Common Implementation Strategy for the Water Framework Directive

Environmental Quality Standards (EQS)

Substance Data Sheet

Priority Substance No. 18

Hexachlorocyclohexanes (incl. Lindane)

CAS-No. 608-73-1 (HCHs)

CAS-No. 58-89-9 (Lindane)

Final version
Brussels, 31 July 2005

Disclaimer

This data sheet provides background information on the setting of the Environmental Quality Standard in accordance with Article 16 of the Water Framework Directive (2000/60/EC). The information was compiled, evaluated and used as outlined in the Manual [4] and has been discussed in a consultative process with the Expert Advisory Forum on Priority Substances and the Expert Group on Quality Standards. Furthermore, it has been peer-reviewed by the SCTEE [14]. The substance data sheet may, however, not necessarily represent the views of the European Commission.

New upcoming information was considered and included up to the date of finalisation of this data sheet. Information becoming available after finalisation of this document will be evaluated in the review process of priority substances according to Art. 16(4) of the Water Framework Directive. If necessary, the Environmental Quality Standard substance data sheets will then be revised in the light of technical and scientific progress.

1 Identity of substance

Priority Substance No: 18	Hexachloracyclohexanes (including Lindane)
CAS-Number:	608-73-1 (HCHs) 58-89-9 (Lindane)
Classification WFD Priority List*:	PHS

* PS: priority substance; PHS: priority hazardous substance; PSR: priority substance under review according to Decision 2455/2001.

2 Proposed quality standards

2.1 Overall quality standards for ΣHCH (Σα-, β-, δ-, ε- ,γ-HCH)

The quality standards derived for the γ-isomer (Lindane) apply for the entire group of HCH-isomers

Ecosystem	Quality Standard	Quality Standard "rounded values"	Comment
AA-QS inland surface waters	0.02 µg/l (10.8 µg/kg SPM dry wt)	**0.02 µg/l** **(11 µg/kg SPM dry wt)**	protection of the pelagic community, see 8.1.1 & 8.3
AA-QS other surface waters covered by the WFD	0.002 µg/l (1.1 µg/kg SPM dry wt)	**0.002 µg/l** **(1 µg/kg SPM dry wt)**	protection of the pelagic community, see 8.1.1 & 8.3
MAC-QS (ECO)	0.04 µg/l	**0.04 µg/l**	see section 8.1.1

2.2 Specific quality standards for Lindane (γ-HCH)

Protection Objective #	Quality Standard	Comment:
Pelagic community (freshwater)	0.02 µg/l (10.8 µg/kg SPM dry wt)	see section 8.1.1
Pelagic community (saltwater)	0.002 µg/l (1.1 µg/kg SPM dry wt)	see section 8.1.1
Benthic community (freshwater sediment)	2.4 µg/kg wet wt (≈ 10.3 µg/kg dry wt)	tentative standard (EP method) see section 8.1.2
Benthic community (marine sediment)	0.24 µg/kg wet wt (≈ 1.1 µg/kg dry wt)	tentative standard (EP method) see section 8.1.2
Predators (secondary poisoning)	33 µg/kg (tissue of prey, wet wt) corresponding conc. in water: 0.026 µg/l	see section 8.1.3
Food uptake by man	61 µg/kg (seafood, wet wt); corresponding conc. in water 0.047 µg/l	based on provisional ADI; see section 8.1.4
Abstraction of water intended for human consumption (AWIHC)	< 1 µg/l	A1-value for Σpesticides in CD 75/440/EEC; see section 8.1.5
Water intended for human consumption (WIHC)	0.1 µg/l	Drinking water standard set in CD 98/83/EC

\# If justified by substance properties or data available, QS for the different protection objectives are given independently for freshwater environments, transitional waters or coastal and territorial waters

2.3 Specific quality standards for HCHs except Lindane (Σα-, β-, δ-, ε- HCH)

Protection Objective #	**Quality Standard**	**Comment**
Pelagic community (freshwater)	0.1 µg/l	see section 8.2.1
Pelagic community (saltwater)	0.01 µg/l	see section 8.2.1
Benthic community	not required	trigger criteria not met see section 8.2.2
Predators (secondary poisoning)	67 µg/kg (tissue of prey, wet wt) corresponding conc. in water: 0.042 µg/l	see section 8.2.3
Food uptake by man	derivation of QS not possible but required according to trigger criteria	no appropriate toxicity data available; see section 8.2.4
Abstraction of water intended for human consumption (AWIHC)	< 1 µg/l	A1-value for Σpesticides in CD 75/440/EEC; see section 8.2.5
Water intended for human consumption (WIHC)	0.1 µg/l	Drinking water standard set in CD 98/83/EC

If justified by substance properties or data available, QS for the different protection objectives are given independently for freshwater environments, transitional waters or coastal and territorial waters

3 Classification

Substance	**R-Phrases and Labelling**	**Reference**
608-73-1 (HCHs)	This chemical substance is not classified in the Annex I of Directive 67/548/EEC.	[16]
58-89-9 (Lindane)	T; R25 - Xn; R20/21-48/22 - R64 - N; R50-53	[16]

4 Physical and chemical properties

4.1 Lindane (γ-HCH)

Property	**Value:**	Ref.
Vapour pressure (in Pa, state temperature)	4.4×10^{-3} Pa at 24°C (>99.5%)	[1]
Henry's law constant (Pa m^3 mol^{-1})	1.483×10^{-6} Atm m^3/mol at 25°C (>99.5%)	[1]
Solubility in water (g/l or mg/l, state temperature)	8.52×10^{-3} g/l in deionized water (25°C) 8.35×10^{-3} g/l in buffered water at pH 5 (25°C) (purity 99.5%)	[1]
Dissociation constant	No data	[1]

4.2 HCHs except Lindane (α-, β-, δ-, ε- HCH)

Property	**Value**	**Ref.**
Solubility in water	α-HCH: 1.59 mg/L (20-25 °C) 1.4 mg/L (in saltwater) β-HCH: 0.32 mg/L (20-25 °C)	[11]

5 Environmental fate and partitioning

5.1 Lindane (γ-HCH)

Property	Value:	Ref.
Hydrolysis (DT_{50}) 25° C	pH 5: 752 d pH 7: 732 d pH 9: 182 d	[1] [1]
Photolytic degradation	photolytically stable	[1]
Readily biodegradable (yes/no)	not enough data available	[1]
Degradation in water/sediment -DT_{50} water -DT_{50} sediment -DT_{50} whole system Mesocosm studies	12 d - >30 d (20°C) 135 d - 162 d (20°C) 91 d - 697 d (degradation time for mineralisation; 5-15°C) no water/sediment study according to guideline was submitted DT_{50} water: 15 - 47 d DT_{50} sediment: 48 d	[1] [1]
Relevant metabolites- name and/or code- % of applied (range and maximum)	no metabolites >10 % AR	[1]
Mineralization	1.9 % AR (after 112 days)	[1]
Distribution in water / sediment systems (active substance)	not submitted	[1]
Distribution in water / sediment systems (metabolites)	not submitted	[1]
Partition co-efficient (log P_{OW})	3.5	[1]
Partition co-efficient (Koc)	871 – 1671 (ph dependence not proven) Soil 640 – 7000 L/kg Sediment 3800 - 5460 L/kg	[1] [7] [7]
BCF Fish Crustacea (Daphnia magna) Mollusca (Mytilus edulis)	 1300 (whole fish) 2200 (viscera) 780 (fillet) 220 240	 [1] [7] [7]

