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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 (c) (i) of the provisional agenda*

Listing of chemicals in Annex III of the Rotterdam Convention: consideration of the draft decision guidance documents for: endosulfan

Draft decision guidance document for endosulfan

Note by the Secretariat

1. At its second session, the Chemical Review Committee reviewed the notifications of final regulatory actions for endosulfan from the Netherlands and Thailand, including the supporting documentation referenced therein, and, taking into account each of the specific requirements set out in Annex II of the Rotterdam Convention, concluded that the requirements of that Annex had been met.

2. Accordingly, the Committee agreed to recommend to the Conference of the Parties to the Rotterdam Convention that endosulfan should be listed in Annex III of the Rotterdam Convention. The Committee also adopted a rationale for that recommendation and agreed to establish an intersessional drafting group to produce a draft decision guidance document for endosulfan.[1] A detailed work plan for the development of the decision guidance document was prepared by the drafting group, in line with the process adopted by the Conference of the Parties at its second meeting, in decision RC-2/2. The rationale, decision and workplan were attached to the report of the second meeting of the Committee (UNEP/FAO/RC/CRC.2/20, annex II). The timetable of the workplan was subsequently modified and an updated version posted on the Convention website.

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

[1] The members of the drafting group on endosulfan, established by the Chemical Review Committee at its second meeting, were Mr. Lars Juergensen and Mr. Mario Nichelatti (co-chairs), Mr. Hamoud Al-Hasani, Mr. Cesar Grisolia, Ms. Karmen Krajnc, Mr. Ernest Mashimba and Mr. Angelo Valois.

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3. The material available to the drafting group included a summary of the outcome of the second meeting of the Committee, a copy of the working paper on the preparation of internal proposals and decision guidance documents for banned or severely restricted chemicals, the notifications of final regulatory actions and the relevant supporting documentation available to the Chemical Review Committee at its second meeting.

4. In accordance with the agreed workplan, the co-chairs of the drafting group, in consultation with the Secretariat, prepared an internal proposal document based on the notifications and the supporting documentation. That proposal was circulated to members of the drafting group for comment on 15 May 2006. The document was amended in the light of the comments received and was circulated, on 7 July 2006, to all members of the Chemical Review Committee and the observers who had attended the second meeting of the Committee.[2] Responses were received from members of the Committee and observers. The draft decision guidance document on endosulfan was prepared by the drafting group chairs in the light of the comments received.

5. A report on the work of the drafting group chairs, including the draft decision guidance document and a compilation of the comments, was circulated to drafting group members on 18 October 2006. A tabular summary of all of the comments received and how they were addressed is available as document UNEP/FAO/RC/CRC.3/INF5. As a result of this last round of comments, several minor editorial changes were incorporated in the draft decision guidance document.

6. The text of the draft decision guidance document on endosulfan, as submitted to the Secretariat by the drafting group, is set out in the annex to the present note. The annex has not been formally edited by the Secretariat.

[2] The observers comprised 26 countries, nine non-governmental organizations and three intergovernmental organizations.

Annex

Rotterdam Convention
Operation of the Prior Informed Consent procedure
for banned or severely restricted chemicals

Draft
Decision Guidance Document

ENDOSULFAN

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

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[3] for inclusion in the Prior Informed Consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[4] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control/reduce such risks. However, inclusion does not imply that all Parties to the Convention have banned or severely restricted this chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its XXXX meeting, held in XXXX on XXXX the Conference of the Parties agreed to list endosulfan in Annex III of the Convention and adopted the decision guidance document with the effect that this chemical became subject to the PIC procedure.

The present decision guidance document was communicated to the Designated National Authorities on [xxxx] in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the Decision Guidance Document

For each chemical included in Annex III of the Rotterdam Convention a decision guidance document has been approved by the Conference of the Parties. Decision guidance documents are sent to all Parties with a request that they provide a decision regarding future import of the chemical.

The decision guidance document is prepared by the Chemical Review Committee (CRC). The CRC is a group of government designated experts established in line with Article 18 of the Convention, that evaluates candidate chemicals for possible inclusion in the Convention. The decision guidance document reflects the information provided by two or more Parties in support of the national regulatory actions to ban or severely restrict the chemical. It is not intended as the only source of information on a chemical nor is it updated or revised following its adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical as well as others that have not banned or severely restricted it. Such risk evaluations or information on alternative risk mitigation measures submitted by Parties may be found on the Rotterdam Convention web-site (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

Disclaimer

The use of trade names in this document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to

[3] "'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial."

[4] "'Party' means a State or regional economic integration organisation that has consented to be bound by this Convention and for which the Convention is in force."

include all trade names presently in use, only a number of commonly used and published trade names have been included in this document.

While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) disclaim any responsibility for omissions or any consequences that may flow there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

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

ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
>>	much greater than
µg	microgram
µm	micrometer
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
a.i.	active ingredient
AOEL	acceptable operator exposure level
ARfD	acute reference dose
ATP	adenosine triphosphate
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CA	chemical association
CAS	chemical abstract service
cc	cubic centimetre
ChE	cholinesterase
CHO	Chinese hamster ovary
cm	centimetre
CS	capsule suspension
d	day(s)
DNA	Deoxyribose nucleic acid
DT_{50}	time 50% of a chemical to degrade
E.C.	European Community
EC	Emulsifiable Concentrate
EC_{50}	effect concentration, 50% (median effective concentration)
ED_{50}	effect dose, 50% (median effective dose)
EEC	European Economic Community
EINECS	European inventory of existing commercial substances
EHC	Environmental Health Criteria
FAO	Food and Agriculture Organisation of the United Nations
g	gram
GEMS/Food	Global Environment Monitoring System - Food contamination monitoring and assessment programme
h	hour
ha	hectare
i.m.	intramuscular

ABBREVIATIONS

i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	inhibition concentration, 50%;
IESTI	international estimate of short-term dietary intake
ILO	International Labour Organisation
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
kg	kilogram
Koc	organic carbon-water partition coefficient
l	litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LD_{LO}	lowest lethal dose
LOEL	lowest observed effect level
Log P	logarithm of the octanol/water partition coefficient
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
MOE	margin of exposure
mPa	milliPascal
MRL	maximum residue level (or limit)
MTD	maximum tolerated dose
ng	nanogram
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect-concentration
NOEL	no-observed-effect level
NRA	National Registration Authority for Agricultural and Veterinary Chemicals (Australia)
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
OHS	Occupational Health and Safety
PCM	phase contrast microscopy
PEC	predicted environmental concentration
PNEC	predicted no-effect concentration
Pow	octanol-water partition coefficient
PPE	personal protective equipment

