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Chemical Review Committee
Third meeting
Rome, 20–23 March 2007
Item 5 (b) (iii) of the provisional agenda*

Listing of chemicals in Annex III of the Rotterdam Convention: review of notifications of final regulatory actions to ban or severely restrict a chemical: endosulfan

Endosulfan

Note by the Secretariat

The Secretariat has the honour to provide, in the annex to the present note, documentation received from the European Commission to support its notification of final regulatory action on endosulfan.

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

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Annex

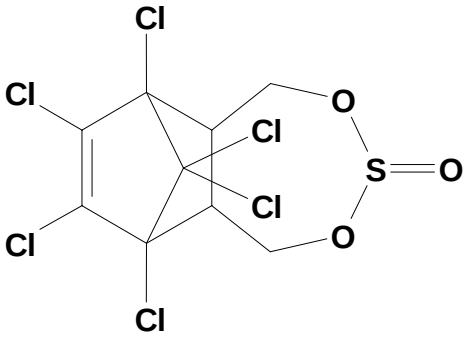
- Endpoints, July 2004. A monograph on endosulfan.
- A Commission working document on endosulfan – 15/02/2005.
- Commission decision of 2/12/2005.

Chapter 1: **Identity, Physical and Chemical Properties, Details of Uses, Further Information and Proposed Classification and Labelling**

Active substance (ISO Common Name)	Endosulfan
Function (*e.g.* fungicide)	Insecticide

Rapporteur Member State	Spain

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzo-dioxathiepin-3-oxide
Chemical name (CA)	6,9-methano-2,4,3-benzodioxathiepin,6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-3-oxide
CIPAC No	89
CAS No	115-29-7
EEC No (EINECSor ELINCS)	204-079-9
FAO Specification (including year of publication)	CP/228
Minimum purity of the active substance as manufactured (g/kg)	940 +/- 20 g / Kg (FAO)
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	No relevant impurities
Molecular formula	$C_9H_6Cl_6O_3S$
Molecular mass	406.96 g/mol
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity if not purified)	α - endosulfan: 109.2 °C (Aventis) β - endosulfan: 213.3 °C (Aventis) Mixture of isomers (99 %): 76 – 124 °C (Calliope)
Boiling point (state purity if not purified)	**Not required**
Temperature of descomposition	**Not required**
Appearance (state purity if not purified)	Flakes with tendency to agglomeration cream to tan mainly beige. Odour like sulphur dioxide.
Relative density (state purity if not purified)	1.87 g / cm^3 (Calliope)
Surface tension	**Not required.** Solubility < 1 mg / l
Vapour pressure (in Pa. State temperature)	α - endosulfan: 1.05 x 10^{-3} Pa (Calliope) β - endosulfan: 1.38 x 10^{-4} Pa (Calliope)
Henry's law constant (Pa m^3 mol^{-1})	α - endosulfan: 1.1 Pa x m^3 x mol^{-1} at 20 °C. β - endosulfan: 0.2 Pa x m^3 x mol^{-1} at 20 °C.
Solubility in water (g/l or mg/l state temperature)	α - endosulfan: 0.41 mg / l (Makhteshim-Agan) β - endosulfan: 0.23 mg / l (Makhteshim-Agan) Thionex (mixture of isomers): 0.63 mg / l No pH dependency observed (Calliope)
Solubility in organic solvents (in g/l or mg/l state temperature)	dichloromethane: 2007g / l (Calliope)
	ethyl acetate: 1009 g / l (Calliope)
	ethanol (aprox) ≅ 65 g / l (Aventis)
	n – hexane = 24 g / l (Aventis)
	acetone = 1164 g / l (Calliope)
	toluene = 2260 g / l (Mackteshim-Agan)
Partition co-efficient (log P_{ow}) (state pH and temperature)	log P_{ow} = 4.7 No pH dependence is observed.
Hydrolityc stability (DT_{50}) (state pH and temperature)	**α - endosulfan** T = 25°C (Aventis) pH 5: > 200 days
	pH 7: 19 days
	pH : 0.26 days
	β - Endosulfan T = 25°C pH 5: > 200 days
	pH 7: 10.7 days
	pH : 0.17 days
Dissociation constant	According molecular structure Endosulfan cannot dissociate.
UV/VIS absortion (max.) (if absortion > 290 nm state ε at wavelength)	No significant absorvance above 290 nm.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Photolitically stable
Quantum yield of direct phototranformation in	Photolitically stable

water at $\lambda > 290$ nm	
Flammability	Not capable of burning
Explosive properties	Non-explosive

LIST OF USES SUPPORTED BY AVAILABLE DATA – REPRESENTATIVE USES (DATE: JULY 2004) *

Active substance: **Endosulfan**

1	2	3	4	5	6	7	8				9			10	11
Crop and/or situation	Member State or Countrry	Product Name	F G or	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
			I		Type	Conc. of a.s.	method, kind	growth stage & season	number (range)	interval betw. appl. (minimum)	kg a.s./hl (range)	water l/ha (range)	kg a.s./ha (range)		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)					(l)	(m)
Cotton	Spain	Thionex 35EC Thiodan 35EC	F	thrips	EC	350 g/l	hydraulic spray	n/a	1	n/a	0.0525	750 -1000	0.394 – 0.525	21	Chosen dose for risk assessments
Cotton	Greece	Thionex 35EC Thiodan 35EC	F	thrips	EC	350 g/l	hydraulic spray	n/a	1	n/a	0,07-0,098	500-800	0,35-0,784	21	
Tomatoes	Spain	Thionex 35EC Thiodan 35EC	F	aphids	EC	350 g/l	hydraulic spray	n/a	1	n/a	0.0525	500, 750 - 1000	0.262, 0.394, 0.525	3	Chosen dose for risk assessments
Tomatoes	Spain	Thionex 35EC Thiodan 35EC	G	aphids	EC	350 g/l	hydraulic spray	n/a	1	n/a	0.0525	500 - 750	0.262 – 0.394	3	Chosen dose for risk assessments
Tomatoes	Greece	Thionex 35EC Thiodan 35EC	G	aphids	EC	350 g/l	hydraulic spray	n/a	1	n/a	0.0399	500 - 2000	0.199 – 0.798	3	

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

* Uses for which the risk assessment can not be concluded are marked grey.

Classification and proposed labelling (Annex IIA, point 10)

With regard to physical/chemical data	None
With regard to toxicological data	T+ Very toxic R21 Harmful in contact with skin R28 Very toxic if swallowed R26 Very toxic by inhalation
With regard to fate and behaviour data	N Dangerous for the environment
With regard to ecotoxicological data	R50/53 Highly toxic to aquatic organism, may cause long-term adverse effects in the aquatic environment.

Chapter 2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	CIPAC 89/TC/M2/-(CIPAC hand book 1C, 2110-2113, 1985). GC8-TCD detection.
Impurities in technical as (principle of method)	GC8-TCD detection. See ANNEX C
Plant protection product (principle of method)	CIPAC 89/TC/M2/-(CIPAC hand book 1C, 2110-2113, 1985). GC8-TCD detection.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	There are methods for rape seed, peach and tomato that have been validated and have been validated by an independent laboratory. Intended uses are supported by these methods. Capillary GC/ECD. LOQ = 0.02 mg / kg for each analyte (enddosulfan-alpha, beta and sulfate). Two alternative stationary phases are proposed to be employed as confirmatory technque.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Multiresidue method Detection: GC/ECD; Confirmatory GC/MSD. LOQ = 0.025 mg/kg for each analyte (enddosulfan-alpha, beta and sulfate). Fish: LOQ = 0.025 mg/kg for each analyte (enddosulfan-alpha, beta and sulfate).
Soil (principle of method and LOQ)	Method AL 60/86. Extracted from soil with acetone and anlysed GC-ECD. Confirmatory method with GC-MS available.
Water (principle of method and LOQ)	Endosulfan and endosulfan sulfate are extracted with hexane and analysed by GC-ECD. Confirmatory technique available using a GC column with a different stationary phase. LOQ = 0.05 µg / L for drinking water and for surface water. **The validation of the method was submitted in June 2004 and was not evaluated by the RMS because was submitted after the deadline**
Air (principle of method and LOQ)	Absortion in Tenax tubes. Eluted with ethyl acetate. GC-ECD. LOQ = 0.5 µg / m^3. Confirmatory technique is available with GC/MS.
Body fluids and tissues (principle of method and LOQ)	Method available for alpha- beta- endosulfan, endosulfan sulfate, endosulfan alcohol, endosulfan lactone and hydroxyendosulfan ether (endosulfan aldehyde) by GC-MS. LOQ = 0.05 mg /kg. Fish: A validated method for determination of endosulfan and metabolites in fish (alpha-endosulfan, beta-endosulfan and endosulfan sulphate) was submitted Oct 2001. The method was found acceptable with a LOQ = 0.025 mg/kg for each residue component.

