

Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

Decision Guidance Document

ENDOSULFAN



**Secretariat of 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 chemicals¹ 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 Parties² 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 or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the 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 fifth meeting, held in Geneva from 20 to 24 June 2011, 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 designated national authorities on 24 October 2011, 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 make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (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.

1 According to the Convention, the term “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.

2 According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Disclaimer

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

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise 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.

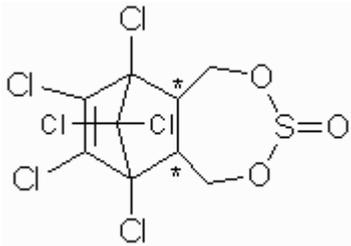
STANDARD CORE SET OF ABBREVIATIONS

<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
µg	Microgram
µm	Micrometre
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
ADP	adenosine diphosphate
AMAP	Arctic Monitoring and Assessment Programme
AOEL	acceptable operator exposure level
APVMA	Australian Pesticides and Veterinary Medicines Authority
ATP	adenosine triphosphate
a.s.	active substance
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CA	Chemicals Association
CAS	Chemical Abstracts Service
cc	Cubic centimetre
CHO	Chinese hamster ovary
CILSS	Permanent Interstate Committee for Drought Control in the Sahel
cm	centimetre
CSP	Sahelian Pesticides Committee
DNA	Deoxyribose Nucleic Acid
DT	Degradation time
E.C.	European Community
EC ₅₀	Effect concentration, 50%
ED ₅₀	Effect dose, 50%
EEC	European Economic Community
EHC	Environmental Health Criteria
FAO	Food and Agriculture Organization of the United Nations
g	Gram
h	hour
ha	Hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC ₅₀	inhibition concentration, 50%;
ILO	International Labour Organisation
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of

STANDARD CORE SET OF ABBREVIATIONS

	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
m	Metre
m.p.	melting point
mg	Milligram
ml	Millilitre
mPa	MilliPascal
MTD	maximum tolerated dose
ng	Nanogram
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NOEC	no-observed-effect concentration
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
PCM	Phase contrast microscopy
PEC	Predicted Environmental Concentration
PIRI	Pesticide Impact Rating Index
Pow	octanol-water partition coefficient
PPE	Personal protective equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).
RfD	reference dose for chronic oral exposure (comparable to ADI)
SMR	standardized mortality ratio
STEL	short term exposure limit
TER	toxicity exposure ratio
TLV	threshold limit value
TWA	time weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
VOC	volatile organic compound
WHO	World Health Organization
wt	Weight

1. Identification and uses (see Annex 1 for further details)

Common name	Endosulfan
Chemical name and other names or synonyms	<p>ISO: endosulfan</p> <p>IUPAC: (1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-en-2,3-ylenebismethylene) sulfite,</p> <p>CAS name: 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin- 3-oxide</p>
Molecular formula	C ₉ H ₆ Cl ₆ O ₃ S
Chemical structure	
CAS-No.(s)	115-29-7
Harmonized System Customs Code	2920 90
Other numbers	<p>EINECS: 2040794</p> <p>OPP chemical code: 079401</p> <p>E.C. customs code: 2920 90 85</p>
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	<p>Endosulfan was used in the European Community as a non-systemic insecticide with acaricidal properties on arable crops and in greenhouses in agriculture, horticulture, orchards, forestry and nurseries to control numerous chewing, sucking and boring insect pests and mites in a wide variety of crops including 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.</p> <p>In Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal, endosulfan was used as an insecticide and/or acaricide in cotton production to control pests, e.g. <i>Helicoverpa armigera</i>, and cotton mites.</p>
Trade names	<p>Benzoepin, Beosit, Caiman, Callistar, Captus, Chlorthiepin, Cyclodan, Endo 35 EC, Endocel 35 EC, Endocoton, Endofan, Endosan EC, Endosulfan 35 EC, Endozol, FAN 35, Farnoz, FMC 5462, Hildan 35 EC, Insectophene, Kop-thiodan, Malix, Mistral, Nufarm Endosulfan 350EC, Phaser, Plexus, Rocky, Termicidol, Thiodan, Thifor, Thiofanex, Thiomul, Thiosulfan, Tionel, Tiovel, Thionex, Thimul, Thyonex</p> <p><i>This is an indicative list. It is not intended to be exhaustive.</i></p>
Formulation types	<p>Endosulfan is available in a variety of formulations, such as a wettable powder (WP), granules (GR), emulsifiable concentrations (EC), capsule suspension (CS), dustable powder (DP) and ultra low volume liquid (UL).</p> <p>Technical endosulfan consists of a mixture of α and β isomers in the approximate ratio of 2:1</p>
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, Aimco Pesticides limited, Bayer Crop Science, Becot Pty Ltd., Coromandel Fertilisers, Drexel, Excel Crop Care, Farnoz Pty Ltd., FMC Corporation, Gowan, Hindustan Insecticides, Huangma Agrochemical Co, Jiangsu Kuaida Agrochemical Co, Jiangsu Xuzhou Shengnong Chemicals Co, Luxan, Makhteshim-Agan, Milenia, Parry, Pivot Ltd., Platte Chemical, Seo Han, Sharda, Zhangjiagang Tianheng Chemical Co..

