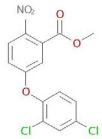
BIFENOX

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 commented that little justification was given for the assessment factor of 3 for the MAC-QS, and that the Committee did not support generic addition of an additional assessment factor of 10 for the marine EQS. The magnitudes of the two assessment factors have been better justified.

1 CHEMICAL IDENTITY

Common name	Bifenox
Chemical name (IUPAC)	Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate
Synonym(s)	5-(2,4-Dichlorophenoxy)-2-nitrobenzoic acid methyl ester 2,4-dichlorophenyl 3-(methoxycarbonyl)-4-nitrophenyl ether
Chemical class	Herbicides
CAS number	42576-02-3
EU number	255-894-7
Molecular formula	$C_{14}H_9Cl_2NO_5$
Molecular structure	
Molecular weight (g.mol^{-1})	342.14
Known metabolites	Major metabolites observed in the environment *Soil:* - Bifenox acid (max. 50.8 – 78.7% under aerobic and max. 16.5% under anaerobic conditions) *Water:* - Aminobifenox (max. 66.7% in sediment phase of water/sediment systems) - Aminobifenox acid (max 12.7% in water phase of water/sediment systems)

2 EXISTING EVALUATIONS AND REGULATORY INFORMATION

Legislation	
Annex III EQS Directive (2008/105/EC)	Not included
Existing Substances Regulation (793/93/EC)	Not applicable
Pesticides(91/414/EEC)	Included in Annex I
Biocides (98/8/EC)	Not investigated
PBT substances	Not investigated (EU) – Remark: *Bifenox used to be included in the List of Substances of Potential Concern of OSPAR Convention but was deselected for the reason that it does not fulfil the P criterion.*
POPs (Stockholm convention)	No
Substances of Very High Concern (1907/2006/EC)	No
Other relevant chemical regulation (veterinary products, medicament, ...)	Not applicable
Endocrine disrupter	Bifenox is not included in Commission Staff Working Document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706) (E.C., 2004)

Bifenox has been included into Annex I to Directive 91/414/EC. It is used as a control of weeds in post-emergence applications in winter cereals (E.C., 2006).

3 PROPOSED QUALITY STANDARDS (QS)

3.1 ENVIRONMENTAL QUALITY STANDARD (EQS)

$QS_{water, eco}$.is the "critical QS" for derivation of an Environmental Quality Standard for bifenox.

Data are available on 3 trophic levels for both acute and chronic ecotoxicity and an assessment factor of 10 is applied for derivation of QS_{water_eco}. Significant differences between freshwater and marine species cannot be demonstrated from the information available, Significant differences between freshwater and marine species cannot be demonstrated from the information available, but data from additional marine taxonomic groups are not available that might have reduced the uncertainties associated with extrapolation to the marine ecosystem, i.e. with the greater species diversity in the marine environment and the possibly greater sensitivity of marine species and taxa not in the experimental dataset.

	Value	**Comments**
Proposed AA-EQS for [freshwater] [µg.L^{-1}]	1.25 10^{-2}	**Critical QS is $QS_{water, eco}$**
Proposed AA-EQS for [marine water] [µg.L^{-1}]	1.25 10^{-3}	**See section 7.1**
Proposed MAC-EQS for [freshwater] [µg.L^{-1}]	4 10^{-2}	**See section 7.1**
Proposed MAC-EQS for [marine water] [µg.L^{-1}]	4 10^{-3}	

3.2 SPECIFIC QUALITY STANDARD (QS)

Protection objective[*]	**Unit**	**Value**	**Comments**
Pelagic community (freshwater)	[µg.l^{-1}]	1.25 10^{-2}	See section 7.1
Pelagic community (marine water)	[µg.l^{-1}]	1.25 10^{-3}	
Benthic community (freshwater)	[µg.kg^{-1} $_{dw}$]	0.33	EqP, see section 7.1
Benthic community (marine)	[µg.kg^{-1} $_{dw}$]	0.033	
Predators (secondary poisoning)	[µg.kg^{-1} $_{biota\ ww}$]	25 000	See section 7.2
	[µg.l^{-1}]	16.7 (freshwater) 16.7 (saltwater)	
Human health via consumption of fishery products	[µg.kg^{-1} $_{biota\ ww}$]	18 261 µg.kg^{-1} $_{biota\ ww}$	See section 7.3
	[µg.l^{-1}]	12.2 (freshwater) 12.2 (saltwater)	
Human health via consumption of water	[µg.l^{-1}]	0,1	

