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

Review of potential risks from hexabromocyclododecanes in the diet of children aged 1 to 5 years and updated exposures for infants aged 0 to 12 months.

Background

1. The Scientific Advisory Committee on Nutrition (SACN) is undertaking a review of scientific evidence that will influence the Government's dietary recommendations for infants and young children. SACN is examining the nutritional basis of the advice. The Committee on Toxicity in Food, Consumer Products and the Environment (COT) was asked to review the risks of toxicity from chemicals in the diet of infants, most of which has been completed, and young children. The reviews will identify new evidence that has emerged since the Government's recommendations were formulated, and will appraise that evidence to determine whether the advice should be revised. The recommendations cover diet from birth to age five years, but are being considered in two stages, focusing first on infants aged nought to 12 months, and now on advice for young children aged one to five years.

2. This discussion paper focusses on the brominated flame retardants (BFRs) hexabromocyclododecanes (HBCDDs). There are currently no Government dietary recommendations for infants and young children which relate to HBCDDs.

3. The 2015 COT statement on potential risks from HBCDDs in the infant diet is included in Annex A. This discussion paper provides estimated HBCDD exposures for children in the UK aged one to five years and also provides an update to exposures for infants aged 0-12 months as new data have become available since the 2015 COT statement.

4. The terms used for literature searching for ADME and toxicology are given in Annex B.

ADME

5. Recent data confirm the findings noted in the 2015 COT Statement. All isomers of HBCDD are orally well absorbed, although skin absorption may be poorer, deposit preferentially in lipid-rich tissues (Abdallah et al 2015, Dominguez-Romero et al 2016), undergo differential metabolism (Hakk 2016, Zheng et al 2016a, Zheng et al 2016b) and are excreted via both urine and faeces. The α isomer appears to be most stable to metabolism and hence the longest lasting in the tissues. Calculation of elimination half-lives of HBCDD stereoisomers in female mice, based on concentrations in adipose tissue, vary from 3-4 days for γ-HBCDD, to 17 days for α-HBCDD. The half-life in humans for HBCDDs (reported as sum of α-, β- and γ-HBCDD) was estimated to be 64 days (range 23-219 days). (EFSA2011). Chengelis (2001, quoted in ECHA Risk assessment R044_0805_env_hh_final_ECB.doc) stated that the elimination half life of HBCDDs in rats, from limited available data may be "in the order of weeks to months for the three diastereomers, with the longest half-life for the α-diastereomer."

Toxicology

6. EFSA (2011) identified neurodevelopmental effects as the critical end-point and derived a BMDL10 from a study by Eriksson et al (2006). Eriksson et al. administered a single oral gavage dose of HBCDDs (α-, β- and γ-HBCDD in relative proportions of 3 %, 8 % and 89 %) at either 0.9 or 13.5 mg/kg bw to mouse pups at the age of 10 days, which is the peak time of brain growth in mice. At 3 months of age the mice were tested for effects on locomotion and memory. The mice treated with HBCDDs at the higher dose initially scored lower than controls and low dose animals in the tests of locomotion, but maintained their level of activity such that after 40 minutes they were significantly more active than the other two groups ($p < 0.01$). The higher dose group also took significantly longer than the other groups to complete a swim maze test ($p < 0.05$), suggesting that spatial learning was impaired. EFSA modelled the dose-response data from this study to derive a BMDL10 of 0.93 mg/kg bw. They noted limitations of the single-administration protocol, but concluded that use of this BMDL10 in the risk assessment was justified because the observed effects occurred at the lowest doses that had been associated with developmental effects on behaviour and covered a relevant neurodevelopmental period in the experimental animals. The COT (2015) concluded that the BMDL10 value derived from the Eriksson paper by EFSA was adequate as a point of departure from which to determine a margin of exposure for infants exposed to HBCDDs.

7. The much slower rate of elimination in humans than in rodents led EFSA to take differing toxicokinetics into account by estimating the daily human intake which, after attainment of steady state, would produce the same body burden as might occur in rodents following a single dose by gavage at the BMDL10 (assuming 85% uptake from the gut). Using the longest estimated human half-life of 219 days, this intake was calculated to be 3 µg/kg bw/day, which was then used as the reference point in the MOE approach. The COT agreed that the reference point identified by EFSA from the study by Eriksson *et al*. (2006), remained the best available starting point for risk assessment.

New toxicological data

8. The recent in vitro findings included alterations in metabolic homeostasis and induced oxidative stress (Wang F et al 2016); specific dopaminergic neuronal toxicity (Genskow et al 2015) and different effects on intracellular signalling pathway activity (An et al 2016). HBCDDs may be proinflammatory (Almughams and Whalen 2015, Koike et al 2016) and either stimulate cancer progression (Kim et al,2016); have no effect (Zhang et al 2016) or be toxic to cancer cells (Zhang et al, 2015)., depending upon the concentration used and the cell type.