Chapter 3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and exent of absortion:	Between 70% (m) and 87% (f) in the rat within 96 h in the rat.
Distribution:	Initially widely distributed. Highest residues in kidney and liver (7 days)
Potential for accumulation:	No relevant accumulation
Rate and exent of excretion:	Mainly via faeces (65-82% males, 60-72% females) within 120 h. Urine (11-13% males, 2-24% females), within 120 h.
Metabolism in animals	Extensively metabolised. 15-18 % unchanged in faeces
Toxicologically significant compounds (animals, plants and environment)	Parent compound and its metabolites (endosulfan-sulphate and endosulfan-lactone, mainly).

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	10-22.7 mg/kg bw (f)
Rat LD_{50} dermal	500 mg/kg bw (f)
Rat LC_{50} inhalation	0.0126 mg/l air for 4 hours (f)
Skin irritation	Non-irritant
Eye irritation	Non-irritant.
Skin sensitisation (test method used and result)	Non-sensitizer (M&K)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Neurological signs
Lowest relevant oral NOAEL / NOEL	0.6 mg/kg bw/day: 1-year dog study
Lowest relevant dermal NOAEL / NOEL	3 mg/kg bw/day (m): 28-day rat study
Lowest relevant inhalation NOAEL / NOEL	NOEL>0.002 mg/l/day: 29-day rat study

Genotoxicity (Annex IIA, point 5.4)

Negative *in vitro* and *in vivo* in somatic cells.

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target / critical effect	Rats: kidney alterations Mice: changes in body and organ weights.
Lowest relevant NOAEL / NOEL	0.6 mg/kg bw/day: 104-week oral rat study
Carcinogenicity	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	Not identified.
Lowest relevant reproductive NOAEL / NOEL	75 ppm, equivalent to 5 mg/kg bw/day (males) and 6 mg/kg bw/day (females): 2-generation reproduction toxicity study in rats.
Developmental target / critical effect	Rats: fetotoxicity (isolated skeletal variations) at maternally toxic doses.

	Rabbits: no effects.
Lowest relevant developmental NOAEL/NOEL	2 mg/kg bw/day: teratology study in rats.

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Neurotoxicity	NOAEL: 1.5 mg/kg bw (females): rat neurotoxicity study
Delayed neurotoxicity	No evidence: hen delayed neurotoxicity.

Other toxicological studies (Annex IIA, point 5.8)

Toxicity of plant and mammalian metabolites

Endosulfan-sulphate (included in the residue definition)	Toxicologically significant metabolite based on results from oral acute and subchronic toxicity studies. Rat LD_{50} oral =25-50 mg/kg bw (f) (T, R25) Rat LD_{50} dermal =280 mg/kg bw (f) (T, R24) NOAEL (provisional) = 0.75 mg/kg bw/day (90-day dog). No genotoxic potential.
Endosulfan-diol (not included in the residue definition)	Non-toxicologically significant metabolite
Endosulfan-lactone (not included in the plant residue definition but present in equilibrium with endosulfan hydroxy carboxylic acid which is included in the water residue definition)	Toxicologically significant metabolite based on results from oral acute and subchronic toxicity studies. Rat $_{LD50}$ oral= 25-200mg/kg bw (m) (T. R25) NOAEL= 0.6 mg/kg bw/day (90-day rat) No genotoxic potential
Endosulfan-hydroxyether (not included in the residue definition)	Non-toxicologically significant metabolite based on results from an oral acute toxicity study.
Endosulfan-ether (not included in the residue definition)	Non-toxicologically significant metabolite based on results from an oral acute toxicity study.

Additional studies (Annex IIA, point 5.8)

Immunotoxicity studies	No evidence of immunotoxicity.
Endocrine system	Weight of evidence is that Endosulfan is not an endocrine disruptor
Tumour-promoting potential	Data were not of concern due to the lack of carcinogenicity seen in standard chronic studies.

Medical data (Annex IIA, point 5.9)

	Evidence of several cases of incidental poisoning and in production workers.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.006 mg/kg bw/day	104-week, rat	100
Systemic AOEL	0.0042 mg/kg bw/day	1-year, dog	100. Correction factor for oral absorption, 70%
Drinking water limit	Not allocated		
ArfD	0.015 mg/kg bw/day	Neurotoxicity study, rat	100

Acceptable exposure scenarios (including method of calculation)

Operator	Accepted for proposed uses (cotton and tomato)
Thiodan EC 35 Scenario 1: Field crop (cotton, tomatoes). Tractor mounted hydraulic nozzles, low crop Scenario 2: Greenhouse (tomatoes) Tractor mounted hydraulic nozzles, high crop	 Tier 1 German model: 23.81% AOEL (Standard PPE) Tier 1 German model: 119% AOEL (Standard PPE) Tier 2 Exposure study (Idstein et al., 1991) 106.7% AOEL (Standard PPE) 58.13% AOEL (Standard PPE+ Mask (5%) in M/L + Hood & visor (5%) in Application)
Workers Hoernicke et al., 1998 model TC followed EPA data for re-entry	Accepted for proposed uses 25 % AOEL for scouting of efficacy in cotton fields. 24 % AOEL for tomatoes collection, taking into account the use of shoes, socks and protection clothes for arms and legs.
Bystanders Drift data from Ganzelmeier et al., 1995	Accepted for proposed uses 1.09% and 4.46% AOEL by cotton and tomatoes treated fields

Dermal absorption (Annex IIIA, point 7.3)

2.2% for diluted formulation and 0.8% for concentrate formulation based on *in vivo* and *in vitro* studies (24 h)

Chapter 4: Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7; Annex IIIA, point 8.1 and 8.6)

Plants group covered	**Fruits (pome fruit; tomato and cucumber) and Oilseeds (soyabean)**
Rotation crops	No data available
Plant residue definition for monitoring	Endosulfan (α+β) and endosulfan sulfate
Plant residue definition for risk assessment	Endosulfan (α+β) and endosulfan sulfate
Conversion factor (monitoring to risk assessment)	

Metabolism in livestock (Annex IIA, point 6.2 and 6.7; Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating cow and laying hens
Animal residue definition for monitoring	Endosulfan (α+β), endosulfan sulfate, and endosulfan lactone
Animal residue definition for risk assessment	Endosulfan (α+β), endosulfan sulfate, and endosulfan lactone
Conversion factor (monitoring to risk assessment)	
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes

Residues in succeeding crops (Annex IIA, point 6.6; Annex IIIA, point 8.5)

Spinach: <0.06 mg/kg 97 DAA Lettuce: < 0.06 mg/kg 141 DAA Wheat: <0.06 mg/kg 247 DAA

Stability of residues (Annex IIA, point 6 introduction; Annex IIIA, point 8 introduction)

Stable for 18 months in grape, potato, tomato, melon and lettuce, grape juice, potato flakes, potato wet peel, tomato paste and tomato puree. **Data required on cotton to be dealt with at MS level** Endosulfan (alpha, beta and sulfate) is stable in all animal matrices for 12 months. **The stability of endosulfan lactone must be demonstrated at MS level.**

Residues from livestock feeding studies (Annex IIA, point 6.4; Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes/no	Poultry: Yes/no	Pig: Yes/no
Muscle	Not required for Annex I listing		
Liver			
Kidney			
Fat			
Milk			
Eggs			