5.2 HCHs except Lindane (α-, β-, δ-, ε- HCH)

Property	Value:	Ref.
Partition co-efficient (log K_{OW})	<u>α-HCH</u> 3,77 (mean value, n = 5) <u>β-HCH</u> 3,85 (mean value, n = 7)	[11]
Partition co-efficient (Koc)	<u>α-HCH</u> sediment 3800 L/kg <u>β-HCH</u> sediment 3800 L/kg soil 1680 L/kg	[11]

Table continued overleaf

Property	**Value:**	**Ref.**
BCF		
- Fish	α-HCH	[11]
Lebistes reticulatus	500 (1 d) [2] 710 [32]	
Oncorhyncus mykiss)	210 [33] 1600 – 2400 (7 – 96 d) [34]	
(Brachydanio rerio)	1100 [32]	
	β-HCH	
(Leuciscus idus)	450 (3 d) [37]	
(Oncorhyncus mykiss)	290 [33]	
(Brachydanio rerio)	1460 – 1520 [32]	
(Guppy)	1040 [32]	
- Molluscs	α-HCH	[11]
(Blue Mussel)	105 (50 h) [2]	
(Mussels)	161 [32]	
	β-HCH	
(Mussels)	127 [32]	

6 Effect data (aquatic environment)

6.1.1 Aquatic effect data (Lindane, (γ-HCH)

The data addressing aquatic toxicity and bioaccumulation potential of lindane that have been provided by the notifier are at least partially considered as inadequate by the rapporteur. This can be concluded from the following comments in the monograph [1]:

- No tests of acute toxicity of lindane technical, nor its formulated products to algae have been provided.

- Besides daphnids no data have been submitted for estimation of the acute and chronic risk of lindane to insects and crustaceans.

  In the literature the sensitivity of other crustaceans[1] (e.g. *Gammarus pulex*) is markedly higher with LC_{50} alues of 19.5 µg/l after 48 h and 5.9 µg/l after 96 hours in hard water *(Stephenson,1983,* literature not submitted by the notifier) . Other data from literature (*Taylor et.al., 1991*, literature not submitted by the notifier) give a LC_{50} value of 7.9 µg/l (96) for *Gammarus pulex*. Thus it is evident that some crustaceae species show similar and even higher sensitivity to lindane than rainbow trout. Acute toxicity data from literature indicate a high sensitivity to insects, too. Taylor reports a LC_{50} of 55 µg/l for the 2^{nd} instar larvae of Chironomus riparius. The acute toxicity of a 80%-lindane formulation on the 5^{th} instar larvae of the trichoptera *Limnephilus lunatu* is 9.6 µg/l (LC_{50} / 96h) (*Schulz and Liess,1995*, literature not submitted by the notifier). According to this toxicity data from literature, further information will be necessary to enable a risk assessment for crustaceans and insects.

  According to literature the NOEC of the chronic toxicity of *Chironomus tentans* is 0.0022 mg/l (*Macec et. al. 1976*, literature not submitted by the notifier). A 80%-lindane formulation affected the emergence of the freshwater caddisfly larvae (*Limnephilus lunatus*) even at very low concentrations (90-day NOEC: <1 ng/l). The chronic toxicity of the very sensitive species L. lunatus was nearly 5 orders of magnitude higher than the acute LC_{50} (*Schulz and Liess,1995*, literature not submitted by the notifier).

1 than daphnia

- No data have been submitted on the effects of lindane on sediment dwelling organisms.

  Lindane is supposed to partition to sediment, thus the long-term effects to sediment dwelling organisms ..... have to be investigated.

- Bioaccumulation

  Results of the bioconcentration study conducted with bluegill sunfish exposed 28 days to lindane concentrations of 0.54 µg/l indicated that accumulation in fish was very high with BCFs of over 1000. Only one level of lindane concentration was evaluated for testing the bioaccumulation potential. ..... The concentration tested for bioaccumulation is no relevant environmental concentration. Thus BCFs of fish tested in a mesocosm study have to be investigated.

  Bioconcentration is also reported in literature in algae, aquatic plants, snails and mussels with corresponding BCFs of 1.8, 27 to 38, 116 and 159 (*Lin, 1987; Hinman and Klaine, 1992; Caquet, 1990; Nagel and Loskill, 1990*, literature not submitted by the notifier). The occurrence of lindane in numerous aquatic organisms, especially the very high BCF in fish and the dedection of residues in wild birds and mammals indicates that organisms consuming fish are at risk. These risks need further investigation.

  Due to the high bioconcentration factor of > 1000 and the low depuration in bluegill sunfish a life cycle test in fish is required. Facts about the development of the gonads e.g. decrease in testes growth, induction of intersex (ovotestes) and facts about the vitellogenin production have to be reported.

- It should be stressed that lindane is reported to have reproductive and endocrine-disrupting effects (*Colborn, T.; vom Saal, F.S.; Soto, A. M. (1993)*, literature not submitted by the notifier). But there is still a lot of research to be done. The current endpoints of most tests to assess the mutagenic and teratogenic risk of pesticides do not demonstrate endocrine-disrupting effects. These effects cannot be recognised until young adulthood, at which time abnormalities, particularly relating to the function of the reproductive system, become apparent. Because of the impossibility to assess this important environmental risk of endocrine disrupting substances Member States should be cautious when releasing such pesticides into the environment.

In order to derive the quality standards for lindane on the best possible data base, relevant aquatic toxicity data from other available sources [5, 6, 7, 8, 9] (see table 6.2) will be used together with the data given in the monograph [1] (table 6.1).

