POLYBROMINATED DIPHENYL ETHERS (BDES)

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 on a number of issues. In response, some amendments have been made and explanation added to the dossier.

Introduction

The substances "pentaBDE" and "octaBDE" have been prioritised through 2 consecutive prioritisation procedures: pentaBDE was prioritised following COMMPS[1] (COmbined Monitoring-based and Modelling-based Priority Setting scheme) procedure in 2001, while octaBDE has recently been prioritised in the context of the second European Commission proposal for a new list of priority substances, for the reason that it is a PBT (Persistent, Bioaccumulative and Toxic) and a vPvB (very Persistent and very Bioaccumulative) substance. Following this latter prioritisation and the fact that pentaBDE EQS needed to be revised, it was decided to produce a unique fact sheet reporting a common EQS for all BDE congeners linked to c-pentaBDE and c-octaBDE, that is to say tetra- to nona-BDE congeners.

The polybrominated diphenyl ethers (polyBDE) are diphenyl ethers with degrees of bromination varying from 2 to 10 representing a list of 209 congeners (see section "Nomenclature of all 209 BDE congeners", page 4). Among these polyBDEs which are mainly used as flame retardants, three are available commercially: "pentaBDE commercial product", "octaBDE commercial product" and "decaBDE commercial product". However, these products are all a mixtures of diphenyl ethers as shown in the table hereunder. Therefore, to differentiate "pentaBDE commercial product" and "octaBDE commercial product" from "pentaBDE substance" and "octaBDE substance", respectively, these commercial products will be referred to as "c-pentaBDE" and "c-octaBDE" in the present fact sheet.

Commercial mixtures / **Content (% w/w) of Substance**	**c-PentaBDE**	**c-OctaBDE**
TriBDE (CAS 49690-94-0)	0 – 1	
TetraBDE (CAS 40088-47-9)	**24 – 38**	
PentaBDE (CAS 32534-81-9)	**50 – 62**	≤ 0.5
HexaBDE (CAS 36483-60-0)	**4 – 12**	**≤ 12**
HeptaBDE (CAS 68928-80-3)	Trace	**≤ 45**
OctaBDE (CAS 32536-52-0)		**≤ 33**
NonaBDE (CAS 63936–56–1)		**≤ 10**
DecaBDE (CAS 1163-19-5)		≤ 0.7

As stated above, the present fact sheet addresses pentaBDE and the newly prioritised substance octaBDE for derivation of EQS values. However, the data on toxicity and ecotoxicity that are reported in the EU Risk Assessment Report all come from studies performed with the following commercial products: c-pentaBDE, c-octaBDE and c-decaBDE.
DecaBDE was not prioritised along the prioritisation process. However, given the faculty of brominated diphenyl ether compound – including decaBDE – to degrade into lower brominated ones (UNEP, 2010),

[1] Revised proposal for a list of priority substances in the context of the Water Framework Directive (COMMPS procedure). Fraunhofer-Institut, June 1999. Available at http://ec.europa.eu/environment/water/water-dangersub/pdf/commps_report.pdf.

information on uses, restrictions and emissions of decaBDE has been reported in the present fact sheet. The EQS does not cover decaBDE.
So far, there is not enough scientific background on these heterogeneous compounds as regards their effects assessment, even if historically, pentaBDE 99 came up as a representative of BDE toxicity. In general, mixture toxicity can only be predicted, if enough information is available on the single toxicity of the mixture components, which is not the case here as there is not enough data to derive an EQS for individual component of the commercial products. Furthermore, because of the high log K_{OW} values there seems to be not even the possibility of using QSAR estimations for setting up a toxicity ranking between the mixture components. Integrative approach such as the Toxic Equivalent (TEQ) approach is not a way out since the representativeness of BDE congeners within the group is not scientifically defined yet at this stage.

As long as it is deemed impossible to monitor every single of the 209 BDE congeners, an alternative is to work with a limited number of congeners which are usually monitored in the environment. The repartition pattern of the various congeners in the environment remains incompletely described. However, "*Based on the analytical feasibility to measure the chemical compounds routinely in accredited laboratories, the production volumes* [as registered in 2006]*, the occurrence of the chemical compounds in food and feed, their persistence in the environment and their toxicity*" (EFSA, 2006), eight congeners were recommended by EFSA (EFSA, 2006): triBDE 28, tetraBDE 47, pentaBDE 99 and 100, hexaBDE 153 and 154, heptaBDE 183, and decaBDE 209. EFSA has further published a scientific opinion on PBDEs in food in 2011, analysing the information on these PBDEs in food samples provided by 11 Member states (EFSA, 2011) from 2001 to 2009. In this opinion, EFSA, 2011 underlines the analytical difficulties which remain for heptaBDE 183, and decaBDE 209.In line with EFSA recommendations, these indicators may be chosen as indicators congeners for BDE compounds in food, with the exception of decaBDE 209 which is not prioritised. With regards to heptaBDE183, in addition to analytical difficulties toxicological data are lacking for this compound.

It is thus proposed to limit the list of indicators proposed by EFSA to six congeners: triBDE 28, tetraBDE 47, pentaBDE 99 and 100, hexaBDE 153 and 154.

It is noted that:

- The data set available provides information on commercial mixture and individual compounds, and shows that PBDEs can cause a wide range of effects, in particular on mammals. The data set available however did not allow for the identification of one congener that would be systematically more toxic, or a mode of action that would be specific of one congener. Approaches such as toxic equivalent can not be applied. Therefore, for each protection goal, the use of the lowest available measured data in the overall dataset was adopted as worst case.
- Consequently, the compounds from which the QS were derived may not be the best marker of PAHs occurrence and effects on field;
- In line with the EFSA work, six indicators can be used as indicators congeners for BDE compounds, based on analytical feasibility, production volume and occurrence;
- It is recognised that the consideration of only 6 congeners for monitoring may be underprotective if an additive mode of action is assumed for all 209 BDE congeners,
- It is also recognised that it is deemed impossible to monitor every single of the 209 BDE congeners and the work made by EFSA in order to identify the most relevant marker, including consideration of occurrence, should be acknowledged.

Therefore, it is proposed to derive in this fact sheet a unique Environmental Quality Standard (EQS) for the pentaBDE and octaBDE, including data on their main components which are tetra-, penta-, hexa- and hepta-BDE where appropriate.

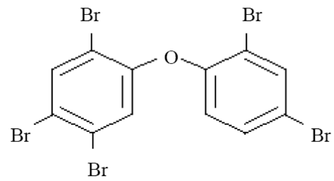
This EQS value, expressed in $\mu g.kg^{-1}_{food}$ and proposed for compliance check with biota concentrations, will apply in monitoring terms to the sum of the following six indicator congeners in fish: triBDE 28, tetraBDE 47, pentaBDE 99 and 100, hexaBDE 153 and 154.

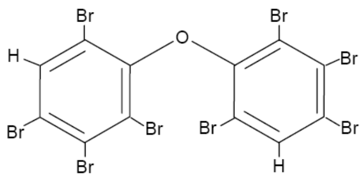
During the review process, it was underlined that the current proposal might, in some cases, be less conservative than an approach where the sum of all BDEs would have been considered. It is noted that this would be the case in sampling sites where the six indicators are not the main contributors to the BDEs concentration.

If Member States wished, after due justification, to apply EQS for sediment rather than biota, this could be done provided the same level of environment and human health protection is ensured. In this case, the EQS proposed in the present document should be back calculated to sediment ant could apply then to the same 6 congeners already recommended for biota[2].

[2] OctaBDE congeners 196 and 197 found in certain lakes (Unpublished data cordially forwarded by and belonging to Dr. Christoph Scheffknecht (Clara, pers. com. 2011)) were not recommended in addition of these 6 indicators above cited because according to SE's opinion, more or less 50-100 congeners can possibly be analysed in non biological samples if the most sophisticated techniques available are used, but SE was of the opinion that even if 25 congeners or more could be analysed and quantified, it would just add uncertainty if all of these congeners were added to form the basis for an EQS. Therefore, other congeners such as BDE-196 and BDE-197 could be monitored but they would not be detected by most laboratories in a majority of samples. Finally, if these were found one would still not know how to interpret the result in terms of effects/risks.

1 CHEMICAL IDENTITY

Common name	Pentabromodiphenylether
Chemical name (IUPAC)	Diphenyl ether, pentabromo derivative
Synonym(s)	Pentabrominated bi(di)phenyl ethers Pentabrominated bi(di)phenyl oxides Pentabrominated phenoxybenzene Benzene, 1,1' oxybis-, pentabromo derivative PentaBDE
Chemical class (when available/relevant)	Polybrominated diphenyl ethers
CAS number	32534-81-9
EC number	251-084-2
Molecular formula	$C_{12}H_5Br_5O$
Molecular structure	 (example structure of a pentaBDE congener)
Molecular weight ($g.mol^{-1}$)	564.7 [3]

Common name	Octabromodiphenyl ethers
Chemical name (IUPAC)	Diphenyl ether, octabromo derivative
Synonym(s)	Octabrominated bi(di)phenyl ethers Octabrominated bi(di)phenyl oxides Octabrominated phenoxybenzene Benzene, 1,1' oxybis-, octabromo derivative OctaBDE
Chemical class (when available/relevant)	Polybrominated diphenyl ethers
CAS number	32536-52-0
EU number	251-087-9
Molecular formula	$C_{12}H_2Br_8O$
Molecular structure	 (example structure of an octaBDE congener)

[3] Penta brominated compounds

Molecular weight ($g.mol^{-1}$)	801.38[4]

[4] Octa brominated compounds

Nomenclature of all 209 BDE congeners.

Congener type	No.	Br sites
Mono-BDE	1	2
	2	3
	3	4
Di-BDE	4	2,2’
	5	2,3
	6	2,3’
	7	2,4
	8	2,4’
	9	2,5
	10	2,6
	11	3,3’
	12	3,4
	13	3,4’
	14	3,5
	15	4,4’
Tri-BDE	16	2,2’,3
	17	2,2’,4
	18	2,2’,5
	19	2,2’,6
	20	2,3,3’
	21	2,3,4
	22	2,3,4’
	23	2,3,5
	24	2,3,6
	25	2,3’,4
	26	2,3’,5
	27	2,3’,6
	28	2,4,4’
	29	2,4,5
	30	2,4,6
	31	2,4’,5
	32	2,4’,6
	33	2,3’,4’
	34	2,3’,5’
	35	3,3’,4
	36	3,3’,5
	37	3,4,4’
	38	3,4,5
	39	3,4’,5

Congener type	No.	Br sites
Tetra-BDE	40	2,2’,3,3’
	41	2,2’,3,4
	42	2,2’,3,4’
	43	2,2’,3,5
	44	2,2’,3,5’
	45	2,2’,3,6
	46	2,2’,3,6’
	47	2,2’,4,4’
	48	2,2’,4,5
	49	2,2’,4,5’
	50	2,2’,4,6
	51	2,2’,4,6’
	52	2,2’,5,5’
	53	2,2’,5,6’
	54	2,2’,6,6’
	55	2,3,3’,4
	56	2,3,3’,4’
	57	2,3,3’,5
	58	2,3,3’,5’
	59	2,3,3’,6
	60	2,3,4,4’
	61	2,3,4,5
	62	2,3,4,6
	63	2,3,4’,5
	64	2,3,4’,6
	65	2,3,5,6
	66	2,3’,4,4’
	67	2,3’,4,5
	68	2,3’,4,5’
	69	2,3’,4,6
	70	2,3’,4’,5
	71	2,3’,4’,6
	72	2,3’,5,5’
	73	2,3’,5’,6
	74	2,4,4’,5
	75	2,4,4’,6
	76	2,3’,4’,5’
	77	3,3’,4,4’
	78	3,3’,4,5
	79	3,3’,4,5’
	80	3,3’,5,5’
	81	3,4,4’,5

Congener type	No.	Br sites
Penta-BDE	82	2,2’,3,3’,4
	83	2,2’,3,3’,5
	84	2,2’,3,3’,6
	85	2,2’,3,4,4’
	86	2,2’,3,4,5
	87	2,2’,3,4,5’
	88	2,2’,3,4,6
	89	2,2’,3,4,6’
	90	2,2’,3,4’,5
	91	2,2’,3,4’,6
	92	2,2’,3,5,5’
	93	2,2’,3,5,6
	94	2,2’,3,5,6’
	95	2,2’,3,5’,6
	96	2,2’,3,6,6’
	97	2,2’,3,4’,5’
	98	2,2’,3,4’,6’
	99	2,2’,4,4’,5
	100	2,2’,4,4’,6
	101	2,2’,4,5,5’
	102	2,2’,4,5,6’
	103	2,2’,4,5’,6
	104	2,2’,4,6,6’
	105	2,3,3’,4,4’
	106	2,3,3’,4,5
	107	2,3,3’,4’,5
	108	2,3,3’,4,5’
	109	2,3,3’,4,6
	110	2,3,3’,4’,6
	111	2,3,3’,5,5’
	112	2,3,3’,5,6
	113	2,3,3’,5’,6
	114	2,3,4,4’,5
	115	2,3,4,4’,6
	116	2,3,4,5,6
	117	2,3,4’,5,6
	118	2,3’,4,4’,5
	119	2,3’,4,4’,6
	120	2,3’,4,4’,5
	121	2,3’,4,5’,6
	122	2,3,3’,4’,5’
	123	2,3’,4,4’,5’
	124	2,3’,4’,5,5’
	125	2,3’,4’,5’,6
	126	3,3’,4,4’,5
	127	3,3’,4,5,5’

Congener type	No.	Br sites
Hexa-BDE	129	2,2’,3,3’,4,5
	130	2,2’,3,3’,4,5’
	131	2,2’,3,3’,4,6
	132	2,2’,3,3’,4,6’
	133	2,2’,3,3’,5,5’
	134	2,2’,3,3’,5,6
	135	2,2’,3,3’,5,6’
	136	2,2’,3,3’,6,6’
	137	2,2’,3,4,4’,5
	138	2,2’,3,4,4’,5’
	139	2,2’,3,4,4’,6
	140	2,2’,3,4,4’,6’
	141	2,2’,3,4,5,5’
	142	2,2’,3,4,5,6
	143	2,2’,3,4,5,6’
	144	2,2’,3,4,5’,6
	145	2,2’,3,4,6,6’
	146	2,2’,3,4’,5,5’
	147	2,2’,3,4’,5,6
	148	2,2’,3,4’,5,6’
	149	2,2’,3,4’,5’,6’
	150	2,2’,3,4’,6,6’
	151	2,2’,3,5,5’,6
	152	2,2’,3,5,6,6’
	153	2,2’,4,4’,5,5’
	154	2,2’,4,4’,5,6’
	155	2,2’,4,4’,6,6’
	156	2,3,3’,4,4’,5
	157	2,3,3’,4,4’,5’
	158	2,3,3’,4,4’,6
	159	2,3,3’,4,5,5’
	160	2,3,3’,4,5,6
	161	2,3,3’,4,5’,6
	162	2,3,3’,4’,5,5’
	163	2,3,3’,4’,5,6
	164	2,3,3’,4,5’,6
	165	2,3,3’,5,5’,6
	166	2,3,4,4’,5,6
	167	2,3’4,4’,5,5’
	168	2,3’,4,4’,5’,6
	169	3,3’,4,4’,5,5’

