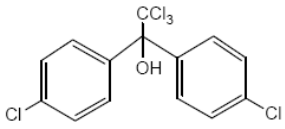
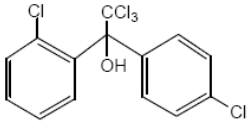
DICOFOL

This EQS dossier was prepared by the Sub-Group on Review of the Priority Substances List (under Working Group E of the Common Implementation Strategy for the Water Framework Directive).

The dossier was reviewed by the Scientific Committee on Health and Environmental Risks (SCHER), which agreed with the identification of the QS_{biota} as the critical EQS but indicated a need to reassess its value in the light of the available literature. As a result of the reassessment, the QS_{biota} has been revised.

This version of the Dicofol dossier includes information retrieved from the non-public version of the Draft Assessment Report (DAR) elaborated in the context of Directive 91/414/EEC (E.C., 2006). Despite the DAR, it was not possible to derive a $QS_{water, eco}$ value because of a lack of reliable ecotoxicological data, notably of chronic data on invertebrates which usually represent the main sensitive taxa for organochlorinated pesticides such as Dicofol. Such data were not provided by the notifier, who decided not to proceed with the Annex I notification. The critical EQS proposed for this highly bioaccumulative substance is based on $QS_{biota, sec.pois.}$.

1 CHEMICAL IDENTITY

Common name	Dicofol
Chemical name (IUPAC)	2,2,2-trichloro-1,1-bis(4-chlorophenyl)ethanol
Synonym(s)	Kelthane
Chemical class (when available/relevant)	Organochlorinated acaricide
CAS number	115-32-2 (p,p'-isomer)
EU number	204-082-0
Molecular formula	$C_{14}H_9Cl_5O$
Molecular structure	 p,p'-dicofol CAS No. 115-32-2  o,p'-dicofol CAS No. 10606-46-9
Molecular weight ($g.mol^{-1}$)	370.47

p, p'-dicofol is the main isomer contained in the commercial product (E.C., 2008a). Most of the data contained in the present fact sheet are therefore presented for this isomer but o'p-dicofol data are also provided as supplemental information when available.

2 EXISTING EVALUATIONS AND REGULATORY INFORMATION

Dicofol is not included in the Annex I of Directive 91/414/EEC. A US-EPA « Reregistration Eligibility Decision (RED) » dossier is however available (US-EPA, 1998). An OSPAR Background document is also available (OSPAR, 2004) as well as a report from UK (DEFRA, 1996).

Annex III EQS Dir. (2008/105/EC)		Included
Existing Substances Reg. (793/93/EC)		Not applicable
Pesticides (91/414/EEC)		Not included in Annex I (Harmful effects on human health identified, in particular for operators and workers - E.C., 2008a)
Biocides (98/8/EC)		Identified (Annex I to reg1451/2007) but not included in the review programme
PBT substances		Not investigated
Substances of Very High Concern (1907/2006/EC)		No
POPs (Stockholm convention)		No
Other relevant chemical regulation (veterinary products, medicament, ...)		No
Endocrine disrupter	Human health	Cat. 3: No evident scientific basis for inclusion in the list
(Groshart and Okkerman, 2000)	Wildlife	Cat. 2: Evidence of potential to cause endocrine disruption

3 PROPOSED QUALITY STANDARDS (QS)

3.1 ENVIRONMENTAL QUALITY STANDARD (EQS)

Physico-chemical properties show that the substance is most likely to bioaccumulate in biota and $QS_{biota,\ sec.\ pois.}$ for protection of top predators from secondary poisoning is considered the "critical QS" for derivation of an Environmental Quality Standard. A $QS_{water,\ eco}$ could not be derived because of a lack of available data but pelagic organisms are deemed protected by $QS_{biota,\ sec.\ pois.}$ given that back calculation of this latter value in water is 4 orders of magnitude lower than the lowest validated NOEC for fish.