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 European Community, Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal to ban endosulfan as a pesticide.

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

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

European Community:

Endosulfan is not included in the list of authorised active ingredients in Annex 1 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, under specific conditions, in specific Member States (listed in the Annex to the Commission Decision 2005/864/EC) a prolonged period of withdrawal of existing authorisations was allowed until 30 June 2007. The period of grace for use of existing stocks expired on 2 June 2007 and for essential uses on 31 December 2007 (see section 3.1).

Reason: Human Health and Environment

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal:

The Sahelian Pesticide Committee (8 May 2007) recommended that endosulfan be prohibited for use in agriculture. In line with the Common Regulations of the Member States of CILSS on the registration of Pesticide (Resolution No: 08/34/CM/99) taken by the Council of Ministers of CILSS in 1999 in N'Djamena Tchad, and based on the recommendation by the Sahelian Pesticide Committee Le Ministre Coordonnateur du CILSS decided to prohibit the use of endosulfan in agriculture. Taking into account the necessary delay for the use of existing stocks, the decision entered into effect for distribution on 13 November 2007 and 31 December 2008 for use.

Reason: Human Health and Environment

2.2 Risk evaluation (see Annex 1 for further details)

European Community:

Directive 91/414/EEC provided 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 inclusion in Annex I to that Directive. Within this context, a number of companies notified their wish to secure the inclusion of endosulfan as an authorized active ingredient.

A risk assessment of endosulfan was carried out by a Member State, based on the dossier submitted by companies wishing to include endosulfan in Annex 1 to Directive 91/414/EEC. The results were reviewed by the Member States and the European Commission within the Standing Committee on the Food Chain and Animal Health (SCFAH). Unacceptable risks were identified in the following areas:

Human health:

Occupational: Using common 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 Acceptable Operator Exposure Level (AOEL), even when using standard Personal Protective Equipment (PPE). Exposure of operators under indoor conditions was not considered to have been sufficiently addressed with the available information.

Environmental impact:

During the evaluation of this active substance, a number of areas of concern were identified. In the case of environmental fate and behaviour, 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 for long range transport and potential for bioaccumulation were objects of concern. Using no-observed-effect concentration (NOEC) values for the most sensitive aquatic organism, fish, after spray drift and run-off entry, for different crop uses (cotton, tomatoes and arable crops), the Toxicity Exposure Ratios (TER) indicated a potential long-term risk to fish, even assuming large buffer zones. There were also potentially high risks to terrestrial birds and mammals, honey bees and earthworms.

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal:

The Sahelian Pesticides Committee (CSP) is the pesticide registration authority for nine CILSS member states (CILSS: Permanent Interstate Committee for Drought Control in the Sahel). This Committee conducted a risk evaluation for the use of endosulfan in cotton in the Sahelian countries.

Human health:

Endosulfan has a high acute oral toxicity and is classified as “moderately hazardous” by the WHO. Reviews of endosulfan use on cotton in Australia and the USA at application rates comparable to those used in the Sahel led to strict measures to reduce occupational exposure to acceptable levels in those countries. In Australia only authorised persons with a pesticide applicator license may apply endosulfan containing products. Applicators are required to wear full personal protective equipment (PPE) including overalls closed at the neck and wrists and when filling the sprayer to also wear long PVC gloves and a respirator with complete face mask. In the USA applicators must wear overalls over a long-sleeved shirt and trousers as well as chemical resistant shoes and gloves and a respirator; further engineering measures are in place to reduce exposure during mixing and loading.

In the Sahel, endosulfan is applied to cotton generally twice per season using handheld and sometimes backpack sprayers by farmers, generally without any specialised training or personal protective equipment. Application rates in the Sahel are comparable to those in Australia and the USA although the concentration of endosulfan in the material sprayed is higher. In the light of the risk mitigation measures in place in Australia and the USA it was concluded that the occupational risk to farmers from using endosulfan in cotton under the conditions in the Sahel were considered unacceptable. It was further observed that many dwellings in the Sahel were surrounded by cotton fields which could lead to unacceptable bystander exposure.

Environment:

Endosulfan is highly toxic to fish and certain aquatic invertebrates. Reviews in both Australia and the USA, at application rates to cotton comparable to those used in the Sahel, led to strict measures to reduce contamination of surface waters. In the USA, such measures include general buffer zones of up to 33 m and vegetated buffer zones of 10 m between treated plots and surface waters. In Australia the required mitigation measures include the avoidance of spray drift onto adjacent areas and water bodies, no applications if heavy rains or storms that are likely to cause surface runoff are forecasted within two days and no applications during hot weather conditions (temperatures >30°C).

In the cotton growing areas of the Sahel, surface waters are abundant and are often situated adjacent to cotton fields, particularly during the rainy season when treatments are carried out. The rainy season is characterized by hot temperatures and heavy rainstorms of which the locality and timing are difficult to predict. The conditions thus make it virtually impossible to put in place comparable risk reduction measures such as those required in Australia or the USA. Given the high toxicity of endosulfan to aquatic fauna, the risk of surface water exposure in the cotton growing areas of the Sahel and taking into account the risk mitigation measures required under similar conditions in Australia and the USA, it was concluded that the risks to the environment from endosulfan under the conditions of use in the Sahel were unacceptable.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

European Community The ban of endosulfan as an active ingredient in plant protection products reduces the exposure of operators and the environment, including the aquatic environment and non-target organisms to this chemical.