9. In vivo a reported toxic effects include perturbation of the tricarboxylic acid (TCA) cycle, lipid and gut microbial metabolism and amino acid homeostasis (Wang D et al, 2016) , isomer-specific up or down-regulation of CYPs (Du et al, 2015), effects on immune responses (Canbaz et al 2016) and impaired cardiac development (Hong et al, 2015, Wu et al, 2016).

10. A recent paper (Maurice et al, 2015) (Annex D) looked at the effects of oral intake of α-HBCDD, the isomer that predominates in the environment, on neurodevelopment in rats and suggested that at least this isomer may cause neurodevelopmental toxicity at lower intakes than previously reported. Hens were fed α-HBCDD at a 40µg/kg complete feed for 5 or 10 days after which time their eggs were found to contain 33 and 102 ng α-HBCDD/g lipid weight. Homogenates of these eggs were administered by gavage to groups of 6 female Wistar rats from the day of fertilisation through to weaning of the pups on postnatal day (PND) 21, with eggs from untreated hens as a control. The authors calculated that the dams were exposed to 22 (low dose) or 66 (high dose) ng HBCDD/kg bw/day for a 42-day period that included both gestation and lactation. Various physiological and behavioural data were collected on the dams and the pups up to post-natal day 28. Gestational period was increased significantly ($p = 0.005$) and body weight by PND28 was reduced in female pups but not males at the low dose but not the high dose ($p < 0.001$). Exposure to the low dose but not the high dose also appeared to reduce forelimb grip strength ($p = 0.051$) and increase the time needed to climb a metal rod out of water ($p< 0.001$) in both sexes, but more obviously in females, Other tests to assess locomotor activity and environment-induced

anxiety showed that the low dose appeared to decrease anxiety in female pups but not in males.

11. Assuming that the half-life of a α-HBCDD in a rat is longer than the dosing period so that there would be essentially no elimination, the body burden (BB) in the dams may be calculated as:

Dose (ng/kg bw/day) x proportion absorbed (F) x number of doses
= 22 ng/kg bw/day x 0.85 x 42 = 785 ng/kg

EFSA (2011) used the following equation to calculate the equivalent dose in humans corresponding to this body burden (D):

$$D = \frac{BB \times \ln 2 / \text{half life}}{F}$$

Where the longest human half-life of 219 days and 100% absorption (F = 1) are assumed. Therefore
D = 785 ng/kg x 0.693 / 219 = 2.5 ng/kg bw/day

This value is lower than the reference point of 3 µg/kg bw/day adopted previously by COT by a factor of 1200.

12. Conversely, Song et al (2016) exposed Sprague-Dawley rats of both sexes to HBCCD (enantiomeric ratio not stated) as a dust aerosol in a 14-day repeated dose study at up to 2000 mg/m^3 over 6 hours per day. No adverse effects were observed following the repeated dosing at 2000 mg/m^3 on a range of haematological, (including RBC, WBC and platelets) serum biochemical (including AST and ALT) or histopathological factors (lung, liver, spleen, kidney, heart, ovary, uterus, testis and epididymis).

13. Assuming that a rat breathes at a rate of 85 breaths per minute[a] with a tidal volume of 1.6 ml[a], that a 7-week-old Sprague Dawley rat weighs on average about 200g[b] and HBCCDs, being lipophilic are 100% absorbed by the lungs, an inhalatory dose of 2000 mg/m^3 for 6 hours would be equivalent to an acute systemic dose of:

2 mg/litre x 6 hours x 5100 breaths/hour x 0.0016 litres/breath / 0.20 kg bw
= 490 mg/kg bw/day

Again assuming essentially no elimination over the course of the experiment and 100% absorption in the lungs, the body burden from this dose would be
490 x 14 = 6860 mg/kg

[a] Johns Hopkins Committee on Animal Care and Use.

[a] Pass, D. and G. Freeth. 1993. The rat. ANZCCART News 6(4): 1-4

The value for D would then be
6860 x 0.693 / 219 = 21.7 mg/kg bw/day

HBCDD exposures in infants and young children aged 4 months to 5 years

Sources of HBCDD exposure

Dietary occurrence of HBCDDs

Human milk

14. There were no new UK data for HBCDD levels in human milk. Occurrence data used previously for estimating exposure from human milk (Table 2 of Annex A) were used to estimate exposure from this route in this paper.

Infant formula and commercial infant foods.