Congener type	No.	Br sites
Hepta-BDE	170	2,2’,3,3’,4,4’,5
	171	2,2’,3,3’,4,4’,6
	172	2,2’,3,3’,4,5,5’
	173	2,2’,3,3’,4,5,6
	174	2,2’,3,3’,4,5,6’
	175	2,2’,3,3’,4,5’,6
	176	2,2’,3,3’,4,6,6’
	177	2,2’,3,3’,4,5’,6’
	178	2,2’,3,3’,5,5’,6
	179	2,2’,3,3’,5,6,6’
	180	2,2’,3,4,4’,5,5’
	181	2,2’,3,4,4’,5,6
	182	2,2’,3,4,4’,5,6’
	183	2,2’,3,4,4’,5’,6
	184	2,2’,3,4,4’,6,6’
	185	2,2’,3,3’,5,5’6
	186	2,2’,3,4,5,6,6’
	187	2,2’,3,4’,5,5’,6
	188	2,2’,3,4’,5,6,6’
	189	2,3,3’,4,4’,5,5’
	190	2,3,3’,4,4’,5,6
	191	2,3,3’,4,4’,5’,6
	192	2,3,3’,4,5,5’,6
	193	2,3,3’,4’,5,5’,6
Octa-BDE	194	2,2’,3,3’,4,4’,5,5’
	196	2,2’,3,3’,4,4’,5,6’
	197	2,2’,3,3’,4,4’,6,6’
	198	2,2’,3,3’,4,5,5’,6
	199	2,2’,3,3’,4,5,5’,6’
	200	2,2’,3,3’,4,5,6,6’
	201	2,2’,3,3’,4,5’,6,6’
	202	2,2’,3,3’,5,5’,6,6’
	203	2,2’,3,4,4’,5,5’,6
	204	2,2’,3,4,4’,5,6,6’
	205	2,3,3’,4,4’,5,5’,6
Nona-BDE	206	2,2’,3,3’,4,4’,5,5’,6
	207	2,2’,3,3’,4,4’,5,6,6’
	208	2,2’,3,3’,4,5,5’,6,6’
Deca-BDE	209	2,2’,3,3’,4,4’,5,5’,6,6’

2 EXISTING EVALUATIONS AND REGULATORY INFORMATION

Legislation	OctaBDE	PentaBDE
Annex III EQS Dir. (2008/105/EC)	Not Included	Not Included
Existing Substances Reg. (793/93/EC)	Priority List No 1 EU-RAR finalised (E.C., 2003)	Priority List No 2 EU-RAR finalised (E.C., 2001)
Pesticides(91/414/EEC)	No	No
Biocides (98/8/EC)	No	No
PBT substances	Not investigated under Dir. 67/548/EEC and Reg. 793/93/EC	Not investigated under Dir. 67/548/EEC and Reg. 793/93/EC
Substances of Very High Concern (1907/2006/EC)	Not listed as such – October 2010	Not listed as such – October 2010
POPs (Stockholm convention)	Not the octa derivative per se	Yes Included in Annex A
Protocol of the 1979 Convention on LRATP[5] on POPs	Not the octa derivative per se	Yes
Other relevant chemical regulation (veterinary products, medicament, ...)	Dir. 2002/95/EC and Reg. 552/2009/EC	Dir. 2002/95/EC and Reg. 552/2009/EC
Endocrine disrupter Groshart and Okkerman, 2000 Petersen *et al.*, 2007	Category 2 for human life for the 3 compounds, as well as the 2,2',4,4'-tetraBDE. Category 2 means "*Potential for endocrine disruption. In vitro data indicating potential for endocrine disruption in intact organisms. Also includes effects in-vivo that may, or may not, be ED-mediated. May include structural analyses and metabolic considerations*"	

[5] LRTAP: Long-Range Transboundary Air Pollution

3 PROPOSED QUALITY STANDARDS (QS)

3.1 ENVIRONMENTAL QUALITY STANDARD (EQS)

$QS_{biota,\ hh}$ for protection of human health from consumption of fishery products is 0.016 $\mu g.kg^{-1}{}_{biota\ ww}$ and is deemed the “critical QS” for derivation of an Environmental Quality Standard for the sum of polybrominated diphenyl ethers.

$QS_{biota,\ hh}$ is based on mice dietary toxicity studies (Branchi et al., 2002; Branchi et al., 2005) consisting in exposure to BDE-99 during gestational and 21 post-natal days. A $BMDL_{10}$ of 9 $\mu g.kg^{-1}{}_{bw}$ was derived, to which an internal daily dose of 4.2 $ng.kg^{-1}{}_{bw}.d^{-1}$ can be associated and an assessment factor of 30 is applied, given that toxico-dynamics differences between experimental animals and humans are already taken on board by the back calculation from $BMDL_{10}$ to the daily dose. Therefore, the threshold level is deemed reliable.

Conversion from EQS in biota to an equivalent concentration into water should be considered with caution, since the BCF and BMF chosen for the conversion have been derived from data on individual compounds.

	Value	Comments
Proposed AA-EQS for [biota] [$\mu g.kg^{-1}{}_{biota\ ww}$]	**$8.5\ 10^{-3}$**	**Critical QS is $QS_{biota,\ hh}$**
Corresponding AA-EQS for [freshwater] [$\mu g.l^{-1}$]	$4.9\ 10^{-8}$	**See section 7**
Corresponding AA-EQS in [marine water] [$\mu g.l^{-1}$]	$2.4\ 10^{-9}$	
Proposed MAC-EQS for [freshwater] [$\mu g.l^{-1}$]	**0.14**	**See section 7.1**
Proposed MAC-EQS for [marine water] [$\mu g.l^{-1}$]	**0.014**	

3.2 SPECIFIC QUALITY STANDARD (QS)

Protection objective[6]	Unit	Value	Comments
Pelagic community (freshwater)	[$\mu g.l^{-1}$]	0.049	See section 7.1
Pelagic community (marine water)	[$\mu g.l^{-1}$]	0.0049	
Benthic community (freshwater)	[$\mu g.kg^{-1}{}_{dw}$]	1 550	See section 7.1
	[$\mu g.l^{-1}$]	$2.1\ 10^{-5}$ – 0.433	
Benthic community (marine)	[$\mu g.kg^{-1}{}_{dw}$]	310	
	[$\mu g.l^{-1}$]	$4.1\ 10^{-6}$ – $8.6.10^{-2}$	
Predators (secondary poisoning)	[$\mu g.kg^{-1}{}_{biota\ ww}$]	44	See section 7.2
	[$\mu g.l^{-1}$]	$2.5\ 10^{-4}$ (freshwater) $1.3\ 10^{-5}$ (marine waters)	
Human health via consumption of fishery products	[$\mu g.kg^{-1}{}_{biota\ ww}$]	$8.5.10^{-3}$	See section 7.3
	[$\mu g.l^{-1}$]	$4.9\ 10^{-8}$ (freshwater)	

[6] 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.

		$2.4\ 10^{-9}$ (marine waters)	
Human health via consumption of water	[µg.l^{-1}]	$0.49.10^{-3}$	

4 MAJOR USES AND ENVIRONMENTAL EMISSIONS

4.1 RESTRICTIONS

PolyBDE, including pentaBDE and octaBDE, are mainly used as flame retardants. The use of pentaBDE and octaBDE is however restricted within the EU since August 15, 2004 (Commission regulation (EC) No 552/2009). PentaBDE and OctaBDE are not allowed to be placed on the market as substances, in mixtures or in articles in higher concentration than 0.1 % by weight.

Furthermore, use of polyBDEs in electrical and electronic products (E&Es) was restricted even earlier by the Directive 2002/95/EC (RoHS). From June 30, 2008, this directive covers also DecaBDE (Designation of the Chamber responsible for cases of the kind referred to in Article 104b of the Rules of Procedure of the Court of Justice 2008/C 116/02). This implies that the only permitted use of PBDEs in Europe is now the application of decaBDE in products other than E&Es. As a result of this new regulation, the majority of the previous use of decaBDE in the EU is now prohibited (corresponding to ca 80 percent of the total EU use in 2001). It is, however, still possible for industries to apply for exemptions for certain applications under the procedure laid out in article 5 of the RoHS Directive.

4.2 USES AND QUANTITIES

Stocks of products and articles flame retarded with polyBDE in higher concentrations than what is now permitted may however still exist in society due to their long service life. The products that are flame retarded with commercial polyBDE are often consumer available, such as TV-sets and computer housings, and thus common in homes and offices (La Guardia *et al.*, 2006; WHO, 1994).

PolyBDE are flame retardants of the additive type, which means that they are physically combined with the material being treated rather than chemically combined (as in reactive flame retardants). Hence, there is the possibility that the flame retardant may diffuse out of the treated material to some extent (E.C., 2001; E.C., 2003).

OctaBDE was primarily used in acrylonitrile-butadiene-styrene (ABS) polymers (95 % of total EU use, at the time when the risk assessment report was written, E.C., 2003). In the final product, the content of octaBDE is 12-18 % by weight. Other uses are in high impact polystyrene (HIPS), polybutylene terephthalate (PBT), polyamide polymers, nylon, low density polyethylene polycarbonate, phenol-formaldehyde resins, unsaturated polyesters and in adhesives and coatings (E.C., 2003; OECD, 1994; WHO, 1994).

The major use of pentaBDPE was in flexible polyurethane foam for furniture and upholstery. Four main uses of polyurethane containing pentaBDPE have been identified in the EU. Around 95% was use in the manufacture of flexible polyurethane foams. These were used: a) in foam-based laminated automotive applications such as headrests; b) for domestic furniture, some of which includes cot mattresses ; and c) in foam-based packaging (E.C., 2001).

Information provided by industry indicates that there has been a decline in the import and hence usage of polyBDE in the EU in recent years.

PentaBDE is now included in Annex A (Elimination) to the Stockholm Convention and should not longer be on the EU market (UNEP, 2009b) as well as hexaBDE and heptaBDE contained in c-octaBDE (UNEP, 2009a).

4.3 ESTIMATED ENVIRONMENTAL EMISSIONS

Commercial pentaBDEs and octaBDEs are no longer produced within the EU (UNEP, 2006; UNEP, 2007), which means that there are no industrial point sources.

Stocks of flame retarded products may however reside in society and as pentaBDE and octaBDE are physically combined with the material and not chemically bound there is a possibility of release from the material via diffusion. These emissions would thus occur mainly indoors and might enter the environment either *via* the ventilation streams or *via* the wastewater. Also after disposal there is a risk of environmental release of octaBDE from flame retarded products (E.C., 2001; E.C., 2003)

The estimated releases of penta- and octaBDE into the environment are summarised in the tables below.

Estimated releases of pentaBDE into the environment (E.C., 2001)

		Estimated releases (tonnes/year)			
Source	**Receptor compartment**	**Local scale (kg/d)**	**Regional scale [a]**	**In the EU**	**Continental scale [b]**
Polyurethane foam manufacture	To waste water	0.15	0.045	0.18	0.135
	To air	0.124	0.037	0.15	0.113
Polyurethane foam use	To air	-	4.3	43	38.7
Polyurethane foam "waste remaining in the environment" [c]	To surface water	-	0.53	5.26	4.73
	To air	-	0.002	0.021	0.019
	To industrial soil	-	1.59	15.86	14.27
Polyurethane foam disposal	To landfill (or incineration)	-	103.6	1.036	932.4
Total	To waste water	-	0.045	0.18	0.135
	To surface water	-	0.53	5.26	4.73
	To air	-	4.3	43.2	38.7
	To industrial soil	-	1.59	15.86	14.27
	To landfill (or incineration)	-	103.6	1.036	932.4

a) The regional model is based on 10% of the total EU activity. However, for polyurethane foam manufacture the release at I single site accounts for more than 10% to the total release and so the region is assumed to contain this site as a worst case approach; b) Continental release = total EU release minus regional release; c) Release estimates for particulate matter containing pentaBDPE; d) In the EUSES modelling, a 70% connection rate to the waste water treatment plant is assumed.

Estimated releases of octaBDE into the environment (E.C., 2003)

		Estimated releases (tonnes/year)					
Use	**Receptor compartment**	**Local scale***		**Regional scale***		**Continental scale***	
		1994	1999	1994	1999	1994	1999
Polymers: handling of raw materials	To landfill / incineration (as dust)	0.08	0.024	0.54	0.095	4.86	0.85
Polymers: compounding and conversion	To air	0.0191	0.0057	0.128	0.023	1.15	0.203
	To waste water	0.0191	0.0057	0.128 [a)]	0.023 [a)]	1.15 [a)]	0.203
Polymers: service life	To air as vapour	-	-	1.38	0.729	12.4	6.56
Polymers: "waste remaining in the environment" (service life and disposal)	To industrial / urban soil	-	-	4.18	2.02	37.6	18.18
	To air	-	-	0.006	0.0027	0.050	0.024
	To surface water	-	-	1.39	0.669	12.5	6.02
Polymers: disposal	To landfill / incineration	-	-	248	132	2 232	1 184
Maximum total emission figure for regional and continental modelling	To air	-	-	1.51	0.755	13.60	6.79
	To waste water via WWTP	-	-	0.090	0.016	0.805	0.142
	Direct to surface water	-	-	1.43	0.676	12.85	6.08
	To industrial / urban soil	-	-	4.18	2.02	37.6	18.18
	To landfill / incineration	-	-	249	132	2 237	1 185

* Local scale = at a site scale; Release in continental model = total release in EU – estimated release in regional model
a) In the regional and continental model a 70% connection rate to the wastewater treatment plant is assumed. Therefore, 30% of these releases are taken as going direct to surface water.

