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COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Scoping paper on potential risks from polybrominated diphenyl ethers (PBDEs) in the infant diet

Introduction

1. The Committee on Toxicity (COT) has been asked to consider aspects related to the toxicity of chemicals in the infant diet, in support of a review by the Scientific Advisory Committee on Nutrition (SACN) of Government recommendations on complementary and young child feeding. Members concluded that brominated flame retardants (BRFs) should be considered as part of that body of work. The BFRs are used to make various materials such as plastics, plastic foam, textiles and consumer appliances.

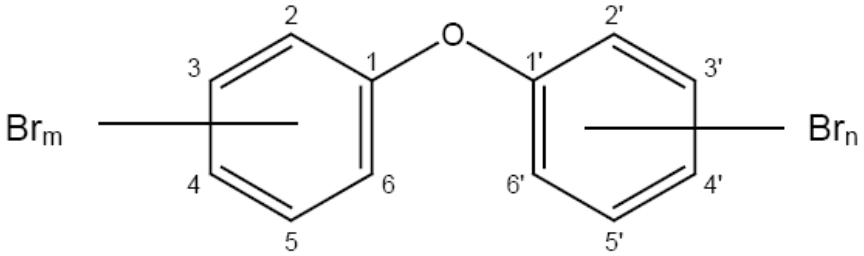
2. Committee paper TOX/2014/09 outlined past considerations by the COT and the EFSA of BFR classes. This scoping paper continues the COT's assessment of BRFs with information on polybrominated diphenyl ethers (PBDEs), which comprise 209 brominated diphenyl ether (PBE) congeners.

3. In 2004, the COT published a statement on PBDE residues in fish from two rivers in England[1]. Then in 2006, the COT published a risk assessment for PBDEs residues found in a broader range of fish and shellfish[2]. The EFSA Panel on Contaminants in the Food Chain (CONTAM) has also assessed PBDEs (EFSA, 2011).

PBDEs

4. PBDEs comprise two phenyl rings linked by an ether group and bromine atoms substituting different combinations of ring hydrogens. Their generic structure is represented within Figure 1. The ten homologues and their 209 isomeric congeners within the PBDE category are listed in Table 1. Table 2 lists the 8 congeners focused on by EFSA (2011) on the basis that they were present in the largest amounts in commercial technical mixtures of pentaBDE, octaPBE and decaPBE.

[1] http://cot.food.gov.uk/pdfs/bfrstatement.pdf
[2] http://multimedia.food.gov.uk/multimedia/pdfs/cotstatementfishsurveys.pdf



Where (m) plus (n) equal between 1 and 10 bromine atoms

Figure 1: Generic structure of the PBDEs (from EFSA, 2011)

Table 1: PBDE homologues and congeners (from EFSA, 2011)

Homologues	Chemical formula	Molecular mass	Isomeric congeners	Number of congeners
monoBDEs	$C_{12}H_9BrO$	249.1	BDE-1 to BDE-3	3
diBDEs	$C_{12}H_8Br_2O$	328.0	BDE-4 to BDE-15	12
triBDEs	$C_{12}H_7Br_3O$	406.9	BDE-16 to BDE-39	24
tetraBDEs	$C_{12}H_6Br_4O$	485.8	BDE-40 to BDE-81	42
pentaBDEs	$C_{12}H_5Br_5O$	564.7	BDE-82 to BDE-127	46
hexaBDEs	$C_{12}H_4Br_6O$	643.6	BDE-128 to BDE-169	42
heptaBDEs	$C_{12}H_3Br_7O$	722.5	BDE-170 to BDE-193	24
octaBDEs	$C_{12}H_2Br_8O$	801.4	BDE-194 to BDE-205	12
nonaBDEs	$C_{12}HBr_9O$	880.3	BDE-206 to BDE-208	3
decaBDE	$C_{12}Br_{10}O$	959.2	BDE-209	1

Table 2: Eight isomeric congeners focused on in EFSA (2011)

Congener	Bromine substitution	CAS number
BDE-28	2,2’,4-triBDE	41318-75-6
BDE-47	2,2’,4,4’-tetraBDE	5436-43-1
BDE-99	2,2’,4,4’,5-pentaBDE	60348-60-9
BDE-100	2,2’,4,4’,6-pentaBDE	189084-64-8
BDE-153	2,2’,4,4’,5,5’-hexaBDE	68631-49-2
BDE-154	2,2’,4,4’,5,6’-hexaBDE	207122-15-4
BDE-183	2,2’,3,4,4’,5’,6-heptaBDE	207122-16-5
BDE-209	2,2’,3,3’,4,4’,5,5’,6,6’-decaBDE	1163-19-5

5. Technical mixtures of PBDEs have been used as additive flame retardants and because they are not chemically bound to the polymers they can leach into the environment. They have been widely used in polymers and textiles, construction materials, furniture, and electrical equipment. International agreements on bans and regulations for production and use of technical mixtures of PBDEs have been introduced since 2004, leading to declining levels in the environment (EFSA, 2011). There are still some uses of commercial deca-BDE.