Summary of critical residues data (Annex IIA, point 6.3; Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP[(a)]	Recommendation/comments	MRL	STMR [(b)]
Fruiting vegetables (tomatoes-Solanacea)	S(F)	1x0.03, 3x0.04, 2x0.06, 2x0.07, 2x0.08, 1x0.10, 1x0.12, 2x0.20	Data from field trials	0.3	0.07
	S(G)	1x0.06, 1x0.09; 1x0.1, 1x0.11, 1x0.12, 1x0.18; 1x0.19; 1x0.20; 2x0.23, 1x0.24, 1x0.27, 1x0.28, 1x0.32, 1x0.65	Data from greenhouse trials. . 0.65 was considered as outlier	0.5	0.20
Cotton	S	2x0.01, 1x0.02, 2x0.03, 1x0.05, 3x0.06, 2x0.08, 1x0.11, 1x0.51		0.5	0.055

(a) Numbers of trial in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical

Consumer risk assessment (Annex IIA, point 6.9; Annex IIIA, point 8.8)

ADI	0.006 mg/kg bw/day
TMDI (% ADI)	9.17% (only tomato) 30.79% (tomato and other crops LOQ)
IEDI (European Diet) (% ADI)	UK Adults (mean): 12.87% UK Child (mean): 17.55% UK Infant (mean): 60.8% UK Todler (mean): 42.8%
Factors included in IEDI	
ARfD	0.015
Acute exposure (% ArfD)	Tomatoes 19.47% Adults; 88.27% Tolders

Processing factors (Annex IIA, point 6.5; Annex IIIA, point 8.4)

Crop/proccessed crop	Number of studies	Transfer factor	% Transference
Tomato/Fruits washed	2	0.66-1.0	
Tomato/Fruits peeled	2	0.04-0.2	
Tomato/Peel	2	16.7-12.1	
Tomato/Tomato Raw juice	2	0.20-0.40	
Tomato/Wet tomato pomace	2	5.60-11.5	
Tomato/Canned peeled tomato (pasteurised)	2	0.07-0.2	
Tomato/Canned unpeeled tomato (sterilised)	2	0.45-0.7	
Tomato/Tomato juice (pasteurised)	2	0.27-0.4	
Tomato/Canned Peeled tomato (pasteurised)	2	0.10-0.4	

Proposed MRLs (Annex IIA, point 6.7; Annex IIIA, point 8.6)

Crop/Commodity	Proposed MRL
Tomatoes (field)	0.5
Tomatoes (greenhouse)	0.5
Cotton	0.5

Chapter 5: Fate and Behaviour in the Environmental

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

α+β Endosulfan

Mineralization after 100 days	Probably less than 5 %. It was not correctly measured in any study.
Non-extractable residues after 100 days	< 20% after 100 days 9.5-34.2% after 365 days.
Relevant metabolites – name and/or code, % of applied (range and maximum)	Endosulfan sulphate Max. 54.2-77% (30-365 d) 34.3-77% at 365 days

Endosulfan sulphate

Mineralization after 100 days	1.01 – 13.08% at 120 d (n=4)
Non-extractable residues after 100 days	15.02-28.51% at 120 d (n=4)
Relevant metabolites – name and/or code, % of applied (range and maximum)	Endosulfan sulphate 8.36-45.5% at 365 d (n=4) **Unknown** Max 9.23 -15.23% at 120-30 d; <LOD at 365 (n=4) referred to the amount of endosulfan sulphate **Identification of the unknown metabolite is required**

Route of degradation in soil – Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	Slower and with no significant differences between the isomers than during the aerobic degradation. Endosulfan sulphate was the main degradation product (15-33 % Applied radioactivity at 53 days)
Soil photolysis	DT_{50} > 200 days

Rate of degradation in soil (Annex IIA, point 7.1.1.2; Annex IIIA, point 9.1.1)

Method of calculation	First order kinetics
Laboratory studies (range or median, with n value, with r^2 value)	Sandy loam $DT_{50\ lab}$ endosulfan (α+β): (20°C aerobic): 98 $DT_{90\ lab}$ endosulfan (α+β): (20°C aerobic): 326 r^2: 0.77; n:12
	Loamy sand $DT_{50\ lab}$ endosulfan (α+β): (20°C aerobic): 128 $DT_{90\ lab}$ endosulfan (α+β): (20°C aerobic): 426 r^2: 0.90; n:13
	Silt loam $DT_{50\ lab}$ endosulfan (α+β): (20°C aerobic): 90 $DT_{90\ lab}$ endosulfan (α+β): (20°C aerobic): 299 r^2: 0.90; n:13
	Sandy loam $DT_{50\ lab}$ endosulfan (α+β): (20°C aerobic): 92 $DT_{90\ lab}$ endosulfan (α+β): (20°C aerobic): 305 r^2: 0.71; n:8

	Sandy loam $DT_{50\ lab}$ endosulfan (α+β): (20°C aerobic): 80 $DT_{90\ lab}$ endosulfan (α+β): (20°C aerobic):265 r^2: 0.84; n:11
	Silty loam $DT_{50\ lab}$ endosulfan (α+β): (20°C aerobic): 25.6 $DT_{90\ lab}$ endosulfan (α+β): (20°C aerobic): 85 r^2: 0.96; n:8
	Loamy sand $DT_{50\ lab}$ endosulfan (α+β): (20°C aerobic): 37.5 $DT_{90\ lab}$ endosulfan (α+β): (20°C aerobic): 124.7 r^2: 0.57; n:8
	$DT_{50\ lab}$ endosulfan (α+β): (28°C aerobic): 37 $DT_{90\ lab}$ endosulfan (α+β): (28°C aerobic):194 r^2:0.99; n:4 DT50s have been calculated for α+βendosulfan due to the fact that both isomers are the active sustance. A degradation study of α and β endosulfan in a separate way shows that no interconversion occurs during the degradation. **Endosulfan sulphate (First order kinetics)** DT50lab=123-391d (20±2ºC;30-40% MWHC) (n=4;r^2=0.92-0.98)
Degradation in the saturated zone:	No data
Field studies (state location, range or median with n value)	Germany (silty loam) DT_{50f}(α+β): 91.6 days; DT_{90f}(α+β): 304.2 days (First order kinetics) r^2=0.90; n=10; 29% Endosulfan sulphate 151 DAT
	Germany (sandy silty) DT_{50f} (α+β): 35.9 days; DT_{90f} (α+β): 395.9 days (Root First order kinetics) r^2= 0.64; n=8; 17% Endosulfan sulphate 447 DAT
	Germany (loamy sandy) DT_{50f} (α+β): 38.5 days; DT_{90f} (α+β):424.6 (Root First order kinetics); r^2= 0.94; n=10; 50% Endosulfan sulphate 28 DAT
	Germany (Sandy loam) DT_{50f} (α+β): 16.5 days; DT_{90f} (α+β):181.8 (Root First order kinetics); r^2= 0.76; n=10; 67% Endosulfan sulphate 336 DAT
	Georgia (Sandy loam) DT_{50f} (α+β): 75.86 days; DT_{90f} (α+β):252 days (First order kinetics); r^2=0.88; n=18
	Georgia (Sandy loam) DT_{50f} (α+β): 89.6 days; DT_{90f} (α+β):297.7 days (First order kinetics); r^2=0.86; n=18
	California (Clay loam) DT_{50f} (α+β): 92.9 days; DT_{90f} (α+β): 308.8 days (First order kinetics); r^2=0.89; n=13
	California (Clay loam) DT_{50f} (α+β): 89.5 days; DT_{90f} (α+β): 297.5 days (First order kinetics); r^2=0.82; n=13
(1) . The soil samples of these studies were analysed for α-β-endosulfan and endosulfan sulphate, other metabolites were not analysed in this study. In previous studies (included in the monograph) endosulfan diol was detected in the field dissipation studies after several applications of endosulfan (Hacker 1989 (A42193); Mester 1990	Spain (Loam) DT_{50f} (α+β):**7.4 days** ; DT_{90f} (α+β):24.6 days: r^2 = 0.97 n=5 SFO Endosulfan sulphate: max 7.5 % of applied parent at 14 DAT. DT_{50f} (endosulfan sulfate): 75.2 days, $DT90_f$ (endosulfan sulphate) 249.7 days (r^2=0.89; (TopFIt FOMC) Greece: DT_{50f} (α+β):**21 days** ; DT_{90f} (α+β):70 days; r^2 = 0.96; n=5 DT_{50f} (endosulfan sulfate): 161 days (r^2=0.873; (TopFIt FOMC)
	Modelling should be recalculated by the notifier taking into account the considerations made to calculate formation and degradation constants of metabolite endosulfan sulphate