Although estimated releases into the environment have substantially decreased between 1994 and 1999, it is worth noting that a Dutch study has demonstrated that the content of flame retardants in Dutch breast milk did not decline between 1998 and 2003, which is an evidence of the persistence and accumulation of this substance in the environment and which allow warning that decrease of releases does not necessarily means decrease of the concentrations in the environmental media (de Winter-Sorkina *et al.*, 2006).

5 ENVIRONMENTAL BEHAVIOUR

5.1 ENVIRONMENTAL DISTRIBUTION

Given that both c-pentaBDE and c-octaBDE are mixtures containing significant amounts of other brominated diphenyl ethers, notably tetra- and hexa- congeners for c-pentaBDE and hexa-, hepta- and nona- congeners for c-octaBDE, it was deemed of relevance to report hereunder physico-chemical parameters linked to environmental distribution for all the brominated diphenyl ethers above cited. In fact, these substances present physico-chemical similarities between each others that may allow a read-across of their ecotoxicological properties.

TetraBDE		**Master reference**
Water solubility (mg.l^{-1})	0.011 (*measured*) 1.46 10^{-3} (*estimated-EPI*)	E.C., 2003
Volatilisation	**TetraBDE is not likely to volatilize from water phase**	
Vapour pressure (Pa)	2.5 10^{-4} – 3.3 10^{-4} (measured) 3.2 10^{-5} (*estimated-EPI*)	E.C., 2003
Henry's Law constant (Pa.m^3.mol^{-1})	0.86 (*estimated-EPI*) 10.6 (*estimated from vapour pressure and solubility*)	E.C., 2003
Adsorption	**TetraBDE is very likely to adsorb on particulate matter.**	
Organic carbon – water partition coefficient (K_{OC})	K_{OC}= 565 860 (*measured*) K_{OC}= 71 560–122 900; 383 440 (*estimated from K_{OW}*)	E.C., 2003
Sediment – water partition coefficient ($K_{sed\ -water}$)	14 147 (*calculated from K_{OC} = 565 860*)	E.C., 2011
Hydrophobicity	**TetraBDE is a hydrophobic substance**	
Octanol-water partition coefficient (Log Kow)	5.87 – 6.16 (*measured*) 6.77 (*estimated-EPI*)	E.C., 2003
Bioaccumulation – biomagnification	cf. dedicated section 5.3	

PentaBDE		**Master reference**
Water solubility (mg.l^{-1})	13.3 10^{-3} (commercial, *measured*) 2.4 10^{-3} (*measured* for congener 2,2',4,4',5) 0.079 (*estimated-EPI*)	E.C., 2001
Volatilisation	**PentaBDE is not likely to volatilize from water phase**	
Vapour pressure (Pa)	4.69 10^{-5} (commercial, *measured*) 2.9 10^{-5} – 7.3 10^{-5} (*measured*) 3.3 10^{-6} (*estimated-EPI*)	E.C., 2001
Henry's Law constant (Pa.m^3.mol^{-1})	0.36 (*measured*) 2 (commercial, *estimated from vapour pressure and solubility*) 0.78 – 522 (*estimated from vapour pressure and solubility*)	E.C., 2001
Adsorption	**PentaBDE is very likely to adsorb on particulate matter.**	
Organic carbon – water partition coefficient (K_{OC})	983 340 (*measured*) 215 080 – 556 801; 2 10^6 (*estimated from K_{OW}*) 264 060 (commercial, *estimated from K_{OW}*)	E.C., 2001
Sediment – water partition coefficient ($K_{sed\text{-}water}$)	5 378 – 13 921 (*calculated from measured K_{OC}*)	E.C., 2011
Hydrophobicity	**PentaBDE is a hydrophobic substance**	
Octanol-water partition coefficient (Log Kow)	6.57 (commercial, *measured*) 6.46 – 6.97 (*measured*) 7.66 (*estimated-EPI*)	E.C., 2001
Bioaccumulation – biomagnification	cf. dedicated section 5.3	

HexaBDE		**Master reference**
Water solubility (mg.l^{-1})	4.2 10^{-6} (estimated-EPI)	E.C., 2003
Volatilisation	**HexaBDE is not likely to volatilize from water phase**	
Vapour pressure (Pa)	4.3 10^{-6} – 9.5 10^{-6} (measured) 3.8 10^{-7} (estimated-EPI)	E.C., 2003
Henry's Law constant (Pa.m^3.mol^{-1})	0.15 (*estimated-EPI*) 58.2; 659 – 1 456 (*estimated from vapour pressure and water solubility*)	E.C., 2003
Adsorption	**HexaBDE is very likely to adsorb on particulate matter**	
Organic carbon – water partition coefficient (K_{OC})	1 250 000 (*measured*) 453 520 – 3 270 000; 10 600 000 (*estimated from K_{OW}*)	E.C., 2003
	measured / *estimated* 2,2',4,4',5,5'-: 1 740 000 / 49 000 000 2,2',4,4',5,6'-: 2 690 000 / 40 700 000	Guan *et al.*, 2009
Sediment – water partition coefficient ($K_{sed\text{-}water}$)	31 251 (*calculated from measured K_{OC}*)	E.C., 2011
Hydrophobicity	**HexaBDE is a hydrophobic substance**	

Octanol-water partition coefficient (Log Kow)	6.86 – 7.92 (*measured*) 8.55 (*estimated-EPI*)	E.C., 2003
Bioaccumulation – biomagnification	cf. dedicated section 5.3	

HeptaBDE		**Master reference**
Water solubility (mg.l^{-1})	2.2 10^{-7} (*estimated-EPI*)	E.C., 2003
Volatilisation	**HeptaBDE is not likely to volatilize from water phase**	
Vapour pressure (Pa)	4.4 10^{-8} (estimated-EPI)	E.C., 2003
Henry's Law constant (Pa.m^3.mol^{-1})	0.06 (*estimated-EPI*) 144 (*estimated from vapour pressure and solubility*)	E.C., 2003
Adsorption	**HeptaBDE is very likely to adsorb on particulate matter**	
Organic carbon – water partition coefficient (K_{OC})	55 800 000 (*estimated from K_{OW}*)	E.C., 2003
	measured *estimated* 2,2',3,4,4',5',6-: 1 480 000 115 000 000	Guan *et al.*, 2009
Sediment – water partition coefficient ($K_{sed\ -water}$)	1 395 001 (*calculated from estimated K_{OC}*)	E.C., 2011
Hydrophobicity	**HeptaBDE is a very hydrophobic substance**	
Octanol-water partition coefficient (Log Kow)	9.44 (*estimated-EPI*)	E.C., 2003
Bioaccumulation – biomagnification	cf. dedicated section 5.3	

OctaBDE		**Master reference**
Water solubility (mg.l^{-1})	5 10^{-4} (commercial, *measured*) 1.1 10^{-8} (*estimated-EPI*)	E.C., 2003
Volatilisation	**OctaBDE is not likely to volatilize from water phase**	
Vapour pressure (Pa)	6.59 10^{-6} at 21°C (commercial, *measured*) 1.2 10^{-7} – 2.3 10^{-7} (measured) 4.9 10^{-9} (*estimated-EPI*)	E.C., 2003
Henry's Law constant (Pa.m^3.mol^{-1})	0.03 (*measured*) 7.9 10^{-3} – 16 756 (*estimated from vapour pressure and solubility*) 10.6 (commercial, *estimated from vapour pressure and solubility*)	E.C., 2003
Adsorption	**OctaBDE is very likely to adsorb on particulate matter.**	
Organic carbon – water partition coefficient (K_{OC})	1 363 040 (*extrapolated from measurements with other brominated diphenyl ethers*) 7.3 10^6 – 2.93 10^8 (*estimated from K_{OW}*) 156 640 (commercial, *estimated from K_{OW}*)	E.C., 2003
Sediment – water partition coefficient ($K_{sed\ -water}$)	34 077 (*calculated from extrapolated K_{OC}*)	E.C., 2011
Hydrophobicity	**OctaBDE is a very hydrophobic substance**	
Octanol-water partition coefficient (Log Kow)	6.29 (commercial, *measured*) 8.35 – 8.9 (*measured*) 10.33 (*estimated-EPI*)	E.C., 2003
Bioaccumulation – biomagnification	cf. dedicated section 5.3	

NonaBDE		Master reference
Water solubility ($mg.l^{-1}$)	5.6 10^{-10} (*estimated-EPI*)	E.C., 2003
Volatilisation	**NonaBDE is not likely to volatilize from water phase**	
Vapour pressure (Pa)	5.4 10^{-10} (estimated-EPI)	E.C., 2003
Henry's Law constant ($Pa.m^3.mol^{-1}$)	0.01 (*estimated-EPI*) 849 (*estimated from vapour pressure and solubility*)	E.C., 2003
Adsorption	**NonaBDE is very likely to adsorb on particulate matter**	
Organic carbon – water partition coefficient (K_{OC})	1.54 10^9 (*estimated from K_{OW}*)	E.C., 2003
Sediment – water partition coefficient ($K_{sed-water}$)	38 500 001 (*calculated from estimated K_{OC}*)	E.C., 2011
Hydrophobicity	**NonaBDE is a very hydrophobic substance**	
Octanol-water partition coefficient (Log Kow)	11.22 (*estimated-EPI*)	E.C., 2003
Bioaccumulation – biomagnification	cf. dedicated section 5.3	

5.2 ABIOTIC AND BIOTIC DEGRADATIONS

		Master reference
Hydrolysis	No information is currently available on the hydrolytic degradation of pentaBDE and octaBDE in aqueous solution. It is thought that these compounds will be hydrolytically stable under conditions found in the environment.	E.C., 2001 E.C., 2003
Photolysis	From the available information it is clear that polybrominated diphenyl ethers have the potential to photodegrade in the environment. In water, and at environmentally relevant wavelengths, the most likely initial reaction products from these reactions are hydroxylated diphenyl ethers, which possibly then react further. The first step in the reaction is probably cleavage of a C-Br following the absorption of radiation, followed by reaction of the radical intermediate (radical cation intermediates species may be formed in water) with oxygen and/or water to give substituted (e.g. hydroxylated) products (Larson and Weber, 1994; Mill and Mabey, 1985). The formation of lower brominated diphenyl ethers during direct photolysis in the environment would require the presence of H-atom donors at concentrations sufficiently high to compete with other oxidants for the aromatic radical intermediate formed. It is not possible to say anything about the significance or rates of these reactions for polybrominated diphenyl ethers in the environment.	E.C., 2001 E.C., 2003
	$DT_{50\ -\ pentaBDE-99}$ ≈12,6 d (estimated from Syracuse Research Corporation AOP estimation program).	E.C., 2001
	In a mixture of methanol (80%) and water (20%) photolysis half-lives are: $DT_{50\ -\ tetraBDE}$ = 12 – 16 d $DT_{50\ -\ heptaBDE}$ = 1.2 d $DT_{50\ -\ pentaBDE}$ = 2.4 d $DT_{50\ -\ octaBDE-203}$ = 5h $DT_{50\ -\ hexaBDE}$ = 1.2 d	Eriksson *et al.*, 2001a *quoted in* E.C., 2003
	HexaBDE-153 is rapidly photohydrodebrominated in aquatic systems to some of the most prevalent penta- and tetra-BDE typically observed in environmental matrices	Rayne *et al.*, 2006
Biodegradation	PentaBDE has been considered as Persistent in the framework of the POP Convention	E.C., 2001
	PentaBDE is not readily biodegradable according to a standard OECD test	UNEP, 2006

	with aerobic activated sludge. Biotic degradation of pentabromodiphenyl ether in sediment and water have not been reported in experimental studies but the half-lives for pentaBDE-99 and tetraBDE-47 have been estimated at 600 days (aerobic sediment) and 150 days (water) for both congeners.	

In an experimental study, carps were fed with food spiked with individual BDE congeners for 62 days, and tissue and excreta were examined. Around 10% of pentaBDE-99 and 17% of heptaBDE-183 were reductively debrominated in the gut to lower brominated congeners, tetraBDE-47 and hexaBDE congeners, respectively, showing evidence of debromination into congener with one less bromine atom. Therefore, the authors showed that body burdens of BDE congeners in aquatic organisms may reflect direct uptake from exposure as well as debromination of more highly brominated congeners (Stapleton *et al.*, 2004).

In another study (Munschy *et al.*, 2011), accumulation and biotransformation of BDEs in fish (*Solea solea*) was observed. They showed that contamination efficiencies were related to their hydrophobicity potential and influenced biotransformation. Biotransformation was shown to be driven mostly by debromination process rather than biotransformation in hydroxylated metabolites.

Overall, several studies have been lead on diverse degradation processes which lead to debromination of BDE congeners. It is now considered that all highly brominated congener will end as low brominated congeners in environmental matrices (pers. comm., POP Review Committee, 2010).

5.3 BIOACCUMULATION AND BIOMAGNIFICATION POTENTIAL

Congeners	BCF fish	Master reference
tetraBDE	28 800 – 35 100 (*measured*) 19 480 – 37 090; 46 050 (*estimated from log* K_{OW})	E.C., 2003
pentaBDE	44 550 (commercial, *estimated from log* K_{OW}) 1 440; 17 700 (*measured*) 34 141; 43 061 – 45 880 (*estimated from log* K_{OW})	E.C., 2001
hexaBDE	5 640 (*measured*) 46 180 – 27 260; 12 200 (*estimated from log* K_{OW})	E.C., 2003
	up to 2 580 and 5 640 depending on the congener	CITI, 1982 *quoted in* UNEP, 2007
heptaBDE	2 100 (*estimated from log* K_{OW})	E.C., 2003
octaBDE	39 980 (commercial, *estimated from log* K_{OW}) 6 670 – 16 390; 175 (*estimated from log* K_{OW})	E.C., 2003
	Experimental results indicate that octaBDE does not bioconcentrate. A single study on a mixed commercial octabromodiphenyl ether product indicated essentially no bioaccumulation in carp (Cyprinus carpio) (CBC, 1982 cited in E.C., 2003). Assuming that the actual concentration of octabromodiphenyl ether in the water was around 0.5 µg/l, BCFs would be of the order of <10-36 l/kg. Bioconcentration is however considered relevant for hexaBDE, which is included in the commercial octaBDE product (see BCF values for hexaBDE congeners in the corresponding table above.	E.C., 2003
nonaBDE	7 (*estimated from log* K_{OW})	E.C., 2003

Congeners	BAF	Master reference
triBDE	Freshwater food web (South-China reservoir surrounded by several e-waste recycling workshops) including invertebrates (1 snail and 1 prawn species), fish (3 carp species) and snakes (2 species): BDE-28: BAF_{snail} = 794	Wu *et al.*, 2008

	Lake trouts from Lake Michigan[7] BDE-47: BAF_{trout} = 19.9 10^6	Streets *et al.*, 2006
tetraBDE	No available information	
pentaBDE	Lake trouts from Lake Michigan[7] BDE-99: BAF_{trout} = 5 10^6 BDE-100: BAF_{trout} = 31.6 10^6	Streets *et al.*, 2006
hexaBDE	See details above for TriBDE-28. BDE-154: BAF_{snail} = 199 526	Wu *et al.*, 2008

[7] In their study, Streets et al. (2006) report very high values of BAF compared to the other study reported above (Wu *et al.*, 2008). This may be partly explained by the large differences in exposure scenarios. In fact, water concentrations reported in Streets et al. (2006) are ca. 1 000 times lower compared to water concentrations reported by Wu et al. (2008) or 3 times lower to Law et al. (2006), while concentrations in lake trout in Lake Michigan (Streets *et al.*, 2006) are higher compared to data fish concentrations from Lake Geneva (Cheaib *et al.*, 2009, cf. section 6.2). Furthermore, Lake trout has very high lipid content (approx. 15%) and is a high trophic level species which could also partly explain the high values of BAF.

