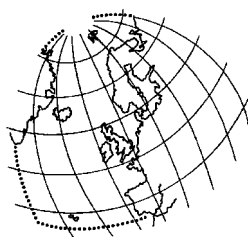


Endosulphan



OSPAR Commission
2002 (2004 Update)

The Convention for the Protection of the Marine Environment of the North-East Atlantic (the “OSPAR Convention”) was opened for signature at the Ministerial Meeting of the former Oslo and Paris Commissions in Paris on 22 September 1992. The Convention entered into force on 25 March 1998. It has been ratified by Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, Netherlands, Norway, Portugal, Sweden, Switzerland and the United Kingdom and approved by the European Community and Spain.

La Convention pour la protection du milieu marin de l'Atlantique du Nord-Est, dite Convention OSPAR, a été ouverte à la signature à la réunion ministérielle des anciennes Commissions d'Oslo et de Paris, à Paris le 22 septembre 1992. La Convention est entrée en vigueur le 25 mars 1998. La Convention a été ratifiée par l'Allemagne, la Belgique, le Danemark, la Finlande, la France, l'Irlande, l'Islande, le Luxembourg, la Norvège, les Pays-Bas, le Portugal, le Royaume-Uni de Grande Bretagne et d'Irlande du Nord, la Suède et la Suisse et approuvée par la Communauté européenne et l'Espagne.

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EXECUTIVE SUMMARY

Endosulphan belongs to the group of chlorinated hydrocarbon containing a sulfite group (synthetic cyclodienes) and technical endosulphan consists of a 2:1 mixture of the α - and β -isomer. Endosulphan is used as a contact insecticide on a wide variety of insects and mites, predominantly in temperate, subtropic and tropic climatic zones. Endosulphan and its metabolite endosulphan sulphate are highly persistent substances in soil and sediment. Endosulphan is highly bioaccumulative at constant exposure and very toxic to all organisms. Endosulphan and endosulphan sulphate are potentially endocrine disrupting chemicals. OSPAR identified endosulphan in 2000 as requiring priority action, and it was therefore included in the OSPAR List of Chemicals for Priority Action.

Endosulphan is registered in Europe for more than 40 years. The current use in OSPAR states in Northern Europe is about 37 tonnes per year; the OSPAR States in Southern Europe have a consumption of 306 tonnes per year and the predominant use in the OSPAR area is in Spain. Other OSPAR states that still have uses of endosulphan are Belgium, France, Portugal and Switzerland. The main uses are in agriculture; the non-agricultural uses have ceased.

Endosulphan occurs in concentrations up to 0,06 $\mu\text{g/l}$ in water and 81,6 $\mu\text{g/kg}$ in sediments (90 percentiles). It is therefore found at concentrations which may cause harm to organisms in rivers and sediments. It is semi-volatile, its half-life in air is 9-27 days and it is found in the Arctic. Long-range atmospheric transport is therefore likely.

Seven out of nine countries bordering the North Sea achieved the 50% reduction target for endosulphan between 1985 and 1999/2000. This included significant reductions in France and the United Kingdom, whilst the use had ceased in Denmark, Germany, the Netherlands, Norway and Sweden. Only Belgium and Switzerland did not yet achieve the reduction target. Endosulphan is under re-evaluation for a possible inclusion in Annex I of Council Directive 91/414/EEC concerning the placing on the market of plant protection products. A decision is expected in May 2003. Endosulphan is on the list of priority substances of the Water Framework Directive 2000/60/EC and will be reviewed shortly for identification as priority hazardous substance.

The action recommended is: to invite the European Commission to severely restrict, or to ban the use of endosulphan under Council Directive 91/414/EEC; in the meantime, Contracting States to inform OSPAR what uses remain permitted and what controls they will apply to these uses; Contracting States permitting continued use or those that expect to receive transboundary loads from neighbouring countries, to continue or initiate monitoring of endosulphan and its metabolite endosulphan sulphate; in the case of continued permitted use, to collect and report statistics on the quantities sold and used; to assist the European Community with the identification of endosulphan as a priority hazardous substance under the Water Framework Directive; and to ask other relevant international forums to take account of this background document.

A monitoring strategy for endosulphan has been added to this background document.

RÉCAPITULATIF

L'endosulphan appartient au groupe des hydrocarbures chlorés, qui comprend un groupe de sulfites (cyclodiènes de synthèse) et l'endosulphan technique consiste en un mélange de d'isomères α et β dans une proportion de 2 :1. L'endosulphan est utilisé comme insecticide de contact pour combattre un large éventail d'insectes et de mites, surtout dans les zones au climat tempéré, subtropical et tropical. L'endosulphan et son métabolite, le sulfate d'endosulphan, sont des substances hautement persistantes dans le sol et dans les sédiments. L'endosulphan est fortement bioaccumulatif en cas d'exposition constante et est très toxique pour tous les organismes. L'endosulphan et le sulfate d'endosulphan sont des produits chimiques potentiellement perturbateurs du système endocrinien. En 2000, OSPAR a considéré que l'endosulphan devait faire l'objet de mesures prioritaires, et il a donc été inscrit sur la Liste OSPAR des produits chimiques devant faire l'objet de mesures prioritaires.

L'endosulphan est homologué en Europe depuis plus de 40 ans. La consommation actuelle dans les Etats d'OSPAR d'Europe du nord est de l'ordre de 37 tonnes par an ; dans les Etats d'OSPAR d'Europe méridionale, la consommation est de 306 tonnes par an, l'Espagne ayant la consommation la plus forte. Les autres Etats d'OSPAR qui consomment encore de l'endosulphan sont la Belgique, la France, le Portugal et la Suisse. Les principales applications se situent dans l'agriculture ; il n'est plus employé en dehors de l'agriculture.

L'endosulphan est présent à des teneurs pouvant atteindre 0,06 $\mu\text{g/l}$ dans l'eau, et 81,6 $\mu\text{g/kg}$ dans les sédiments (90^{ème} pourcentile). Il est donc présent à des teneurs susceptibles de porter atteinte à des organismes vivant dans les cours d'eau et dans les sédiments. Il est semi-volatile, sa demi-vie dans l'air est de 9 à 27 jours et on constate sa présence dans l'Arctique. Il est donc probable qu'il est transporté dans l'atmosphère sur de grandes distances.

Sept des neuf pays riverains de la mer du Nord ont atteint l'objectif de 50% de baisse de l'endosulphan entre 1985 et 1999/2000. Ce sont notamment les réductions significatives obtenues en France et au Royaume-Uni, sa consommation ayant en outre cessé au Danemark, en Allemagne, aux Pays-Bas, en Norvège et en Suède. Seules la Belgique et la Suisse n'ont pas atteint l'objectif de réduction. L'endosulphan fait à l'heure actuelle l'objet d'une réévaluation, en vue de son inscription éventuelle à l'annexe 1 à la Directive 91/414/CEE du Conseil, concernant la mise sur le marché des produits phytosanitaires. Une décision devrait être prise en mai 2003. L'endosulphan figure sur la liste des substances prioritaires de la Directive cadre 2000/60/CE, relative à l'eau, et fera sous peu l'objet d'un réexamen afin de déterminer s'il y a lieu de le classer parmi les substances dangereuses prioritaires.

Les mesures recommandées sont les suivantes : inviter la Commission européenne à restreindre rigoureusement, voire à interdire l'utilisation de l'endosulphan en vertu de la Directive 91/414/CEE du Conseil ; entre-temps, il conviendrait que les Etats contractants renseignent OSPAR sur les applications qui restent autorisées, ainsi que sur les contrôles qu'ils exerceront sur ces applications ; que les Etats contractants qui autorisent encore son utilisation, ou ceux qui pensent recevoir des charges transfrontières provenant de pays voisins, continuent de ou commencent à surveiller l'endosulphan et le sulfate d'endosulphan, son métabolite ; dans le cas où son utilisation est encore autorisée, recueillir et communiquer les statistiques des quantités vendues et utilisées ; aider la Communauté européenne à déterminer si l'endosulphan doit être inscrit parmi les substances dangereuses prioritaires dans le contexte de la Directive cadre relative à l'eau ; et demander aux instances internationales compétentes de prendre le présent document de fond en considération.

Une stratégie de surveillance sur l'endosulphan a été ajoutée à ce document de fond.

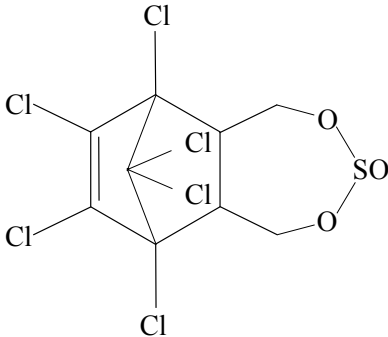
1. INTRODUCTION

Endosulphan¹ acts as a contact insecticide on a wide variety of insects and mites. It is used world-wide in the temperate, subtropic and tropic climatic zones. It has been registered in Europe for more than 40 years. Trade or other names for endosulphan products include Afidan, Beosit, Cyclodan, Devisulfan, Endocel, Endocide, Endosol, FMC 5462, Hexasulfan, Hildan, Hoe 2671, Insectophene, Malix, Phaser, Thiodan, Thimul, Thifor, and Thionex (source: EXTTOXNET, <http://ace.orst.edu/cgi-bin/mfs/01/pips/endosulf.htm>, revised June 1996).

Endosulphan has been used to control aphids, thrips, beetles, foliar feeding larvae, mites, borers, cutworms, bollworms, bugs, whiteflies, leafhoppers, and slugs on deciduous, citrus, and small fruits, vegetables, forage crops, oil crops, grains, cotton, coffee, tea, cacao, tobacco, and soy bean, in forest and on ornamentals. It is also used to control termites and tsetse fly (Pesticide Information Profile, EXTTOXNET-Database; <http://pmep.cce.cornell.edu>; revision date 4/85).

Endosulphan belongs to the group of chlorinated hydrocarbons (synthetic cyclodienes). The chemical identity of endosulphan is presented in Table 1, further physico-chemical data are given in Appendix 1.

Table 1 Chemical identity of endosulphan

CAS-No. endosulphan		6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide (1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-en-2,3-ylenebismethylene) sulfite
α -:		
β -:		
techn.:		

Technical endosulphan is a 2:1 mixture of the α - and the β -isomer.

Under natural conditions, endosulphan degrades via abiotic hydrolysis, oxidation and metabolism into several break-down chemicals (see Appendix 2). One of the most environmentally important degradation products is endosulphan sulphate, which has the CAS Number 1031-07-8.

In the context of the review of endosulphan under Council Directive 91/414/EEC concerning the placing on the market of plant protection products, the Rapporteur Member State Spain has compiled a monograph which, for the time being, is still confidential. However, efforts are being made to utilise to the extent possible in this background document the data given in the monograph. In the meantime, Spain has identified several data gaps. A decision by the European Commission on the inclusion of endosulphan into Annex I of Council Directive 91/414/EEC is expected in 2003.

Results from reviews, compilations and existing assessments, some of which are based on internationally accepted rules and methodologies, have not been re-evaluated for this background document and were

¹ Throughout this background document, endosulphan is being spelled with an "ph" in accordance with the spelling used within the framework of OSPAR. It should be noted, however, that the spelling "endosulfan" is more commonly used at international level (see text sections cited from internet and literature sources).

included as such in the present report unless new information and findings differed considerably from the data already assessed.

2. IDENTIFICATION OF SOURCES OF ENDOSULPHAN AND ITS PATHWAYS TO THE MARINE ENVIRONMENT

2.1 Production of endosulphan and main use as agricultural insecticide

The OSPAR Commission published a report on the use of pesticides in agriculture, horticulture and forestry based on responses of Contracting Parties to a questionnaire. It summarises information received by the end of February 1996 (OSPAR, 1996). According to this report, endosulphan is considered to be a Category B pesticide (“used in more limited quantities or in significant quantities only in some countries”).

The report states that France (266 tonnes) and Spain (150 tonnes) were the main users of endosulphan in 1993/1994. Insignificant quantities were reported to be used elsewhere. The Netherlands noted that, although the use of endosulphan was not approved in the Netherlands, it had been detected in the environment (ibid.).

In Norway, endosulphan was only approved for integrated pest management in fruit trees and exemption could be given for use in the cultivation of strawberry plants. In the UK, endosulphan was used as a specific insecticide on soft fruit (to control mites) and on ornamental cut flowers and bulbs, for which no approved substitutes were available. In France, it had a much wider range of application and was used for spraying of soil and seed in both agriculture and horticulture. Spain reported its use as an insecticide in vineyards. Only Switzerland reported the use of endosulphan in forestry in the early 90s (ibid.).

Some data on the world production of endosulphan, though relatively old, are given in Table 2.

Table 2 Production volume of endosulphan

Production volume 1992	[1]	5 000 – 10 000 tonnes
Estimated world production 1984	[2]	10 000 tonnes
World production	[3]	12 000 – 13 000 tonnes/year

[1] IUCLID-Dataset (1995)

[3] AYRES & AYRES (1996)

[2] WHO (1988)

Within the framework of OSPAR's dynamic selection and prioritisation of hazardous substances (DYNAMEC mechanism), the plant protection industry has provided actual information on the endosulphan consumption in Europe (Table 2).

