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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Third meeting
Rome, 20–23 March 2007
Item 5 (b) (iii) of the provisional agenda*

Listing of chemicals in Annex III of the Rotterdam Convention: review of notifications of final regulatory actions to ban or severely restrict a chemical: endosulfan

Endosulfan

Note by the Secretariat

1. Under article 5 of the Rotterdam Convention, when the Secretariat has received at least one notification from each of two prior informed consent (PIC) regions containing the information required in Annex I to the Convention, it shall forward the notifications and accompanying documentation to the members of the Chemical Review Committee. The Committee shall review the documentation provided in such notifications and, in accordance with the criteria set out in Annex II to the Convention, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III to the Convention and whether a decision-guidance document should be drafted.

2. At its second meeting, the Chemical Review Committee reviewed two notifications of final regulatory action related to endosulfan from two different PIC regions (Europe (the Netherlands) and Asia (Thailand)). The Committee concluded that the two notifications met the requirements set forth in Annex I and Annex II to the Convention. Subsequently, a drafting group was established to develop a decision guidance document.

3. The Secretariat has received a new notification for final regulatory action related to endosulfan from the European Community. The notification, as received by the Secretariat, is set out in the annex to the present note. A summary of the notification was published in PIC Circular XXIV of December 2006.

4. The supporting documentation provided by the European Community may be found in document UNEP/FAO/RC/CRC.3/10/Add.1.

* UNEP/FAO/RC/CRC.3/1.

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Annex

Notification of final regulatory action for endosulfan by the European Community

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: EUROPEAN COMMUNITY

(Member States: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and United Kingdom)

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**	IUPAC: 6,7,8,9,10,10-hexachloro-1,5,5^{a},6,9,9^{a}-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide CA: 6,9-methano-2,4,3-benzodioxathiepin-6,7,8,9,10,10-hexachloro-1,5,5^{a},6,9,9^{a}-hexahydro-3-oxide
1.3	**Trade names and names of preparations**	Formulation types: emulsifiable concentrate liquid at normal temperatures (EC) Trade names: Thiodan, Cyclodan, Thionex, Endofan, Thyonex, FAN 35, Callistar, Endosulfan 35 EC, Endocel 35 EC, Endo 35 EC
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)**	EC: 602-052-00-5 EINECS: 204-079-4 CIPAC: 89

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.

PLEASE RETURN THE COMPLETED FORM TO:

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

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

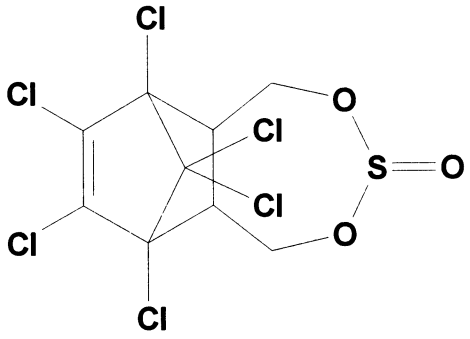
1.5.2	θ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ θ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	**Hazard class**
WHO Classification	Toxicity Class II
EPA	Toxicity Class I (Formulation)
IARC	Not evaluated
UN	Hazard Class 6.1 Packing Group II (80-100%) III (20-80% solid) (8-80% liquid)
Classification of the EC in accordance with Council directive 67/548/EEC	T (Toxic) Xi (Irritant) N (Dangerous for the environment) R24/25; R36; R50/53 (Toxic in contact with skin and if swallowed; Irritating to eyes; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment)
Other classification systems	**Hazard class**

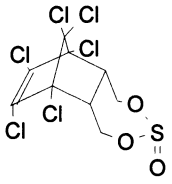
1.7 Use or uses of the chemical	
1.7.1	☑ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	Endosulfan containing plant protection products are used as non-systemic, versatile insecticides with acaricidal properties. They function via the GABA receptor system to open chloride transport and increase glutamate levels within the central nervous system. They are absorbed via ingestion and also, to a lesser extent, via dermal absorption. They are used to control numerous chewing, sucking and boring insect pests and some mites (including gall mites and soft or broad mites) in a wide variety of crops grown in temperate, subtropical and tropical climate zones. Use within the European Community included use on arable crops and greenhouse use in agriculture, horticulture, orchards, forestry and nurseries. Crops included citrus, hazelnut, pome fruits, stone fruits, berries and small fruit, table and wine grapes, root and tubular vegetables, sugar beet, fruiting vegetables, tomatoes, cucurbits inedible peel, pepper, potatoes, olives, hops, sugar cane, tobacco, alfalfa, mushrooms, vegetables, ornamentals, glasshouse crops, cotton. It was also used on tsetse flies in Southern Europe.
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**

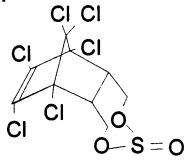
Minimum Purity: 940 +/- 20 g/kg
FAO Specification: CP/228
Molecular Formula: $C_9H_6Cl_6O_3S$
Molecular Mass: 406.96 g/mol
Structural Formula:



α endosulfan...