All uses as plant protection products had been prohibited by the regulatory action, including the essential uses listed below, for which the prohibition was delayed.

Authorisations for essential uses may have been 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 have granted a period of grace for disposal, storage, placing on the market and use of existing stocks that had to expire no later than 2 June 2007. For essential uses that could have continued to be authorised until 30 June 2007, the grace period for disposal, storage, placing on the market and use of existing stocks was 6 months (i.e. up to 31 December 2007).

List of essential uses that may have continued to be authorised:

<u>Member State</u>	<u>Use</u>
Greece	Cotton, tomato, peppers, pears, potato, alfalfa
Spain	Hazel nut, cotton, tomato
Italy	Hazel nut
Poland	Hazel nut, strawberry, gerbera, ornamental bulbs

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger, Senegal 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 human health and the aquatic environment.

3.2 Other measures to reduce exposure

European Community:

None

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal:

None

General

None

3.3 Alternatives

It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

European Community:

There was no detailed assessment conducted on the alternatives to endosulfan.

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal:

Alternative products are registered formulations containing profenofos, indoxacarb, spinosad and malathion.

General

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) and organic strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through National IPM focal points, the FAO, IFOAM (International Federation of Organic Movements), 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.

3.4 Socio-economic effects

European Community

There was no detailed assessment conducted on the socio-economic effects of a ban of endosulfan.

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal:

No detailed assessments of socio-economic effects were undertaken.

4. Hazards and Risks to human health and the environment

4.1 Hazard Classification

WHO / IPCS	Toxicity Class II (moderately hazardous)
IARC	Not evaluated
European Community	Classification in accordance with Council Directive 67/548/EEC: T+ (Very Toxic) Xn (Harmful) N (Dangerous for the environment) Risk phrases: R26/28 (Very toxic by inhalation and if swallowed) R21 (Harmful in contact with skin) R50/53 (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

E.C. 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).

Acceptable Operator Exposure Level (AOEL) = 0.0042 mg/kg bw/day (based on the NOAEL of 0.6 mg/kg bw/day from the 104 week oral rat study and applying a correction factor for oral absorption of 70 % and an uncertainty factor of 100 to account for inter- and intraspecies variation).

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).

US EPA:

Acute RfD = 0.015 mg/kg/day (based on NOAEL of 1.5 mg/kg bw/day and an uncertainty factor of 100)
Chronic RfD = 0.006 mg/kg/day (based on NOAEL of 0.6 mg/kg bw/day and an uncertainty factor of 100)
Drinking water: Maximum allowable water exposure: 0.0003 mg/kg/day for US population

FAO/WHO:

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 0.02 mg/kg bw (JMPR 1998).

WHO Drinking Water Guidelines: a health-based value of 20 µg/l can be calculated for endosulfan on the basis of an ADI of 0.006 mg/kg bw (WHO 2003). However, because endosulfan occurs in drinking-water at concentrations well below those at which toxic effects are observed, it was not considered necessary to derive a guideline value (WHO, 2004a).

4.3 Packaging and labelling	
The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:	
Hazard Class and Packing Group:	Hazard class: UN: 6.1 Packing class: 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.

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 European Community 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.

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal avoided creating stockpiles of endosulfan by taking a stepwise approach to the phase-out of permitted uses.

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, and to contain effluent from fire extinguishing. (IPCS, 1988)

Annexes

- Annex 1 **Further information on the substance**
- Annex 2 **Details on Final regulatory action**
- Annex 3 **Address of designated national authorities**
- Annex 4 **References**

Introduction

The information presented in this Annex reflects the conclusions of the notifying parties: the European Community and Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal. These eight African countries are members of the Sahelian Pesticides Committee. The members of the Committee work together to take decisions on the registration of pesticides on a regional basis and the eight notifications refer to the same final regulatory action. The notification from the European Community was published in PIC Circular XXIV of December 2006. The notifications from Burkina Faso, Cape Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal were published in PIC Circular XXVIII of December 2008.

Where possible, information on hazards provided by the notifying parties has been presented together, while the evaluation of the risks, specific to the conditions prevailing in the notifying Parties are presented separately. This information has been taken from the documents referenced in the notifications in support of their final regulatory actions to ban endosulfan and includes the monograph on the Review of endosulfan by the European Community published in 2005; reviews of endosulfan by the US EPA (2002) and Australian authority (APVMA, previously known as the NRA (2005, 1998)) which were used to support the risk evaluation under taken by the Sahelian Pesticides Committee, as well as, the Evaluation of mammalian toxicology published by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in 1998.

Some of the conclusions from the international Arctic Monitoring and Assessment Programme (AMAP) Assessment in 2002 have been presented in this document. These results do not differ substantially from the information provided by the notifying countries, but the AMAP report provides additional data on the environmental fate in air and the potential for bioconcentration/bioaccumulation (Sections 4.1.3 and 4.1.4).

A recent risk profile on endosulfan from POPRC is available since October 2009 (POPRC (Stockholm Convention on Persistent Organic Pollutants POPs Review Committee, October 2009): Endosulfan. Risk profile.

