UNITED NATIONS

PIC

UNEP/FAO/PIC/ICRC.5/10

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

Distr.: General
4 December 2003

English only

Interim Chemical Review Committee
Fifth session
Geneva, 2–6 February 2004
Item 5 (a) (iii) 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:
Endosulfan

Endosulfan

Note from the secretariat

1. In line with Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, when the Secretariat has received at least one notification from each of two interim 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.5/INF/3.

3. The Secretariat has identified three verified notifications from two interim PIC regions relating to endosulfan (Near East-Jordan and Europe-the Netherlands and Norway). Summaries of these notifications are included in the PIC circulars XII, for December 2000, XIII, for June 2001 and XVIII, for December 2003.

4. The annex to the present note contains the three notifications as they were received from the notifying countries.

* UNEP/FAO/PIC/ICRC.5/10.

K0363822 181203

5. The relevant documentation, including focused summaries, provided by Jordan, the Netherlands and Norway in conjunction with their respective notifications are available as addenda to this note (UNEP/FAO/PIC/ICRC.5/10/Add.1, UNEP/FAO/PIC/ICRC.5/10/Add.2 and UNEP/FAO/PIC/ICRC.5/10/Add.3, respectively).

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

UNEP

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

IMPORTANT: See instructions before filling in the form

COUNTRY: JORDAN

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	IDENTITY OF CHEMICAL	
1.1	**Common name**	Endosulfan
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-en-2,3-ylenebismethylene) sulfite; 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepine 3-oxide
1.3	**Trade names and names of preparations**	; THIODAN WP
1.4	**Code numbers**	
1.4.1	**CAS number**	*115-29-7]* endosulfan; *[959-98-8]* formerly *[33213-66-0],* alpha-endosulfan; *[33213-65-9]* formerly *[891-86-1*
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	θ This is a first time notification of final regulatory action on this chemical (YES)
1.5.2	θ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ θ 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-
CH

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	WHO (a.i.) II

Other classification systems	**Hazard class**

1.7 Use or uses of the chemical

1.7.1

θ **Pesticide**

θ **YES**

Describe the uses of the chemical as a pesticide in your country:

INSECTICIDES

1.7.2

θ **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**
	omposition Endosulfan is a mixture of two stereoisomers: alpha-endosulfan, endosulfan (I), stereochemistry 3α,5aβ,6α,9α,9aβ-, comprises 64-67% of the tech. grade; beta-endosulfan, endosulfan (II), stereochemistry 3α,5aα,6β,9β,9aα-, 29-32%. Earlier reports on the stereochemistry of these isomers gave conflicting reports (W. Riemschneider, *World Rev. Pest Control,* 1963, **2**(4), 29). **Mol. wt.** 406.9 **M.f.** $C_9H_6Cl_6O_3S$ **Form** Colourless crystals; (tech., cream to brown, mostly beige). **M.p.** ≥80 °C (tech.); α- 109.2 °C; β- 213.3 °C **V.p.** 0.83 mPa (20 °C) for 2:1 mixture of α- and β-isomers K_{OW} logP for α- = 4.74; β- = 4.79 (both at pH 5) **Henry** α- 1.48; β- 0.07 (both Pa m^3 mol^{-1}, 22 **S.g./density** *c.* 1.8 (20 °C) (tech.) **Solubility** In water alpha-endosulfan 0.32, beta-endosulfan 0.33 (both in mg/l, 22 °C). In ethyl acetate, dichloromethane, toluene 200, ethanol *c.* 65, hexane *c.* 24 (all in g/l, 20 °C). **Stability** Stable to sunlight. Slowly hydrolysed in aqueous acids and alkalis, with the formation of the diol and sulfur dioxide.

1.8.2	**Description of toxicological properties of the chemical**
	FAO/WHO 83, 85 (see part 2 of the Bibliography). **Oral** Acute oral LD_{50} for rats 70 mg (in aqueous suspension)/kg, 110 mg tech. (in oil)/kg, 76 mg alpha- isomer/kg, 240 g beta- isomer/kg; for dogs 77 mg tech./kg. **Skin and eye** Acute percutaneous LD_{50} for rabbits 359 mg (in oil)/kg; for male rats >4000, female rats 500 mg/kg. **Inhalation** LC_{50} (4 h) for male rats 0.0345, female rats 0.0126 mg/l. **NOEL** (2 y) for rats 15 ppm diet; (1 y) for dogs 10 ppm diet. **ADI** (JMPR) 0.006 mg/kg b.w. [1998]. **Toxicity class** WHO (a.i.) II; EPA (formulation) I (tech.) **EC hazard** T; R24/25| Xi; R36| N; R50, R53
1.8.3	**Description of ecotoxicological properties of the chemical**
	Birds Acute oral LD_{50} for mallard ducks 205-245, ring-necked pheasants 620-1000 mg/kg. **Fish** Highly toxic (LC_{50} (96 h) for golden orfe 0.002 mg/l water) but, in practical use, should be harmless to wildlife. **Daphnia** LC_{50} (48 h) 75-750 µg/l. **Algae** EC_{50} (72 h) for green algae >0.56 mg/l. **Bees** Not toxic to bees under field conditions at an application rate of 1.6 l/ha (560 g endosulfan/ha). **Worms** NOEC 0.1 mg/kg dry weight.

