UNITED
NATIONS

RC

UNEP/FAO/RC/COP.5/13*

Distr. General
2 September 2010

Original: English

United Nations
Environment Programme

Food and Agriculture Organization
of the United Nations

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Conference of the Parties
Fifth meeting
Geneva, 20–24 June 2011
Item 5 (c) of the provisional agenda**

Matters related to the implementation of the Convention: consideration of chemicals for inclusion in Annex III to the Convention

Inclusion of endosulfan in Annex III to the Rotterdam Convention, as recommended by the Chemical Review Committee at its sixth meeting following notifications of final regulatory action from Burkina Faso, Cape Verde, the European Community, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger and Senegal

Note by the Secretariat

Introduction

1. Paragraphs 1 and 2 of Article 7 of the Rotterdam Convention provide that:

> 1. For each chemical that the Chemical Review Committee has decided to recommend for listing in Annex III, it shall prepare a draft decision guidance document. The decision guidance document should, at a minimum, be based on the information specified in Annex I, or, as the case may be, Annex IV, and include information on uses of the chemical in a category other than the category for which the final regulatory action applies.
>
> 2. The recommendation referred to in paragraph 1 together with the draft decision guidance document shall be forwarded to the Conference of the Parties. The Conference of the Parties shall decide whether the chemical should be made subject to the Prior Informed Consent procedure and, accordingly, list the chemical in Annex III and approve the draft decision guidance document.

* Reissued for technical reasons on 3 February 2011.
** UNEP/FAO/RC/COP.5/1/Rev.1.

2. Subparagraph 5 (a) of Article 22 of the Convention states that:

> Amendments to Annex III shall be proposed and adopted according to the procedure laid down in Articles 5 to 9 and in paragraph 2 of Article 21.

3. Paragraph 2 of Article 21 provides that:

> Amendments to this Convention shall be adopted at a meeting of the Conference of the Parties. The text of any proposed amendment shall be communicated to the Parties by the Secretariat at least six months before the meeting at which it is proposed for adoption. The Secretariat shall also communicate the proposed amendment to the signatories to this Convention and, for information, to the Depositary.

4. At its third meeting, the Chemical Review Committee reviewed a notification of final regulatory action for endosulfan from the European Community, including the supporting documentation referenced therein, and, taking into account each of the specific requirements set out in Annex II to the Rotterdam Convention, concluded that the requirements of that Annex had been met (UNEP/FAO/RC/CRC.3/15, paras. 36–39 and annex II).

5. At its fifth meeting, the Committee reviewed notifications of final regulatory action for endosulfan from Burkina Faso, Cape Verde, the Gambia, Mali, Mauritania, the Niger and Senegal, including the supporting documentation referenced therein, and, taking into account each of the specific requirements set out in Annex II to the Convention, adopted a rationale as to how the notifications had met those criteria. The Committee decided, in the light of past practice in drafting decision guidance documents, to establish a drafting group to develop a decision guidance document for endosulfan for consideration at its sixth meeting on the understanding that responses to outstanding questions regarding the notifications from the above-mentioned Sahelian countries would be made available at the same time (UNEP/FAO/RC/CRC.5/16, paras. 22–73 and annex II).

6. At its sixth meeting, the Committee agreed that all outstanding questions identified at its fifth meeting regarding the Sahelian notifications had been sufficiently answered. The Committee concluded that the additional notification on endosulfan received from Guinea-Bissau referred to the same final regulatory action as the notifications from the seven Sahelian countries that it had reviewed at its fifth meeting and decided to add Guinea-Bissau as one of the notifying countries in the draft decision guidance document on endosulfan. The Committee at its sixth meeting decided to recommend to the Conference of the Parties that endosulfan should be listed in Annex III to the Rotterdam Convention based on the notifications of final regulatory action from the European Community and the eight Sahelian countries. The Committee finalized the draft decision guidance document and decided to forward it and the recommendation to list endosulfan in Annex III to the Rotterdam Convention to the Conference of the Parties for consideration at its fifth meeting (UNEP/FAO/RC/CRC.6/16, paras. 69, 70 and 115–146 and annex I).

7. In accordance with decision RC-2/2 on the process for the preparation of decision guidance documents, various materials are presented in the annexes to the present note for consideration by the Conference of the Parties: a draft decision on the inclusion of endosulfan in Annex III to the Convention is set out in annex I; the text of the Committee's recommendation at its sixth meeting on endosulfan is set out in annex II; rationales based on the criteria listed in Annex II to the Convention are set out in annex III; and a tabular summary of comments received on the draft decision guidance document and how they were addressed is set out in annex IV. The draft decision guidance document itself is set out in annex V. It has not been formally edited.

8. In accordance with the time frame specified in paragraph 2 of Article 21 of the Rotterdam Convention, the Secretariat is circulating the present note, including the text of the proposed amendment annexed hereto, on 1 December 2010.

Possible action by the Conference of the Parties

9. The Conference of the Parties may wish, by adopting the draft decision set out in annex I to the present note, to amend Annex III to the Rotterdam Convention in accordance with the provisions of Article 7 to include endosulfan. The Conference of the Parties may also wish to approve the draft decision guidance document forwarded by the Chemical Review Committee.

Annex I

Draft decision of the Conference of the Parties on the inclusion of endosulfan in Annex III to the Rotterdam Convention

The Conference of the Parties,

Noting with appreciation the work of the Chemical Review Committee,

Having considered the recommendation of the Chemical Review Committee to make endosulfan subject to the prior informed consent procedure and accordingly to list it in Annex III to the Rotterdam Convention,

Satisfied that all the requirements for listing in Annex III to the Rotterdam Convention have been met,

1. *Decides* to amend Annex III to the Rotterdam Convention to list the following chemical:

Chemical	**Relevant CAS number(s)**	**Category**
Endosulfan	115-29-7	Pesticide

2. *Also decides* that this amendment shall enter into force for all parties on [1 October 2011].