Soil accumulation and plateau concentration	Study conducted in The Netherlands: Residues of endosulfan are not expected, residues of endosulfan sulphate could be expected almost 7-9 months after last application. (0.4 mg/kg) Endosulfan sulphate Plateu: 20-50% of the initial concentration. **The available information suggests a potential high persistence of a soil residue constituted by a number of chlorinated metabolites, which may not account individually for more than 10% of applied dose but that all together may represent high amount of it.**

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f / K_{oc}	OM= 1.06-4.53%; pH=5.4-5.9 α Endosulfan: 7969-21347 β Endosulfan: 8612-13906 Endosulfan sulfate: 5667-11445 Endosulfan diol: 724-1216
K_d	OM= 1.06-4.53%; pH=5.4-5.9 α Endosulfan: 81-1022; β Endosulfan: 89-473; Endosulfan sulfate: 53.5-358 Endosulfan diol: 8.7-37.4
PH dependence (yes / no) (<u>if yes type of dependence</u>)	No data available

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	No data
Aged residues leaching	<0.2% of the applied radioactivity were found in the leachate
Lysimeter/field leaching studies	No data

PEC (soil) (Annex IIIA, point 9.1.3)

α+β Endosulfan

Method of calculation	0% and 50% of crop interception. Top 5 cm soil column. Bulk density 1.5 g/cm^3. DT_{50}= 93 days for α+β Endosulfan.
Application rate	

Crops	Maximum Single Treatment Rate kg a.s./ha	Number of Applications	Spraying interval
Cotton	0.784	1	N/A
Tomatoes (field)	0.53	1	N/A
Tomatoes (greenhouse)	0.8	1	N/A

Crops (50% interception)	Maximum Single Treatment Rate kg a.s./ha	Number of Applications	PIEC mg sa/kg single application
Cotton	0.784	1	0.523
Tomatoes (field)	0.53	1	0.35
Tomatoes (greenhouse)	0.8	1	0.53

Crops (0% interception)	Maximum Single Treatment Rate kg a.s./ha	Number of Applications	PIEC mg sa/kg single application
Cotton	0.784	1	1.045
Tomatoes (field)	0.53	1	0.7066
Tomatoes (greenhouse)	0.8	1	1.066

Estimated $PEC_{(s)}$ and TWA $PEC_{(s)}$ after last application in cotton (assuming 50% of interception)

PEC (mg/Kg) time after last application		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.523		N/A	N/A
Short term	24h	0.519	0.521	N/A	N/A
	2d	0.515	0.519	N/A	N/A
	4d	0.507	0.515	N/A	N/A
Long term	7d	0.496	0.509	N/A	N/A
	14d	0.471	0.496	N/A	N/A
	28d	0.424	0.472	N/A	N/A
	50 d	0.36	0.436	N/A	N/A
	100 d	0.248	0.368	N/A	N/A

Estimated $PEC_{(s)}$ and TWA $PEC_{(s)}$ after last application in tomato (field)

$PEC_{(s)}$ (mg/Kg) time after last application		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.353		N/A	N/A
Short term	24h	0.351	0.352	N/A	N/A
	2d	0.348	0.351	N/A	N/A
	4d	0.343	0.348	N/A	N/A
Long term	7d	0.335	0.344	N/A	N/A
	14d	0.318	0.336	N/A	N/A
	28d	0.287	0.319	N/A	N/A
	50d	0.243	0.295	N/A	N/A
	100d	0.168	0.249	N/A	N/A

Estimated $PEC_{(s)}$ and TWA $PEC_{(s)}$ after last application in tomato (greenhouse)

$PEC_{(s)}$ (mg/Kg) time after last application		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.533		N/A	N/A
Short term	24h	0.529	0.531	N/A	N/A
	2d	0.525	0.529	N/A	N/A
	4d	0.518	0.525	N/A	N/A
Long term	7d	0.506	0.520	N/A	N/A

$PEC_{(s)}$ (mg/Kg) time after last application	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
14d	0.480	0.506	N/A	N/A
28d	0.433	0.481	N/A	N/A
50d	0.367	0.445	N/A	N/A
100d	0.253	0.376	N/A	N/A

Endosulfan sulphate

Method of calculation	13.4% of the applied concentration (initial PEC) multiplied by a factor of 1.0393 DT50= 161 days

Southern conditions

Crops (50% of interception)	Maximum Single Treatment Rate kg a.s./ha	Number of Applications	Spraying interval	PIEC mg /kg single applications
Cotton	0.784	1	N/A	0.0728
Tomatoes (field)	0.53	1	N/A	0.0491
Tomatoes (greenhouse)	0.8	1	N/A	0.0742

Crops (0% of interception)	Maximum Single Treatment Rate kg a.s./ha	Number of Applications	Spraying interval	PIEC mg /kg single applications
Cotton	0.784	1	N/A	0.1455
Tomatoes (field)	0.53	1	N/A	0.098
Tomatoes (greenhouse)	0.8	1	N/A	0.148

Estimated $PEC_{(s)}$ and TWA $PEC_{(s)}$ after last application in cotton (assuming 50% of interception)

PEC (mg/Kg) time after last application	Southern conditions	
	Single Application Actual	Single Application Time weighted average
Initial	0.148	
Short term24h	0.147	0.148
2d	0.147	0.147
4d	0.145	0.147
Long term 7d	0.144	0.146
14d	0.139	0.144
28d	0.131	0.139
60 d	0.114	0.13
100 d	0.096	0.120

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 5: >200 days
	pH 7: α Endosulfan 19 d β Endosulfan 10.7 d
	pH 9: α Endosulfan 6.2 h β Endosulfan 4.1 h
Photolytic degradation of active substance and relevant metabolites	Stable
Readily biodegradable (yes/no)	No
Degradation in Water/sediment	pH 7.3-7.8
-DT_{50} water	15 days; R^2=0.86; n=8 (River main) (α+β endosulfan plus endosulfan sulphate 12 days; R^2=0.85; n=8 (Gravel pit) (α+β endosulfan plus endosulfan sulphate
-DT_{90} water	No estimated
- DT_{50} whole system	21 days; R^2=0.82; n=8 (River main) (α+β endosulfan plus endosulfan sulphate 18 days; R^2=0.83; n=8 (Gravel pit) (α+β endosulfan plus endosulfan sulphate
- DT_{90} whole system	68 days; R^2=0.82; n=8 (River main) (α+β endosulfan plus endosulfan sulphate 59 days; R^2=0.83; n=8 (Gravel pit) (α+β endosulfan plus endosulfan sulphate
Mineralization	< 0.1%
Bound residue	20-23 % at the end of the study (51 DAT)
Distribution in water / sediment systems (active substance)	10.8% / 37.7 % at 4 DAT
Distribution in water / sediment systems (metabolites)	0.8 % / 10.6 % at 51 DAT of endosulfan sulfate 28.4% / 4% at 32 DAT of Endosulfan hydrocarboxylic acid 29.6%/43.1% at 4 DAT (α+β endosulfan plus endosulfan sulphate
Degradation in Water/sediment **at 20±2ºC and different pH**	
DT_{50} water (α+βendosulfan; simple 1st order kinetics)	Krempe system (pH in water 7.3): 0.7 days (r^2=99%) Ohlau system (pH in water 6.8): 1.6 days (r^2=94.8%) Pinnsee system (pH in water 6.7): 1.52 days (r^2=82.52%) Tonteich system (pH in water 4.5): 2.072 days (r^2=94.841%)
DT_{90} water (α+βendosulfan; simple 1st order kinetics)	Krempe system (pH in water 7.3): 2.4 days (r^2=99%) Ohlau system (pH in water 6.8): 6.1 days (r^2=94.8%) Pinnsee system (pH in water 6.7): 5.211 days (r^2=82.52%) Tonteich system (pH in water 4.5): 6.8 days (r^2=94.841%)
DT_{50} whole system (α+βendosulfan; simple 1st order kinetics)	Krempe system (pH in water 7.3): r^2< 70% Ohlau system (pH in water 6.8): 28.31 days (r^2=97.67%) Pinnsee system (pH in water 6.7): 34.7 d (r^2=96.37%) Tonteich system (pH in water 4.5): 164.4 d