PART II: FINAL REGULATORY ACTION

2.	FINAL REGULATORY ACTION
2.1	**The chemical is:**BANNED θ **banned (** **OR** θ **severely restricted**
2.2	**Information specific to the final regulatory action**
2.2.1	**Summary of the final regulatory action**
	it is prohibited to place on the market or use plant protection products containing Endosulfan
2.2.2	**Reference to the regulatory document**

	Session 325 date 4/5/1994
2.2.3	**Date of entry into force of the final regulatory action** 1994

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	θ Yes
	If yes, give information on such evaluation	
	Reference to the relevant documentation	

2.4	**Reasons for the final regulatory action**	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	θ Yes
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	θ Yes
	If yes, give summary of the known hazards and risks to the environment	
	,persistence in the environment (soil and ground water)	
	Reference to the relevant documentation	
	Study made by Jordanian people in MOA	
	Expected effect of the final regulatory action	
	Decrease pollution of water ,drinking 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**	θ **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	θ Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action ALL FORMULATION.	
	Formulation(s) and use or uses that remain allowed	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced		
Imported	240KG	1990
Exported		
Used		

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	

2.7.2	Information on alternatives and their relative risks

PART II : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Designated National Authority	
Institution	MINISTRY OF AGRICULTURE
Address	P.O.BOX :961044- -2099 AMMAN
Name of person in charge	MAHMOUD AL-KHTOOM
Position of person in charge	DIRECTOR OF PLANT PROTECTION DEPARTMENT
Telephone	5686151
Telefax	5686310
E-mail address	PRD@JOINNET.COM.JO.

Date, signature of DNA and official seal:

وزارة الزراعة
قسم الشهادات

IC 585/1.1

Date12/11/2003

To: The Interim Secretariat of Rotterdam Convention,
Food and Agriculture Organization of the United Nations,
AGPP, Rome, Italy
Attention: Murray William
Cc: Elisabetta Tagliati

Subject: Amendments to entries in the notification submitted by the Hashemite Kingdom of Jordan regarding endosulfan, vinclozolin, endrin, dimefox and mevinphos

Dear Sir,

Reference your fax dated 28/10/2003 regarding clarification of some entries in the notification forms submitted by Jordan; please amend the forms to read as indicated below:

1-Endosulfan:

- Section 2.2.2

Amend entries to read as session 271 of Agricultural Pesticide Committee, date 25/7/1991. Application for registration of endosulfan was also rejected by the committee in session 325 date 4/5/1994.

- Section 2.2.1

Amend entries to read as stop granting any new import license for formulations containing this active ingredient. Registered products will continue to be used until the expiry of their license (max. 4 years) after which registration will be cancelled.

- Section 2.2.3

Amend date of entry into force to read as 1991

- Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

2-Vinclozolin:

- Section 2.2.2

Waiting for translation into English

- Section 2.1.1 (reference to relevant documents)

Amend entry to read as information submitted by manufacturer (BASF)

- Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

3-Endrin

- Section 2.2.2;

Amend entry to read as session 68 of the Agricultural Pesticide Committee, date 29/10/1980

- Section 2.2.3

Amend date of entry into force to read as 1/1/1981.

- Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

4-Dimefox:

- Section 1.6

Please refer to WHO Hazard Classification, table 6, Active Ingredients believed to be obsolete,

- Section 1.8.1

Please refer to Organophosphorus pesticides (group monograph 1989) by INCHEM,

- Section 2.2.2

Amend entry to read as session 68 of the Agricultural Pesticide Committee, date 29/10/1980

- Section 2.2.3

Amend date of entry into force to read as 1/1/1981

- Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

5- **Mevinphos:**

- Section 2.2.2

Amend entry to read as session 331 of the Agricultural Pesticide Committee, date 9/8/1994

- Section 2.5.2

Amend uses remain allowed to read as no uses remain allowed.

Please find attached all relevant documentation translated into English.

Regards

Mahmoud Al-Khtoom
Director of Plant Protection Department
(DNA for Pesticides)

مدير وقاية النبات
المهندس محمود الختوم

Rijnstraat 8
2515 XP Den Haag
Interne postcode 655
Tel : 3394744
Fax: 3391297
The Netherlands

Directorate-General for Environmental Protection
Directorate for Chemicals External Safety and Radiation Protection
Chemicals and Environmental Health Division
Q:1106/KG

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

Your ref.	Your letter of	Our ref.	Date
		SVS/SN/1106	21 June 2000

Subject

Notifications of final regulatory action

Dear Mr. Van der Graaff,

In accordance with the provisions of Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade please find enclosed notifications for two chemicals that have been banned in The Netherlands in the past. The notifications have been brought into line with the "interim PIC procedure".

