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INTERIM CHEMICAL REVIEW COMMITTEE

Third session

Geneva, 18 - 22 February 2002

Item 6 (a) of the provisional agenda \*

INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED CONSENT PROCEDURE -  
REVIEW OF NOTIFICATIONS OF FINAL REGULATORY ACTIONS TO BAN OR SEVERELY  
RESTRICT A CHEMICAL -

Dinoterb

Note from 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 in February 2000. An excerpt of the decision is contained in document UNEP/FAO/PIC/ICRC.3/INF.3
3. The Secretariat has identified two verified notifications from two PIC regions relating to dinoterb (Asia – Thailand and Europe – European Community). Summaries of these notifications were included in PIC Circular XIV (12 December 2001).
4. Attached to this note are the notifications circulated to the members of the Interim Chemical Review Committee in a letter dated 22 November 2001.
5. The relevant documentation provided by Thailand and the European Commission in support of their respective notifications was circulated to members of the Interim Chemical Review Committee with a letter dated 30 November 2001 and is available as an addendum to this note (UNEP/FAO/PIC/ICRC.3/15/Add1).

\* UNEP/FAO/PIC/ICRC3/1

**Status regarding the submission of the supporting documentation on Dinoterb**  
(As of 22 November 2001)

<b>Notifying Country name</b>	<b>Interim PIC Regions</b>	<b>Supporting Documentation Submitted</b>
European Community	Europe	Yes
Thailand	Asia	Yes



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

IMPORTANT: See instructions before filling in the form

**COUNTRY:** European Community

(MEMBER STATES: AUSTRIA, BELGIUM, DENMARK, FINLAND, FRANCE, GERMANY, GREECE, IRELAND, ITALY, LUXEMBOURG, THE NETHERLANDS, PORTUGAL, SPAIN, SWEDEN AND UNITED KINGDOM).

**PART I: PROPERTIES, IDENTIFICATION AND USES**

1. IDENTITY OF CHEMICAL		
1.1	Common name	Dinoterb
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	2-tert-butyl-4,6-dinitrophenol(IUPAC) 2-(1,1-dimethylethyl)-4,6-dinitrophenol (CAS)
1.3	Trade names and names of preparations	Herbogil liquid, Tolkan V, Tolkan S
1.4	Code numbers	
1.4.1	CAS number	1420-07-1
1.4.2	Harmonized System customs code	2908.90 – (ISO) 3808.30 – (DNTBP), put as insecticide and herbicide. 3808.30 – put as herbicide 3808.30 –acetate, put as a acaricide and herbicide.
1.4.3	Other numbers (specify the numbering system)	EEC : 609-030-004 CIPAC : 238 einesc : 215-813-8
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.	

**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

OR

Interim Secretariat for the Rotterdam Convention  
UNEP Chemicals

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

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

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

<b>1.5.2</b>	<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: _____	

<b>1.6 Information on hazard classification where the chemical is subject to classification requirements</b>	
<b>International classification systems</b>	<b>Hazard class</b>
Classification in the EU in accordance with Directive 67/548/EEC (Annex I)	T+ (very toxic). R28 (very toxic if swallowed). T (toxic) R24 (toxic in contact with skin) T (toxic, reproduction cat.2). R61 (may cause harm to the unborn child). N (dangerous for the environment) R50-53 (very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).
<b>Other classification systems</b>	<b>Hazard class</b>

<b>1.7 Use or uses of the chemical</b>	
<b>1.7.1</b>	<input checked="" type="checkbox"/> <b>Pesticide</b> <b>Describe the uses of the chemical as a pesticide in your country:</b> Used as post emergence herbicide on maize, beans, peas, potatoes and sweet corn.
<b>1.7.2</b>	<input type="checkbox"/> <b>Industrial</b> <b>Describe the industrial uses of the chemical in your country:</b> Not used

<b>1.8 Properties</b>	
<b>1.8.1</b>	<b>Description of physico-chemical properties of the chemical</b>