ETOX database[†] refers to existing German Quality Criteria (Nendza, 2003)

[*] Please note that as recommended in the 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.

[†] http://webetox.uba.de/webETOX/public/basics/ziel.do?id=3107

- for protection of aquatic life = 0.01 µg.l^{-1}
- for protection of human health via consumption of drinking water = 0.1 µg.l^{-1}
- for protection of aquatic life from transient concentration peaks = 0.6 µg.l^{-1}

4 MAJOR USES AND ENVIRONMENTAL EMISSIONS

4.1 USES AND QUANTITIES

Bifenox is included in Annex I of Directive 91/414/EEC and used as a “control of broad leaved weeds in post-emergence applications in winter cereals. Bifenox is especially active on difficult to control broadleaf weeds like *Veronica*, *Viola* and *Galium* spp. Other species like *Lamium* spp. are also controlled.” (E.C., 2006)

Authorisations at national level have been granted in 19 out 27 Member States (AT, BE, BG, CZ, DE, DK, ES, FI, FR, HU, IE, IT, LU, NL, PL, RO, SE, SK, UK).

Summary of representative uses evaluated (Bifenox)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Winter wheat, winter barley	North and South Europe	Milan	F	Broad leaved weeds	SC	B: 500 P: 9	Tractor mounted boom sprayer	Post emergence in spring BBCH 13 to BBCH 29	1	Not applicable	B: 0.188 – 0.750 P: 0.003 – 0.0135	100 - 400	B: 0.750 P: 0.0135	Not applicable	none

B: Bifenox
P: Pyraflufen-ethyl

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

4.2 ESTIMATED ENVIRONMENTAL EMISSIONS

No information available

5 ENVIRONMENTAL BEHAVIOUR

5.1 ENVIRONMENTAL DISTRIBUTION

		Master reference
Water solubility (mg.l^{-1})	<0.1 at 20°C (at pH 4)	EFSA, 2007
Volatilisation	Bifenox is very slightly volatile.	
Vapour pressure (Pa)	4.74 10^{-8} at 20°C	EFSA, 2007
Henry's Law constant (Pa.m^3.mol^{-1})	>1.62 10^{-4} at 20°C	
Adsorption	Bifenox is strongly adsorbed to soil and sediment particles.	
Organic carbon – water partition coefficient (K_{OC})	K_{OC} soils = 7 143 (500 – 23 000) L/kg log K_{OC} = 3.85 (2.7 – 4.4)	EFSA, 2007
Sediment – water partition coefficient ($K_{sed-water}$)	894	*Calculated from mean K_{OC}*
Bioaccumulation	Bifenox is liposoluble and has a bioconcentration potential. **The BCF value of 1 500 on fish is used for derivation of quality standards (BMF_1 = 1, BMF_2 = 1)**	
Octanol-water partition coefficient (Kow)	log K_{OW} = 3.64	EFSA, 2007
BCF (measured)	BCF values of 460 (fillet), 1 500 (whole fish) and 2 400 (viscera) were found for fish. *Remark: BCF refers to total radioactive residue. Since 88-86% of radioactivity was present as bifenox at day 21-28, this BCF based on TTR can be used for bifenox.*	