Table 3 Endosulphan consumption in Europe (metric tonnes); Source: Aventis CropScience

COUNTRY	YEAR					
	NORTHERN EUROPE [tonnes]					
	1994	1995	1996	1997	1998	1999
Belgium ²	0	0	0	0	0	18,1
Denmark ³	1	0	0	0	0	0
Finland ⁴	3,5	0,8	0,7	1,3	0,9	0
France (north) ⁵	272,6	391,9	382,8	44,7	26	28
Germany	0	0	0	0	0	0
Iceland	0	0	0	0	0	0
Ireland ⁶	0,4	0,3	0,2	0,4	0,4	0
Luxembourg	0	0	0	3,8	0	0
Netherlands	0	0	0	0	0	0
Norway	1,7	1,8	0,8	0	0	0
Sweden	2	1,6	0	0	0	0
Switzerland ⁷	5,7	3,9	10,9	9,9	9,8	7,6
United Kingdom	6,8	3	0	3	2,4	1
Austria	1,3	3,4	0	4,7	3	1,5
Total Northern Europe	294,4	406,2	394,7	67,8	42,6	38,1

	SOUTHERN EUROPE [tonnes]					
Portugal	6,6	5,6	5,5	0,5	0	3
Spain	235	275,5	242,9	257	314	221
France (south)	60	60	61,5	47	29,4	42,8
Italy	146,4	175	140,2	113,2	91,2	90,6
Greece	94,2	105,7	116,2	105,2	50,9	73,8
Total Southern Europe	542,2	621,8	566,3	522,9	485,5	431,2
Total Europe	836,6	1028	961	590,7	528,1	469,3

As can be seen from Table 3, Spain has replaced France as the major consumer of endosulphan up to 1999. Spain is also the Rapporteur Member State for endosulphan in the context of the review under Council Directive 91/414/EEC. The consumption of endosulphan in Northern Europe is declining to a greater extent than in Southern Europe.

² The figure for Belgium in 1999/2000 (sales statistics) is taken from the Progress Report to the Fifth North Sea Ministerial Conference (2002). It is not known whether earlier sales were 0, or "not reported".

³ According to the Danish Environmental Protection Agency, the authorisation was withdrawn in 1994 and there were no more sales of Endosulphan after that year. The figure of 1 tonne in 1998 (given by industry) has been changed to zero.

⁴ Consumption data for Finland were corrected according to information provided by the Finnish Environment Institute. Consumption in 2000 increased to 108 kg (0,1 tonnes) again.

⁵ For the whole of France, the reduced sales in 1999/2000 are reported to be 200 tonnes/year in the Progress Report to the Fifth North Sea Ministerial Conference (2002).

⁶ Endosulphan has never been registered in Iceland, but temporary exemptions were given in 1994-1996 (less than 0,03 tonne in total).

⁷ Switzerland reports 50 kg/year (0,05 tonne/year) to the Rhine watershed downstream of the lakes within Swiss territory for 1999/2000 according to the Progress Report to the Fifth North Sea Ministerial Conference.

2.2 Point and diffuse sources

Point sources

In Europe, there is only one production site for endosulphan in Frankfurt-Griesheim (Germany) located at the river Main. According to industry, discharges of endosulphan from this plant to the river Main, if any, meet the legal requirements in Germany and are below the limit of detection of 0,05 µg/l (gas chromatography) of the actual enforcement method for drinking and surface water (Source: Aventis CropScience C005528). As such, the plant may be considered a potential, but not an actual point source for endosulphan.

Diffuse sources

The main use of endosulphan is in agriculture. The plant protection industry describes the diffuse input into the environment as follows (Source: Aventis CropScience):

Beside some minimal input possibilities via drift from fields or orchards very close to the coast, or via air transport, endosulphan might enter the marine environment via transport from rivers. Here it might be transported either dissolved or – more likely, due to its high K_{oc} (cf. Appendix 1) – adsorbed to particles and sediment.

In controlled run-off studies with significant slopes and forced irrigation one day after application, about 1% of the endosulphan applied was found at the edge of the fields. Depending on length and vegetation, buffer strips significantly reduced the amount transported, as much as by a factor of 1000.

The diffuse input results in measurable concentrations of endosulphan in rivers (see § 3.1.5).

2.3 Non-agricultural use of endosulphan

In 1999 the OSPAR Commission published a report on non-agricultural uses of certain pesticides by OSPAR Contracting Parties (OSPAR, 1999). This report summarises the information received through a questionnaire up to the end of 1997. However, the report reflects the time period during the late 1980s/early 1990s and points to the fact that an actual complementary inventory on non-agricultural uses of pesticides will probably emerge due to the implementation of the EU Biocide Directive (98/8/EC). Similar to the OSPAR report on agricultural pesticides (OSPAR, 1996), also in this report endosulphan is referred to as a “Category B Pesticide” (“agricultural pesticide used in more limited quantities or in only some countries”).

Endosulphan was only used in Belgium as an industrial and domestic wood preservative with a consumption of 187 kg per year up to the early 1990s. A possible contamination of water via the various routes was considered either to be “unlikely” (industrial use) or of “minor importance” (domestic use). The use of endosulphan for wood preservation is restricted to high pressure impregnation in closed systems.

3. MONITORING DATA, QUANTIFICATION OF SOURCES AND ASSESSMENT OF THE EXTENT OF PROBLEMS

3.1 Monitoring data

3.1.1 Data on marine monitoring and atmospheric transport

Endosulphan is not a substance under observation in the 'Joint Assessment and Monitoring Programme' (JAMP). Therefore, no marine monitoring data on endosulphan are to be expected from OSPAR's subsidiary bodies.

The environmental database of the 'International Council for the Exploration of the Sea' (ICES) lists some stations along the Belgian coast and the Schelde estuary, where α - and β -endosulphan had been found in March 1990 in sediments and the water phase. Due to data base constraints, these data were not accessible for this report. Provided they will be made available, they will be considered in the next revision of this background document.

BAART ET AL. (1995; quoted in the OSPAR 2002 Quality Status Report for the Celtic Seas, Region III) modelled bulk deposition fluxes to the North Sea and the Irish Sea of 2,5-7,5 $\mu\text{g}/\text{m}^2/\text{yr}$ for endosulphan. Endosulphan may be considered a semi-volatile substance. The vapour pressure varies from α -endosulphan ($1,9 \cdot 10^{-3}$ Pa at 25 °C) to β -endosulphan ($9,2 \cdot 10^{-5}$ Pa at 25 °C). Therefore, atmospheric transport may be expected. Calculations of the half-life in air (Atkinson model) resulted in 8,7 to 27 days according to the EU-Monograph.

In the document for the Reregistration Eligibility Decision on endosulphan by the US-EPA (see <http://www.epa.gov/pesticides/reregistration/endosulfan/>) occurrence in the arctic air is mentioned:

HALSALL ET AL. (1998) performed a multi-year (1992-1994) and multi-site (Canadian and Russian Arctic) study of atmospheric measurements of several organohalogen pesticides. The sampling locations were Tagish (Canada), Alert (Canada) and Dunai (Russia). At each site filters and polyurethane foam plugs were used to collect the various materials to be tested. Endosulfan was one of the pesticides present in the Arctic air at relatively high concentrations. Hexachlorobenzene and hexachlorocyclohexanes were the most predominant compounds in the atmosphere; endosulfan and the chlordanes were the next most predominant.

Table B-5 (here Table 4) provides mean and range of concentrations of endosulfan. Even though this is not shown in the table, there appeared to be some correlation between the concentration of endosulfan and the time of the year at which it is normally applied (i.e. the concentration of endosulfan in the Arctic air was higher during the summer, even though the actual temperatures at the sampling sites averaged only about 5°C during the summer).

Table 4 Arithmetic mean (range) of endosulphan (α - + β -isomer) in Arctic air (filter and polyurethane foam plug) (HALSALL ET AL. 1998)

Site	Time	Endosulphan [$\mu\text{g} / \text{m}^3$]
Canadian Ice Is.	June 1994	3,4 (1,8-5,0)
Alert	1993	3,60 (0,02-9,42)
	1994	4,84 (0,07-16,2)
Tagish	1993	5,76 (0,08-15,3)
	1994	8,33 (0,08-88,6)
Dunai	1993	2,99 (0,05-7,18)

A survey of several pesticides in air, ice, fog, sea water and surface microlayer in the Bering and Chuckchi Seas from the summer of 1993 (CHERNYAK ET AL. 1996) identifies frequent traces of α -endosulphan in air and water (around 2 pg/l), while in melted ice less than 9 pg/l and in the surface microlayer less than 40 pg/l were found. Reports of β -endosulphan in water are rather scarce, but β -endosulphan was detected in several air samples at concentrations ranging from 0,7 to 1 pg/m³ (ibid.).

No other marine monitoring data were found in the screening of available sources.

3.1.2 Endosulphan in European rivers

Endosulphan concentrations are being monitored in rivers of several OSPAR Contracting Parties, *inter alia*, as a consequence of observed pollution effects (e.g. the accidental fish kill in the river Rhine in 1969) and the agreement made at the 3rd North Sea Ministerial Conference to achieve a significant (50% or more) reduction of riverine inputs and atmospheric emissions of endosulphan.

Within the Water Framework Directive 2000/60/EC, the European Commission has set up a legal framework and a clear methodological basis for the prioritisation of substances potentially hazardous to the aquatic environment. A combined monitoring-based and modelling-based priority setting procedure (COMMPS) was applied in the selection process of the proposed priority substances. In this context, monitoring data from many European rivers were collected, weighted and aggregated (see Chapter 3.3 of the COMMPS-Report; available at <http://www.iuct.fhg.de/comps/comps.zip>).

Monitoring data in COMMPS passed a check for representativeness at EU-level; monitoring stations with less than 10% positive (i.e. > detection limit) findings were discarded. For the remaining sampling stations, arithmetic means were calculated and the EU-level 90-percentile for each substance was derived from its sampling station mean levels. Corresponding figures are given in Table 5.

Although many measurements resulted in findings below the detection limit, findings stated in Table 5 represent the situation, where endosulphan is to be expected due to uses. Belgium, France, Greece and the United Kingdom reported to the COMMPS data base, but Spain, as a major user, only in the case of endosulphan sulphate in water. In the context of this background document it was not possible to evaluate the status of monitoring data in every EU Member State.

Table 5 Results of the aggregation of monitoring data for endosulphan in the freshwater aquatic phase and sediment from the COMMPS procedure (EC 1999; from Tables A9 and A10; DL: detection limit)

CAS No.	Compound	90-perctle.	Median [µg/l]	Arithm. Mean [µg/l]	Stand. Deviat. [µg/l]	Sample Stat.	Entries used	Entries > DL
Water phase		[µg/l]	[µg/l]	[µg/l]	[µg/l]	[-]	[-]	[-]
959-98-8	α -endosulphan	0,0582	0,0073	0,0169	0,0242	27	191	93
33213-65-9	β -endosulphan	0,0194	0,0053	0,0088	0,0073	25	180	82
1031-07-8	endosulphan sulphate	0,0194	0,0069	0,0094	0,0033	37	246	126
Sediment		[µg/kg]	[µg/kg]	[µg/kg]	[µg/kg]	[-]	[-]	[-]
959-98-8	α -endosulphan	81,63	3,30	37,80	123,26	20	75	45

Medians for α - and β -endosulphan are in the range of the German quality standard for endosulphan in surface waters with respect to aquatic biocoenoses (0,005 µg/l). The 90-percentile value is lower than the drinking water threshold concentration for plant protection products (0,1 µg/l).

3.1.3 Endosulphan in animal food items

Endosulphan and endosulphan residues have been found in numerous food products at very low concentrations. They have been detected in vegetables (0,0005 - 0,013 ppm), in tobacco, in various seafoods (0,2 ppt - 1,7 ppb), and in milk (Pesticide Information Profile, ECOTOXNET-Database). In the period from 1995 to 1998, endosulphan and the metabolite endosulphan sulphate were found in 0,1-9,9% of meat samples and in fish, crab and mollusc samples in Germany (UBA, 2001).

3.2 Assessment of risks to the marine environment

The assessment of risks to the marine environment and the assessment of the extent of the problem posed by endosulphan in the environment takes into consideration ecotoxicological and chronic human health data, as well as data on the fate and behaviour of the substance in the environment (e.g. degradability), the liability for bioaccumulation, and any information on occurrence in the marine environment. Metabolites and degradation products with intrinsic properties which give rise to similar or greater concern than the parent substance (as in the case for the metabolites of endosulphan) also have to be taken into consideration. A collection of data on intrinsic properties of endosulphan is given in the Appendices 1-7; conclusions are presented below.