15. Data on the concentrations of HBCDDs in infant formula were not available previously. The concentrations of α, β and γ-HBCDDs in different varieties of infant formula and commercial infant foods were investigated recently in a FSA Survey (Rose *et al* 2015). HBCDDs were not detected in the vast majority of infant formula tested. When individual infant formulae were grouped according to different types (e.g. first milk and growing up milk), the calculated mean occurrence value of each congener for each group did not exceed the limit of detection (LOD) of 0.01 µg/kg, with the exception of the follow-on milk group where a mean concentration of 0.02 µg/kg was derived for α-HBCDD.

16. Similarly, HBCDDs were not detected in the vast majority of individual commercial infant food samples. α-HBCDD was detected in only two samples of fish-based foods and one sample of cereal-based foods at very low levels (<0.03 µg/kg). The mean concentration of each congener calculated for different groups of commercial infant foods (e.g. cereal-, fruit- and meat-based foods) did not exceed the LOD of 0.01 µg/kg.

Other food (Total Diet Study)

17. The most recent measurements of HBCDDs in other foods sampled in the UK were for the composite food groups of the 2012 Total Diet Study (TDS) (Fernandes *et al.,* 2012) and the analytical results were presented previously in Table 3 of Annex A.

Environmental

Air

18. There were no new UK data on HBCDD levels in indoor air. Occurrence data used previously for estimating exposure from air (Annex A) were used to estimate exposure from this route in this paper.

Dust

19. Data on the concentrations of α, β and γ-HBCDDs in domestic dust were recently reported by Kuang *et al* (2016). Range of levels of 5.2-4900, 2.3-1600 and 1.7-21000 µg/kg for the α, β and γ-HBCDDs respectively, were reported in the living room of 30 UK homes during 2015. These levels are considerably lower than those reported previously by Abdallah & Harrad (2009) (n= 21, mean=10021 µg/kg and range: 228 – 140774 µg/kg) which could be a reflection of recent changes on the use of these BFRs. There were no new UK data for HBCDD levels in soil.

20. Occurrence data used previously for estimating exposure (Abdallah& Harrad (2009); Table 1 of Annex A) were used to estimate exposure from dust and soil in this paper. This was because many houses will still be furnished with furniture bought before the November 2014 ban on the use of HBCDDs in domestic products and continuing higher levels of exposure cannot be ruled out.

Exposure

21. Consumption data from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013), and from years 1-4 of the National Diet and Nutrition Survey Rolling Programme years 1-4 (NDNS) (Bates et al., 2014) have been used for the estimation of dietary exposures. Average body weight data used in the estimation of exposures are shown in Table 1 below.

Table 1: Body weights used in exposure assessments

Age bands (months)	Weighted bodyweight
0 - <4	5.9 kg[a]
≥4 - <6	7.8 kg[b]
≥6 - <9	8.7 kg[b]
≥9 - <12	9.6 kg[b]
≥12 - <15	10.6 kg[b]
≥15 - <18	11.2 kg[b]
≥18 - <24	12.0 kg[c]
≥24 - <60	16.1 kg[c]

[a] *DH, 1994.*
[b] *DH, 2013.* [c] *Bates et al., 2014.*

Dietary exposure to HBCDDs

Human milk

22. The estimated exposures of exclusively breast-fed infants, aged 0 to 6 months for a range of HBCDDs were previously reported in Table 4 of Annex A.

23. Data on breast milk consumption have now become available from DNSIYC and these were used in estimating exposure from breast milk in the 4 - <18 months age groups (Table 2). There were too few records of breast milk consumption for children older than 18 months in NDNS to allow a reliable exposure assessment, and breast milk is expected to contribute minimally in this age group.

24. Mean and high level exposure estimates to α, β and γ-HBCDDs were 0.0020-0.063 ng/kg bw/day and 0.0041-0.11 ng/kg bw/day, respectively. High-level exposure to the sum of α, β and γ-HBCDDs in 4 to 18 month infants from human milk did not exceed 0.12 ng/kg bw/d; α-HBCDD levels made the main contribution to total exposure.

Table 2: Estimated exposure to HBCDDs from breastmilk in infants and young children aged 4 to <18 months.

somers (maximum ncentrations in ng/kg whole weight)	HBCDDE Exposure from Breast Milk (ng/kg bw/d) by age group (months)									
	≥4 - <6		≥6 - <9		≥9 - <12		≥12 - <15		≥15 - <18	
	Mean	97.5	Mean	97.5	Mean	97.5	Mean	97.5	Mean	97.5
α (0.69)	0.063	0.11	0.046	0.11	0.026	0.080	0.020	0.052	0.017	
β (0.26)	0.024	0.040	0.017	0.041	0.0099	0.030	0.0076	0.020	0.0066	
γ (0.08)	0.0074	0.012	0.0053	0.013	0.0030	0.0093	0.0023	0.0060	0.0020	
Sum (0.78)	0.072	0.12	0.052	0.12	0.030	0.090	0.023	0.059	0.020	