β endosulfan...



Appearance:
Purified endosulfan: off white (clotty) powder; white crystalline solid.
Technical endosulfan: flakes with a tendency to agglomerate; cream to tan mainly beige, yellow crystalline solid; beige slightly yellow granules.

Odour:
Although it has been described as being like sulphur dioxide, it has also been reported to be odourless.

Melting Point: α endosulfan = 109.2110°C
β endosulfan = 213.3-212°C
Mixture of isomers (99%) = 76-124°C

Boiling Point: not relevant, decomposition/sublimation occurs at >353°C

Vapour Pressure: α endosulfan = 1.05 $x10^{-3}$ Pa
β endosulfan = 1.38 $x10^{-4}$ Pa

Volatility: α endosulfan = 1.1 $Pa.m^3/mol$ at 24°C
β endosulfan = 0.2 $Pa.m^3/mol$ at 24°C

Henry's Law Constant: α endosulfan = 1.1 $Pa.m^3/mol$ at 20°C
β endosulfan = 0.2 $Pa.m^3/mol$ at 20°C

Solubility in Water: α endosulfan:
= 0.41 mg/l

β endosulfan: = 0.23 mg/l
thionex (mix of isomers) 0.63 mg/l
No pH dependency observed

Solubility in Organic Solvents: At 20°C (g/l):

n-hexane:	24
ethyl acetate:	1009

		acetone: 1164 ethanol: approx. 65 toluene: 2260 dichloromethane: 2007
	Density:	1.745 g/cm^3 at 20°C 1.87 g/cm^3 at 20°C (purified endosulfan)
	Dissociation Constant (pKa):	N/A (endosulfan cannot dissociate)
	Log K_{ow}:	4.67 (Thionex) 4.94 at pH 4, 20°C (α endosulfan) 4.87 at pH 4, 20°C (β endosulfan) 4.77 at pH 7, 20°C (α endosulfan) 4.55 at pH 7, 20°C (β endosulfan) 5.64 at pH 10, 20°C (α endosulfan) 5.65 at pH 10, 20°C (β endosulfan)
	Hydrolysis Rate:	Half-life (days) at 25°C:

	α endosulfan	β endosulfan
pH 5	>200	>200
pH 7	19	10.7
pH 9	0.26	0.17

Photochemical Degradation:

Data derived from a laboratory closed system with intensive irradiation (>290 nm; stated to be not relevant for outdoor conditions):

	half-life (hours)
α endosulfan	6.4
β endosulfan	2.7

Endosulfan is non-flammable, non-self-ignitable, non-explosive, non-volatile and non-oxidising.

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

Absorption, distribution, excretion and metabolism in mammals:
Endosulfan is rapidly absorbed from the gastrointestinal tract at reported levels of between 60 and 87% in rats, of which 60% is reported to occur within 24 hours. Absorption through the skin also occurs, which is reported to be slow, but almost complete. Distribution is reported to be rapid, with peak blood levels in rat occurring at 7 and >18 hours for males and females, respectively. Metabolism occurs in the liver and kidneys, with metabolites including endosulfan-sulphate, endosulfan-diol, endosulfan-ether, endosulfan-hydroxy-ether, endosulfan-lactone and unspecified conjugates of these metabolites. Metabolism is extensive with only 15-18% of endosulfan remaining unchanged in faeces. Endosulfan does not significantly accumulate in fat or any other tissue: in rats, 3.7 and 4.7% remained in organs and tissues (male and females, respectively) dosed for 7 days; in rats, 1.5% remained in kidneys and liver following one single dose; in mice, 0.4% remained following 24 days; and in mice, small amounts were detected after 35 days. Endosulfan appears to remain preferentially in the liver and kidneys. Endosulfan has been detected in cow's milk, however, bioaccumulation was reported not to occur. Excretion (within 120 hours) is mainly via faeces (5-82% males, 60-72% females) with urine accounting for 11-13% in males and 2-24% in females

Acute Toxicity:
Endosulfan is of high acute oral and inhalation toxicity and low acute dermal toxicity.