Kind regards,

drs. K.A. Gijsbertsen
(designated national authority)

Cc: Mr M. Debois DG/ENV

Enclosures: notifications for dicofol and endosulfan

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

UNEP

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

IMPORTANT: See instructions before filling in the form

COUNTRY: THE NETHERLANDS

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	Endosulfan
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	6,7,8,9,10,10-Hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzo-dioxa-thiepin-3-oxide (CAS name)
1.3	**Trade names and names of preparations**	Benzoepin; Insectophene; Thiosulfan; Tiovel; Tionel; Thiodan; Thionex; Thionate Malix; HOE 2671; FMC 5462; Cyclodan'Thifor; Beosit 'Chlorthiepin Endocide; Endosulphan
1.4	**Code numbers**	
1.4.1	**CAS number**	115-29-7
1.4.2	**Harmonized System customs code**	2920 9090
1.4.3	**Other numbers (specify the numbering system)**	2040794 (EINECS)

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	☐ This is a first time notification of final regulatory action on this chemical.
1.5.2	☐ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ X This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: before 1995

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	**Hazard class**
WHO	Toxicity Class II (DOSE)
EPA	Toxicity Class I (formulation) (DOSE)
EU (Annex I)	T (toxic); N (dangerous for the environment) R24/25, R36, R50/53
IARC	Not evaluated
Other classification systems	**Hazard class**

1.7 Use or uses of the chemical	
1.7.1	X **Pesticide**
	Describe the uses of the chemical as a pesticide in your country: Prior to ban: insecticide used against a variety of insects on tall and small fruit, full field vegetables, arable agriculture, mushrooms and full field ornamentals
1.7.2	❑ **Industrial**
	Describe the industrial uses of the chemical in your country: Not relevant.

1.8 Properties

1.8.1 Description of physico-chemical properties of the chemical

Identity	Brown crystals	
Formula	$C_9H_6Cl_6O_3S$	
Chemical name	Endosulfan	
Chemical type		
CAS number	115-29-7	
Molecular weight	406.95	
Solubility	0.51 mg/l (α-endosulfan); 0.45 mg/l (β-endosulfan) at 20 °C	(Howard, 1989)
	0.32 mg/l (α-endosulfan); 0.33 mg/l (β-endosulfan) at 22 °C	(DOSE)
	1.487 mg/l at 25 °C (EPIWIN)	
logKow	3.83 (α-endosulfan) (Howard, 1989; HSDB; EPIWIN)	
	4.74 (α-endosulfan) ; 4.79 (β-endosulfan) (DOSE)	
Vapour pressure	0.133 E-2 Pa at 25 °C (Howard, 1989)	
	0.360 E-4 Pa at 25 °C (EPIWIN)	
	0.830 E-2 Pa at 20°C (HSDB)	
Melting point	106 °C (Howard, 1989; HSDB)	
	109 °C (α-endosulfan); 213.3 °C (β-endosulfan) (DOSE)	
Boiling point	401.28 °C (EPIWIN)	
Dissociation constant		
Henry's law constant	1.12 E-5 atm-m^3/mole (Howard, 1989)	
	9.03 E-8 atm-m^3/mole (EPIWIN)	

1.8.2 Description of toxicological properties of the chemical

1.Acute toxicity to laboratorium animals

oral	LD50 rat: 70-100 mg/kg bw	(DOSE)
	LD50 rat: 64 mg kg bw (in olive oil)	
	LD50 rat: 40-50 mg/kg bw (in 95% alcohol)	
	LD50 rat: 43 mg/kg bw; male (in peanut oil)	
	LD50 rat: 18 mg/kg bw, female (in peanut oil)	
	LD50 rat: 121 mg/kg bw; male (in cottonseed oil)	
	LD50 rat: 355 mg/kg bw	
	LD50 hamster: 118 mg/kg bw (in olive oil)	(EHC, 1984)
	LD50 mouse: 7.36 mg/gk bw	
	LD50 rabbit: 28 mg/kg bw	
	LD50 dog: 7.67 mg/kg bw	
	LD50 cat: 2 mg/kg bw	(RTECS)
dermal	LD50 rat: 130 mg/kg bw, male (in xylene)	
	LD50 rat: 74 mg/kg bw, female (in xylene)	
	LD50 rat: 681 mg/kg bw(in cottonseed oil)	(EHC, 1984)
	LD50 rat: 34 mg/kg bw	(RTECS)
	LD50 rabbit: 359 mg/kg bw (in oil)	(DOSE)
	LD50 rabbit: 147 mg/kg bw (in cottonseed oil)	
	LD50 rabbit: 360 mg/kg bw (in cottonseed oil)	
	LD50 rabbit: 187 mg/kg bw (in chloroform)	
	LD50 Guinea pig: 1000 mg/kg bw (in cottonseed oil)	(EHC, 1984)