	Value	Comments
Proposed AA-EQS for [biota] [$\mu g.kg^{-1}_{biota\ ww}$] Corresponding AA-EQS in [freshwater] [$\mu g.l^{-1}$] Corresponding AA-EQS in [marine water] [$\mu g.l^{-1}$]	33 $1.3\ 10^{-3}$ $3.2\ 10^{-5}$	**Critical QS is $QS_{biota,\ sec.pois.}$** **See section 7**
Proposed MAC-EQS for [freshwater] [$\mu g.l^{-1}$] **Proposed MAC-EQS for [marine water] [$\mu g.l^{-1}$]**	*No QS derived*	**See section 7.1**

3.2 SPECIFIC QUALITY STANDARD (QS)

Protection objective*	Unit	Value	Comments
Pelagic community (freshwater)	[$\mu g.l^{-1}$]	*No QS derived*	See section 7.1
Pelagic community (marine water)	[$\mu g.l^{-1}$]		
Benthic community (freshwater)	[$\mu g.kg^{-1}_{dw}$]		See section 7.1
Benthic community (marine)	[$\mu g.kg^{-1}_{dw}$]		
Predators (secondary poisoning)	[$\mu g.kg^{-1}_{biota\ ww}$]	33 $\mu g.kg^{-1}_{biota\ ww}$	See section 7.2
	[$\mu g.l^{-1}$]	$1.3\ 10^{-3}$ $\mu g.l^{-1}$ (freshwater) $3.2\ 10^{-5}$ $\mu g.l^{-1}$ (marine waters)	
Human health via consumption of fishery products	[$\mu g.kg^{-1}_{biota\ ww}$]	134 $\mu g.kg^{-1}_{biota\ ww}$	See section 7.3
	[$\mu g.l^{-1}$]	$5.4\ 10^{-3}$ $\mu g.l^{-1}$ (freshwater) $1.3\ 10^{-4}$ $\mu g.l^{-1}$ (marine waters)	
Human health via consumption of water	[$\mu g.l^{-1}$]	0.1	

* Please note that as recommended in the draft Technical Guidance for deriving EQS (E.C., 2011), "EQSs […] are not reported for 'transitional and marine waters', but either for freshwater or marine waters". If justified by substance properties or data available, QS for the different protection objectives are given independently for transitional waters or coastal and territorial waters.

4 MAJOR USES AND ENVIRONMENTAL EMISSIONS

4.1 USES AND QUANTITIES

Dicofol is an organochlorinated acaricide. It was used in plant protection products on a number of fruits, vegetables, ornamental crops and field cultures, and as a biocide.

However, dicofol is no longer included in Annex I of Directive 91/414/EEC, nor has it been included in the Biocidal Products Review Programme.

Commission Decision 2008/764/EC concerning the non-inclusion of dicofol in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (E.C., 2008a) states that "*Any period of grace granted by a Member State for the disposal, storage, placing on the market and use of existing stocks of plant protection products containing dicofol should be limited to 12 months in order to allow existing stocks to be used in one further growing season, which ensures that plant protection products containing dicofol remain available for 18 months from the adoption of this Decision.*"

4.2 ESTIMATED ENVIRONMENTAL EMISSIONS

Dicofol is not included in Annex I of Directive 91/414/EC. Therefore, it should not be used anymore and future primary emissions are not expected.

5 ENVIRONMENTAL BEHAVIOUR

5.1 ENVIRONMENTAL DISTRIBUTION

		Master reference
Water solubility (mg.l^{-1})	0.8	DEFRA, 1996
Volatilisation	**According to Henry constant, Dicofol is not likely to volatilize.**	
Vapour pressure (Pa)	5.3 10^{-5} at 25°C	DEFRA, 1996
Henry's Law constant (Pa.m^3.mol^{-1})	0.015	US-EPA, 1998
Adsorption	**The K_{OC} range 5 000 – 21 096 is used for derivation of quality standards.**	
Organic carbon – water partition coefficient (K_{OC})	K_{OC} – p,p'-dicofol = 5 000 – 6 983 (mean=5 080) K_{OC} – o,p'-dicofol = 13 949 – 21 096 (mean=16 995)	Daly, 1987 Cook, 2003
Sediment – water partition coefficient($K_{susp-water}$)	p,p'-dicofol = 127.8 o,p'-dicofol = 425.7	*Calculated from K_{oc}*
Bioaccumulation	**Dicofol is likely to highly bioaccumulate. Biota Quality Standards are back calculated into water by using the following values: BCF=25 000; BMF_1=1 and BMF_2=42 (see below).**	
Octanol-water partition coefficient (Log Kow)	K_{OW} – p,p'-dicofol = 4.08 K_{OW} – o,p'-dicofol = 4.32	E.C., 2008a