LD_{50} (rat, oral)	10-22.7 mg/kg bw
LD_{50} (rat, dermal)	>4000 and 500 mg/kg bw for males and females, respectively
LD_{50} (rat, inhalation, 4 hour)	0.0345 and 0.0126 mg/l for males and females, respectively

Irritation & Sensitisation:
Endosulfan is classed as not irritating to the skin and eyes according to EU criteria. It is also not classed as a contact skin allergen/sensitiser.

Subchronic Toxicity:
Male rats (dietary, 90 days): NOAEL = 3.85 mg/kg bw/day (haematological effects)
Male & female mice (dietary, 90 days): NOAEL = 2.3 mg/kg bw/day (mortality and neurological effects)
Male rats (dermal, 28 days): NOAEL = 3 mg/kg bw/day (clinical signs and mortality)
Rat (inhalation, 29 days): NOEL = >0.002 mg/l (lack of effects observed at the highest dose tested)

Chronic Toxicity:
Male & females dogs (dietary, 1 year): NOAEL = 0.65 and 0.57 mg/kg bw/day, respectively (clinical signs (violent muscular contractions of the abdominal muscles) and reduced bodyweight)
Male & female rats (dietary, 104 weeks): NOAEL = 0.6 and 0.7 mg/kg bw/day, respectively (decreased bodyweight gain, enlarged kidneys in females, increased blood vessel aneurysms in males, enlarged lumbar lymph nodes in males)
Male & female mice (dietary, 24 months): NOAEL = 0.84 and 0.97 mg/kg bw/day, respectively (increased mortality in female, decreased bodyweight in males, decreased relative lung and ovary weights in females)

Genotoxicity:
A number of studies have suggested that endosulfan is not mutagenic *in vitro* and *in vivo* for somatic cells, however, equivocal results obtained in *in vivo* germ cell studies suggest that it may induce mutations specifically in spermatogonia.
Endosulfan gave the following results in genotoxicity tests: did not induce gene mutation in bacterial or mammalian cells; it appears to be non-mutagenic for yeast (however, the conduct of these studies is questionable); it was not clastogenic in cultured human lymphocytes following acute exposure (however, effects of chronic exposure or in the presence of metabolic activation were not assessed); it did not induce DNA damage in bacteria (rec-assay) or in cultured mammalian cells (UDS) (however, the conduct of these studies is questionable); it is non-clastogenic in mammalian somatic cells *in vivo*; it induced sperm abnormalities in rodents.

Carcinogenicity:
No carcinogenic potential was observed in any of the three chronic studies detailed above.

Reproductive Toxicity:
Rat (dietary, 2 generation reproduction study):
Paternal & maternal NOAELs = 1 and 1.23 mg/kg bw/day, respectively (histopathological effects and organ weight changes)
Male & female reproductive NOAELs = 5 and 6 mg/kg bw/day, respectively (lack of effects observed at the highest dose tested)

Rat (oral gavage, developmental teratology study):
Maternal NOAEL = 0.66 mg/kg bw/day (clinical signs (face rubbing and alopecia) and reduced bodyweight gain)

Developmental NOAEL = 2 mg/kg bw/day (reduced foetal weight and length and significant skeletal variations (no teratogenic effects observed))

Rat (oral gavage, developmental embryotoxicity study):
Maternal NOAEL = 2 mg/kg bw/day (mortality, clinical signs (tonoclonic convulsions, increased salivation and blood crusted nose) and decreased bodyweight)
Developmental NOAEL = 2 mg/kg bw/day (minor abnormalities such as fragmentation of thoracic vertebral centra (no teratogenic effects observed))

Rabbit (oral gavage, developmental teratology study):
Maternal NOAEL = 0.7 mg/kg bw/day (mortality, clinical signs (noisy, rapid breathing, hyperactivity and convulsions))
Developmental NOAEL = 1.8 mg/kg bw/day (lack of effects observed at the highest dose tested)

Neurotoxicity:
Hens (oral, acute delayed neurotoxicity): no clinical signs of neurotoxicity were observed at the LD_{50} of 96 mg/kg bw

Male & female rats (oral gavage, neurotoxicological screening): NOAELs = 12.5 and 1.5 mg/kg bw/day (clinical signs (general discomfort, squatting posture and irregular respiration) and mortality)

Endocrine Effects:
Endosulfan is classed as not being an endocrine disruptor.