	LD50 rabbit: 90 mg/kg bw	(RTECS)
inhalation	LC50 rat: 12.6 µg/l, male (4 h exposure)	
	LC50 rat: 34.5 µg/l ,female (4 h exposure)	(DOSE)
	LC50 rat: 350 µg/l (4 h exposure)	(EHC, 1984)
	LC50 rat: 80 µg/l (4 h exposure)	(RTECS)
	LC50 cat: 0.09 µg/l (4 h exposure)	(RTECS)
intraperitoneal	LD50 rat: 8 mg/kg bw	
	LD50 mouse: 7.5 mg/kg bw, female (in 95% alcohol)	
	LD50 mouse: 6.9 mg/kg bw, male (in 95% alcohol)	
	LD50 mouse: 13.5 mg/kg bw, female (in alcohol & peanut oil)	
	LD50 mouse: 12.6 mg/kg bw, male (in alcohol & peanut oil)	(EHC,1984)
	LD50 hamster: 80 mg/kg bw	(RTECS)
Irritation	Studies in experimental animals have shown that dermal exposure is only Slightly to moderately irritating at relatively high doses (ATSDR, 1998)	
2. Short-term exposure	- Rats treated with oral doses of endosulfan at 1.6-3.2 mg/kg bw for 12 weeks: no effects on growth rate. -Rats received diets containing endosulfan at 2 to 200 mg/kg diet for 2 weeks: induction of MFO-activity. - Female rats treated with oral doses of endosulfan at 1 to 5 mg/kg bw for 7 or 15 days: at 2.5 and 5 mg/kg bw increased liver weight and decreased pentobarbital sleeping time, induction of aminopyrine demethylase, aniline hydroxylase, and amino-transferase activity, and spontaneous lipid peroxidation. - Male rats dosed orally with endosulfan at 5 or 10 mg/kg bw for 15 days: at 10 mg/kg bw reduced body weight, 25% mortality. - Male rats dosed orally with endosulfan at 0.625 to 20 mg/kg bw for 7 weeks: at 20 mg/kg bw slicht increase in blood glucose and decrease in plasma Ca. - Four dogs dosed orally with endosulfan at 2.5 mg/kg bw for 3 days: vomiting in all dogs, tremors, convulsions, rapid respiration and mydriasis, no microscopic abnormalities. - Canulated cats dosed intravenously with endosulfan at 2, 3, or 4 mg/kg bw: muscular twitching and convulsions in all groups, at 3 and 4 mg/kg bw marked rise in blood glucose after 15 and 20 min. with gradual fall up to 4 h. (EHC, 1984)	
3. Long-term exposure	- Rats received endosulfan in the diets at 10 to 100 mg/kg diet for 104 weeks: reduced survival in the second year in female rats at 10 and 30 mg/kg, reduced survival and changes in weight gain and haematological parameters in females at 100 mg/kg diet. At autopsy reduced relative testis weight at 10 mg/kg diet, enlarged kidneys and renal tubular damage at 100 mg/kg diet. No increased tumour incidences. - Dogs orally treated with endosulfan at 0.075 to 0.75 mg/kg bw for 10 m: No gross or microscopic findings.	(EHC, 1984)
4. Effects on reproduction	Although the available reproductive studies indicate that endosulfan has no adverse effects on reproductive performance in animals, severe adverse effects on male reproductive organs have been seen in rats and mice. Endosulfan may potentially cause reproductive toxicity in humans (ATSDR, 1998)	

5. Mutagenicity

- Tests with endosulfan and *E. coli* and *S. typhimurium* : negative
- Mitotic conversion in *Saccharomyces cerevisiae*: negative.
- Technical grade endosulfan induced reverse mutation, cross over, and mitotic gene conversions in *Sacharomyces cerevisiae.*
- Chromosome aberration test in bone marrow cells or spermatogonia of rats treated for 5 days with oral doses of endosulfan at 11-55 mg/kg bw: negative.
- Micronucleus test in bone marrow cells of mice treated with endosulfan in the drinking water: increased number of micronuclei, not significant.
- Dominant lethal test in mice: negative. (EHC, 1984)
- *Saccharomyces cerevisiae* T2 without metabolic activation induced mitotic recombination.
- *Salmonella typhimurium* TA97a, TA98, TA100 with metabolic activation: negative
- *Salmonella typhimurium* TA97a in modified assay using preincubation procedure with and without metabolic activation: positiv
- *Salmonella typhimurium* Ta98, Ta100, Ta1535, TA1537 with and without metabolic activation: negative
- In vitro mouse lymphoma L5178Y tk+/tk-: positive
- In vitro peripheral human lymphocytes, 5 and 100 µig/ml: negative
- In vivo oral mice, meiotic germ cells: increased polyploidy, aneuploidy, and chromosomal aberrations.
  In vivo mice: induction of dominant lethal mutations and dose dependent increase in sperm abnormalities. No changes in sperm mobility .
  (DOSE)

Genotoxic studies have provided evidence that this compound is mutagenic and clastogenic, and that it induces effects on cell cycle kinetics in two different mammalian species. However, some of these data may be suspect because some formulations of endosulfan have contained epichlorohydrin, a known genotoxic chemical, as stabilizer. It should be noted that humans may also be exposed to epichlorohydrin along with endosulfan. (ATSDR, 1998)