Values rounded to 2 significant figures (SF).
Sum = sum of $\alpha + \beta + \gamma$

Food

Infant Formulae

Exclusive feeding on formula

25. Possible upper bound (UB) HBCDD exposure from infant formulae were calculated for infants up to 6 months of age assuming exclusive feeding on formula (Table 3). UB exposure estimates were derived using the concentration value for ready-to-feed 'first milk' infant formula (0.01 µg/kg, the LOD). Exposures to the sum of α, β and γ HBCDDs based on consumption of either 800mL or 1200mL formulae, were up to 6 ng/kg bw/day in 0 to 6 month old infants.

Table 3: Estimated UB exposures to HBCDDs from exclusively infant formula fed infants aged 0 to <6 months.

HBCDD isomer	UB HBCDDs Exposures from Infant Formula (first milk) (ng/kg bw/day) by age group (months)			
	0 - <4		≥4 - <6	
	800 mL[a]	1200 mL[a]	800 mL[a]	1200 mL[a]
α	1.4	2.0	1.0	1.5
β	1.4	2.0	1.0	1.5
γ	1.4	2.0	1.0	1.5
Sum	4.2	6.0	3.0	4.5

Values rounded to 2 SF.
[a] Mean and high level exposures were based on exclusive feeding on infant formula and consumption of 800 and 1,200mL, respectively (COT, 2013).
Sum = sum of α, β and γ

Infants 4 to 18 months

26. Exposures of infants and children aged 4.0 to <18 months from infant formula were also estimated using DNSIYC consumption data (DH 2013) (Table 4). The detailed exposure data are presented in Annex B.

27. Exposures to the sum of α, β and γ HBCDDs based on consumption of all varieties of infant formulae, did not exceed 4.7 ng/kg bw/day in 4 to <18 month old infants. The detailed exposure assessments for infant formulae are provided in Annex C.

Table 4: Estimated exposure to HBCDDs from Infant Formula in infants and young children aged 4 to <18 months.

HBCDD isomer	UB dietary exposure to HBCDDs (ng/kg bw/day) by age group (months)									
	≥4 - <6		≥6 - <9		≥9 - <12		≥12 - <15		≥15 - <18	
	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th Percentile	Mean	97.5th percentile	Mean	97.5th percentile
α	0.73	1.9	0.80	1.9	0.66	1.8	0.22	1.2	0.12	0.74
β	0.65	1.4	0.52	1.1	0.38	0.91	0.15	0.69	0.083	0.50
γ	0.65	1.4	0.52	1.1	0.38	0.91	0.15	0.69	0.083	0.50
Sum[a]	2.0	4.7	1.8	4.1	1.4	3.6	0.52	2.6	0.29	1.7

Values rounded to 2 SF.
[a] Sum = sum of α, β and γ

Commercial Infant Foods

28. Table 5 summarises the exposure from commercial infant foods to HBCDDs estimated for infants and young children up to 18 months using DNSIYC consumption data (DH 2013). The detailed exposure data are presented in Annex C.

29. Table 5 summarises the mean and high-level exposures to α, β and γ –HBCDDs in commercial infant foods were lower than those estimated for infant formula. Exposures to the sum of α, β and γ –HBCDDs based on consumption of all varieties of commercial infant foods, did not exceed 1.6 ng/kg bw/day in 4 to <18 month old infants.

Table 5: Estimated exposures to HBCDDs from commercial infant foods in infants and young children aged 4 to <18 months.

HBCDD isomer	UB dietary exposure to HBCDDs (ng/kg bw/day) by age group (months)									
	≥4 - <6		≥6 - <9		≥9 - <12		≥12 - <15		≥15 - <18	
	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th Percentile	Mean	97.5th percentile	Mean	97.5th percentile
A	0.099	0.46	0.14	0.53	0.12	0.51	0.067	0.36	0.04	0.22
B	0.099	0.46	0.14	0.53	0.12	0.51	0.067	0.36	0.04	0.22
γ	0.099	0.46	0.14	0.53	0.12	0.51	0.067	0.36	0.04	0.22
Sum[a]	0.30	1.4	0.42	1.6	0.36	1.5	0.20	1.1	0.12	0.66

Values rounded to 2 SF.

[a] Sum = sum of α, β and γ

Other foods (from TDS)

30. Table 6 summarises UB dietary exposures to α, β and γ –HBCDDs for 12 to 60 month old children. These were estimated using concentrations reported previously for the 19 composite food groups of the 2012 TDS (Fernandes *et al* 2012) (Table 3 of Annex A) together with consumption data from the DNSIYC (DH 2013) and NDNS (Bates *et al.,* 2014).

