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INTERIM CHEMICAL REVIEW COMMITTEE

Second session

Rome, 19 – 23 March 2001

TWO VERIFIED NOTIFICATIONS OF FINAL REGULATORY ACTION
FROM EACH OF TWO PRIOR INFORMED CONSENT REGIONS -

MONOCROTOPHOS

Note by the secretariat

1. In line with Article 5 of the Rotterdam Convention, when the Secretariat has received at least one notification from each of two PIC regions, that contain the information required in Annex I of the Convention, it shall forward the notifications and accompanying documentation to the members of the Interim Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II, recommend to the Intergovernmental Negotiating Committee whether the chemical in question should be made subject to the interim PIC procedure and a decision guidance document drafted.
2. The Intergovernmental Negotiating Committee, in decision INC.7/6, adopted a process for drafting decision guidance documents. The process is based on that developed by the Interim Chemical Review Committee at its first session in Geneva, February 2000. An excerpt of the decision is contained in document UNEP/FAO/PIC/ICRC.2/INF.5.
3. The Secretariat has identified two verified notifications from two PIC regions relating to monocrotophos (Southwest Pacific – Australia and Europe – Hungary). Summaries of these notifications were circulated in PIC Circular XII on 12 December 2000. This note contains the two notifications as they were circulated to the members of the Interim Chemical Review Committee in a letter of, 5 February 2001 in line with Article 5 of the Convention.
4. The relevant documentation provided by Australia and Hungary in conjunction with their respective notifications will be made available as addendums to this note.
5. Severely hazardous pesticide formulations of monocrotophos (soluble liquid formulations that exceed 600 g a.i./l) are already subject to the PIC procedure in accordance with Article 6 (severely hazardous pesticide formulations) of the Convention. The newly notified regulatory actions relate to a ban of all uses in agriculture and would fall under Article 5 (banned and severely restricted chemicals).



FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: AUSTRALIA

PART I: PROPERTIES, IDENTIFICATION AND USES

1. IDENTITY OF CHEMICAL	
1.1	Common name monocrotophos
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists dimethyl (E)-1-methyl-2-(methylcarbamoyl)vinyl phosphate (IUPAC)
1.3	Trade names and names of preparations Azodrin 400 Systemic Insecticide/Miticide Farmoz Monocron 400 Systemic Insecticide Phoskill 400 Systemic Insecticide
1.4 Code numbers	
1.4.1	CAS number 6923-22-4
1.4.2	Harmonized System customs code 2924.10.00 (technical grade active constituent) 3808.10.90 (formulated product)
1.4.3	Other numbers (specify the numbering system) EEC No. 230-042-7
1.5 Indication regarding previous notification on this chemical, if any	
1.5.1	<input checked="" type="checkbox"/> This is a first time notification of final regulatory action on this chemical.
1.5.2	<input type="checkbox"/> This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ <input type="checkbox"/> This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _____	

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH - 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	Hazard class
WHO a.i.	Ib
USEPA (formulation)	I
Other classification systems	Hazard class
Standard for the Uniform Scheduling of Drugs and Poisons (Australia)	Dangerous Poison Schedule 7

1.7 Use or uses of the chemical	
1.7.1	<input checked="" type="checkbox"/> Pesticide
	Describe the uses of the chemical as a pesticide in your country:
	Monocrotophos is a broad spectrum, systemic insecticide and acaricide used in crops such as sorghum, sunflowers, tomatoes, cotton, maize, soybeans and tobacco.
1.7.2	<input type="checkbox"/> Industrial
	Describe the industrial uses of the chemical in your country:

1.8 Properties	
1.8.1	Description of physico-chemical properties of the chemical
	Form: colourless, hygroscopic crystals, (tech., $\geq 74\%$: dark brown semi-solid). Melting point: 54-55°C Boiling point: 125°C/0.0005mmHg Vapour pressure: 2.9×10^{-1} mPa at 20°C; 9.8×10^{-1} mPa (separate studies). Solubility (20°C): 100% in water, 100% in methanol, 70% in acetone, 25% in n-octanol, 6% in toluene.