Identity	Yellow crystals (Purity $\geq$ 99%)
Formula	$C_{10}H_{12}N_2O_5$
Chemical type	dinitrophenol
Molecular weight	240.2
Melting point	127.2°C
Boiling point	decomposition above 222°C
Relative density	0.705
Vapor pressure	$0.97 \times 10^{-3}$ Pa at 20°C
Henry's law constant	$10 \times 10^{-4}$ Pa x m <sup>3</sup> /mol at pH7
Solubility in water	2.95 mg/l at pH 4 230 mg/l at pH 7 550 mg/l at pH 9
Solubility in organic solvents at 25°C:	n-heptane : 9 g/kg isopropanol : 9 g/kg xylene : 200 g/kg acetone : 190 g/kg ethyl acetate : 130 g/kg
Partition coefficient (log Pow)	3.46 at pH4 20°C 1.91 at pH7 1.57 at pH10
Hydrolytic stability (DT <sub>50</sub> )	stable at pH 5 and 9 at 22°C
Photostability (DT <sub>50</sub> )	14-18 days in water
Dissociation constant pK <sub>a</sub>	=5.0 at 20°C
<u>Full Report on dinoterb (ECCO-Team, 1348/ECCO/BBA/97 of 14 April 1997).</u>	

1.8.2	<b>Description of toxicological properties of the chemical</b> Main properties and lack of information considered: - Developmental toxicity: rat, oral: NOEL embryo-foetotoxicity: 2mg/kg bw/d (maternal NOEL; 2 mg/kg bw/d), rat, oral: NOEL embryo-foetotoxicity: 2.5 mg/kg bw/d (maternal NOEL: 2.5 mg/kg bw/d), rabbit, oral: NOEL embryotoxicity: 1.25 mg/kg bw/d (maternal NOEL: 1.5 mg/kg bw/d), rat, dermal: NOEL embryo-foetotoxicity: 5 mg/kg bw/d (maternal NOEL : 5 mg/kg bw/d) rat, oral: NOEL embryotoxicity: 3 mg/kg bw/d (maternal NOEL; 3 mg/kg bw/d). - No AOEL available - No ADI available Full Report on dinoterb (ECCO-Team, 1348/ECCO/BBA/97 of 14 April 1997).	
1.8.3	<b>Description of ecotoxicological properties of the chemical</b> Properties and lack of information: a) <u>Fate and behaviour:</u> Soil: Degradation not sufficiently documented, Mobility: no acceptable data for field studies, Dinoterb is slowly degraded in water sediment (50% in 94 days), b) <u>Ecotoxicity</u> Serious risks to birds and mammals, High toxicity for fish and daphnia was concluded, No information was presented for bees and other arthropods, The preliminary data provided indicated a risk to earthworms, From the data available, it was concluded dinoterb is toxic to soil micro organisms. Full Report on dinoterb (ECCO-Team, 1348/ECCO/BBA/97 of 14 April 1997).	

## PART II: FINAL REGULATORY ACTION

2. FINAL REGULATORY ACTION	
2.1	The chemical is: <input checked="" type="checkbox"/> <b>banned</b> OR <input type="checkbox"/> <b>severely restricted</b>
2.2 Information specific to the final regulatory action	
2.2.1	<b>Summary of the final regulatory action</b> It is prohibited to place on the market or use plant protection products containing dinoterb. Dinoterb is not included as an active ingredient in Annex 1 to Directive 91/414/EEC. The authorisations for plant protection products containing dinoterb were withdrawn within a period of 6 months from the Commission Decision 98/269/EC. From the date of decision, no authorisations for plant protection products containing dinoterb will be granted or renewed.
2.2.2	<b>Reference to the regulatory document</b> Commission Decision 98/269/EC of 7 April 1998 concerning the non-inclusion of dinoterb in Annex 1 to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Official Journal of the European Communities L117 of 21/04/1998, p. 13) (copy attached).
2.2.3	<b>Date of entry into force of the final regulatory action</b> 6/10/1998 (Authorisations for plant protection products containing dinoterb were withdrawn within a period of 6 months from the date of the final regulatory action)