31. Mean and high level UB exposures in other foods were higher than those estimated from infant formula or commercial infant foods. This is due to the presence of a larger number of other food items that are not produced specifically for infants in the TDS. The highest UB high-level exposure to the sum of α, β and γHBCDDs was 7.5 in 12 to <60 month old children. This value is slightly lower than the highest UB high-level exposure value estimated for the same sum of HBCDDs in 4 to 12 month old infants (10 ng/kg bw/day) (Annex A). As with infant formula and commercial foods, HBCDDs were not detected in most of the food groups in TDS and thus, it is possible that the UB estimates are substantially higher than actual exposures. Estimates of exposure for individual food groups in the TDS are presented in Annex C.

Table 6: Estimated exposure of toddlers to HBCDDs from food in infants and young children aged 12 to 60 months.

HBCDD Isomer	UB dietary exposure to HBCDDs (ng/kg bw/day) by age group (months)							
	≥12 - <15		≥15 - <18		≥18 - <24		≥24 - <60	
	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th percentile
α	1.5	3.2	1.7	3.1	1.9	3.9	1.5	2.7
β	0.90	1.8	0.93	1.6	1.0	1.7	0.81	1.3
γ	0.95	1.9	0.99	1.7	1.1	1.9	0.90	1.6
Sum[a]	3.4	6.9	3.6	6.4	4.0	7.5	3.2	5.6

Values rounded to 2 SF.
Sum = sum of α, β and γ

Dietary supplements

32. Although dietary supplements like cod liver oil are not recommended for children under 3 years of age, there were five recorded cases in the DNSIYC in which infants aged 12 to 18 months were given daily doses of 9 to 45 mg fish oil /kg bw, either by spoon or as capsules. However, assuming the highest UB concentration of HBCDDs reported by EFSA, 45mg fish oil /kg bw would lead to an exposure of 0.13 ng HBCDDs /kg bw. The NDNS recorded no cases of children aged 18 to 24 months being given fish oil dietary

supplements like cod liver oil. There were six recorded cases in the NDNS in which infants aged 24 to 60 months were given daily doses of 11 to 117 mg fish oil /kg bw, either by spoon or as capsules. Assuming the highest UB concentration of HBCDDs reported by EFSA, 117mg fish oil /kg bw would lead to an exposure of 0.35 ng HBCDDs /kg bw/day. The small number of consumers in DNSIYC and NDNS and the incompleteness of the recorded data on consumption mean that there are large uncertainties in performing a risk assessment for HBCDDs in fish oil

Environmental exposures to HBCDD

Air

33. The estimated exposures to the sum of α, β and γ–HBCDDs from air that were reported for infants previously (Annex A) are updated in Table 7 on the basis of ventilation rates for infants and young children of similar age (US EPA, 2011) using the total mean reported occurrence value of 250 pg/m^3 (range 67 – 1300 pg/m^3) in indoor air from 45 homes in Birmingham UK (from Annex A). Table 7 also provides exposure to the same sum of HBCDDs in 12 to 60 month old children. The exposure to the sum of α, β and γ –HBCDDs via air in 0 to 60 month old children ranged from 0.13 to 0.19 ng/k bw/day.

Table 7: Estimated exposure to sum of α, β and γ HBCDDs from domestic air in infants and children

Σ HBCDD mean concentration	**Exposure to HBCDDs in air (ng/kg bw/d) by age group (months)**							
	0 - <4[a]	**≥4 - <6[b]**	**≥6 to <9[c]**	**≥9 to <12[d]**	**≥12 - <15[e]**	**≥15 - <18[f]**	**≥18 - <24[g]**	**≥24 - <60[h]**
250pg/m3	0.15	0. 13	0. 16	0.14	0.19	0.18	0.17	0.16

[a] *Based on a ventilation rate of 3.6 m^3/day and a bodyweight of 5.9 kg.*
[b] *Based on a ventilation rate of 4.1 m^3/day and a bodyweight of 7.8 kg.*
[c] *Based on a ventilation rate of 5.4 m^3/day and a bodyweight of 8.7 kg.*
[d] *Based on a ventilation rate of 5.4 m^3/day and a bodyweight of 9.6 kg.*
[e] *Based on a ventilation rate of 8.0 m^3/day and a bodyweight of 10.6 kg.*
[f] *Based on a ventilation rate of 8.0 m^3/day and a bodyweight of 11.2 kg.*
[g] *Based on a ventilation rate of 8.0 m^3/day and a bodyweight of 12 kg.*
[h] *Based on a ventilation rate of 10.1 m^3/day and a bodyweight of 16.1kg.*

Dust and soil

34. Exposure to HBCDDs in 6 to 12 month old children through ingestion of dust (and soil) were estimated (Table 8), assuming ingestion of 60mg dust (and soil)/day (US EPA, 2011) and based on the mean and maximum concentrations used previously for dust (Table 1 of Annex A).