3.2.1 Environmental effects

Endosulphan is a very toxic chemical to nearly all kinds of organisms. Also the first metabolite of biological degradation (endosulphan sulphate) has a similar toxicity as the parent substance. The metabolite from hydrolysis (endosulphan diol) is less toxic to fish by a factor of 1000. Therefore, endosulphan has to be assessed together with its two main transformation products – endosulphan sulphate and endosulphan diol.

Summarising the toxic effects to vertebrates, it is evident that endosulphan has a high acute and also chronic toxicity. Metabolism is rapid, but the oxidised metabolite, endosulphan sulphate, shows an acute toxicity similar to that of the parent compound.

The investigation of chronic human toxicity shows that in mammals endosulphan is neither a carcinogen, nor a reproductive toxin or a teratogen. There are several results *in vitro* and *in vivo* showing no mutagenic effects, which indicate that mutagenic effects in humans are unlikely, but indications from other sources make it necessary to further evaluate mutagenicity.

There are several indications that endosulphan as well as its metabolite endosulphan sulphate are potentially endocrine disrupting chemicals. OSPAR listed endosulphan as a substance which has “been reported in the scientific literature to induce changes to the endocrine system of varying severity in the course of *in vitro* tests” (see Annex 3 of OSPAR Strategy with regard to Hazardous Substances). Under specifically tested *in vivo* conditions for fish, endosulphan did not show estrogenic effects, despite findings that it binds to receptors *in vitro*. Further *in vitro* and *in vivo* results show a variety of endocrine effects which support the indication of an endocrine disruption potential of endosulphan.

The potential for bioaccumulation of endosulphan is high (log P_{OW} is 4,8 and BCF values nearly reach 5000). This BCF value exceeds the B-criterion of 2000 as proposed in the ‘PBT assessment’ in the chapter on marine risk assessment in the current revision of the Technical Guidance Documents (TGD; EC 1996).

Therefore, taking into account the effects, there is reason for considerable concern when endosulphan enters the environment.

3.2.2 Occurrence in the environment

Monitoring data for endosulphan from European rivers are available as 90-percentile values (α -endosulphan.: 0,0582 $\mu\text{g/l}$; β -endosulphan.: 0,0194 $\mu\text{g/l}$; endosulphan sulphate 0,0194 $\mu\text{g/l}$). In sediment, only α -endosulphan is recorded with a 90-percentile of 81,63 mg/kg. This monitoring data is aggregated from the COMMPS data base and takes into account findings from selected measurement stations, while in many other measurements endosulphan was not found above the detection limit. The main entry into the rivers is by drift and run-off from treated areas.

Additionally, transport of endosulphan via the atmosphere is likely. Endosulphan is a semi-volatile substance (the volatility of the α -isomer being higher than that of the β -isomer). Laboratory experiments indicate a significant evaporation and of the calculated half-life in air (Atkinson model; as provided with the dossier for the EU-Monograph) is beyond the trigger value for POPs of 2 days. Hydroxylation of endosulphan and endosulphan sulphate results in removal of the substances from the air by precipitation and their entry into the soil or the sea.

Further, in the 1990s, endosulphan was observed in Arctic air. In another publication regarding the Bering Sea and the Chukchi Sea, endosulphan was found as a widely distributed currently used pesticide in the polar atmosphere and sea.

Transformation of the parent substance in water occurs significantly due to hydrolysis. In addition, there is a high and rapid adsorption of the parent compound and the sulphate metabolite from the water to the sediment. Therefore, persistence, bioaccumulation potential, and toxicity of the degradation products of endosulphan, namely endosulphan sulphate and endosulphan diol, have to be taken into consideration. The sulphate degrades slower than the parent substance and is also found in rivers and soil. The other important metabolite, endosulphan diol, is more polar than the parent substance and the sulphate and can be considered as an intermediate to the further transformation.

All known metabolites of endosulphan (as far as the lactone) still contain the bicyclic chlorinated basic molecule part. In laboratory experiments (water/sediment studies and soil studies), mineralisation ($^{14}\text{CO}_2$ formation) is negligible or limited, respectively.

The PEC/PNEC relationship gives clear indications of high risks to the aquatic environment. According to the marine risk assessment scheme in the current revision of the Technical Guidance Documents (TGD; EC 1996), the "PBT assessment" applies for substances which may reach remote areas of the marine environment via long-range atmospheric transport, as it must be assumed for endosulphan and possibly its metabolite endosulphan sulphate (which is less volatile than the parent substance). In this case a risk characterisation using the PEC/PNEC ratio is not applicable.

Therefore, the distribution and occurrence of endosulphan and its metabolites in the environment, especially in rivers and ultimately in the sea, as well as the possible long-range atmospheric transport give reason for considerable concern.

3.2.3 Summary of assessment of risks

A summary of data, characterising the high risk endosulphan poses to the marine environment is given in Table 6.

Table 6 Summary of risk factors from Endosulphan

Criteria		Test result (example)	Evaluation
PBT	Persistence	moderately persistent in water with stable metabolites, but high persistence in soil and sediment for the parent substance together with the metabolite endosulphan sulphate	endosulphan and the metabolite endosulphan sulphate are highly persistent substances in soil and sediment.
	Liability to bioaccumulate	log P _{OW} is 4.8. BCF up to 4 830 in algae and up to 3 600 in a fish. Rapid depuration from fish	endosulphan is highly bioaccumulative at constant exposure
	Toxicity	for all organisms < 1mg/l; LC ₅₀ as low as 0,04 µg/l for a crustacean	endosulphan is very toxic to all organisms
Other effects		no estrogenic effects <i>in vivo</i> , but other endocrine effects (e.g. changes of ovaries) have been observed	endosulphan and its metabolite endosulphan sulphate are potentially endocrine disrupting chemicals
Occurrence		up to 0,06 µg/l in water (α-E.; 90 %-ile) and 81,6 µg/kg in sediment (α-E.; 90 %-ile); semi-volatility and half-life in air 9-27 days (Atkinson model); findings in the Arctic	endosulphan is found at concentrations which may cause harm to organisms in rivers and sediments; long-range atmospheric transport is likely

Endosulphan meets the PBT-criteria set forth as proposed in the 'PBT assessment' in the chapter on marine risk assessment in the current revision (Draft of 1.10.2001; Chapter 3B, Section 9.2) of the Technical Guidance Documents (TGD; EC 1996). Therefore, endosulphan can be considered as a PBT-substance of concern:

Persistence:	$t_{1/2} > 120$ days (for metabolite endosulphan sulphate in soil); long range transport likely
Bioaccumulation:	BCF > 2 000, log P _{OW} > 4
Toxicity:	Chronic NOEC < 0,01 mg/l for all aquatic organisms
Other effects:	Potential for endocrine disruption

4. DESIRED REDUCTION

OSPAR 2000 agreed to include endosulphan on the OSPAR List of Chemicals for Priority Action under the OSPAR Strategy with regard to Hazardous Substances. The OSPAR objective with regard to hazardous substances on this list is to prevent pollution of the maritime area by continuing to reduce discharges, emissions and losses of hazardous substances, with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances. Every endeavour will be made to move towards the target of cessation of discharges, emissions and losses of hazardous substances by the year 2020.

Taking into account this objective, it can be concluded that in the light of the information and data compiled in the previous chapters in terms of:

- the identification and quantification of consumption figures of endosulphan, and especially the concentration of uses in certain regions;
- the available monitoring data from rivers, which indicate considerable concentrations in some regions, and the tendency of endosulphan and its metabolite endosulphan sulphate to persist in sediments and soils;
- the evidence of occurrence of endosulphan in remote areas (e.g. the Arctic);
- the intrinsic properties of endosulphan and its metabolites, in particular their high toxicity, persistence and endocrine disrupting potential;

there are sufficient and reasonable grounds for concern from the point of view of the marine environment to justify that all uses of endosulphan should be reduced to a level where any inputs into the marine environment are avoided and where concentrations of endosulphan or its metabolites in the marine environment (sediment, water and biota) are close to zero.

5. IDENTIFICATION OF POSSIBLE MEASURES

5.1 Review of agreed national and international measures for the regulation of endosulphan

OSPAR Strategy with regard to Hazardous Substances

Endosulphan is on the 1998 List of Candidate Substances for selection, assessment and prioritisation according to paragraph 3.1.c or paragraph 3.1.e of the OSPAR Strategy with regard to Hazardous Substances (see Annex 3 to the OSPAR Strategy with regard to Hazardous Substances; reference number: 1998-16). Within this list, endosulphan is earmarked as a priority substance agreed by the Third North Sea Ministerial Conference (Annex 1A to the Hague Declaration), and as a potential endocrine disruptor, according to the corresponding OSPAR List – Part B, containing substances which have been reported in the scientific literature to induce changes to the endocrine system of varying severity in the course of *in vitro* tests.

North Sea Ministerial Conference

The Progress Report to the Fifth North Sea Ministerial Conference indicates that the reduction target of 50% for endosulphan discharges/releases to water from 1985 to 1999/2000 has been achieved in 7 out of 9 countries discharging into the North Sea. This includes significant reductions in France and the United Kingdom, while use was discontinued in Germany, Denmark, the Netherlands, Norway, and Sweden. The reduction target of 50% has not been achieved in Belgium (18,1 tonnes/year, see Table 3) and Switzerland (50 kg/year only).

Council Directive 91/414/EEC concerning the placing of plant protection products on the market

The status of current authorisations of endosulphan in Member States of the EU in January 2001 is published by the European Commission on the internet (see Indicative List at http://europa.eu.int/comm/food/fs/ph_ps/pro/eva/existing/index_en.htm). Endosulphan has current authorisations in Austria, Belgium, Finland, France, Greece, Ireland, Italy, Luxembourg, Portugal, Spain, and the United Kingdom.

Endosulphan is under re-evaluation for the possible inclusion into Annex I of Council Directive 91/414/EEC. A Monograph has been prepared by the Rapporteur Member State Spain; a decision is expected in 2003. Some of the information provided for the dossier to the European Commission by the plant protection industry has been made available to OSPAR by CEFIC/ECPA and has been included in this background document (information from CEFIC to the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety of January 8, 2001). Further documents from the dossier and from studies conducted to supplement the EU-Monograph were provided by the notifier, Aventis CropScience in January 2002.

EU Water Framework Directive 2000/60/EC

Following the adoption of the EU Water Framework Directive (2000/60/EC; OJ L327 from 22.12.2000, p.1-73), the European Commission has identified a list of 33 priority substances, 11 of which are designated as priority hazardous substances that are of particular concern to the aquatic environment (see Decision Number 2455/2001/EC of 20.11.2001, OJ L331 of 15.12.2001, p 1). These substances shall be subject to cessation or phase-out of discharges, emissions and losses into surface, transitional and coastal waters within 20 years of the adoption of proposals for such controls by the European Parliament and the Council.

Among others, endosulphan is on the list of priority substances and will be reviewed for identification as possible “priority hazardous substance” within one year from the adoption of the list. A final decision by the Commission will be taken in the review of the list of priority substances as foreseen under Article 16(4) of Directive 2000/60/EC.

Quality standards

In Germany, quality standards for pesticides in drinking water sources were established by a sub-committee on EU Quality Criteria (Länderarbeitsgemeinschaft Wasser – Unterausschuss EU-Qualitätskriterien; LAWA-UA “EUQ”) and its predecessors. These national quality standards are derived from ecotoxicological data for the most important trophic levels. Quality standards should not be exceeded, if possible, i.e. they give guidance for protection. In case that actual concentrations exceed the quality standard value, priorities for future measures of water protection may be justified on this basis. The quality standard for both α - and β -endosulphan with respect to aquatic biocoenoses was set at 0,005 $\mu\text{g/l}$ respectively while for drinking water resources a general quality standard of 0,1 $\mu\text{g/l}$ is applied. Quality standards will also be further developed under the Water Framework Directive.

In the years 1996-1998, concentrations exceeding the German quality standard for endosulphan with respect to aquatic biocoenoses were recorded for more than 25% of the sampling stations (UMWELTBUNDESAMT 2001). The concentrations did not exceed the German quality standard with respect to the protection of drinking water resources.

For the Directorate for Environmental Protection and the Directorate for Chemicals of the Netherlands, RIVM calculated maximum permissible concentrations for surface water and soil based on direct effects for birds and mammals (VAN DE PLASSCHE 1994).

Table 7 Maximum permissible concentrations (MPC) for endosulphan for surface water and soil based on direct effects for birds and mammals (VAN DE PLASSCHE 1994)

Compound	MPC freshwater [$\mu\text{g/l}$]	MPC saltwater [$\mu\text{g/l}$]	MPC aquatic combined [$\mu\text{g/l}$]	MPC soil [mg/kg]
Endosulphan	0,013	0,0004	0,0004	0,05

Compound	MPC bird [mg/kg food]	MPC mammal [mg/kg food]	MPC bird/mammal combined [mg/kg]
Endosulphan	8,1	0,68	0,68

In the report, MPCs to cover secondary poisoning were also provided.