$\underline{DT_{90}}$ whole system (α+βendosulfan; simple 1st order kinetics)	(r^2=93.56%) Krempe system (pH in water 7.3): r^2< 70% Ohlau system (pH in water 6.8): 94.05 days (r^2=97.67%) Pinnsee system (pH in water 6.7): 115 d (r^2=96.37%) Tonteich system (pH in water 4.5): 546.25 d (r^2=93.56%)
Mineralization	Krempe system: max 1.5 at 93 DAT Ohlau system: max 1.5 at 93 DAT Pinnsee system: max 3% at 365 DAT Tonteich system: max 1.8% at 365 DAT.
Bound residue	Krempe system : max 19% at 120 DAT Ohlau system : max 8.2% at 120 DAT Pinnsee system : max 18.35% at 156 DAT Tonteich system : max 15.5% at 365 DAT.
Distribution in water / sediment systems (active substance)	Krempe system (pH in sediment 6.6): sediment: max 55.6 % at 30 DAT. At the end of the study (120 Days): 19.4% Ohlau system (pH in sediment 6.1): sediment: max 54.4 % at 10 DAT. At the end of the study (120 Days): 6.2% Pinnsee system (pH in sediment 7.2): max 66.6% at 3 DAT. At the end of the study (365 Days): 2.8% Tonteich system (pH in sediment 4.9): max 81.8% at 10 DAT. At the end of the study (365 Days): 23.8%

Distribution in water / sediment systems (metabolites)

water phase:

Endosulfan diol
Krempe max 35% at 2 DAT (1.2% at 120 DAT)
Ohlau max 23.66% at 3 DAT (2.8% at 120 DAT)

Endosulfan carboxylic acid:
Krempe: max 32.9% at 93 DAT (25.3% at 120 DAT)
Ohlau max 44.3 at 93 DAT (25.3% at 120 DAT)
Pinnsee max 15.6 % at 365 DAT (no plateau)

sediment:

Endosulfan sulphate:
Ohlau: max 22.3% at 120 DAT (no plateau)
Pinnsee: max 46.2 % at 118 DAT (35% at 365 DAT)
Tonteich: max 28.5 % at 365 DAT (no plateau)

Endosulfan diol:
Krempe : max 41.5 % at 10 DAT (15.2% at 120 DAT)
Ohlau: max 12.4 at 10 DAT (1.7 at 120 DAT)
Pinnsee: max 10.7% at 45 DAT (<0.1% at 365 DAT)
Tonteich: 11.3% at 91 DAT (6.2% at 365 DAT)

Endosulfan lactone:
Tonteich: 13.3% at 365 DAT (no plateau)

whole system

Endosulfan sulphate:
Krempe : max 7.1% at 120 DAT
Ohlau: max 25.3 at 58 DAT
Pinnsee: max 51.6% at 156 DAT
Tonteich: 28.68% at 365 DAT

Endosulfan diol:
Krempe : max 50.1% at 2 DAT
Ohlau: max 34.7 at 7 DAT
Pinnsee: max 16.5 % at 45 DAT
Tonteich: 13.1% at 91 DAT

Endosulfan carboxylic acid:
Krempe : max 32.9% at 93 DAT
Ohlau: max 44.3 at 93 DAT
Pinnsee: max 19.2 % at 365 DAT
Tonteich: <10%TAR

Endosulfan lactone:
Krempe <10%TAR
Ohlau <10%TAR
Pinnsee: 8.8 % at 91 DAT (6.6% at 365 DAT)
Tonteich: 14.8% TAR AT 365 DAT (pH 5)

Endosulfan hydroxyether
Krempe: 9.8% at 10 DAT (2.8 at 120 DAT)
Ohlau: 10.1% at 14 DAT (1.1 at 120 DAT)
Pinnsee <10%TAR
Tonteich <10 % TAR

PEC (surface water) (Annex IIIA, point 9.2.3)

Method of calculation	Drift . 0-30 m buffer zone.
Application rate	See table
Main routes of entry	Drift, runoff.

$PIEC_{sw}$ values for the selected crops after the last application

Crop	Application rate Kg as/ha	Nº	SI days	Distance m	Drift %	Initial PECsw (µg as/L) 0.3 m depth
Arable crops (cotton)	0.784	1	N/A	0	100.0	261.33
				1	2.77	7.239
				3		
				5	0.57	1.49
				10	0.29	0.758
				15	0.2	0.523
				20	0.1	0.392
				30	0.1	0.261
Arable crops (Tomato field)	0.53	1	N/A	0	100.0	176.66
				1	2.77	
				3	-	4.894
				5	0.57	1.007
				10	0.29	0.512
				15	0.2	0.353
				20	0.1	0.265
				30	0.1	0.177

The longest half life for the dissipation of endosulfan from the water body amounted to 1.6 days. Based on the PIEC and this DT50 the actual and time weighted average PECs are given in the following tables on the worst case (cotton)

	1 m		5 m		10 m		20 m		30 m	
DAT	**PEC**	**PECtwa**	**PEC**	**PECtwa**	**PEC**	**PECtwa**	**PEC**	**PECtwa**	**PEC**	**PECtwa**
0	7.2389	7.2389	1.4896	1.4896	0.7579	0.7579	0.3920	0.3920	0.2613	0.2613
1	4.6939	5.8748	0.9659	1.2089	0.4914	0.6151	0.2542	0.3181	0.1695	0.2121
2	3.0436	4.8421	0.6263	0.9964	0.3186	0.5069	0.1648	0.2622	0.1099	0.1748
3	1.9735	4.0514	0.4061	0.8337	0.2066	0.4242	0.1069	0.2194	0.0712	0.1463
4	1.2797	3.4390	0.2633	0.7077	0.1340	0.3600	0.0693	0.1862	0.0462	0.1242
7	0.3489	2.2721	0.0718	0.4675	0.0365	0.2379	0.0189	0.1230	0.0126	0.0820
10	0.0951	1.6490	0.0196	0.3393	0.0100	0.1726	0.0052	0.0893	0.0034	0.0595
14	0.0168	1.1908	0.0035	0.2450	0.0018	0.1247	0.0009	0.0645	0.0006	0.0430
15	0.0109	1.1123	0.0022	0.2289	0.0011	0.1165	0.0006	0.0602	0.0004	0.0402
21	0.0008	0.7956	0.0002	0.1637	0.0001	0.0833	0.0000	0.0431	0.0000	0.0287
28	0.0000	0.5968	0.0000	0.1228	0.0000	0.0625	0.0000	0.0323	0.0000	0.0215
29	0.0000	0.5762	0.0000	0.1186	0.0000	0.0603	0.0000	0.0312	0.0000	0.0208
30	0.0000	0.5570	0.0000	0.1146	0.0000	0.0583	0.0000	0.0302	0.0000	0.0201
35	0.0000	0.4774	0.0000	0.0982	0.0000	0.0500	0.0000	0.0259	0.0000	0.0172
42	0.0000	0.3979	0.0000	0.0819	0.0000	0.0417	0.0000	0.0215	0.0000	0.0144
60	0.0000	0.2785	0.0000	0.0573	0.0000	0.0292	0.0000	0.0151	0.0000	0.0101
90	0.0000	0.1857	0.0000	0.0382	0.0000	0.0194	0.0000	0.0101	0.0000	0.0067