Table 8: Estimated exposure to HBCDDs from dust and soil in infants aged 6 to 12 months

Isomers (mean and max concentrations in µg/kg)	Exposure to HBCDDs in dust and soil (ng/kg bw/d) by age group (months)			
	≥6 - <9		≥9 - <12	
	Mean[a]	Max[b]	Mean[a]	Max[b]
Sum α+β+γ HBCDD (10021; 140774)	69	970	63	880

Values are rounded to 2 SF.
[a] *Isomer present at mean measured concentration,* Abdallah *and* Harrad *(*2009*).*
[b] *Isomer present at maximum measured concentration* Abdallah and Harrad (2009)*.*

35. Exposure to HBCDDs in 12 to 60 month old children through ingestion of dust and soil, assuming ingestion of 100mg dust and soil/day (US EPA, 2011) and based on the mean and maximum concentrations reported for dust previously (Table 1 of Annex A) are presented in Table 9. Exposures of up to 1300 ng/kg bw/day were noted for the sum of α, β and γ -HBCDDs when using a maximum concentration of 140774 µg/kg in the exposure assessment. Since the dust was sampled in 2007 (Table 1 of Annex A), and there have been changes in usage of HBCDDs since then, it is possible that these estimates are not representative of current exposures in some homes.

Table 9: Estimated exposure to HBCDDs in dust and soil in infants and children aged 12 to <60 months

Congeners (mean and max concentrations in µg/kg)	Exposure to HBCDDs in dust and soil (ng/kg bw/d) by age group (months)							
	≥12 - <15		≥15 - <18		≥18 - <24		≥24 - <60	
	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]
Sum α+β+γ HBCDD (10021; 140774)	95	1300	89	1200	84	1200	62	870

Values are rounded to 2 SF.

[a] *Isomer present at mean measured concentration,* (Abdallah & Harrad 2009).

[b] *Isomer present at maximum measured concentration (*Abdallah *et al.,* 2009).

Risk characterisation

36. Potential risks from the exposure of infants and young children to HBCDDs were characterised by margins of exposure (MOEs), calculated as the ratio of the reference points previously agreed by COT (Annex A) to the estimated exposures for dietary and non-dietary sources.

37. EFSA (2011) noted that usually an MOE of 100 is considered to provide adequate reassurance that there is no health concern regarding the toxic effect on which it is based. A margin of this magnitude covers uncertainties regarding toxicokinetic and toxicodynamic differences between experimental animals and humans (factor 4 x 2.5 = 10), and within the human population (factor 3.2 x 3.2 = 10). This breakdown of the uncertainty factors is consistent with the COT Report on Variability and Uncertainty in Toxicology (COT, 2007)[1]. Since for HBCDDs the MOE approach was based on a body burden comparison between animals and humans, using the higher end of the reported range for elimination half-life in humans, EFSA (2011) considered that the potential for kinetic differences between species had been taken into account. Similarly, by focusing on the body burden associated with a BMDL10 for neurobehavioural effects in mice induced during a relevant period for brain development, and applying that body burden to the entire life span in humans, EFSA (2011) took the view that individual differences in susceptibility had been covered. EFSA thus concluded that in their risk assessment for HBCDDs, the calculated MOEs needed to cover inter-species differences in dynamics (factor 2.5) and the uncertainties in the elimination half-life in humans (factor 3.2). This implied that an MOE greater than 8 (2.5 x 3.2) would indicate that there was no concern for health

38. The COT agreed that inter-species differences in toxicokinetics were accounted for by the body burden approach, and that the use of data relating to a critical period of development reduced uncertainties in the risk assessment. However, they considered that MOEs should be rather higher than 8 to provide reasonable assurance of safety.

39. Table 10 shows MOEs for exposure to breast milk for infants and children aged between four and 18 months using the estimated equivalent dose of Eriksson et al (2006) of 3 µg/kg bw. The MOEs are all 30000 or greater. Using the estimated equivalent dose from the results of Maurice et al (2015), these values would be divided by 1200. The lowest MOE would then be 30.