5.2 ABIOTIC AND BIOTIC DEGRADATIONS

		Master reference
Hydrolysis	At 25°C: DT_{50} = 265 d at pH7; 4 d at pH9 Bifenox is hydrolytically stable at pH 4, slightly hydrolysing at pH7 and fairly hydrolysing at pH9. Main hydrolysis product is corresponding carboxylic acid: Bifenox acid	EFSA, 2007
Photolysis	- Under continuous artificial irradiation for 72 h, at 20°C, in pH 5 buffer: DT_{50} = 24.4 h. - Under conditions equated to natural summer sunlight at	EFSA, 2007

	40°N: DT_{50} ca. 2.18 d. Main photodegradation product is 2,4-dichlorophenol (79% AR after 72 hours)[‡].	
Biodegradation	Bifenox is not readily biodegradable: 11.8 – 14.0 % $ThCO_2$ after 28 days.	EFSA, 2007

6 AQUATIC ENVIRONMENTAL CONCENTRATIONS

6.1 ESTIMATED CONCENTRATIONS

Compartment	**Distance between the crop and the water (m)**	**Predicted environmental concentration (PEC)**	**Master reference**
Freshwater (µg/l)	1	6.930	E.C., 2006
	3	2.502	
	30	0.250	
	-	27.1	Daginnus *et al.*, 2009[(1)]
Marine waters (coastal and/or transitional)	-	No data available	
Sediment (µg/kg)	1	259.690	E.C., 2006
	3	93.751	
	30	9.375	
Biota (freshwater)	-	No data available	
Biota (marine)	-	No data available	
Biota (marine predators)	-	No data available	

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

6.2 MEASURED CONCENTRATIONS

Compartment	**Measured and quantified environmental concentrations (*nb analysis*)**	**Master reference**
Freshwater (µg/l)	PEC 1: 0.56 PEC 2: 0.05	James *et al.*, 2009[(1)]
Marine waters (coastal and/or transitional) (µg/l)	(*0*)	

[‡] Under environmental conditions in a mesocosm study the maximum observed amount of 2,4-dichlorophenol was 5.2%. Thus the EU-DAR (EFSA, 2007) concluded that this compound (which can be formed only by photodegradation in the upper layer of a surface water) would be a minor degradation product of bifenox in natural surface water.

WWTP effluent (µg/l)		No data available	
Sediment (µg/kg dw)	Sed <2 mm	PEC 1: 5000 PEC 2: 50	James *et al.*, 2009[(1)]
	Sed <20 µm	(*0*)	
	Sed <63 µm	(*0*)	
Biota	Invertebrates (µg/kg ww)	(*0*)	James *et al.*, 2009[(1)]
	Fish (µg/kg ww)	(*0*)	
	Marine predators	No data available	

[(1)] *data originated from EU monitoring data collection*

7 EFFECTS AND QUALITY STANDARDS

The active substance causes herbicide contact effect via cellular membrane disruption and inhibition of photosynthesis (E.C., 2006).

All data presented extracted from EU-DAR, including the final addendum to the Draft Assessment Report (DAR) (E.C., 2006, E.C., 2007), and from the EFSA Scientific Report (EFSA, 2007) thereafter are considerer valid.

7.1 ACUTE AND CHRONIC AQUATIC ECOTOXICITY

ACUTE EFFECTS			**Reliability Klimisch codes**	**Master reference**
Algae & aquatic plants (mg.l^{-1})	**Freshwater**	***Desmodesmus subspicatus* / 96h** **E_bC_{50} = 0.000175 ; E_rC_{50} = 0.00019**	1	E.C., 2006 EFSA, 2007
		Navicula pelliculosa / 72h E_bC_{50} = 0.0049 ; E_rC_{50} = 0.038	1	
		Lemna gibba / 14d E_rC_{50} = 0.0021	1	
	Marine	No available information		
Invertebrates (mg.l^{-1})	**Freshwater**	*Daphnia magna* / 48h EC_{50} = 0.66	1	E.C., 2006 EFSA, 2007
	Marine	*Mysidopsis bahia* / 96h LC_{50} = 0.065	4	FCS, unpublished
	Sediment	No available information		
Fish (mg.l^{-1})	**Freshwater**	*Oncorhynchus mykiss* / 96h LC_{50} = 0.67	1	E.C., 2006 EFSA, 2007
		Lepomis macrochirus / 96h LC_{50} > 0.27	1	
	Marine	*Cyprinodon variegatus* / 96h LC_{50} = 0.37	4	FCS, unpublished