Administrative rules concerning substances hazardous to water

According to the German Administrative Rules (Verwaltungsvorschrift wassergefährdende Stoffe GMSMA6, 16, 327, 1996), endosulphan is classified as “severely hazardous to water” (Water Hazard Class WHC 3, 1996). The classification forms the basis for water protection requirements for industrial plants in which hazardous substances are handled.

5.2 Choice of substitutes

The report on the use of pesticides in agriculture, horticulture and forestry by the OSPAR Commission of 1996 (OSPAR, 1996) lists substitutes for endosulphan proposed by Contracting Parties as in 1993/1994. Therefore, the information in the report must be considered outdated to some extent. However, the report points to the fact that the evaluation of substitutes is a very complex issue, and no reliable conclusions can be drawn from the data without further information on the properties of the substitutes.

Substitutes from other insecticide compound groups (e.g. pyrethroids, carbamates, organic phosphoric esters and neonicotinoid compounds) are not necessarily more environmentally compatible. And certain advantages of endosulphan, for example, that target organisms are less likely to develop a resistance against endosulphan, and its lower toxicity to beneficial organisms have to be taken into account. Nevertheless, it has been demonstrated that major crops which are regularly treated with endosulphan (such as cotton and tomatoes in sub-tropic zones) may also be grown without the use of synthetic insecticides (i.e. by organic farming).

Detailed information was only available from the UK which indicated that no substitutes were available for certain minor crop pests: blackberry mite and big bug mite on cane fruit and against bulb scale mite in narcissi and other flower bulbs. In Sweden, fenprothrin was a substitute used for insects on fruits and ornamental plants. France indicated that pyrethroids were available as substitutes. In Norway, endosulphan was restricted to the use on those crops and pests for which no substitutes were available, and the substance was prohibited after 1997. Finland reported that no substitutes were available but the use is restricted to plant protection of black currant and strawberries before plantation (ibid.).

6. CHOICE FOR ACTION

6.1 The need to severely restrict or ban the use of endosulphan

On the basis of the information given in this background document, it is obvious that endosulphan and its – even worse – metabolite endosulphan sulphate pose a threat to the marine environment. Data show that the use of endosulphan in the OSPAR catchments has led, or can lead, to inputs into rivers and, ultimately, into the OSPAR maritime area. In addition, long-range atmospheric transport is likely. Furthermore, the intrinsic properties of endosulphan and its stable degradation products show that they meet the criteria to justify a PBT-Assessment under the (draft) Joint EC/OSPAR Marine Environmental Risk Assessment procedure, and that such an assessment would require risk reduction measures. Furthermore, if PEC/PNEC ratios are considered on the basis of monitored freshwater data and measured-effect data, risk reduction measures are also clearly shown to be very necessary, since the ratio is far beyond 1. There are thus sufficient clear and reasonable grounds for concern to justify avoiding any further use of endosulphan. In order to meet the goals of the OSPAR Strategy with regard to Hazardous Substances and in particular the ultimate aim of achieving for man-made synthetic substances close to zero concentrations in the marine environment, it is necessary to severely restrict or ban the use of endosulphan.

Under Council Directive 91/414/EEC concerning the placing on the market of plant protection products, the risks of active substances are evaluated at the Community level. A complete dossier on endosulphan is expected to be available in May 2003. A full risk evaluation of endosulphan will be carried out by Spain in its capacity as Rapporteur Member State. The decision on inclusion or non-inclusion to Annex I will be taken by the Commission after a vote among all Member States at the Standing Committee on the Food Chain and Animal Health. Until the Community evaluation procedure has been finalised, national legislation continues to apply (endosulphan is still authorised in 11 Member States). If endosulphan is not included in Annex I, use of any plant protection products containing endosulphan would cease in the EU countries.

Verification of the notifications received in the framework of the Biocides Directive 98/8/EC has shown that endosulphan has not been notified for inclusion into any of the annexes of the Directive. Biocidal products containing endosulphan can hence not longer be authorised by EU Member States in the near future.

This background document reflects the findings of the OSPAR Contracting Parties on endosulphan and its possible adverse effects on the marine environment and concludes that endosulphan should be severely

restricted or banned. The European Commission will be requested to take these OSPAR findings into account together with any possible information that will become available when deciding on the inclusion of endosulphan into Annex I of Council Directive 91/414/EEC. Therefore,

- OSPAR should urge the European Commission to take the appropriate steps to severely restrict, or to ban, the use of endosulphan. Other Contracting Parties not being EU Member States should do the same;
- in operating the arrangements under the Council Directive 91/414/EEC, OSPAR Contracting States that are also EU Member States should take account of the fact that the continued use of endosulphan in the OSPAR catchments appears incompatible with achieving the goals of the OSPAR Strategy with regard to Hazardous Substances. Other OSPAR Contracting States should also take this into account under their national systems;
- until such measures have been developed and implemented, OSPAR Contracting States should inform OSPAR what uses remain permitted in their jurisdictions and what controls they will apply to those uses.

6.2 The need for further monitoring and assessment of endosulphan and its metabolites

Currently, endosulphan is found in the monitoring of rivers of several OSPAR Contracting Parties, as demonstrated by the data collected under COMMPS. However, monitoring data from the marine environment (water, sediment, biota) is not available. Therefore,

- OSPAR should invite those Contracting States which will permit continued use of endosulphan or which expect to receive transboundary loads of that substance from neighbouring countries, to continue or initiate the monitoring of endosulphan and its metabolites, especially endosulphan sulphate, and to report the results to OSPAR. The monitoring methods should be agreed in the framework of both the EU Water Framework Directive 2000/60/EC and the OSPAR Joint Assessment and Monitoring Programme;
- OSPAR should invite those Contracting States which will permit continued use of endosulphan to collect and report statistics on the quantities of endosulphan sold or used.

If endosulphan is severely restricted, or banned, within the EC, there will be no further need for data-gathering or investigations, unless sources outside the EC can be identified, from which endosulphan might be transported into the OSPAR Convention area via long-range air or river transport.

6.3 The need for consistency in actions by other bodies

As has been stated before, endosulphan is on the list of priority substances of the EU Water Framework Directive as a priority substance under review. The 'review' for identification as priority hazardous substance is due by November 2002. By providing information on the risk for the marine environment and on their intention to take action to achieve concentrations in the marine environment close to zero,

- OSPAR Contracting States that are also EU Member States should assist the EC in the above review of endosulphan as a possible "Priority Hazardous Substance" under the Water Framework Directive.

To ensure that the information in this background document and the conclusions reached by OSPAR are formally communicated to the European Commission,

- OSPAR should write to the European Commission communicating this background document.

To ensure that the information in this background document can be considered in the context of other international agreements, which deal with hazardous substances and to, which Contracting Parties are associated,

- OSPAR should send copies of this background document to the appropriate bodies dealing with those agreements and invite Contracting Parties who are common parties to OSPAR and those other agreements to promote action to take account of this background document by those other international bodies in a consistent manner.

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A 38455	Müller, W (1988b): Unscheduled DNA Synthesis test in Mammalian cells in vitro (evaluation) Endosulfan substance, technical, Code: Hoe 002671 0I ZD95 0005. Hoechst AG, Pharma Research Toxicology and Pathology, Doc. No. A38455
A 39397	Diehl K.-H., Leist K.-H. (1988): Testing for acute dermal toxicity in the male and female Wistar rat, Endosulfan active ingredient technical, Code: Hoe 002671 0I ZD96 0002. Hoechst AG, Pharma Research Toxicology and Pathology, Doc. No. A39397
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A 41265	Leist, K.-H. (1989): Combined chronic toxicity/carcinogenicity study (104-week feeding in rats) Endosulfan, active ingredient technical, Code: Hoe 002671 0I ZD97 0003, residue determination. Hoechst AG, Pharma Research, Toxicology and Pathology, Doc. No. A41265
A 41 298	Cornaby, B. W., Maciorowski, A. F., Griffith, M. G. Navarro, J. E. Pomeroy, S. E., Reichenbach, N. G., Shuey, J. S. Yancey, M. F. Hickey, S. (1989): Assessment of the fate and effects of endosulfan on aquatic ecosystems adjacent to agricultural fields planted with tomatoes. Battelle Columbus Ohio and Hickey's Agricultural Service Laboratory Inc., Camilla Georgia, USA conducted on behalf of Hoechst Celanese Corp. USA, Doc. No. A41298
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A 67217	Heusel, R., Gosch, H. (1998): Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>), AE F051329 technical substance, Code: AE F051329 00 1D99 0002, Metabolite of endosulfan (AE F002671). Hoechst Schering AgrEvo GmbH, Umweltforschung Oekobiologie, Doc. No. A67217
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C 004471	Heusel, R. (1999) : Endosulfan, Evaluation of Possible Endocrine Effects in Fish, Code: AE F002671. Hoechst Schering AgrEvo GmbH, Umweltforschung Oekobiologie, Doc. No. C004471
C 005031	Bremmer, J.N., Leist, K.H., Lehr, W. (1999): Evaluation of Endosulfan for further assessment in relation to endocrine disruption. Hoechst Schering AgrEvo GmbH, Frankfurt, Germany, Doc. No. C005031
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C 010869	Gries, T., van der Kolk, J. (2000b): 14C-Endosulfan sulfate (metabolite of 14C-endosulfan): Acute toxicity test with carp (<i>Cyprinus carpio</i>) under semi-static conditions. Springborn Laboratories (Europe) AG, Horn, Switzerland on behalf of Aventis CropScience GmbH, Doc. No. C010869
C 013506	Griffon B. (2001a): Endosulfan-lactone (AE F051328), acute oral toxicity in rats. Centre International de Toxicologie, Evreux, France on behalf of Aventis CropScience, Centre de Recherche, Sophia Antipolis, France, Doc. No. C013506
C 013508	Griffon B. (2001b): Endosulfan-ether (AE F051330) , acute oral toxicity in rats. Centre International de Toxicologie, Evreux, France on behalf of Aventis CropScience, Centre de Recherche, Sophia Antipolis, France, Doc. No. C013508
C 013510	Griffon B. (2001c): Endosulfan-hydroxyether (AE F051326), acute oral toxicity in rats. Centre International de Toxicologie, Evreux, France on behalf of Aventis CropScience, Centre de Recherche, Sophia Antipolis, France, Doc. No. C013510
C 015651	Hardy, I. A. J. (2001): Endosulfan: Field Dissipation Study in Spain. Aventis CropScience UK Ltd. , Doc. No. C015651
C 016132	Gries, T., van der Kolk, J. (2000a): 14C-Endosulfan sulfate (metabolite of 14C-endosulfan): Acute toxicity test with rainbow trout (<i>Oncorhynchus mykiss</i>) under semi-static conditions. Springborn Laboratories (Europe) AG, Horn, Switzerland on behalf of Aventis CropScience GmbH, Doc. No. C016132
C 018180	Balluff, M. (2001): Field Soil Dissipation Study of AE F002671 (Endosulfan) Following a Single Application to Bare (pre-emergence) Cotton Plants at 1 Location in Greece, 2000. Arbeitsgemeinschaft GAB Biotechnology GmbH & IFU Umweltanalytik GmbH, study conducted on behalf of Aventis CropScience, Doc. No. C018180
C013856	Hemmer M. J., Hemmer B. L., Bowman C. J., Kroll K. J., Folmar L. C., Marcovich D., Hoglund M. D., Denslow N. D. (2001): Effects of p-nonylphenol, methoxychlor, and endosulfan on vitellogenin induction and expression in sheepshead minnow (<i>Cyprinodon variegatus</i>). Environmental Toxicology and Chemistry, 20 (2), 336-343, Doc. No. C013856

APPENDIX 1: PHYSICO-CHEMICAL PROPERTIES OF ENDOSULPHAN

Differences between the two isomers, α - and β -endosulphan, are marginal if not stated otherwise.