Table 10. MOEs for exposure to HBCDDs from consumption of breast milk

Isomers (maximum concentrations in ng/kg whole weight)	MOEs for exposure to HBCDDs from Breast Milk by age group (months)									
	≥4 - <6		≥6 - <9		≥9 - <12		≥12 - <15		≥15 - <18	
	Mean	97.5	Mean	97.5	Mean	97.5	Mean	97.5	Mean	97.5
α (0.69)	50000	30000	60000	30000	100000	40000	200000	60000	200000	80000
β (0.26)	100000	80000	200000	70000	300000	100000	400000	200000	500000	200000
γ (0.08)	400000	300000	600000	200000	1000000	300000	1000000	500000	2000000	700000
Sum (0.78)	40000	30000	60000	30000	100000	30000	100000	50000	200000	80000

All MOEs are rounded to 1 significant figure.

40. Table 11 summarises the MOEs for the exposure to HBCDDs for infants aged nought to six months fed exclusively infant formula, using the estimated equivalent dose of Eriksson *et al* (2006) of 3 µg/kg bw/day. The MOEs are all 500 or greater. Using the estimated equivalent dose from the results of Maurice *et al* (2015), these values would be divided by 1200. The lowest MOE would then be 0.4.

Table 11. MOEs for exposure to HBCDDs for infants aged 0-6 months exclusively fed infant formula.

HBCDD isomer	MOEs for exposure to HBCDDs from infant formula (first milk) by age group (months)			
	0 - <4		≥4 - <6	
	800 mL[a]	1200 mL[a]	800 mL[a]	1200 mL[a]
α	2000	2000	3000	2000
β	2000	2000	3000	2000
γ	2000	2000	3000	2000
Sum	700	500	1000	700

All MOEs are rounded to 1 significant figure.

41. Tables 12 shows the MOEs for exposure to infant formula in infants and children aged four to 18 months using the upper bound estimates of exposure and the estimated equivalent dose of Eriksson *et al* (2006) of 3 µg/kg bw. The MOEs are all 600 or greater. Using the estimated equivalent dose from the results of Maurice *et al* (2015), these values would be divided by 1200. The lowest MOE would then be 0.5.

Table 12. MOEs for exposures to HBCDDs from infant formulae for infants aged 4 to 18 months.

HBCDD isomer	MOEs for exposure to HBCDDs in infant formula by age group (months)									
	≥4 - <6		≥6 - <9		≥9 - <12		≥12 - <15		≥15 - <18	
	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th Percentile	Mean	97.5th percentile	Mean	97.5th percentile
α	4000	2000	4000	2000	5000	2000	10000	3000	30000	4000
β	5000	2000	6000	3000	8000	3000	20000	4000	40000	6000
γ	5000	2000	6000	3000	8000	3000	20000	4000	40000	6000
Sum[a]	2000	600	2000	700	2000	800	6000	1000	10000	2000

All MOEs are rounded to 1 significant figure.

42. Table 13 shows the MOEs for exposure to commercial infant food for infants and children aged four to 18 months using the upper bound estimates of exposure and using the estimated equivalent dose of Eriksson *et al* (2006) of 3 μg/kg bw. The MOEs are all 2000 or greater. Using the estimated equivalent dose from the results of Maurice *et al* (2015), these values would be divided by 1200. The lowest MOE would then be 2.

Table 13. MOEs for exposures to HBCDDs from commercial infant food for children aged 12 to 18 months.

HBCDD isomer	MOEs for exposure to HBCDDs in infant food by age group (months)									
	≥4 - <6		≥6 - <9		≥9 - <12		≥12 - <15		≥15 - <18	
	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th Percentile	Mean	97.5th percentile	Mean	97.5th Percentile
α	30000	7000	20000	6000	30000	6000	50000	8000	80000	10000
β	30000	7000	20000	6000	30000	6000	50000	8000	80000	10000
γ	30000	7000	20000	6000	30000	6000	50000	8000	80000	10000
Sum[a]	10000	2000	7000	2000	8000	2000	20000	3000	30000	5000

All MOEs are rounded to 1 significant figure.

43. Tables 14 summarises the MOEs for exposure from foods for infants and children aged 12 to 60 months, using the estimated equivalent dose of Eriksson *et al* (2006) of 3 μg/kg bw. The MOEs are all 400 or greater. Using the estimated equivalent dose from the results of Maurice *et al* (2015), these values would be divided by 1200. The lowest MOE would then be 0.3.

Table 14. MOEs for exposures to HBCDDs from foods for infants and young children aged 12 to 60 months.