CHRONIC EFFECTS			**Reliability Klimisch codes**	**Master reference**
Algae & aquatic plants ($mg.l^{-1}$)	**Freshwater**	***Desmodesmus subspicatus* / 96h** **NOEC = 0.000125**	1	E.C., 2006
		Navicula pelliculosa / 72h NOEC = 0.00016	1	
		Lemna gibba / 14d NOEC < 0.00045	1	
	Marine	No available information		
Invertebrates ($mg.l^{-1}$)	**Freshwater**	*Daphnia magna* / 21d NOEC = 0.00015	1	E.C., 2006 EFSA, 2007
	Marine	No available information		
	Sediment	*Chironomus riparius* / 28d (spiked water, nominal concentrations) NOEC = 0.015	Cannot be used for QS	E.C., 2006
Fish ($mg.l^{-1}$)	**Freshwater**	*Oncorhynchus mykiss* / 21d NOEC = 0.0091	1	E.C., 2006 EFSA, 2007
		Lepomis macrochirus / 14d NOEC = 0.13	1	
	Marine	No available information		

It has to be mentioned that an indoor mesocosm study is available in the EU-DAR addendum (E.C., 2007) but was considered invalid. This study was superseded in the EU pesticide risk assessment by an outdoor mesocosm study which was done on a plant protection product (Foxtril super) containing 3 active substances. This study was carried out with a single application as exposure regimen. The test systems contained various macrophytes (*Potamogeton natans, Potamogeton sp., Ceratophyllum demersus*, and the alga *Chara intermedia*) of comparable density and composition and *Lemna sp.* with each 40 individuals per enclosure at start of exposure. Phytoplankton was identified to at least the following level: *Bacillariophyceae*, *Chlorophyceae*, *Chrysophyceae*, *Conjugatophyceae*, *Cryptophyceae*, *Cyanophyceae*, *Dinophyceae*, *Euglenophyceae*, *Prasinophyceae*, *Xanthophyceae*. The addendum to the Draft Assessment report (E.C., 2007) concludes that "Reliable short-term effects on the community structure were observed at 22 µg Foxtril super/L and higher directly after treatment. Based on the Principal Response Curves (PRCs), slight short-term effects could not be excluded at 11 µg Foxtril super/L. The NOEC for the phytoplankton community structure is set to 5.5 µg Foxtril super/L (equivalent to 1.0 µg bifenox/L). Similarity index and PRCs indicate a recovery of community structure within 4 weeks up to the highest treatment level. […] Based on clear short-term effects with recovery within 8 weeks, the NOAEC for the phytoplankton is set to 44 µg Foxtril super/L (equivalent to 8.0 µg bifenox/L)."

This NOEC of 1.0 µg bifenox/L can be used for acute effect assessment. An assessment factor of 5 leads to MAC value of 0.2 µg/L for freshwater and 0.02 µg/L for marine water.

The MAC value derived based on the mesocosm study is equivalent to the E_rC_{50} = 0.19 µg/L observed on the most sensitive laboratory species *Desmodesmus subspicatus*., which would lead to a MAC of 0.019 $\mu g.l^{-1}$ with an assessment factor of 10.

According to the TGD-EQS (E.C., 2011), "*for substances that do not dissipate quickly, the MAC-$QS_{freshwater,eco}$ values should be based on measured time weighted average (TWA) concentrations, and biological effects determined over a time span that is representative for most acute toxicity studies (i.e.*

48–96 h). […] *Furthermore it is important to determine which part of the exposure profile is most relevant. For example, if the peak concentration causes the effect, the actual initial concentration in the cosms is relevant*". In the mesocosm reported above, concentrations are expressed as initial concentrations and do not take into account the adsorption of bifenox to sediment (Koc = 500 – 23 000 L/kg).