<b>2.3</b>	<b>Was the final regulatory action based on a risk or hazard evaluation?</b>	<input checked="" type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> <b>No</b>
	<b>If yes, give information on such evaluation</b>		
	<p>It was concluded that dinoterb could not fulfil the safety requirements laid down in Article 5 (I) (a) and (b) of Directive 91/414/EEC.</p> <p>the principal issues which laid to these overall conclusions relate mainly to concerns about human health protection under the proposed conditions of use. Additionally, important data gaps made it impossible to further investigate environmental safety.</p> <p><b>Concerns:</b></p> <p>a) Human health protection: The data available indicate a high risk or danger to health. The main problem areas are: - Teratogenicity: dinoterb is classified as a substance which should be regarded as if it impairs fertility in humans (Toxic; R61: may cause harm to the unborn child). - The risk for the operator and the consumers cannot be assessed as no AOEL and no ADI are available.</p> <p>b) Environment: The data available indicate a high risk or danger to terrestrial and aquatic organisms. The main problem areas are the toxicity to birds, earthworms, soil micro-organisms, fish and Daphnia.</p>		
	<b>Reference to the relevant documentation</b>		
	Review report 8083/VI/97-rev 4 of 16 December 1997, copy attached, and supporting background documents (dossier, monograph, and the peer review report under the Peer Review Programme (ECCO April 1997).		
<b>2.4</b>	<b>Reasons for the final regulatory action</b>		
<b>2.4.1</b>	<b>Is the reason for the final regulatory action relevant to the human health?</b>	<input checked="" type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> <b>No</b>
	<b>If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers</b>		
	Based on available data, none of the intended uses are considered acceptable as regards operator exposure to the active substance and consumers exposure to potential residues resulting from use.		
	<b>Reference to the relevant documentation</b>		
	Review report 8083/VI/97-rev 4 of 16 December 1997, copy attached, and supporting background documents (dossier, monograph, and the peer review report under the Peer Review Programme (ECCO, April 1997)		
	<b>Expected effect of the final regulatory action</b>		
	Complete risk reduction for plant protection use.		
<b>2.4.2</b>	<b>Is the reason for the final regulatory action relevant to the environment?</b>	<input type="checkbox"/> <b>Yes</b>	<input checked="" type="checkbox"/> <b>No</b>
	<b>If yes, give summary of the known hazards and risks to the environment</b>		
	High risk or danger for terrestrial and aquatic organisms.		
	<b>Reference to the relevant documentation</b>		
	Review Report 8083/VI/97-rev 4 of December 1997, copy attached, and supporting background documents (dossier, monograph, and the peer review report under the Peer Review Programme (ECCO, April 1997)		
	<b>Expected effect of the final regulatory action</b>		
	Complete risk reduction for plant protection use		
<b>2.5</b>	<b>Category or categories where the final regulatory action has been taken</b>		
<b>2.5.1</b>	<b>Final regulatory action has been taken for the chemical category</b>	<input type="checkbox"/> <b>Industrial</b>	
	<b>Use or uses prohibited by the final regulatory action</b>		
	Not relevant.		
	<b>Use or uses that remain allowed</b>		
	Not relevant.		

<b>2.5.2</b>	<b>Final regulatory action has been taken for the chemical category</b>	<input checked="" type="checkbox"/> <b>Pesticide</b>
	<b>Formulation(s) and use or uses prohibited by the final regulatory action</b>	
	All applications as plant protection products are prohibited.	
	<b>Formulation(s) and use or uses that remain allowed</b>	
	EU Member States may have granted a period of grace for disposal, storage, placing on the market and use of existing stocks, no longer than 18 months from the date of notification of Commission Decision Commission Decision 98/269/EC of 7 April 1998.	