1.8.2	Description of toxicological properties of the chemical
	Acute oral: LD ₅₀ for rats 1430-2490. Acute percutaneous: LD ₅₀ for rats >2000 mg/kg. Inhalation: LC ₅₀ (4 h) for rats >3.39 mg/l air. NOEL: (2y) for rats 10 ppm diet (0.5 mg/kg b.w. daily). ADI: 0.005 mg/kg b.w. Information obtained from The Pesticide Manual, 11 th Edition, British Crop Protection Council 1997.
1.8.3	Description of ecotoxicological properties of the chemical
	Birds Acute oral LD ₅₀ for bobwhite quail 1260, Japanese quail >1690, mallard ducks >500 mg/kg Fish LC ₅₀ (96 h) for carp 74, rainbow trout 56-75 mg/l. Bees LD ₅₀ (oral) >296.3 µg/g b.w. Worms LC ₅₀ (14d) for <i>Eisenia foetida</i> >100 mg/kg. Daphnia LC ₅₀ (48 h) 32.5 mg/l. Information obtained from The Pesticide Manual, 11 th Edition, British Crop Protection Council 1997.

PART II: FINAL REGULATORY ACTION

2. FINAL REGULATORY ACTION	
2.1	The chemical is: <input checked="" type="checkbox"/> banned OR <input type="checkbox"/> severely restricted
2.2	Information specific to the final regulatory action
2.2.1	Summary of the final regulatory action The active constituent approval for monocrotophos, together with all product registrations and associated label approvals for all products containing monocrotophos, were cancelled.
2.2.2	Reference to the regulatory document National Registration Authority for Agricultural and Veterinary Chemicals (NRA) Board Resolution 793, Action 99-77a, 9 December 1999.
2.2.3	Date of entry into force of the final regulatory action 9 December 1999

2.3	Was the final regulatory action based on a risk or hazard evaluation? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give information on such evaluation The NRA conducted a review of monocrotophos under its Existing Chemicals Review Program. The review was undertaken because of concerns about high mammalian toxicity, occupational exposure and potential for adverse environmental impacts. Risk evaluation considered Australian patterns of use and environmental conditions. The review demonstrates that data have been generated according to scientifically recognised methods, and the review was conducted according to accepted scientific principles and procedures. The final regulatory action was based on the risk evaluation.
	Reference to the relevant documentation The NRA review of monocrotophos, January 2000. NRA Review Series 00.1. National Registration Authority for Agricultural and Veterinary Chemicals.

2.4	Reasons for the final regulatory action
2.4.1	Is the reason for the final regulatory action relevant to the human health? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers Monocrotophos posed a high level of occupational exposure risk.
	Reference to the relevant documentation The NRA review of monocrotophos, January 2000. NRA Review Series 00.1. National Registration Authority for Agricultural and Veterinary Chemicals.
	Expected effect of the final regulatory action Banning monocrotophos will reduce human health risks to workers.

2.4.2	Is the reason for the final regulatory action relevant to the environment? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks to the environment Monocrotophos posed risks to the environment, especially birds and aquatic species.
	Reference to the relevant documentation The NRA review of monocrotophos, January 2000. NRA Review Series 00.1. National Registration Authority for Agricultural and Veterinary Chemicals.
	Expected effect of the final regulatory action The potential for adverse environmental effects is expected to be significantly reduced as monocrotophos is replaced with less hazardous alternatives.

2.5 Category or categories where the final regulatory action has been taken		
2.5.1	Final regulatory action has been taken for the chemical category	<input type="checkbox"/> Industrial
	Use or uses prohibited by the final regulatory action	
	Use or uses that remain allowed	

2.5.2	Final regulatory action has been taken for the chemical category	<input checked="" type="checkbox"/> Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	The formulation was a soluble concentrate. This formulation and all uses of monocrotophos are prohibited.	
	Formulation(s) and use or uses that remain allowed	
	Nil.	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced	No data available	
Imported	No data available	
Exported	No data available	
Used	No data available	

2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions
	The action has minimal relevance as monocrotophos is already subject to the PIC procedure.