Property	Value	Source
Chemical name	6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide	IUCLID (1995)
CAS-No.	α -: 959-98-8 β -: 33213-65-9 techn.: 115-29-7	
EEC No. (EINECS)	204-079-4	IUCLID (1995)
Molecular formula	C ₉ H ₆ Cl ₆ O ₃ S	IUCLID (1995)
Molecular Mass M [g/mol]	406,9	IVA/Hoechst (not dated)
Physical state of matter at 20 °C	solid crystals	IVA/Hoechst (not dated)
Colour / odour	brown (techn.) hardly any odour	IVA/Hoechst (not dated)
Density ρ [g/cm ³]	1,745	IVA/Hoechst (not dated)
Solubility in water S [mg/l]	0,32 (22 °C) 0,33 0,52 0,33 (pH 5) 0,1 (20 °C) 0,32 (22 °C) 0,53 (25 °C) α -Endosulphan 0,41 β -Endosulphan 0,23	TOMLIN (1997) IVA/Hoechst (not dated) HOWARD (1991) IUCLID (1995) ARS Pesticide Database (1995) ARS Pesticide Database (1995) ARS Pesticide Database (1995) Docs. submitted for rev. under 91/414/EEC
Solubility in hexane [g/100g]	2,4	EXTOXNET (1992) IVA/Hoechst (not dated)
log P _{OW}	4,74 ~ 4,7 (25°C, pH 7) 2,23; 3,13; 3,62; 3,55; 3,38 α -Endosulphan 4,74 (22 °C, pH 5) β -Endosulphan 4,79 (22 °C, pH 5)	IUCLID (1995) IVA (1990) ARS Pesticide Database (1995) HOWARD (1991) TOMLIN (1997); Doc. submit. for review under 91/414/EEC
Adsorption coeff. log K _{oc} [l/kg]	3,48-4,3 5,30; 3,31; 4,09	TOMLIN (1997) ARS Pesticide Database (1995)
Melting point T _m [°C]	α -: 109,2 °C β -: 213,3 °C	EXTOXNET (1992)
Boiling point T _b [°C]	213,3 ^b	IUCLID (1995)
Vapour pressure P (25 °C) [Pa]	1,70 · 10 ⁻⁵ (25 °C) 7,52 · 10 ⁻⁶ (25 °C) 8,26 · 10 ⁻⁶ (20 °C) 8,30 · 10 ⁻⁶ ^a 1,9 · 10 ⁻⁷ 2,30 · 10 ⁻⁷ (25 °C) α -Endosulphan 1,9 · 10 ⁻³ (25 °C) β -Endosulphan 9,2 · 10 ⁻⁵ (25 °C)	IUCLID (1995) HOWARD (1991); EC-JRC (1998); WHO (1984) ARS Pesticide Database (1995) TOMLIN (1997) IUCLID (1995) ARS Pesticide Database (1995) Doc. submitted for review under 91/414/EEC
Henry's Law constant [-]	6,03 · 10 ⁻⁴ (22 °C) ^c 4,60 · 10 ⁻⁴ 4,40 · 10 ⁻⁴ (25 °C) 1,16 · 10 ⁻⁵ (25 °C)	TOMLIN (1997) HOWARD (1991) ARS Pesticide Database (1995) ARS Pesticide Database (1995)
Toxicological classification (EU)	T, N, Xi	IUCLID (1995) IVA/Hoechst (not dated)

Property	Value	Source
R-Phrases	R23, R 24/25, R 36, R 38, R 50/53	IUCLID (1995) IVA/Hoechst (not dated) UNEP/IRPTC Legal File
S-Phrases	S ½, S 13, S 28, S 36/37, S 44, S 45, S 60, S 61	IUCLID (1995) IVA/Hoechst (not dated) UNEP/IRPTC Legal File

- a) α - : β -endosulphan = 2 : 1.
- b) β -endosulphan.
- c) Calculated value.
- d) Technical endosulphan.

Endosulphan is a poorly water soluble and semi-volatile substance and with a relatively strong tendency to adsorb to particles (high K_{oc}). There are distinct differences between α - and β -endosulphan with the solubility in water (α -: 0,41 mg/l; β -: 0,23 mg/l), melting points (α -: 109,2 °C; β -: 213,3 °C), and the vapour pressure (α - : $1,9 \cdot 10^{-3}$ Pa (25 °C); β - : $9,2 \cdot 10^{-5}$ Pa (25 °C)). Detailed physico-chemical data for the first metabolite endosulphan sulphate are not available, but endosulphan sulphate is known to have a similar tendency to adsorb as the parent substance.

APPENDIX 2: DATA ON DEGRADATION

Hydrolysis

Endosulphan possesses a significant abiotic sink by hydrolysis. Hydrolysis takes place by the separation of the SO-group and leads to diol, probably via an intermediate monoester. The diol still contains the aliphatic side chains ($-\text{CH}_2\text{-OH}$) and the unchanged highly chlorinated rest of the molecule (see Figure 2 below).

The hydrolysis rate (k_{hydro}) increases towards higher pH-values and is therefore more significant in the alkaline marine environment than in the limnic environment with a more neutral or slightly acid pH. Hydrolysis rates of the two isomers (α - and β -endosulphan) differ only slightly and increase a little again at low pH-values (Figure 1; see also Table 8 with references).

Figure 1 shows that the half-life of endosulphan is about 1 day in the pH range of sea water (pH 7,8-8,2). The parent substance will probably not accumulate in the sea to a significant degree, regardless of the fact that the rate constant will be lower under the real temperature conditions in sea water as it was during the measurements in Figure 1 and Table 8.

Table 8 Hydrolysis rates of endosulphan at different pH-values

pH	k_{hydro} [s ⁻¹] (20 - 30 °C)	Half life $t_{1/2}$ [d] (20 - 30 °C)	References, comments
α-Endosulphan			
4,5	$(8,60 \pm 0,18) \cdot 10^{-8}$	93,3	SINGH ET AL. (1991)
5,5	$5,33 \cdot 10^{-8}$	150,6	⁸
7,0	$2,27 \cdot 10^{-7}$	35,4	⁸
7,0	$(2,92 \pm 0,04) \cdot 10^{-7}$	27,5	SINGH ET AL. (1991)
7,3-7,7	$3,65 \cdot 10^{-7}$	22	Sea water-sedim. ⁹
8,0	$2,59 \cdot 10^{-6}$	3,1	Sea water, sterile ^{9a}
8,2	$4,22 \cdot 10^{-6}$	1,9	Sea water, sterile ^{9a}
9,5	$(4,61 \pm 0,31) \cdot 10^{-4}$	0,017 ¹⁰	SINGH ET AL. (1991)
β-Endosulphan			
4,5	$(9,14 \pm 0,09) \cdot 10^{-8}$	87,8	SINGH ET AL. (1991)
5,5	$4,28 \cdot 10^{-8}$	187,3	⁸
7,0	$2,14 \cdot 10^{-7}$	37,5	⁸
7,0	$(3,42 \pm 0,09) \cdot 10^{-7}$	23,5	SINGH ET AL. (1991)
7,3-7,7	$9,7 \cdot 10^{-7}$ ¹¹	8,3	Sea water-sedim. ^{9a}
8,0	$4,0 \cdot 10^{-6}$ ¹¹	2,0	Sea water, sterile ^{9a}
8,2	$6,2 \cdot 10^{-6}$ ¹¹	1,3	Sea water, sterile ^{9a}
9,5	$(5,61 \pm 0,47) \cdot 10^{-4}$	0,014 ¹⁰	SINGH ET AL. (1991)
Techn. Endosulphan			
7,5 \pm 0,5	$2,9 \cdot 10^{-6}$ ¹¹	2,8	Tap water
9 \pm 0,5	$3,8 \cdot 10^{-6}$ ¹¹	2,1	Sea water ^{9a}

⁸ GREVE & WITT (1971), cited in HOWARD (1991), S.331.

⁹ Compiled from ANGERHÖFER (1994) according to data from COTHAM & BIDLEMAN (1989); FERRANDO ET AL. (1992) und WALKER ET AL. (1988).

¹⁰ Calculated from k_{hydro} .

¹¹ Calculated from the half-life with a 1. order kinetics.

Hydrolysis makes endosulphan itself relatively non-persistent in sea water. In the metabolite endosulphan sulphate, the sulphurous group is oxidised to a sulphate group and as such, the molecule is principally susceptible to hydrolysis (hydrolysis product is the diol as with the parent substance). Detailed hydrolysis rates for the metabolite endosulphan sulphate are not available, but water/sediment studies (see below) indicate a somewhat slower disappearance of the sulphate with regard to the parent compound.

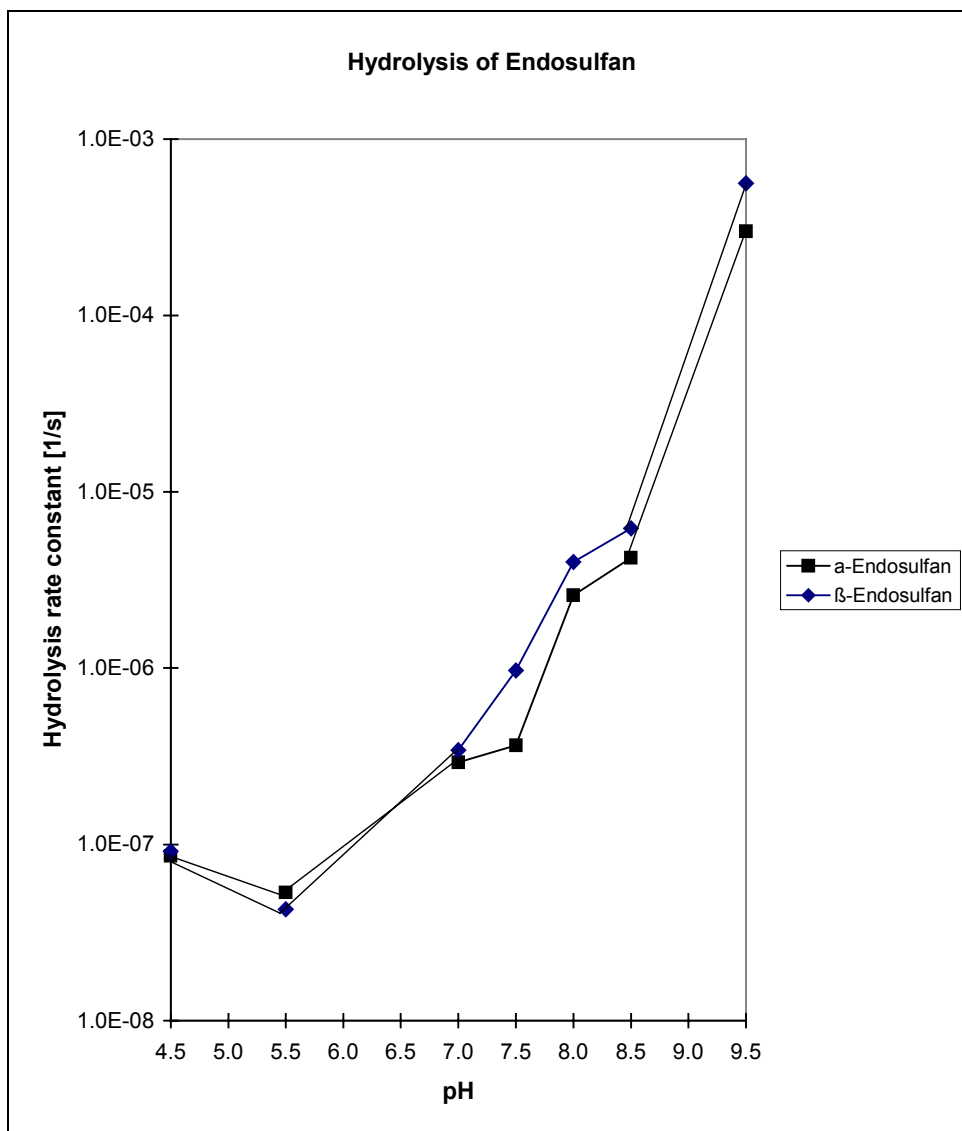


Figure 1 Dependency of hydrolysis of endosulphan on the pH (1st order hydrolysis rate constant; see Table 8 in Appendix 2 with references)

Photochemical transformation in the atmosphere

Evaporated organic chemicals are susceptible to reaction with hydroxyl radicals, ozone or other highly reactive, photochemically formed intermediates. This results in hydrogen abstraction, addition to double or triple bonds, reaction with N, S and –OH, addition to fused rings among others. The resulting transformation products are generally washed out of the air with the precipitation and return to the soil or the sea.

In the case of endosulphan and endosulphan sulphate which are considered to be semi-volatile, experimental determination of the reaction rate with photochemically formed intermediates fails due to

the immeasurable low vapour concentration. Therefore, estimation methods based on structure-activity relationships developed by Atkinson and co-workers are applied.

In the EU-Monograph, the half-life for endosulphan with regard to indirect photochemical transformation has been calculated with the Atkinson model to 8,7 to 27 days. This qualifies endosulphan for long-range transport in the atmosphere (half-life is larger than the trigger value of 2 days for POPs).

Aerobic biodegradation

The conversion of α - and β -endosulphan and its metabolites is shown in Figure 2 (Source: Aventis CropScience). Hydrolysis in water leads to the endosulphan alcohol (endosulphan diol), while microbial metabolisation leads to endosulphan sulphate, which may further hydrolyse to the diol. Both metabolites are further converted to other metabolites.

In a freshwater/sediment-system (Aventis CropScience A31182), endosulphan was found to have a half-life of 4 to 8 days in water. Mineralisation (measured as % $^{14}\text{CO}_2$) is given as “insignificant” (1,2-2,7%) in this test at day 51, and bound residues account for 20-27% of the radioactivity at the end of the study. Metabolites endosulphan sulphate reached a maximum of 18% in the sediment, decreasing slowly towards the end of the study, and endosulphan hydroxycarbonacid accounted for 28% in water at day 16, also decreasing to the end of the study. Although the test duration is comparatively short (51 days) and a test duration of at least 100 days would be preferable, from this study, endosulphan can be characterised as moderately persistent in water with formation of stable metabolites (cf. BEEK ET AL. 2001).