Annex 1 – Further information on notified chemical

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-benzodioxathiepin-3-oxide
1.2	Formula	C ₉ H ₆ Cl ₆ O ₃ S
1.3	Colour and Texture	Flakes with tendency to agglomeration, cream to tan, mostly beige crystals
1.4	Decomposition temperature	Mixture of isomers (99 %): Possibly reaction of decomposition at about 218 °C.
1.6	Density (g/cm³)	1.745 g/cm ³ at 20°C 1.87 g/cm ³ at 20°C (purified endosulfan)
1.7	Resistance to acids	endosulfan is sensitive to acids
1.8	Resistance to alkalis	endosulfan is sensitive to alkalis
1.9	Tensile strength (10³ kg/cm²)	No information available

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 include: vomiting, agitation, convulsions, cyanosis, dyspnoea, foaming at the mouth and noisy breathing.
2.1.3	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, dosed for 7 days, 3.7 and 4.7 % remained in organs and tissues (male and females, respectively); 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 in rats (within 120 hours) is mainly via faeces (65-82 % males, 60-72 % females) with urine accounting for 11-13 % in males and 2-24 % in females (E.C., 2005).

2.2 Toxicology studies

- 2.2.1 Acute toxicity** The LD₅₀ 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 showed that it is highly toxic after oral or inhalation administration and has low acute dermal toxicity (E.C., 2005, EPA, 2002 and IPCS, 1984): **Oral LD₅₀** values for rats from 10 - 355 mg/kg bw (lowest figure for females only),
- **Dermal LD₅₀** values for rats from 74 mg/kg bw in females to > 4000 mg /kg bw in males,
 - **Inhalation LC₅₀ value:** 0.0126 mg/l (12.6 mg/m³) for female rats, to 0.5 mg/l (sex and species not specified),
- Irritation and sensitization:** Endosulfan is classified as harmful in contact with skin and not irritating to eyes according to E.C. criteria. It is not classified as a contact skin allergen/sensitizer (E.C., 2005). US EPA classified endosulfan as an eye irritant and a skin non-irritant/sensitizer.
- Clinical signs of acute intoxication include piloerection, salivation, hyperactivity, respiratory distress, diarrhoea, tremors, hunching, and convulsions (JMPR 1998).
- 2.2.2 Short term toxicity** Rats (dermal, 21-28 days): NOAEL = 3 - 12 mg/kg bw/day (clinical signs and mortality, lowest figure for males only).
Rat (nose-only-inhalation, 29 days): NOEL = 0.002 mg/l (no effects observed at the highest dose tested, E.C., 2005).
Rat (21-days inhalation): NOAEL = 0.001 mg/l equivalent to 0.2 mg/kg/day (US EPA, 2002)
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).
Beagle dogs received concentrations in the diet of 3, 10, and 30 ppm (equivalent to 0.23, 0.77 and 2.3 mg/kg bw/day) for 1 year. A LOAEL of 2.3 mg/kg bw/day was observed based on clinical signs (violent contractions of the abdominal muscles) and reduction in body weight gain. The NOAELs were 0.65 mg/kg bw/day for males and 0.57 mg/kg bw/day for females (E.C., 2005).
- 2.2.3 Genotoxicity (including mutagenicity)** 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 (E.C., 2005).
- 2.2.4 Long term toxicity and carcinogenicity** Male & female rats (dietary, 104 weeks): NOAELs = 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): NOAELs = 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).
- No carcinogenic potential was observed in either of the chronic studies outlined above or in the 1-year Beagle dog study.

2.2.5 Effects on reproduction

Rat (dietary, 2 generation reproduction study):
Male & female reproductive NOAELs = 5 and 6 mg/kg bw/day, respectively (no effects observed at the highest dose tested),
Paternal & maternal NOAELs = 1 and 1.23 mg/kg bw/day, respectively (histopathological effects and organ weight changes).

Rat (oral gavage, developmental teratology study):
Developmental NOAEL = 2 mg/kg bw/day (reduced foetal weight and length and significant skeletal variations (no teratogenic effects observed)),
Maternal NOAEL = 0.66 mg/kg bw/day (clinical signs (face rubbing and alopecia) and reduced body weight gain).

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

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

2.2.6 Neurotoxicity/delayed neurotoxicity, Special studies where available

Hens (oral, acute delayed neurotoxicity): no clinical signs of neurotoxicity were observed at the LD₅₀ 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).

2.2.7 Summary of mammalian toxicity and overall evaluation

Endosulfan is not classified as being either an endocrine disrupter or an immunotoxicant.

WHO has classified endosulfan as moderately hazardous (WHO 2004b). The LD₅₀ of endosulfan varies widely depending on the route of administration, species, vehicle, and sex of the animal. Endosulfan is highly toxic after oral or inhalation administration and has low acute dermal toxicity (E.C., 2005). Clinical signs of acute intoxication include piloerection, salivation, hyperactivity, respiratory distress, diarrhoea, tremors, hunching, and convulsions. Endosulfan was neither 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 clear 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 (E.C., 2005).

From the **E.C. Risk Assessment**, the following exposure limits were derived:

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).