<b>2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.</b>		
	<b>Quantity per year (MT)</b>	<b>Year</b>
<b>Produced</b>	Not Available	
<b>Imported</b>	Not Available	
<b>Exported</b>	Not Available	
<b>Used</b>	Not Available	
<b>2.6</b>	<b>Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions</b>	
	Health protection in states where the substance is used as a plant protection product, particularly for operators, especially in developing countries. A ban would also protect the general public and the environment.	
<b>2.7</b>	<b>Other relevant information that may cover:</b>	
<b>2.7.1</b>	<b>Assessment of socio-economic effects of the final regulatory action</b>	
<b>2.7.2</b>	<b>Information on alternatives and their relative risks</b>	
<b>2.7.3</b>	<b>Relevant additional information</b>	



**PART III : GOVERNMENT AUTHORITIES**

<b>Ministry/Department and authority responsible for issuing/enforcing the final regulatory action</b>	
<b>Institution</b>	European Commission
<b>Address</b>	Rue de la Loi 200 B-1049 Brussels Belgium
<b>Telephone</b>	+32.2.2994860
<b>Telefax</b>	+32.2.2956117
<b>E-mail address</b>	klaus.berend@cec.eu.int
<b>Designated National Authority</b>	
<b>Institution</b>	DG Environment European Commission
<b>Address</b>	Rue de la Loi 200 B-1049 Brussels Belgium
<b>Name of person in charge</b>	Klaus BEREND
<b>Position of person in charge</b>	Administrator
<b>Telephone</b>	+32.2.2994860
<b>Telefax</b>	+32.2.2956117
<b>E-mail address</b>	klaus.berend@cec.eu.int

Date, signature of DNA and official seal: .....



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

IMPORTANT: See instructions before filling in the form

COUNTRY: THAILAND

**PART I: PROPERTIES, IDENTIFICATION AND USES**

<b>1. IDENTITY OF CHEMICAL</b>		
<b>1.1</b>	<b>Common name</b>	Dinoterb
<b>1.2</b>	<b>Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists</b>	2-tert-butyl-4,6-dinitrophenol
<b>1.3</b>	<b>Trade names and names of preparations</b>	Herbogil
<b>1.4</b>	<b>Code numbers</b>	
<b>1.4.1</b>	<b>CAS number</b>	CAS RN [1420-07-1]
<b>1.4.2</b>	<b>Harmonized System customs code</b>	
<b>1.4.3</b>	<b>Other numbers (specify the numbering system)</b>	EEC. No. 215-813-8

<b>1.5 Indication regarding previous notification on this chemical, if any</b>	
<b>1.5.1</b>	<input checked="" type="checkbox"/> This is a first time notification of final regulatory action on this chemical.
<b>1.5.2</b>	<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

OR

Interim Secretariat for the Rotterdam Convention  
UNEP Chemicals

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

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

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 (Technical products)	Ia
Other classification systems	Hazard class
EC Risk (R 61)	T

1.7 Use or uses of the chemical	
1.7.1	<input checked="" type="checkbox"/> <b>Pesticide</b> Describe the uses of the chemical as a pesticide in your country:  Herbicide. This pesticide has never been imported for use in Thailand
1.7.2	<input type="checkbox"/> <b>Industrial</b> Describe the industrial uses of the chemical in your country:  

1.8 Properties	
1.8.1	<b>Description of physico-chemical properties of the chemical</b>  Molecular weight:240.2. Molecular formula : $C_{10}H_{12}N_2O_5$ . Form : Pale yellow solid with a phenol-like odour. Melting point 125.5-126.5 C Vapour pressure: 20 mPa (20 C). Solubility in water 4.5 mg/l (pH 5,20 C). Soluble in alcohols, glycols, aliphatic hydrocarbons, aqueous alkalis. Stable below melting point. Decompose above 220 C. Stable at least 34 days at pH 5-9 (22 C).

<b>1.8.2</b>	<b>Description of toxicological properties of the chemical</b>
	Acute oral LD <sub>50</sub> for rats 62, mice 25, rabbits 28mg/kg. Skin and eyes: acute percutaneous LD <sub>50</sub> for guinea pigs 150 mg/kg. NOEL(2y) for rats 0.375 mg/kg diet..
<b>1.8.3</b>	<b>Description of ecotoxicological properties of the chemical</b>
	Fish LD <sub>50</sub> (96h) for rainbow trout 0.0034 mg/l. Toxic to bees.