Congeners	Biomagnification parameters	Master reference
TMF values		
triBDE	Marine food web including invertebrates (5 species), fish (9 species) and seabirds (2 species): BDE-28: TMF = 1.47 (invertebrates and fish) BDE-28: TMF = 3.2 (seabirds)	Zhang *et al.*, 2010
	Freshwater food web (reservoir surrounded by several e-waste recycling workshops) including invertebrates (1 snail and 1 prawn species), fish (3 carp species) and snakes (2 species): BDE-28: TMF = 1.64	Wu *et al.*, 2009
tetraBDE	BDE-47: TMF = 1.6 (significantly ≠ from 1) BDE-49: TMF = 1.2 BDE-66: TMF = 0.44 (significantly ≠ from 1)	Kelly *et al.*, 2008
	Marine food web including invertebrates (5 species), fish (9 species) and seabirds (2 species): BDE-47: TMF = 3.91 (invertebrates and fish) BDE-47: TMF = 19.54 (seabirds)	Zhang *et al.*, 2010
	Freshwater food web (reservoir surrounded by several e-waste recycling workshops) including invertebrates (1 snail and 1 prawn species), fish (3 carp species) and snakes (2 species): BDE-47: TMF = 2.28	Wu *et al.*, 2009
	Freshwater food web including phytoplankton, zooplankton, mussels and fish (6 species): BDE-47: TMF = 1.5	Law *et al.*, 2006
pentaBDE	Trophic magnification factors not significantly different from 1 in an Arctic marine food web BDE-99: TMF = 0.76 BDE-100: TMF = 0.96	Kelly *et al.*, 2008
	Marine food web including invertebrates (5 species), fish (9 species) and seabirds (2 species): BDE-99: TMF = 3.21 (invertebrates and fish) BDE-99: TMF = 84.72 (seabirds) BDE-100: TMF = 3.71 (invertebrates and fish) BDE-100: TMF = 51.76 (seabirds)	Zhang *et al.*, 2010
	Freshwater food web (reservoir surrounded by several e-waste recycling workshops) including invertebrates (1 snail and 1 prawn species), fish (3 carp species) and snakes (2 species): BDE-99: TMF = 0.53 BDE-100: TMF = 2.64	Wu *et al.*, 2009
	Freshwater food web including phytoplankton, zooplankton, mussels and fish (6 species): BDE-99: TMF = 0.7 BDE-100: TMF = 1.6	Law *et al.*, 2006
hexaBDE	Trophic magnification factors not significantly different from 1 in an Arctic marine food web BDE-153: TMF = 0.59 BDE-154: TMF = 0.46	Kelly *et al.*, 2008
	Marine food web including invertebrates (5 species), fish (9 species) and seabirds (2 species): BDE-153: TMF = 1.36 (invertebrates and fish) BDE-153: TMF = 97.05 (seabirds) BDE-154: TMF = 2.77 (invertebrates and fish) BDE-154: TMF = 23.77 (seabirds)	Zhang *et al.*, 2010
	Freshwater food web (reservoir surrounded by several e-waste recycling workshops) including invertebrates (1 snail and 1 prawn species), fish (3 carp species) and snakes (2 species):	Wu *et al.*, 2009

Congeners	Biomagnification parameters	Master reference
TMF values		
	BDE-153: TMF = 0.81 BDE-154: TMF = 2.25	
heptaBDE	Marine food web including invertebrates (5 species), fish (9 species) and seabirds (2 species): BDE-183: TMF = 0.53 (invertebrates and fish) BDE-183: TMF = 13.68 (seabirds)	Zhang *et al.*, 2010
	Freshwater food web (reservoir surrounded by several e-waste recycling workshops) including invertebrates (1 snail and 1 prawn species), fish (3 carp species) and snakes (2 species): BDE-183: TMF = 0.81	Wu *et al.*, 2009
octaBDE	No data available	
nonaBDE	No data available	
SumBDEs	Marine food web including invertebrates (5 species), fish (9 species) and seabirds (2 species): SumBDEs: TMF = 2.37 (invertebrates and fish) SumBDEs: TMF = 29.17 (seabirds)	Zhang *et al.*, 2010
	Freshwater food web (reservoir surrounded by several e-waste recycling workshops) including invertebrates (1 snail and 1 prawn species), fish (3 carp species) and snakes (2 species): SumBDEs: TMF = 1.86	Wu *et al.*, 2009

Congeners	Biomagnification parameters (continued)	Master reference
Single BMF1 values		
tetraBDE BDE-47	$BMF_{zoopk-fish}$ = 1.48 (liver) ; 2.25 (muscle) $BMF_{fish.pred-fish.prey}$ = 1.12 – 1.59 (livre) ; 1.07 – 1.17 (muscle)	Kuo *et al.*, 2010
	Range (geometric mean): $BMF_{zoopk-zoopk}$ = 10.9 (4.1 - 29.1) $BMF_{zoopk-fish}$ = 2.6 (0.4 - 10.1)	Sørmo *et al.*, 2006
pentaBDE	BAF_{fish} = 16 – 20 (Bioaccumulation factors, defined as concentration in fish / concentration in food)	Holm *et al.*, 1993 as cited *in* E.C., 2001
	BDE-99: $BMF_{zoopk-fish}$ = 0.4 (liver) ; 0.73 (muscle) BDE-99: $BMF_{fish-fish}$ = 0.88 – 0.89 (liver) ; 0.49 – 0.61 (muscle) BDE-100: $BMF_{zoopk-fish}$ = 1.45 (liver) ; 1.52 (muscle) BDE-100: $BMF_{fish-fish}$ = 1.14 – 1.41 (liver) ; 1.09 – 1.18 (muscle)	Kuo *et al.*, 2010
	Range (geometric mean): BDE-99: $BMF_{zoopk-zoopk}$ = 5.6 (0.65 - 47.6) BDE-99: $BMF_{zoopk-fish}$ = 0.9 (0.04 - 3.4) BDE-100: $BMF_{zoopk-fish}$ =0.6 (0.2 ; 1.6)	Sørmo *et al.*, 2006
hexaBDE	Biomagnification factors estimated for two hexaBDE isomers for several food chains examples, using the North Sea data: $BMF_{fish-invertebrate}$ = ~0.6 – 0.7	de Boer *et al.*, 2001 as cited *in* E.C., 2003
heptaBDE	No data available	
octaBDE	No data available	
nonaBDE	No data available	

Congeners	Biomagnification parameters (continued)	Master reference
	Single BMF2 values	
tetraBDE	$BMF_{polar\ bear – ringed\ seal}$: geometric mean of 5 locations (range) BDE-47: 3.5 (1.8 – 7.4)	Muir *et al.*, 2006
	$BMF_{harbor\ seal – fishes}$: range (geometric mean of 7 marine fish species) BDE-47: 38.1 (21.4 – 109) BDE-49: 0.4 (0.12 – 1.03) BDE-66: 0.1 (0.04 – 0.83) BDE-75: 0.3 (0.05 – 0.63)	Shaw *et al.*, 2009
	BDE-47: $BMF_{mammal - fish}$ 56 BDE-47: $BMF_{mammal - mammal}$ 0,5	Sørmo *et al.*, 2006
	Mean +/- s.d.: BDE-47: $BMF_{harbor\ seal – fish}$ = 8.4 +/- 5.7 (juveniles) ; 4.6 +-/ 2.4 (adults) BDE-47: $BMF_{harbor\ porpoise – fish}$ = 18 +/- 21(juveniles) ; 15 +/- 10 (adults)	Weijs *et al.*, 2009
pentaBDE	Geometric mean of 5 locations (range) BDE-99: $BMF_{polar\ bear – ringed\ seal}$ = 4.5 (1 – 11) BDE-100: $BMF_{polar\ bear – ringed\ seal}$ = 3.1 (0.6 – 8.8)	Muir *et al.*, 2006
	Range (geometric mean of 7 marine fish species) BDE-99: $BMF_{harbor\ seal – fishes}$ = 37.6 (17.9 – 213) BDE-100: $BMF_{harbor\ seal – fishes}$ = 10.3 (6.9 – 29.8)	Shaw *et al.*, 2009
	BDE-99: $BMF_{ringed\ seal – fish}$ = 13.7 BDE-99: $BMF_{polar\ bear – ringed\ seal}$ = 0.3 BDE-100: $BMF_{ringed\ seal – fish}$ = 26.1 BDE-100: $BMF_{polar\ bear – ringed\ seal}$ = 0.3	Sørmo *et al.*, 2006
	Mean +/- s.d.: BDE-99: $BMF_{harbor\ seal – fish}$ = 5.9 +/- 6.1 (juveniles) ; 2.9 +/- 1.2 (adults) BDE-99: $BMF_{harbor\ porpoise – fish}$ = 19 +/- 24 (juveniles) ; 33 +/- 23 (adults) BDE-100: $BMF_{harbor\ seal – fish}$ = 1.7 +/-1.1 (juveniles) ; 1.3 +/- 0.7 (adults) BDE-100: $BMF_{harbor\ porpoise – fish}$ = 13 +/- 15 (juveniles) ; 15 +/- 9.7 (adults)	Weijs *et al.*, 2009
hexaBDE	Biomagnification factors estimated for two hexaBDE isomers for several food chains examples, using the North Sea data: $BMF_{porpoise – fish}$ = 40 – 70 $BMF_{seal – fish}$ = 5 – 10	de Boer *et al.*, 2001 as cited *in* E.C., 2003
	$BMF_{polar\ bear – ringed\ seal}$: geometric mean of 4 locations (range) BDE-153: BMF= 49.6 (8.8 – 130) BDE-154: BMF= 1.0 (0.2 – 2.9)	Muir *et al.*, 2006
	$BMF_{harbor\ seal – fishes}$: range (geometric mean of 7 marine fish species) BDE-153: 367.7 (148 – 700) BDE-154: 26.4 (11.3 – 447) BDE-155: 64.0 (12.4 – 236)	Shaw *et al.*, 2009
	BDE-153: $BMF_{polar\ bear – ringed\ seal}$ = 7.5 BDE-154: $BMF_{ringed\ seal – fish}$ = 7.9 BDE-154: $BMF_{polar\ bear – ringed\ seal}$ = 0.32	Sørmo *et al.*, 2006
	Mean +/- s.d.: BDE-99: $BMF_{harbor\ seal – fish}$ = 15 +/- 13 (juveniles) ; 15 +/- 7.8 (adults) BDE-99: $BMF_{harbor\ porpoise – fish}$ = 17 +/- 21 (juveniles) ; 77 +/- 53 (adults) BDE-100: $BMF_{harbor\ seal – fish}$ = 2.2 +/-1.5 (juveniles) ; 4.8 +/- 3.6 (adults) BDE-100: $BMF_{harbor\ porpoise – fish}$ = 16 +/- 17 (juveniles) ; 50 +/- 32 (adults)	Weijs *et al.*, 2009
heptaBDE	No data available	
octaBDE	No data available	
nonaBDE	No data available	

SumBDEs	BMF value derived from Osprey egg based on measurements in egg, several fish species and their relative contribution in Osprey diet: $BMF_{fish – birds eggs}$ = 25.1	Chen *et al.*, 2010
	$BMF_{harbor seal – fishes}$ = 17.1 – 76.5	Shaw *et al.*, 2009

Overall, measured BCF values for BDE congeners range from very low values for highly brominated congeners (<5) to very high values for lower brominated congeners (up to 35 100 (measured value) for tetraBDE). Considering the fact that any highly brominated BDE congeners ends as debrominated via diverse degradation processes, the highest measured **BCF of 35 100** for tetraBDE congeners **should be retained**. This choice is consistent with the application of the worst case.

Looking at the values reported here above, the single BMF1 values are in a range below 10 for all BDE congeners. However, looking more closely at these values, it appears that maximal BMF1 values (5.6 and 10.9) are encountered only for a specific trophic interval, i.e. from zooplankton to zooplankton. The third maximal value is reported by Sormo et al. (2006) 2.6 for BMF1 from zooplankton to fish.

Thus, a value of 5 for BMF1 could be proposed, that covers almost all trophic chains among the ones reported in TMF studies, except the ones including top predators, e.g. seabirds. In line with the TGD-EQS, the food chain is defined with its trophic levels as water –BCF→ aquatic organisms –BMF1→ fish → fish-eating predator for freshwater ecosystems. It seems therefore that a **BMF1 value of 5** would be appropriate to cover biomagnification from lower trophic levels to fish species. Such a value is still a worst case, considering the high BAF values reported by Streets and his collaborators (2006) as well as the wide range of BMF values in general.

For marine ecosystems, however, another trophic level may be introduced: water –BCF→ aquatic organisms –BMF1→ fish –BMF2→ fish-eating predator → top predator. As regards BMF2, the values reported above are rather low for tetraBDE congeners other than BDE-47, but some very high values are reported for tetraBDE-47 as well as some values for pentaBDE, the highest values being reported for hexaBDE congeners. Indeed, values as high as 700 are reported by Shaw et al. (2009) for hexaBDE-153. However, on the overall, it is more frequent to encounter values between 10 and 70.TMF studies show a high degree of biomagnification for top predators, e.g. seabirds. The data reported by Kelly et al., 2008 however indicate a low degree or absence of biomagnification of PBDEs in a marine Arctic food web. The authors explain that the field observations suggest PBDEs exhibit a relatively rapid rate of depuration though biotransformation in Arctic marine organisms, which is consistent with laboratory studies in fish and rats.