Acceptable Operator Exposure Level (AOEL) = 0.0042 mg/kg bw/day (based on the NOAEL of 0.6 mg/kg bw/day from the 104 week oral rat study and applying a correction factor for oral absorption of 70 % and an uncertainty factor of 100 to account for inter- and intraspecies variation).

Acute Reference Dose (RfD) = 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).

US EPA:

Acute RfD = 0.015 mg/kg/day (based on NOAEL of 1.5 mg/kg bw/day and an uncertainty factor of 100)

Chronic RfD = 0.006 mg/kg/day (based on NOAEL of 0.6 mg/kg bw/day and an uncertainty factor of 100)

Drinking water: Maximum allowable water exposure: 0.0003 mg/kg/day for US population

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** **European Community**
A number of outside and indoor operator scenarios were used to calculate the potential exposure of operators to endosulfan (E.C., 2005). Using the German BBA model, exposure during mixing and loading and spray application was estimated, then the amount potentially absorbed and inhaled was calculated. This exposure was then compared to the AOEL (0.0042 mg/kg bw/day) to decide whether a potential use was acceptable.

The following scenarios were accepted for establishing the final endpoints of the European Community risk evaluation based on the use of Thiodan EC 35:

Scenario 1: field crop (cotton, tomatoes) sprayed with tractor mounted hydraulic nozzle, low crop

Scenario 2: Greenhouse (tomatoes) sprayed with tractor mounted hydraulic nozzles, high crop.

It was predicted that in Scenario 2 there was the potential for the exposure to exceed the AOEL (119 %) leading to a risk to the operator.

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal

Endosulfan is applied to cotton at 300-750 g ai/ha generally twice per cotton growing season. As a rule it is sprayed in very low volumes, at about 10 litres of diluted product per hectare using handheld and sometimes backpack sprayers by the farmers themselves. Applicators generally use little if any protective equipment because of limited financial resources or because the climate is too hot to wear it.

In Australia endosulfan may be used in cotton at a dose rate of 735 g ai/ha up to three times per season. The product is applied in a volume of water of at least 50 litres per ha generally using vehicle or tractor mounted sprayers. The product is only used by authorized persons having a pesticide applicator licence and under the condition that applicators wear full personal protective equipment including overalls closed at the neck and wrists, in addition, when filling the sprayer, long PVC gloves and a respirator with a complete face mask must also be worn.

In the USA endosulfan may be applied at a maximum dose rate of 1700 g ai /ha. For applications with pressurised backpack sprayers, overalls worn over a long-sleeved shirt and trousers as well as chemical resistant shoes and gloves and a respirator are required. Engineering measures, such as closed mixing and loading systems or tractors/vehicles with closed cabs are also recommended.

In the Sahel, while overall dose rates are comparable to those in Australia and the USA, mixers and applicators are exposed to more concentrated spray solutions due to the low spray volumes used. In light of the absence of PPE and engineering measures required in Australia and the USA to mitigate the risks associated with the use of endosulfan in cotton, and the limited training of Sahelian farmers in judicious pesticide use, the risks of occupational exposure in the Sahel were considered unacceptable.

In addition in Sahel countries human dwellings may often be found adjacent to cotton fields. As a result there are unacceptable risks to bystanders from the use of endosulfan in cotton.

Other reported occupational exposure

Poisoning of three workers not 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).

3.5 Medical data contributing to regulatory decision 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 **European Community** has conducted a risk evaluation of the human health effects of endosulfan. An assessment of the potential exposure of operators to certain scenarios led to the conclusion that operators may be exposed to levels of endosulfan above the acceptable operator exposure level (AOEL).

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal: In countries like the USA and Australia endosulfan may only be used by trained operators with full personal protective equipment (PPE; full overalls, chemical resistant shoes and gloves, respirator etc.). In the Sahelian countries farmers do not have access to PPE or training. In conclusion, the risk for operators and for families who have their habitations in or near cotton fields was considered unacceptable.

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

In a 9 month field dissipation study in which endosulfan was applied once in accordance with its use pattern as insecticide, 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 to 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 of > 200 days. Volatilisation from soil also occurs. The non-extractable residue after 200 days is < 20 % (E.C., 2005).

4.1.2 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 was not considered significant 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.