	1 m		5 m		10 m		20 m		30 m	
DAT	**PEC**	**PECtwa**	**PEC**	**PECtwa**	**PEC**	**PECtwa**	**PEC**	**PECtwa**	**PEC**	**PECtwa**
100	0.0000	0.1671	0.0000	0.0344	0.0000	0.0175	0.0000	0.0090	0.0000	0.0060
120	0.0000	0.1392	0.0000	0.0287	0.0000	0.0146	0.0000	0.0075	0.0000	0.0050
150	0.0000	0.1114	0.0000	0.0229	0.0000	0.0117	0.0000	0.0060	0.0000	0.0040
170	0.0000	0.0983	0.0000	0.0202	0.0000	0.0103	0.0000	0.0053	0.0000	0.0035
180	0.0000	0.0928	0.0000	0.0191	0.0000	0.0097	0.0000	0.0050	0.0000	0.0034
190	0.0000	0.0879	0.0000	0.0181	0.0000	0.0092	0.0000	0.0048	0.0000	0.0032
200	0.0000	0.0835	0.0000	0.0172	0.0000	0.0087	0.0000	0.0045	0.0000	0.0030
250	0.0000	0.0668	0.0000	0.0138	0.0000	0.0070	0.0000	0.0036	0.0000	0.0024
300	0.0000	0.0557	0.0000	0.0115	0.0000	0.0058	0.0000	0.0030	0.0000	0.0020
350	0.0000	0.0477	0.0000	0.0098	0.0000	0.0050	0.0000	0.0026	0.0000	0.0017
365	0.0000	0.0458	0.0000	0.0094	0.0000	0.0048	0.0000	0.0025	0.0000	0.0017

PEC (sediment)

Method of calculation	Max observed in the sediment: 66.6% 0.8 g/cc 5 cm of depth
Application rate	

$PEC_{(sed)}$ mg/kg	Single application Actual 0 m	Single application Actual 1 m	Multiple application Actual	Multiple application Time weighted average
Initial	1.305	0.03616	N/A	N/A

Metabolites

Endosulfan sulphate

Method of calculation	Max observed in the sediment: 46.2% 0.8 g/cc 5 cm of depth
Application rate	0.784 Kg/ha

$PEC_{(sed)}$ mg/kg	Single application Actual 0 m	Single application Actual 1 m	Multiple application Actual	Multiple application Time weighted average
Initial	0.376	0.01042	N/A	N/A

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, Lysimeter)	Parent Endosulfan and endosulfan sulfate and endosulfan diol can be regarded as immobile.
Application rate	

$PEC_{(gw)}$

Maximum concentration	

Average annual concentration	

Fate and behaviour in air (Annex IIA, point 7.2.2; Annex IIIA, point 9.3)

Direct photolysis in air	No direct photolysis
Photochemical oxidative degradation in air (DT_{50})	8.5 to 27 days Atkinson Calculation. (EU scenario) 1.3 days using a realistic average of the hydroxyl radical concentration of 1.5 x 10^6 OH^- radicals cm^{-3} for 12 hours per day (US EPA)
Volatilization	From soil: α isomer > β isomer 25 to 29% of TAR (24h) Leaf surfaces: α isomer > β isomer 63.6-63.7% of TAR (24h) Vapor Pressure: α - endosulfan: 1.05 x 10^{-3} Pa β - endosulfan: 1.38 x 10^{-4} Pa Henry Law Constant: α - endosulfan: 1.1 Pa x m^3 x mol^{-1} at 20 °C. β - endosulfan: 0.2 Pa x m^3 x mol^{-1} at 20 °C

PEC (air)

Method of calculation	No data

$PEC_{(a)}$

Maximum concentration	No data

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environmental	**Soil:** Both isomers of the active substance (α endosulfan; β endosulfan) and endosulfan sulphate. **Water phase:** α + β endosulfan , hydroxy carboxylic acid and endosulfan diol **Sediment:** α + β endosulfan, endosulfan sulphate, endosulfan diol and endosulfan lactone**.** **Air**: α endosulfan

Monitoring data, <u>if available</u> (Annex IIA, point 7.4)

Soil (<u>indicate location and type of study</u>)	No data available
Surface water (<u>indicate location and type of study</u>)	No data available
Ground water (<u>indicate location and type of study</u>)	No data available
Air (<u>indicate location and type of study</u>)	**Canadian Arctic:** α endosulfan: 2.7 to 9.7 pg/m^3 in 1986; 1.8 to 5.0 pg/m^3 in 1987 β endosulfan: non detected. **Hoff et al**
	Stable Island (Canada):

Endosulfan (sum of 2 isomers) 24-159 pg/m^3 in summer. 1.4-3.0 pg/m^3 (endosulfan α only) in winter.
Germany: Water and snow. Not detected.

Chapter 6: Effects on Non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals	Rat LD50= 10 mg/kg b.w.
Long-term toxicity to mammals	Rat, (two generation study) NOEL = 5 mg/kg b.w Rat (teratogenic study) NOEL = 2 mg/kg bw/day
Acute toxicity to birds	Mallard duck LD50 = 28 mg/kg bw.
Dietary toxicity to birds	Bobwhite quail = 805 ppm
Reproductive toxicity to birds	Mallard duck NOEC = 30 ppm

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.784	Cotton	Medium herbivorous birds	Acute	0.54	10
0.784	Cotton	Medium herbivorous birds	Short-term	6.75	10
0.784	Cotton	Medium herbivorous birds	Long-term	0.31	5
0.525	Tomatoes	Medium herbivorous birds	Acute	0.8	10
0.525	Tomatoes	Medium herbivorous birds	Short-term	10.08	10
0.525	Tomatoes	Medium herbivorous birds	Long-term	0.47	5
0.784	Cotton	Insectivorous birds	Acute	0.67	10
0.784	Cotton	Insectivorous birds	Short-term	10.66	10
0.784	Cotton	Insectivorous birds	Long-term	2.96	5
0.525	Tomatoes	Insectivorous birds	Acute	1	10
0.525	Tomatoes	Insectivorous birds	Short-term	16.1	10
0.525	Tomatoes	Insectivorous birds	Long-term	4.39	5
0.784	Cotton	Medium herbivorous mammals	Acute	0.52	10
0.784	Cotton	Medium herbivorous mammals	Long-term	0.43	5
0.525	Tomatoes	Medium herbivorous mammals	Acute	0.78	10
0.525	Tomatoes	Medium herbivorous mammals	Long-term	0.64	5

Risk assessment for birds and mammals has been made following the new guidance document on birds and mammals.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
fish	technical	Acute	96h LC50 range	0.0001-0.160
fish	technical	Acute	96h LC50 95th percentile	0.00013
fish	α endosulfan	Acute	96h LC50	0.00075
			96 h NOEC	0.00017
fish	β endosulfan	Acute	96h LC50	> 0.00311
			96 h NOEC	0.00078
fish	Endosulfan ether	Acute	96h LC50	>1.65

			96 h NOEC	0.38
fish	Endosulfan lactone	Acute	96h LC50	0.57
			96 h NOEC	0.33
fish	Endosulfan hydroxyether	Acute	96h LC50	2.32
			96 h NOEC	0.65
fish	Endosulfan sulfate	Acute	96h LC50	0.0022
Fish	Endosulfan sulfate	Acute	96h LC50	0.00082
			96 h NOEC	0.00092
fish	formulation	Acute	96h LC50	0.00024
invertebrates	technical	Acute	LC50 range	0.00004 – 5.6
invertebrates	technical	Acute	LC50 most sensitive invertebrate	0.00004
Invertebrates (Daphnia)	technical	Acute	48 h EC50 range	0.062-0.740
Invertebrates (Daphnia)	technical	Acute	48h EC50 Daphnia 90th percentile	0.15
Invertebrates (Daphnia)	α endosulfan	Acute	48h LC50	0.224
Invertebrates (Daphnia)	β endosulfan	Acute	48h LC50	0.528
Invertebrates (Daphnia)	Endosulfan ether	Acute	48h LC50	0.577
Invertebrates (Daphnia)	Endosulfan lactone	Acute	48h LC50	>1.3
Invertebrates (Daphnia)	Endosulfan hydroxyether	Acute	96h LC50	1.6
			96 h NOEC	
Invertebrates (Daphnia)	Endosulfan sulfate	Acute	48h LC50	0.3
invertebrates	Formulation	Acute	48 h LC50	0.0001
algae	Technical	Chronic	72 h NOEC	0.56
fish	technical	Chronic	28 d NOEC	0.00005
Fish	Technical	Chronic	21 d NOEC	0.00028
Fish	Endosulfan (98%)	Chronic	260 d NOEC	0.000056
invertebrates	technical	Chronic	21 d NOEC	0.063

Microcosm or mesocosm tests

A pond study is considered the essential work, fish mortalities were observed for water concentrations of 0.4 and 1 µg/l and the percentage of species affected is in agreement with the proportion estimated by the sensitivity distribution curve. No effects on water column invertebrates were observed. No conclusions on the effects on sediment dwelling organisms can be achieved.