6. PBDE congeners are susceptible to photolysis, reductive debromination and radical reactions. The chemical stability of the PBDE congeners varies with the individual structure but in general rule congeners with up to three bromine substituents and those with nine and ten bromine substituents are more susceptible to abiotic transformations.

Evaluations by COT and EFSA

COT

7. The COT's 2004 and 2006 Statements are included in Annexes A and B, respectively.

8. In the 2004 Statement, the COT noted that toxicity studies were mainly conducted on commercial mixtures of PBDEs, the composition of which was unclear and likely to differ from the profile of congeners in food and the environment. In view of the inadequacies in the toxicological databases it was not possible to establish a tolerable daily intake. Instead, Members decided to take a Margin of Exposure (MoE) approach. The most sensitive effect of pentaBDE was considered to be neurodevelopmental, with a lowest observed adverse effect level (LOAEL) of 600 µg/kg bw obtained from a study in which BDE-99 was administered by a single oral dose to mice on postnatal days 3 or 10. However, the focus of the 2004 Statement was on exposure to PBDEs from fish, and the available data did not allow an assessment of exposure to infants of a comparable developmental stage (up to one month), and there a relevant MoE could not be calculated for neurodevelopmental effects.

9. Liver toxicity was considered the most relevant and sensitive effect for older children and adults. The COT identified a no observed adverse effect level for liver effects induced by a penta-PBE formulation in the rat (450 µg/kg bw/day) as a point of departure (POD).

10. In 2006, the COT considered exposure to PBDEs in fish and shellfish collected over 2003-2004 (UKAS, 2005a) and from the rest of the diet using the 2003 Total Diet Study (TDS; UKAS, 2005b), again taking a MoE approach with the same POD.

EFSA

11. The EFSA 2011 opinion is included in Annex C. The potential for additive effects of PBDEs was considered but based on observations of divergent toxicological responses and limitations in the available information, it was not possible to conclude on a common mode of action between congeners. Therefore the risk assessment was based on the individual congeners.

12. EFSA focussed on 8 specific congeners (BDE-28, -47, -99, -100, -153, -154, -183 and -209) on the basis that they were present in the largest

amounts in commercial technical mixtures of pentaBDE, octaPBE and decaPBE, and were ubiquitously present in biota and in food. The EFSA panel concluded that relevant toxicological data were available for 4 of these 8 congeners: BDE-47 (a tetraBDE), BDE-99 (a pentaBDE), BDE-153 (a hexaBDE) and 209 (decaBDE). From studies of neurodevelopmental behavioural changes in mice following a single oral administration, EFSA calculated benchmark dose lower confidence limits for a 10% response ($BMDL_{10}$s) of 309, 12, 83 and 1700 µg/kg bw for BDE-47, -99, -153 and -209, respectively. The $BMDL_{10}$ for BDE-47 was derived from effects on locomotion, whilst those for the other three were derived from effects on total activity (see Table 40 in EFSA 2011).

13. On the basis of differences in the elimination kinetics of PBDE congeners (except BDE-209) between humans and animals, the derived $BMDL_{10}$s were converted into estimated human intakes associated with the body burden at the $BMDL_{10}$. These estimated human intakes at $BMDL_{10}$s were 172, 4.2, 9.6 ng/kg bw for BDE-47, -99, -153, and unchanged at 1700 µg/kg bw for BDE-209. These values were used in an MoE approach.

Differences between the assessments of the COT and the EFSA

14. Both assessments concluded that it was not possible to establish health-based guidance values and therefore a MoE approach was adopted. Both also concluded that the most sensitive endpoint was the neurodevelopmental effects, based primarily on studies involving a single administration of individual PBDE congeners to neonatal mice. The COT based its assessments on the liver because the focus was on fish consumption, and no data were available to support an assessment of exposure that could lead to neurodevelopmental effects in infants.

15. EFSA expressed reservations about the protocol of a single administration of PBDE to neonatal mice and the relevance of the findings. Limitations included the single dose, not taking into account the litter effect, and that most studies were conducted in a single laboratory with no independent verification of the results (see section 8.5, Annex C). EFSA took a conservative approach in using these data to calculate $BMDL_{10}$ values and the body burden at the $BMDL_{10}$ for the PBDE congeners for which data were available

Sources of exposure to PBDEs

Environmental occurrence of PBDEs

Dust and soil

16. Concentrations of selected PBDEs have been measured in dust sampled in the UK with widely varying results depending on the specific

PBDEs measured, and the location of sampling, but generally showing higher levels of BDE-209 (see Table 3). It is also likely that the levels of specific PBDEs have altered over time due to progressive phasing out of BFR usage.