Annex II

Recommendation to the Conference of the Parties on the decision guidance document for endosulfan

The Chemical Review Committee,

Recalling its decision, at its sixth meeting, in accordance with paragraph 6 of Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, to recommend to the Conference of the Parties that it should include endosulfan in Annex III to the Convention,

Recalling also paragraphs 1 and 2 of Article 7 of the Convention,

Decides to agree on the draft text of the decision guidance document on endosulfan and to forward it to the Conference of the Parties for its consideration.

Annex III

Rationales

I. Rationale for the conclusion by the Committee that the notification for endosulfan (CAS No. 115-29-7) from the European Community meets the criteria of Annex II of the Rotterdam Convention

1. In reviewing the notification of final regulatory action by the European Community, together with the supporting documentation provided by the Party, the Committee was able to confirm that the action had been taken in order to protect human health and the environment

2. The notification and supporting documentation identified endosulfan as a pesticide. It was used in the European Community as an insecticide on arable crops and for greenhouse use in agriculture, horticulture, orchards, forestry and nurseries. Crops included citrus and pome fruits, grapes, root and tubular vegetables, tomatoes, cotton and glasshouse crops. It was also used on tsetse flies in Southern Europe.

3. The Committee established that the final regulatory action had been taken on the basis of a risk evaluation and that the evaluation had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognized methods and that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures. It also showed that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within the European Community.

4. Regarding human health, it was determined through exposure modelling that workers applying endosulfan in a number of scenarios would be exposed to levels above the acceptable operator exposure level (AOEL), even when using standard personal protective equipment. The level was based on the lowest relevant toxicity endpoint.

5. Regarding the environment, toxicity exposure ratios based on the no-observed-effect concentration (NOEC) for the most sensitive aquatic organism (bluegill sunfish, *Lepomis macrochirus*) and predicted concentrations resulting from spray drift and run-off entry indicated an unacceptable long-term risk, even with the application of buffer zones. There was also a potential high risk to terrestrial birds and mammals, honey bees and earthworms. In addition, the risk evaluation revealed the occurrence of an unknown metabolite in soil and water or sediment degradation that might cause concern.

6. The Committee concluded that the final regulatory action taken by the European Community on the basis of the available supporting documentation provided a sufficiently broad basis to merit including endosulfan in Annex III of the Rotterdam Convention in the pesticide category. It noted that the action had led to a decrease in the quantities of the chemicals used in the notifying Party. All uses of endosulfan had been banned, with noted exceptions allowed in a small number of Member States until the end of 2007 to allow for the development of alternatives. Therefore, continued exposure would be reduced to zero in the European Union as from 2008. Hence, the risk for human health and the environment in the European Community had been significantly reduced.

7. There was no indication that there were any industrial uses of endosulfan in the European Community. The Committee also took into account that the considerations underlying the final regulatory action were not of limited applicability since all uses had been banned. On the basis of information provided to the members at the third meeting of the Chemical Review Committee and other available information, the Committee concluded also that there was evidence of ongoing international trade in endosulfan.

8. The Committee noted that the final regulatory action was not based on concerns about intentional misuse of endosulfan.

9. At its third meeting, the Committee concluded that the notification of final regulatory action by the European Community met the information requirements of Annex I and the criteria set out in Annex II to the Convention.

II. Rationale as to how the notifications of final regulatory action on endosulfan (CAS No. 115-29-7) from Burkina Faso, Cape Verde, the Gambia, Mali, Mauritania, the Niger and Senegal meet the information requirements of Annex I and the criteria of Annex II to the Convention

1. In reviewing the notification of final regulatory action by the Sahelian countries Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal, together with the supporting documentation, the Committee concluded at its fifth session that the actions had been taken in order to protect human health and the environment.

2. Endosulfan was used in Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal, which are members of the Sahelian Pesticides Committee (CSP), as insecticide/acaricide in cotton.

3. The regulatory actions of Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal were to ban all uses of endosulfan by the end of 2008. The final regulatory action was taken in order to protect human health and environment. The actions were based on hazard and risk evaluations taking into account local exposure conditions for pesticide operators and of the aquatic environment. It was found that the substance posed an unacceptable risk to operators, to families who had their habitations in or near cotton fields and to aquatic ecosystems. The notifications and supporting documentation describe the specific risks.

4. The risk evaluations performed by the Sahelian countries include an assessment of the hazards to human health (high acute toxicity) and human exposure (occupational exposure), that were performed by the USA and Australia under comparable use pattern, and taking into account the prevailing conditions in the Sahel (lack of training, hot climate, no PPE available). Therefore the evaluations meet the criteria for the risk evaluation.

5. The risk evaluations also contain an assessment of the hazards to aquatic organisms (high toxicity to fish and invertebrates) and exposure in surface waters. Two argumentation lines were presented. Firstly, a pesticide risk evaluation for surface waters carried out in Burkina Faso was reported and documented. This evaluation used an Australian computer model (PIRI) and land use data including application rates of the Sahelian countries that was applied to 14 pesticides which were used in cotton in the Sahel. Five exposure scenarios of surface water were evaluated, including buffer zones and rain events. The result of the evaluation was that endosulfan was the only substance which posed a high or very high risk to aquatic ecosystems under all 5 scenarios and even taking into account buffer zones up to 1000 m.