Immunotoxic Effects:
Endosulfan is classed as not being an immunotoxicant.

Safety Values:
EU Risk Assessment Acceptable Daily Intake (ADI) = 0.006 mg/kg bw/day (based on the NOAEL of 0.6 mg/kg bw/day from the 104 week oral rat study and an uncertainty factor of 100 to account for inter- and intraspecies variation)

EU Risk Assessment Acceptable Operator Exposure Level (AOEL) = 0.0042 mg/kg bw/day (based on the NOAEL of 0.6 mg/kg bw/day from the 1 year oral dog study and applying the correction factor for oral absorption of 70% and an uncertainty factor of 100 to account for inter- and intraspecies variation)

EU Risk Assessment Acute Reference Dose (ARfD) = 0.015 mg/kg bw/day (based on the NOAEL of 1.5 mg/kg bw/day from the rat neurotoxicity study and applying an uncertainty factor of 100 to account for inter- and intraspecies variation)

1.8.3	**Description of ecotoxicological properties of the chemical**

Soil: In a 9 month field dissipation study in which endosulfan was applied once in accordance with its insecticidal uses, it was found to dissipate moderately fast (DT_{50} = 7.4 days, DT_{90} = 24.6 days). Low mobility was also observed, despite significant precipitation and irrigation. Endosulfan degrades aerobically via oxidation, with the α isomer degrading quicker than its β counterpart (DT_{50} values at 21-22°C range from 12-39 and 108-264 days, respectively). Endosulfan-sulphate is the main metabolite formed. Anaerobic degradation also occurs, but at a slower rate than aerobic and the main metabolite is also endosulfan-sulphate. The mineralisation of endosulfan is <5%. Photolysis is not considered significant with a suggested half-life is >200 days. Volatilisation from soil also occurs. Non-extractable residues after 200 days is <20%.

Water: In water, hydrolysis is the main degradation route of endosulfan and it is extremely dependent on pH. Half-lives of >200 days (estimate), 10-19 days and <1 day were observed under acidic, neutral and alkaline conditions, respectively. In all cases the metabolite was endosulfan diol. Photolysis does not significantly occur, but oxidation does occur. Primary metabolites are endosulfan sulphate, endosulfan diol, endosulfan lactone and endosulfan hydroxy carboxylic acid. Water-sediment studies have shown that endosulfan adsorbs to sediment. Endosulfan in water is not readily biodegradable. Less than 0.1% is mineralized and 20-23% is bound residue.

Air: In air, endosulfan is stable to photolysis, but photooxidation to endosulfan sulphate occurs; half-lives of endosulfan exposed to photochemical reaction with hydroxyl radicals under European and USA scenarios are reported to be 2 and 1.3 days, respectively.

Bioaccumulation: The BCF for endosulfan is between 2500 and 10000 and with a log Kow of 4.7, this indicates that it has a high potential to bioaccumulate. However, its clearance is very rapid (CT_{50} = 2 days), so the real risk of biomagnification is reported to be negligible.

Ecotoxicology

• Terrestrial birds

Acute oral, gavage toxicity: Mallard duck (*Anas platyrhynchos*) LC_{50} = 28 mg/kg bw
Subchronic oral, dietary toxicity: Bobwhite quail (*Colinus virginianus*, 5 day study) LC_{50} = 161 mg/kg bw/day
Reproductive toxicity: Mallard duck (*Anas platyrhynchos*, >20 week dietary study) NOEC = 4 mg/kg bw/day

• Honey bee

Acute oral toxicity: LD_{50} 2 µg/bee
Acute dermal toxicity: LD_{50} 0.82 µg/bee

• Earthworm

Subchronic toxicity: Earthworm (*Eisenia foetida*; 14 day study) LC_{50} = 11 mg/kg (geometric mean of validated data)

• Bacteria

Aerobic activated sludge bacteria (unspecified): 3 hours EC_{20} & EC_{50} (inhibition of respiration (oxygen consumption)) = >1000 mg/l
No effects were observed on nitrogenase activity, ammonification, nitrification processes and soil respiration at application rates 5-10 times higher than the maximum intended rate, thus the risk to soil micro-organisms is relatively low.

• Freshwater species

Extensive data are available for endosulfan, thus the data reported below represent only a selection based on the lowest values for each species and/or those highlighted in the risk evaluation.