Table 3: Concentrations of some PBDEs in UK dust

Location	Congeners	Total concentrations for single or groups of PBDE congeners in dust (ng/g)			Reference
		Mean	Median	Maximum	
Homes	13 PBDEs[1]	260,000	-	-	Harrod, 2008
Homes	BDE-209	-	-	2,200,000	Harrod, 2008
Homes	7 PBDEs[2]	-	10,000	54,000	Sjödin, 2006
Offices	13 PBDEs[1]	-	31,000	-	Harrod, 2008
Offices	BDE-209	-	-	1,400,000	Harrod, 2008
Cars	13 PBDEs[1]	-	340,000	-	Harrod, 2008
Cars	BDE-209	-	-	2,600,000	Harrod, 2008
Cars	11 PBDEs[3]	-	2.5 to 130	-	Harrad and Abdallah, 2011
Cars	3 PBDEs[4]	-	3,700 to 4,800	-	Harrad and Abdallah, 2011
Cars	BDE-209	-	190,000	-	Harrad and Abdallah, 2011

1. BDE-28, -47, -49, -66, -99, -100, -153, -154, -183, -196, -197, -203 and -209
2. BDE-47, -99, -100, -153, -154, -183 and -209.
3. BDE-47, -85 -99, -100, -153, -154, -183, -196, -197, -202 and -203.
4. BDE-206, -207 and -208.

Air

17. Concentrations of selected PBDEs have been measured in air sampled in the UK (prior to 2006) and summarised by Harrad *et al*. (2010) (Table 4).

Table 4: Concentrations of some PBDEs in UK air

Air microenvironment	Sum of tri+hexa-BDE concentration (pg/m^3)		
	Minimum	Median	Maximum
Homes	4	24	245
Offices	10	71	1416
cars	11	41	8184
Outdoor	0.49	8.7	30

Dietary occurrence of PBDEs

Food

18. Concentrations of selected PBDEs were measured in food groups of the 2003 (UKAS, 2005a) and 2012 TDS (FERA, 2012). They were also

measured in fish and shellfish in 2003/4 (UKAS, 2005b). Table 5 shows the ranges of congeners measured in the 2012 TDS, expressed on a fat weight basis. Table 6 shows those 2012 data for key congeners converted to a whole food basis.

Table 5 a-e: Levels of PBPE congeners 19 composite food groups, expressed on a fat weight basis

5a) Levels of BPE congeners in bread, carcass meat or offal

Homologue	Congener	Bread		Cereals		Carcass meat		Offal	
		µg/kg fat	%U	µg/kg fat	%U	µg/kg fat	%U	µg/kg fat	%U
triBDE	BDE-17	0.002	200	<0.001	200	<0.001	200	<0.001	200
	BDE-28	<0.018	200	0.005	81	0.003	67	<0.005	200
tetraBDE	BDE-47[e]	0.13	55	0.067	61	0.124	19	0.074	26
	BDE-49	0.014	186	0.012	35	0.003	67	<0.003	200
	BDE-66	<0.013	200	0.013	33	0.004	51	<0.003	200
	BDE-71	<0.001	200	<0.001	200	<0.001	200	<0.001	200
	BDE-77	<0.001	200	<0.001	200	<0.001	200	<0.001	200
	BDE-85	0.006	35	0.005	160	0.004	101	<0.001	200
pentaBDE	BDE-99[e]	0.138	35	0.081	43	0.156	16	0.089	17
	BDE-100	0.02	41	0.009	46	0.036	12	0.022	14
	BDE-119	<0.004	200	<0.001	200	0.001	200	<0.001	200
	BDE-126	<0.002	200	<0.002	200	<0.001	200	<0.001	200
hexaBDE	BDE-153[e]	0.04	71	0.022	47	0.049	16	0.03	29
	BDE-138	<0.009	200	<0.006	200	<0.001	200	<0.003	200
	BDE-154	0.013	62	<0.006	200	0.023	28	0.016	16
heptaBDE	BDE-183	0.232	11	0.008	175	0.023	36	0.025	13
Lower total PBDE levels[1]		0.555		0.222		0.426		0.256	
Upper total PBDE levels[2]		0.603		0.240		0.431		0.276	
Lower total as % of upper[3]		92%		93%		99%		93%	