## **PART II: FINAL REGULATORY ACTION**

<b>2. FINAL REGULATORY ACTION</b>	
<b>2.1</b>	<b>The chemical is:</b> <input checked="" type="checkbox"/> <b>banned</b> OR <input type="checkbox"/> <b>severely restricted</b>
<b>2.2</b>	<b>Information specific to the final regulatory action</b>
<b>2.2.1</b>	<b>Summary of the final regulatory action</b>
	Banned for import, production, having in possession, and use as an agricultural pesticide.
<b>2.2.2</b>	<b>Reference to the regulatory document</b>
	Notification of Ministry of Industry dated 26 May 2000, published in the Royal Gazette volume no. 117, section 61 Ng, dated 23 June 2000.
<b>2.2.3</b>	<b>Date of entry into force of the final regulatory action</b>
	24 June 2000

<b>2.3</b>	<b>Was the final regulatory action based on a risk or hazard evaluation?</b>	<input checked="" type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> <b>No</b>
	<b>If yes, give information on such evaluation</b>		
	The acute oral LD <sub>50</sub> 25mg/kg is very high risk to human.		
	<b>Reference to the relevant documentation</b>		
	The WHO Recommended Classification of Pesticide by Hazard and Guideline to Classification, 1996-1997.		

<b>2.4</b>	<b>Reasons for the final regulatory action</b>		
<b>2.4.1</b>	<b>Is the reason for the final regulatory action relevant to the human health?</b>	<input checked="" type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> <b>No</b>
	<b>If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers</b>		
	Extremely hazardous to workers during formulating and application by spraying because of very high acute toxicity.		
	<b>Reference to the relevant documentation</b>		
	The WHO Recommended Classification of Pesticide by Hazard and Guidelines to Classification, 1996-1997		
	<b>Expected effect of the final regulatory action</b>		
	No poisoning case caused by dinoterb is reported.		

<b>2.4.2</b>	<b>Is the reason for the final regulatory action relevant to the environment?</b> <input type="checkbox"/> <b>Yes</b> <input checked="" type="checkbox"/> <b>No</b>
	<b>If yes, give summary of the known hazards and risks to the environment</b>
	<b>Reference to the relevant documentation</b>
	<b>Expected effect of the final regulatory action</b>

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

2.5.2	<b>Final regulatory action has been taken for the chemical category</b>	<input checked="" type="checkbox"/> Pesticide
	<b>Formulation(s) and use or uses prohibited by the final regulatory action</b>	
	All formulations and uses were prohibited by the final regulatory action.	
	<b>Formulation(s) and use or uses that remain allowed</b>	
	None	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced	-	-
Imported	-	-
Exported	-	-
Used	-	-

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

2.7	<b>Other relevant information that may cover:</b>
2.7.1	<b>Assessment of socio-economic effects of the final regulatory action</b>

<b>2.7.2</b>	<b>Information on alternatives and their relative risks</b>
<b>2.7.3</b>	<b>Relevant additional information</b>

### PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
<b>Institution</b>	Department of Agriculture
<b>Address</b>	50 Phaholyothin Rd., Chatuchak, Bangkok 10900 Thailand
<b>Telephone</b>	66-2-5790586
<b>Telefax</b>	66-2-5615024
<b>E-mail address</b>	Anantad@doa.go.th
Designated National Authority	
<b>Institution</b>	Department of Agriculture
<b>Address</b>	50 Phaholyothin Rd., Chatuchak, Bangkok 10900 Thailand
<b>Name of person in charge</b>	Dr. Ananta Dalodom
<b>Position of person in charge</b>	Director - General
<b>Telephone</b>	66-2-5790586
<b>Telefax</b>	66-2-5615024
<b>E-mail address</b>	Anantad@doa.go.th

Date, signature of DNA and official seal: \_\_\_\_\_