Schanne, 2002

[^{14}C]-α,β-Endosulfan formulated as emulsifiable concentrate (352g/l endosulfan): outdoor aquatic microcosm study of the environmental fate and ecological effects.

The objectives of this freshwater field test were the following:

1. Fate and relative distribution of 352 g/l EC formulated α,β-Endosulfan and its metabolites in major compartments of outdoor aquatic ecosystems after application as simulated realistic spray drift and run-off.
2. Investigation of acute and sublethal effects on bluegill sunfish (*Lepomis macrochirus*) including fish residue analysis.
3. Analysis of the community of sediment-dwelling organisms at test end, including residue analysis in these organisms and various compartments of the sediment.

The results lead to the conclusion, that the residue of endosulfan and its metabolites disappears from the water phase with time due to volatilisation after treatment (spray-drift), biodegradation and distribution to other compartments of the ecosystem. This is valid for both entry routes. Endosulfan, endosulfan diol and endosulfan hydroxy ether disappear rather fast from water, whereas other components like endosulfan lactone, **M1 and M4** increase with time but stay at low levels throughout the study. Endosulfan sulfate is found at about constant, but low levels in the water. All of the above components are found in sediments and plant materials at different amounts, depending on the matrix and the total residue. The residue of endosulfan in the sediment is

higher after run-off, due to deposition of treated particles onto the sediment surface.

The **NOEC** for toxic effects of endosulfan 352 g/l EC formulation on bluegill sunfish (*Lepomis macrochirus*) is **1.96 µg ai/l** after spray-drift entry and **2.09 µg soil residue/l** after run-off entry (triplicate treatment at increments of 14 days). The **NOEC** for toxic effects on sediment-dwelling organisms is **3.50 µg ai/l** after spray-drift and **3.99 µg soil residue/l** after run-off entry for triplicate treatment scenario at increments of 14 days.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Application rate (kg as/ha)	Crop	Isomer metabolite	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
0.784	Cotton		Fish		1	**0.0077**	100
0.784	Cotton		Fish		30	**0.2**	100
0.525	Tomatoes		Fish		1	**0.01**	100
0.525	Tomatoes		Fish		30	**0.3**	100
0.84 (3X)	Arable crop	Technical	Fish	acute	1 10 30	**0.035** **0.089** **0.35**	100
0.84 (3X)	Arable crop	α endosulfan	Fish	Acute	1 10 30	**0.067** **0.67** **2.68**	100
0.84 (3X)	Arable crop	β endosulfan	Fish	Acute	1 10 30	**>0.28** **>2.77** **11**	100
0.84 (3X)	Arable crop	Formulated product (352 g/l)	Fish	Microcoms study	1 30	**0.17** **7**	
0.84 (3X)	Arable crop	Endosulfan sulfate	Fish	Acute	1 10 30	**0.19** **1.96** **7.86**	100
0.84 (3X)	Arable crop	Endosulfan ether	Fish	Acute	1 10	>147 >1473	100
0.84 (3X)	Arable crop	Endosulfan lactone	Fish	Acute	1 10	**50.9** 509	100
0.84 (3X)	Arable crop	Endosulfan hydroxiether	Fish	Acute	1 10	207 2071	100
0.84 (3X)	Arable crop	Technical	Daphnia	Acute	1 10 30	**53.57** **18.75** 535.71	100
0.84 (3X)	Arable crop	α endosulfan	Daphnia	Acute	1 10	**20** 200	100
0.84 (3X)	Arable crop	β endosulfan	Daphnia	Acute	1 10	**47** 471	100
0.84 (3X)	Arable crop	Endosulfan sulfate	Daphnia	Acute	1 10	**26.7** 267	100
0.84 (3X)	Arable crop	Endosulfan ether	Daphnia	Acute	1 10	**51** 515	100
0.84 (3X)	Arable crop	Endosulfan lactone	Daphnia	Acute	1 10	>116 >1160	100
0.84 (3X)	Arable crop	Endosulfan hydroxiether	Daphnia	Acute	1 10	143 1429	100

TERs are calculated for the initial PECsw using the BBA spray drift method

Bioconcentration

Bioconcentration factor (BCF)	2500-11000
Annex VI Trigger:for the bioconcentration factor	100
Clearance time (CT_{50})	1.74-4.04 days

(CT_{90})	

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	LD50 = 2 µg ai/bee (based on formulation product)
Acute contact toxicity	LD50 = 0.82 µg ai/bee (based on formulation product)

Hazard quotients for honey bees (Annex IIIA, point 10.4)

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

Field or semi-field tests

Mortality: Qm (average) = 0.7 (Northern Spain); Qm (average) = 31 (middle Spain)
Flight Intensity: Similar in the test substance and the control (Northern Spain); Slightly decresed (middle Spain)
Honey bee brood development: No abnormal difference

The submitted study indicates possibility of some treated related effects at the selected dose which corresponds to the higher intended dose but using a single application. The relevance of these effects for actual GAP is not very high, risk reduction methods should be required.
One single application has been proposed in the new GAPs.

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
						30%
						30%
						30%

Field or semi-field tests
Field study in citrus orchard in Spain. : the study indicates some effects related to the treatment with endosulfan, but only for certain specific groups and with recovery after treatment. The results on citrus orchard can be extrapolated to other crops. The need for risk management measures should be considered at MS level.
In the tripartite meeting, the Commission stated that a safe use has to be demonstrated and the notifier should demonstrate that the mitigation measures for citrus are relevant for cotton and tomatoes. However, this information has not been submitted by the notifier.

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	11 mg/kg (geometric mean validated data)
Acute toxicity (endosulfan sulphate)	51.5 mg/kg LC50 14 days <1 mg/kg NOEC 14 days
Reproductive toxicity	No data submitted

Field or semi-field tests

Forster and Salaün, 2003.

Field study to evaluate the effects of endosulfan 35 EC on earthworms in a grass field in Cornwall, UK. Application rates: control, (water), 28.6 g ai/ha Endosulfan 35 EC, 490 g ai/ha Endosulfan 35 EC, 840 g ai/ha Endosulfan 35 EC, 4000 g ai/ha carbendazim (reference item) applied on first application occasion only. The overall conclusion of this study is that endosulfan 35 EC applied at a rate of 28.6 g ai/ha had no detrimental effect on earthworm populations during the duration of the study.

Klein, 2003.

Effects of endosulfan 352 g/l (nominal) on the decomposition of organic matter enclosed in the litter bags in the field

The conclusion of the study was that endosulfan 352 g/l do not cause an adverse impact on organic matter breakdown under field conditions.

The lack of information on soil metabolites does not allow to conduct a proper long-term risk assessment. However, based on the risk assessment presented by the notifier based on field studies, a high risk for earthworm should be considered for the proposed GAPs.

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

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

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralisation	No relevant effects for 5x the a.r.
Metabolite endosulfan sulphate: Carbon mineralisation Nitrogen transformation	it does not have any long term influence on soil microflora when endosulfan-sulfate applied up to 11.2 mg/kg soil dry weight.

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
E3 - Chemicals, Contaminants and Pesticides

Endosulfan

SANCO/4327/2000 - rev. 2

15.2.2005

COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Review report for the active substance **endosulfan**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on **15 February 2005**

in support of a decision concerning the non-inclusion of endosulfan in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of endosulfan, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92([1]) laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000([2]), has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Endosulfan is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, United Phosphorus Ltd on 26 July 1993, AGREVO GMBH on 27 July 1993, Makhteshim Agan on 20 July 1993, Helm AG on 23 July 1993, Calliope SA on 21 July 1993, Industrias Afrasa on 27 July 1993 and B.V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance endosulfan in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94([3]), as last amended by Regulation (EC) No

[1] OJ No L 366, 15.12.1992, p.10.