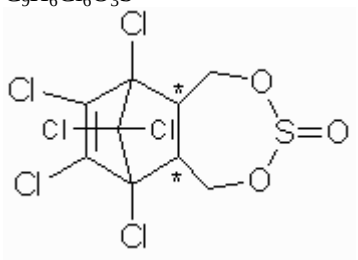
ABBREVIATIONS

RfD	reference dose for chronic oral exposure (comparable to ADI)
SMR	standardized mortality ratio
STEL	short term exposure limit
STMR	supervised trials median residues
TER(s)	toxicity/exposure ratio(s)
TLV	threshold limit value
TWA	time weighted average
UL	ultra low volume liquid
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
UV	ultraviolet
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

Endosulfan **Published:**

1. Identification and uses (see Annex 1)

Common name	**Endosulfan**
Chemical name	ISO: endosulfan
Other names/ synonyms	IUPAC: (1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-en-2,3-ylene-bismethylene) sulphite CAS: 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-No.	115-29-7
Harmonised System Customs Code	2920 9090
Other numbers:	EINECS: 2040794
Molecular formula	$C_9H_6Cl_6O_3S$
Structural formula	
Category	Pesticide
Regulated Category	Pesticide
Use(s) in regulated category	Insecticide used against a variety of insects on tall and small fruit, full field vegetables, arable agriculture, mushrooms and full field ornamentals. Insecticide used for controlling: aphids and leafhoppers in cotton, webworm and hawk moth worm in sesame, and berry borer in coffee.
Trade names	Benzoepin, Beosit, Callistar, Chimac endo 350, Chlorthiepin, Chlorthiepin Endocide, Cyclodan, EC FAN 35, End 35 LAPA, Endo 35 EC, Endocel 35 EC, Endofan Endosulfan 35 Endosulphan, FMC 5462, Galgofon, HOE 2671, Insectophene, Malix, Rocky, Palmarol, Thecn'ufan, Thiosulfan, Thiodan, Tionel, Thionate, Thionex, Thyonex, Tiovel, Thifor *This is an indicative list. It is not intended to be exhaustive.*
Formulation types	Endosulfan is available in a variety of formulations, such as a wettable powder (WP), granules (GR), emulsifiable concentrations (EC), capsule suspension (CS) and dustable powder (DP) and ultra low volume liquid (UL). Technical endosulfan consists of a mixture of α and ß isomers in the approximate ratio of 70: 30
Uses in other categories	No reported use as an industrial chemical.
Basic manufacturers	Introduced by Hoechst (now Aventis), and also produced by a number of other manufactures including: Aako, Bayer Crop Science, Drexel, Excel, Hindustan, Luxan, Makhteshim-Agan, Milenia, Parry, Seo Han, Sharda.

This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.

2. Reasons for inclusion in the PIC procedure

Endosulfan is included in the PIC procedure as a pesticide. It is listed on the basis of the final regulatory actions taken by the Netherlands to ban endosulfan as pesticide and by Thailand to severely restrict endosulfan by banning all formulations except the CS formulation of endosulfan.

No final regulatory actions relating to industrial chemical uses have been notified.

2.1 Final regulatory action: (see Annex 2 for details)

The Netherlands: In January 1986 the "Commissie Toelating Bestrijdingsmiddelen" ("Commission for the Registration of Pesticides") informed the registrant of the decision to withdraw the substance by a phase-out process. On 1 January 1987, most applications of endosulfan were registered for one final year to allow the sale and use of existing stocks. An exception was made for the use of endosulfan as an insecticide in integrated pest management for apple orchards; the use in apple orchards was prohibited on 1 January 1990.

The registration of endosulfan and all related products were withdrawn by 1 January 1990. As of that date it is prohibited to sell, stock or use endosulfan as a pesticide. The registrant appealed the decision and asked the Board of Appeal for the Business Community to reverse the withdrawal decision. The appeal took place on 28 February 1990. The decision to withdraw the registration was upheld resulting in a complete ban of endosulfan use in the Netherlands.

Reason: Unacceptable risk for aquatic organisms, especially fish.

Thailand: As notified by the ministry of Industry and published in the Royal Gazette, Endosulfan in formulations other than the CS formulation is prohibited from import, production, having in possession and use as agricultural pesticide as of 19 October 2004. A CS formulation of endosulfan is registered for use in cotton only.

Reason: EC and GR formulations of endosulfan are highly toxic to fish and other aquatic organisms.

2.2 Risk evaluation (see Annex 1 for details)

The Netherlands: The Netherlands risk assessment was performed by the Commission for the Registration of Pesticides (CTB). The evaluation of all data was carried out taking into account the latest requirements for data quality.

Environmental impact
Endosulfan was used as an insecticide for treatment of tall[5] and small[6] fruits. In the risk assessment an amount of 10% of the dosage applied was estimated to drift and potentially reach surrounding surface waters. Drift reducing measures or buffer zones may result in a smaller percentage reaching surface waters. Endosulfan was applied in spring and summer at a rate of 0.75 – 1.5 kg a.i./ha for tall fruit and 0.5 – 1.0 kg a.i/ha for small fruit. Based on an application rate of 0.525 kg/ha calculated as α-endosulfan, a range of concentrations may be calculated in surface water in a ditch with a depth of 25 cm. The concentrations in surface water ranged between 0.2 – 14 µg/l and were found to exceed the level at which toxicity had been demonstrated in fish (LC_{50} = 0.17 µg /l). It was concluded that the application of endosulfan according to recommended rates would cause unacceptable risks for fish as the ratio of the predicted environmental concentration (14 µg/l) and the lowest 50% lethal concentration for fish (LC_{50} = 0.17 µg /l) is 82 (For further details, see Annex 1).

Thailand: The Department of Agriculture became aware that many farmers applied endosulfan (granular (GR) and emulsifiable concentrate (EC) formulations) to paddy fields to control golden apple snails (*Pomacea canaliculata*),

[5] tall fruits: apples and pears
[6] small fruits: all kinds of berries

even though this use was not authorized. This use caused adverse effects to the environment, especially to non-target aquatic organisms. Consequently, the Department conducted a field survey during March 1999 – April 2000, to collect information on the use and to assess the impact of endosulfan in paddy fields.

Environmental impact
The results of the field survey undertaken in five provinces of the central region showed that 94 per cent of farmers used pesticides and of those 60–76 % used EC and GR formulations of endosulfan for golden apple snail control in paddy fields. Those formulations of endosulfan were very effective in combating snails but also were very toxic to fish and other aquatic organisms. Almost all farmers in every province reported mortality of fish, snake, frog, eel and toad. However, farmers confirmed that they would continue using endosulfan to control golden apple snail unless it is ineffective.