5b) Levels of BPE congeners in meat products, poultry, fish or fats+oils

Homologue	Congener	Meat products		Poultry		Fish		Fats+oils	
		µg/kg fat	%U	µg/kg fat	%U	µg/kg fat	%U	µg/kg fat	%U
triBDE	BDE-17	<0.001	200	<0.001	200	0.02	14	<0.001	200
	BDE-28	0.004	200	<0.005	200	0.084	14	0.003	67
tetraBDE	BDE-47[e]	0.119	16	0.073	27	1.443	11	0.05	45
	BDE-49	0.007	86	0.004	150	0.464	11	0.003	67
	BDE-66	0.006	101	<0.003	200	0.065	14	0.003	67
	BDE-71	<0.001	200	<0.001	200	0.003	67	<0.001	200
	BDE-77	<0.001	200	<0.001	200	0.003	67	<0.001	200
	BDE-85	<0.001	200	0.003	67	0.028	13	<0.002	200
pentaBDE	BDE-99[e]	0.129	13	0.08	18	0.244	12	0.047	40
	BDE-100	0.023	14	0.021	14	0.542	10	0.006	35
	BDE-119	0.002	101	<0.001	200	0.038	12	<0.001	200
	BDE-126	<0.001	200	<0.001	200	<0.001	200	<0.001	200
hexaBDE	BDE-153[e]	0.027	25	0.019	43	0.076	13	0.011	56
	BDE-138	0.003i	134	0.002	200	<0.002	200	<0.001	200
	BDE-154	0.013	19	0.01	23	0.237	11	0.004i	150
heptaBDE	BDE-183	0.017	16	0.034	12	0.017	16	0.005	160
Lower total PBDE levels[1]		0.350		0.246		3.264		0.132	
Upper total PBDE levels[2]		0.355		0.259		3.267		0.140	
Lower total as % of upper[3]		99%		95%		100%		94%	

5c) Levels of BPE congeners in eggs, sugars+preserves, green vegatables or potatoes

Homologue	Congener	Eggs		Sugar+preserves		Green vegetables		Potatoes	
		µg/kg fat	%U	µg/kg fat	%U	µg/kg fat	%U	µg/kg fat	%U
triBDE	BDE-17	<0.001	200	0.056	13	0.01	160	<0.001	200
	BDE-28	0.002	101	0.194	16	0.043	48	0.002	101
tetraBDE	BDE-47[e]	0.134	19	1.997	11	0.53	43	0.09	39
	BDE-49	0.008	27	0.375	11	0.057	43	0.006	67
	BDE-66	0.002	101	0.26	12	0.055	45	0.005	81
	BDE-71	<0.001	200	0.022	14	<0.004	200	<0.001	200
	BDE-77	<0.001	200	0.01	23	<0.006	200	<0.001	200
	BDE-85	<0.002	200	0.038	12	<0.02	200	<0.003	200
pentaBDE	BDE-99[e]	0.17	16	1.027	11	0.51	38	0.1	30
	BDE-100	0.041	12	0.137	11	0.091	24	0.019	24
	BDE-119	<0.001	200	0.012	35	<0.008	200	<0.001	200
	BDE-126	<0.002	200	<0.002	200	<0.012	200	<0.002	200
hexaBDE	BDE-153[e]	0.052	16	0.117	19	0.055i	102	0.013	62
	BDE-138	<0.002	200	0.014	86	<0.008	200	<0.001	200
	BDE-154	0.04i	23	0.052	13	0.065i	111	0.005i	200
heptaBDE	BDE-183	0.02	41	0.035	20	0.099	81	0.008	150
Lower total PBDE levels[1]		0.471		4.346		1.403		0.249	
Upper total PBDE levels[2]		0.479		4.348		1.453		0.258	
Lower total as % of upper[3]		98%		100%		97%		97%	

5d) Levels of BPE congeners in other vegatables, canned vegatables, fresh fruit or fruit products

Homologue	Congener	Other vegetables		Canned vegetables		Fresh fruit		Fruit products	
		µg/kg fat	%U	µg/kg fat	%U	µg/kg fat	%U	µg/kg fat	%U
triBDE	BDE-17	0.002	101	<0.005	200	<0.016	200	<0.013	200
	BDE-28	0.008	27	<0.035	200	0.028	143	<0.094	200
tetraBDE	BDE-47[e]	0.094	32	0.122	112	0.583	77	0.297	124
	BDE-49	0.028	13	<0.025	200	0.048	101	<0.068	200
	BDE-66	0.031	12	<0.025	200	0.044	110	<0.068	200
	BDE-71	0.002	101	0.005	81	<0.008	200	<0.006	200
	BDE-77	0.003	67	<0.002	200	<0.011	200	<0.006	200
	BDE-85	0.006	67	<0.002	200	<0.04	200	<0.019	200
pentaBDE	BDE-99[e]	0.142	20	0.089	102	0.435	88	0.236	103
	BDE-100	0.017	16	0.011	128	0.068	63	0.029	131
	BDE-119	0.002	101	<0.005	200	<0.016	200	<0.013	200
	BDE-126	<0.001	200	<0.005	200	<0.024	200	<0.013	200
hexaBDE	BDE-153[e]	0.025	26	<0.026	200	0.116i	97	0.097	147
	BDE-138	0.003i	67	<0.017	200	<0.036	200	<0.045	200
	BDE-154	0.009	90	<0.007	200	<0.072	200	0.023	166
heptaBDE	BDE-183	0.015	67	<0.01	200	0.196	82	<0.026	200
Lower total PBDE levels[1]		0.387		0.253		1.518		0.682	
Upper total PBDE levels[2]		0.388		0.391		1.741		1.053	
Lower total as % of upper[3]		100%		65%		87%		65%	