- 4.1.3 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 (E.C., 2005).
- 4.1.4 Bioconcentration** The endosulfan α and β isomers have log Kow values of 4.77 and 4.55, 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; E.C., 2005). The BCF (bioconcentration factor) is between 2500 and 11583 and with a log Kow of 4.7, this indicates a high potential to bioaccumulate. However, the clearance is very rapid ($CT_{50} = 2$ days, $CT =$ clearance time), so the real risk of biomagnification is assumed to be lower.
- 4.1.5 Persistence** Based on laboratory studies, which demonstrated DT_{50} values of < 30 days, α - and β -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 sulfate (Pesticide Manual 2003), to 900 days for β -endosulfan (IPCS 1984; E.C., 2005). The estimated half-lives for the combined toxic residues (endosulfan plus endosulfan sulfate) ranged from roughly 9 months to 6 years. (US EPA, 2002). Endosulfan is not expected to persist in water, except under acidic conditions, where half-lives can reach > 200 days (estimate, see 4.1.2).
- 4.2 Effects on non-target organisms**
- 4.2.1 Terrestrial vertebrates**
- 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 (805 ppm).
Reproductive: Mallard duck (*Anas platyrhynchos*, >20 week dietary study) NOEL = 4 mg/kg bw/day (30 ppm).
- 4.2.2 Aquatic 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 μ g/l
Zebra fish (*Brachydanio rerio*): 24 hours LC_{50} (semistatic) = 1.6 μ g/l
Common carp (*Cyprinus carpio*): 96 hours LC_{50} (semistatic) = 0.1 μ g/l
Rainbow trout (*Oncorhynchus mykiss*): 96 hours LC_{50} (static) = 0.3 μ g/l
Median estimate for 95 % of fish species: LC_{50} 0.13 μ g/l (acute)
- Rainbow trout (*Oncorhynchus mykiss*): 21 days NOEC (juvenile growth test) = 0.05 μ g/l
Sheepshead minnow (*Cyprinodon variegatus*): 28 d NOEC (early life stage) = 0.4 μ g/l
Fathead minnow (*Pimephales promelas*): NOEC (life cycle) = 0.2 μ g/l
- Water flea (*Moina micrura*): 24 hours LC_{50} (static) = 16.2 μ g/l
Water flea (*Daphnia magna*): 48 hours LC_{50} (static) = 62 μ g/l
Water mite (*Hydrachna trilobata*): 48 hours LC_{50} (static) = 2.8 μ g/l
Scud (*Gammarus lacustris*): 96 hours LC_{50} (static) = 5.8 μ g/l
Prawn (*Caridina weberi*): 96 hours LC_{50} (static) = 5.1 μ g/l
Stonefly (*Pteronarcys californica*): 96 hour $LC_{50} = 2.3$ μ g/l
Eastern Oyster (*Crassostrea virginica*): 96 hour $LC_{50} = 0.45$ μ g/l
Water flea (*Daphnia magna*): 21 days NOEC (unspecified) = 63 μ g/l

Green algae (*Scenedesmus subspicatus*): 72 hours NOEC (growth inhibition) = 560 µg/l

Sediment species

True midges (*Chironomus tentans*): 96 hours LC₅₀ (sediment test) = 20 µg/kg
NOEC = < 6 µg/kg

Polychaete (*Streblospio benedicti*): 7 days NOEC (sediment test) = < 50 µg/kg

Information from the open literature has indicated that amphibians exposed to endosulfan exhibited impaired development of tadpoles into adults (EPA, 2002)

4.2.3 Honeybees and other arthropods

Acute oral toxicity: LD₅₀ = 2 µg a.s./bee (based on formulated product)

Acute contact toxicity: LD₅₀ = 0.82 µg a.s./bee (based on formulated product) (E.C., 2005)

Metasyrphus corollae (Syrphidae) (contact toxicity, topical application): LD₅₀ (72 h) > 250 µg/organism

Coccinella septempunctata (Coccinellidae) (contact toxicity, topical application): LD₅₀ (72 h) = 5.31 µg/organism

Tachyporus hypnorum (Staphylinidae) (contact toxicity, topical application): LD₅₀ (72 h) = 0.2 µg/organism

Notiophilus biguttatus (Carabidae) (contact toxicity, topical application): LD₅₀ (72 h) = 6.41 µg/organism

4.2.4 Earthworms

Subchronic toxicity: Earthworm (*Eisenia foetida*; 14 day study) LC₅₀ = 11 mg/kg (geometric mean of validated data)

A field study investigated the effects of endosulfan 35% EC on earthworms in a semi-arid tropical grassland. The results showed that no earthworms were recorded in plots treated with the high dose of endosulfan (1.2 l/ha) until 80 days after treatment, and the earthworm abundance was reduced significantly in the plots treated with the normal dose (0.4 l/ha).

4.2.5 Soil microorganisms

There is no long-term influence on soil microflora when endosulfan sulphate is applied at up to 11.2 mg/kg soil dry weight (E.C., 2005).

Aerobic activated sludge bacteria (unspecified): 3 hours EC₂₀ & EC₅₀ (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 (E.C., 2005).

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 to 54.6 and 8.1 %, respectively, compared to control.

Necrotic spots on the leaves of several species of cucurbitae was found at concentrations ranging 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

European Community

The Toxicity Exposure Ratio (TER) is a ratio of the toxicity of a chemical to a test organism (LD₅₀ or NOEL), and the predicted exposure to the substance. TERs were derived for acute, short-term and long-term toxicity to terrestrial vertebrates for application to a number of different crops (E.C., 2005).