The toxicological hazards identified in the existing scientific data, taken together with the effects observed in the field survey, led to the decision to ban all formulations of endosulfan except capsulated suspension (CS) formulations.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

The Netherlands: The final regulatory action banned all uses of endosulfan as a pesticide. The phase-out that included a stepwise approach in order to avoid creating stockpiles led to a complete reduction of the risks to the aquatic environment.

Thailand: All formulations except the CS formulations were banned in Thailand. The CS formulation of endosulfan has been shown to be ineffective in controlling golden apple snails and hence is not expected to be used for golden apple snail control in paddy fields. Therefore, the prohibition of import, production and use of endosulfan in formulations other than the CS formulation led to significant reduction of the risks to the aquatic environment.

3.2 Other measures to reduce exposure

None.

3.3 Alternatives

There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under consideration. Countries should consider promoting, as appropriate, integrated pest management (IPM) strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through National IPM focal points, the FAO, and agricultural research or development agencies. Where it has been made available by governments, additional information on alternatives to endosulfan may be found on the Rotterdam Convention website www.pic.int.

The Netherlands: The following alternatives were available at the time of final regulatory action;
Carbaryl and bromophos for insect control apple blossom beetle (*Tropinota hirta)* and apple sawfly (*Hoplocampa testudinea)* (Klug) in apples; diflubenzuron, teflubenzuron and fenoxycarb against caterpillars; pirimicarb against aphids (*Aphidoidae sp*.); and fenbutatinoxide against rust acarids.

Thailand: The control of golden apple snails applied by the farmers in Thailand include destruction of adult snails and eggs and the use of nets to prevent snails entry into rice field and pasturing ducks in the rice paddies between the growing seasons.

3.4 Socio-economic effects

No detailed assessments of socio-economic effects were undertaken by the notifying parties.

4. Hazards and Risks to human health and the environment

4.1 Hazard Classification

WHO / IPCS	Technical a.i.:	Class II (moderately hazardous) LD_{50} rat: 80 mg/kg bw (WHO 2004)	
	Formulations		
		Oral toxicity LD_{50} rat: 80 mg/kg bw (WHO 2004)	
	Liquid	a.i. (%)	Hazard class
		≥ 40	Ib
		≥ 4	II
		< 4	III
	Solid	≥ 16	II
		< 16	III
IARC	Not evaluated		
European Community	Classification of the active substance is (Commission Directive 93/72/EEC, 1 September 1993): T (toxic) Xi (Irritant) N (dangerous for the environment) R 24/25 (Toxic in contact with skin/ if swallowed) R 36 (Irritating to eyes) R 50/53 (Very toxic to aquatic organisms / may cause long-term adverse effects in the aquatic environment)		
US EPA	Toxicity Class I (formulation)		

4.2 Exposure limits

Food: The FAO/WHO Joint Meeting on Pesticide Residues (JMPR) established an Acceptable Daily Intake (ADI) of 0-0.006 mg/kg bw and an acute reference dose (ARfD) of 0.02mg/kg bw. (JMPR1998).

Drinking water: No limits were reported. WHO Drinking Water Guidelines: a health-based value of 20µg/l can be calculated for endosulfan on the basis of an ADI of 0.006 mg/kg bw (WHO 2003).

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class:	UN: 6.1
Packing Group:	UN: II
International Maritime Dangerous Goods (IMDG) Code	Severe marine pollutant Do not transport with food and feedstuff.
Transport Emergency Card	TEC (R)-61G41b

4.4 First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Signs of symptoms of (acute) ingestion are: confusion, headache, weakness, dizziness, nausea, vomiting, diarrhoea, convulsions, laboured breathing and unconsciousness. The victim may become cyanosed, with blue lips or fingernails.

First aid personnel should wear protective gloves, and clothing. If skin contact occurs, remove contaminated clothes. Rinse and then wash skin with water and soap. Eyes should be rinsed with plenty of water for several minutes (remove contact lenses if easily possible), then take to a doctor. In case of inhalation, remove to fresh air.

If the victim is unconscious or convulsing, do NOT give anything by mouth and do NOT induce vomiting.

Effects of short-term exposure: endosulfan may cause effects on the central nervous system, resulting in irritability, convulsions and renal failure. Exposure at high levels may result in death. The effects may be delayed. Medical observation is indicated.

Persons who have been poisoned (accidentally or otherwise) must consult a doctor.

Use of alcoholic beverages enhances the harmful effect.

If the substance is formulated with solvent(s), also consult the International Chemical Safety cards (ICSC) of the solvent(s). Carrier solvents used in commercial formulations may change physical and toxicological properties.

Further information may be found on the website of the IPCS/WHO at ***www.inchem.org***

4.5 Waste management

Regulatory actions to ban a chemical should not result in creation of a stockpile requiring waste disposal. For guidance on how to avoid creating stockpiles of obsolete pesticide stocks the following guidelines are available: *FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks* (1995), *The Pesticide Storage and Stock Control Manual* (1996) and *Guidelines for the management of small quantities of unwanted and obsolete pesticides* (1999).

The Netherlands avoided creating stockpiles of endosulfan by taking a stepwise approach to the phase-out of permitted uses. The risk was considered manageable during this phase-out period.

In all cases waste should be disposed in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines there under (SBC, 1994), and any other relevant regional agreements.

It should be noted that the disposal/destruction methods recommended in the literature are often not available in, or suitable for, all countries; e.g., high temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies. Further information on possible approaches may be found in *Technical Guidelines for the Disposal of Bulk Quantities of Obsolete Pesticides in Developing Countries* (1996).

Do not wash away into sewer. Sweep spilled endosulfan into sealable containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder, and then remove to a safe place. A personal chemical protection suit, including a self-contained breathing apparatus, should be worn. Do not take working clothes home (HSG, 1988).

Storage requires provisions to keep dry and well closed, separate from acids, bases, iron, food and feedstuffs, an to contain effluent from fire extinguishing. (IPCS, 1988)

Annexes

Annex 1 Further information on the endosulfan

Introductory text to Annex I

The information presented in this Annex reflects the conclusions of the two notifying parties: Thailand and The Netherlands. In a general way, information provided by these two parties on the hazards are synthesised and presented together, while the risk assessments, specific to the conditions prevailing in The Netherlands and Thailand, are presented separately. This information is contained in the documents referenced in the notifications in support of their final regulatory actions banning endosulfan. The notification from Thailand was first reported in the PIC Circular XXI of June 2005 and the notification from the Netherlands in PIC Circular XII of December 2000.

The FAO/WHO Joint Meeting on Pesticide Residues (JMPR) has reviewed endosulfan on several occasions. The last review of mammalian toxicity data was in 1998, whereas residues were last re-evaluated in 1989. The full evaluation by the JMPR is not included here, although the relevant conclusions regarding acceptable daily intake (ADI) and acute reference dose (ARfD), are reported in the interest of completeness.