Fathead minnow (*Pimephales promelas*): 7 days LC_{50} (intermittent flow bioassay) = 0.86 µg/l
Zebra fish (*Brachydanio rerio*): 24 hours LC_{50} (semistatic) = 1.6 µg/l
Common carp (*Cyprinus carpio*): 24 hours LC_{50} (semistatic) = 1.6 µg/l
Rainbow trout (*Oncorhynchus mykiss*): 21 days NOEC (juvenile growth test) = 0.05 µg/l
Bluegill sunfish (*Lepomis macrochirus*): 6 weeks NOEC (lethal & sublethal effects) = 1.96 and 2.09 µg/l for spray-drift entry route and run-off entry route, respectively (used in risk evaluation)

Fathead minnow (*Pimephales promelas*): 260 days for F0 and 30 days post hatch for F1 NOEC (unspecified effects on number eggs/spawn, spawns/female and number eggs/female) = 0.056 µg/l
Copepod (*Cyclops sirenus*): 24 hours LC100 (static) = 1000 µg/l
Scud (*Gammarus roeselii*): 24 hours LC100 (static) = 5 µg/l
Water flea (*Moina micrura*): 24 hours LC50 (static) = 16.2 µg/l
Water flea (*Daphnia magna*): 48 hours LC50 (static) = 150 µg/l
Water mite (*Hydrachna trilobata*): 48 hours LC50 (static) = 2.8 µg/l
Scud (*Gammarus lacustris*): 96 hours LC50 (static) = 5.8 µg/l
Water flea (*Daphnia magna*): 21 days NOEC (unspecified) = 63 µg/l
Green (*Scenedesmus subspicatus*): 72 hours NOEC (unspecified) = 560 µg/l

• Sediment species
True midges (*Chironomus tentans*): 96 hours LC50 (sediment test) = 20 µg/kg
NOEC (unspecified) = <6 µg/kg
Polychaete (*Streblospio benedicti*): 7 days NOEC (unspecified) = <50 µg/kg

1.9 References used in Part I

EU Draft Assessment Report & Addenda (December 1999 to December 2003).
EU Draft Assessment & Addenda Endpoints (July 2004 rev. 0-5)

PART II: FINAL REGULATORY ACTION

2. FINAL REGULATORY ACTION

2.1 The chemical is: **X banned** **OR** **θ severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

Endosulfan is not included in the list of authorised active ingredients in Annex I to Directive 91/414/EEC. The authorisations for plant protection products containing endosulfan had to be withdrawn by 2 June 2006. From 3 December 2005 no authorisations for plant protection products containing endosulfan could be granted or renewed. For certain essential uses for specific member States listed in the Annex to the Commission Decision 2005/864/EC a prolonged period of withdrawal may be allowed until 30 June 2007 under specific conditions (see point 2.5.2).

2.2.2 Reference to the regulatory document

Commission Decision 2005/864/EC concerning the non-inclusion of endosulfan in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Official Journal of the European Union L 317 of 3.12.2005, p.25-27) (copy attached and also available at:
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_317/l_31720051203en00250028.pdf

2.2.3 Date of entry into force of the final regulatory action

02/06/2006 (Authorisations for plant protection products containing endosulfan had to be withdrawn by that date with the exception of certain essential uses as described in point 2.5.2).

2.3 Was the final regulatory action based on a risk or hazard evaluation? ☑ **Yes** θ **No**

If yes, give information on such evaluation

	Directive 91/414/EEC provides for the European Commission to carry out a programme of work for the examination of existing active substances used in plant protection products which were already on the market on 25 July 1993, with a view to their possible inclusion in Annex I to the Directive. Within this context, a number of companies notified their wish to secure the inclusion of endosulfan as an authorised active ingredient. A Member State was designated to undertake a risk assessment based on the dossier submitted by the notifiers. The assessment report was subject to peer review, during which the Commission undertook extensive consultations with experts of the Member States as well as with the main notifiers. The results were then reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health (SCFCAH). The evaluation was based on a review of scientific data generated for endosulfan in the context of the conditions prevailing in the European Community (intended uses, recommended application rates, good agricultural practices). Only data that has been generated according to scientifically recognised methods were validated and used for the evaluation. Moreover, data reviews were performed and documented according to generally recognised scientific principles and procedures. Assessments made on the basis of the information submitted did not demonstrate that it may be expected that, under the proposed conditions of use, plant protection products containing endosulfan satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
	Reference to the relevant documentation Review Report for the active substance Endosulfan SANCO/4327/2000-rev. 2 Final 15 February 2005 (copy attached) and supporting background documents (dossier, monograph and the peer review report under the Peer Review Programme). http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_317/l_31720051203en00250028.pdf http://ec.europa.eu/food/plant/protection/evaluation/existactive/endosulfan_en.pdf

