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**Rotterdam Convention on the Prior Informed
Consent Procedure for Certain Hazardous
Chemicals and Pesticides in International Trade
Chemical Review Committee**

Third meeting

Rome, 20–23 March 2007

Item 5 (c) (ii) of the provisional agenda*

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

Consideration of the draft decision guidance document for endosulfan

Note by the Secretariat

1. In accordance with the process for the development of decision guidance documents agreed by the Chemical Review Committee at its first meeting and later set forth in decision RC-2/2, the internal proposal for endosulfan was circulated to the Chemical Review Committee and its observers for their information and comments. The annex to the present note contains a tabular summary of the comments received on the internal proposal and how they were addressed in preparing the draft decision guidance document on endosulfan. The annex has not been formally edited.

2. The draft decision guidance document for endosulfan is set out in document UNEP/FAO/RC/CRC.3/13.

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

Annex

Tabular summary of comments on the internal proposal for endosulfan

Section	Author	Comments	How deal with
Section 1	Thailand / Slovenia / Samoa / Swiss	Under the heading "formulation" request to add "UL" in Standard Core Set of Abbreviations or to spell out	Amended in the text and in the abbreviations
	Ecuador	Under the heading "Use(s) in regulated category" propose to add "and other uses" to the heading	No change required: All recorded uses in the notifications are listed under current heading
	Ecuador	Under the heading "trade names" request to include Palmarol and Galgofon, delete Endosulphan	Amended as follows: Palmarol and Galgofon were added together with other trade names, Endosulphan not deleted because quoted in publications
	Samoa	Under the heading "trade names" ask whether checked with Basic Manufacturers	No change required: The internal proposal was circulated to all observers of the CRC2 including Industry for comment
	Jamaica / Swiss	Under the heading "trade names" request to delete repetition of the names Cyclodan, Thifor, Thiodan, Endosulfphan	Amended as suggested
Section 2.1	South Africa	Para.4: request to add a reference of the relevant government publication of the Thai final regulatory action	Brief reference is added to the text while full reference of the relevant publication is in annex 2
Section 2.2	South Africa	Para.1: request to add the date of the accidental discharge at the end of the paragraph.	Last sentence is deleted as this information was not mentioned in the relevant information.
	Jamaica / Swiss / Samoa	Para.2: question: what are "tall and small fruits?"	Added as a foot note: tall fruit is e.g. apples and pears; small fruit is all kinds of berries.
	Thailand	Para. 4: request to add "Farmers confirmed that they would continue using endosulfan to control golden apple snail unless it is ineffective"	Amended as suggested
	Netherlands	Para.3 the name of the spicies should be in italic: (<i>Pomacea canaliculata</i>)	Amended as suggested
	Slovenia	Para. 5 to be modified to read: The toxicological hazards identified in the existing scientific data, taken together with the effects observed in the field survey, led to the decision to ban the EC and GR formulations of endosulfan. <u>all formulations of endosulfan except the CS.</u>	Amended as suggested

Section	Author	Comments	How deal with		
Section 3.1	South Africa	Para.1 under the heading The Netherlands: request a reference regarding the handling of existing stocks	Brief reference included		
Section 3.3	Samoa	Para. 3 under the heading The Netherlands: comment species would be more useful than common names	Amended according to information available		
Section 3.4	Samoa	Comment - description by Cote d'Ivoire could be useful	No change: Description was not reported in notifications found to meet Annex II criteria		
Section 4.1	Swiss/Samoa/Netherlands	Missing dermal toxicological value based on calculation	Dermal toxicological data was deleted as per comments from WHO		
	WHO	Comment: The "WHO guidelines to classification" does not classify Endosulfan by its dermal toxicity, therefore the table should not contain the classification based on dermal toxicity. For the formulations the classification should be as the following:	Amended as suggested		
		formulations			
				a.i.	Hazard class
		Liquid		≥ 40	Ib
				≥ 4	II
				< 4	III
		Solid	≥ 16	II	
			< 16	III	
	European Community	Request to add "Xi (Irritant)" between T (toxic) and N (dangerous for the environment)	Amended as suggested		
Section 4.2	WHO	Para.1 under the heading Food: to be modified to read the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) established an Acceptable Daily Intake (ADI) of 0 - 0.006 mg/kg body weight <u>and an acute reference dose (ARfD) of 0.02mg/kg body weight.</u> (JMPR1998). Para.2 under the heading Drinking water: No limits were reported. <u>WHO Drinking Water Guidelines: a health-based value of 20µg/litre can be calculated for endosulfan on the basis of an ADI of 0.006 mg/kg of body weight (WHO 2003).</u>	Amended as suggested		
Section 4.3	South Africa	Request to add a generic statement regarding FAO guidelines on Good Labelling Practice for Pesticides.	No change required : FAO guidelines are referenced in Annex IV		