The results of the international Arctic and Monitoring and Assessment Progamme (AMAP) Assessment 2002 were also considered while drafting this document. These results do not differ substantially from the information provided by the notifying countries, but the AMAP does provide additional data on the environmental fate in air and the potential for bioconcentration/bioaccumulation (Sections 4.1.3 and 4.1.4).

Annex 1 – Further information on endosulfan

1. Physico-Chemical properties

1.1	**Identity**	ISO: endosulfan IUPAC: (1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-en2,3-ylenebismethylene) sulfite CAS: 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
1.2	**Formula**	$C_9\ H_6\ Cl_6\ O_3\ S$
1.3	**Chemical type**	Mixture of α- and ß- isomers (α: 64 – 67%, ß: 29 – 32% of techn. Grade) α-endosulfan is the active component of the mixture.
1.4	**Colour and Texture**	Technical endosulfan: cream to brown, mostly beige crystals Formulation: colourless crystals
1.5	**Decomposition temperature**	Not available.
1.6	**Density (g/cm^3)**	Technical endosulfan: 1.8 at 20 °C
1.7	**Solubility**	In water: 0.32 mg/l (α-endosulfan); 0.33 mg/l (ß-endosulfan) at 22 °C In water: 0.51 mg/l (α-endosulfan); 0.45 mg/l (ß-endosulfan) at 20 °C In ethyl acetate, dichloromethane and toluene: 200 g/l at 20 °C In ethanol c. 65 g/l at 20 °C In hexane c. 24 g/l at 20 °C
1.8	**Log P**	4.74 (α-endosulfan), 4.79 (ß-endosulfan) 3.83 (α-endosulfan)
1.9	**Vapour pressure**	1.33 mPa at 25 °C 8.3 mPa at 20 °C 0.83 mPa at 20 °C for the 2:1 mixture of α- and ß- isomers.
1.10	**Melting point**	106 °C Technical endosulfan: ≥ 80 °C; α-isomer: 109.2 °C; ß-isomer: 213.3 °C.
1.11	**Boiling point**	401.28 °C
1.12	**Reactivity**	Hydrolysis: slowly hydrolysed in aqueous acids and alkalis, with formation of the diol and sulphur dioxide.
1.13	**Stability**	Stable to sunlight
1.14	**Molecular Weight**	406.9 g/mol
1.15	**HENRY'S LAW CONSTANT**	1.12 E-5 atm-m^3/mole

2 Toxicological properties

2.1	**General**	
2.1.1	**Mode of Action**	Endosulfan has an affinity for the γ-aminobutyric acid receptors (GABA) in the brain and acts as a non-competitive GABA antagonist. Binding of GABA to its receptor induces the uptake of chloride ions by neurons, resulting in hyperpolarisation of the membrane. The blockage of this activity results in only partial repolarisation of the neuron and a state of uncontrolled excitation.
2.1.2	**Symptoms of poisoning**	The clinical symptoms included: vomiting, agitation, convulsions, cyanosis, dyspnoea, foaming at the mouth and noisy breathing.
2.1.3	**Absorption, distribution,**	Endosulfan can be absorbed following ingestion, inhalation and skin contact. More than 90% of an oral dose of endosulfan was absorbed in rats, with maximum plasma

excretion and metabolism in mammals

concentrations occurring after 3-8 h in males and about 18 h in females. Elimination occurs mainly in the faeces and to a lesser extent in the urine, with more than 85% being excreted within 120 h. The highest tissue concentrations were in the kidneys. The metabolites of endosulfan include endosulfan sulfate, diol, hydroxy-ether, ether, and lactone but most of its metabolites are polar substances which have not yet been identified (JMPR 1998).

2.2 Toxicological studies

2.2.1 Acute toxicity

The LD_{50} of endosulfan varies widely depending on the route of administration, species, vehicle, and sex of the animal. Endosulfan, administered by any route, is more toxic to female than to male rats and, on the basis of a single study, this sex difference appears to apply to mice also. A battery of tests for acute toxicity in several species with technical-grade endosulfan showed that it is highly toxic after oral or dermal administration (JMPR 1998)

- **Oral LD_{50}** values for rats from 9.6 mg/kg bw in females to 160 mg/kg bw in males
- **Dermal LD_{50}** values for rats from 500 mg/kg bw in females to >4000 mg /kg bw in males
- **Inhalation LC_{50}** value for rats (4 h) in a single study was 13 mg/m^3 in females and 35 mg/m^3 in males

Irritation: endosulfan showed no irritating effect for eye and skin of rabbits (JMPR, 1998).
Sensitization: endosulfan was considered to be non-sensitizing to Guinea-pig skin (JMPR, 1998).

Clinical signs of acute intoxication include piloerection, salivation, hyperactivity, respiratory distress, diarrhoea, tremors, hunching, and convulsions (JMPR 1998).

2.2.2 Short term toxicity

Endosulfan in the diet of male rats at 2 – 200 mg/kg feed for 2 weeks resulted in changes in mixed-function oxidase (MFO) activity. Endosulfan at the highest level of 200 mg/kg feed (approximately 10 mg/kg bw/d) induced MFO activity.

Female rats administered at daily oral doses of 1.0, 2.5, or 5.0 mg/kg bw/d for 7 or 15 days, showed no changes in body, ovary or adrenal weights. At 2.5 and 5.0 mg/kg bw/d liver weight was increased pentobarbital sleeping time was decreased and induction of aminopyrine demethylaseaniline hydroxylase was found as well as a dose-related increase in amino-transferase activity and spontaneous lipid peroxidation.

Oral intubation in male rats at 5 or 10 mg/kg bw/d for 15 days resulted in a reduction in body weight at 10 mg/kg bw/d. Three out of twelve animals died during testing.

Oral administration to 4 dogs for 3 days at 2.5 mg/kg bw/d endosulfan resulted in vomiting in all dogs and tremors, convulsions, rapid respiration and mydriasis in 3 animals.

Cats received endosulfan intravenously via a cannula at levels of 2, 3, or 4 mg/kg bw/d. At all treatment levels muscular twitching followed by convulsions was observed. At 3 and 4 mg/kg bw/d a marked rise in blood glucose levels was found after 15 and 30 minutes with a gradual fall up to 4 hours.

Sub-chronic studies.

Rats that received a daily oral doses of endosulfan at 1.6 – 3.2 mg/kg bw/d for 12 weeks showed no effects on growth rate.

Male rats dosed orally at levels of 0.625, 5.0 or 20 mg/kg bw/d, 6 days per week for

7 weeks, showed a slight increase in blood glucose levels and a decrease in plasma calcium levels (all IPCS 1984).