2.7 Other relevant information that may cover:	
2.7.1	Assessment of socio-economic effects of the final regulatory action
	More effective, less costly and less hazardous alternatives are available for most situations, and together with increasing adoption of integrated pest management in the relevant cropping systems, the socio-economic effects are expected to be minimal.

2.7.2	Information on alternatives and their relative risks
	The following alternatives are considered at this time to pose lower risks to workers and the environment. World Health Organisation hazard classifications are provided as an aid to consideration of relative risks. These classifications are for active constituents. Actual hazard depends on formulations. Moderately hazardous: <ul style="list-style-type: none"> ▪ chlorpyrifos ▪ diazinon ▪ dimethoate ▪ fenitrothion Slightly hazardous: <ul style="list-style-type: none"> ▪ azamethiphos ▪ malathion It is suggested 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.
2.7.3	Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	National Registration Authority for Agricultural and Veterinary Chemicals
Address	PO Box E240 KINGSTON ACT 2604 AUSTRALIA
Telephone	+61 2 6272 5158
Telefax	+61 2 6272 4753
E-mail address	nra.contact@nra.gov.au
Designated National Authority	
Institution	Policy Development Section Chemicals and Biologicals Branch Food and Agribusiness Industries Division Department of Agriculture, Fisheries and Forestry – Australia
Address	GPO Box 858 CANBERRA ACT 2601 AUSTRALIA
Name of person in charge	Mr Ian Coleman
Position of person in charge	Director
Telephone	+61 2 6271 6371
Telefax	+61 2 6272 5899
E-mail address	ian.coleman@affa.gov.au

Date, signature of DNA and official seal: 8 September 2000 (sign) _____



**FORM
FOR NOTIFICATION OF FINAL REGULATORY ACTION
TO BAN OR SEVERELY RESTRICT A CHEMICAL**

IMPORTANT: See instructions before filling in the form

COUNTRY: HUNGARY

PART I: PROPERTIES, IDENTIFICATION AND USES

1. IDENTITY OF CHEMICAL		
1.1	Common name	Monocrotophos
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	Dimethyl (E)-1-methyl-2-(methyl-carbamoyl) vinyl phosphate
1.3	Trade names and names of preparations	Nuvacron 40 WSC, Azodrin 40 WSC
1.4	Code numbers	
1.4.1	CAS number	6923-22-4
1.4.2	Harmonized System customs code	
1.4.3	Other numbers (specify the numbering system)	

1.5 Indication regarding previous notification on this chemical, if any	
1.5.1	<input type="checkbox"/> This is a first time notification of final regulatory action on this chemical.
1.5.2	<input type="checkbox"/> This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____
	<input checked="" type="checkbox"/> This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: 3/11/1997 _____	

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH - 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	Hazard class
WHO classification	I.b. (a.i.) highly hazardous
Other classification systems	Hazard class
National classification system	Toxicity formulations: strong poison
	(Hazard classification was not introduced at that time)

1.7 Use or uses of the chemical	
1.7.1	<input checked="" type="checkbox"/> Pesticide
	Describe the uses of the chemical as a pesticide in your country: Insecticide in maize, sugar beet, soya, sunflower and alfalfa.
1.7.2	<input type="checkbox"/> Industrial
	Describe the industrial uses of the chemical in your country:

1.8 Properties	
1.8.1	Description of physico-chemical properties of the chemical Pure monocrotophos forms colourless, hygroscopic crystals. Technical monocrotophos is dark brown, semi-solid product. It is very well soluble in water and methanol (100 %), well soluble in acetone, n-octanol and toluene, sparingly soluble in kerosene and diesel oil. Unstable in short chain alcohols, decomposes at > 38 °C.
1.8.2	Description of toxicological properties of the chemical Highly toxic in animal experiments (oral, dermal, inhalation routes). No irritating to skin and eyes (rabbit). No carcinogenic effect.
1.8.3	Description of ecotoxicological properties of the chemical Highly toxic to fish, other aquatic organisms, birds and bees. Rapidly degraded in soil, rapidly excretes in mammals after oral administration.