Section	Author	Comments	How deal with
Section 4.4	WHO	<p>Comment: A more appropriate reference source would be the Poisons Information Monograph since this is more up to date than the ICSC. The modified text: Signs of symptoms of (acute) ingestion are: blue lips or fingernails, confusion, headache, weakness, dizziness, nausea, vomiting, diarrhoea, convulsions, laboured breathing and unconsciousness. <u>The victim may become cyanosed, with blue lips or fingernails.</u></p> <p>First aid personnel should wear protective gloves, and clothing. To protect the eyes, a face shield or another eye protection in combination with breathing protection should be used. [Comment, the previous sentence deleted as it is more for protection of people working with endosulfan that for first aiders.] 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 should be given. If the victim is conscious induce vomiting. 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 and blood, resulting in....</p>	Amended as suggested
Annex 1 / 1.7	Slovenia	Make correction to the following date: solubility in ethanol c. 0.65 mg/l; in hexane c. 0.24 mg/l	No change required, data consistent with source (Pesticide Manual 2004)
Annex 1 / 2.2.1	Thailand	1 st bullet: "Oral LD50 Values for rats from 9.6 mg/kg bw in females to 160 mg/kg bw in males" please check oral LD50, because it is much lower than the figures derived from WHO (80 mg/kg)	Editorial change made and data verified with source (JMPR 1998; WHO 2004)
	Swiss	Line 3: Delete "on the basis of a single study"	Amended as per source
	Swiss	Line 5: replace "highly" by "moderately" toxic to be in line with WHO classification as stated in Section 4.1	No change required, data verified with source (JMPR 1998; WHO 2004)
Annex 1 / 2.2.2	Jamaica	<p>Para. 4: should read..... 3 days at 2.5 mg/kg;</p> <p>Para. 6 should read rats that received a daily dose</p> <p>Para. 7 should read Male rats dosed orally at levels</p>	Amended as suggested
Annex 1 / 2.2.4	Jamaica	Para. 1 should read ... in the 100 mg/kg feed female group the mortality was significantly different compared to control; this was observed after 26 weeks	Amended as per source

Section	Author	Comments	How deal with
Annex 1 / 3.4	South Africa	Request to add when and where the poisoning of the three workers occurred	No change made, information not indicated in the source (IPCS 1984)
	WHO	<p>Provided the following additional information to be added: 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 (Chugh SN et al 1998 referred to in IPCS PIM 576).</p> <p>Chugh SN et al (1998) Endosulfan poisoning in Northern India: a report of 18 cases. <i>Int J Clinical Pharmacol Therapeutics</i> 36(9):474-7</p> <p>IPCS (2000), International Programme on Chemical Safety, Poisons Information Monograph 576. Available at http://www.inchem.org/documents/pims/chemical/pim576.htm</p>	Amended as suggested
Annex 1 / 4.1.1	Swiss	Request to add Sediment to the heading Soil to read Soil / Sediment	Amended as suggested
Annex 1 / 4.1.2	Swiss	Line 1: add after normal water (pH 7 and normal oxygen concentration)	Amended as suggested
Annex 1 / 4.1.2	US	<p>Request to add the following information: In surface water, endosulfan tends to be sorbed onto benthic sediment where compound is likely to be persistent under anaerobic environment ($t_{1/2} > 105$ days).</p> <p><i>Source: U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Ecological Risk Assessment, Reregistration Eligibility Document, 2002</i></p>	No change required: Information was not referenced by the notifying Parties as the basis for their final regulatory actions, nor was the result of an international review. According to the Working Paper for Preparing DGDs the information provided here would not be included in the DGD.
Annex 1 / 4.1.5	US	<p>Request to add the following information: In terms of the persistence characteristics of endosulfan, the major transformation products found in the environmental fate studies are endosulfan sulfate (soil metabolism) and endosulfan diol (hydrolysis). Available data suggest that endosulfan-sulfate is more persistent than the parent [half-lives for the <u>combined toxic residues</u> from roughly 9 months to 6 years (Table attached at the end of this document)].</p> <p><i>Source: U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Ecological Risk Assessment, Reregistration Eligibility Document, 2002</i></p>	No change required: see above