6. Teratogenicity

Based on existing data in animals, there is inconclusive evidence to characterize endosulfan as a potential developmental toxicant in humans. (ATSDR, 1998)

7. Carcinogenicity

- Rats received diets containing endosulfan at 3 to 75 mg/kg diet for 24 months:

at 75 mg/kg reduced body weights, enlarged kidneys in females , progressive glomerulonephrosis and renal aneurysms in males, no increased tumour incidences. NOAEL=15 mg/kg diet (=0.6 mg/kg bw) (DOSE)

- Mice received diets containing endosulfan at 2 to 18 mg/kg diet for 24 months: at 18 mg/kg diet increased mortalities, slight reduced body weight gain in males, no increased tumour incidences. NOAEL=0.84 mg/kg diet (=0.97 mg/kg bw) (DOSE)
- Rats consuming 3.8 mg/kg/day (females) or 2.9 mg/kg/d (males) for 2 years did not indicate an increased incidence of any neoplastic lesion. A similar conclusion was found in a 2 year study with mice (ATSDR, 1998).

Effects on human health

		- Symptoms of poisoning: death followed a few hours after ingestion of endosulfan, clinical symptoms included vomiting, agitation, convulsions, cyanosis, dyspnoea, foaming at the mouth, and noisy breathing. Post mortem findings included congested and oedematous lungs and cyanosis. - Three men without protective clothing and masks filled bags with endosulfan: symptoms of toxicity occurred after 3 weeks, 1 months and 1 year and consisted of headaches, restlessness, irritability, vertigo, stupor, disorientation, and epileptic convulsive seizures. Changes in electroencephalogram. (EHC, 1984)
1.8.3	**Description of ecotoxicological properties of the chemical**	
	Fish	*Sarotherodon mossambicus*, 9-w NOEC (reproduction)=0.2 µg/l (v.d Plassche et al, 1994) Acute LC50-values for *Oncorhynchus mykiss, Pimephales promelas* and *Ictalurus* punctatus were 0.3 to 1.4 µg/l , 0.86 to 1.5 µg/l, and 1.5 µg/l respectively. For *Leuciscus idus melanotus* the 96-hours LC50 was 2 µg/l. (EHC, 1984; DOSE)
	Mollusca	Marine oyster, *Crassostrea virginica*, 96-hour EC50 (growth)=65 µg/l Freshwater snail, Aplexa hypnorum, 96-hours LC50= 1890 µg/l (EHC, 1984)
	Crustacea	*Daphnia magna*, 64-days NOEC(mortality)=2.7 µg/l (v.d Plassche et al, 1994) Acute L(E)C50-values ranged from 0.2 µg/l for the marine shrimp (Crangon semtemspinosa) to 55 µg/l for the blue crab (Callinectus sapidus)
	Annelida	Nereis nereis, 12-days LC50=100 µg/l (EHC, 1984)
	Algae	Chlorella vulgaris, 14-d NOEC (growth)=700 µg/l (v.d. Plassche et al, 1994)
	Protozoa	*Paramecium aurelia, 5-d NOEC (growth)=100 µg/l (v.d. Plassche et al, 1994)*
	Rotatoria	Acute 24-hour LC50 for freshwater rotifers: 4.15 mg/l (DOSE)
	Aquatic insects	Acute 96-hours L(E)C50-values ranged from 2.3 µg/l for the stonefly Pteronarcys californica to 2.8 µg/l for the freshwater mite *Hydrachna trilobata* (EHC, 1984)
	Birds	Acute oral LD50-values for the mallard duck (*Anas platyrhynchos*) ranged from 6.47 to 33 mg/kg bw.LC50-values for diet studies with *Coturnix coturnix japonica, Colinus virginianus* and *Phasianus colchicus* were 1250, 805, and 1275 mg/kg diet, respectively. (EHC,1984)
	Bees	For honey bees a contact LD50 of 7.1 µg/bee and an oral LD50 of 6.9 µg/bee was found.
	Macrophyta	Phytotoxic effects included: - reduction in pollen tube length and germination rate of cucumber pollen - necrotic spots and leaves of *Cucurbitae* - reduced viability and delayed germination of *Cicer arietinum* seeds - in vitro changes in permeability of root membranes

- Green gram (*Vigna radiata*), coiling of the radical, inhibition of root growth, stunting of shoots, burning of tips and margins of leaves, and plants were dwarfed and chlorotic
- germinating *Cicer arietinum* showed fall in pectin

References

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HSDB (through oktober 1999) Hazardous Substances Data Bank, National Library of Medicines.

Howard, P.H. (1989) Handbook of environmental fate and exposure data for organic chemicals, Lewis Publishers, Boca Raton, (volume I-IV).

RTECS, Registry of Toxic Effects of Chemical Substances, provided by NIOSH.