2.2.3 Genotoxicity (including mutagenicity)

Endosulfan was tested for genotoxicity effects using a wide range of assays, both *in vitro* (with and without metabolic activation) and *in vivo*. There was no evidence of genotoxicty in most of these assays. It was concluded that endosulfan is not genotoxic (JMPR, 1998).

2.2.4 Long term toxicity and carcinogenicity

Male and female rats received technical grade endosulfan at 10, 30, and 100 mg/kg feed for 104 weeks. Mortality of female rats was found in the 10 and 30 mg/kg feed group in the second year. In the 100 mg/kg feed female group survival was significantly lower compared to control after 26 weeks of exposure and accompanied by abnormalities in weight gain and haematological parameters. Relative testes weights were significantly reduced in the 10 mg/kg group. Histopathological findings were observed only in the 100 mg/kg group and included: enlarged kidneys, signs of renal tubular damage with interstitial nephritis, and hydropic changes in liver cells. No increased tumour incidence was determined. NOEL: 30 mg/kg feed, equivalent to 1.5 mg/kg bw/d (IPCS 1984).

Male and female rats were fed diets containing technical endosulfan at 3, 7.5, 15, and 75 mg/kg feed during 24 months. Body weight and body weight gains were reduced in the 75 mg/kg feed group. No clinical signs of toxicity were observed at any dose. Increased incidences of enlarged kidneys in females and enlarged lumbar lymph nodes in males were seen at 75 mg/kg feed. Histopathological examinations showed an increased incidence of aneurysm and marked progressive glomerulonephrosis at 75 mg/kg feed in males but no increase in tumour incidence. The NOAEL was 15 mg/kg feed, equivalent to 0.6 mg/kg bw/d on the basis of reduced body weights and pathological findings at higher doses (JMPR, 1998).

Mice received diets containing endosulfan at 2 – 18 mg/kg feed for 24 months. Increased mortalities and a slight reduced body weight gain was observed in males at 18 mg/kg feed. No increased tumour incidence. NOAEL is 0.84 mg/kg feed, equivalent to 0.97 mg/kg bw/d. (JMPR, 1998).

The JMPR found that no carcinogenic effect was observed in mice at 18 ppm for 24 months, in female rats at 445 ppm for 78 weeks in one study or in male or female rats at 75 ppm or 100 ppm for two years in two other studies (JMPR 1998).

2.2.5 Effects on reproduction and teratogenicity

Endosulfan at dietary concentrations of 0, 3, 15, or 75 ppm did not affect reproductive performance or the growth or development of the offspring of rats over a two-generation study. The NOAEL was 75 ppm, the highest dose tested, equal to 5 mg/kg bw/d for males and 6.2 mg/kg bw/d for females. The NOAEL for parental toxicity was 15 ppm, equal to 1 mg/kg bw/d for males and 1.2 mg/kg bw/d, on the basis of increased liver and kidney weights at 75 ppm (JMPR 1998).

In two studies of developmental toxicity in rats given oral doses of 0, 0.66, 2, or 6 mg/kg bw/d, the NOAEL for maternal toxicity was 0.66 mg/kg bw/d in one study and 2 mg/kg bw/d in the other. In the first case, the NOAEL was based on decreased body-weight gain at 2 mg/kg bw/d and decreased body-weight gain and clinical signs of toxicity at 6 mg/kg bw/d; in the second case, the NOAEL was based on mortality, clinical signs of toxicity, and decreased body-weight gain at 6 mg/kg bw /d. In both studies, the NOAEL for developmental toxicity was 2 mg/kg bw/d, in the first case on the basis of delayed development and a low incidence of skeletal variations seen at 6 mg/kg/d, and in the second on the basis of an increased incidence of fragmented thoracic vertebral centra seen at 6 mg/kg bw/d. In neither study was there any treatment-related major malformation (JMPR 1998).

In a study of developmental toxicity in rabbits given oral doses of 0, 0.3, 0.7, or 1.8 mg/kg bw/d, the NOAEL for maternal toxicity was 0.7 mg/kg bw/d on the basis of clinical signs of toxicity at 1.8 mg/kg bw/d. The NOAEL for developmental toxicity

was 1.8 mg/kg bw/d, the highest dose tested (JMPR 1998).

2.2.6 Special studies on neurotoxicity

In a number of studies, endosulfan (purity, 95%) was given by gavage to rats at a dose of 2 mg/kg bw/d for 90 days or up to 6 mg/kg bw/d for 30 days, and behavioural and biochemical changes were determined. Signs of frank toxicity (reduced body weights, reduced food consumption, death, increased intensity of tremors, and increased liver enzyme activity) were observed in all studies, and some changes in behaviour were noted, including increased motor activity and inhibition of conditioned and unconditioned escape and avoidance responses (JMPR 1998).

2.2.7 Summary of mammalian toxicity and overall evaluation

WHO has classified endosulfan as moderately hazardous (WHO 2004). The LD_{50} of endosulfan varies widely depending on the route of administration, species, vehicle, and sex of the animal. Endosulfan, administered by any route, is more toxic to female than to male rats. The oral LD_{50} in the rat ranged from 9.6 mg/kg bw in females to 160 mg/kg bw in males. Clinical signs of acute intoxication include piloerection, salivation, hyperactivity, respiratory distress, diarrhoea, tremors, hunching, and convulsions. Endosulfan was non-irritating to the eye or skin of rabbit nor was it deemed a skin sensitizer. Endosulfan is not genotoxic nor were carcinogenic effects observed in studies on mice and rats. In studies reported, no effects were observed at the doses tested with respect to reproductive performance in rats or the growth or development of the offspring in rats and rabbits (JMPR 1998).

Acute Reference Dose (ARfD)
The ARfD was 0.02 mg/kg bw, based on a NOAEL of 2 mg/kg bw/d in a neurotoxicity study with rats and using a safety factor of 100 (JMPR 1998).

Acceptable Daily Intake (ADI)
The ADI was 0 - 0.006 mg/kg bw based on NOAEL of 0.6 mg/kg bw/d in a 2-year dietary study in rats and using a safety factor of 100 (JMPR 1998).

3 Human exposure/Risk evaluation

3.1 Food

Food is the main source of exposure of the general population to endosulfan. Endosulfan residues in food have been found to be generally below the FAO/WHO maximum residue limits (JMPR 1993).

3.2 Air

Not considered relevant for endosulfan

3.3 Water

Not considered relevant for endosulfan

3.4 Occupational exposure

Poisoning of three workers without wearing protective clothing and masks occurred when they filled bags with endosulfan. Symptoms developed after 3 weeks, 1 month and 18 months, respectively, and consisted of headaches, restlessness, irritability, vertigo, stupor, disorientation, and epileptiform convulsive seizures. Changes in the electroencephalogram were also observed (IPCS 1984).