Section	Author	Comments	How deal with
Annex 1 / 4.2	US	<p>Under the heading Effects on non-target organisms, request to add the following information:</p> <p>Ecological Incidents Data:</p> <p>At the time the US EPA completed its ecological risk assessment of endosulfan in 2002, there were 91 incidents in the US Ecological Incidents Information System. Most of the incidents occurred in California, South Carolina, North Carolina, and Louisiana; 89% of incidents involved aquatic animals (fish and macroinvertebrates kills).</p> <p>Evaluation of incidents subsequent to 1992 when the EPA imposed a 300-ft buffer on the use of endosulfan:</p> <ul style="list-style-type: none"> • <u>In general, incidents associated with endosulfan use were among the most frequently reported causes of aquatic incidents for pesticides.</u> • Of the <u>91 incidents</u> reported for endosulfan, 96% were related to aquatic environments, 33% occurred after 1991. • Of the 33 incidents reported since 1991, 20 (61%) were attributed to cause other than “misuse.” • Cotton and tobacco were the crops most frequently associated with incidents that were not attributed to misuse. • Louisiana, California, Alabama, Indiana and Virginia accounted for 72% of the reported incidents since 1991. • For fish, endosulfan-related incidents averaged 5,090 killed and ranged as high as 240,000 fish. • According to the US National Oceanic and Atmospheric Agency’s fish-kill database, endosulfan was responsible for more fish kills in U.S. estuaries and coastal rivers between 1980 and 1989 than all currently used pesticides at that time. The report noted that endosulfan was one of the most often found of the pesticides in aquatic biota and in one case affected estuarine biomass. • Major fish kill in the Rhine river in June 1969 (concentrations as high as 0.1 mg/L). Sediment-bound endosulfan in the Rhine River continued to affect fish as recently as 1986, when endosulfan-induced changes in gut epithelial tissue were associated with enhanced toxicity of other chemical pollutants released into the river at Basel, Switzerland. • In 1999 Australian beef was rejected for export because of excessive residues of endosulfan that resulted from cattle grazing on pastures contaminated from spray drift from neighboring cotton fields treated with endosulfan. 	No change required: see above

Section	Author	Comments	How deal with
		<ul style="list-style-type: none"> • Beef in Puerto Rico was found to be contaminated with endosulfan. <p>Although a large percentage of incidents are reported as a result of misuse, there is concern that any pesticide would be as toxic and persistent as to facilitate such nontarget mortality.</p> <p><i>Source: U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Ecological Risk Assessment, Reregistration Eligibility Document, 2002</i></p>	
Annex 1 / 5	US	<p>Request to add the following information to this section:</p> <p>Acute and chronic risk to endangered/threatened species:</p> <p>At the current application rates, endosulfan use is likely to result in both acute and chronic risks to endangered/threatened species of animals. In 1989 the U.S. Fish and Wildlife Service (USFWS) issued a biological opinion on endosulfan. A total 130 species (6 amphibians, 77 fish, 32 mussels, 6 crustaceans, 4 miscellaneous aquatic invertebrates, and 5 bird species) were considered potentially affected by the use of endosulfan (41 aquatic species as jeopardized, of which 54% were endangered/ threatened species of freshwater mussels; and two avian species also classified as being in jeopardy).</p> <p>Endocrine Disruption Potential</p> <p>Endosulfan is classified as an endocrine disruptor. Endocrine disruption potential - both reproductive, and developmental effects (to all birds, mammals, fish, and amphibians); it binds to human estrogen receptor.</p> <ul style="list-style-type: none"> • Technical grade endosulfan and each of the α- and β-isomers were estrogenic at concentrations of 10 to 25 μM as measured in the E-screen test using Michigan Cancer Foundation human breast cancer estrogen sensitive cells (MCF-7 cells). • At concentrations of 2.5×10^{-5} M endosulfan resulted in a 4-fold induction in a yeast-based estrogenic response assay (Ramamoorthy <i>et al.</i> 1997). • More recent <i>in vitro</i> studies (Massaad and Barouki 1999) have detected significant estrogenic activity of endosulfan at concentrations as low as 10^{-6} M. • Although endosulfan's affinity for the human estrogen receptor is reported to be considerably lower than the endogenous estradiol 	No change required: see above