[2] OJ No L 259, 13.10.2000, p.27.

[3] OJ No L 107, 28.04.1994, p.8.

2230/95([4]), designated Spain as rapporteur Member State to carry out the assessment of endosulfan on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for endosulfan this deadline was 31 October 1995.

Only AGREVO GMBH & Makhteshim Agan as a task force, Calliope SA, and B.V. Luxan submitted in time a dossier to the rapporteur Member State.

AGREVO GMBH (now BAYER CROPSCIENCE) on behalf of the endosulfan task force (comprising AGREVO GMBH & Makhteshim Agan), submitted a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore, AGREVO GMBH being the designated representative of the endosulfan task force, was considered to be the main data submitter.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Spain submitted on 22 February 2000 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of endosulfan in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on endosulfan from AGREVO GMBH & Makhteshim Agan on 06 June 2000.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 27 June 2000 as well as to AGREVO GMBH being the designated representative of the endosulfan task force on 25 August 2000.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from January to July 2001.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States on 27 June 2001 and the main data submitter on 25 August 2001 for comments and further clarification.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the

[4] OJ No L 225, 22.09.1995, p.1.

Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 17 May 2004.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the **Standing Committee on the Food Chain and Animal Health**, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. This final examination took place from July 2001 to September 2004, and was finalised in the meeting of the **Standing Committee** on 15 February 2005.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of Decision **2005/864/EC**[5] concerning the non-inclusion of endosulfan in Annex I to Directive 91/414/EEC.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to all operators having notified for this active substance under Article 4(1) of this Regulation.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion of this evaluation, based on the information available and the proposed conditions of use, is that:

- **the information available is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to

    - the environmental fate and ecotoxicology of the substance
    - the operator exposure under indoor conditions
    - certain data gaps concerning methods of analysis and the route and rate of degradation of the substance in soil and water/sediment systems

- **concerns were identified with regard to**

    - the fate and behaviour of the substance in the environment, in particular its degradation, persistence, potential of long range transport and potential of bioaccumulation
    - its possible impact on non-target organisms
    - its possible impact on operators under indoor conditions

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

Endosulfan should therefore not be included in Annex I to Directive 91/414/EEC.

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5 **OJ No L 317, 03.12.2005**

COMMISSION DECISION

of 2 December 2005

concerning the non-inclusion of endosulfan in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance

(notified under document number C(2005) 4611)

(Text with EEA relevance)

(2005/864/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular the fourth subparagraph of Article 8(2) thereof,

Whereas:

(1) Article 8(2) of Directive 91/414/EEC provided for the Commission to carry out a programme of work for the examination of the active substances used in plant protection products which were already on the market on 25 July 1993. Detailed rules for the carrying out of this programme were established in Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [2].

(2) Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Commission Regulation (EEC) No 3600/92 [3], designated the active substances which should be assessed in the framework of Regulation (EEC) No 3600/92, designated a Member State to act as rapporteur in respect of the assessment of each substance and identified the producers of each active substance who submitted a notification in due time.

(3) Endosulfan is one of the 89 active substances designated in Regulation (EC) No 933/94.

(4) In accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92, Spain, being the designated rapporteur Member State, submitted on 22 February 2000 to the Commission the report of its assessment of the information submitted by the notifiers in accordance with Article 6(1) of that Regulation.

(5) On receipt of the report of the rapporteur Member State, the Commission undertook consultations with experts of the Member States as well as with the main notifiers Bayer CropScience and Makhteshim Agan as provided for in Article 7(3) of Regulation (EEC) No 3600/92. It appeared that further data were required. Commission Decision 2001/810/EC [4] laid down a deadline for data submission by the notifier, which expired 25 May 2002. The same decision set a further deadline of 31 May 2003 for specified long term studies.

(6) The Commission organised a tripartite meeting with the main data submitters and the rapporteur Member State for this active substance on 17 May 2004.

(7) The assessment report prepared by Spain has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. This review was finalised on 15 February 2005 in the format of the Commission review report for endosulfan.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2005/58/EC (OJ L 246, 22.9.2005, p. 17).
[2] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 27).
[3] OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).
[4] OJ L 305, 22.11.2001, p. 32.

(8) During the evaluation of this active substance, a number of areas of concern have been identified. This was in particular the case concerning its environmental fate and behaviour as the route of degradation of the active substance is not completely clear and unknown metabolites were found in soil degradation, water/sediment degradation and mesocosm studies. In ecotoxicology many concerns remain since the long term risk, in particular, due to the presence of the abovementioned metabolites, cannot be sufficiently addressed with the available information. In addition exposure of operators under indoor conditions has not been considered to be sufficiently addressed with the available information. Moreover endosulfan is volatile, its main metabolite is persistent and it has been found in monitoring results of regions where the substance was not used. Consequently, as these concerns remain unsolved, assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing endosulfan satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(9) Endosulfan should therefore not be included in Annex I to Directive 91/414/EEC.

(10) Measures should be taken to ensure that existing authorisations for plant protection products containing endosulfan are withdrawn within a prescribed period and are not renewed and that no new authorisations for such products are granted.

(11) In the light of the information submitted to the Commission it appears that, in the absence of efficient alternatives for certain limited uses in certain Member States, there is a need for further use of the active substance so as to enable the development of alternatives. It is therefore justified in the present circumstances to prescribe under strict conditions aimed at minimising risk a longer period for the withdrawal of existing authorisations for the limited uses considered as essential for which no efficient alternatives appear currently to be available for the control of harmful organisms.

(12) Any period of grace for disposal, storage, placing on the market and use of existing stocks of plant protection products containing endosulfan allowed by Member States, should be limited to a period no longer than 12 months to allow existing stocks to be used in no more than one further growing season.

(13) This Decision does not prejudice any action the Commission may undertake at a later stage for this active substance within the framework of Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances [1],

(14) This decision does not prejudice the submission of an application for endosulfan according to the provisions of Article 6(2) of Directive 91/414/EEC in view of a possible inclusion in its Annex I.

(15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Endosulfan shall not be included as active substance in Annex I to Directive 91/414/EEC.

Article 2

Member States shall ensure that:

1. authorisations for plant protection products containing endosulfan are withdrawn by 2 June 2006;

2. from 3 December 2005 no authorisations for plant protection products containing endosulfan are granted or renewed under the derogation provided for in Article 8(2) of Directive 91/414/EEC;

3. in relation to the uses listed in column B of the Annex, a Member State specified in column A may maintain in force authorisations for plant protection products containing endosulfan until 30 June 2007 provided that it:

   (a) ensures that such plant protection products remaining on the market are relabelled in order to match the restricted use conditions;

[1] OJ L 33, 8.2.1979, p. 36. Directive as last amended by Regulation (EC) No 850/2004 of the European Parliament and of the Council (OJ L 158, 30.4.2004, p. 7).

(b) imposes all appropriate risk mitigation measures to reduce any possible risks in order to ensure the protection of human and animal health and the environment; and

(c) ensures that alternative products or methods for such uses are being seriously sought, in particular, by means of action plans.

The Member State concerned shall inform the Commission on 31 December 2005 at the latest on the application of this paragraph and in particular on the actions taken pursuant to points (a) to (c) and provide on a yearly basis estimates of the amounts of endosulfan used for essential uses pursuant to this Article.

Article 3

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC, shall be as short as possible and:

(a) for the uses for which the authorisation is to be withdrawn on 2 June 2006, shall expire not later than 2 June 2007;

(b) for the uses for which the authorisation is to be withdrawn by 30 June 2007, shall expire not later than 31 December 2007.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 2 December 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

List of authorisations referred to in Article 2(3)

Column A	Column B
Member State	Use
Greece	Cotton, tomato, peppers, pears, potato, alfa-alfa
Spain	Hazel nut, cotton, tomato
Italy	Hazel nut
Poland	Hazel nut, strawberry, gerbera, ornamental bulbs