In another freshwater/sediment system endosulphan had a dt_{50}^{12} of 18-21 days and a dt_{90}^{13} of 59-60 days in the complete system (Document submitted for review under 91/414/EEC; cf. OSPAR Minimum Fact Sheet).

In a seawater/sediment microcosm system (COTHAM & BIDDLEMAN 1989) the dt_{50} for the disappearance from water and sediment were determined to be 8,3 days for α - and 22 days for β -endosulphan. However, disappearance from water can not be the decisive criterion, because endosulphan and its metabolite endosulphan sulphate tend to bind to the sediment, and therefore it can be concluded that sediment-dwelling organisms can be more affected than organisms living in the water phase.

In a study provided for re-registration of endosulphan in 1990, biodegradation in soil was determined as follows, thus characterising endosulphan as highly persistent in soil (cf. BEEK ET AL. 2001):

- | | |
|-----------------------------------|--------------|
| • Half-life (dt_{50}): | 140-240 days |
| • Mineralisation (365 d): | 18% |
| • Bound residues (365 d): | 30-40% |

In a field dissipation study of terrestrial uses on tomatoes from 1984 (Aventis CropScience A42193), half-lives on planted fields and bare ground appeared to be as follows:

- | | | |
|--------------------------|--------------------|--------------------------|
| • α -endosulphan: | 46 days (planted) | 47 days (non-cropped) |
| • β -endosulphan: | 91 days (planted) | 100 days (non-cropped) |
| • endosulphan sulphate: | 655 days (planted) | 2 210 days (non-cropped) |
| • endosulphan diol: | 36 days (planted) | 45 days (non-cropped) |

¹² dt_{50} : disappearance time of 50% of the substance
¹³ dt_{90} : disappearance time of 90% of the substance

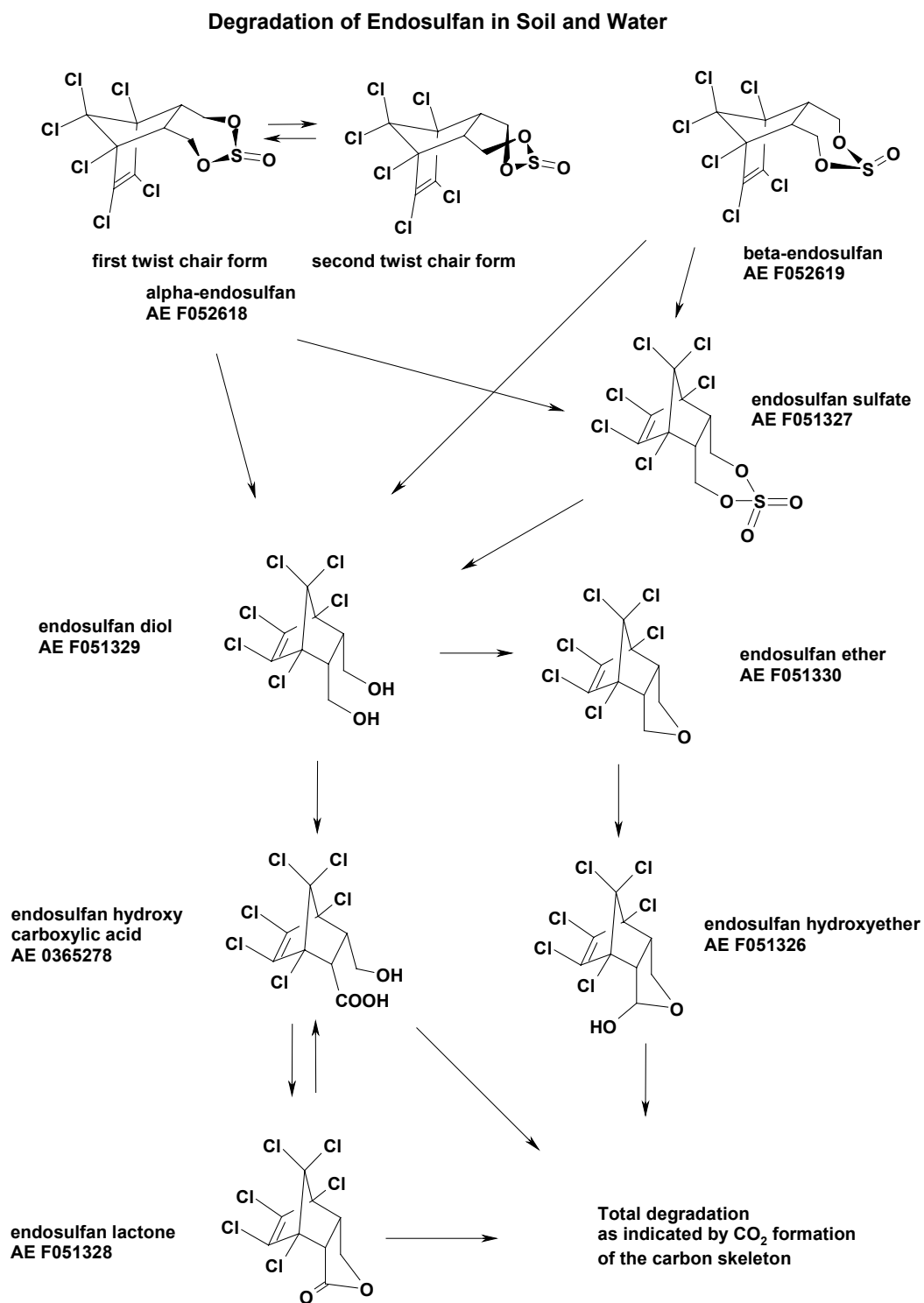


Figure 2: Conversion of α - and β -endosulphan Source: Aventis CropScience)

It appears that β -endosulphan is somewhat more stable than α -endosulphan and that the half-life of endosulphan including the metabolite E. sulphate exceeds 120 days in soil which is considered as a trigger for persistence (see PBT-criteria). Further, the laboratory data indicate the formation of bound residues in soil. It should be noted that dissipation does not mean mineralisation, and that volatilisation and bound residues can still be relevant for the environment. This also holds true for the two newer field dissipation studies following.

A field dissipation study performed in Spain (Aventis CropScience C015651) resulted in the following half-lives: α -endosulphan 1,4 day, β -endosulphan 7,5 days and endosulphan sulphate 75 days. The metabolite endosulphan sulphate achieved a maximum residue of 7,5% of the applied parent substance amount at 14 days and then declined to leave no detectable residues after 6 months.

A similar field dissipation study in Greece (Aventis CropScience C018180; test duration 12 months) revealed the half-lives: α -endosulphan 2 day, β -endosulphan 14-16 days and endosulphan sulphate 47-161 days. The residue level of endosulphan sulphate did not exceed 13,5% of the initial amount of radioactivity in soil. α - and β -endosulphan were not detectable 2 months after application while residues of endosulphan sulphate were still present after 12 months in concentrations very close the limit of quantification of 0,01 mg/kg.

The metabolite endosulphan sulphate has been observed in several terrestrial field studies (before 1975) involving plants. The sulphate is more persistent than the parent compound, accounting for 90% of the residue in a study lasting 11 weeks (NRC CANADA 1975).

When considering the PBT-properties of endosulphan, the persistence criterion (rev. TGD, 1.10.2001, Chapter 3B) has been set to:

- half-life > 60 d in marine water or > 40 d in fresh water (criterion not fulfilled due to rapid hydrolysis); or
- half-life > 180 d in marine sediment or > 120 d in freshwater sediment

Due to lack of data from sediment studies the half-lives in soil are applied here. Half-life of the parent substance is significantly lower than the trigger, but the metabolite endosulphan sulphate exceeds the triggers (half-life data from above: 140-240 d; 655-2210 d; 75 d; 47-161 d; therefore P-criterion fulfilled).

Conclusions regarding the degradability of endosulphan

Endosulphan hydrolyses quite fast in water, especially in the more alkaline marine water. However, in water/sediment systems mineralisation of endosulphan is low. Bound residues occur in significant amounts as well as stable metabolites, mainly endosulphan sulphate. Hydrolysis of endosulphan sulphate is possible, but no detailed information on rates is available. Nearly half of the radioactivity remains in the water phase in the water/sediment experiment. Overall, endosulphan can be characterised as moderately persistent in water with formation of stable metabolites.

In soil, mainly the metabolite endosulphan sulphate appears to be persistent with a half-life exceeding the persistence criterion of 120 d. Again mineralisation is limited and bound residues occur in significant amounts. With regard to the persistence of the metabolite endosulphan sulphate, the parent substance endosulphan can be characterised as highly persistent in soil.

Calculations of the half-life of endosulphan in air with respect to transformation by hydroxyl radicals (Atkinson model) are given in the EU-Monograph for endosulphan. They indicate a potential for long-range transport due to half-lives between 8,7 to 27 days. Further, there is evidence of occurrence of endosulphan in remote areas of the Arctic.

APPENDIX 3: DATA ON BIOACCUMULATION AND BIOCONCENTRATION

Information on bioaccumulation (in terms of bioconcentration, BCF) for endosulphan can be derived from the log P_{OW} using the formula:

$$\log BCF = 0,77 \log P_{OW} - 0,70 \quad (\text{MEYLAN ET AL. 1999});$$

$$\text{thus } \log BCF = 0,77 \cdot 4,77 - 0,70 = \underline{2,97}; \quad \text{calculated BCF} = \underline{940}.$$

The log P_{OW} value of more than 4 itself indicates a “potential for bioaccumulation”.

Data provided for re-registration of endosulphan in Germany 1990 (Source: Aventis CropScience A43406) indicate BCF-values of 350 to 4800 for fish (*Mugil cephalus*; *Carassius auratus*; $ct50^{14}$: 2-3 days) and 600 for mussel together with a clearance time ($ct50$ -value) of around 1 day (7 days of exposure and 2 days of depuration). This results in a high level of bioaccumulation and rapid depuration. Documents submitted for review under Directive 91/414/EEC showed BCF values of below 3000 in fish and in mussels. All studies confirmed the rapid elimination of the residues within 2-4 days (cf. OSPAR Factsheet).

Measured BCF values were obtained from the AQUIRE database (<http://www.epa.gov/ecotox/>; Table 9). The LC_{50} -values (as indicator for toxicity) and the water solubility ($\sim 0,4$ mg/l) are well above the test concentrations, indicating appropriate test conditions in bioaccumulation studies.

Table 9 Selected data on the bioaccumulation of endosulphan (CAS No. 115-29-7)

Test organism	Trophic level / Habitat	LC_{50} Test concentr.	Test conditions	BCF	Source / Year
<i>Anabena spec.</i>	pProd FW	2 150 µg/l 100 µg/l	2 d; FLO; FORM; whole	4 839	[1] / 1987
<i>Crassostrea madrasensis</i>	Filt SW	13-27 µg/l 0,14 µg/l	10 d; FLO; FORM; n.r.	70	[2] / 1991
<i>Mugil cephalus</i>	sCons SW	0,38 µg/l 0,035 µg/l	28 d; FLO; FORM; n.r.	2 755	[3] / 1977
<i>Cyprinodon variegatus</i>	sCons SW	> 0,3 µg/l 0,043-0,075 µg/l	28 d; FLO; ACT; whole	2 000 – 3 600	[4] / 1991
<i>Hyphessobrycon bifasciatus</i>	sCons FW	2,6 µg/l 0,3 µg/l	21 d; REN; FORM; whole	11 583	[5] ^a / 1993

[1] AQUIRE / 14044; RAO ET AL. 1987

[2] AQUIRE / 80; RAJENDRAN & VENUGOPALAN 1991

[3] AQUIRE / 5882; SCHIMMEL ET AL. 1977

[4] AQUIRE / 14143; HANSEN & CRIPE 1991

[5] AQUIRE / 7009; JONSSON & TOLEDO 1993¹⁵

Complete references may be obtained from the AQUIRE-Database.

pProd: primary producer; sCons: secondary consumer; Filt: filter-feeding organism; FW: freshwater species; SW: saltwater species; FLO: flow-through of test substance; REN: renewal of test substance; ACT: Active substance was used in the test; FORM: Formulation instead of active substance was used in the test, n.r.: not reported.

¹⁴ $ct50$: half-life clearance time, i.e. the time needed to reach 50% removal

¹⁵ The study of JONSSON & TOLEDO (1993) is not considered relevant by the notifier under Directive 91/414/EEC, because steady-state was not reached in the study and the BCF was calculated from uptake and elimination kinetics.

The BCF values obtained under laboratory conditions are used as a standard parameter for bioaccumulation assessment. The trigger value for bioaccumulation (B-criterion) in the current revision of the Technical Guidance Document (TGD, EC 1996; Environmental Risk Assessment – Marine; Chapter 3B; Draft of 1.10.2001) is set to $BCF > 2000$. BCF values for endosulphan, as stated above, exceed this trigger, therefore, endosulphan fulfils the B-criterion.