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** θ **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 Exposure of operators under indoor conditions was not considered to have been sufficiently addressed with the available information. Using acceptable exposure scenarios, the use of endosulfan on tomatoes in greenhouses, spraying with tractor mounted hydraulic nozzles for high crops, led to exposure potentially greater than the AOEL even when using standard PPE.	
	Reference to the relevant documentation Review Report for the active substance Endosulfan SANCO/4327/2000-rev. 2 Final 15 February 2005 (copy attached) and supporting background documents (dossier, monograph and the peer review report under the Peer Review Programme). http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_317/l_31720051203en00250028.pdf http://ec.europa.eu/food/plant/protection/evaluation/existactive/endosulfan_en.pdf	
	Expected effect of the final regulatory action Reduction of risk from plant protection products.	

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	☑ **Yes** θ **No**
	If yes, give summary of the known hazards and risks to the environment	

	During the evaluation of this active substance, a number of areas of concern were identified. This was in particular the case concerning its environmental fate and behaviour, since the route of degradation of the active substance was not completely clear and unknown metabolites were found in soil degradation, water/sediment degradation and mesocosm studies. In ecotoxicology many concerns remained since the long-term risk, in particular, due to the presence of the above mentioned metabolites, could not be sufficiently addressed with the available information. Moreover endosulfan is volatile, its main metabolite is persistent and it has been found in monitoring results of regions where the substance was not used. Overall, the fate and behaviour of the substance in the environment, and in particular its degradation, persistence, potential of long range transport and potential of bioaccumulation were object of concerns. Using NOEC values for the most sensitive aquatic organism, fish, after spray drift and run-off entry, for crop use (cotton, tomatoes and arable crops), the Toxicity Exposure Ratios (TER) indicated a potential long-term risk to fish even assuming a large buffer zone. There is also a potential high risk to terrestrial birds and mammals, honey bees and earthworms.
	Reference to the relevant documentation Review Report for the active substance Endosulfan SANCO/4327/2000-rev. 2 Final 15 February 2005 (copy attached) and supporting background documents (dossier, monograph and the peer review report under the Peer Review Programme) http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_317/l_31720051203en00250028.pdf http://ec.europa.eu/food/plant/protection/evaluation/existactive/endosulfan_en.pdf
	Expected effect of the final regulatory action Reduction of risk from plant protection products.

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 Not relevant	
	Use or uses that remain allowed Not relevant	

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 the applications as plant protection products, except the essential uses listed below	
	Formulation(s) and use or uses that remain allowed	

Authorisations for essential uses may be maintained until 30 June 2007 by the EC Member States indicated below, provided that they:

(a) ensure that such plant protection products remaining on the market are relabelled in order to match the restricted use conditions;

(b) impose all appropriate risk mitigation measures to reduce any possible risks in order to ensure the protection of human and animal health and the environment; and

(c) ensure that alternative products or methods for such uses are being seriously sought, in particular, by means of action plans.

For all non-essential uses, for which existing authorisations had to be withdrawn by 2 June 2006, the EC Member States may grant a period of grace for disposal, storage, placing on the market and use of existing stocks that must expire no later than 2 June 2007. For essential uses that can continue to be authorised until 30 June 2007, the grace period for disposal, storage, placing on the market and use of existing stocks is 6 months (i.e. up to 31 December 2007).

List of essential uses that may continue to be authorised

Member State	Use
Greece	Cotton, tomato, peppers, pears, potato, alfa-alfa
Spain	Hazel nut, cotton, tomato
Italy	Hazel nut
Poland	Hazel nut, strawberry, gerbera, ornamental bulbs

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

Similar concerns to those identified are likely to be encountered in other countries where the substance is used, particularly in developing countries.

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	European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Telephone	+322 299 3530

Telefax	+322 296 7617
E-mail address	Leena.yla-mononen@ec.europa.eu
Designated National Authority	
Institution	DG Environment European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Name of person in charge	Leena Yla-Mononen
Position of person in charge	Deputy Head of Unit
Telephone	+322 299 3530
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Date, signature of DNA and official seal: 3/10/2006