage and disposal. It also allowed users time to change over to other pesticides.

Reason: Occupational 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 wildlife 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.

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* 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".

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 impacts on wildlife. Further reduction in 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 at large-scale farms, no hare deaths were 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 dead animals and their unborn progeny, the estimated loss in Hungary amounted to 5 to 10 million pheasants since the use of Azodrin 40 WSC begun (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

Australia 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.

Hungary *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.*

Other measures to reduce exposure

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

Where it has been made available, additional information on protective measures (regulatory and other measures) taken in other countries concerning monocrotophos may be found on the Rotterdam Convention website www.pic.int.

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.

Where it has been made available, additional information on alternatives to monocrotophos may be found on the Rotterdam Convention website www.pic.int.

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

WHO	Technical product: 1b (highly hazardous), classification based on oral toxicity (WHO, 1999)				
	Classification of formulations				
		oral toxicity LD_{50}: 14 mg/kg bw		**dermal toxicity** LD_{50}: 112 mg/kg bw	
	Formulation	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
E.C.	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.				
USEPA	Category 1 (highly toxic) (USEPA, 1985)				
IARC	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:

Hazard Class	6.1, poisonous substance.
Packing	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 feedstuff.
Internat. Maritime Dangerous Goods (IMDG) Code	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 Revised guidelines on good labelling practice for pesticides (1995).

First aid

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 may become 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 (WHO, 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 the 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

Introduction 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 2.2.7 includes a brief comparative summary of the conclusions of the two toxicological evaluations.

Annex I – Further information on the substance

1.	**Physico-chemical properties (Tomlin, 2000)**	
1.1	**Identity**	Monocrotophos
1.2	**Formula**	$C_7H_{14}NO_5P$
1.3	**Chemical name (IUPAC)**	Dimethyl (E)-1-methyl-2-(methylcarbamoyl) vinyl phosphate
1.4	**Chemical type**	Organophosphate
	Form	Pure monocrotophos: colourless hygroscopic crystals. Technical monocrotophos, a reddish-brown semi-solid, is at least 75% pure
1.5	**Solubility**	At 20°C - in water 100%, methanol 100%, acetone 70%, n-octanol 25%, toluene 6%
	K_{ow}logP	–0.22 (calculated), K_{ow} 0.60 (calculated)
1.6	**Vapour pressure**	2.9×10^{-4} Pa at 20°C
1.7	**Melting point**	54–55°C
1.8	**Reactivity**	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.
1.9	**Stability**	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, phosphorus 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.
1.10	**Molecular Weight**	223.2
2.	**Toxicological properties**	
2.1	**General**	
2.1.1	**Mode of action**	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.
2.1.2	**Symptoms of poisoning**	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 3.5).

2.1.3 Absorption, distribution, excretion and metabolism in mammals

Monocrotophos is systemically absorbed if it is swallowed, inhaled or comes in contact with the skin. Dermal absorption of ^{14}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_{50} 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_{50} values ranging from 119 to >2,000 mg/kg) and of moderate to high toxicity in rabbits (LD_{50} values ranging from 130 to 709 mg/kg).

Inhalation

Monocrotophos had high inhalation toxicity in rats, with an LC_{50} (4 h) of 80 mg/m^3.

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 two-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 two-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 two 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

Overall, development signs were seen only at doses at or near maternotoxic doses, and there were no significant treatment-related teratogenic findings. 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.

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_{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 (4 h) 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 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 or other genotoxic 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 (LOEL 0.04 mg/kg/d) in one- and two-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).

Australia (2001)

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 acetylcholin esterase 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 (LOEL 0.0057 mg/kg/d) and using a 10-fold safety factor.

The 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 JMPR (1995)

The 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 acetylcholinesterase inhibition and using a 10-fold safety factor.

3. Human exposure/risk evaluation

3.1 Food

Australia

An estimate of monocrotophos intake was derived from the Australian Market Basket Survey. This procedure is based on me asured 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.