PART II: FINAL REGULATORY ACTION

2. FINAL REGULATORY ACTION	
2.1	The chemical is: <input checked="" type="checkbox"/> banned OR <input type="checkbox"/> severely restricted
2.2	Information specific to the final regulatory action
2.2.1	Summary of the final regulatory action Banned for all agricultural use.
2.2.2	Reference to the regulatory document 9032/1992, 21175/1996
2.2.3	Date of entry into force of the final regulatory action 1996

2.3	Was the final regulatory action based on a risk or hazard evaluation?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give information on such evaluation	
	The decision was based on wide expert evaluation, involved in different ministries and institution.	
	Reference to the relevant documentation	
	Program and documents of the Ministry of Agriculture on the prohibition of agricultural use of monocrotophos. No official evaluation report was issued.	

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to the human health?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	Highly toxic to humans, high risk to workers.	
	Reference to the relevant documentation	
	National and international documents and experiences.	
	Expected effect of the final regulatory action	
	Decrease of chemical risk on humans (mainly on workers). The product could be replaced.	
2.4.2	Is the reason for the final regulatory action relevant to the environment?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks to the environment	
	Risk to fish, aquatic organisms, birds and bees during the treatment with monocrotophos containing products.	
	Reference to the relevant documentation	
	International publications and national documents. No official report was issued.	
	Expected effect of the final regulatory action	
	Lower toxicological risk humans and to the environment, no residues in crops, water and soil.	

2.5	Category or categories where the final regulatory action has been taken	
2.5.1	Final regulatory action has been taken for the chemical category	<input checked="" type="checkbox"/> Industrial
	Use or uses prohibited by the final regulatory action	
	No action was taken, because the product was not authorised for industrial use.	
	Use or uses that remain allowed	
	NO	
2.5.2	Final regulatory action has been taken for the chemical category	<input checked="" type="checkbox"/> Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	All agricultural use is prohibited.	
	Formulation(s) and use or uses that remain allowed	
	NO	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced	NO	1973-1996
Imported	some tones	1973-1996
Exported	NO	
Used	some tons	1973-1996

2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

2.7	Other relevant information that may cover:
2.7.1	Assessment of socio-economic effects of the final regulatory action The withdrawal of monocrotophos caused no technological problems. Other insecticides registered by the Ministry of Agriculture arranged its temporary shortage.

2.7.2	Information on alternatives and their relative risks Alternatives: other organophosphorus and other types of products, with lower acute toxicity and lower risk to humans and environment.
2.7.3	Relevant additional information NO

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action		
Institution	Ministry of Agriculture and Regional Development Plant Protection and Agro-Environment Management Department	
Address	1860 Budapest 55, P.O.B. 1 HUNGARY	
Telephone	36-1-301-4000	
Telefax	36-1-302-0402	
E-mail address		
Designated National Authority		
Institution	Ministry of Agriculture and Regional Development Plant Protection and Agro-Environment Management Department	
Address	1860 Budapest 55, P.O.B. 1 HUNGARY	
Name of person in charge	Ferenc Tar	Dr.Zoltán Ocskó
Position of person in charge	Head of Department	Chief Counsellor
Telephone	36-1-301-4015	36-1-301-4248
Telefax	36-1-301-4644	36-1-301-4644
E-mail address	zoltan.ocsko@fvm.hu	

Date, signature of DNA and official seal: (Budapest, 29 September 2000) (sign) (seal)_____