5e) Levels of BPE congeners in milk, milk & dairy products or nuts

Homologue	Congener	Milk		Milk & dairy products		Nuts	
		µg/kg fat	%U	µg/kg fat	%U	µg/kg fat	%U
triBDE	BDE-17	<0.001	200	<0.001	200	<0.001	200
	BDE-28	0.003	67	<0.003	200	<0.001	200
tetraBDE	BDE-47[e]	0.091	35	0.099	15	0.014	115
	BDE-49	0.004	101	0.002	200	0.002	101
	BDE-66	0.006	67	0.003	134	<0.001	200
	BDE-71	<0.001	200	<0.001	200	<0.001	200
	BDE-77	<0.001	200	<0.001	200	<0.001	200
	BDE-85	<0.003	200	0.002	101	<0.002	200
pentaBDE	BDE-99[e]	0.099	28	0.109	12	0.011	128
	BDE-100	0.014	18	0.018	15	0.002	101
	BDE-119	0.001	200	<0.001	200	<0.001	200
	BDE-126	0.002	200	<0.001	200	<0.001	200
hexaBDE	BDE-153[e]	0.025	34	0.025	19	0.003	134
	BDE-138	<0.003	200	<0.001	200	<0.001	200
	BDE-154	0.01	101	0.01	23	<0.003	200
heptaBDE	BDE-183	0.014	72	0.01	23	<0.003	200
Lower total PBDE levels[1]		0.269		0.278		0.032	
Upper total PBDE levels[2]		0.278		0.287		0.048	
Lower total as % of upper[3]		97%		97%		67%	

%U: Percentage uncertainty surrounding the measurement (higher closer to LODs).
e: Three of the four congeners that EFSA identified relevant toxicological data for.
i: An indicative finding.
<: a non-detect at the limit of detection, which follows the arrow.
1. Total BPDE levels assuming "i" values are accurate and "<" values are zero.
2. Total BPDE levels assuming "i" values are accurate and "<" values are real values.
3. Included to summarise the impact of how “<” values were treated in 1 and 2.

Table 6. Levels of selected or total PBDE congeners in food expressed on a whole weight basis

Food group	% fat content	PBDE concentrations in food (µg/kg food)				
		BDE-47	BDE-99	BDE-153 [4]	Lower total[1]	Upper total[2]
Bread	4.14	0.0054	0.0057	0.0017	0.0230	0.0250
Cereals	9.42	0.0063	0.0076	0.0021	0.0209	0.0226
Carcase meat	14.4	0.0179	0.0225	0.0071	0.0614	0.0621
Offal	9.92	0.0073	0.0088	0.0030	0.0254	0.0274
Meat products	14.9	0.0177	0.0192	0.0040	0.0520	0.0528
Poultry	7.32	0.0053	0.0059	0.0014	0.0180	0.0190
Fish	9.31	0.1340	0.0227	0.0071	0.3040	0.3040
Fats+oils[3]	73.8	0.0369	0.0347	0.0081	0.0974	0.1030
Eggs	9.55	0.0128	0.0162	0.0050	0.0450	0.0457
Sugar and preserves	6.05	0.1210	0.0621	0.0071	0.2630	0.2630
Green vegetables	0.29	0.0015	0.0015	0.0002i	0.0041	0.0042
Potatoes	5.19	0.0047	0.0052	0.0007	0.0129	0.0134
Other vegetables	5.46	0.0051	0.0078	0.0014	0.0211	0.0212
Canned vegetables	0.53	0.0007	0.0005	<0.0001	0.0013	0.0021
Fresh fruit	0.21	0.0012	0.0009	<0.0002	0.0032	0.0037
Fruit products	0.42	0.0013	0.0010	0.0004	0.0029	0.0044
Milk	1.97	0.0018	0.0020	0.0005	0.0053	0.0055
Dairy products	23.3	0.0231	0.0254	0.0058	0.0648	0.0669
Nuts	41.8	0.0059	0.0046	0.0013	0.0134	0.0201

1-2. Total BPDE levels, as described within Table 5.
3. The names of food groups are used consistently across total diet surveys. For reference, the Fats+oils group contains things such as margarines leading to a sub-100% fat content.
4. Amongst the PBDE statistics listed above, two were below LODs (BDE-153 in canned vegetables and fresh fruit) and one (BDE-153 in green vegetables) was indicative.