In India, eighteen workers were accidentally poisoned with endosulfan during spraying. They were not wearing protective clothing and did not follow the correct instructions for use either because of ignorance or illiteracy. The main symptoms reported were nausea, vomiting, abdominal discomfort, tonic and clonic convulsions, confusion, disorientation, and muscular twitching (IPCS 2000).

In the field survey undertaken by the Thai Government, farmers reported effects on human health such as headache, nausea, weakness and irritated eyes (Thailand 2000).

3.5 Medical data

In general, the doses of endosulfan involved in cases of poisoning have been poorly characterized. In a summary of case reports, the lowest reported dose that resulted in death was 35 mg/kg bw; deaths have also been reported after ingestion of 295 and 467 mg/kg bw, within 1 h of ingestion in some cases. Intensive medical treatment within 1 h was reported to be successful after ingestion of doses of 100 and 1000 mg/kg bw. The clinical signs in these patients were consistent with those seen in

laboratory animals, dominated by tonic-clonic spasms. In a case in which a dose of 1000 mg/kg bw was ingested, neurological symptoms requiring anti-epileptic therapy were still required one year after exposure (JMPR 1998).

3.6 Summary - overall risk evaluation

The notifications of final regulatory action, which were the basis for review of endosulfan by the Chemical Review Committee, concerned the environmental effects of endosulfan. There were no detailed risk evaluations of the human health effects of endosulfan submitted by the notifying Parties.

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil and sediment

The α-isomer of endosulfan disappears more rapidly than the ß-isomer. Endosulfan sulphate is the major degradation product; degradation to endosulfan diol also occurs. According to field studies, DT_{50} values are 60 days and 900 days for α- and ß-isomer, respectively (IPCS 1984); and 5 to 8 months for total endosulfan (α- and ß-endosulfan and endosulfan sulphate) (Pesticide Manual 2003). No leaching in soil is reported for both isomers and endosulfan sulphate. The degradation of endosulfan appears to be different in soil from sediment. Studies with flooded soil demonstrated that the degradation products endosulfan diol increased and endosulfan sulphate decreased compared with soil studies (IPCS 1984).

4.1.2 Water

Endosulfan has a DT_{50} in normal water (pH 7 and normal oxygen concentration) of 7 days. A drop in pH and oxygen content inhibited degradation. Under anaerobic conditions at pH 7, the DT_{50} was 5 weeks and at pH 5.5 the DT_{50} was nearly 5 months (IPCS 1984).

Photodegradation: Both α- and ß-isomer of endosulfan are fairly resistant to photodegradation, but endosulfan sulphate and endosulfan diol are susceptible to photodegradation (IPCS 1984).

4.1.3 Air

Based on vapour pressures for the α- and β-isomers, calculated Henry's law constants and available monitoring data, both endosulfan isomers have an intermediate to high volatility under field conditions and can be subject to long-range transport. The α–isomer is more volatile than the β-isomer. Endosulfan has been detected in air, snow and biota samples in remote areas such as the Arctic which has resulted from long range atmospheric transport (AMAP 2002).

4.1.4 Bioconcentration /bioaccumulation

The endosulfan α and β isomers and endosulfan sulfate have log K_{ow} values of 4.74, 3.83 and 4.79, respectively, which indicate a potential for bioaccumulation in biota. Endosulfan has been detected in biota samples in remote areas such as the Arctic (AMAP 2002).

4.1.5 Persistence

Based on laboratory studies, which demonstrated DT_{50} values of < 30 days, α- and ß -endosulfan were not expected to be persistent in soil. However, from field studies, the DT_{50} values in soil reported varied from 3-8 months for technical endosulfan and endosulfan sulphate (Pesticide Manual 2003), to 900 days for ß-endosulfan (IPCS 1984).

Endosulfan is not expected to persist in water (see 4.1.2).

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

Birds

Oral LD_{50} values

- mallard duck *(Anas platyrhynchos*): 6.47 – 245 mg/kg bw. (IPCS 1984; Pesticide Manual 2003)
- ringnecked pheasants (*Phasianus colchicus*): 620-1000 mg/kg bw (Pesticide Manual 2003)

LC_{50} values (5-days diet) (IPCS 1984)

- mallard duck (*Anas platyrhynchos*): 1053 mg/kg feed.
- ringnecked pheasant (*Phasianus colchicus*): 1275 mg/kg feed.
- Japanese quail (*Coturnix coturnix japonica*): 1250 mg/kg feed
- bobwhite quail *(Colinus virginianus*): 805 mg/kg feed

4.2.2 Aquatic species

Endosulfan is very toxic for **fish**.

LC_{50} values for 96% technical endosulfan (IPCS 1984)

- 96- hours LC_{50} rainbow trout : 1.4 µg/l
- 96-hours LC_{50} fathead minnow: 1.5 µg/l
- 96-hours LC_{50} channel catfish: 1.5 µg/l

LC_{50} values for α-endosulfan

- 96-hours LC50 (*Labeo rohita)*: 0.33 µg/l (RIVM)
- 96-hours LC50 (*Mystus vittatus)*: 0.17 µg/l (RIVM)

LC_{50} values for ß-endosulfan:

- 96-hours LC50 (*Labeo rohita)*: 7.1 µg/l (RIVM)

Chronic toxicity

- A 9-weeks No Observed Effect Concentration (NOEC) for reproduction as fry mortality of 0.2 µg/l (expressed as 100 % endosulfan which is equivalent to 0.14 µg/l as α-endosulfan) was determined for the fish *Sarotherdon mossambicus*. (RIVM).

Endosulfan is toxic for **mollusca**.

- EC_{50} (96 hours) 65 µg/l for the marine oyster *Crassostrea virginica*, based on a decrease in shell growth
- LC_{50} (96 hours) 1890 µg/l for adult freshwater snail *Aplexa hypnorum*.

Endosulfan is very toxic for **Crustacea**.

- LC_{50} (96 hours) marine shrimp *(Crangon septemspinosa*): 0.2 µg/l.
- LC_{50} (96 hours) blue crab: 55 µg/l. (IPCS 1984)

- NOEC (64-days, mortality) for *Daphnia magna*: 2.7 µg/l (v.d. Plassche 1994)
- EC_{50} (48 hours) for *Daphnia magna*: 75 – 750 g/l. (Pesticide Manual 2003)

Endosulfan is toxic for **Algae.**

- 14-days NOEC(growth) for *Chlorella vulgaris*: 700 µg/l. (v.d. Plassche 1994)

Annelida.

- LC_{50} (12 days), adult polychaete worm *Nereis nereis*: 100 µg/l. (IPCS 1984)

Protozoa.