In an outdoor pond study, bioaccumulation factors were determined to be 100-200 in fish (Source Aventis CropScience A41298). These values might be useful for assessing secondary poisoning under relevant field conditions, but are not taken into account considering PTB-criteria. Therefore, the laboratory BCF is still and further being used as the standard parameter for bioaccumulation assessment.

Endosulphan does not easily dissolve in water; however, it is very lipophilic and does adsorb to suspended matter and sediment. In the treatment of a pond for control of tsetse fly in 1975-1978 in Botswana¹⁶, endosulphan was still traceable in fish after one year (less than 0,01 mg/kg). This was attributed to desorption of endosulphan from the sediment. Acute toxic concentrations were not achieved by these values, but the bioavailability is increased (Source: Aventis CropScience A43406).

Conclusions regarding the bioaccumulation potential

The log P_{OW} of 4,8 for the parent compound as well as laboratory bioconcentration studies indicate a high potential for bioaccumulation (BCF values of nearly 5 000). Thereby the BCF values of endosulphan exceed the trigger value of $BCF > 2\ 000$ for the B-criterion which has been set for the Environmental Risk Assessment in the marine environment in the current revision of the Technical Guidance Document (TGD, EC 1996; Draft of 1.10.2001; Chapter 3B; section 9.2).

¹⁶) Direct application of endosulphan in water bodies is not a recommended use by Aventis CropScience.

APPENDIX 4: DATA ON ACUTE AND CHRONIC ECOTOXICITY EFFECTS

Table 10 below shows that endosulphan is very highly toxic to fish species and aquatic invertebrates.

Table 10 Selected data on the ecotoxicity of endosulphan (CAS No. 115-29-7)

Test organism	Trophic lev. / Habitat	Endpoint / Effect	Test conditions	Endpoint concentr.	Source Year
<i>Scenedesmus subspicatus</i>	pProd FW	EC50 GRO	3 d	< 560 µg/l	OECD ^a prior GLP
<i>Penaeus duorarum</i>	pCons SW	LC50 MOR	4 d; FLO FORM	0,04 µg/l	[1] 1977
<i>Penaeus indicus</i>	pCons SW	LC50 MOR	4 d; REN; FORM	0,13 µg/l	[2] 1988
<i>Lagodon rhomboides</i>	sCons SW	LC50 MOR	4 d; FLO;	0,3 µg/l	[3] 1977
<i>Palaemonetes pugio</i>	sCons SW	LC50 MOR	4 d; REN; ACT	0,96 µg/l	[4] 1990
<i>Daphnia magna</i>	pCons FW	EC50 IMM	2 d; STA FORM	220 µg/l	[5] 1992
<i>Daphnia cephalata</i>	pCons FW	NOEC REP	14 d; REN ACT	49 µg/l	[6] 1996
<i>Tilapia mossambica</i>	sCons FW	LC50 MOR	4 d; REN; FORM	0,06 µg/l	[7] 1984
<i>Cyprinus carpio</i>	sCons FW	LC50	4 d	0,1 µg/l	BBA prior GLP ¹⁷
<i>Oncorhynchus mykiss</i>	sCons FW	NOEC	21 d	0,05 µg/l	OECD 204, GLP
<i>Morone saxatilis</i>	sCons FW	LC50 MOR	4 d; FLO; ACT	0,23 µg/l	[8] 1991

- [1] AQUIRE / 5882; SCHIMMEL ET AL. (1977)
- [2] AQUIRE / 13231; RAO ET AL. (1988)
- [3] SCHIMMEL ET AL. (1977)
- [4] AQUIRE / 18932; MOORE ET AL. (1990)
- [5] AQUIRE / 9597; FERRANDO ET AL. (1992)
- [6] AQUIRE / 17637; BARRY ET AL. (1996)
- [7] AQUIRE / 10431; MATTHIESSEN & LOGAN (1984)
- [8] AQUIRE / 15472; FUJIMURA ET AL. (1991)

Complete references may be obtained from the AQUIRE-Database.

pProd: primary producers; pCons: primary consumer; sCons: secondary consumer; FW: freshwater species; SW: saltwater species; GRO: Growth; MOR: Mortality, Immobilisation; STA: static test; REN: semi-static (renewal) test; ACT: active substance; FORM: Formulation instead of active substance was used in the test.

Compared to other aquatic species, LC₅₀-values of endosulphan with *Daphnia* are higher (and thus toxicity is lower). However, the LC₅₀-values for all species, including *Daphnia*, are well below 1 mg/l, and thus the substance is classified as “highly toxic for aquatic organisms”. The marine crustacean *Penaeus duorarum* shows an especially high sensitivity to endosulphan. The reference, SCHIMMEL ET AL. (1977), is considered to be a valid source in more recent references, although it is already quite old.

¹⁷ Document submitted for review under 91/414/EEC (OSPAR Minimum Fact Sheet).

Beyond the characterisation as PBT-substance, it can be shown that endosulphan poses a risk to organisms in the aquatic environment (Table 11). The available data refer to fresh water (monitoring data for the marine environment where not available), and risk in the marine environment may be higher. Even if there would be a higher dilution in the coastal and marine areas, there would be still a quite high PEC/PNEC ratio which would call for immediate action on risk reduction.

Table 11 shows several calculations of PEC/PNEC ratios with acute or chronic data and different assessment factors according to the proposed derivation of PNEC in the Marine risk Assessment in the current revision of the Technical Guidance Document. Since a large number of studies covering freshwater species as well as marine species is available for endosulphan, and the dose-response relationship has shown to be steep, the relevant PNEC has to be derived from a NOEC of the most sensitive species using an assessment factor of 100.

Due to lack of an appropriate model to calculate PECs for endosulphan in sea water and in lack of marine monitoring data, the freshwater PEC derived from the COMMPS data (see Table 5) is used as worst case. The risk characterisation in the water phase is used as surrogate, since it is acknowledged that endosulphan and the metabolite endosulphan sulphate are rapidly removed from the water phase by hydrolysis and/or adsorption to the sediment and suspended matter and may thus affect other sediment organisms more than those living exclusively in the water phase. PEC-values from sediment monitoring data (COMMPS aggregation, 90-percentile) are quite high: 81,6 µg/kg for α-endosulphan. A risk characterisation of the sediment toxicity is not possible due to the lack of data on sediment dwelling organisms. Nevertheless, a risk for sediment dwelling organisms can also be anticipated from the generally high toxicity of endosulphan.

Table 11 Risk Assessment for α-endosulphan (PEC/PNEC) with 90-percentile value from the COMMPS aggregation (river water; cf. Table 5). See Appendix 4 (Table 10) for data on toxicity for aquatic organisms

Toxicity test	Toxicity value (µg/l)	Assessment factor	PNEC (µg/l)	PEC (µg/l)	PEC/PNEC
Acute pink shrimp LC ₅₀	0,04	1000	$4 \cdot 10^{-5}$	0,0582	1 455
Acute fish LC ₅₀	0,23	1000	$2,3 \cdot 10^{-4}$	0,0582	253
Chronic fish NOEC	0,05	100	$5 \cdot 10^{-4}$	0,0582	116

Some toxicity data are available for the metabolites, indicating that endosulphan sulphate has a similar toxicity as the parent substance (Source: Aventis CropScience C010869, C016132) and endosulphan diol has a toxicity to fish which is less by about the factor of 1000 (Source: Aventis CropScience A67217). Other metabolites, following transformation of endosulphan diol (e.g. endosulphan lactone), do not show a significant toxicity and/or occur in minor amounts (Source: Aventis CropScience C013506, C013508, C013510).

Conclusions regarding ecotoxicity and risk characterisation

Endosulphan is a very toxic chemical to nearly all kinds of organisms. Also endosulphan sulphate has a similar toxicity as the parent substance. The risk characterisation (PEC/PNEC) for the freshwater phase, using a chronic NOEC from a sensitive species, indicates a high risk resulting from endosulphan in the aquatic environment.

APPENDIX 5: DATA ON CARCINOGENICITY, MUTAGENICITY OR HARMFUL REPRODUCTIVE EFFECTS

The following toxicological information is taken from the Pesticide Information Profile of the EXTOTOXNET database (<http://ace.orst.edu/cgi-bin/mfs/01/pips/endosulf.htm>); revision date is June 1996; see the PIP in the Internet for references).

Carcinogenic effects: In a long-term study done with both mice and rats, the males of both groups experienced such a high mortality rate that no conclusions could be drawn. However, the females of both species failed to develop any carcinogenic conditions 78 weeks after being fed diets containing up to about 23 mg/kg. The highest tolerated dose of endosulfan did not cause increased incidence of tumours in mice over 18 months, and a later study also showed no evidence of carcinogenic activity in mice or rats. **It appears that endosulfan is not carcinogenic.**

Mutagenic effects: Endosulphan is mutagenic to bacterial cells and yeast cells. The metabolites of endosulfan have also shown the ability to cause cellular changes. This compound has also caused mutagenic effects in two different mammalian species. **Thus, evidence suggests that exposure to endosulfan may cause mutagenic effects in humans if exposure is great enough.**

Reproductive effects: Rats fed doses of endosulfan of 2,5 mg/kg/day for three generations showed no observable reproductive effects, but 5,0 mg/kg/day caused increased dam mortality and resorption. Female mice fed the compound for 78 weeks (0,1mg/kg/day) had damage to their reproductive organs. Oral doses for 15 days at 10 mg/kg/day in male rats caused damage to the semeniferous tubules and lowered testes weights. **It is unlikely that endosulfan will cause reproductive effects in humans at expected exposure levels.**

Teratogenic effects: An oral dose of 2,5 mg/kg/day resulted in normal reproduction in rats in a three-generation study, but 5 and 10 mg/kg/day resulted in abnormalities in bone development in the offspring. **Teratogenic effects in humans are unlikely at expected exposure levels.**

The notifier for re-registration under Council Directive 91/414/EEC confirms with newer studies that endosulphan is not carcinogenic (Source: Aventis CropScience A55880, A40440, A44604, A41265, A38008, A41617).

The notifier for re-registration under Council Directive 91/414/EEC has presented several studies from the late 80s which did not show mutagenic effects in bacteria, yeast cells and different mammalian species at all dose levels used (Source: Aventis CropScience A21215, A29312, A29313, A29800, A29800, A29801, A33127, A38059, A38455, A40411). This was confirmed by JMPR Report 1998 (Joint FAO/WHO Meeting on Pesticide Residues; see [http:// www.inchem.org/documents/jmpr](http://www.inchem.org/documents/jmpr)). The references in the above stated PIP regarding mutagenic effects are the Handbook of Pesticide Toxicology (SMITH 1991) and a Toxicological Profile for endosulphan by the US-ATSDR (1990). These two references were not further evaluated in this background document. Linking the possibility of effects in humans with high exposures can not be reconstructed presently. For the moment, it is merely stated that the extrapolation of "no mutagenic effects" in tests with animals to humans might need further consideration.

Conclusions regarding CMRT

The investigation of chronic human toxicity shows that in mammals endosulphan is neither a carcinogen, nor a reproductive toxin or a teratogen. There are several results *in vitro* and *in vivo* showing no mutagenic effects, which indicate that mutagenic effects in humans are unlikely, but indications from other sources make it necessary to further evaluate mutagenicity.

APPENDIX 6: DATA ON TOXICOLOGICAL EFFECTS

The following toxicological information is taken from Pesticide Information Profile of the EXTOTOXNET database (<http://ace.orst.edu/cgi-bin/mfs/01/pips/endosulf.htm>); revision date is June 1996).

Acute toxicity: Endosulfan is highly toxic via the oral route, with reported oral LD₅₀ values ranging from 18 to 160 mg/kg in rats, 7,36 mg/kg in mice, and 77 mg/kg in dogs. It is also highly toxic via the dermal route, with reported dermal LD₅₀ values in rats ranging from 78 to 359 mg/kg. **Endosulfan may be only slightly toxic via inhalation**, with a reported inhalation LC₅₀ of 21 mg/l for 1 hour, and 8,0 mg/l for 4 hours. It is reported not to cause skin or eye irritation in animals. The alpha-isomer is considered to be more toxic than the beta-isomer. Animal data indicate that toxicity may also be influenced by species and by level of protein in the diet; rats which have been deprived of protein are nearly twice as susceptible to the toxic effects of endosulfan. Solvents and/or emulsifiers used with endosulfan in formulated products may influence its absorption into the system via all routes; technical endosulfan is slowly and incompletely absorbed into the body whereas absorption is more rapid in the presence of alcohol, oils, and emulsifiers. **Stimulation of the central nervous system is the major characteristic of endosulfan poisoning.** Symptoms noted in acutely exposed humans include those common to the other cyclodienes, e.g., uncoordination, imbalance, difficulty breathing, gagging, vomiting, diarrhoea, agitation, convulsions, and loss of consciousness. Reversible blindness has been documented for cows that grazed in a field sprayed with the compound. The animals completely recovered after a month following the exposure. In an accidental exposure, sheep and pigs grazing on a sprayed field suffered a lack of muscle coordination and blindness.