Drinking water

19. Concentrations of TBBPA in water were not reported in EFSA (2011). In a series of international studies looking for PBDEs in water (BRE, 2009), the only EU findings were for Sweden and all were below the limit of detection (LOD). There were a range of LODs across di-BDE-15 (0.8 ng/L), “tri-BDE-15” (perhaps miss-numbered; 1.1 ng/L), tetra-BDE-47 (0.6 ng/L), penta-BDE-99 (2.9 ng/L), penta-BDE-100 (2.3 ng/L), hexa-BDE-153 (2.0 ng/L), hexa-BDE-154 (1.1 ng/L) and hepta-BDE-183 (2.3 ng/L). Such LODs are several orders of magnitude below food concentrations in Table 6. If PBDEs are present in water, levels are expected to be low due to the lipophilicity of these compounds.

Breast milk

20. Fürst (2006) noted that PBDE levels in milk samples collected in the early 2000s were approximately 60% higher compared to specimens sampled 10 years before. A review by Costa *et al*. (2008) reported that levels of PBDEs in breast milk had been increasing in the past 20-30 years, along with serum levels in the general population though a slight decline had started to emerge in the recent years. The most recent review by EFSA did not find a consistent trend (EFSA, 2011). For the UK, Kalantzi *et al.* (2004) reported data for selected PBDEs in breast milk sampled in 2001-3 (Table 7). BDE-209 was not measured.

Table 7. PBDE congeners in breast milk (n=54) sampled in the UK during 2001-3 (Kalantzi *et al.,* 2004)

Congener	Geometric mean (µg/L whole milk)	Range (µg/L whole milk)
BDE-28	0.0105	ND - 0.0735
BDE-47	0.105	0.0035 - 1.295
BDE-99	0.0315	ND - 0.455
BDE-100	0.021	ND - 0.245
BDE-153	0.049	ND - 0.1715
BDE-154	0.0175	ND - 0.0875

Data converted to whole milk basis from fat weight basis assuming breast milk contains 3.5% fat. ND = not detected

Infant formulae and complementary foods

21. Table 8 presents mean occurrence values for some PBDE congeners in foods classified as “food for infants and small children” (EFSA, 2011). These relate to 42 samples, of which 29 were “ready-to-eat meal for infants and young children”, 8 were “infant formulae” and “follow on formulae”, 2 were “cereal based food for infants and young children” and one was unspecified (EFSA, 2011). The data were reported by a number of European countries.

22. Minimum, mean and maximum upper bound values within Table 8 for PBE-47, -99 and -153 are 0.006, 0.097 and 0.208 µg/kg, respectively.

Table 8: Mean concentrations of some PBDEs in “food for infants and small children” in EFSA (2011)

Range[1]	Mean occurance values in some foods (µg/kg)							
	BDE-28	BDE-47	BDE-99	BDE-100	BDE-153	BDE-154	BDE-183	BDE-209
Lower bound	0.001	0.207	0.076	0.021	0.002	0.005	0.002	0.115
Upper bound	0.002	0.208	0.078	0.023	0.006	0.007	0.005	0.127

1. In the lower bound, values below the LOD are replaced by zero. In the upper bound they are replaced by the LOD.

Exposure to PBDEs

23. The exposure assessments for air, soils and dust and the diet presented here are based on external exposure. Bodyweight data are from

the recently published UK Dietary and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013), with average bodyweights of 7.8, 8.7 and 9.6 kg for infants aged >4.0-6.0, >6.0-9.0 and >9.0-12.0 months old, respectively. Since DNSIYC did not include infants younger than 4 months, in this statement a value of 5.9 kg for infants aged 0-3 months from an earlier survey (DH, 1994), is assumed for infants aged 0-4 months.

Environmental exposure to PBDEs

Dust and soil

24. Table 9 shows potential exposures of infants to PBDEs through ingestion of soil/dust were calculated assuming ingestion of 100 mg dust/day (WHO, 2007) based on the occurrence data in Table 3.

Table 9: Potential exposures of infants to some PBDEs in UK dust

Location	Congeners	Estimated exposure to PBDE congeners for a >9-12 month old (µg/kg bw/day)		
		Mean	Median	Maximum
Homes	13 PBDEs[1]	2.71	-	-
Homes	BDE-209	-	-	22.9
Homes	7 PBDEs[2]	-	0.104	0.563
Offices	13 PBDEs[1]	-	0.323	-
Offices	BDE-209	-	-	14.6
Cars	13 PBDEs[1]	-	3.54	-
Cars	BDE-209	-	-	27.1
Cars	11 PBDEs[3]	-	0.00003 to 0.0014	-
Cars	3 PBDEs[4]	-	0.0385 to 0.0500	-
Cars	BDE-209	-	1.98	-

1. BDE-28, -47, -49, -66, -99, -100, -153, -154, -183, -196, -197, -203 and -209
2. BDE-47, -99, -100, -153, -154, -183 and -209.
3. BDE-47, -85 -99, -100, -153, -154, -183, -196, -197, -202 and -203.
4. BDE-206, -207 and -208.