- 5-days NOEC (growth) for *Paramecium aurelia*: 100 µg/l. (v.d. Plassche 1994)

Rotatoria.

- LC_{50} (24 hours) freshwater rotifer: 5.15 mg/l. (v.d. Plassche 1994)

4.2.3	**Honeybees and other arthropods**	Endosulfan has a moderate to low toxicity to bees (IPCS 1984) Contact LD_{50}: 7.1 µg/bee. Oral LD_{50} 6.9 µg/bee. Endosulfan was considered non-toxic to bees under field conditions at an application rate of 560 g/ha (1.6 l/ha) (Pesticide Manual 2003). **Aquatic insects** (IPCS 1984) LC_{50} (96 hours) for stonefly (***Pteronarcys californica)***: 2.3 µg/l. EC_{50} (48 hours, immobilisation) for freshwater mite (***Hydrachna trilobata): 2.8 mg/l***
4.2.4	**Earthworms**	NOEC 0.1 mg/kg dw. (Pesticide Manual 2003)
4.2.5	**Soil microorganisms**	No data available
4.2.6	**Terrestrial plants**	Some phytotoxic effects on plants are reported (IPCS 1984) A concentration of 1000 mg a.i./l reduced the germination and length of cucumber pollen to 54.6 and 8.1%, respectively, compared to control. Necrotic spots on the leaves of several species of cucurbitae was found at concentrations ranged from 0.035 – 0.14%. Reduced viability and inhibition on germination was observed in *Cicer arietinum* seeds. Inhibition was reversed at exposure concentrations up to 1 mg/l, but at 10 mg/l inhibition persisted. Endosulfan affected all major stages of germination and seedling growth. *In-vitro* experiments showed dose-related changes of the permeability of root membranes. It should be noted that these *in-vitro* experiments were very isolated. Normal use of endosulfan has not been shown to be significantly toxic to plants.

5 Environmental Exposure/Risk Evaluation

5.1 Terrestrial vertebrates

No risk assessment for non-target terrestrial vertebrates or birds was performed.

5.2 Aquatic species

The Netherlands

The risk evaluation of the use of endosulfan in the Netherlands was performed based on an application rate of 0.75 kg endosulfan/ha for orchards.

Exposure assessment

Endosulfan is typically used on fruit crops as an insecticide in spring and summer, at application rates of 0.75 – 1.5 kg a.i./ha for tall fruit and 0.5 – 1.0 kg a.i./ha for small fruit. The application can be repeated once in the growing season, approximately three weeks later.

The α-isomer of endosulfan is the active component. Technical endosulfan consists of 70% α- and 30% ß-endosulfan. Recalculating the application rate of 0.75 kg/ha to α-endosulfan gives 0.7 x 0.75 = 0.525 kg α-endosulfan/ha.

For the purpose of estimating the amount of a pesticide entering the aquatic environment as a result of spray application using Good Agricultural Practices, the Netherlands determined that, under experimental conditions, an emission of 4% of the application would drift to surface water when no buffer zone is used, and an emission of 0.1% of the application would drift to surface water when a 25 m buffer zone is used. In practice, these values are expected to be exceeded. For application in orchards, an emission of 10% of the application is estimated to drift to surface water.

The following three scenarios are taken into account:

1. no buffer zone and an emission of 4%
2. a buffer zone of 25 m with an emission of 0.1%
3. an emission of 10% and the model SLOOTBOX (Linders *et al*. 1990).

The concentration in surface water of a ditch with a depth of 25 cm is calculated according to:

Concentration (mg/l) = 0.4 x dosage (kg/ha) x emission.

The value of 0.4 is a correction factor for dosage in kg/ha to the concentration in the ditch at 25 cm in mg/l.

The predicted environmental concentrations (PEC) of α-endosulfan in surface water for the three scenarios are:

1. 8.4 µg α-endosulfan/l = 0.4 x 0.525 (kg α-endosulfan/ha) x 0.04
2. 0.2 µg α-endosulfan/l = 0.4 x 0.525 (kg α-endosulfan/ha) x 0.001
3. 14 µg α-endosulfan/l, as determined by the model

Acute toxicity

Effect assessment

The lowest LC_{50} value of α-endosulfan for fish is 0.17 µg/l.
The lowest EC_{50} of technical endosulfan for *Daphnia magna* is 75 µg/l. Calculation of this EC_{50}-value to α-endosulfan gives 0.7 x 75 = 52.5 µg/l.

Risk evaluation

In each of the three scenarios the predicted concentration of α-endosulfan in surface water exceeds the LC_{50} value for fish.

For the risk evaluation, the predicted environmental concentrations (PEC) of α-endosulfan in surface water in the three scenarios were compared to $L(E)C_{50}$ values (see table below). Where the ratio is > 10, severe risk is expected and is considered unacceptable. If the ratio is greater than 1 but less than 10, a large risk can be expected and is also considered unacceptable.

Table with PEC/toxicity ratio for three acute scenarios

Scenario	**Predicted Environmental Concentration surface water (PEC) [mg/l]**	**Fish PEC/LC50 ratio**	**Daphnia magna PEC/EC_{50} ratio**
Scenario 1: no buffer zone	8.4	**49**	0.16
Scenario 2: 25 m buffer zone	0.2	**1.2**	0.004
Scenario 3: Emission of 10%	14	**82**	0.267

Unacceptable ratios are marked in bold.

Field studies performed in Africa confirmed the acute risk of endosulfan to non target organisms. In a comprehensive study, 6 dosages of 6 – 12 g/ha were used. A mortality of 24 – 60% was found for fish, independent of the species. The concentrations in water were ± 1 µg endosulfan/l (0.7 µg α-endosulfan/l), shortly after application.

Chronic Toxicity

Effect assessment

The NOEC for fish is 0.2 µg endosulfan/l., The calculation of α-endosulfan gives a NOEC of 0.14 µg/l (0.7 x 0.2 µg/l). The NOEC for *Daphnia magna* is 2.7 µg endosulfan/lL, which gives a NOEC of 1.89 µg/l for α-endosulfan.

Risk evaluation

Using the two buffer zone scenarios(with and without), and a predicted environmental concentration (PEC) in surface water of 0.2 and 8.4 µg α endosulfan/l, respectively, the concentrations in surface water three weeks after application, (using a DT_{50} of 3 weeks) would be expected to be 0.1 and 4.2 µg α endosulfan/l, respectively.

Table with PEC/toxicity ratio for two chronic scenarios.

Unacceptable ratios are marked in bold.