Table 6.1: Toxicity data for aquatic species (most sensitive species of each group) (source: Level 2 Appendix 3 of [1])

Group	Test substance	Time-scale	Endpoint	Toxicity (µg a.i./l)
Laboratory tests				
Rainbow trout	25% wettable powder	96 h, acute	LC_{50}	22
Daphnia magna	25% wettable powder	48 h, acute	LC_{50}	1600
Rainbow trout	Lindane technical	85 d, chronic	NOEC	2.9
Daphnia magna	Lindane technical	21d, chronic	NOEC	54

Table 6.2: Overview on Lindane aquatic toxicity data for most sensitive species from different sources (master reference)

Species	Taxon. Grp.	Medium *	Duration	Effect	Endpoint	Value	Unit	Master Ref.	Reference in master ref.
Freshwater Species									
Baetis	Insecta	fw	28 d	Increase in drift	NOEC	0.2	µg/l	[7]	Mitchell et al. 1993 [38]
Gammarus pulex	Crustacea	fw	28 d	Increase in drift	NOEC	0.8	µg/l	[7]	Mitchell et al. 1993 [38]
Gammarus fasciatus	Crustacea	fw	120 d	Mortality	NOEC	2	µg/l	[5]	Macek et al (1976)
Chironomus tentans	Insecta	fw	2 generations	Reproduction	NOEC	2.2	µg/l	[6], [9]	Macek et al 1976
Oncorhynchus mykiss	Pisces	fw	85 d	Growth	NOEC	2.9	µg/l	[7], [9]	Suprenant, 1986b
Gammarus fasciatus	Crustacea	fw	120 d	Mortality	NOEC	4.3	µg/l	[6]	RIVM report no. 679101012
Salvelinus fontinalis	Pisces	fw	261 d	Mortality	NOEC	8.8	µg/l	[5]	Macek et al (1976)
Daphnia magna	Crustacea	fw	64 d	Mortality, Reproduction	NOEC	11	µg/l	[6]	RIVM report no. 679101012
Selenastrum capricornutum	Algae	fw	120 h	Growth	NOEC	110	µg/l	[9]	Bell 1997
Microcystis aeroginosa	Cyanobacteria	fw	8 d	Growth	NOEC	150	µg/l	[7]	Bringmann et al. 1978 [32]
Chlorophyta	Algae	fw	5 d	Growth	NOEC	250	µg/l	[6]	NOEC as EC17/2; 17% inhibition (dry weight) at lowest test concentration RIVM report no. 679101012
Lymnea stagnalis	Mollusca	fw	10 m	Fecundity	NOEC	330	µg/l	[6]	RIVM report no. 679101012
Anguilla anguilla	Pisces	fw	4 d	Mortality	LC50	320	µg/l	[7]	Ferrando et al. 1988 [46]
Salmo trutta	Pisces	fw	96 h	Mortality	LC50	2	µg/l	[5]	Macek & McAllister (1970)
Pteronarcys californica	Insecta	fw	96 h	Mortality	LC50	4.5	µg/l	[9]	Sanders & Cope 1968
Gammarus pulex	Crustacea	fw	96 h	Mortality	LC50	5.9	µg/l	[1]	Stephenson 1983
Limnephilus lunatus	Insecta	fw	96 h	Mortality	LC50	9.6	µg/l	[1]	Schulz & Liess 1995
Salmo gairdneri	Pisces	fw	96 h	Mortality	LC50	22	µg/l	[9]	Bowman et al. 1986a
Bufo bufo	Amphibia	fw	48 h	Mortality	LC50	250	µg/l	[8]	Lüdeman et al. 1960
Selenastrum capricornutum	Algae	fw	120 h	Growth	EC50	780	µg/l	[9]	Bell 1997
Chlamydomonas reinhardtii	Algae	fw	10 d	Growth	EC50	1280	µg/l	[7]	Schafer at al. 1993 [36]

*: fw = freshwater, sw = saltwater

Table continued overleaf

Table 6.2: (continued) Overview on Lindane aquatic toxicity data for most sensitive species from different sources (master reference)

Saltwater Species									
Arcartia tonsa	Crustacea	sw	48 h	Survival	NOEC EC10 EC50	< 1.2 < 1.2 1.5	µg/l	[15]	
Penaeus duorarum	Crustacea	sw	96 h	Mortality	LC50	0.17	µg/l	[9]	Schimmel et al. 1977
Menidia menidia	Pisces	sw	96 h	Mortality	LC50	9	µg/l	[9]	Eisler 1970b
Crassostrea gigas	Mollusca	sw	48 h	Larval development	NOEC EC10 EC50	≥ 450 ≥ 450 ≥ 450	µg/l	[15]	
Crassostrea virginia	Mollusca	sw	48 h	Larval development	EC50	2820	µg/l	[9]	Ward & Winslow 1986
Psammechinus miliaris	Echinodermata	sw	48 h	Larval development	NOEC EC10 EC50	≥ 680 ≥ 680 ≥ 680	µg/l	[15]	
Monohystera disjuncta	Nematoda, J2 larvae	sw	96 h	Mortality	LC50	6700	µg/l	[9]	Vranken et al. 1991
Chlorophyta	Algae	sw			NOEC	1000	µg/l	[6]	RIVM report no. 679101012

*: fw = freshwater, sw = saltwater

6.1.2 Effects on birds (Lindane, (γ-HCH) [1]

The two dietary toxicity studies submitted were performed in compliance with EPA Guideline 71-2 as well as OECD Guideline 205 and conducted in compliance with GLP standards.

Table 6.3: Dietary toxicity of lindane (at least 99.5 % ai) to two bird species (table B.9.1.2-1 of [1])

Species tested	Age	Sex[a]	Test duration[b]	LC_{50} [mg/kg feed]	NOEC [mg/kg feed]	Guidelines	Reference
Bobwhite quail	11 ds	-	11 days	919	163	EPA 71-2 & OECD 205	(1)
Mallard duck	8 ds	-	11 days	695	< 163	EPA 71-2 & OECD 205	(2)

(1) *Rodgers et al., 1997a*
(2) *Rodgers et al., 1997b*
a No attempt was made to determine the sex of the birds because of their size and age.
b Period of pre-treatment: 3 ds; period of treatment: 5 ds; period of post-treatment: 3 ds.

6.1.3 Subchronic toxicity to mammals (Lindane, (γ-HCH) [1]

Table 6.4: Subchronic and long term toxicity of lindane technical to terrestrial vertebrates (table B.9.3.1.2-1 in [1])

Species / Sex	Study type	Duration		NOEC (ppm)	LOEC (ppm)	Reference
Rat / M + F	Subchronic toxicity range finding	42 days		80	200	(1)
Rat / M + F	Subchronic toxicity	3 months		4	20	(2)
Rat / M + F	Chronic toxicity, Carcinogenicity	104 weeks		10	100	(3)
Rat / M + F	Reproduction toxicity	2 generations (21 weeks)	Morphological changes: Reproduction:	1* 20**	20** 150*	(4)
Rabbit	Effects on pregnancy	29 days		20	20	(5)

(1) *Jones et al., 1988*
(2) *Suter et al., 1983*
(3) *Amyes, 1990*
(4) *King, 1991*
(5) *Palmer and Neuff, 1971*
* 150 ppm: Reductions in bodyweight gain of both adults and offspring, reduction of viability of F1 and F2 offspring up to Day 4 *post partum.* Delay in onset and completion of tooth eruption and in completion of hair growth. Histological changes.
** 20 ppm: histological changes only

6.1.4 Summary on endocrine disrupting potential (Lindane, (γ-HCH)

Substance with evidence of ED or evidence of potential ED, already regulated or being addressed under existing legislation	[2]
There is evidence from published literature, suggesting that lindane caused hormonal disruption with effects on oestrous cycle and ovulation rate, mating behaviour and female sex hormone levels whereby, in a short term oral study in rabbits, adverse effects on the ovulation rate were already determined at a dose of 0.8 mg/kg bw/d.	[1]