Considering the high variability of the data reported and additional evidence that BDEs can be eliminated by top predators, a **BMF2 value of 20** is proposed as reasonable worst case.

6 AQUATIC ENVIRONMENTAL CONCENTRATIONS

6.1 ESTIMATED CONCENTRATIONS

Production of c-pentaBDE and c-octaBDE no longer occurs in the EU. Therefore, the following figures extracted from EU-RARs are reported hereunder for information only. Information is also available on hexaBDE component, a main constituent of both c-pentaBDE and c-octaBDE.

Compartment		**Predicted environmental concentration (PEC)**		
		c-octaBDE (1999 – 1994)	**HexaBDE component**	**c-pentaBDE**
Freshwater ($\mu g.l^{-1}$)	$PEC_{local – production}$			
	Emission period	7 – 41.7	-	0.37
	Annual average	1.6 – 11.4		0.305
	$PEC_{local – polymer\ processing}$			
	Emission period	0.27	0.017 – 0.019	-
	Annual average	0.025 – 0.08		
	$PEC_{regional\ (dissolved)}$	$3.6\ 10^{-3}$ – $7.5\ 10^{-3}$	$1.5\ 10^{-4}$ – $1.6\ 10^{-3}$	$1.5\ 10^{-3}$
	$PEC_{continental\ (dissolved)}$	$5.6\ 10^{-4}$ – $1.2\ 10^{-3}$	-	$6\ 10^{-4}$
Wastewater treatment plant ($\mu g.l^{-1}$)	$PEC_{local – polymer\ processing}$	8	-	-
Marine waters ($\mu g.l^{-1}$)		No information available		
Freshwater sediment ($\mu g.kg^{-1}$ ww)	$PEC_{local –production}$	20 700 – 1 236 000	-	4 490
	$PEC_{local – polymer\ processing}$	8 000	400 – 430	-
	$PEC_{regional}$	190 – 390	6.2 – 63	32
	$PEC_{continental}$	29 – 60	-	0.013
Marine sediment ($\mu g.kg^{-1}$ ww)		No information available		
Biota (freshwater) ($\mu g.kg^{-1}$ ww)	$PEC_{fish – polymer\ processing}$	0.057 – 0.18	8.6 – 13	-
	$PEC_{earthworms – polymer\ processing}$	5 340 – 5 570	670 – 690	-
Biota (marine)		No information available		
Biota (marine predators)		No information available		

6.2 MEASURED CONCENTRATIONS

Compartment	Site	Component	Measured environmental concentration (MEC)[8]	Master reference
Freshwater and marine waters ($\mu g.l^{-1}$)	EU	TetraBDE 47	PEC_1= - ; PEC_2= 0.01; Max= - Anal*: 0 / 606	James *et al.*, 2009 and EU monitoring database[9]
		PentaBDE 99	PEC_1= 0.0025; PEC_2= 0.1; Max= 0.003 Anal*: 5 / 1 459	
		PentaBDE 100	PEC_1= - ; PEC_2= 0.1; Max= - Anal*: 0 / 910	
		HexaBDE 153	PEC_1= - ; PEC_2= 0.05; Max= - Anal*: 0 / 1 049	
		HexaBDE 154	PEC_1= - ; PEC_2= 0.05; Max= - Anal*: 0 / 659	
		OctaBDE	PEC_1= 0.05 ; PEC_2= 0.25; Max= 0.25 Anal*: 1 / 9 827	
Freshwater ($\mu g.l^{-1}$)	FR - River Seine (total water)	TetraBDE 47	Range = $46\ 10^{-6}$ – $205\ 10^{-6}$	Labadie *et al.*, 2010
		PentaBDE 99	Range = $46\ 10^{-6}$ – $181\ 10^{-6}$	
		PentaBDE 100	Range = $13\ 10^{-6}$ – $29\ 10^{-6}$	
		HexaBDE 153	Range = $14\ 10^{-6}$ – $38\ 10^{-6}$	
		HexaBDE 154	Range = $9\ 10^{-6}$ – $25\ 10^{-6}$	
		HeptaBDE 183	Range = $10\ 10^{-6}$ – $32\ 10^{-6}$	
Marine waters ($\mu g.l^{-1}$)	No data available			
WWTP effluent ($\mu g.l^{-1}$)	No data available			

[8] Anal : nb quantified analysis / nb all analysis
[9] http://www.priority.substances.wfd.oieau.fr/indexRank.php

Compartment		**Site**	**Component**	**Measured environmental concentration (MEC)**	**Master reference**
Sediment ($\mu g.kg^{-1}{}_{dw}$)	Sed < 2 mm	EU	OctaBDE	PEC_1= 1.2 ; PEC_2= 50; Max= 38.5 Anal*: 278 / 1 775	James *et al.*, 2009 and EU monitoring database[9]
	Sed 20 µm		TetraBDE 47	PEC_1= 6.85 ; PEC_2= 6.85; Max= 7.7 Anal*: 18 / 22	
			PentaBDE 99	PEC_1= 9.1 ; PEC_2= 9.1; Max= 10.5 Anal*: 10 / 17	
			PentaBDE 100	PEC_1= 1 ; PEC_2= 0.8; Max= 1 Anal*: 1 / 25	
			HexaBDE 153	PEC_1= 1 ; PEC_2= 1 ; Max= 1.1 Anal*: 2 / 24	
			HexaBDE 154	PEC_1= - ; PEC_2= 0.45; Max= - Anal*: 0 / 16	
	Sed 63µm		No data available		
	Sediment fraction not reported	IT - Lake Maggiore	TriBDE 28	Range = 5.7 10^{-4} – 0.034	Mariani *et al.*, 2008
			TetraBDE 47	Range = 0.018 – 0.66	
			PentaBDE 99	Range = 0.016 – 1.3	
			PentaBDE 100	Range = 3.5 10^{-3} – 0.025	
			HexaBDE 153	Range = 3.2 10^{-3} – 0.16	
			HexaBDE 154	Range = 2.2 10^{-3} – 0.18	
			HeptaBDE 183	Range = 6.8 10^{-3} – 0.18	
		CH – Greifensee (2001)	TriBDE28	0.031	Kohler *et al.*, 2008
			TetraBDE 47	0.74	
			PentaBDE 99	0.51	
			PentaBDE 100	0.098	
			HexaBDE 153	0.056	
			HexaBDE 154	0.064	
			HeptaBDE 183	0.079	
			OctaBDE 196/200	0.022	
			OctaBDE 197/204	0.033	
			Σ octaBDE 194, 196, 197, 198, 201, 202 and 205	0.14 + increasing trend	

Compartment		Site	Component	Measured environmental concentration (MEC)	Master reference
Sediment (µg.kg$^{-1}{}_{dw}$) (continued)	Sediment fraction not reported (continued)	ES – rivers Anoia and Cardener	TetraBDE 47	Range = 0.23 – 0.40	Labandeira *et al.*, 2007
			PentaBDE 99	Range = 0.03 – 0.98	
			PentaBDE 100	Range = 0.07 – 0.39	
			HexaBDE 153	Range = 0.77 – 1.15	
			HexaBDE 154	Range = > LOD – 0.98	
			HeptaBDE 183	Range = < LOD – 1.23	
		FR – River Seine (total water)	TetraBDE 47	Range = 0.19 – 0.78	Labadie *et al.*, 2010
			PentaBDE 99	Range = 0.34 – 2.99	
			PentaBDE 100	Range = 0.092 – 0.54	
			HexaBDE 153	Range = 0.07 – 0.13	
			HexaBDE 154	Range = 0.05 – 0.1	
			HeptaBDE 183	Range = 0.02 – 0.09	
		AT – remote lakes	TriBDE28	Median (range) = 1.4 (nd – 2.1)	Unpublished data cordially forwarded by and belonging to Dr. Christoph Scheffknecht (Clara, pers. com. 2011)
			TetraBDE 47	Median (range) = 11 (2 – 49)	
			PentaBDE 99	Median (range) = 4.8 (1.3 – 34)	
			PentaBDE 100	Median (range) = 1.5 (0.5 – 10)	
			HexaBDE 153	Median (range) = 3.8 (2.6 – 8.1)	
			HexaBDE 154	Median (range) = nd (nd – 1.8)	
			HeptaBDE 183	Median (range) = 16 (4.5 – 24)	
			OctaBDE 196	Median (range) = 16 (11 – 20)	
			OctaBDE 197	Median (range) = 14 (7.1 – 20)	
		AT – lakes influenced by anthropogenic uses	TriBDE28	Median (range) = 240 (57 – 1200)	
			TetraBDE 47	Median (range) = 340 (30 – 1100)	
			PentaBDE 99	Median (range) = 66 (17 – 360)	
			PentaBDE 100	Median (range) = 21 (4.5 – 110)	
			HexaBDE 153	Median (range) = 7 (3.7 – 38)	
			HexaBDE 154	Median (range) = 1.3 (0.62 – 27)	
			HeptaBDE 183	Median (range) = nd (nd – 38)	
			OctaBDE 196	Median (range) = 61 (5.5 – 210)	
			OctaBDE 197	Median (range) = 44 (10 – 350)	
		Canada – Hudson Bay and Hudson Strait (1999-2003)	HexaBDE 153	0.01 (mean)	Kelly *et al.*, 2008
			HexaBDE 154	0.02	
			HeptaBDE 183	Not detected	
			HeptaBDE 183	< 0.1	

Compartment		Site	Component	Measured environmental concentration (MEC)	Master reference
Biota fresh and marine water (µg.kg$^{-1}_{ww}$)	Invertebrates	EU	TetraBDE 47	PEC_1= 7 ; PEC_2= 4.5; Max= 36.7 Anal*: 97 / 127	James *et al.*, 2009 and EU monitoring database[9]
			PentaBDE 99	PEC_1= 0.115 ; PEC_2= 0.088 ; Max= 0.123 Anal*: 38 / 103	
			PentaBDE 100	PEC_1= 10 ; PEC_2= 2.5; Max= 15 Anal*: 22 / 127	
			HexaBDE 153	PEC_1= 11.7 ; PEC_2= 2.5; Max= 15 Anal*: 8 / 127	
			HexaBDE 154	PEC_1= 11.7 ; PEC_2= 2.5; Max= 15 Anal*: 7 / 127	
Biota freshwater (µg.kg$^{-1}_{ww}$)	Zebra mussel	IT – Lake Maggiore	TriBDE 28	<LOD – 4.7	Binelli *et al.*, 2008
			TetraBDE 47	23.1 – 309.5	
			PentaBDE 99	5.0 – 69.5	
			PentaBDE 100	2.3 – 29.5	
			HexaBDE 153	<LOD – 7.0	
			HexaBDE 154	<LOD – 6.6	
			HeptaBDE 183	<LOD – 6.3	
	Fish – diverse species[10] -> as lipid weight	IT – Po River	HexaBDE 153	Range = <0.86 – 24	Viganò *et al.*, 2008
			HexaBDE 154	Range = <0.86 – 27	
			HexaBDE 155	Range = <0.86 – 7	
	Fish – feral carp -> as lipid weight	ES - Rivers Anoia and Cardener	TetraBDE 47	Range = 18.5 – 565	Labandeira *et al.*, 2007
			PentaBDE 99	Range = < LOD – 7.04	
			PentaBDE 100	Range = < LOD – 82.2	
			HexaBDE 153	Range = < LOD – 26.7	
			HexaBDE 154	Range = < LOD – 84.3	
			HeptaBDE 183	Range = < LOD – 25.5	
	Fish – Lake trout -> as lipid weight	CH – Lake Geneva	TriBDE 28	Median (range) = 3.6 (1.3 – 6.6)	Cheaib *et al.*, 2009
			TetraBDE 47	Median (range) =104 (48 – 189)	
			PentaBDE 99	Median (range) = 46 (24 – 127)	
			PentaBDE 100	Median (range) =14 (5.2 – 31)	
			HexaBDE 153	Median (range) = 3.2 (0.7 – 8.9)	
			HexaBDE 154	Median (range) = 3.6 (1.1 – 8.9)	
			HeptaBDE 183	Median < LOD (LOD = 0.14)	
	Fish – Eel -> as lipid weight	NL – freshwaters	Σ HexaBDE 153 + HexaBDE 154	< 0.1 – 5.7	van Leeuwen and de Boer, 2008
			HeptaBDE 183	< 0.1 – 0.2	
	Fish – Pike-perch -> as lipid weight		Σ HexaBDE 153 + HexaBDE 154	< 0.1 – 0.1	
			HeptaBDE 183	< 0.1	

[10] bleak, nase, gudgeon, chub and barbel

Compartment		Site	Component	Measured environmental concentration (MEC)	Master reference
Biota marine (µg.kg$^{-1}_{ww}$)	Fish (n=8) Roach muscle	Baltic Sea – Åland archipelago	HexaBDE 153	0.021 – 0.26	Burreau *et al.*, 2004
			HexaBDE 154	0.18 – 3.4	
			HexaBDE 155	0.13 – 0.4	
			HeptaBDE 183	<0.001 – 0.035	
			OctaBDE 203	<0.002	
	Fish (n=33) Perch muscle -> as lipid weight		HexaBDE 153	<0.006 – 8.7	
			HexaBDE 154	0.094 – 11	
			HexaBDE 155	<0.006 – 2.4	
			HeptaBDE 183	<0.001 – 0.069	
			OctaBDE 203	<0.002 – 0.30	
	Fish (n=25) Pike muscle -> as lipid weight		HexaBDE 153	0.60 – 36	
			HexaBDE 154	2.0 – 52	
			HexaBDE 155	0.51 – 10	
			HeptaBDE 183	<0.001 – 6.0	
			OctaBDE 203	<0.002 – 1.8	
	Fish – Herring -> as lipid weight	Baltic Sea	TetraBDE 47	Mean (Range) = 22.2 (18.5 – 26)	Szlinder-Richert *et al.*, 2010
	Fish – Sprat -> as lipid weight			Mean (Range) = 10.5 (8.7 – 12.3)	
	Fish – Salmon -> as lipid weight			Mean (Range) = 25.1 (16.7 – 33.6)	
	Fish – Herring and sprat -> as wet weight	Greater North Sea	TriBDE 28	Mean (Range) = 0.05 (<LOQ – 0.06)	Carlsson *et al.*, 2011
			TetraBDE 47	Mean (Range) = 0.59 (0.39 – 0.83)	
			PentaBDE 99	Mean (Range) = 0.22 (<LOQ – 0.51)	
			PentaBDE 100	Mean (Range) = 0.21 (<LOQ – 0.28)	
			HexaBDE 153	Mean (Range) = non detected	
			HexaBDE 154	Mean (Range) = non detected	
			HeptaBDE 183	Mean (Range) = non detected	
Biota marine predators (µg.kg$^{-1}_{ww}$)	Birds – Peregrine falcon eggs -> as lipid weight	SE (N and SW)	TetraBDE 47	Range = 15 – 3 800	Johansson *et al.*, 2009
			PentaBDE 99	Range = 110 – 9 200	
			PentaBDE 100	Range = 77 – 5 200	
			HexaBDE 153	Range = 270 – 16 000	
			HexaBDE 154	Range = 50 – 4 400	
			HeptaBDE 183	Range = 43 – 1 300	
			HeptaBDE 184	Range = <1.3 – 54	
			HeptaBDE 185	Range = <3.6 – 42	
			OctaBDE 196	Range = 9.1 – 190	
			OctaBDE 197	Range = 18 – 220	
			OctaBDE 203	Range = <2.1 – 180	
	Birds – Common eider eggs -> as wet weight	Greater North Sea	TriBDE 28	Mean (Range) = non detected	Carlsson *et al.*, 2011
			TetraBDE 47	Mean (Range) =0.28 (0.15 – 0.55)	
			PentaBDE 99	Mean (Range) = 0.34 (<LOQ – 0.65)	
			PentaBDE 100	Mean (Range) = non detected	