	Predicted Environmental Concentration after 3 weeks [mg/l]	**Fish PEC /NOEC ratio**	**Daphnia magna PEC /NOEC ratio**
Scenario 1 no buffer zone	0.1	0.7	0.05
Scenario 2 25 m buffer zone	4.2	**30**	**2.22**

In case of a ratio > 1, large risks are expected at multiple applications. This is the case in scenario 2 (without a buffer zone).

Thailand

The risk evaluation undertaken by Thailand was based on a field survey, and included observations of the death of fish and other aquatic organisms after application of EC and GR formulations of endosulfan in paddy fields used to control golden apple snails. The risk evaluation also took into account hazard information taken from internationally recognized sources.

Exposure assessment

A survey was carried out by the Thai authorities during March 1999 and April 2000 in 5 provinces (Pathum Thani, Supan Buri, Nontha Buri, Nakorn Pathom, Cha Choengsao) located in three major basins and connected to natural surface water.

The study involving, 234 farmers, showed that 60–76 % of the farmers used endosulfan to control golden apple snail control in paddy fields. It revealed that on average, endosulfan (EC) was applied at a concentration of 50-100 cc per rai (1 ha = 15.44 rai or 1 acre = 6.25 rai) per application by 40.6% of farmers, while concentrations of 101-150 cc per rai and 151-200 cc per rai were applied by 18.8% and 17.9% of farmers, respectively. Granule formulations (GR) of endosulfan at a concentration of 1to 3 kg per rai ware used by 27.6%, 2.2%, and 2.2% of farmers in Nontha Buri, Nakorn Pathom, and Pathum Thani, respectively. The substance was applied one to three times in each rice crop. Most farmers apply endosulfan after sowing.

After the application of endosulfan (after 1 to 3 days, to more than 7 days) the water was released from the paddy field into irrigation channels, rivers, and canals.

Effect assessment

It was observed by 75-89% of the farmers () that the use of endosulfan causes the death of non-target organisms such as fish, frog and snake. Shrimp, crab, rat, eel, and toad mortality was also observed by some farmers after the use of endosulfan. On average, 84.2%, 62.4%, 60.7%, 15.4%, and 12.4% of farmers reported the death of fish, snake, frog, bird, and shrimp, respectively, while very few farmers (0.4%-1.7%) reported the death of crab, rat, eel, and toad. On average, 65.4% of farmers observed the death of fish in rivers and canals after the application of endosulfan.

5.3 Honey bees

No risk assessment was performed.

5.4 Earthworms

No risk assessment was performed.

5.5 Soil microorganisms

Normal agricultural use of endosulfan will not cause effects on the carbon and nitrogen mineralization cycle in soil.

5.6 Summary – overall risk evaluation

Netherlands

A risk assessment for the aquatic compartment was performed in the Netherlands based on the application rates approved for fruit crops using various use scenarios.

- The predicted environmental concentrations in surface water ranged from 0.2 to 14 µg α-endosulfan/l, which exceeds the lowest LC_{50} value of 0.17 µg α-endosulfan/l for fish. Exposure / toxicity ratios for three application scenarios were calculated to be above 1, resulting in an unacceptable acute risk for non-target aquatic species.

- Further calculation found that the levels in surface water three weeks after application could range from 0.1-4.2 µg α-endosulfan/l, which would exceed the NOEC for fish and *Daphnia magna* of 0.14 µg α-endosulfan/l

and 1.89 µg α-endosulfan/l , respectively. Exposure / toxicity ratios for one scenario was calculated to be above 1, resulting in an unacceptable chronic risk for non-target species.

It was concluded that the risks to the aquatic environment, in particular fish, was unacceptable.

Thailand

A field survey of the farmers using emulsifiable concentrates and granular formulations of endosulfan to control golden apple snail in rice paddies found that the impact on non-target organisms in the aquatic environment, in particular for fish, was unacceptable.

Annex 2 – Details on final regulatory actions reported

Country Name: Thailand

1	**Effective date(s) of entry into force of actions**	From 19th of October 2004: registration of GR and EC formulations of endosulfan is cancelled.
	Reference to the regulatory document	Notification of the Ministry of Industry, dated 30 September 2004. Published in the Royal Gazette volume no 121, special section 118 Ng dated. 18 October 2004.
2	**Succinct details of the final regulatory action(s)**	Endosulfan was severely restricted in that formulations other than capsule Suspension (CS) had been prohibited for import, production, having in possession and use as agriculture pesticide. CS formulation is registered for use in cotton only.
3	**Reasons for action**	The unacceptable risk for aquatic organisms, especially for fish.
4	**Basis for inclusion into Annex III**	Final regulatory action to severely restrict endosulfan based on a risk evaluation taking into account the normal pattern of use in Thailand and the effects caused by the application of the substance.
4.1	**Risk evaluation**	It was concluded that the risk for aquatic organisms was unacceptable if used to fight golden apple snail in paddy rice systems.
4.2	**Criteria used**	Risk to the environment
	Relevance to other States and Region	Of special concern to the neighbouring countries due to the same pest problems.
5	**Alternatives**	Control of golden apple snails applied by the farmers in Thailand include destruction of adult snails and eggs, use of nets to prevent snails entry into rice field and pasturing ducks in the rice paddies between the growing seasons.
6	**Waste management**	No specific measures outlined
7	**Other**	

Country Name: The Netherlands.

1	**Effective date(s) of entry into force of actions**	From 28 February 1990, registration of endosulfan was withdrawn.
	Reference to the regulatory document	Decision of De Voorzitter van het College van Beroep voor het Bedrijfsleven No. 89 2403/060/029 (in Dutch). (English translation available)
2	**Succinct details of the final regulatory action(s)**	Placing on the market, to sell and use products containing endosulfan is prohibited.
3	**Reasons for action**	The unacceptable acute risk for aquatic organisms, especially for fish.
4	**Basis for inclusion into Annex III**	Final regulatory action to ban endosulfan was based on a risk evaluation taking into consideration local conditions.
4.1	**Risk evaluation**	It was concluded that the use of endosulfan would pose an unacceptable risk to the environment (especially fish).
4.2	**Criteria used**	Exposure/ effect ratio for the environment.
	Relevance to other States and Region	Of special concern to developing countries due to the high environmental risk associated with spraying of endosulfan, even when Good Agricultural Practices (GAP) are employed.
5	**Alternatives**	Carbaryl and bromophos for insect control (apple blossom beetle and apple sawfly) in apples; diflubenzuron, teflubenzuron and fenoxycarb against caterpillars; pirimicarb against aphids; and fenbutatinoxide against rust acarids.
6	**Waste management**	The Netherlands avoided creating stockpiles of endosulfan by taking a stepwise approach to the phase-out.
7	**Other**	

Annex 3 – Addresses of designated national authorities

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Annex 4 – References

Final Regulatory Actions

The Netherlands

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