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PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**	
2.1	**The chemical is:** X **banned** **OR** ❑ **severely restricted**	
2.2	**Information specific to the final regulatory action**	
2.2.1	**Summary of the final regulatory action**	
	It is prohibited to sell, stock, store or use Endosulfan as pesticide	
2.2.2	**Reference to the regulatory document**	
	Decree of Ministry of Agriculture and Fisheries, Ministerial Order of 27 November 1989	
2.2.3	**Date of entry into force of the final regulatory action**	
	1-1-1990	

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	X **Yes** ❑ **No**
	If yes, give information on such evaluation	
	See under 2.4.2.	
	Reference to the relevant documentation	
	Decision of De Voorzitter van het College van Beroep voor het Bedrijfsleven No. 89 2403/060/029 (in Dutch).	

2.4	Reasons for the final regulatory action	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	❑ Yes X 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	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	X Yes ❑ No
	If yes, give summary of the known hazards and risks to the environment	
	Application (good agricultural practice) of endosulfan will result in surface water concentrations that will significantly affect aquatic organisms (especially fish). Emission of endosulfan to surface water will be due to spraying drift during application (fruit). The surface water concentration of endosulfan during application was estimated with a dispersion model. Assuming a drift emission factor of 10% an endosulfan concentration of 0.014 mg/l was calculated. Comparing this concentration with the lowest LC50 for fish (0.00017 mg/l) results in a risk quotient of 82 which was considered unacceptable. Field experiments in Africa support these conclusions. (i) Evaluation is based on a review of scientific data in the context of the conditions prevailing in the country.	
	Reference to the relevant documentation	
	Internal reports of National Institute of Public Health and Environment (RIVM). Bilthoven, the Netherlands. Confidential (partly).	
	Expected effect of the final regulatory action	
	Complete risk reduction	

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**	❑ **Industrial**
	Use or uses prohibited by the final regulatory action	
	Not relevant.	
	Use or uses that remain allowed	

2.5.2	**Final regulatory action has been taken for the chemical category**	❑ **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	
	All applications.	
	Formulation(s) and use or uses that remain allowed	
	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	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions
	EU, USA, ASIA, AFRICA

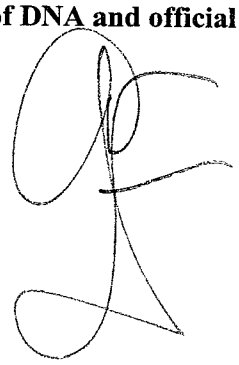
2.7	Other relevant information that may cover:
2.7.1	Assessment of socio-economic effects of the final regulatory action

2.7.2	Information on alternatives and their relative risks
2.7.3	Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Ministry of Housing, Spacial Planning and the Environment Ministry of Agriculture
Address	P.O. Box 30945 2500 GX The Hague The Netherlands
Telephone	+31 70 339 3939
Telefax	+31 70 339 1297
E-mail address	
Designated National Authority	
Institution	Ministry of Housing, Spacial Planning and the Environment
Address	P.O. Box 30945 2500 GX The Hague The Netherlands
Name of person in charge	drs. K.A. Gijsbertsen
Position of person in charge	Designated national authority
Telephone	+31 70 339 4744
Telefax	+31 70 339 1297
E-mail address	karel.gijsbertsen@dsvs.dgm.minvrom.nl

Date, signature of DNA and official seal: The Hague, 7 June 2000



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

UNEP

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

IMPORTANT: See instructions before filling in the form

COUNTRY: NORWAY

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	IDENTITY OF CHEMICAL	
1.1	Common name	Endosulfan
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzo-dioxathiepin-3-oxide
1.3	Trade names and names of preparations	Thiodan 35 EC
1.4	Code numbers	
1.4.1	CAS number	115-29-7
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	X This is a first time notification of final regulatory action on this chemical.
1.5.2	❑ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ❑ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification:

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	**Hazard class**
EU	Toxic; R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
WHO	Class II
Other classification systems	**Hazard class**
Norwegian	Extremely toxic to fish – 10 meters "buffer zone" Toxic to bees

1.7 Use or uses of the chemical	
1.7.1	X **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	Not relevant, not in use since 31.12.98.
1.7.2	❑ **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**

Identity	crystalline, colourless, close to odourless
Formula	$C_9H_6Cl_6O_3S$
Chemical name	endosulfan
Chemical type	
CAS number	115-29-7
Molecular weight	406.9
Solubility	0.32-0.33 ppm (20 °C)
logKow	
Vapour pressure	1.3x10-3 Nxm-2 (20 °C)
Melting point	109.2 °C (α-isomer), 213.3 °C (β-isomer)
Boiling point	166 °C at 0.7 mm Hg (technical)
Dissociation constant	
Henry's law constant	

1.8.2	**Description of toxicological properties of the chemical**

1.Acute toxicity to laboratory animals

oral: LD_{50} -

rats, males (Sherman):		48 mg/kg bw
rats, females (Sherman):		10 "
rats, males (albino):		110 "
rats, males (?)	:	50-125 "
rats, males (?)	:	7.36 "
dog, both (?)	:	76.7 "
hens,	:	96 "

dermal: LD_{50} -

rabbits, both (") : 359 mg/kg bw
rabbits, females (") : 167-187 "

inhalation: LC_{50} -

rats, males (Wistar): 34.5 mg/m^3
rats, females (") : 12.6 "

intraperitoneal: LD_{50} -

rats, males (ITRC) : 46.7 mg/kg bw
rats, females (") : 22.1 "
rats, males (") : 89.4 "
rats, females (") : 48.6 "
mice, males (") : 6.9 "
mice, females (") : 7.5 "
mice, males (") : 12.6 "
mice, females (") : 13.5 "
doves, both : 12-14 "

The clinical signs of toxicity include hyperactivity, tremors, convulsions followed by death. As little as 30 mg/kg bw could be fatal for dogs.