Compartment		Site	Component	Measured environmental concentration (MEC)	Master reference
			HexaBDE 153	Mean (Range) < LOQ	
			HexaBDE 154	Mean (Range) = 0.22 (< LOQ – 0.29)	
			HeptaBDE 183	Mean (Range) = non detected	
	Birds – Herring gull eggs -> as wet weight	Greater North Sea	TriBDE 28	Mean (Range) < LOQ	Carlsson *et al.*, 2011
			TetraBDE 47	Mean (Range) = 2.58 (0.50 – 4.94)	
			PentaBDE 99	Mean (Range) = 1.39 (0.33 – 3.21)	
			PentaBDE 100	Mean (Range) = 1.42 (0.33 – 4.09)	
			HexaBDE 153	Mean (Range) = 0.61 (>LOQ – 1.19)	
			HexaBDE 154	Mean (Range) =0.36 (>LOQ – 0.73)	
			HeptaBDE 183	Mean (Range) = 0.58 (>LOQ – 0.09)	
	Birds – Herring gull liver -> as wet weight	Greater North Sea	TriBDE 28	Mean (Range) < LOQ	Carlsson *et al.*, 2011
			TetraBDE 47	Mean (Range) = 2.34 (0.43 – 7.72)	
			PentaBDE 99	Mean (Range) = 2.65 (0.38 – 13.00)	
			PentaBDE 100	Mean (Range) = 1.02 (0.37 – 3.21)	
			HexaBDE 153	Mean (Range) = 0.73 (>LOQ – 2.49)	
			HexaBDE 154	Mean (Range) = 0.46 (>LOQ – 0.99)	
			HeptaBDE 183	Mean (Range) = unknown (>LOQ –)	
	Mammals – Ringed seal (liver) -> as wet weight	Baltic Sea	TriBDE 28	Mean (Range) = 0.032 (0.014 – 0.074)	Routti *et al.*, 2009
			TetraBDE 47	Mean (Range) = 4.4 (0.62 – 26)	
			PentaBDE 99	Mean (Range) =0.57 (0.21 – 1.4)	
			PentaBDE 100	Mean (Range) = 0.55 (0.21 – 2.0)	
			HexaBDE 153	Mean (Range) = 0.4 (0.076 – 1.8)	
			HexaBDE 154	Mean (Range) = 0.48 (0.052 – 3.1)	
			HeptaBDE 183	Mean (Range) = 0.013 (0.003 – 0.075)	
	Mammals – Harbour seal (blubber) -> as lipid weight	USA – NW Atlantic (Long Island and Gulf of Maine)	HexaBDE 153	<0.09 – 6 090	Shaw *et al.*, 2008
			HexaBDE 154	<0.2 – 613	
			HexaBDE 155	<0.1 – 805	
			HeptaBDE 183	<1.7 – 45	
			OctaBDE 197	<0.02 – 57	
	Mammals – Beluga (blubber, n: 35) -> as lipid weight	Canada – Hudson Bay and Hudson Strait (1999-2003)	HexaBDE 153	0.13 – 2.9	Kelly *et al.*, 2008
			HexaBDE 154	0.02 – 53	
			HeptaBDE 183	0.02 – 0.27	
	Mammals – Ringed seal (blubber, n: 11) -> as lipid weight		HexaBDE 153	0.03 – 5.5	
			HexaBDE 154	0.02 – 1.18	
			HeptaBDE 183	50 and 40 (female and male)	

7 EFFECTS AND QUALITY STANDARDS

The data reported in this section hereafter correspond to the most relevant effect data extracted from pentaBDE and octaBDE EU-RAR (E.C., 2001; E.C., 2003).

7.1 ACUTE AND CHRONIC AQUATIC ECOTOXICITY

The data considered as valid for effects assessment purpose in the RAR were not further assessed. Concentrations are all expressed as in commercial products when commercial products were tested.

Since EU-RARs were published in 2001, 2002 and 2003, other studies were available on exposure of aquatic organisms to PBDE congeners and/or commercial products. Some are reported in the table hereunder and were assessed for their reliability, but there are numerous articles (e.g. Crump *et al.*, 2008; Muirhead *et al.*, 2005; Raldúa *et al.*, 2008; Timme-Laragy *et al.*, 2006) which report endpoints that are not usually accepted as effects assessment endpoints (developmental and behavioural effects, genotoxic effects, dietary exposure instead of direct exposure). Other studies have not been validated because not deemed reliable enough for effects assessment purpose (e.g. Breitholtz and Wollenberger, 2003; Key *et al.*, 2008). Only studies which could be attributed a Klimisch code (Klimisch *et al.*, 1997) 1 or 2 were reported in the tables.

7.1.1 Organisms living in the water column

ACUTE EFFECTS			Reliability	Master reference
Algae & aquatic plants ($mg.l^{-1}$)	**Freshwater**	No information available		
		Selenastrum capricornutum / 96h Compound tested: c-pentaBDE 24h-EC_{10} = 2.7 10^{-3} – 3.1 10^{-3} 48h and 96h : no effects observed	Evaluated in EU-RAR (E.C., 2001)	Palmer *et al.*, 1997c
	Marine	*Skeletonema costatum* / 72h / growth rate Compound tested: TetraBDE (BDE-47) 48h-EC_{50}= 0.07 48h-NOEC= 6.6 10^{-3}	2	Källqvist *et al.*, 2006
Invertebrates ($mg.l^{-1}$)	**Freshwater**	No information available		
		***Daphnia magna* / 48 h** Compound tested: c-pentaBDE **$EC_{50\text{ – mortality, immo}}$ = 0.014 (mm)** $NOEC_{\text{mortality, immo}}$ = 4.9 10^{-3} (mm)	Evaluated in EU-RAR (E.C., 2001)	Palmer *et al.*, 1997a
		Daphnia magna / 21d Compound tested: c-pentaBDE 96h-EC_{50immo} =0.017 (mm) 7-21d-EC_{50immo} = 0.014 (mm)		Drottar and Krueger, 1998
	Marine	No information available		
	Sediment	No information available		
Fish ($mg.l^{-1}$)	**Freshwater**	*Oryzias latipes* / 48h Compound tested: c-pentaBDE, c-octaBDE and c-decaBDE 48h-LC_{50} > 500 for the three compounds	Evaluated in EU-RARs (E.C., 2001; E.C., 2002; E.C., 2003)	CITI, 1982
		Oncorhynchus mykiss / 96h Compound tested: c-pentaBDE 96h-LC_{50} and NOEC > 0.021	Evaluated in EU-RAR (E.C., 2001)	Palmer *et al.*, 1997b
	Marine	No information available		
	Sediment	No information available		

mm : mean measured concentrations

Notes regarding some of the acute tests reported in the table above:

<u>Selenastrum capricornutum / 96h / c-pentaBDE</u> (Palmer *et al.*, 1997c as cited in E.C., 2001)

The effects observed after 24h of exposure had disappeared by 48 hours exposure. The results of this study, and significance of the effects seen, are difficult to interpret, as it appears that the test substance was removed from solution (by adsorption onto the algal cells) during the experiment, but it may indicate that the commercial pentaBDE has the potential to cause effects on algae at similar concentrations as seen in long-term studies with *Daphnia magna*.

<u>Skeletonema costatum / 96h / tetraBDE</u> (Källqvist *et al.*, 2006)

Because of the high specific growth rate (2.35/d) in the control, the exponential phase was not maintained for 72 h in the control and at the two lowest concentrations of BDE 47, and analysis of the data therefore was based on growth rates measured during the first 48 h. Although lead over a 72h-exposure duration, this study can not be used to provide chronic data as such.

<u>Daphnia magna / 48 h / c-pentaBDE</u> (Palmer *et al.*, 1997a as cited in E.C., 2001)

It was stated in the test report that the effects seen could have been due to physical impairment (undissolved test substance adsorbed onto the daphnids and adversely affecting respiration, swimming, etc.) rather than a direct toxic effect.

Oryzias latipes (CITI, 1982 and Palmer *et al.*, 1997b as cited in E.C., 2001)

No effects were observed up to the highest concentration tested, which were far above the water solubility of the compound tested.

CHRONIC EFFECTS			**Valid according to**	**Master reference**
Algae & aquatic plants **($mg.l^{-1}$)**	**Freshwater**	*Selenastrum capricornutum* / 96h Compound tested: c-pentaBDE 24h-EC_{10} = 2.7 10^{-3} – 3.1 10^{-3} 48h and 96h : no effects observed	Evaluated in EU-RAR (E.C., 2001)	Palmer *et al.*, 1997c
	Marine	No information available		
Invertebrates **($mg.l^{-1}$)**	**Freshwater**	*Daphnia magna* / 21d Compound tested: c-pentaBDE 21d-$NOEC_{growth}$ = 5.3 10^{-3} (mm)	Evaluated in EU-RAR (E.C., 2001)	Drottar and Krueger, 1998
		Daphnia magna / 21d Compound tested: c-octaBDE $NOEC_{survival, repro, growth}$ > 0.002 (n) $NOEC_{survival, repro, growth}$ > 1.7 10^{-3} (m)	Evaluated in EU-RAR (E.C., 2003)	Graves *et al.*, 1997
		Daphnia magna / 21d / reproduction Compound tested: TetraBDE (BDE-47) NOEC= 0.014	2	Källqvist *et al.*, 2006
	Marine	No information available		
Fish **($mg.l^{-1}$)**	**Freshwater**	*Oncorhynchus mykiss* / ELS / 87 days Compound tested: c-pentaBDE 60d post-hatch-$NOEC_{growth}$ = 8.9 10^{-3} (mm)	Evaluated in EU-RAR (E.C., 2001)	Wildlife, 2000d
	Marine	***Psetta maxima* / ELS (part)** - 2d exposure of embryos $NOEC_{tetraBDE-47}$= 2.03 10^{-3} $NOEC_{pentaBDE-99}$= 3.22 10^{-3} - **4d exposure of larvae** **$NOEC_{tetraBDE-47}$= 4.9 10^{-4}** $NOEC_{pentaBDE-99}$= 1.61 10^{-3}	2	Mhadhbi *et al.*, 2010
	Sediment	No information available		
Other taxonomic groups		No information available		

om: organic matter content; oc: organic carbon content; n: nominal concentrations; mm: mean measured concentrations

Notes regarding some of the chronic tests reported in the table above:

Selenastrum capricornutum / 96h / c-pentaBDE (Palmer *et al.*, 1997c as cited in E.C., 2001)

See acute toxicity section.

Daphnia magna / 21d / c-octaBDE (Graves *et al.*, 1997 as cited in E.C., 2003)

Since octaBDE is a mixture of congeners between hexa- to nonaBDE, some consideration has to be given as to whether the lower brominated components, particularly the hexaBDE, could be more toxic than indicated by the results of the test. In the test, stock solutions of the test substance were prepared by dissolving in dimethylformamide, with one stock solution being prepared for each concentration tested. These stock solutions were then injected into the diluter mixing chambers to give the desired test concentrations, with the solvent concentration being 0.07 ml/l in all cases. This method ensures that the composition of the substance in solution is as close as possible to that in the commercial preparation, providing all the test substance enters into solution. Since the hexaBDE component is likely to be the most soluble of all the components in the commercial octaBDE, it is very likely that this component was present in true solution and so the concentration of this component can be estimated from the nominal concentration using the known composition of the commercial substance tested (e.g. 5.5% hexaBDE). Thus the NOEC of >2 µg/l for the commercial compound is equivalent to a NOEC of >0.11 µg/l for the hexaBDE component.

In section 5.1, the water solubility of the hexaBDE component is estimated/extrapolated to be around 47 µg/l. Thus it is theoretically possible for the hexaBDE isomers to be present in solution at concentrations higher than those used in this experiment. As part of the 21-day reproduction test carried out for the commercial octaBDE, a range finding 9-day Daphnia immobilisation test was carried out using higher nominal concentrations (0.0081, 0.027, 0.09, 0.3 and 1 mg/l) of the commercial octaBDE. Details of the test system used are not reported. Deaths occurred in seven out of the ten exposed Daphnia at the 1 mg/l nominal concentration after two to three days but no other mortalities were noted. The numbers of neonates produced were reported as 32 in the control, 21 in the solvent control, 0 at 0.0081 mg/l, 19 at 0.027 mg/l, 27 at 0.09 mg/l 0 at 0.3 mg/l and 0 at 1.0 mg/l. The significance of these results is unknown. The test concentrations used in this range finding test exceed the water solubility of the substance by a considerable amount and thus the mortality seen at 1 mg/l could have been due to a physical effect caused by undissolved test substance. However, it is possible that the effects seen were related to the dissolved chemical. Since the nominal concentration tested was well in excess of the water solubility of the commercial mixture, then each component of the mixture could be present in solution at concentrations close to their individual solubilities. If this is assumed then the effects seen could be due to the most water soluble component of the commercial mixture at a concentration of around 4.7 µg/l. The results of this analysis should be treated with caution due to the assumptions made, and the fact that the experiment was a range finding, rather than definitive, test.