3.2 Air

Not relevant.

3.3 Water

Not relevant.

3.4 Occupational

Australia

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.

End-use applications

There were no measured worker exposure studies for mixing, loading or application of monocrotophos. Therefore, the UKPOEM was used to estimate exposure from which margins of exposure (MOE) for the Australian use pattern were determined wherever possible.

As a result of the occupational risk assessment, the following conclusions were reached.

Acceptable and supported uses of monocrotophos

Broadacre crops, potatoes and bananas

Broadacre crops including tobacco, cereals, wheat, oilseeds and cotton are treated with monocrotophos mainly 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 remained available only to licensed and authorized personnel.

As the risk could not be quantified, the following control measures are needed for aerial spraying on these crops:

- Essential uses only;
- Development of enclosed mixing/loading systems;
- Farm chemical user training for workers handling monocrotophos;
- 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.

Unacceptable and not-supported uses of monocrotophos

Fruit trees and vegetables

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.

Monocrotophos use by high-volume or low-volume boom-spraying on tomatoes, French beans and maize is not supported as the risk is unacceptable. Measured worker exposure data is needed to quantify risk for these uses.

Ground-spraying on broadacre crops is not supported as the risk is also unacceptable. Measured worker exposure data is needed to quantify risk for this use.

Flowers – control of budworms

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 one and seven days, and thus it is unlikely to persist in soil beyond one week

following application. It is not expected to bioaccumulate. Based on currently available data, a re-entry period of five 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

4.1 Fate

4.1.1 Soil

The degradation of monocrotophos under aerobic conditions in soil is fast, with a half-life of between <1 and 7 days, based on five 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 seven 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.

4.1.2 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.

4.1.3 Air

Volatilization from soil, or water, is not expected to be a significant route for dissipation, but volatilization from other non-adsorbing surfaces cannot be ruled out. Significant concentrations in air are not expected.

4.1.4 Bioconcentration Based on water solubility, low K_{oc} and ready soil degradation, significant bioaccumulation in the aquatic environment is not expected.

4.1.5 Persistence Does not accumulate in soil because it is biodegradable and photolabile. 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 (by USEPA) 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 USEPA (Ecological Fate and Effects Division, Office of Pesticide Programs) of studies reviewed by them and judged to meet USEPA guidelines.] Results in the literature for toxicity also indicate very high toxicity to birds – acute toxicity: 1.0 – 4.21 mg/kg; chronic toxicity: NOEC 0.5 mg/kg/d (Japanese quail, 21 d).

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 a.i./ha and above, except for one study that showed mortalities at 0.32 kg a.i./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 or return to their nests, and so on.

4.2.2 Aquatic species

Fish

Fish are the least sensitive aquatic species, with LC_{50}s ranging from 1.9 to 180 mg a.i./l based on 9 species. Monocrotophos is rated as moderately to slightly toxic to fish, again according to USEPA 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_{50}s between 5.2 and 50 mg/l.

Aquatic invertebrates

Monocrotophos is rated according to USEPA 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_{50}s of 6.8 mg/l (nominal), but non-toxic to *Scenedesmus subspicatus*, another green alga, where the EC_{50} was >100 mg/l and NOEC = 100 mg/l. USEPA considers both as insensitive species.

4.2.3 Honey bees and 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_{50} = 2.4 ppm, 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 USEPA) and literature reports, when used according to current label directions. At the lowest rate examined, 140 g a.i./ha, the risk to less sensitive aquatic invertebrates was acceptable at 300 metres but only with placement spraying (coarse droplets, vmd 350 ìm). It should be noted that a high risk exists at high rates from runoff 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 a.i./ha (2 l/ha), and just acceptable at 100 metres. At the lowest rate, 140 g a.i./ha (350 ml/ha), the risk at 30 metres was just acceptable. Runoff remained a potential problem for rates $\geq$280 g a.i./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 that 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