Section	Author	Comments	How deal with
		<p>(Heufelder and Hofbauer 1996; Matthews <i>et al.</i> 2000), its ability to bind to the receptor at all renders the chemical capable of competing with the endogenous hormone and capable of eliciting hormone-like effects.</p> <ul style="list-style-type: none"> • Exogenous agents that interfere with the production, release, transport, metabolism, binding, action or elimination of endogenous hormones responsible for homeostasis and the regulation of developmental processes in organisms have been referred to as endocrine disruptors (Ankley <i>et al.</i> 1998). • Any exogenous agent that causes adverse effects in an intact organism or its progeny, consequent to changes in endocrine function, qualifies as an endocrine disruptor (Gillesby and Zacharewski 1998). <p>Effects have been observed, such as:</p> <ul style="list-style-type: none"> • decreased mean length of tadpoles exposed to the chemical, and failing to metamorphose • Tadpoles exposed to endosulfan for 96 hours followed by a 10-day recovery period exhibited significantly higher post-exposure mortality (Berrill <i>et al.</i> 1998). Mean length of unexposed tadpoles was significantly larger ($P < 0.01$) than the mean length of tadpoles exposed to 0.132 mg/L endosulfan. Relative to controls, endosulfan-treated tadpoles had impaired development and failed to metamorphose. The study concluded that at concentrations likely to be encountered in the environment, 2-week-old tadpoles exhibited greater sensitivity of posthatching development of the neuromuscular system. • impairment of the development of genital tract in birds <p>Additionally, studies on the intersexuality of the genital system in birds revealed that endosulfan impaired the development of the avian genital tract (Lutz and Lutz-Ostertag 1975).</p> <p><i>Source: U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Ecological Risk Assessment, Reregistration Eligibility Document, 2002</i></p>	
Annex 1 /5.2	South Africa	<p>Para 12: Under aquatic toxicity and the calculation for the amount of alpha endosulfan the symbol for alpha is missing</p> <p>Para. 18: request to change " * 1 acre = 6.25 rai " into 1 ha = 15.44 rai (ha is used in the abbreviations and it is also the scientific description of a surface area)</p>	Editorial comment added and rai information amended as follows: 1 ha = 15.44 rai or 1 acre=6.25 rai
	Swiss	Line 4: change the heading aquatic toxicity to exposure assessment	Amended as suggested

Section	Author	Comments	How deal with
		<p>Para.4 Question: what does good agriculture practice mean? Comment that the whole paragraph could be made clearer and unambiguous</p> <p>“drift emission” instead of “emission”;</p>	<p>Amended as follows :</p> <p>For the purpose of estimating the amount of a pesticide entering the aquatic environment as a result of spray application using Good Agricultural Practices, the Netherlands determined that, under experimental conditions, an emission of 4 % of the application would drift to surface water when no buffer zone is used, and an emission of 0.1 % of the application would drift to surface water when a 25 m buffer zone is used. In practice, these values are expected to be exceeded. For application in orchards, an emission of 10 % of the application is estimated to drift to surface water.</p> <p>Good Agriculture Practice is a common term used in agriculture.</p> <p>Amended as suggested</p>
		<p>Para.8 rewording : The <u>predicted environmental concentrations (PEC)</u> in surface water (PEC= predicted environmental concentration) for the three scenarios are...</p>	<p>Amended as suggested</p>
		<p>Para.9 add the heading “effects assessment” to the original heading “acute toxicity” to read “Effects assessment: Acute toxicity”</p>	<p>Amended as suggested</p>
		<p>Para. 10 add heading “risk evaluation”</p>	<p>Amended as suggested</p>
		<p>Para.11 rewording: For the risk evaluation the predicted environmental concentrations (PEC) of α-endosulfan in surface water in the three scenarios were compared <u>may also be calculated as a ratio of</u> to the L(E)C50 values (<u>PEC/L(E)C50</u>; see table below). Where the ratio is > 10, severe risk is expected, which is considered unacceptable. If the ratio is greater than 1 but less than 10, a large risk can be expected, <u>which is also considered unacceptable.</u></p>	<p>Amended as suggested</p>