For bifenox, the most sensitive species are algae and macrophytes. For these groups, the reported endpoint growth rate is per definition not caused by the actual initial concentration, because it is defined as the exponential increase averaged over time. The mesocosm study and a laboratory single species study include both the same species. However, the NOEC in the mesocosm study is 1 $\mu g.l^{-1}$, the NOEC in the single species test is 0.125 $\mu g.l^{-1}$and the EC_{50} is 0.19 $\mu g.l^{-1}$, *i.e.* a factor of 8 between the two. This difference can be explained by sorption of this compound of moderate hydrophobicity causing the actual concentration to be reduced over the time of observation for acute effects to algae. If a TWA concentration had been applied, the two values would very likely be more in line with each other. For this reason, the single species test in which the concentration was well defined is preferred to base the final derivation upon.

The additional information provided by the mesocosm should nevertheless be taken into account in a weight of evidence approach. In the mesocosm study, in total, 119 phytoplankton taxa were differentiated in the 240 samples. The dominating classes were *Chlorophyceae*, *Crysophyceae*, *Bacillariophyceae* and *Cryptophyceae*. Considering that the *Chlorophyceae* to which belongs *Desmodesmus subspicatus* were well represented in the mesocosm studies, and the presence of several species of macrophytes, it can be considered that the relevant taxa were considered in the mesocosm for this herbicide. Periphyton was also analysed.

For this reason, it is proposed to derive the MAC with the use of the NOEC instead of the EC_{50} from the most sensitive single species test (data originate from the same study with the same exposure time) and a reduced AF of 3 considering that the uncertainty related to the interspecies variability can be reduced based on the information from the mesocosm in which several phytoplankton taxa were differentiated, including the *Chlorophyceae* to which belongs the most sensitive species in experimental data set.

The MAC is then calculated as 0.125 / 3 = 0.04 $\mu g.l^{-1}$.

Tentative QS_{water}	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS**
$MAC_{freshwater, eco}$	*Desmodesmus subspicatus* / 96h	3	4 10^{-2} $\mu g.l^{-1}$
$MAC_{marine\ water, eco}$	NOEC = 0.000125 $mg.l^{-1}$ µg/L	30	4 10^{-3} $\mu g.l^{-1}$
$AA\text{-}QS_{freshwater, eco}$	*Desmodesmus subspicatus* / 96h	10	1.25 10^{-2} $\mu g.l^{-1}$
$AA\text{-}QS_{marine\ water, eco}$	NOEC = 0.000125 $mg.l^{-1}$	100	1.25 10^{-3} $\mu g.l^{-1}$
$AA\text{-}QS_{freshwater, sed.}$	-	EqP	0.13 – 5.54 $\mu g.kg^{-1}_{ww}$ 0.33 – 25.5 $\mu g.kg^{-1}_{dw}$
$AA\text{-}QS_{marine\ water, sed.}$	-	EqP	0.013 – 0.55 $\mu g.kg^{-1}_{ww}$ 0.033 – 2.54 $\mu g.kg^{-1}_{dw}$

7.2 SECONDARY POISONING

Secondary poisoning of top predators		Master reference
Mammalian oral toxicity	Mouse / Oral / 2 years / Carcinogenicity / 0-50-200-1000 ppm / Reduced reticulocytes and platelets at terminal sacrifice NOAEL = 30 $mg.kg^{-1}_{bw}.d^{-1}$ NOEC = 200 $mg.kg^{-1}_{feed\ ww}$ (CF=study specific)	EFSA, 2007
	Rat / Oral / Two generations / decreased pup and litter weight NOAEL = 44.5 $mg.kg^{-1}_{bw}.d^{-1}$ NOEC = **750 $mg.kg^{-1}_{feed\ ww}$** (CF=study specific)	EFSA, 2007
Avian oral toxicity	*Coturnix coturnix japonica* /Oral /6 weeks /repro NOEC= 1400 mg/kg_{food} NOAEL= 290 $mg.kg^{-1}_{bw}.d^{-1}$	EFSA, 2007

The lowest NOAEL is observed in a 2-year carcinogenicity study on mouse. However, the relevance of blood parameters for population effects is not clear. The NOAEL from a 2-y reproduction study with rats is 750 mg/kg food, based on decreased pup and litter weight is preferred (see http://www.efsa.europa.eu/en/scdocs/doc/119r.pdf).