Air

25. Table 10 shows potential exposures of UK infants to PBDEs in air were calculated assuming a ventilation rate of 3 m^3/day (US EPA, 1989), using the occurrence data in Table 4.

Table 10 a-d: Potential exposure of infants to some PBDEs in UK air

a) Exposure to tri- and hexa-BDEs in UK home air

Sum of tri+hexa-BDEs in home air (pg/m^3)		Exposure (pg/kg bw/d) for infant age ranges			
		0-4 mths	4-6 mths	6-9 mths	9-12 mths
4	(min)	2.0	1.5	1.4	1.3
24	median	12.2	9.2	8.3	7.5
245	(max)	124.6	94.2	84.5	76.6

b) Exposure to tri- and hexa-BDEs in UK office air

Sum of tri+hexa-BDEs in office air (pg/m^3)		Exposure (pg/kg bw/d) for infant age ranges			
		0-4 mths	4-6 mths	6-9 mths	9-12 mths
10	(min)	5.1	3.8	3.4	3.1
71	median	36.1	27.3	24.5	22.2
1416	(max)	720.0	544.6	488.3	442.5

c) Exposure to tri- and hexa-BDEs in UK car air

Sum of tri+hexa-BDEs in car air (pg/m^3)		Exposure (pg/kg bw/d) for infant age ranges			
		0-4 mths	4-6 mths	6-9 mths	9-12 mths
11	(min)	5.6	4.2	3.8	3.4
41	median	20.8	15.8	14.1	12.8
8184	(max)	4161.4	3147.7	2822.1	2557.5

d) Exposure to tri- and hexa-BDEs in UK outdoor air

Sum of tri+hexa-BDEs in outdoor air (pg/m^3)		Exposure (pg/kg bw/d) for infant age ranges			
		0-4 mths	4-6 mths	6-9 mths	9-12 mths
0.49	(min)	0.25	0.19	0.17	0.15
8.7	median	4.42	3.35	3.00	2.72
30	(max)	15.25	11.54	10.34	9.38

Dietary exposure to TBBPA

Food

26. Table 11 shows dietary exposure of infants aged 4 to 18 months to PBDEs estimated using the data from the 19 food groups of the 2012 TDS in Table 6 and consumption data from the DNSIYC (DH, 2013). The exposure from a particular food group is based only on individuals who ate the foods represented by the group. The number of survey respondents who ate a food may differ by food group. The last scenario presented in Table 11, “All”, is based on all survey respondents who consumed food from the 19 food groups. Therefore an “All” exposure estimates does not equal the sum of the 19 separate food groups.

Table 11 a-b: Chronic exposures to infants aged 4 to 18 months from some PBDEs in UK food

a) Chronic exposures to some PBDE congeners for mean consumption rates

Food group	Estimated chronic exposure to PBDEs from food for mean consumption (ng/kg bw/d)				
	BDE-47	BDE-99	BDE-153	Lower total	Upper total
Bread	0.01	0.01	0.00	0.05	0.05
Cereals	0.03	0.03	0.01	0.10	0.11
Carcase meat	0.03	0.03	0.01	0.10	0.10
Offal	0.00	0.00	0.00	0.02	0.02
Meat products	0.03	0.03	0.01	0.09	0.09
Poultry	0.01	0.01	0.00	0.03	0.03
Fish	0.21	0.21	0.01	0.47	0.47
Fats+oils	0.01	0.01	0.00	0.03	0.03
Eggs	0.02	0.02	0.01	0.06	0.07
Sugar and preserves	0.07	0.07	0.00	0.15	0.15
Green vegetables	0.00	0.00	0.00	0.01	0.01
Potatoes	0.02	0.02	0.00	0.04	0.04
Other vegetables	0.02	0.02	0.00	0.07	0.07
Canned vegetables	0.00	0.00	0.00	0.00	0.00
Fresh fruit	0.01	0.01	0.00	0.02	0.02
Fruit products	0.00	0.00	0.00	0.01	0.01
Milk	0.04	0.04	0.01	0.11	0.12
Dairy products	0.64	0.64	0.16	1.79	1.85
Nuts	0.00	0.00	0.00	0.00	0.01
All	0.87	0.86	0.20	2.43	2.51