BCF (measured)	*Pimephales promelas* – 28d = 8 050 – 13 500	Rasenberg, 2003, as cited *in* OSPAR, 2004
	Lepomis macrochirus – 28d – (p, p'-dicofol) $BCF_{end\ of\ exposure}$= 10 000 $BCF_{steady\text{-}state}$= 25 000 (extrapolated)	Tillman, 1986 as cited *in* E.C., 2008a
Biomagnification potential	In a study lead by Kelly *et al.*, 2007b for which supporting material is available (Kelly *et al.*, 2007a) dicofol biomagnification was studied among other organic chemicals. Experimental trophic magnification factors could not be calculated but BMF values for dicofol were calculated from the physicochemical properties (log Kow and log Koa). Resulting model calculated values are a BMF_1 <1 and a BMF_2 value of 42 which are deemed sufficiently reliable for the purpose of EQS derivation. It is noted that the modeled BMF1 of 1 may be low given to the high aquatic BCF. BMF2 can however be considered as a worst case because potential metabolism has not been taken into account.	Kelly *et al.*, 2007b Kelly *et al.*, 2007a

5.2 ABIOTIC AND BIOTIC DEGRADATIONS

		Master reference
Hydrolysis	Dicofol is stable under acidic conditions. Dicofol hydrolysis is very rapid within neutral and alcaline conditions. One transformation product is dichlorobenzophenone.	US-EPA, 1998
Photolysis	At neutral pH, samples without a photosensitiser: $DT_{50\ –\ exposed}$ = 15d for o,p'-dicofol ; 93d for p,p'-dicofol $DT_{50\ –\ dark}$ = 149 for o,p'-dicofol ; 32 for p,p'-dicofol (Study considered as supplementary, some of the recoveries are out of range)	Carpenter, 1988a; Carpenter, 1988b
Biodegradation	Dicofol biodegrades slowly in aerobic conditions in water/sediment systems. There is no information on mineralisation process or degradation products. $DT_{50\ (water/sediment)}$ = 70-84 d	OSPAR, 2004

6 AQUATIC ENVIRONMENTAL CONCENTRATIONS

6.1 ESTIMATED CONCENTRATIONS

Compartment	**Predicted environmental concentration (PEC)**	**Master reference**
Freshwater (µg.l^{-1})	115	Daginnus *et al.*, 2009[(1)]
Marine waters (coastal and/or transitional)	No data available	Daginnus *et al.*, 2009[(1)]
Sediment	No data available	Daginnus *et al.*, 2009[(1)]
Biota (freshwater)	No data available	Daginnus *et al.*, 2009[(1)]
Biota (marine)	No data available	Daginnus *et al.*, 2009[(1)]
Biota (marine predators)	No data available	Daginnus *et al.*, 2009[(1)]

[(1)] data originated from EU modelling-based prioritisation results.

6.2 MEASURED CONCENTRATIONS

Compartment		Measured environmental concentration (MEC)	Master reference
Freshwater (µg.l^{-1})		PEC 1= 0.097 PEC 2 = 0.025	James *et al.*, 2009[(1)]
Marine waters (coastal and/or transitional) (µg.l^{-1})		No data (*0*)	James *et al.*, 2009[(1)]
		≤ 0.001	Pereira *et al.*, 1996 *in* OSPAR, 2004
		<0.1	Angelidis *et al.*, 1996 *in* OSPAR, 2004
WWTP effluent (µg/l)		No data available	
Sediment	Sed 2 mm	PEC 1= 64 µg.kg^{-1} PEC 2 = 25 µg.kg^{-1}	James *et al.*, 2009[(1)]
	Sed 20 µm	No data (*0*)	
	Sed 63µm	No data (*0*)	
	River sediment	0.0237 (µg.l^{-1})	Pereira *et al.*, 1996 *in* OSPAR, 2004
	River sediment	2.2 (µg.kg^{-1})	Angelidis *et al.*, 1996 *in* OSPAR, 2004
Biota	Invertebrates	No data (*0*)	James *et al.*, 2009[(1)]
		Corbicula fluminea: 97 µg.kg^{-1}	Pereira *et al.*, 1996 *in* OSPAR, 2004
		residues > 100 µg.kg^{-1} for 7,2 % of samples	Bender, 2001 *in* OSPAR, 2004
	Fish	No data (*0*)	James *et al.*, 2009[(1)]
		> 50 – 100 µg/kg^{-1} for 71% of the samples	Bender, 2001 *in* OSPAR, 2004
		Max = 450 µg/kg^{-1}	Wilkinson, 1993 *in* OSPAR, 2004
	Marine predators	No data available	