Chronic toxicity: In rats, oral doses of 10 mg/kg/day caused high rates of mortality within 15 days, but doses of 5 mg/kg/day caused liver enlargement and some other effects over the same period. This dose level also caused seizures commencing 25 to 30 minutes following dose administration that persisted for approximately 60 minutes. **There is evidence that administration of this dose over 2 years in rats also caused reduced growth and survival, changes in kidney structure, and changes in blood chemistry.**

Fate in humans and animals: Endosulfan is rapidly degraded into mainly water-soluble compounds and eliminated in mammals with very little absorption in the gastrointestinal tract. In rabbits, the beta-isomer is cleared from blood plasma more quickly than the alpha-isomer, with reported blood half-lives of approximately 6 hours and 10 days, respectively, which may account in part for the observed differences in toxicity. Cattle fed 0,15 mg/kg for 60 days had no residues in the fat. The metabolites are dependent on the mixture of isomers and the route of exposure. Most of the endosulfan seems to leave the body within a few days to a few weeks.

According to data provided by the notifier in the Council Directive 91/414/EC reregistration process, toxicity for rats is lower as stated above (LD₅₀ is 500 mg/kg for females and over 4000 mg/kg body weight for males; Source Aventis CropScience A39397).

The JMPR Report of 1998 states that more than 90% of an oral dose of endosulphan was absorbed in rats (cf. otherwise statement above) with maximum plasma concentrations occurring after 3-8 hours in males and about 18 h in females. Elimination occurs mainly in the faeces and to a lesser extent in the urine, more than 85% being excreted within 120 hours. The highest tissue concentrations were in the kidneys. The metabolites of endosulphan include endosulphan sulphate, diol, hydroxy-ether, ether, and lactone but most of its metabolites are polar substances which have not yet been identified. Endosulphan would not be expected to accumulate significantly in human tissues. WHO (1996) has classified endosulphan as moderately hazardous.

Conclusions regarding acute and chronic human toxicity

Summarising the toxic effects, it is evident that endosulphan has a high acute and also chronic toxicity. Metabolism is rapid, but the oxidised metabolite, endosulphan sulphate, shows an acute toxicity similar to that of the parent compound.

APPENDIX 7: DATA ON ENDOCRINE DISRUPTING EFFECTS

OSPAR listed endosulphan as a substance which has “been reported in the scientific literature to induce changes to the endocrine system of varying severity in the course of *in vitro* tests” (cf. Annex 3 of OSPAR Strategy with regard to Hazardous Substances).

The plant protection industry however makes the following statement and points out that endosulphan did not show *in vivo* estrogenic effects in several tests (Source: Aventis CropScience C005031, C001570).

Recent literature has implicated endosulfan as an endocrine disruptor in both terrestrial and aquatic species. At present there are no indications that endosulfan causes adverse health effects in fish secondary to changes in endocrine function. Although *in vitro* screening studies indicate binding of endosulfan to various oestrogen and progesterone receptors, an *in vivo* study in fathead minnows and, for example, a publication by ANDERSEN ET AL. (1999) do not indicate induction of vitellogenin up to dose levels, which are lethal to the test fish. Therefore, it is concluded that presently there is no indication that endosulfan has an oestrogenic potential *in vivo*.

The available data from published literature are inconclusive. Except for ANDERSEN ET AL. (1999) none of the *in vivo* studies with fish were conducted according to recognised protocols to detect endocrine effects (e.g. OECD 1997).

The absence of *in vivo* oestrogenic activity in fish is in good agreement with findings in mammals.

Published *in vitro* studies show that endosulfan has low binding potency to human oestrogen receptors, 10^5 to 10^6 times smaller than the natural hormone 17β -oestradiol. The binding potency of endosulfan is also low compared to that of many natural phyto-oestrogens available in the human diet.

Published screening studies for androgenic effects are inconclusive. Isolated findings such as increased steroid metabolism and reduced sperm count have been claimed, but these results are not in line with the outcome of the reproduction studies. Moreover, details on the methods and characterisation of the test substance were often not adequately defined.

In contrast, a large number of proprietary *in vivo* mammalian toxicity studies and published uterotherphic assays indicate that endosulfan does not elicit modulation of any endocrine or reproductive organs, nor any effect on reproductive performance, sexual development, differentiation or maturation, nor activity related to any other endocrinological endpoints was found, although in these studies doses were applied in the toxic range. Synergistic effects of endosulfan with other compounds were not found.

It is therefore concluded that endosulfan does not have an endocrine disrupting effect *in vivo*, despite of findings that it binds to receptors *in vitro*.

The JMPR Report (1998) on toxicology (Part II) confirms that there was no evidence that endosulphan is estrogenic from tests evaluated in the report (SHELBY ET AL. 1996).

The above stated findings have also been presented to the Office of Prevention, Pesticides and Toxic Substances of the United States Environmental Protection Agency. In the decision process on Reregistration Eligibility the US EPA comments on the endocrine potential as follows:

The Agency identifies an environmental endocrine disruptor as an exogenous agent that interferes with the synthesis, secretion, transport, binding action, or elimination of natural hormones in the body that are responsible for the maintenance of homeostasis, reproduction, development, and/or behaviour. Based on these criteria, the Agency disagrees with the conclusion by the registrant that endosulfan does not meet the definition of an endocrine disruptor. Binding to the estrogen receptor is only one potential mode of action for endocrine disruptors, namely direct interaction with a receptor in the target cells. Substances that act as endocrine disruptors may perturb the endocrine system in a variety of ways including but not limited to interfering with the synthesis, secretion, or transport of hormones in the organism. Consequently, the absence of high binding affinity to the estrogen receptor should not be interpreted as lack of endocrine disruption potential. The Agency notes that other organochlorines (i.e. DDT, DDE, dieldrin, and methoxychlor) have been demonstrated to interact with the endocrine system in spite of differing binding affinities to the estrogen receptor. Finally, the registrant states that no effects were reported after administration of endosulfan on the endocrine, reproductive or sexually

regulated systems at doses causing clear toxicity. However, it is noteworthy that testicular atrophy was reported during a Chronic Oral Toxicity Study in Rats (MRID 00004256) submitted to the Agency. Additionally, increased pituitary and uterine weights were also observed during a Multi-Generation Reproduction Study (MRID 00148264). Furthermore, an increase in the incidence of parathyroid hyperplasia was also reported during the Chronic Oral Toxicity study in Rats. The Agency emphasises the fact that the endocrine system integrates a variety of CNS-pituitary target organ pathways that not only affect reproductive or sexually regulated parameters but also regulates a wide array of bodily functions and homeostasis. Though this is not the case for endosulfan, it is important to note that a lack of overt toxicity to the reproductive system should not be interpreted as conclusive evidence of a lack of endocrine disruption. Given the effects noted in the Chronic Oral Toxicity Study in Rats and the Multi-Generation Reproduction Study submitted to the Agency, the potential of endosulfan to act as an endocrine disruptor can not be discounted. The Agency has requested that a Developmental Neurotoxicity Study be conducted; the Agency believes that this study will provide additional data that may help elucidate this matter.

The data presented above by the industry show that endosulphan does not possess an estrogenic effect *in vivo* under the conditions tested. However, from this and other studies it can not be excluded that endosulphan may have an effect on the reproduction of fish. Furthermore, endocrine disruption refers to a variety of effects beyond estrogenic effects (see statement of the US-EPA above) and thus, in this background document, the opinion of the US-EPA can be endorsed, that endosulphan can be considered as a potential endocrine disruptor.

Further *in vitro* results show binding to estrogen and progesterone receptors, LH-induced oocyte maturation and induction of vitellogenin genes. Further *in vivo* tests with fish show changes on ovaries, the steroid genesis, developmental changes, responses of secreting cells, and impact on behaviour, for example.

The above presented information and statements relates to endosulphan but does not address the potential endocrine disrupting effects of its metabolisation/degradation products. Ongoing research on environmentally mediated endocrine disruption in estuarine crustaceans (cf. progress report of US EPA project available on the web site <http://es.epa.gov/ncer/progress/grants/99/endocrine/chandler00.html>) proposes that some of these products, in particular endosulphan sulphate, might have more severe endocrine disrupting effects than its parent substance. In an experiment which induced the formation of endosulphan sulphate by UV exposure, less females of the grass shrimp (*Palaemonetes pugio*) became gravid, and at a lower rate. However, clutch size and hatching success were not affected. This result has to be considered in the light of the above definitions.

Conclusions with regard to endocrine disruption

There are several indications that endosulphan as well as its metabolite endosulphan sulphate are potentially endocrine disrupting chemicals. Under specifically tested *in vivo* conditions for fish, endosulphan did not show estrogenic effects, despite findings that it binds to receptors *in vitro*. Further *in vitro* and *in vivo* results show a variety of endocrine effects which support the indication of an endocrine disruption potential of endosulphan.

APPENDIX 8: MONITORING STRATEGY FOR ENDOSULPHAN

As part of the Joint Assessment and Monitoring Programme (*reference number 2003-22*), OSPAR 2004 adopted an Agreement on monitoring strategies for OSPAR Chemicals for Priority Chemicals (*reference number 2004-15*) to implement the following monitoring for tracking progress towards the objectives of the OSPAR Hazardous Substances Strategy (*reference number 2003-21*) with regard to endosulphan. The Monitoring Strategy for endosulphan will be updated as and when necessary, and redirected in the light of subsequent experience.

The mainly diffuse sources of endosulphan are well known and have been detailed in the Background Document and the EC Water Framework Directive fact sheet on endosulphan.

There are a number of relevant controls (e.g. regulations, directives, recommendations and decisions) on a) marketing and/or use, b) emissions and/or discharges of endosulphan which have been agreed by Contracting Parties both in OSPAR and in other international forums and have been highlighted as important measures for achieving the OSPAR Hazardous Substances objective with respect to endosulphan in the “choice for actions” chapter of the Background Document. Evidence from reports on the implementation of such measures will be used to make an initial judgement of the extent to which the amounts of these substances emitted or discharged are reduced.

Figures exist on the use as a plant protection product, but are scarce for the less important use as biocide and no notification had been submitted for endosulphan under the Biocides Directive. In collaboration with industry OSPAR will seek to compile European data on production and sales of endosulphan building on existing data sources on use as plant protection product and through collection of additional data on use as biocide. OSPAR will also investigate the possibilities for estimating the quantities of endosulphan imported to, and exported from, the OSPAR region.

Inputs of endosulphan to the NE Atlantic are not currently measured by OSPAR. The information currently available on atmospheric deposition should be reviewed to see whether it is adequate. Should it prove inadequate, the OSPAR Comprehensive Atmospheric Monitoring Programme (CAMP) should be amended to include monitoring of endosulphan. Data on riverine inputs of endosulphan will be calculated periodically using the results of monitoring of riverine concentrations under the EC Water Framework Directive.

Concentrations of endosulphan in the marine environment are not currently measured by OSPAR, but concentrations in transitional and coastal waters will be monitored under the EC Water Framework Directive. In order to establish whether the substance is found in the marine environment and to define locations where the substance is found in quantities that give rise to concern, OSPAR will firstly examine information currently available on concentrations of endosulphan in the OSPAR maritime area. If this information is not sufficient OSPAR will carry out a one-off survey of endosulphan. This activity should take into account the need to screen the occurrence of endosulphan in all matrices. Some monitoring data from Portugal are available, although this is based upon a detection limit (3-4 ng/l) which is higher than the WFD environmental quality standard for transitional waters (0.5 ng/l). Data obtained from Norway confirm the occurrence of endosulphan in polar bear blood. Germany is currently carrying out a national one-off survey which may provide experience that is helpful in the planning of a one-off survey.

Since the WFD is using Ecological Quality Standards (EQS) as legally binding limit values for endosulphan in water and since the OSPAR ultimate aim is to reach concentrations of endosulphan close to zero, it is not thought necessary for OSPAR to develop OSPAR EACs as assessment tools.

ENDOSULPHAN MONITORING STRATEGY	
<i>Implementation of actions and measures</i>	<ul style="list-style-type: none"> • Examination of progress in the implementation of regulations on marketing and/or use or emission and/or discharge which have been agreed, or are endorsed, by the Background Document
<i>Production/use/sales/figures</i>	<ul style="list-style-type: none"> • Collect, with assistance from industry, data on quantities produced and/or sold in the countries of the OSPAR Convention Area • Estimate quantities imported to, and exported from, the OSPAR Convention Area
<i>Atmospheric inputs</i>	<ul style="list-style-type: none"> • Monitoring for this substance will be included in the CAMP if information currently available on atmospheric deposition of endosulphan is not adequate
<i>Riverine inputs</i>	<ul style="list-style-type: none"> • Where available, data for riverine inputs will be periodically calculated from EC WFD monitoring
Maritime area:	
<i>Concentrations in sediments, water and biota</i>	<ul style="list-style-type: none"> • A one-off survey (exploratory and hot-spots) will be carried out¹⁸
<i>Concentrations in water</i>	<ul style="list-style-type: none"> • Where available, data will be periodically compiled from EC WFD monitoring

¹⁸ If information available currently should not be sufficient