Toxicity based on:

Mammals: Acute Rat LD₅₀: 10 mg/kg bw/day

Long-term Rat NOEL: 2.5 mg/kg bw/day

Birds: Acute Mallard duck LD₅₀: 28 mg/kg

Dietary toxicity Bobwhite quail LD₅₀: 161 mg/kg/bw/day

Reproductive toxicity NOEL: 4 mg/kg bw/day

Application rate (kg as/ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.784	Cotton	Medium herbivorous birds	Acute	0.54	10
0.784	Cotton	Medium herbivorous birds	Short-term	6.75	10
0.784	Cotton	Medium herbivorous birds	Long-term	0.31	5
0.525	Tomatoes	Medium herbivorous birds	Acute	0.8	10
0.525	Tomatoes	Medium herbivorous birds	Short-term	10.08	10
0.784	Cotton	Insectivorous birds	Acute	0.67	10
0.784	Cotton	Insectivorous birds	Short-term	10.66	10
0.784	Cotton	Insectivorous birds	Long-term	2.96	5
0.525	Tomatoes	Insectivorous birds	Acute	1	10
0.525	Tomatoes	Insectivorous birds	Short-term	16.1	10
0.525	Tomatoes	Insectivorous birds	Long-term	4.39	5
0.784	Cotton	Medium herbivorous mammal	Acute	0.52	10
0.784	Cotton	Medium herbivorous mammal	Long-term	0.43	5
0.525	Tomatoes	Medium herbivorous mammal	Acute	0.78	10
0.525	Tomatoes	Medium herbivorous mammal	Long-term	0.64	5

The Trigger values are set in Annex VI of Directive 91/414/EEC, which provides for the detailed safety requirements for placing of plant protection products on the market. The trigger values indicate acceptable risks for exposure. Those TERs that are below the Trigger (in bold), indicate that risks are not acceptable. Therefore, these results indicate a potentially high risk to birds and mammals.

5.2 Aquatic species

European Community

Toxicity data from laboratory tests were used to derive toxicity endpoints for the most sensitive species of each aquatic group (fish, invertebrates and algae) for both acute and chronic exposure (E.C., 2005). The exposure concentrations (PEC surface water) for the Toxicity Exposure ratio (TER) were estimated using the BBA spray drift method for distances up to 30 m from the field edge for cotton, tomatoes and arable crops. The following table gives examples for acute exposure to technical endosulfan, while similar calculations were conducted for different metabolites. The Trigger value set in Annex VI of Directive 91/414/EEC is 100.

Application rate (kg as/ha)	Crop	Organism	Distance (m)	TER
0.784	Cotton	Fish	1	0.0077
0.784	Cotton	Fish	30	0.2
0.525	Tomatoes	Fish	1	0.01
0.525	Tomatoes	Fish	30	0.3
0.84 (3X)	Arable crop	Fish	1	0.035
			10	0.089
			30	0.35
0.84 (3X)	Arable crop	Daphnia	1	53.57
			10	18.75
			30	535.71

The TER values in bold are below the trigger value and therefore indicate a high risk to the aquatic environment. The risk evaluation concluded that endosulfan posed a high risk to the aquatic environment, even when, in many cases, a buffer zone of up to 30 m was taken into account.

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal

A risk evaluation for surface waters for 14 pesticides applied to cotton was carried out in Burkina Faso using an Australian computer model (PIRI – Pesticide Impact Rating Index). Five exposure scenarios were evaluated, including buffer zones and possible rain events. Data specifying the prevailing conditions in Burkina Faso were included in the model: e.g. land use data, application rates and time of year, soil type and moisture, field cover, soil organic matter content, rainfall and temperature range. Endosulfan was the only substance which posed a high or very high risk for aquatic ecosystems under all 5 scenarios even when buffer zones of up to 1000 m were taken into account. (Toé et al., 2003)

Reviews in both Australia and the USA of the use of endosulfan in cotton at application rates comparable to those used in the Sahel led to measures to reduce contamination of surface waters. In the USA these included general buffer zones of up to 33 m and vegetated buffer zones of 10 m between treated plots and surface waters. In Australia the required mitigation measures for the use of endosulfan include the avoidance of spray drift onto adjacent areas and water bodies, no applications if heavy rains or storms that are likely to cause surface runoff are forecast within two days, and no applications during hot weather conditions (temperatures >30°C). In the cotton growing areas of the Sahel surface waters are abundant and are often situated adjacent to cotton fields, particularly during the rainy season when treatments are carried out. The rainy season is characterized by hot temperatures and heavy rainstorms of which the locality and timing are difficult to predict. The conditions thus make it virtually impossible to put in place risk reduction measures comparable to those required in Australia or the USA.

Taking into account the high toxicity of endosulfan to aquatic fauna, the likelihood of the contamination of surface water in the cotton growing areas of the Sahel and the outcome of the two risk evaluations in particular the risk mitigation measures required under similar conditions in Australia and the USA, the CSP concluded that the environmental risks from endosulfan under the conditions of use in the Sahel were unacceptable.

5.3 Honey bees

European Community

In the assessment of risk of endosulfan to honey bees (E.C., 2005), the following toxicity endpoints were used:

Acute oral toxicity $LD_{50} = 2 \mu\text{g ai/bee}$ (based on the formulation product)

Acute contact toxicity $LD_{50} = 0.82 \mu\text{g ai/bee}$ (based on the formulation product)

The following Hazard Quotients (exposure:toxicity ratio) were estimated. Hazard Quotients in bold are above the Trigger provided for in Annex VI to Directive 91/414/EEC, leading to the conclusion that endosulfan poses a high risk to honey bees.