7 EFFECTS AND QUALITY STANDARDS

7.1 ACUTE AND CHRONIC AQUATIC ECOTOXICITY

Whenever it was possible, information on media renewal and analytical measurement of concentrations were reported. In the tables hereunder, static or flow-through systems are reported as (s) and (ft), respectively, while endpoints based on measured or nominal concentrations are reported as (m) and (n), respectively. ELS stands for "Early Life Stage" toxicity test and FLC for "Full Life Cycle" toxicity test.

ACUTE EFFECTS			**Klimisch codes**	**Master reference**
Algae & aquatic plants (mg.l^{-1})	**Freshwater**	*Scenedesmus subspicatus* / 96h EC_{50} = 0.073	4 [(1)]	RCC, 1983
	Marine	No data available		
Invertebrates (mg.l^{-1})	**Freshwater**	*Daphnia magna* / 48h EC_{50} = 0.14	4	US-EPA, 1998
	Marine	*Crassostrea virginica* / 96h EC_{50} = 0.0151	4 Core [(2)]	Office of Pesticide Programs, 2000
	Sediment	No data available		
Fish (mg.l^{-1})	**Freshwater**	*Oncorhyncus mykiss* / 96h LC_{50} = 0.11 (m, ft)	2	Bowman and Ritchie, 1990 as cited *in* E.C., 2006
		Pimephales promelas / 96h LC_{50} = 0.183 (m, s)	2	Ritchie *et al.*, 1992 as cited *in* E.C., 2006
		Oncorhyncus clarki / 96h EC_{50} = 0.012	4	OSPAR, 2004
		Oncorhyncus clarki / 96h EC_{50} = 0.053	4	Mayer and Ellersieck, 1986
	Marine	No data available		
	Sediment	No data available		
Other taxonomic groups		No data available		

(1) It was not possible to check the exact validity of the test but this study is not determinant for derivation of the quality standard since Dicofol action mode is not meant to affect plants and algae.

(2) The three study categories used by the US-EPA to classify studies are core, supplemental, and invalid. Classification as "core data" means that all essential information was reported and the study was performed according to recommended EPA or ASTM methodology. For more details, please see http://www.ipmcenters.org/Ecotox/DatabaseGuidance.pdf.

CHRONIC EFFECTS			Validity	Master reference
Algae & aquatic plants (mg.l^{-1})	**Freshwater**	No data available		
	Marine	No data available		
Invertebrates (mg.l^{-1})	**Freshwater**			
	Marine	No data available		
	Sediment	No data available		
Fish (mg.l^{-1})	**Freshwater**	*Oncorhyncus mykiss* / juvenile / 21d NOEC = 0.0032 (m, ft)	2	Ritchie *et al.*, 1992 as cited *in* E.C., 2006
		Oncorhyncus mykiss / ELS / 99d NOEC = 0.0091 (m, ft)	2	Rhodes *et al.*, 1994 as cited *in* E.C., 2006
		Pimephales promelas / FLC / 290d NOEC = 0.00452 (m, ft)	2	Ritchie *et al.*, 1992 as cited *in* E.C., 2006
		Oncorhynchus mykiss / ? NOEC = 0.001	4	McAllister, 1991
		Oncorhynchus mykiss / 45d NOEC = 0.00395	4 Core [(2)]	Office of Pesticide Programs, 2000
	Marine	No data available		
	Sediment	No data available		
Other taxonomic groups		No data available		