6.2.1 Aquatic effect data (HCHs, α-, β-, δ-, ε- isomers)

Table 6.5: Overview on HCH aquatic toxicity data for most sensitive species from different sources (master reference)

HCH isomer	Species	Taxon. Grp.	Medium *	Duration	Effect	Endpoint	Value	Unit	Master Ref.	Reference in master ref.
α-HCH	Daphnia magna	Crustacea	fw	25 d	Reproduction	EC10	5	µg/l	[11]	US-EPA [12]
α-HCH	Tetrahymena pyriformis	Protozoa	fw			NOEC	9	µg/l	[6]	RIVM Rep. 679101012
α-HCH	Lymnea stagnalis	Mollusca	fw	40 d exposure	Reproduction	NOEC	20	µg/l	[9], [11], [6]	Canton et al. 1977
α-HCH	Scenedesmus acutus	Algae	fw	5 d	Growth	NOEC	80	µg/l	[11]	Krishnakumari 1977 [11]
α-HCH	Daphnia magna	Crustacea	fw	21 d	Growth	NOEC	90	µg/l	[9], [6]	Canton et al. 1986b
α-HCH	Daphnia magna	Crustacea	fw	21 d		NOEC	90	µg/l	[11]	Jannsen et al. 1988 [15]
α-HCH	Lesbistes reticulatus	Pisces	sw			NOEC	250	µg/l	[6]	RIVM Rep. 679101012
α-HCH	Poecilia reticulata	Pisces	sw	35 d		LC10	500	µg/l	[9]	Canton et al. 1978
α-HCH	Oryzias latipes	Pisces	fw	35 d	Mortality, Growth	NOEC	800	µg/l	[9], [6]	Canton et al. 1986b
α-HCH	Dunaliella sp.	Algae	sw	96 h	Growth	NOEC	1400	µg/l	[9]	Canton 1978
α-HCH	Lymnea stagnalis	Mollusca	fw	40 d exposure	Reproduction	EC50	65	µg/l	[11], [9]	Canton et al. 1977 [23]
α-HCH	Daphnia magna	Crustacea	fw	48 h	Mortality, Immobilisation	EC50	800	µg/l	[9]	Canton et al. 1975
α-HCH	Poecilia reticulata	Pisces	fw	48 h	Mortality, Immobilisation	EC50	800	µg/l	[9]	Canton et al. 1975
α-HCH	Poecilia reticulata	Pisces	sw	96 h	Mortality, Immobilisation	EC50	1310	µg/l	[9]	Canton et al. 1978
α-HCH	Scenedesmus acutus	Algae	fw	5 d		EC50	10000	µg/l	[11]	Krishnakumari 1977 [11]
β-HCH	Artemia salina	Crustacea	sw			NOEC	10	µg/l	[6]	RIVM Rep. 679101012
β-HCH	Oryzias latipes	Pisces	fw	35 d	Mortality, Embryo develop.	NOEC	27	µg/l	[9], [6]	Canton et al. 1982
β-HCH	Oryzias latipes	Pisces	fw	34 d		NOEC	27	µg/l	[11]	Canton et al. 1975 [14]
β-HCH	Tetrahymena pyriformis	Protozoa	fw			NOEC	83	µg/l	[6]	RIVM Rep. 679101012
β-HCH	Daphnia magna	Crustacea	fw	22 d	Reproduction	NOEC	320	µg/l	[9], [11], [6]	Canton et al. 1982
β-HCH	Scenedesmus obliquus	Algae	fw	5 d	Growth	NOEC	500	µg/l	[11]	Krishnakumari 1977 [11]
β-HCH	Scenedesmus acutus	Algae	fw	5 d		EC50	10000	µg/l	[9]	Krishnakumari 1977

*: fw = freshwater, sw = saltwater

Table continued overleaf

Table 6.5: (continued) Overview on HCH aquatic toxicity data for most sensitive species from different sources (master reference)

HCH isomer	Species	Taxon. Grp.	Medium *	Duration	Effect	Endpoint	Value	Unit	Master Ref.	Reference in master ref.
HCH	Oncorhynchus clarki	Pisces	fw	4 d		LC50	9	µg/l	[11]	Johnson et al. 1980 [18]
HCH	Oncorhynchus mykiss	Pisces	fw	4 d		LC50	18	µg/l	[11]	Johnson et al. 1980 [18]
HCH	Micropterus salmoides	Pisces	fw	4 d		LC50	41	µg/l	[11]	Johnson et al. 1980 [18]
HCH	Macrobrachium lamarrei	Crustacea		4 d	Mortality	LC50	41.6	µg/l	[11]	Shukla et al. 1983 [17]
HCH	Gammarus lacustris	Crustacea	fw	4 d	Mortality	LC50	78	µg/l	[11]	Johnson et al. 1980 [18]
HCH	Microhyla ornata	Amphibia	fw	4 d	Mortality	LC50	7270	µg/l	[11]	Pawar et al 1984 [27]

*: fw = freshwater, sw = saltwater

6.2.2 Effects on birds and mammals (HCHs, α-, β-, δ-, ε- isomers)

Table 6.6: $NOECs_{food}$ resulting from feeding studies with birds and mammals [6]

HCH isomer	Species	Taxon. Grp.	NOEC mg/kg food	Master Ref.	Reference in master ref.
alpha-HCH	Rattus norvegicus	Mammalia	50	[6]	RIVM Rep. 679101012
Beta-HCH	Gallus domesticus	Aves	625	[6]	RIVM Rep. 679101012
Beta-HCH	Rattus norvegicus	Mammalia	2	[6]	RIVM Rep. 679101012

6.2.3 Summary on endocrine disrupting potential (HCHs, α-, β-, δ-, ε- isomers)

Hexachlorocyclohexane - no sufficient data available	[2]

7 Effect data (human health)

7.1 Lindane (γ-HCH) [1]

The estimation of the Acceptable Daily Intake (ADI) is based on the lowest no-observed-adverse-effect-level (NOAEL) observed in chronic toxicity, carcinogenicity and reproduction studies provided. In these studies, the organ which was always adversely affected by lindane was the liver. Based on a persistent liver hypertrophy in the chronic toxicity study in rats after dosing with 5.65 mg/kg bw/d for 52 weeks, a NOAEL of 0.47 mg/kg bw/d[2] was estimated and could be used as the basis for setting the ADI (as also proposed by the notifier).

In the oncogenicity part of the combined chronic toxicity/oncogenicity study in rats, the NOAEL was set at 4.8 mg/kg bw/d.

None of the carcinogenicity studies with lindane in mice are considered to be a fully and adequate investigation of this endpoint due to deficient experimental design and insufficient documentation of the results. Although lindane does not represent a genotoxic dangerous chemical, it has to be considered as a tumour promotor, producing a tumorigenic response in different strains of mice. A clear NOAEL for this endpoint could not be established from the studies on mice.