The BCF value of 1 500 on fish is used for derivation of quality standards (BMF_1 = 1, BMF_2 = 1)

Tentative QS_{biota}	Relevant study for derivation of QS	AF	Tentative QS
Biota	NOEC = 750 $mg.kg^{-1}_{feed\ ww}$	30[(1)]	25 000 $\mu g.kg^{-1}_{biota\ ww}$ corresponding to 16.7 $\mu g.L^{-1}$ (freshwater) 16.7 $\mu g.L^{-1}$ (saltwater)

[(1)] proposal made for the purpose of this dossier, according to REACH guidance on information requirements and chemical safety assessment (ECHA, 2008)

7.3 HUMAN HEALTH

Human health via consumption of fishery products		Master reference
Mammalian oral toxicity	Mouse / Oral / 2 years / Carcinogenicity / 0-50-200-1000 ppm (feed) / Reduced reticulocytes and platelets at terminal sacrifice NOAEL : 30 $mg.kg^{-1}_{bw}.d^{-1}$	EFSA, 2007
CMR	Bifenox is not classified for any carcinogenic, mutagenic or reprotoxic properties	E.C., 2008; IARC, 2009

Tentative $QS_{biota,\ hh}$	Relevant study for derivation of $QS_{biota,\ hh}$	AF	Threshold level	Tentative $QS_{biota,\ hh}$

Human health	NOAEL : 30 $mg.kg^{-1}_{bw}.d^{-1}$	100[(1)]	0.3[(1)] $mg.kg^{-1}_{bw}.d^{-1}$	18 261 $\mu g.kg^{-1}_{biota\ ww}$ corresponding to 12.2 $\mu g.L^{-1}$ (freshwater) 12.2 $\mu g.L^{-1}$ (saltwater)

(1) This value and the associated assessment factor are considered valid as they were determined by EFSA, 2007.

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

8 BIBLIOGRAPHY, SOURCES AND SUPPORTIVE INFORMATION

E.C. (2004). Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM(1999) 706)). SEC(2004) 1372. European Commission, Brussels

E.C. (2006). Draft Assessment Report (DAR) - public version. Initial risk assessment by the rapporteur Member States Belgium for the existing active substance BIFENOX in the third stage (part A) of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC

E.C. (2007). Final addendum to the Draft Assessment Report (DAR) - public version. Initial risk assessment by the rapporteur Member States Belgium for the existing active substance BIFENOX in the third stage (part A) of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC. http://www.efsa.europa.eu/en/scdocs/doc/119radd.pdf.

E.C. (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance). Official Journal of the European Union. **L353:** 1355.

ECHA (2008). Guidance on information requirements and chemical safety assessment Chapter R.10: Characterisation of dose [concentration]-response for environment. European Chemicals Agency, Helsinki

E.C. (2011). TGD-EQS: Technical Guidance for deriving Environmental Quality Standards. Common Implementation Strategy for the Water Framework Directive Guidance Document No 27.

EFSA (2007). Conclusion regarding the peer review of the pesticide risk assessment of the active substance bifenox. European Food Safety Authority. EFSA Scientific Report 119. http://www.efsa.europa.eu/en/scdocs/doc/119r.pdf.

FCS (unpublished). Study report BW 85-10-1867. FCS

IARC (2009). "Agents reviewed by the IARC Monographs. Volumes 1-100A." (1-100a).

Nendza M. (2003). Entwicklung von Umweltqualitätsnormen zum Schutz aquatischer Biota in Oberflächengewässern. UBA-FB, Luhnstedt. http://webetox.uba.de/webETOX/public/basics/literatur/download.do.