Section	Author	Comments	How deal with
	Swiss	Para 12 the heading of table add the word “acute” before the word scenarios. In the table 2nd colume 1st line to be changed to read: Predicted Environmental Concentration surface water (PEC) [µg/l]	Amended as suggested
		Para 13 ... acute toxicity to <u>non-target species</u> of endosulfan. ... (0.7 µg α-endosulfan/l), shortly after application.	Amended as suggested
		Para.14 add to the heading “Effect assessment”	Amended as suggested
		Para.15 insert heading “risk evaluation”	Amended as suggested
		Para 16 rewording the heading of the table to be read: Table xx: with PEC/toxicity ratio for two chronic scenarios. In the table 2nd column1st line to be changed to read: Predicted Environmental Concentration surface water (PEC) [µg/l]	Amended as suggested
		propose to insert a summary of risk evaluation at the end of section 5.2 with similar text as in section 5.6.	No change required: summary in 5.6 is considered to be sufficient
Annex 1 / section 5.6	Swiss	Rewording: o The estimated <u>Predicted environmental</u> concentrations in surface water <u>were calculated to ranged</u> from 0.2 – 14 g endosulfan/l, which exceeds the lowest LC50 value of 0.17 g endosulfan/l for fish. <u>Exposure / toxicity ratios for three scenarios were calculated to be above 1, resulting in an unacceptable acute risk for non-target species.</u> O A further calculation found that the levels in surface water three weeks after application could range from 0.1-4.2 ug endosulfan/l, which would exceed the NOEC for fish and daphnia <u>Daphnia magna</u> of 0.14 ug <u>µg</u> α-endosulfan/l and 1.89 ug endosulfan/l, respectively. <u>Exposure / toxicity ratios for one scenario was calculated to be above 1, resulting in an unacceptable chronic risk for non-target species.</u> Overall, it was concluded that the risks to the aquatic environment, in particular fish, was unacceptable. Thailand: A field survey of the farmers using emulsifiable concentrates and granular formulations of endosulfan to control golden apple snail in rice paddies confirmed <u>found</u> that the impact on non-target organisms in the aquatic environment, in particular fish, was unacceptable.	Amended as suggested

Section	Author	Comments	How deal with
Annex 2/	Oman	Thailand, section 1, effective dates of entry into force of actions should be 19 instead of 18 October 2004.	<i>Amended as suggested</i>
		Section 5 Alternatives: suggest to reword the paragraph	<i>Amended as per 3.3</i>
Abbreviations	Samoa	Last raw request to delete wt use mass	No change required mass is not used in the document
	Netherlands	Request to add the hyperlink to the HSG endosulfan:	<i>Amended as requested</i>
General comments	Mauritius	Providing information on regulatory status of endosulfan in Mauritius	<i>Noted</i>

Table below to the comment to Annex 1 / 4.1.5 from US

Selected Environmental Fate Properties of Endosulfan and Endosulfan sulfate

Parameter	Value	Reference/Comments *
<i>Persistence</i>		
Hydrolysis t _{1/2} pH 5 pH 7 pH 9	stable (>200 days) 11 days (α); 19 days (β) 4 hours (α); 6 hours (β)	MRID 414129-01
Soil metabolism (Aerobic) Half lives	<u>α-endosulfan</u> : 35-67 days (5 soils); <u>β-endosulfan</u> : 104-265 days (5); <u>α+β isomers</u> : 75-125 days(5); <u>α-, β-, & endo sulfate</u> : 288-2148 days (5)	MRID 438128-01
Soil metabolism (anaerobic) Half-lives	<u>α-endosulfan</u> : 105-124 days(2 soils) <u>β-endosulfan</u> : 136-161 days(2 soils) <u>combined isomers</u> : 144-154 days <u>endosulfan sulfate</u> : 120 days	MRID 414129-04