Irritant and allergenic properties: mildly irritant for skin and eyes. Not sensitizing, according to the Buehler test.

2. Short-term exposure:

2 weeks, rats: 0, 5, 10 mg/kg bw/day. In both groups there was seen congestion in livers and kidneys with centrilobular dilation of the sinusoids in the liver, focal degeneration/necrosis, Kupffercell hyperplasia and proliferation in the bile ducts. These effects were stronger in the high dose than in the low dose.

4 weeks, rats: 0, 34, 68 mg/kg bw/day (only males were tested). The body weight gain was lower in the dosed group than in the control. The liver weight was increased in both dose groups, but there were no histopathological findings. There was also a dose related increase in the kidney weight, becoming significant in the high dose group. Here there was also seen cellular granules, and proliferation and disturbance of the lysosomes in the proximal tubuli.

3 months, rats: 0, 0.7, 2, 4, 25 mg/kg bw/day. Water consumption was reduced in the high dose group. There was a significant reduction in erythrocyte count and hemoglobin content in the highest dosed females and in the two highest dosed male groups. The hematocrit was also lowered in the high dose group, even after a 4 week dose free period. The females of the high dose group had a reduced cholinesterase activity in the plasma and in the erythrocytes. There was a dose related increase in protein content in the urine in the males. Liver and kidney weight was increased in the high dose group animals, as well as in the males in the 4 mg/kg group. There were some histopathological changes both in the liver and the kidneys, such as centrilobular hypertrophy and dark granules in the proximal tubuli. The males were more strongly effected than the females. The NOEL lies somewhere between 0.7 and 2.2 mg/kg bw/day.

1 month, dermal, rats: 0 – 27 mg/kg bw/day. There was some indication of lowered cholinesterase activity, as well as effects in the liver. These were hypertrophy, focal necrosis, and an increase in mitosis. Some animals were also given 80 mg/kg bw/day, these had clear symptoms of poisoning and an increased mortality.

3. Long-term exposure/ Carcinogenicity:

2- year, mice: 0, 0.3, 0.9, 2.7 mg/kg bw/day. Body weight gain was reduced in the

high dose males. Mortality was higher in the high dose females than in the other groups.
2 year, rats: 0, 1.3, 4, 13 mg/kg bw/day. Mortality was high in all groups. The males in the high dose group had an increased absolute and relative kidney weight. There were histopathological effects in the kidneys and liver similar to those described above in the short term studies – pale, enlarged kidneys with tubular dilation and granules, focal interstitial nephritis and tubular degeneration. In the liver there was seen hydropic degeneration. There was no increase in the frequency of tumors.
1 year, dog: 0, 0.075, 0.25, 0.75 mg/kg bw/day. No symptoms were seen, no effects found except for in one group that was given 2.5 mg/kg for three days. These had clinical symptoms and were taken off the study.

4. Effects on reproduction:
2-generation study, rats: 0, 0.24, 1.15, 6 mg/kg bw/day. There was a lower body weight gain under gestation. In the high dose group there was a tendency toward a lower body weight in the offspring before weaning. The liver weight was increased in the in the high dose parental animals of the F0 and F1b generation, in the males there was also an increase in the kidney weight. There were seen some effects in the kidneys of the F1 generation with granules in the proximal tubuli. There were no effects on reproduction parameters.

5. Teratogenicity:
rats: 0, 0.66, 2, 6 mg/kg bw/day. The two highest dose groups showed clinical signs, stronger in the high dose group. 7 animals died in the high dose group, though some of these deaths probably were caused by accident while gavaging. The offspring were smaller and weighed less than the offspring in the other groups. There was also some delayed ossification in the offspring.
Rabbits: 0, 0.3, 0.7, 1.8 mg/kg bw/day. 4 rabbits of the high dose group died, probably caused by endosulfan. There were no other effects observed.
Endosulfan does not seem to have a teratogenic effect.

6. Mutagenicity: Studies done were -
Gene mutation: *Escherichia coli* and *Salmonella typhimurium*, *Schizo saccharomyces pombe*, *Saccharomyces cerevisiae*, mouse lymphoma line L5178Y, *Drosophila melanogaster*.
DNA damage: *Bacillus subtilis* (rec assay), UDS test in rat hepatocytes and in human cell line (A 549),
Chromosome aberration: *Drosophila melanogaster*, spermatogonias and bone marrow of rats, bone marrow hamster, mouse spermatocytes, micronucleus test, dominant lethal assay.
Some of these tests are poorly documented, but a fair number are well done and none of these well done ones are positive. Endosulfan is probably not a mutagen.