There was also evidence from published literature, suggesting that lindane caused hormonal disruption with effects on oestrous cycle and ovulation rate, mating behaviour and female sex hormone levels whereby in a short term oral study in rabbits, adverse effects on the ovulation rate were already determined at a dose of 0.8 mg/kg bw/d.

Results from supplementary published studies suggest that lindane induced adverse effects on behavioural performance of adult rats, but also on the myelination process in brain and on the behavioural development in suckling rats. In addition, repeated dose studies in rats and mice exhibited myelotoxic and immunosuppressive effects of lindane. Clear NO(A)ELs could not be established for these endpoints because of the dose regime chosen in these studies.

In view of these toxicological concerns, resulting in the requirement of further studies to be provided and in the requirement for clarification of results of some already available studies and in order to perform an overall hazard assessment, it is appropriate to apply an additional safety factor of 5 in addition to the conventional safety factor of 100.

[2] This NOAEL corresponds to a Lindane concentration in food of 10ppm (i.e. 10 mg Lindane /kg food) [1]

Therefore, a provisional acceptable daily intake (ADI) of 0.001 mg/kg bw/d for lindane based on the NOAEL of 0.47 mg/kg bw/d set in the chronic toxicity study in rats is proposed.

7.2 HCHs (α-, β-, δ-, ε- isomers)

No quantitative chronic oral mammalian toxicity data (NO(A)ELs) with relevance to human health available.

EPA classification of different HCH isomers [12]:

HCH isomer	Classification with regard to carcinogenicity
alpha - HCH	B2; probable human carcinogen Dietary alpha-HCH has been shown to cause increased incidence of liver tumors in five mouse strains and in Wistar ra
beta - HCH	C; possible human carcinogen Increases in benign liver tumors in CF1 mice fed beta-HCH
delta - HCH	D; not classifiable as to human carcinogenicity (no data)
epsilon - HCH	D; not classifiable as to human carcinogenicity (no data)
technical - HCH	B2; probable human carcinogen Assays in four strains of mice have yielded positive carcinogenicity results for t-HCH (which is 65% alpha HCH) administered in the diet.

8 Calculation of quality standards

8.1 Calculation of quality standards for Lindane (γ-HCH)

As the toxicity data submitted by the notifiers are considered as (at least partially) inadequate by the rapporteur [1], data available from other sources were used to derive the quality standards for Lindane. This is in derogation from the normal procedural approach proposed for the derivation of quality standards of plant protection products as normally only toxicity data validated in the risk assessment monograph are considered (see section 4.1 of the Manual [4]). However, if new information relevant for the derivation o f an EQS became available after the finalisation of the risk assessment this information should be given due consideration. In order to come up with a reliable proposal for the quality standard it is therefore deemed justified to make best use of the data that have been submitted by Member States and Euro Chlor, respectively.

8.1.1 Quality standards for water (Lindane, γ-HCH)

Freshwater

The lowest chronic endpoint has been obtained for the increased drift of an aquatic insect of the mayfly genus Baetis (0.2 µg/l). Long-term toxicity data are available for at least three trophic levels. Therefore, the lowest NOEC is divided by an assessment factor of 10 in order to derive the long term quality standard for freshwater.

$QS_{freshwater}$ = 0.2 µg/l / AF (10) = 0.02 µg Lindane /l

The log Kp_{susp}[3] is only 2.73 and therefore the trigger criterion to calculate a corresponding $QS_{SPMfreshwater}$ referring to the concentration of Lindane in suspended particulate matter (SPM) is not met.

However, because it is stated in the monograph [1] that Lindane is supposed to partition to sediment the $QS_{SPM.freshwater}$ is calculated:

$$QS_{SPM.freshwat} = \frac{QS_{freshwater}\ [0.02\ \mu g/l]}{C_{SPM}\ [15\ mg/l] * 10^{-6}\ [kg/mg] + Kp^{-1}\ [(546\ l/kg)^{-1}]} = \mathbf{10.8\ \mu g/kg\ SPM}\ \text{(dry wt)}$$

Transitional, coastal and territorial waters

Effect data of marine organisms are not dealt with in the risk assessment monograph[4] but are available from some of the other data sources (see table 6.2).

Long-term NOEC data for sensitive marine organisms are not available. However, based on a comparison of the NOEC and L(E)C50 data of freshwater and saltwater organisms the conclusion can be drawn that saltwater crustaceans appear to be approximately one order of magnitude more sensitive to Lindane than freshwater species of that group whereas freshwater or saltwater fish and algae species appear to be equally sensitive.

Thus, in order to account for the apparently higher sensitivity of saltwater crustaceans to Lindane it is proposed to apply an additional assessment factor of 10 on the $QS_{freshwater}$.

$QS_{saltwater}$ = $QS_{freshwater}$ / AF (10) = 0.002 µg Lindane /l

Normally the trigger criterion to calculate a corresponding $QS_{SPM.saltwater}$ referring to the concentration of Lindane in suspended particulate matter (SPM) is not met (see section on freshwater above). However, as it is stated in the monograph [1] that Lindane is supposed to partition to sediment the $QS_{SPM.saltwater}$ is calculated.

For the TGD standard water, the concentration corresponding to the $QS_{saltwater}$ is 1/10 of that calculated for freshwater. However, the SPM concentration in marine waters is significantly lower than in freshwater (discussed in the context of the marine risk assessment: approx. 3 mg/l as standard concentration). Therefore, the quality standard is, as an example, also calculated for a SPM concentration of 3 mg/l:

$$QS_{SPM.saltwat} = \frac{QS_{freshwater}\ [0.002\ \mu g/l]}{C_{SPM}\ [3\ mg/l] * 10^{-6}\ [kg/mg] + Kp^{-1}\ [(546\ l/kg)^{-1}]} = \mathbf{1.1\ \mu g/kg\ SPM}\ \text{(dry wt)}$$

3 According to the TGD the Kp_{susp} (solid – water partition coefficient in SPM) is calculated as Koc * foc_{SPM} (foc_{SPM} = 0.1 - standard weight fraction of organic carbon in suspended solids). For the calculation of Kp_{susp} a Koc of 5460 was used as sort of "mean" Koc (see section 5 of this data sheet).

4 Effects assessment with regard to the marine environment is normally not necessary in the context of the risk assessment for plant protection products

Quality standard accounting for transient concentration peaks (MAC-QS)

Acute toxicity data are available for freshwater and saltwater organisms (fish, crustacea, insecta, mollusca, nematoda and algae). The lowest LC50 values has been obtained with the marine crustacean *Penaeus duorarum* (96 h LC50 0.17 µg/l, see table 6.2). However, as the occurrence of transient peak concentrations of plant protection products is an irrelevant scenario for coastal and territorial waters, the MAC-QS is derived on the basis of the lowest acute study conducted with freshwater organisms. This is the 96 h LC50 of 2 µg/l for brown trout (*Salmo trutta*) and the MAC-QS is derived on the basis of this LC50 and the guidance given in the TGD on the effects assessment for intermittent releases (section 3.3.2 of part II of [3]). The species apparently most sensitive to Lindane (crustaceans, insects and fish) are covered by the available acute studies and, in addition, tests for a broader spectrum of taxonomic groups living in freshwater are available (e.g. molluscs, amphibia, algae). However, as the acute to chronic toxicity ratio appears to be low for crustaceans and fish and because some acute fish and crustacean toxicity data are lower than the NOEC values obtained for other species of these taxonomic groups, it is suggested to use an assessment factor of 50 for the derivation of the MAC-QS.