6. In the second approach, assessments performed by the USA and Australia under comparable use pattern and which were based on recognized scientific methods and principles, were taken into account. These authorities had concluded that the risk to aquatic organisms was only acceptable provided that mitigation measures such as large vegetated and general buffer zones were respected. In Australia no endosulfan applications may take place if heavy rains or storms are forecast within two days or under hot weather conditions. In the USA endosulfan is not authorized for the use in cotton in the states where surface water bodies are abundant.

7. Taking into account the results of these two approaches and given the prevailing conditions in the Sahel, where surface waters are abundant and treatments take place in the rainy season, which is characterised by heavy and hard to predict rainstorms, it was virtually impossible to guarantee that risk reduction measures such as required in Australia or the US were followed.

8. In conclusion, the Sahelian Pesticide Committee considered the risk to aquatic ecosystems of using endosulfan in their countries as unacceptable.

9. The Committee established that the final regulatory actions had been taken on the basis of risk evaluations and that the evaluations had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognized methods and that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures. Data were generated from internationally recognized sources as the US EPA and the Australian Review for endosulfan. The review process took into account existing use patterns in the Sahelian countries. Overall, the available documents showed that the final regulatory action had been based on a chemical-specific risk evaluation, involving prevailing conditions of exposure within the submitting countries.

10. The Committee noted that, as the regulatory actions in the Sahelian countries was to ban the use of endosulfan, there would be a reduced risk of human and environmental exposure to the toxic effects of endosulfan for all uses.

11. There was no indication that there were any industrial uses of endosulfan in the notifying countries. The Committee also noted that the considerations underlying the final regulatory action were not of limited applicability since similar concerns as identified in the notifying countries could occur in other countries, in particular also developing countries. On the basis of information provided to the Committee there was evidence of ongoing international trade in endosulfan.

12. The Committee noted that the final regulatory action in the Sahelian countries was not based on concerns about intentional misuse of endosulfan, but on concerns from registered label uses.

13. The Committee concluded that the notifications of final regulatory action by the Sahelian countries met the information requirements of Annex I and the criteria set out in Annex II of the Convention.

Annex IV

Tabular summary of comments on the internal proposal on endosulfan

Country	***Section***	***Comment/Suggestion***	***Response***
Australia	*p.2 Purpose of DGD*	*Addition of:* *For example, the Stockholm Convention's draft risk profile on endosulfan was published after the notifying Parties provided the original information reproduced in this DGD. The draft risk profile provides new interpretations on data relating to persistence and bioaccumulation.*	*A reference to the POPRC risk profile (2009) has been included in the introduction to annex I.*
Brazil	*Section 1, p.8 trade names*	*Inclusion of the trade names Captus, Endozol and Termicidol which are used also in Brazil*	*Accepted.*
	Section 3.4, p.12	*Brazil considers important that the socioeconomic effects of the ban on endosulfan both in Europe and in the African countries which have prohibited the product and whose final regulatory actions provided the basis for the elaboration of the above mentioned draft.*	*Noted. However, no analysis of the socioeconomic effects has been done in both regions.*
	general	*Brazil deems necessary that the International Agency for Research of Cancer also evaluates endosulfan.*	*Noted. IARC has not yet evaluated endosulfan.*
	List of abbreviations	*CAS to be included*	*Accepted.*
Chile	*Abbreviations list*	*Suggestion to add the abbreviations "CSP, CILSS, IPM, ICSC, APVMA, NRA, AMAP, BCF, CT, DT, PEC, PIRI" to the list*	*Accepted and list amended, except for few abbreviations that were mentioned only once in the DGD*
		2 minor editorial comments	*Accepted*
Crop Life (MAI)	*Section 2.2*	***Human health:*** *Based on the official minutes of the tripartite meeting (May 2004), the rapporteur and a representative of the Commission stated "Rapporteur identified a safe use for operation. RMS considered the rest of the points in toxicology fulfilled". At that time, it was concluded that endosulfan is safe for operators and that the requirements in the area of toxicology according to 91/414 were fulfilled. The reference of the working group legislation to insufficient data regarding the operator risk is inaccurate, arbitrary, and not justified based on the available information.*	*The text in the draft DGD reflects the review report for the active substance endosulfan, which summarises the final conclusions of the risk assessment obtained by a peer review process. The review report was adopted by the Standing Committee on the Food Chain and Animal Health in support of the regulatory decision on endosulfan. Any disagreement with the review report should be submitted to the appropriate administration and not be raised in the CRC.*
	Annex 1, Section 2	*MAI agrees concerning the toxicological property of endosulfan, stating that endosulfan does not bioaccumulate, is not an endocrine disrupter or immunotoxicant, not a mutagen*	*Noted.*