Daphnia magna / 21d / tetraBDE (Källqvist *et al.*, 2006)

The distribution of the individual data shows a larger variation at 14 mg.l-1 than in the control. Three animals at this exposure level had a higher number of offspring than the average for the control animals, whereas the remaining seven animals showed lower reproductive output than the control mean. Although the high variation in reproduction at 14 mg.l^{-1} may, in itself, be an effect of exposure to BDE 47, further studies to reveal the toxicological relevance were not undertaken.

Psetta maxima / ELS / tetraBDE and pentaBDE (Mhadhbi *et al.*, 2010)

Missing information on material and methods, notably on water quality parameters such as dissolved oxygen and pH.

$QS_{water,\ eco}$ derivation

Chemicals considered: The ecotoxicological data retrieved on aquatic organisms address ecotoxicity of the commercial mixture c-pentaBDE as well as c-octaBDE as well as some data on individual tetra- and penta-congeners, BDE 47 and BDE 99, respectively. The best satisfactory approaches would be either:

- to derive congener-specific QS values which would allow EQS compliance with concentrations of these congeners in the media, or
- to identify the most toxic congener and use it as a reference in a toxic equivalence approach for the determination of an overall EQS.

Most of the tests were conducted on commercial mixture and it is not possible to derive congener-specific QS values based on the commercial product ecotoxicological data because even if the content of the different congeners in each commercial product is well-known, the contribution of these congeners to the overall toxicity is not well-attested.

There are not enough reliable congener-specific ecotoxicological data available to allow the derivation of congener-specific QS values or identify the most toxic congener. Moreover, there were not enough congener-specific data to range the BDE congeners as a function of their toxicity. It is rather well-known that according to their physico-chemical properties, the more brominated the less soluble and the less bioaccumulative (for higher bromination levels) the congeners are, but it is not possible to presume on their direct toxicity properties based on this information.

Based on the information available, and considering the relationships between BDE congeners (i.e., possibilities for higher brominated compounds to degrade in lower brominated compounds) it is proposed to use all the data from the cited commercial products and their main components. The dataset contain data for algae, invertebrates and fish for acute and chronic exposures, and QS values will be derived based on the worst case basis, i.e. derived from the lowest acute and chronic ecotoxicological data.

Freshwater versus marine waters data: The Guidance Document on EQS derivation (E.C., 2011) states that "*in principle, ecotoxicity data for freshwater and saltwater organisms should be pooled for organic compounds, if certain criteria are met*" and that "*the presumption that for organic compounds saltwater and freshwater data may be pooled must be tested, except where a lack of data makes a statistical analysis unworkable*."

This is the case for polybrominated diphenyl ethers. In fact, there are too few marine data (solely one acute data on marine algae and one marine data on marine flatfish) to perform a "*meaningful statistical comparison*" and no further indications of "*a difference in sensitivity between freshwater vs saltwater organisms*". Therefore, in this case, the data sets may be combined for QS derivation according to the Guidance Document on EQS derivation (E.C., 2011).

QS derivation:
As explained above, the acute and chronic dataset can be considered as complete (data available for algae, invertebrates and fish) and the lowest available data are used to derive QS useful for the sum of BDEs, thus to be compared to the sum of the available BDEs monitored in the media.
The lowest available data are found for exposure of *Daphnia magna* for acute exposures, with a 48h-EC_{50} of 14 µg.l^{-1} and for turbot *Psetta maxima* embryos exposed 4d, with a NOEC of 0.49 tetraBDE µg.l^{-1}.
These toxicity data are equal or below water solubility of the different BDE component tested, i.e. 13 µg.l^{-1} for c-pentaBDE and 11 µg.l^{-1} for tetraBDE. QS can therefore be derived on the basis of the lowest available ecotoxicological data.
Algae, crustaceans and fish being represented for both acute and chronic dataset, standard assessment factors of 100 and 1000 can be applied to the lowest data to derive $MAC_{freshwater,\ eco}$ and $MAC_{marine\ water,\ eco}$, respectively. Standard assessment factors of 10 and 100 are applied to the lowest data to derive AA-$QS_{freshwater,\ eco}$ and AA-$QS_{marine\ water,\ eco}$, respectively.

Tentative QS_{water} **Assessment factor method**	**Relevant study for derivation of QS**	**AF**	**Tentative QS**
$MAC_{freshwater,\ eco}$	*Daphnia magna* / 48 h	100	0.14
$MAC_{marine\ water,\ eco}$	$EC_{50\ –\ mortality,\ immo}$= 0.014 $mg_{c\text{-}pentaBDE}.l^{-1}$	1000	0.014
AA-$QS_{freshwater,\ eco}$	*Psetta maxima* / 4d exposure of larvae	10	0.049
AA-$QS_{marine\ water,\ eco}$	NOEC= 4.9 10^{-4} $mg_{tetraBDE}.l^{-1}$	100	0.0049

7.1.2 Sediment-dwelling organisms

SEDIMENT – CHRONIC EFFECTS		**Valid according to**	**Master reference**
Sediment dwelling invertebrates ($mg.kg^{-1}{}_{dw}$)	Spiked sediment test / 28d Compound tested: c-pentaBDE *Hyalella azteca* <2% om-28d-$NOEC_{survival,\ growth}$ = 6.3 (n) *Chironomus riparius* <2% om-28d-$NOEC_{survival,\ growth}$ = 16 (m)	Evaluated in EU-RAR (E.C., 2001)	Wildlife, 2000a Wildlife, 2000b

	Lumbriculus variegatus **<2% om-28d-NOEC$_{survival, repro, growth}$ > 3.1 (n)**		Wildlife, 2000c
	Lumbriculus variegatus / 28d / Spiked sed Compound tested: c-octaBDE • c-octaBDE: 2.4% oc-NOEC$_{survival, repro, growth}$ >1 340 (mm) 5.9% oc-NOEC$_{survival, repro, growth}$ >1 272 (mm)	Evaluated in EU-RARs (E.C., 2003)	Krueger *et al.*, 2001a; Krueger *et al.*, 2001b

Commercial pentaBDE exposure 28d spiked sediment tests

According to the Guidance Document on EQS derivation (E.C., 2011), for sediment organisms, the NOEc should be normalised to the standard organic matter or organic carbon content of sediment. The actual organic carbon contents of the sediments used in the tests are unknown and organic matter content are reported as <2% in each test. Since organic matter contents are usually very approximately two times higher than the organic carbon contents, this would imply that the organic carbon contents of the sediments used were very low at <1%. Assuming this value, the NOEC values of 6.3, 16 and 3.1 mg.kg^{-1}$_{dw}$, are equivalent to lowest NOEc of 30.5, 48 and 15.5 mg.kg^{-1}$_{dw}$.

Lumbriculus variegatus / 28d (Krueger *et al.*, 2001a; Krueger *et al.*, 2001b as cited in E.C., 2003)

The amount of hexaBDE component present in the commercial octaBDE tested was not given. If it is assumed that the test substance contained 5.5% hexaDE (typical of current products) then the estimated NOECs for the hexaBDE component alone based on these results would be ≥74 mg/kg dry weight for the 2.4% organic carbon content sediment and ≥70 mg/kg dry weight for the 5.9% organic carbon content sediment.

QS$_{sediment}$ derivation

A QS$_{sediment}$ can be estimated from the use of sediment-dwelling organisms toxicity data by applying an assessment factor of 10 to the lowest NOEC from the 5%oc long-term studies of 15.5 mg.kg^{-1}$_{dw}$.

The TGD-EQS recommends favouring the use of chronic tests carried out on benthic organisms when available for the derivation of QS$_{sediment}$. Only results obtained with commercial mixtures c-penta-BDE and c-octa-BDE are available for benthic organisms, and they may be considered as acceptable since PBDEs occurs in mixture in the environment.

For pelagic species however, the QS is based on a result obtained with tetra-BDE which lead to the lowest NOEC. For comparison purpose then, QS$_{sediment}$ is then also calculated using the equilibrium partitioning method from the test conducted on *Psetta maxima* with tetra-BDE. The comparison shows that the experimental result is comprised within the range of calculated values using the equilibrium partitioning method, although the large range of Koc available for PBDE must be emphasised.

Whatever the compound used for the derivation of QS$_{sediment}$, and the method applied, the results are higher than the overall EQS driven by the human health protection.

In line with the EQS-TGD, the lowest endpoint from experimental data on benthic organisms is preferred.

Tentative QS$_{water}$ **Assessment factor method**	**Relevant study for derivation of QS**	**AF**	**Tentative QS**
AA-QS$_{freshwater, sed.}$	*Lumbriculus variegatus* / 28d / 5% oc NOEC > 15.5 mg.kg^{-1}$_{dw}$ NOEC > 5.96 mg.kg^{-1}$_{ww}$	10	596 µg.kg^{-1}$_{ww}$ 1 550 µg.kg^{-1}$_{dw}$ corresponding[(2)] to 2.1 10^{-5} – 0.433 µg.l^{-1}
	Psetta maxima / 4d exposure of larvae NOEC= 4.9 10^{-4} mg$_{tetraBDE}$.l^{-1}	EqP Additional AF of 10[(1)]	0.049 µg.l^{-1} corresponding[(2)] to 6.7 – 1.4.10^{5} µg.kg^{-1}$_{ww}$ 17.5 – 3.7.10^{5} µg.kg^{-1}$_{dw}$

AA-$QS_{marine\ water,\ sed.}$	*Lumbriculus variegatus* / 28d / 5% oc NOEC > 15.5 $mg.kg^{-1}_{dw}$ NOEC > 5.96 $mg.kg^{-1}_{ww}$	50	119 $\mu g.kg^{-1}_{ww}$ 310 $\mu g.kg^{-1}_{dw}$ corresponding(2) to 4.1 10^{-6} – 8.6.10^{-2} $\mu g.l^{-1}$
	Psetta maxima / 4d exposure of larvae NOEC= 4.9 10^{-4} $mg_{tetraBDE}.l^{-1}$	EqP Additional AF of 10(1)	0.0049 $\mu g.l^{-1}$ corresponding(2) to 0.7 – 1.4.10^{4} $\mu g.kg^{-1}_{ww}$ 1.75 – 3.7.10^{4} $\mu g.kg^{-1}_{dw}$

(1) an additional assessment factor of 10 is being applied given the high K_{OW} values of BDE congeners and commercial products (log K_{OW} > 5) to take into account the possible ingestion of sediment.

(2) corresponding values in water using conversion via Equilibrium Partitioning (EqP) method with $K_{OC\text{-}BDE\ congeners}$= 71 560 – 1.5 10^{9} $l.kg^{-1}$.

7.2 SECONDARY POISONING

According to the Guidance Document on EQS derivation (E.C., 2011), c-pentaBDE and c-octaBDE as well as all their main components (tetra- to nona-congeners) trigger the bioaccumulation criteria given the high values of log K_{OW} (above 5), the high values of BCF (mostly above 1 000) and that the toxicity data reported for oral toxicity of mammals which demonstrate a somewhat high toxicity (NOEC as low as 0.4 $mg.kg^{-1}_{feed\ ww}$, see below).

Oral exposure is expected to be the most relevant exposure pathway for BDEs. Biota-sediment accumulation factors for hexaBDE and heptaBDE on two freshwater fish species were reported between 1 and 3 and it was concluded that 100% of the exposure was associated to food or food plus sediment (van Beusekom et al., 2006).

As for direct toxicity (see section 7.1), the interpretation of the toxicity data for BDE compounds is not straight forward as data are not available for all congeners separately and as the relative toxicity of these congeners is not elucidated.

The available physico-chemical properties and BCF values (see section 5.1) indicate that tetraBDE as well as pentaBDE and hexaBDE congeners have a much higher bioconcentration potential than the other components of pentaBDE and octaBDE commercial products (heptaBDE, octaBDE and nonaBDE congeners) and so are likely to have a higher potential to cause adverse effects on organisms in the environment. Wherever possible, the effects of the tetraBDE, pentaBDE and hexaBDE components are considered in interpreting the toxicity data for deriving secondary poisoning linked QS.

The data considered as valid for effects assessment purpose in the RAR were not further assessed.

Since EU-RARs were published in 2001, 2002 and 2003, other studies were available on dietary exposure of birds and mammals to PBDE congeners and/or commercial products. Some are reported in the table hereunder and were assessed for their reliability, but there are numerous articles which report endpoints that are not usually accepted as effects assessment endpoints such as developmental and behavioural effects and/or single dose dietary exposure (Viberg *et al.*, 2003a; Kuriyama *et al.*, 2005; Viberg *et al.*, 2006), exposure through egg cell (McKernan *et al.*, 2009).

In an *in vitro* study (Frouin *et al.*, 2010), it was shown that immune system of marine mammals was affected when harbour seal cells were exposed to 5.8 mg BDE-47.l^{-1}, 6.8 mg BDE-99.l^{-1} and 7.7 mg BDE-153.l^{-1}, respectively. However, these data are not dietary exposure data and therefore not usable for calculating $QS_{biota,\ sec.pois.}$ value.