MAC-QS = 2 µg/l / AF (50) = 0.04 µg Lindane /l

This MAC-QS might also be protective for sensitive saltwater crustaceans (e.g. mysids) dwelling in transitional waters.

8.1.2 Quality standard for sediment (Lindane, γ-HCH)

The log Kp_{susp} is only 2.73 (see footnote 3 for details) and therefore the trigger criterion to calculate a qualtiy standard for sediment is not met. However, as it is stated in the monograph [1] that Lindane is supposed to partition to sediment a $QS_{sediment}$ is calculated:

Toxicity data for sediment dwelling organisms are not available. Therefore, according to the TGD [3], the $QS_{sediment}$ may be calculated using the equilibrium partitioning method in the absence of ecotoxicological data for sediment-dwelling organisms.

The approach only considers uptake via the water phase. However, uptake may also occur via other exposure pathways like ingestion of sediment and direct contact with sediment but for substances with a log Kow < 5 uptake via ingestion or contact with sediment is considered negligible [3]. As the log Kow of Lindane is 3.5 (see section 5 of this data sheet) the additional exposure routes need not to be considered in the calculation of $QS_{sediment}$ from the QS_{water}.

$$QS_{sediment}\ [mg.kg^{-1}] = \frac{Kp_{SPM\text{-}water}\ [136.5\ m^3/m^3]}{bulk\ density_{SPM.wet}\ [1150\ kg/m^3]} * 1000 * QS_{water}\ [mg/l]$$

with:

$K_{SPM\text{-}water}$[5] =	136.5 m^3/m^3
bulk $density_{SPM.wet}$	1150 $kg.m^{-3}$
QS_{water} =	$QS_{freshwater}$ = 0.00002 mg/l; $QS_{saltwater}$ = 0.000002 mg/l
1000 =	conversion factor m^3/kg to l/kg

The TGD defines wet SPM as 90% vol/vol water (density 1 kg/l) and 10% vol/vol solids (density 2.5 kg/l), thus giving a wet density of (0.9 × 1) + (0.1 × 2.5) = 1.15 kg/l. The dry weight of solids is therefore 0.25 kg (per litre wet SPM) and thus the wet:dry ratio is 1.15/0.25 = 4.6.

5 According to section 2.3.5.3 of the TGD [3]:
$K_{SPM\text{-}water}$ = $Fsolid_{SPM}$ (0.1 m^3/m^3) * foc_{SPM} (0.1 kg/kg) * Koc (5460 l/kg) / 1000 * RHOsolid (2500 kg/m^3)

This results in the following quality standards for freshwater and marine sediments (wet and dry weight):

$QS_{sed.freshwater}$	**2.4 µg/kg (wet wt)**	**10.3 µg/kg (dry wt)**
$QS_{sed.marine}$	**0.24 µg/kg (wet wt)**	**1.1 µg/kg (dry wt)**

Standards derived by the EP-method should only be considered as tentative. In order to refine the quality standards calculated for the sediment compartment results of tests conducted with benthic organisms using spiked sediment are required.

8.1.3 Secondary poisoning of top predators (Lindane, γ-HCH)

As the trigger value for the derivation of a quality standard referring to secondary poisoning of top predators is met (BCF ≥100), the calculation of the respective standard is required (see table 1a of the Manual [4]).

According to the TGD $LC50s_{food}$ from 5 day feeding studies with birds or $NOECs_{food}$ from feeding studies with mammals (28 d, 90 d or chronic) or birds (chronic) are acceptable to assess secondary poisoning (see section 4.3.2.5 of the Manual [4]).

For Lindane $LC50s_{food}$ from 5 day feeding studies with birds as well as chronic $NOECs_{food}$ from feeding studies with rats are available. According to the TGD an assessment factor of 3000 is appropriate to derive a PNEC from a $LC50_{bird}$ and a factor of 30 to derive it from a chronic $NOEC_{mammal}$. The lower of the resulting $PNECs_{food}$ is to be used in the effects assessment. The $PNEC_{food}$ is equivalent to the "save" concentration in the prey of predators and thus is the quality standard for biota ($QS_{secpois.biota}$).

Mallard Duck, 5d LC50:	695 mg/kg food / AF (3000) = 230 µg/kg food
Rat, chronic NOEC:	1 mg/kg food / AF (30) = 33 µg/kg food

$QS_{secpois.biota}$ = 33 µg Lindane / kg biota tissue (wet wt)

The highest BCF has been found for fish (1300 whole body, see section 5 of this data sheet). This BCF is used to calculate the concentration in water that corresponds to the $QS_{secpois.biota}$. No information is available on observations regarding biomagnification of Lindane.

According to the provisions given in the TGD [3] with regard to the assessment of secondary poisoning of top predators, biomagnification factors (BMF) should be taken into account for the calculation of the PEC_{oral} of top predators. However, the use of a default BMF as proposed in the TGD is not required as the relevant BCF is <2000 (see sections 4.3.2.5 of the final Manual [4] for details).

The $QS_{secpois.water}$ is calculated as follows:

$QS_{secpois.water}$ = $QS_{secpois.biota}$ (33 [µg/kg]) / BCF (1,300 [kg/l]) = 0.026 µg Lindane /l

Thus, the protection of the pelagic community does require a lower QS than the protection of top predators from secondary poisoning (i.e. top predators are protected by the QS for freshwater or saltwater).

8.1.4 Quality standard referring to food uptake by humans (Lindane, γ-HCH)

A provisional acceptable daily intake for Lindane was estimated in the risk assessment monograph (ADI = 1 µg / kg bw d^{-1}).

In the Manual (section 4.3.2.6) [4] it is suggested that the ADI may not be exhausted for more than 10% by consumption of food originating from aquatic sources. For a person weighing 70 kg this results in an acceptable daily intake of 7 µg Lindane per day.

The average fish consumption of an EU citizen is 115 g d-1 (TGD [3]). Thus, 115 g edible fish tissue (or seafood) must not contain more than 7 µg Lindane.

$$\mathbf{QS_{hh.food}} = \frac{7\ \mu g\ \text{Lindane}}{115g\ \text{seafood consumption}} * 1000\ g = \mathbf{61\ \mu g\ Lindane\ /\ kg\ seafood}$$

In the TGD approach for the assessment of secondary poisoning (see section 4.3.2.5 and 4.3.2.6 of the Manual [4]) it is foreseen to consider bioconcentration and biomagnification as relevant factors affecting body burdens and the PEC, respectively. If no information on BMF values is available, it is proposed in the TGD to use default BMFs for substances with a BCF_{fish} >2000. However, as the BCFfish of Lindane is lower than the trigger value BMF needs not to be considered and the water concentration corresponding to the $QS_{hh.food}$ can be calculated as follows:

$$\mathbf{QS_{hh.food.water}} = \frac{QS_{hh.food}\ (61\ [\mu g/kg])}{BCF\ (1{,}300\ [l/kg])} = 0.047\ \mu g\ \text{Lindane} / l$$

Thus, the quality standard required to protect human health from adverse effects due to ingestion of food originating from aquatic environments is not as low as the respective standards required for the protection of freshwater and saltwater communities.