b) Chronic exposures to some PBDE congeners for high consumption rates

Food group	Estimated chronic exposure to PBDEs from food for 97.5th percentile consumption (ng/kg bw/d)				
	BDE-47	BDE-99	BDE-153	Lower total	Upper total
Bread	0.04	0.04	0.01	0.15	0.16
Cereals	0.11	0.11	0.04	0.37	0.39
Carcase meat	0.12	0.12	0.05	0.42	0.42
Offal	0.01	0.01	0.01	0.05	0.05
Meat products	0.10	0.10	0.02	0.30	0.31
Poultry	0.03	0.03	0.01	0.09	0.09
Fish	0.69	0.69	0.04	1.58	1.58
Fats+oils	0.04	0.04	0.01	0.11	0.11
Eggs	0.06	0.06	0.02	0.22	0.23
Sugar and preserves	0.29	0.29	0.02	0.64	0.64
Green vegetables	0.01	0.01	0.00	0.03	0.03
Potatoes	0.05	0.05	0.01	0.15	0.15

Other vegetables	0.05	0.05	0.01	0.21	0.21
Canned vegetables	0.01	0.01	0.00	0.01	0.02
Fresh fruit	0.02	0.02	0.00	0.06	0.07
Fruit products	0.02	0.02	0.00	0.03	0.05
Milk	0.12	0.12	0.03	0.36	0.37
Dairy products	2.50	2.50	0.63	7.01	7.24
Nuts	0.01	0.01	0.00	0.02	0.03
All	2.64	2.81	0.65	7.33	7.57

Breast milk

27. Table 12 shows estimated exposure of exclusively breastfed infants based on the UK data of Kalantzi *et al*. (2004) for average (800 mL) and high-level (1200 mL) volumes of breast milk.

Table 12 PBDE exposure (µg/kg bw/day) from exclusive breastfeeding by infants estimated for average and high level consumption

PBDE concentration (µg/L)	Exposures to PBDE from exclusive breastfeeding (ng/kg bw/day) for different infant age ranges (months) and daily consumption volumes			
	0-4.0 (800 mL)	0-4.0 (1200 mL)	>4.0-6.0 (800 mL)	>4.0-6.0 (1200 mL)
BDE-28 (mean 0.0105)	1.42	2.14	1.08	1.62
BDE-28 (max 0.0735)	10.0	15.0	7.54	11.3
BDE-47 (mean 0.105)	14.2	21.4	10.8	16.2
BDE-47 (max 1.295)	176	263	133	199
BDE-99 (mean 0.0315)	4.27	6.41	3.23	4.85
BDE-99 (max 0.455)	61.7	92.5	46.7	70.0
BDE-100 (mean 0.021)	2.85	4.27	2.15	3.23
BDE-100 (max 0.0875)	33.2	49.8	25.1	37.7
BDE-153 (mean 0.049)	6.64	9.97	5.03	7.54
BDE-153 (max 0.1715)	23.3	34.9	17.6	26.4
BDE-154 (mean 0.0175)	2.37	3.56	1.79	2.69
BDE-154 (max 0.0875)	11.9	17.8	8.97	13.5

Infant formulae, complementary food and drinking water

28. Available information on PBDE in commercially-produced infants foods indicate that exposure from this source is likely to be lower than that from regular foods.

Questions for the Committee

29. Members are invited to comment on the information provided in this paper and to advise on the approach that should be taken in the COT evaluation of PBDEs in the infant diet.

i. Do members consider it feasible to perform a risk assessment for the PBDEs?

ii. If so, what Point(s) of Departure should be used in the risk assessment?

iii. Do Members still consider it appropriate to take a Margin of Exposure approach to the risk assessment of PBDEs?

iv. Would Members wish to group exposure data for individual congeners, or to consider MoEs for individual congeners?

v. Are Members able to provide other advice on the approach to be taken?

Secretariat
May 2014

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TOX/2014/19 Annex A

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Scoping paper on potential risks from polybrominated diphenyl ethers (PBDEs) in the infant diet

COT statement on brominated flame retardants in fish from the Skerne-Tees rivers system

This document is available at:
http://cot.food.gov.uk/pdfs/bfrstatement.pdf

TOX/2014/19 Annex B

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Scoping paper on potential risks from polybrominated diphenyl ethers (PBDEs) in the infant diet

Statement on organic chlorinated and brominated contaminants in shellfish, farmed and wild fish

This document is available at:
http://multimedia.food.gov.uk/multimedia/pdfs/cotstatementfishsurveys.pdf

TOX/2014/19 Annex C

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Scoping paper on potential risks from polybrominated diphenyl ethers (PBDEs) in the infant diet

EFSA (2011). Scientific Opinion on Polybrominated Diphenyl Ethers (PBDEs) in Food. *EFSA Journal;*2156:1-274.

Note: For copyright reasons the paper in this Annex has not been included in the published version on the COT website. It is available at: http://www.efsa.europa.eu/en/efsajournal/doc/2156.pdf