Secondary poisoning of top predators		Master reference
Mammalian oral toxicity	Rats / Oral / 30 d / effects on liver / exposure to c-pentaBDE NOAEL = 0.45 $mg.kg^{-1}.d^{-1}$	E.C., 2001
	CD-1 Swiss mice / oral administration (by trained self-administration from a modified syringe once a day or via gavage to dams) of 0.6, 6, 18 or 30 mg BDE-99.kg^{-1}_{bw} from GD6 to PND21 Effects: hyperactivity and alterations in anxiety-like behavior LOAEL = 0.6 $mg.kg^{-1}_{bw}.d^{-1}$ NOAEL= 0.2 $mg.kg^{-1}_{bw}.d^{-1}$ ($CF_{LOAEL\to NOAEL}$=3) **NOEC= 4 $mg.kg^{-1}_{food}$ ($CF_{NOAEL\to NOEC}$=20)**	Branchi *et al.*, 2002 Branchi *et al.*, 2005

	Male mice / oral administration of one single dose of 0.8 and 12 mg BDE-99.$kg^{-1}{}_{bw}$ Effects: neurotoxicity LOAEL = 0.8 mg.$kg^{-1}{}_{bw}.d^{-1}$	Eriksson *et al.*, 2001b
	Sprague-Dawley rats / administration by gavage to a dose of 2 mg.$kg^{-1}{}_{bw}.d^{-1}$ from GD6 to PND21 Effects: poor short-term memory when tested in the Morris water maze at PND34-36, and lower antioxidant enzyme activity in the brain at PND37	Cheng *et al.*, 2009
	Wistar rats / administration by gavage of a single dose of 0.06 and 0.3 mg pentaBDE-99 (98% purity).$kg^{-1}{}_{bw}$ / rats dosed at GD 6 Effects : reduced sperm production in male offspring at adulthood (age: 150 d) and effects on motor activity As the exposure was a single exposure of the dams, the offspring were exposed *in utero* but also post-natally through lactation. Therefore, it was not possible to calculate the actual internal dose that the offsprings were exposed to in this study. It is however likely that the body burden in the offspring during the period studied would be lower but not far lower than the body burden of the dams. LOAEL= 0.06 mg.$kg^{-1}{}_{bw}.d^{-1}$	Kuriyama *et al.*, 2005
	Rat / Oral / 13 weeks / Increased liver weight Dietary exposure to c-octaBDE LOAEL= 7.2 mg.$kg^{-1}{}_{bw}.d^{-1}$ NOAEL= 2.4 mg.$kg^{-1}{}_{bw}.d^{-1}$ ($CF_{LOAEL\text{->}NOAEL}$=3) NOEC= 48 mg.$kg^{-1}{}_{biota\ ww}$ ($CF_{NOAEL\text{->}NOEC}$=20)	Great Lakes Chemical Corporation, 1977 as cited *in* E.C., 2003
	Rabbit / Oral /exposure days 7-19 of gestation / foetotoxicity Dietary exposure to c-octaBDE NOAEL= 2 mg.$kg^{-1}{}_{bw}.d^{-1}$ **NOEC= 66.6 mg.$kg^{-1}{}_{biota\ ww}$** ($CF_{NOAEL\text{->}NOEC}$ =33.3)	Breslin *et al.*, 1989 as cited *in* E.C., 2003
Avian oral toxicity	Negative correlation between concentration ΣpolyBDE in egg and average productivity for *Falco peregrinus*. Congeners 2,2',4,4',5,5'-HexaBDE ; 2,2',4,4',5,6'-HexaBDE and 2,2',3,4,4',5',6-HeptaBDE constituting approx 50% of total PBDE.	Johansson *et al.*, 2009
	Falco sparverius / oral / 71d $year^{-1}$ / Increased time to egg laying, decreased thickness and mass of eggshell, decreased hatching and reproductive success. Dietary exposure to c-pentaBDE (0.3 and 1.6 mg.$kg^{-1}.d^{-1}$) Resulting concentrations in eggs: ca. 290 and 1 100 mg.$kg^{-1}{}_{ww}$. Time to egg laying, thickness and mass of eggshell significantly associated with concentrations of 2,2',4,4',5,5'-HexaBDE (73 mg.$kg^{-1}{}_{ww}$, mean) and 2,2',4,4',5,6'-HexaBDE (48 mg.$kg^{-1}{}_{ww}$, mean) in eggs.	Fernie *et al.*, 2009

As for aquatic ecotoxicity, results are available mainly for the commercial mixtures of c-pentaBDE and c-octaBDE. The information on individual congener is insufficient to determine the contribution of each compound to the overall toxicity of the mixtures.

The lowest LOAEL= 0.06 mg.$kg^{-1}{}_{bw}.d^{-1}$ is from the study from Kuriyama *et al.*, 2005 where pentaBDE-99 (98% purity) was administered to rats. According to the Joint FAO/WHO expert committee on food additives (JECFA, 2006b; JECFA, 2006a), some “dioxin-like” effects found with BDE compounds are supposed to be mainly due to minor “dioxin-like”, non-BDE contaminants (i.e. impurities of the commercial mixtures). Moreover, Bakker and its collaborators (Bakker et al., 2008) state that “*PBDE impaired postnatal* *spermatogenesis resulting from prenatal exposure has been reported as the most sensitive toxic effect of PBDE toxicity with a LOAEL in rats of 60 $\mu g.kg^{-1}_{bw}$ (Kuriyama et al., 2005). However, for the same effect a NOAEL of 12.5 $ng.kg^{-1}_{bw}$ was reported for 2,3,7,8-TCDD (Ohsako et al., 2001). Thus, a BDE 99 solution of more than 99.99% purity is needed to exclude 2,3,7,8-TCDD as cause for the observed toxicity. This is significantly higher than the reported 98% purity of the solution actually used (Kuriyama et al., 2005). As none of the BDE solutions used in toxicity studies fulfills the mentioned purity criterion, the outcome of these studies is ambiguous".*

In summary, there is thus an obvious kinetic similarity between BDEs and dioxins whereas the mechanistic similarities are much weaker. Therefore, the use of the lowest Ah-receptor-dependent endpoints (such as reduced sperm production in male offspring at adulthood by Kuriyama et al.) may not be relevant until this ambiguity has been solved. Studies with purified BDE material has however confirmed that effects on liver, thyroid and developmental and neurotoxic effects can also be attributed to BDEs.

The next lowest NOEC= 0.4 $mg.kg^{-1}_{food}$ is derived from a test in which pregnant rats administered a single dosage of c-pentaBDE exhibited reduced sperm production in male offspring at adulthood.

Given the data set available and the above considerations, it is proposed to use the studies of Branchi et al. (2002, 2005) for the determination of the $QS_{biota,\ sec.\ pois}$.

Overall, BCF values for BDE congeners range from very low values for highly brominated congeners to very high values for lower brominated congeners. Considering the fact that any highly brominated BDE congeners ends as debrominated via diverse degradation processes, the highest measured BCF of 35 100 for tetraBDE congeners should be retained. This choice is consistent with the application of the worst case (see section 5.1).

Moreover, values chosen to be applied as BMF1 and BMF2 values are 5 and 20, respectively (see section 5.1).

Therefore, for the derivation of BDEs $QS_{biota\ secpois}$, the following bioaccumulation and biomagnification values are used: BCF=35 100, BMF_1 = 5 and BMF_2 = 20.

Tentative $QS_{biota\ sec.\ pois.}$	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS**
Biota	NOEC= 4 $mg.kg^{-1}_{food}$	90 [(1)]	44.4 $\mu g.kg^{-1}_{biota\ ww}$ corresponding to $2.5\ 10^{-4}\ \mu g.l^{-1}$ (freshwater) $1.3\ 10^{-5}\ \mu g.l^{-1}$ (marine waters)

[(1)] An assessment factor of 90 is deemed appropriate to take account of extrapolation of QS from NOEC given that the corresponding study consists in exposure of sensible life stages during gestational and post natal periods.

Given the above considerations on bioaccumulation and biomagnification issues (see section 5.3 and above in section 7.2), the fact that these properties depend on the congener considered, and given that biota repartition depends largely on geographical parameters, the recommendation of a given biota to monitor is more particularly tricky. However, it is well acknowledged that most BDEs covered in the present fact sheet do bioconcentrate (e.g. tetraBDE, pentaBDE and hexaBDEs) and that some BDEs do biomagnify along the trophic food chain. Therefore, fish should be recommended as the trophic level to monitor when considering BDE congeners (ideally it would even be recommendation of a carnivorous fish).

7.3 HUMAN HEALTH

According to the Guidance Document on EQS derivation (E.C., 2011), pentaBDE and octaBDE compounds trigger the bioaccumulation criteria given the high values of log K_{OW} (above 6), the high values of BCF (above 1 000) and that the toxicity data reported for oral toxicity of mammals which demonstrate a somewhat high toxicity (NOEC as low as 0.4 mg.kg^{-1}$_{feed\ ww}$, see below).

Human health via consumption of fishery products		**Master reference**
Mammalian oral toxicity	Rats / Oral / 30 d / effects on liver / exposure to c-pentaBDE NOAEL = 0.45 mg.kg^{-1}.d^{-1}	E.C., 2001
	CD-1 Swiss mice / oral administration (by trained self-administration from a modified syringe once a day or via gavage to dams) of 0.6, 6, 18 or 30 mg BDE-99.kg^{-1}$_{bw}$ from GD6 to PND21 Effects: hyperactivity and alterations in anxiety-like behavior LOAEL = 0.6 mg.kg^{-1}$_{bw}$.d^{-1}	Branchi *et al.*, 2002 Branchi *et al.*, 2005
	Male mice / oral administration of one single dose of 0.8 and 12 mg BDE-99.kg^{-1}$_{bw}$ Effects: neurotoxicity LOAEL = 0.8 mg.kg^{-1}$_{bw}$.d^{-1}	Eriksson *et al.*, 2001b
	Sprague-Dawley rats / administration by gavage to a dose of 2 mg.kg^{-1}$_{bw}$.d^{-1} from GD6 to PND21 Effects: poor short-term memory when tested in the Morris water maze at PND34-36, and lower antioxidant enzyme activity in the brain at PND37	Cheng *et al.*, 2009
	Wistar rats / administration by gavage of a single dose of 0.06 and 0.3 mg pentaBDE-99 (98% purity[1]).kg^{-1}$_{bw}$ / rats dosed at GD 6 Effects: reduced sperm production in male offspring at adulthood (age: 150 d) and effects on motor activity As the exposure was a single exposure of the dams, the offspring were exposed *in utero* but also post-natally through lactation. Therefore, it was not possible to calculate the actual internal dose that the offsprings were exposed to in this study. It is however likely that the body burden in the offspring during the period studied would be lower but not far lower than the body burden of the dams. LOAEL = 0.06 mg.kg^{-1}$_{bw}$.d^{-1}	Kuriyama *et al.*, 2005
	Rabbit / Oral /exposure days 7-19 of gestation / fetotoxicity / exposure to c-octaBDE NOEC= 66.6 mg.kg^{-1}$_{biota\ ww}$	Breslin *et al.*, 1989 as cited *in* E.C., 2003
CMR	Not classified as carcinogenic or mutagenic OctaBDE Classified as reprotoxic 1B = Presumed human reproductive toxicant, i.e. there is evidence from animal studies of adverse effect on sexual function and fertility, or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects.	E.C., 2008

[1] Because BDE-99 was not tested at 99.9% purity, potential dioxin-like effects can not be excluded.

The Joint FAO/WHO expert committee on food additives conducted a Safety evaluation of certain contaminants in food (JECFA, 2006b; JECFA, 2006a) in which they identified a number of difficulties, in particular the complexity of a group of related chemical for which data on individual congeners are lacking.
As regards their toxicity potential, BDE compounds have shown various responses, such as Ah-receptor-dependent responses, e.g. thyroid hormone perturbation (Hallgren and Darnerud, 2002; Zhou *et al.*, 2002; Stoker *et al.*, 2004), hepatic CYP 1A1 enzyme induction (Peters *et al.*, 2004), impaired spermatogenesis (*Kuriyama et al., 2005*)), neurodevelopmental toxicity (Eriksson *et al.*, 2001b; Eriksson *et al.*, 2002; Viberg *et al.*, 2003b; Viberg *et al.*, 2003c; Viberg *et al.*, 2004; Viberg *et al.*, 2006; Sand *et al.*, 2004), or neurobehavioural toxicity (Branchi *et al.*, 2002).

For the same reasons as stated in the section dealing with secondary poisoning of top predators, the study of Kuriyama et al. (2005) may not be relevant until the ambiguity about Ah-receptor dependent endpoints has been solved.

A $BMDL_{10}$ value for pentaBDE-mediated hepatic CYP2B induction in male rats is reported to be 0.07 $mg.kg^{-1}{}_{bw}.d^{-1}$ and no clear evidence for marked differences in CYP-inducing potency of tetraBDE or pentaBDE can be derived from the available literature. Moreover, changes in hepatic drug metabolism and transthyretin expression seem to play a key role in the decrease in serum T4 observed in rodents and BDEs can generate a decrease in apolar hepatic retinoids with a $BMDL_{10}$ value in male rats estimated to 0.5 $mg.kg^{-1}{}_{bw}.d^{-1}$.

Following a body-burden approach, a $BMDL_{10}$ for BDE-99 of 9 $µg.kg^{-1}{}_{bw}$ is recommended, to which an internal daily dose of 4.2 $ng.kg^{-1}{}_{bw}.d^{-1}$ can be associated taking account of a longest human half-life for BDE-99 of 1 442 days.

Given the above considerations on the weakness of the argumentation in favour of taking account of Ah-receptor-dependent endpoints, the former threshold level (based on LOAEL from Branchi's studies) should be used for the derivation of the $QS_{biota,\ hh}$.

As for secondary poisoning section, for the derivation of BDEs $QS_{biota\ hh}$, the following bioaccumulation and biomagnification values are used: BCF=35 100, BMF_1 = 5 and BMF_2 = 20.

Tentative $QS_{biota\ hh}$	Relevant data for derivation of QS	AF	Threshold Level(1)	Tentative $QS_{biota,\ hh}$
Human health	$BMDL_{10}$ = 9 µg BDE-99.$kg^{-1}{}_{bw}$ corresponding to an internal daily dose of: 4.2 10^{-3} µg BDE-99.$kg^{-1}{}_{bw}.d^{-1}$	30	0.14 10^{-3} $µg.kg^{-1}{}_{bw}.d^{-1}$	8.522 10^{-3} $µg.kg^{-1}{}_{biota\ ww}$ corresponding to 4.9 10^{-8} $µg.l^{-1}$ 2.4 10^{-9} $µg.l^{-1}$

(1)Given that toxico-dynamics differences between experimental animals and humans are already taken on board by the back calculation from $BMDL_{10}$ to the daily dose of 4.2 10^{-3} $µg.kg^{-1}{}_{bw}.d^{-1}$, an assessment factor of 30 is deemed sufficient to derive the Threshold Level for human health protection. This is consistent with the recommendations of the REACH guidance: Chapter R.8: Characterisation of dose [concentration]-response for human health (ECHA, 2010).

Given the above considerations on bioaccumulation and biomagnification issues (see section 5.3 and above in section 7.2), and for the same reasons as described in section 7.2, fish should be recommended as the trophic level to monitor when considering BDE congeners (ideally it would even be recommendation of a carnivorous fish).

As regards protection of human health from consumption of drinking water, there are no standard guidelines available. Therefore, a calculated value is proposed to estimate $QS_{hh,\ dw}$.

Human health via consumption of drinking water **Master reference**

Existing drinking water standard(s)	No regulatory standard	Directive 98/83/EC
Drinking water standard (calculated)	$0.49\ 10^{-3}$ µg.l^{-1}	E.C., 2011

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