8.1.5 Quality standard for drinking water abstraction (Lindane, γ-HCH)

The imperative A1 value referring to drinking water abstraction by simple treatment is 1 µg/l for the total amount of pesticides (Council Directive 75/440/EEC). The drinking water standard (DWS) set in CD 98/83/EC is 0.1 µg/l for individual pesticides.

The DWS is a limit value never to be exceeded at the tap. The MAC-QS derived for the protection of the pelagic community (0.04 µg/l) is therefore also protective for drinking water abstraction. Hence, the derivation of a specific MAC-QS for areas designated in accordance with Art. 7 WFD for the **a**bstraction of **w**ater **i**ntended for **h**uman **c**onsumption (AWIHC) is not necessary.

MAC-QS (AWIHC) = MAC-QS (ECO) = 0.04 µg/l

8.2 Calculation of quality standards for HCHs (α-, β-, δ-, ε- isomers)

The α-, β- and δ- isomers of Hexachlorocyclohexane do not have the insecticidal properties of γ-HCH (Lindane) and are therefore not technically used. They are produced as by-products in the synthesis of Lindane. The shares of α-HCH and β-HCH in the raw technical mixture of HCH are approximately 65-70% and 5-12%, respectively [11]. The use of technical HCH as insecticide is prohibited in the EU since 1981 [13].

Physico-chemical data as well as toxicity data have been submitted to the consultant for the alpha and beta isomers only. No data are available for δ-HCH.

As the α-, β- and δ- isomers of Hexachlorocyclohexane are unintentionally produced as by-products and usually occur as mixtures, it is proposed to treat them as a group and to derive uniform quality standards applicable to all isomers of HCH except the γ-isomer.

8.2.1 Quality standards for water (HCHs, α-, β-, δ-, ε- isomers)

Freshwater

The lowest chronic endpoint for HCH has been obtained for the reproduction of Daphnia magna (25 d EC10, 5 µg/l). According to the TGD an EC10 can be used as NOEC surrogate. Long term toxicity data are available for different species representing three trophic levels. However, the available acute toxicity data for salmonid fish are in the same range as the lowest long term NOECs. No long term data for salmonid fish are available. Therefore, the appropriate assessment factor to derive the $QS_{freshwater}$ is 50.

$QS_{freshwater}$ = 5 µg/l / AF (50) = 0.1 µg HCH /l

The log Kp_{susp}[6] is only 2.58 and therefore the trigger criterion to calculate a corresponding $QS_{SPMfreshwater}$ referring to the concentration of hexachlorocyclohexane in suspended particulate matter (SPM) is not met.

Transitional, coastal and territorial waters

Effect data for saltwater organisms are available for fish, algae and crustacea (table 6.5; however, it should be kept in mind that *Artemia* is <u>not</u> a marine organism but living in hypersaline inland waters and that the Guppy [*Lebises reticulatus or Poecilia reticulata*] is normally a freshwater fish that can be adapted to saltwater). No apparent differences in sensitivities of freshwater and saltwater species can be identified on the basis of the limited data available for comparison.

As no toxicity data for additional marine taxonomic groups (beside fish, crustacea and algae) are available, it is suggested, in accordance with the provisions of the TGD regarding marine effects assessment, to use an assessment factor of 500 on the lowest long-term toxicity value (EC10 5 µg/l) for the derivation of the $QS_{saltwater}$.

$QS_{saltwater}$ = 5 µg/l / AF (500) = 0.01 µg HCH /l

As the log Kp_{susp} is only 2.58 the trigger criterion to calculate a corresponding $QS_{SPMfreshwater}$ referring to the concentration of hexachlorocyclohexane in suspended particulate matter (SPM) is not met.

Quality standard accounting for transient concentration peaks (MAC-QS)

Since HCH is not commercially used the occurrence of transient peak concentrations is considered as an irrelevant scenario and therefore the setting of a MAC-QS for HCH might not be necessary.

[6] According to the TGD the Kp_{susp} (solid – water partition coefficient in SPM) is calculated as Koc * foc_{SPM} (foc_{SPM} = 0.1 - standard weight fraction of organic carbon in suspended solids). For the calculation of Kp_{susp} a Koc of 3800 was used (see section 5 of this data sheet).

Acute toxicity data are available for freshwater organisms (fish, crustacea, mollusca, amphibia and algae) and one fish tested in saltwater (see table 6.5). The lowest LC50 values have been obtained for salmonid fish by Johnson et al (1980, cited in [11] for HCH (as the isomers are not specified in [11], it cannot be ruled out that a technical HCH mixture containing the γ-Isomer has been used). As the salmonids appear to be the most sensitive species in acute tests and since tests for a broader spectrum of taxonomic groups living in freshwater are available it is suggested in accordance with the guidance given in the TGD on the effects assessment for intermittent releases (section 3.3.2 of part II of [3]) to use only a reduced assessment factor of 10 (instead of 100) for the derivation of the MAC-QS.

Hence, the MAC-QS is derived on the basis of the 4d LC50 of *Oncorhynchus clarki* (9 µg/l) and an assessment factor of 10.

MAC-QS = 9 µg/l / AF (10) = 0.9 µg HCH /l

8.2.2 Quality standard for sediment (HCHs, α-, β-, δ-, ε- isomers)

The log Kp_{susp} is only 2.58 (see footnote 6 for details) and therefore the trigger criterion to calculate a qualtiy standard for sediment is not met.

8.2.3 Secondary poisoning of top predators (HCHs, α-, β-, δ-, ε- isomers)

As the trigger value for the derivation of a quality standard referring to secondary poisoning of top predators is met (BCF ≥100), the calculation of the respective standard is required (see table 1a of the Manual [4]).

3 $NOECs_{food}$ from feeding studies with mammals and birds are available (see table 6.6). The lowest NOECfood has been obtained for feeding rats with β-HCH (2 mg/kg food). According to the TGD an assessment factor of 30 is appropriate to derive a PNEC from a chronic $NOEC_{food.mammal}$ (see section 4.3.2.5 of the Manual [4]). The $PNEC_{food}$ is equivalent to the "save" concentration in the prey of predators and thus is the quality standard for biota ($QS_{secpois.biota}$).

$PNEC_{food}$ = 2 mg/kg food / AF (30) = 67 µg/kg food

$QS_{secpois.biota}$ = 67 µg HCH / kg biota tissue (wet wt)

The highest BCFs have been found for fish (210 – 2,400, see section 5 of this data sheet). It is suggested to use a BCF of 1,600 (≈ "mean") for the calculation of the concentration in water that corresponds to the $QS_{secpois.biota}$. No information is available on observations regarding biomagnification of HCH.