Country	*Section*	*Comment/Suggestion*	*Response*
		or carcinogen, and not a reproductive toxicant. The WHO classified endosulfan as moderately hazardous	
	Annex 1, Section 3.1	*Food:* *We agree that dietary assessments (acute, chronic) for endosulfan are acceptable.*	*Noted*
	Annex 1, Section 3.2	*No further comment.*	*Noted*
	Annex 1, Section 3.3	*No further comment.*	*Noted*
	Annex 1, Section 3.4	***Occupational Exposure –E.C. Assessment:*** *Using sound science-based input parameters that differ from those developed and used by the E.C. result in lower risks to Mixer/ Loaders and Applicators. Specifically, the use and mischaracterization of the nature and severity of toxicological endpoints (dermal vs. inhalation) to generate the total systemic Acceptable Operator Exposure Level (AOEL) combining the inhalation and dermal route of exposure is unacceptable.* *Before dermal and inhalation exposure can be aggregated for occupational risk, it is essential that the toxicological endpoint for each route of exposure must be the same and the route-specific doses must have a common mechanism of toxicity. The endpoints from the 1-year dog study (Brunk 1989) and repeat dose inhalation study (Hollander and Weigand 1984) are distinct and should not be combined when calculating the AOEL. This summation of risk is not appropriate for endosulfan's occupational risk assessment.* *In addition, a dermal penetration factor of 20 % is excessive. In view of the existing data base it should be less than 14% and can be as low as 2 %. Taking all of this into consideration would result in acceptable AOELs (<100 %)*	*The text in the draft DGD reflects the report on the risk assessment for the active substance endosulfan. The report is the result of the risk assessment carried out by one Member State of the European Community, which was peer reviewed by all other Member States. Any disagreement with the risk assessment should be submitted to the appropriate administration and not be raised in the CRC.*
E.C.	*Abbreviations*	*EC for European Commission* *E.C. for European Community*	*Added / amended as suggested in the whole document*
	Section 1 Identification	*Harmonized System Customs Code 2920 90* *Other numbers: E.C. customs code: 2920 90 85*	*Amended as suggested*
	Section 2.1.	*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 under specific conditions. The period of grace for use of existing stocks*	*Wording amended / Sentence added as suggested*

Country	*Section*	*Comment/Suggestion*	*Response*
		expired on 2 June 2007 and for essential uses on 31 December 2007.	
	Section 2.2.	*European Commission*	*European added*
	Section 3.1.	*DGD proposal* *(E.C.) The ban of endosulfan as an active ingredient in plant protection products is expected to reduce significantly the input of endosulfan into the aquatic environment.* *All the applications as plant protection products, except the essential uses listed below, had been prohibited by the regulatory action.* *New proposal* *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.* *DGD proposal* *(African countries) ... 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.* *New proposal* *... The phase-out that included a stepwise approach in order to avoid creating stockpiles led to an abolition of exposure, thus reducing the risks to human health and the aquatic environment.*	*New wording accepted* *New wording not accepted. The former wording is preferred.*
	Section 4.1.	*DGD proposal* *Classification is (Commission Directive 2004/73/EC)* ***T** (Toxic)* ***Xi** (Irritant)* ***N** (Dangerous for the environment)* *Risk phrases:* ***R24/25** (Toxic in contact with skin and if swallowed)* ***R36** (Irritating to eyes)* *New proposal* *Classification in accordance with Council Directive 67/548/EEC:* ***T+** (Very Toxic)* ***Xn** (Harmful)* ***N** (Dangerous for the environment)* *Risk phrases:*	*New wording accepted. Explanation: The classification given before has not been up-to-date.*

Country	*Section*	*Comment/Suggestion*	*Response*
		R26/28 *(Very toxic by inhalation and if swallowed)* ***R21*** *(Harmful in contact with skin)*	
	Annex 1, Section 2.2.1	*DGD proposal* *Endosulfan is classified as not irritating to the skin and eyes according to EU criteria.* *New proposal* *Endosulfan is classified as harmful in contact with skin and not irritating to eyes according to E.C. criteria.*	*New wording accepted*
	Annex 1, Section 2.2.7	*Comment: The last sentence contradicts information provided under 2.2.5, where effects on reproductive performance are reported.* *Comment: the values for chronic RfD and drinking water as reported in section 4.2 should also be included here.*	*Comment not fully agreed. Effects reported under 2.2.5 were moreover clinical signs and secondary effects (except for rat teratology study). Text was amended to "No clear effects…"* *Values have been added as suggested*
	Annex 1, Section 3.4	*The following scenarios were accepted for establishing the final endpoints of the European Community risk evaluation based on the use of Thiodan EC 35*	*New wording accepted*
	Annex 1, Section 5.3	*endosulfan poses a high risk to honey bees.*	*Accepted*
	Annex 2 – 3	*Unacceptable risk to non-target organisms (fish, birds and mammals, bees and earthworms).*	*Addition of `fish`accepted*
	Annex 2 – 4.1	*DGD proposal* *Reduction of risk from plant protection products.* *New proposal* *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*	*New wording accepted*
	Annex 4	*"European Commission" instead of "EU"*	*Accepted*
Germany	*IUPAC, CAS name*	*The IUPAC name is 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxa-thiepin -3-oxide.* *The CAS name is 6,9-methano-2,4,3-benzodioxathiepin, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-3-oxide*	*Noted.*