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
1.05	Citrus, pome fruit, vineyards	Oral Contact	525 1280	50
0.53	Tomatoes, potatoes, cucurbits	Oral Contact	265 649	50

5.4 Earthworms

European Community

In the risk assessment for earthworms, the following toxicity endpoints were used:

Acute toxicity 11 mg/kg

Acute toxicity (endosulfan sulphate) $LC_{50} = 51.5 \text{ mg/kg}$ (14 days)

NOEC 14 days < 1 mg/kg

The following TER values were obtained indicating that the use of endosulfan presented a high risk to earthworms in two application scenarios (values in bold).

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
2x1.05	Citrus, pome fruits vine grapes	Acute	8.3	10
3x0.84	Cotton	Acute	7.2	10
2x0.53	Tomatoes	Acute	16	10

5.5 Soil microorganisms

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

5.6 Summary – overall risk evaluation

European Community

The risk evaluation conducted by the European Community identified a number of areas of concern. The environmental fate and behaviour was of concern since the route of degradation of the active substance is not completely clear and unknown metabolites were found in soil degradation, water/sediment degradation and mesocosm studies.

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 are objects of concern.

As regards ecotoxicology, many concerns remain since the long-term risk, in particular, due to the presence of the above mentioned metabolites, cannot be sufficiently addressed with the available information.

Using NOEC values for the most sensitive aquatic organism (fish) and taking into account spray drift and run-off entry, for use in different crops (cotton, tomatoes and arable crops), the Toxicity Exposure Ratios (TER) indicate a potential long-term risk to fish even when taking into account a large buffer zone. There is also a potentially high risk to terrestrial birds and mammals, honey bees, non-target arthropods and earthworms.

Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal

The risk evaluation performed by the Sahelian countries identified a very high risk to aquatic ecosystems. Because of the climatic conditions in the rainy season, when endosulfan is applied, and because of the soil characteristics, a high input of endosulfan into surface water bodies takes place due to run-off and soil erosion. Because of the very high toxicity to aquatic organisms, a high lethality of those organisms is predicted in surface water bodies, which are important water and food sources for human and animal life. Under the conditions of use in the Sahelian countries, the respecting of buffer zones to surface waters is not feasible. As a consequence, the Sahelian Pesticide Committee considered the risk to the aquatic environment from the use of endosulfan to be unacceptable.

Annex 2 – Details on final regulatory actions reported

Country Name: European Community

1	Effective date(s) of entry into force of actions	Effective date(s) of entry into force of actions: 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 Section 3.1).
	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) (available at: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_317/l_31720051203en00250028.pdf)
2	Succinct details of the final regulatory action(s)	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 in specific Member States listed in the Annex to the Commission Decision 2005/864/EC a prolonged period of withdrawal may be allowed until 31 December 2007 under specific conditions as described in Section 3.1.
3	Reasons for action	Unacceptable risk to human health particularly the exposure of operators under indoor conditions. Uncertainty concerning the formation of degradation products of endosulfan in the environment. Unacceptable risk to non-target organisms (fish, birds and mammals, bees and earthworms).
4	Basis for inclusion into Annex III	The final regulatory action to ban endosulfan was based on a risk evaluation taking into consideration local conditions in the E.C. Member States.
4.1	Risk evaluation	During the evaluation of endosulfan a number of areas of concern have been identified. The review concluded that exposure of operators under indoor conditions was not sufficiently addressed with the available information. In addition uncertainty concerning the formation of degradation products of endosulfan in the environment remained and risks to non-target organisms (fish, birds and mammals, bees and earthworms) were considered unacceptable.
4.2	Criteria used Relevance to other States and Region	Risks to human health and the environment. Similar concerns to those identified are likely to be encountered in other countries where the substance is used, particularly in developing countries.
5	Alternatives	None reported.
6	Waste	None reported.
7	management	
	Other	

<p>Country Name(s): Burkina Faso, Capo Verde, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal</p>

1	Effective date(s) of entry into force of actions	November 13, 2007 for all distribution; December 31, 2008 for all uses
	Reference to the regulatory document	Common Regulations for Member States of the CILSS on the Regulation of Pesticides (Resolution No. 08/34/CM/99 taken by the Council of Ministers in 1999 in N'Djamena Tchad). Decision taken by Le Ministre Coordonnateur du CILSS November 13, 2007.
2	Succinct details of the final regulatory action(s)	A recommendation to prohibit registration of endosulfan was proposed by the Sahelian Pesticide Committee (8 May 2007). In the light of the existing stocks of endosulfan in member countries the final decision on prohibition of use of endosulfan in agriculture effectively stopped distribution on 13 November 2007 but allowed use of existing stocks until 31 December 2008.
3	Reasons for action	The unacceptable risk for human operators and bystanders and for aquatic organisms in surface waters.
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 substance posed an unacceptable risk to operators, to families who had their habitations in or near cotton fields and to aquatic ecosystems.
4.2	Criteria used	Risk to human health and the environment.
	Relevance to other States and Region	Similar concerns to those identified are likely to be encountered in other countries where the substance is used, particularly in developing countries.
5	Alternatives	Alternative insecticides to control cotton pests are available (see point 3.3)
6	Waste management	No specific measures outlined.
7	Other	

Annex 3 – Addresses of designated national authorities

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C Industrial chemicals

CP Pesticides and industrial chemicals

P Pesticides

Annex 4 – References

Regulatory actions

European Commission

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

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