Acute and chronic ecotoxicological data could be retrieved from various sources but only data on fish could be validated. In the non-public DAR elaborated in the context of Directive 91/414/EEC there are some more invertebrates' ecotoxicological data but tests were deemed not acceptable by the assessors because of the absence of analytical measurement (acute test) or because of a too poor correlation between nominal and measured concentrations which made the approximation of effects concentrations "*too far from real*" (NOEC= 0.125 mg.l^{-1}). US-EPA Aquire database reports a number of other studies on invertebrates, the validity of which could not be thoroughly checked, but some NOEC values are as low as 10 µg.l^{-1} for *Daphnia magna*. This is still higher than the lowest validated NOEC for fish and these values all together are about 4 orders of magnitude higher than the proposed $QS_{biota,\ sec.pois.}$ when back calculated in water. Therefore, it was considered acceptable not to derive a $QS_{water,\ eco}$ because pelagic organisms are deemed protected by $QS_{biota,\ sec.pois.}$.

Tentative QS_{water}	Relevant study for derivation of QS	Assessment factor	Tentative QS
$MAC_{freshwater,\ eco}$	Data available could not be validated	-	-
$MAC_{marine\ water,\ eco}$		-	-
AA-$QS_{freshwater,\ eco}$		-	-
AA-$QS_{marine\ water,\ eco}$		-	-
AA-$QS_{freshwater,\ sed.}$	-	-	-
AA-$QS_{marine\ water,\ sed.}$	-	-	-

AA-$QS_{water,\ eco}$ and MAC-$QS_{water,\ eco}$ could not be derived with a sufficient degree of confidence as they would be based on tests which could not be validated (Klimisch code 3 or 4).

7.2 SECONDARY POISONING

Secondary poisoning of top predators		Master reference
Mammalian oral toxicity	Rat / Oral / 90d / Effects on liver, thyroid, and stomach. NOAEL = 0.07 $mg.kg^{-1}_{bw}.d^{-1}$ NOEC = 1 $mg.kg^{-1}_{feed\ ww}$ (Conversion Factor (CF) study specific)	US-EPA, 1998; WHO, 1992; WHO, 2007
	Rat / Oral / 2y / Effects on liver and adrenal cortical cells. NOAEL = 0.22 $mg.kg^{-1}_{bw}.d^{-1}$ NOEC = 5 $mg.kg^{-1}_{feed\ ww}$ (CF study specific)	US-EPA, 1998; WHO, 1992; WHO, 2007
	Dog / Oral / 1 y / Hormonal effects (Cortisol) *According to US-EPA* NOAEL = 0.12 $mg.kg^{-1}_{bw}.d^{-1}$ NOEC = 5 $mg.kg^{-1}_{feed\ ww}$ (CF study specific) *According. to WHO* NOAEL = 0.82 $mg.kg^{-1}_{bw}.d^{-1}$ NOEC = 30 $mg.kg^{-1}_{feed\ ww}$ (CF study specific)	US-EPA, 1998 WHO, 1992
Avian oral toxicity	*Falco sparverius* / Reproduction NOAEL = 0.125 $mg.kg^{-1}_{bw}.d^{-1}$ NOEC = 1 $mg.kg^{-1}_{feed\ ww}$ (CF = 8)	Office of Pesticide Programs, 2000
	Anas platyrhynchos / 1 generation / Reproduction NOAEL = 0.26 $mg.kg^{-1}_{bw}.d^{-1}$ NOEC = 2.5 $mg.kg^{-1}_{feed\ ww}$ (CF study specific)	Beavers *et al.*, 1992 as cited *in* E.C., 2006

US-EPA report a NOAEL (0.12 $mg.kg^{-1}_{bw}.d^{-1}$) from a one year study on beagle dogs whereas WHO selected a different NOAEL (0.82 $mg.kg^{-1}_{bw}.d^{-1}$) from the same study (WHO, 1992). In the Assessment Report drafted for the purpose of Directive 91/414/EC, the rapporteur selected the same NOAEL of 0.82 $mg.kg^{-1}_{bw}.d^{-1}$ as WHO, but discarded the study since the results were only partially available (E.C., 2006). It is to be noted that the first assessment made by the US-EPA (US-EPA, 1998) was based on this one-year dog study whereas the 2006 revision used a new dermal study.

The most relevant studies on rats are reported above, with a NOAEC of 1 ppm obtained from the 90-days studies and 5 ppm from a 2 years study.