Country	*Section*	*Comment/Suggestion*	*Response*
	Annex 1, Section 2.1	*Discrepancy between the date indicated for the meeting of the Sahelian Pesticide Committee in the annex to the notification - May 8th, 2007 - and the date of the meeting as 24 - 26 July 2006 in the notifications of the Sahel States*	*The date in the official document is May 8th.*
	Annex 1, Section 2.2.1 and 2.2.7	*According to the Preliminary Risk and Value Assessments of Endosulfan REV2007-13 from PRMA Health Canada (2007), endosulfan is highly acutely toxic via the oral and inhalation routes in rats. It was also highly toxic via the dermal route in rabbits. Replacing of "low acute dermal toxicity" to "highly toxic via the dermal route in rabbits" is suggested.* *Information from the draft risk profile on endosulfan (Stockholm Convention) stating that Endosulfan is a slight eye and skin irritant in rabbits should be included.*	*High acute and inhalation toxicity is already mentioned. Furthermore, the PMRA Assessment is not an information source for the DGD.* *A reference to the POPRC risk profile (2009) has been included in the introduction.*
	Annex 1, Section 4.1.1	*The high persistency (much more than the parent compounds and about the same toxicity) of the main metabolite endosulfan sulfate should be mentioned. The draft risk profile on endosulfan (Stockholm Convention) states from the E.C. risk assessment that the DT50 for aerobic soil degradation for endosulfan sulfate ranges from 123 -391 days under laboratory conditions. It is also important to mention that all the metabolites maintain the chlorinated cyclic structure of endosulfan which indicates a potential for persistency and bioaccumulation.*	*A reference to the POPRC risk profile (2009) has been included in the introduction.*
	Annex 1, Section 4.1.3	*It should be mentioned, that endosulfan and its metabolites undergo long range atmospheric transport (LRAT) and can be found in the arctic biota.*	*See response above.*
	Annex 1, Section 4.1.4	*It is not clear, from which species this data is derived and so this information should be added. In the Preliminary Risk and Value Assessments of Endosulfan REV2007-13 depuration half-lives of 2.9 - 5.9 days are reported for zebra fish.*	*It is not clear, to which data the question on species is related.*
	Annex 1, Section 4.1.5	*The last sentence seems to be contradicting, because in 4.1.2 a half-live of >200 days under acidic conditions was mentioned and there are many water bodies in the northern hemisphere which are quite acidic nowadays due to acidification processes (e.g. acid rain). The last sentence should be*	*The text has been amended as suggested.*

Country	*Section*	*Comment/Suggestion*	*Response*
		altered to reflect the persistency of endosulfan under acidic conditions.	
Netherlands	*Abbreviations list*	*Editorial comments on the list of abbreviations*	*Accepted.*
Nigeria		*No comments*	*Noted*
Norway	*Annex 1*	*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).*	*`does provide`changed to `provides` as suggested*
	Annex 1, Section 4.1.4	*the real risk of biomagnification is assumed to be lower*	*New wording accepted*
	Annex 4	*Persistent Organic Pollutants in the Arctic - Chapter 4B: Regional and Circumpolar Levels and Trends in Abiotic and Biotic Media.*	*more detailed reference added as suggested*
PAN	*Manufacturers*	*Additional maunufacturer`s names provided*	*The maunufacturer`s names provided were added to the list; former manufacturers were kept*
	Section 3.3.	*General* *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.*	*Amendmends accepted*
	Annex 1, Section 2.1.3	*In humans it is widely found in breast milk (Cerillo et al 2005). See PANAP monograph*	*The PANAP monograph is not an information source for the DGD*
	Annex 1, Section 2.2.2	*inhalation NOAEL of 0.001 mg/l from EPA assessment should be reported* *pregnant rabbit 12-days NOAEL of 0.7 mg/kg/bw to be mentioned*	*NOAEL added* *NOAEL not added, because it is not found in the information sources of the DGD*
	Annex 1, section 2.2.3	*<u>DGD proposal</u>* *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*	*A reference to the POPRC risk profile (2009) has been included in the introduction.*

Country	*Section*	*Comment/Suggestion*	*Response*
		studies is questionable); it is non-clastogenic in mammalian somatic cells in vivo; it induced sperm abnormalities in rodents (E.C., 2005). *<u>New proposal</u>* *The assessments conducted by the EU, Canada or the USA considered that endosulfan is not carcinogenic. However, Bajpayee et al., (2006) found that exposure to sublethal doses of endosulfan and its metabolites induce DNA damage and mutation. Although the contribution of the metabolites to the genotoxicity of the parent compound in Salmonella and mammalian cells was unclear, and the pathways leading to bacterial mutation and mammalian cell DNA damage appeared to differ (draft POPRC risk profile, 2009).*	
	Annex 1, Section 2.2.6	*<u>DGD proposal</u>* *Endosulfan is not classified as being either an endocrine disruptor or an immunotoxicant.* *<u>New proposal</u>* *There are contradictory opinions on whether endosulfan is an endocrine disruptor. Recent information indicates that endosulfan mimics non-utertrophic E(2) actions, strengthening the hypothesis that endosulfan is a widespread xenoestrogen, acts via a membrane version of the estrogen receptor-a on pituitary cells and can provoke CA^{++} influx via L-type channels, leading to prolactin (RL) secretion, and is also anti-progestative (draft POPRC risk profile, 2009).*	*A reference to the POPRC risk profile (2009) has been included in the introduction.*
	Annex 1, Section 2.2.7	*Endosulfan is genotoxic in some studies, but carcinogenic effects were not observed in studies on mice and rats.*	*A reference to the POPRC risk profile (2009) has been included in the introduction.*
	Annex 1, Section 3.1	*Addition of: However, residues in food are widespread and thought to be the main cause of endosulfan residues in humans (Campoy et al 2001)*	*New sentence not accepted, because it is not found in the information sources of the DGD.*
	Annex 1, Section 3.3	*The US EPA (2007) considers that the contribution from residues in drinking water is the major dietary risk contributor*	*Not added, because it is not found in the information sources of the DGD.*
	Annex 1, Section 3.4	*Reported occupational exposure: Addition of:* *An agricultural pilot exposed to endosulfan showed persistent "nonspecific epileptic foci in the cerebral frontal lobes" (ATSDR 2000).* *A range of surveys carried out by*	*Not added, because it is not found in the information sources of the DGD.* *Not added, because it is not found in the information sources of the DGD*