According to the provisions given in the TGD [3] with regard to the assessment of secondary poisoning of top predators, biomagnification factors (BMF) should be taken into account for the calculation of the PEC_{oral} of top predators. However, the use of a default BMF as proposed in the TGD is not required as the relevant BCF is <2000 (see section 4.3.2.5 of the Manual [4] for details).

The $QS_{secpois.water}$ is calculated as follows:

$QS_{secpois.water}$ = $QS_{secpois.biota}$ (67 [µg/kg]) / BCF (1,600 [kg/l]) = 0.042 µg HCH /l

Thus, the protection of to predators from secondary poisoning requires a lower quality standard than the protection off the pelagic communities in inland waters.

8.2.4 Quality standard referring to food uptake by Humans (HCHs, α-, β-, δ-, ε- isomers)

Hexachlorocyclohexane is classified as carcinogen of category 3 (R40) and further as toxic if swallowed (R25). Moreover, it has a BCF >100. Therefore the trigger values are met and the derivation of a quality standard referring to adverse effects on human health due to ingestion of fishery products. However, no toxicity data relevant for humans are available. Therefore, the respective quality standard cannot be derived.

8.2.5 Quality stamdard for drinking water abstraction (HCHs, α-, β-, δ-, ε- isomers)

The imperative A1 value referring to drinking water abstraction by simple treatment is 1 µg/l for the total amount of pesticides (amongst them HCH, Council Directive 75/440/EEC). The limit value for individual pesticides in drinking water is 0.1 µg/l (CD 98/83/EC).

The DWS is a limit value never to be exceeded at the tap. The MAC-QS (ECO) derived for the protection of the freshwater community (0.9 µg/l) may therefore not suffice to allow for compliance with the DWS if only simple purification techniques (category A1 of CD 75/440/EEC, i.e. filtration and disinfection) are used for the abstraction of drinking water from surface water bodies according to Art. 7 of the WFD.

An assessment by experts in drinking water technology with regard to the question which fraction of the amount of HCHs present in raw water can be removed by usual simple treatment procedures might be helpful. If the respective fraction were known, this figure could be used together with the drinking water standard to set the maximum acceptable concentration in surface water bodies designated for the **a**bstraction of **w**ater **i**ntended for **h**uman **c**onsumption (AWIHC).

MAC-QS (AWIHC) = DWS (0.1 µg/l) / fraction not removable by simple treatment

8.3 Overall quality standard

It is suggested to set a group standard for all HCH-isomers, including the gamma-isomer (Lindane). As Lindane is the most important isomer that has been used until the recent past and because data availability is best for this substance and the quality standards the lowest because of its toxicity, it is suggested to use the quality standards derived for the protection of the pelagic communities as overall quality standards for the group of HCHs. This proposal is supported by the CSTEE in its opinion on the suggested quality standards for hexachlorocyclohexanes [14].

If the drinking water standard is exceeded in areas designated for the abstraction of water intended for human consumption in accordance with Art. 7 of the WFD, specific measures need to be taken in order to guarantee compliance with the drinking water standard at the tap.

As data on sediment dwelling organisms are not available the standard derived for sediment by the equilibrium partitioning method should be revised as soon as appropriate experimental data become available.

9 References

[1] Lindane Monograph: Report and Proposed Decision, Annex B (Summary, Scientific Evaluation and Assessment). Federal Ministry of Agriculture and Forestry, Vienna, Austria

[2] COM(2001)262 final: Communication from the Commission to the Council and the European Parliament on the implementation of the Community Strategy for Endocrine Disrupters – a range of substances suspected of interfering with the hormone system of humans and wildlife.

[3] Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and the Council Concerning the placing of biocidal products on the market. Part II. European Commission Joint Research Centre, EUR 20418 EN/2, © European Communities 2003. Available at the internet-site of the European Chemicals Bureau: http://ecb.jrc.it/existing-chemicals/

[4] Manual of the Methodological Framework Used to Derive Environmental Quality Standards for Priority Substances of the Water Framework Directive. Peter Lepper, Fraunhofer-Institute Molecular Biology and Applied Ecology, 15 November 2004. Available at the internet-site of the European Commission: http://europa.eu.int/comm/environment/water/water-dangersub/pri_substances.htm

[5] Les Etudes des Agences de l'Eau Nº 64: Systéme d'Évaluation de la Qualite de l'Eau des Cours d'Eau. SEQ-Eau (version 1) Annexe A – Grilles de seuils par altération avec justifications (Annexe 4: Classes d'Aptitude Pour Divers Micropollutants, Fonction "Potentialites Biologiques de l'Eau", Lindane - Fiche de Donnees). Agences de l'Eau, Janvier 1999. ISSN 1161-0425

[6] Excel - database provided by RIVM. Personal communication (e-mail Dr. Dick Sijm, 14 February 2002)

[7] Frimmel, FH et al., 2001: Ableitung von Qualitätszielen für Kandidatenstoffe der prioritären Liste für die EU-Wasserrahmenrichtlinie. Projektbericht zum Forschungsvorhaben. Substance data sheet for Lindane

[8] International Commission for the Protection of the Rhine. Rhine Action Programme. Data Sheets for Quality Objectives. RIZA, NL-Lelystad, 1994

[9] Hecachlorocyclohexane. Euro Chlor Risk Assessment for the Marine Environment. OSPARCOM Region – North Sea. Draft, April 2001

[10] Draft 29th ATP list, Revision 16, status: 17.3.2003. European Chemicals Bureau, Work Area Classification and Labelling. http://ecb.jrc.it/classification-labelling/

[11] Frimmel, FH et al., 2001: Ableitung von Qualitätszielen für Kandidatenstoffe der prioritären Liste für die EU-Wasserrahmenrichtlinie. Projektbericht zum Forschungsvorhaben. Substance data sheet for hexachlorohexane

[12] Integrated Risk Information System (IRIS). http://www.epa.gov/iris/subst/. HCH isomers. Carcinogenicity assessment for life time exposure

[13] International Commission for the Protection of the Rhine. Rhine Action Programme. Data Sheets for Quality Objectives. RIZA, NL-Lelystad, 1994

[14] Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) on "The Setting of Environmental Quality Standards for the Priority Substances included in Annex X of Directive 2000/60/EC in Accordance with Article 16 thereof", adopted by the CSTEE during the 43rd plenary meeting of 28 May 2004, European Commission Health & Consumer Protection Directorate General, Brussels. http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out230_en.pdf

[15] AquaSense (2005). Toxicity tests with priority substances in the Water Framework Directive. Sponsor: Institute for Inland Water Management and Waste Water Treatment (RIZA). Report number: 2034

[16] ESIS: European Chemicals Bureau – ESIS (European Substances Information System), July 2005. http://ecb.jrc.it/existing-chemicals/ ⇒ tick ESIS button, then enter CAS or EINECS number of substance.