The chosen value for $QS_{biota,\ sec.\ pois}$ is the reproduction study on the American kestrel (reduced shell thickness). This study is preferred to the 90 days study on rat corresponding to the same 1 ppm NOEC (effects on liver, thyroid and stomach) which when repeated did not reproduced this thyroid effect in a second 13-week study using dietary concentrations of 0, 50, 200, 1000 or 3000 mg/kg.

Dicofol is considered as suspected endocrine disrupter for wildlife (see Section 2). Thus an additional factor of 5 could be applied to the assessment factor expected for protection of top predators from secondary poisoning. However, given that the toxicological data used should be sufficiently protective to cover effects on thyroid, it is deemed acceptable not to use this additional assessment factor. The BCF value used for back calculation of $QS_{biota,\ sec.\ pois}$ in water is 25 000, which is extrapolated for steady state from laboratory study on *Lepomis macrochirus* exposed to p,p'-isomer (cf. section 5.1). The BMF values used also for this calculation are BMF_1=1 and BMF_2=42 (see section 5.1).

Tentative QS_{biota}	Relevant study for derivation of QS	Assessment factor	Tentative QS
Biota	*Falco sparverius* / Reproduction NOEC = 1 $mg.kg^{-1}_{feed\ ww}$	30[(1)]	33.33 $\mu g.kg^{-1}_{biota\ ww}$ corresponding to 1.33 10^{-3} $\mu g.l^{-1}$ (freshwater) 3.17 10^{-5} $\mu g.l^{-1}$ (marine waters)

(1) Default value of 30 for birds according to the Technical Guidance on EQS derivation (E.C., 2011).

7.3 HUMAN HEALTH

Human health via consumption of fishery products		Master reference
Mammalian oral toxicity	Rat / Oral / 90d / Effects on liver, thyroid, and stomach. NOAEL = 0.07 $mg.kg^{-1}_{bw}.d^{-1}$	US-EPA, 1998; WHO, 1992; WHO, 2007;E.C., 2006
	Rat / Oral / 2y / Effects on liver and adrenal cortical cells. NOAEL = 0.22 $mg.kg^{-1}_{bw}.d^{-1}$	US-EPA, 1998; WHO, 1992; WHO, 2007 E.C., 2006
	Dog / Oral / 1 y / Hormonal effects (Cortisol) *According to US-EPA* NOAEL = 0.12 $mg.kg^{-1}_{bw}.d^{-1}$ *According. to WHO* NOAEL = 0.82 $mg.kg^{-1}_{bw}.d^{-1}$	US-EPA, 1998 WHO, 2007 E.C., 2006
CMR	Not classified for any carcinogenic, mutagenic or reprotoxic effects according to Regulation 1272/2008/EC	E.C., 2008b

The chosen value for $QS_{biota\ hh}$ is the NOAEL from the two year study on rat, which covers diverse systemic effects on a long period including effects on liver and adrenal cortical cells. This data was retained by WHO for defining an acceptable daily intake (WHO, 1992), as well as the Draft Assessment Report prepared for the purpose of Directive 91/414/EC (E.C., 2006). Both WHO, 1992 and E.C., 2006 proposed the application of an assessment factor of 100.

The values used for back calculation of $QS_{biota,\ hh.}$ in water are: BCF=25 000, BMF_1=1 and BMF_2=42 (see section 5.1).

Tentative $QS_{biota,\ hh}$	Relevant study for derivation of $QS_{biota,\ hh}$	AF	Threshold level	Tentative $QS_{biota,\ hh}$
Human health	0.22 $mg.kg^{-1}_{bw}.d^{-1}$	100	0.002 $mg.kg^{-1}_{bw}.d^{-1}$	134 $\mu g.kg^{-1}_{biota\ ww}$ corresponding to 5.36 10^{-3} $\mu g.l^{-1}$ (freshwater) 1.28 10^{-4} $\mu g.l^{-1}$ (marine waters)

Human health via consumption of drinking water		Master reference
Existing drinking water standard(s)	0.1 $\mu g.l^{-1}$ (preferred regulatory standard)	Directive 98/83/EC
Drinking water standard(s) (*calculated*)		

The existing regulatory standards (Directive 98/83/EC) are less stringent than the proposed QS_{water}. Therefore, a quality standard for drinking water abstraction is not needed.

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