Country	*Section*	*Comment/Suggestion*	*Response*
		PAN Africa in Senegal, in 2003-2004, mainly in cotton growing areas of the Velinagar region, identified endosulfan as the cause in 31.2 to 39.9% of cases of poisoning. Of all the 162 poisonings, including 20 deaths, 73.2% occurred from exposure during application (Glin et al 2006). *In Bénin, 37 people (producers and others) died between May and September 1999, while 36 others suffered severe poisonings from Callisulfan (endosulfan 350 g) in the Borgou department, according to the Regional Action Centre for Borgou Rural Development. These poisonings were either direct (while using endosulfan, mainly while treating cotton plants) or indirect (after consumption of contaminated food, mainly vegetables) (PAN & IPEN 2009)*	*Not added, because it is not found in the information sources of the DGD*
	Annex 1, Section 4.1.4	*Addition of:* *Endosulfan also has a log Koa of 10.29 which indicates a high potential to bioccumulate in air-breathing organisms resulting in biomagnification in the terrestrial food chain (Kelly & Gobas 2003; Kelly et al 2007).* *<u>DGD proposal</u>* *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), so the real risk of biomagnification is assumed to be lower.* *<u>New proposal</u>* *However, the clearance is very rapid (CT_{50} = 2 days, CT = clearance time), so the real risk of biomagnification is assumed to be lower in aquatic food chains and higher in terrestrial food chains. Model estimations, based on measured concentration of key elements from remote Arctic food chains, indicates a significant biomagnification of endosulfan in terrestrial ecosystems (POP draft risk profile, 2009).*	*A reference to the POPRC risk profile (2009) has been included in the introduction.* *see above*
	Annex 1, Section 4.1.5	*Addition of: The estimated half-lives for the combined toxic residues (endosulfan plus endosulfan sulfate) ranged from roughly 9 months to 6 years. (US EPA, 2002. Reregistration Eligibility Decision).*	*Text added as suggested*

Country	*Section*	*Comment/Suggestion*	*Response*
	Annex 1, Section 4.2.5	*Addition of: Endosulfan treatment of cotton fields in India resulted in a 60.5% decrease in the population of actinomycetes 10 days after treatment (Vig et al 2008).* *Endosulfan is also toxic to the major groups of beneficial small soil invertebrates, mites and springtails, causing a persistent decline in populations. These invertebrates are key to maintaining soil fertility and mixing the organic and mineral components of soil (Joy & Chakravorty 1991).*	*Not added, because it is not found in the information sources of the DGD*
	Annex 1, Section 5.5	*Addition of: It is however expected to cause effects on the humic content of the soil, because of its effects on the major groups of beneficial small soil invertebrates, mites and springtails, which are are key to maintaining soil fertility and mixing the organic and mineral components of soil (Joy & Chakravorty 1991).*	*Not added, because it is not found in the information sources of the DGD*
Switzerland	*Abbreviations list*	*DT_{50} resp. DT_{90} (disappearance time for 50 % resp. 90 % of the initial residues) to be mentioned in the list of abbreviations*	*"DT" has been added to the list*
Turkey		*No comments*	*Noted*

Annex V

Rotterdam Convention

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

Draft 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 chemicals[1] 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[2] 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 […] meeting, held in […] on […], 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 […], 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.

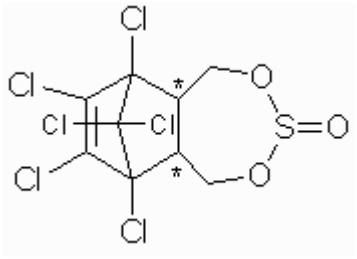
STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
µg	Microgram
µm	Micrometre
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
ADP	adenosine diphosphate
AMAP	Arctic Monitoring and Assessment Programme
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
^{o}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

STANDARD CORE SET OF ABBREVIATIONS	
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
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

Decision guidance document for a banned or severely restricted chemical

Endosulfan **Published:**

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

Common name	**Endosulfan**
Chemical name and other names or synonyms	ISO: endosulfan IUPAC: (1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-en-2,3-ylenebismethylene) sulfite, 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
Molecular formula	$C_9H_6Cl_6O_3S$
Chemical structure	
CAS-No.(s)	115-29-7
Harmonized System Customs Code	2920 90
Other numbers	EINECS: 2040794 OPP chemical code: 079401 E.C. customs code: 2920 90 85
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	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. 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. *Helicoverpa armigera*, and cotton mites.
Trade names	Benzoepin, Beosit, Caiman, Callistar, Captus, Chlorthiepin, Cyclodan, Endo 35 EC, Endocel 35 EC, Endocoton, Endofan, Endosan EC, Endosulfan 35 EC, Endozol, FAN 35, Farmoz, 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 *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), 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 2:1
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, Farmoz 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 Members 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 (SCFCAH). 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:

Member State	Use
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, an to contain effluent from fire extinguishing. (IPCS, 1988)

Annexes

Annex 1 Further information on the substance

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-benzo-dioxa-thiepin-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 ^{o}C.
1.6	**Density (g/cm^3)**	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 (10^3 kg/cm^2)**	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 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 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 LD_{50}** values for rats from 10 - 355 mg/kg bw (lowest figure for females only),

- **Dermal LD_{50}** values for rats from 74 mg/kg bw in females to > 4000 mg /kg bw in males,
- **Inhalation LC_{50} value**: 0.0126 mg/l (12.6 mg/m^3) 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 LD_{50} of 96 mg/kg bw. Male & female rats (oral gavage, neurotoxicological screening): NOAELs = 12.5 and 1.5 mg/kg bw/day (clinical signs (general discomfort, squatting posture and irregular respiration) and mortality). Endosulfan is not classified as being either an endocrine disrupter or an immunotoxicant.
2.2.7	**Summary of mammalian toxicity and overall evaluation**	WHO has classified endosulfan as moderately hazardous (WHO 2004b). The LD_{50} 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 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 sulfate (Pesticide Manual 2003), to 900 days for ß-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 µg/l
Zebra fish (*Brachydanio rerio*): 24 hours LC_{50} (semistatic) = 1.6 µg/l
Common carp (*Cyprinus carpio*): 96 hours LC_{50} (semistatic) = 0.1 µg/l
Rainbow trout (*Oncorhynchus mykiss*): 96 hours LC_{50} (static) = 0.3 µg/l
Median estimate for 95 % of fish species: LC_{50} 0.13 µg/l (acute)