		two 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 effect 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 a.i./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 a.i./ha at 100 metres. However, spray drift from the lowest rate, 140 g a.i./ha is expected to be toxic to *Apanteles spp.*, the most sensitive insects to topical applications of monocrotophos.
5.4	**Earthworms**	The risk to earthworms from the 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.
5.6	**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 a.i/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.	**Effective date(s) of entry into force of actions**	From 9 December 1999: registration of monocrotophos cancelled, further imports prohibited. Use phased out according to the following schedule: **Wholesale supply:** to cease by 30 June 2000; **Retail sale:** to cease by 31 December 2000; and **MRLs withdrawn:** from 30 June 2002.
	Reference to the regulatory document	(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.	**Succinct details of the final regulatory action(s)**	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 30 June 2002.
3.	**Reasons for action**	Unacceptable occupational health and safety risks.
4.	**Basis for inclusion in Annex III**	Decision follows a review of monocrotophos under the Australian National Registration Authority's Existing Chemical Review Programme, which failed to satisfy the National Registration Authority 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	**Risk evaluation**	The review concluded that continued use of monocrotophos would pose an unacceptably high risk to workers, wildlife and trade.
4.2	**Criteria used**	Risks to the environment, occupational health and safety (OHS), public health and trade.
	Relevance to other States and regions	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.	**Alternatives**	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. ***Moderately hazardous:*** • Chlorpyrifos, diazinon; dimethoate; fenitrothion ***Slightly hazardous:*** • 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.	**Waste management**	Halting imports followed by phase-out of existing stocks
7.	**Other**	Australia has established a Health Value of 0.001 mg/l for monocrotophos in drinking water. (The "Health Value" is the concentration of contaminant that is not expected to result in any significant health risk to consumers, assuming a lifetime intake of 2 litres of 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 (which is 0.0003 mg/kg bw/d).

Country Name: Hungary

1.	**Effective date(s) of entry into force of actions**	Registration of monocrotophos-containing insecticides withdrawn in 1996.
	Reference to the regulatory document	The registration of products with monocrotophos as their active ingredient 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. 9032/1992; 21175/1996.
2.	**Succinct details of the final regulatory action(s)**	Banned for all agricultural uses.
3.	**Reasons for action**	Unacceptably high adverse impact on wildlife.
4.	**Basis for inclusion in Annex III**	A review based on field observations and studies which showed that monocrotophos has an unacceptably high adverse impact on the environment.
4.1	**Risk evaluation**	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. 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	**Criteria used**	Assessment of impact upon wildlife.
	Relevance to other States and regions	Because of the similar ecological parameters (climate, crops and pests), the action by Hungary is highly relevant to neighbouring States.
5.	**Alternatives**	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.	**Waste management**	As monocrotophos has not been used in Hungary since 1996, there are no waste management problems.

7. Other

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 *Bothynoderes punctiventris*, *Psalidium maxillosum*, *Tanymecus dilaticollis* and *Tanymecus palliatus* 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 Ipartelepek, Hungary), with the same active ingredient, was registered for use on sugar beet against *Aphis fabae*, *Bothynoderes punctiventris*, *Chaetocnema tibialis*, *Pegomya betae* and *Lixus scabricollis* (rate: 0.75 – 1.25 l/ha); *Psalidium maxillosum* (rate: 1.0 – 1.25 l/ha); *Scrobipalpa ocellatella* (rate: 1.5 l/ha); *Mamestra brassicae* (rate: 1.5 – 2.5 l/ha); and spider mites (*Tetranychus urticae*) (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 *Tanymecus dilaticollis* and *Oscinella frit* 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.*, *Psalidium 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 and 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*, *Psalidium maxillosum*, *Tanymecus dilaticollis*, *Tanymecus palliatus* and *Chaetocnema tibialis*. Other pests such as *Aphis fabae*, *Pegomya betae* and *Scrobipalpa ocellatella* 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

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C Industrial and consumer product chemicals
CP Pesticides, industrial and consumer product chemicals
P Pesticides

Annex IV – References

Regulatory actions

Australia

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