7.Effects on human health:
Poisoning incidents: A report from Bulgaria described the circumstances, clinical symptoms, and morphological changes n 5 cases associated with endosulfan poisoning. These cases comprised 2 suicides and 3 accidental poisonings. Death generally followed a few hours after ingestion. The clinical symptoms included vomiting, agitation, convulsions, cyanosis, dyspnoea, foaming at the mouth and noisy breathing. Another report lists the findings on 2 cases, apparently suicides, of men who died after ingesting endosulfan. Again death was noted to occur within a few hours of ingestion, and significant post-mortem findings included congested and

	oedematous lungs and cyanosis. Tissue analysis for residues indicated the possible synergistic effect of endosulfan and alcohol in one patient and endosulfan, alcohol, and dimethoate in the second. Occupational exposure: three cases of poisoning in workers employed in a chemical factory have been reported. Poisoning occurred when the men filled bags with insecticide without wearing protective clothing and masks. Symptoms developed after 3 weeks, 1 month and 18 months – headaches, restlessness, irritability, vertigo, stupor, disorientation and epileptiform convulsive seizures. Electorencephalogram changes were noted. Endosulfan has been shown to persist on the hands of pest control operators for up to 31 days after exposure.
1.8.3	**Description of ecotoxicological properties of the chemical** **Fish:** Acute LC_{50}: 0.3-4 µg/l (a large number of different species) **Crustacea:** Acute LC_{50} for Daphnia: 0.1-0.2 mg/l **Algae:** *Scenedesmus subspicus*: 0.56 mg/l - no effects, *Chlamydamonas reinhardtii*: LC_{50}: 10 mg/l **Honeybees:** Oral LD_{50}: 6.9 µg/bee, contact LD_{50}: 7.1 µg/bee **Birds:** Acute oral LD_{50}: 28-240 mg/kg. Diet LC_{50}: 805-1275 mg/kg **Degradation** Aerobe, soil: the main degradation product is endosulfan sulfate. DT50: up to 10 years in field studies included degradation of endosulfan sulfate. DT50: 20 and 800 days for the a- og b-isomer, respectively Water/sediment: DT50: about 1 week, but endosulfan is adsorbed to the sediment **Mobility** In Sweden found at concentrations up to 0.07 µg/l in water

PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**	
2.1	**The chemical is:** X **banned** **OR** ❑ **severely restricted**	
2.2	**Information specific to the final regulatory action**	
2.2.1	**Summary of the final regulatory action**	
	It is prohibited to sell, stock or use endosulfan as a pesticide.	
2.2.2	**Reference to the regulatory document**	
	Decree of the Norwegian Agricultural Inspection Service of 20.12.94.	
2.2.3	**Date of entry into force of the final regulatory action**	
	01.01.99.	

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	X Yes	❑ No
	If yes, give information on such evaluation		
	Endosulfan has a low LD_{50} and is thus characterised as toxic. Endosulfan has high persistence in soil, is extremely toxic to fish and toxic to bees.		

	Reference to the relevant documentation
	- Data submitted by the producer - A swedish report (R. Franson, Karolinska Institutet, Institutet för miljömedisin, Toxicologisk utvärdering av insecticiden endosulfan, 1990) - WHO/IPCS Environmental Health Criteria 40, Endosulfan, 1984

2.4	**Reasons for the final regulatory action**	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	X **Yes** ❑ **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	
	Endosulfan is highly toxic and there have been cases of intoxication among workers.	
	Reference to the relevant documentation	
	See 2.3	
	Expected effect of the final regulatory action	
	Complete risk reduction	

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	X **Yes** ❑ **No**
	If yes, give summary of the known hazards and risks to the environment	
	Persistence in soil Extremely toxic to fish Toxic to bees	
	Reference to the relevant documentation	
	Mainly data submitted by the producer	
	Expected effect of the final regulatory action	
	Reduction of risk to the environment	

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**	❑ **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**	X **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	
	Thiodan 35 is not allowed for use as a pesticide in Norway	
	Formulation(s) and use or uses that remain allowed	
	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	813 kg	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	
2.7.2	Information on alternatives and their relative risks	
2.7.3	Relevant additional information	

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Norwegian Agricultural Inspection Service Pesticide Section
Address	PO Box 3 1431 Ås Norway
Telephone	+ 47 64 94 44 00
Telefax	+ 47 64 94 44 10
E-mail address	Postmottak@slt.dep.no
Designated National Authority	
Institution	Norwegian Agricultural Inspection Service Pesticide Section
Address	PO Box 3 1431 Ås Norway
Name of person in charge	Reidunn Stokke / Cécile Blom
Position of person in charge	Ecotoxicologist / toxicologist
Telephone	+ 47 64 94 44 00
Telefax	+ 47 64 94 44 10
E-mail address	Reidunn.stokke@slt.dep.no Cecile.blom@slt.dep.no

2nd Sept. 2000, Cécile Blom

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