Rainbow trout (*Oncorhynchus mykiss*): 21 days NOEC (juvenile growth test) = 0.05 µg/l
Sheepshead minnow (*Cyprinodon variegatus*): 28 d NOEC (early life stage) = 0.4 µg/l
Fathead minnow (*Pimephales promelas*): NOEC (life cycle) = 0.2 µg/l

Water flea (*Moina micrura*): 24 hours LC_{50} (static) = 16.2 µg/l
Water flea (*Daphnia magna*): 48 hours LC_{50} (static) = 62 µg/l
Water mite (*Hydrachna trilobata*): 48 hours LC_{50} (static) = 2.8 µg/l
Scud (*Gammarus lacustris*): 96 hours LC_{50} (static) = 5.8 µg/l
Prawn (*Caridina weberi*): 96 hours LC_{50} (static) = 5.1 µg/l
Stonefly (*Pteronarcys californica)*: 96 hour LC_{50} = 2.3 µg/l
Eastern Oyster (*Crassostrea virginica*): 96 hour LC_{50} = 0.45 µg/l
Water flea (*Daphnia magna*): 21 days NOEC (unspecified) = 63 µg/l

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

Sediment species
True midges (*Chironomus tentans*): 96 hours LC_{50} (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: LD_{50} = 2 µg a.s./bee (based on formulated product)
Acute contact toxicity: LD_{50} = 0.82 µg a.s./bee (based on formulated product) (E.C., 2005)
Metasyrphus corollae (Syrphidae) (contact toxicity, topical application): LD_{50} (72 h) > 250 µg/organism
Coccinella septempunctata (Coccinellidae) (contact toxicity, topical application): LD_{50} (72 h) = 5.31 µg/organism
Tachyporus hypnorum (Staphylinidae) (contact toxicity, topical application): LD_{50} (72 h) = 0.2 µg/organism
Notiophilus biguttatus (Carabidae) (contact toxicity, topical application): LD_{50} (72 h) = 6.41 µg/organism

4.2.4 Earthworms

Subchronic toxicity: Earthworm (*Eisenia foetida*; 14 day study) LC_{50} = 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 EC_{20} & EC_{50} (inhibition of respiration (oxygen consumption)) = > 1000 mg/l.
No effects were observed on nitrogenase activity, ammonification, nitrification processes and soil respiration at application rates 5-10 times higher than the maximum intended rate, thus the risk to soil micro-organisms is relatively low (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 (LD_{50} 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 LD_{50}: 10 mg/kg bw/day
Long-term Rat NOEL: 2.5 mg/kg bw/day
Birds: Acute Mallard duck LD_{50}: 28 mg/kg
Dietary toxicity Bobwhite quail LD_{50}: 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 10 30	**0.035** **0.089** **0.35**
0.84 (3X)	Arable crop	Daphnia	1 10 30	**53.57** **18.75** 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^{o}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 µg ai/bee (based on the formulation product)
Acute contact toxicity LD_{50} = 0.82 µg 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 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 management**	None reported.
7	**Other**	

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

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

EUROPEAN COMMUNITY

DG Environment **European Commission** Rue de la Loi, 200 B-1049 Brussels Belgium Leena Yla-Mononen Deputy Head of Unit	**Phone** +322 299 48 60 **Fax** +322 296 69 95 **E-mail** leena.yla-mononen@cec.eu.int

BURKINA FASO

Direction de la Protection des Vegetaux et du Conditionnement 01 BP 5362 Ouagadougou 01 Mamadou Coulibaly, Directeur	**Phone** (226) 50 36 19 15 **Fax** (226) 50 36 18 65 **E-mail** dpvc@agriculture.gov.bf

CAPO VERDE

Direction Generale de l´Àgriculture, Sylvieculture et Elevage Achada S. Filipe, Praia, Cap-Vert, BP 278 Carla Helena Marques Tavares Responsable du Secteur de la Protection des Vegetaux	**Phone** (238) 264 75 39/47 or (238) 264 72 27 **Fax** (238) 264 75 43 **E-mail** Carla.Tavares@maap.gov.cv or tavarescarla@yahoo.fr

THE GAMBIA

National Environment Agency Executive Director 5, Fitzgerald Street Banjul The Gambia Mr. Momodou B. Sarr	**Phone** ++220 4223868 **Fax** ++220 4229701 ++220 4223987 **E-mail** nea@gamtel.gm

GUINEA-BISSAU

Service National de Protection des Vegetaux Caixa Postal No. 884-Bissau Republic of Guinea-Bissau Chef of Department of Phytopharmaceutics Mr. Pedro Correia Landim	**Phone** ++245 664 68 30 **Fax** / **E-mail** pedrocorreialandim@yahoo.com.br

MALI

Ministère de l'Environnement et de l'Assainissement et de la Contrôle des pollutions et des nuisances BP E-3114 Bamako Mali BPE3114 Abdoulaye Traore	**Phone** 00223 229 2410 **Fax** 00223 229 5090 **E-mail** aotraore@yahoo.fr

MAURITANIA

Ministère de l'Agriculture et de l'Elevage Delegation Regionale en Adrar Dr. Mohamed El Hadi Ould Taleb Atar Mauritania	**Phone** +222 5464329 **Mobile** +222 6543582 +222 2387478 **Fax** +222 5484338 **E-mail** ouldtalebma@yahoo.fr

NIGER

Chef de la section Contrôle des Pesticides Direction de la Protection des Végétaux Ministère du développement agricole Mme Abdou Alimatou Douki B.P. 323 Niamey Niger	**Phone** +227 96979501 **Fax** +227 741983 **E-mail** douki_a@yahoo.fr

SENEGAL

Direction de Lènvironnement at des Etablissements Classés 106, rue Carnot Dakar Gatta Soule BA Chef de Division des Etablissements Classés	**Phone** 00 221 33 822 38 48 00 221 33 821 07 25 **Fax** 00 221 33 822 62 12 **E-mail** gattassouleba@yahoo.fr

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

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

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.

Other Documents

AMAP (2002). The international Arctic and Monitoring and Assessment Program (AMAP) Assessment 2002. Persistent Organic Pollutants in the Arctic - Chapter 4B: Regional and Circumpolar Levels and Trends in Abiotic and Biotic Media. Available at: www.amap.no

APVMA (2005). The reconsideration of approval of the active constituent Endosulfan, registrations of products containing endosulfan and their associated labels. Final review report and regulatory decision. June 2005. Australian Pesticides & Veterinary Medicines Authority, Canberra.

EPA (2002). Reregistration eligibility decision for endosulfan. November 2002. United States Environmental Protection Agency, Washington D.C..

European Commission (2005) Review Report for the active substance Endosulfan SANCO/4327/2000-rev. 2 Final 15 February 2005 and supporting background documents (dossier, monograph and the peer review report under the Peer Review Programme
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_317/l_31720051203en00250028.pdf
http://ec.europa.eu/food/plant/protection/evaluation/existactive/endosulfan_en.pdf

HSG (1988), Health and Safety Guide Nr 17, Endosulfan available at
http://www.inchem.org/documents/hsg/hsg/hsg017.htm

IPCS (1984), International Programme on Chemical Safety, Environmental Health Criteria 40, Endosulfan. World Health Organization, Geneva, 1984. Available at http://www.inchem.org/documents/ehc/ehc40.htm

IPCS (1988), International Programme on Chemical Safety, International Chemical Safety Card: 0742, Endosulfan (Mixed Isomers). Available at http://www.inchem.org/documents/icsc/icsc/eics0742.htm

IPCS (2000), International Programme on Chemical Safety, Poisons Information Monograph 576. Available at
http://www.inchem.org/documents/pims/chemical/pim576.htm

JMPR (1993) FAO/WHO, Joint Meeting on pesticide residues in food, Endosulfan - residue and analytical aspects. Available: http://www.fao.org/ag/AGP/agpp/Pesticid//JMPR/Download/93_eva/endosulf.pdf

JMPR (1998). FAO/WHO, Joint Meeting on pesticide residues in food, Endosulfan - toxicological evaluation. Available at http://www.fao.org/ag/AGP/agpp/Pesticid/Default.htm or
http://www.inchem.org/documents/jmpr/jmpmono/v098pr08.htm

NRA (1998). The NRA review of endosulfan. August 1998. National Registration Authority for Agricultural and Veterinary Chemicals, Canberra.

POPRC (Stockholm Convention on Persistent Organic Pollutants POPs Review Committee, October 2009): Endosulfan. Risk profile.

Toé A., Correll R, Kookana R & Miller R (2003). Application of the Pesticide Rating Index to cotton production in Burkina Faso: surface and ground water risk assessment. Institut des Racherches en Science de la Santé, Bobo Dioulaso & Commonwealth Scientific and Industrial Research Organisation CSIRO Adelaide Laboratory, Urrbrae.

Toé A. (2007). Rapport de mission de consultation – Etude des dossiers pour le passage de làutorisation provisoire de vente a l`homologisation. Comité Sahelién des Pesticides, Bamako.

WHO (2003), Endosulfan in drinking-water. Background document for preparation of WHO Guidelines for drinking-water quality (WHO/SDE/WSH/03.04/92). World Health Organization, Geneva.

WHO (2004a) Guidelines for Drinking-water Quality. Third Edition, Vol 1. Recommendations. World Health Organization, Geneva.

WHO (2004b), The WHO recommended classification of pesticides by hazard and guidelines to classification. Available: http://www.who.int/ipcs/publications/pesticides_hazard/en/

Relevant guidelines and reference documents

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal 1996. Available: www.basel.int

FAO (2006) Framework of FAO guidelines on pesticide management in support of the Code of Conduct. Available: http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Guidelines/Framework.htm

FAO (1990). Guidelines for personal protection when working with pesticides in tropical countries. FAO, Rome. Available: http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Guidelines/Use.htm

FAO (1995). Revised guidelines on good labelling practices for pesticides. FAO, Rome. Available: http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Guidelines/Registration.htm

FAO (1995). Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks. FAO, Rome. Available: http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Guidelines/Prevention.htm

FAO (1996). Technical guidelines on disposal of bulk quantities of obsolete pesticides in developing countries. FAO, Rome. Available: http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Guidelines/Prevention.htm

FAO (1996). Pesticide Storage and Stock Control Manual. FAO, Rome. Available: http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Guidelines/Distribution.htm

FAO (1999). Guidelines for the management of small quantities of unwanted and obsolete pesticides. Available: http://www.fao.org/docrep/x1531e/X1531e00.HTM