BCDD Isomer	MOEs for UB dietary exposure to HBCDDs by age group (months)							
	≥12 - <15		≥15 - <18		≥18 - <24		≥24 - <60	
	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th percentile	Mean	97.5th percentile
α	2000	900	2000	1000	2000	800	2000	1000
β	3000	2000	3000	2000	3000	2000	4000	2000
γ	3000	2000	3000	2000	3000	2000	3000	2000
Sum[a]	900	400	800	500	800	400	900	500

All MOEs are rounded to 1 significant figure

44. Tables 15 summarises the MOEs for exposure to HBCDDs from domestic air for infants and children aged 12 to 60 months and using the estimated equivalent dose of Eriksson *et al* (2006) of 3 μg/kg bw. The MOEs are all over 20000. Using the estimated equivalent dose from the results of Maurice *et al* (2015), these values would be divided by 1200. The lowest MOE would then be 20.

Table 15 MOEs for exposure to sum of α, β and γ HBCDDs from domestic air in infants and children

Σ HBCDD mean concentration	**MOEs for exposure to HBCDDs in air by age group (months)**							
	0 - <4	**≥4 - <6**	**≥6 to <9**	**≥9 to <12**	**≥12 - <15**	**≥15 - <18**	**≥18 - <24**	**≥24 - <60**
250pg/m3	20000	20000	20000	20000	20000	20000	20000	20000

All MOEs are rounded to 1 significant figure

45. Table 16. MOEs for exposure to HBCDDs from consumption of dust in homes for infants aged 6 to 9 months and 9 to 12 months and using the estimated equivalent dose of Eriksson *et al* (2006) of 3 μg/kg bw. The MOEs are all 3 or greater. Using the estimated equivalent dose from the results of Maurice *et al* (2015), these values would be divided by 1200. The lowest MOE would then be 0.003.

Table 16. MOEs for exposure to HBCDDs from dust and soil in infants aged 6 to 12 months.

Isomers (mean and max concentrations in μg/kg)	**MOEs for exposure to HBCDDs in dust and soil by age group (months)**			
	≥6 to <9		**≥9 to <12**	
	Mean	**Max**	**Mean**	**Max**
Sum α+β+γ HBCDD (10021; 140774)	40	3	50	3

All MOEs are rounded to 1 significant figure.

46. Table 17 MOEs for exposure to HBCDDs from consumption of dust and soil in homes for infants aged 12 to 18 months and 18 to 60 months and using the estimated equivalent dose of Eriksson et al (2006) of 3 μg/kg bw/day. The MOEs are all 2 or greater. Using the estimated equivalent dose from the results of Maurice et al (2015), these values would be divided by 1200. The lowest MOE would then be 0.002.

Table17: MOEs for exposure to HBCDDs from dust and soil in infants and children aged 12 to <60 months.

Congeners (mean and max concentrations in µg/kg)	MOEs for exposure to HBCDDs in dust and soil by age group (months)							
	≥12 - <15		≥15 - <18		≥18 - <24		≥24 - <60	
	Mean	Max	Mean	Max	Mean	Max	Mean	Max
Sum α+β+γ HBCDD (10021; 140774)	30	2	30	3	40	3	50	3

All MOEs are rounded to 1 significant figure.

Dietary supplements

47. An exposure of 0.35 ng HBCDDs /kg bw/d in fish oil would lead to a MOE of 9000 using the estimated equivalent dose of Eriksson *et al* (2006) of 3 μg/kg bw. Using the estimated equivalent dose from the results of Maurice *et al* (2015), these values would be divided by 1200. The lowest MOE would then be 8.

Summary and discussion

48. Since HBCDD in the diets of infants aged 0-1 was initially discussed by COT, some new toxicology and updated exposure data have become available. The study by Maurice *et al* (2015), was not available to EFSA. If considered valid, it suggests that adverse effects could be occurring at lower levels of exposure than previously thought with much lower MOEs being estimated

49. From the above evaluation, using the estimated equivalent dose of Eriksson *et al* (2006) of 3 □g/kg bw as used, EFSA, the MOE values for HCDDs in air, breast milk and food are all in excess of 8, but for dust the highest estimated exposure gives an MOE below this value. Using the estimated equivalent dose from the results of the recent study by Maurice *et al* (2015), these values would be divided by 1200, giving much lower MOEs in all cases.

Questions on which the views of the Committee are sought

50. Members are invited to comment on the information provided in this paper and to answer the following questions.

i. Should new data from Maurice *et al* (2015) be used to calculate the reference point for risk assessment

ii. Should the new data on HBCDD levels in domestic dust reported by Kuang *et al* (2016), only a year after the ban on HBCDD use in domestic products, be used in preference to the data from Abdallah and Harrad (2009)?

iii. Do the new data change the Committee's opinion on the safety of exposure to environmental HBCDDs?

iv. Do Member have advice on estimating aggregate exposure to HBCDDs?

v. Should the information in this paper be summarised in an addendum to the 2015 statement, or is a new statement required?

Secretariat
July 2016

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

Review of potential risks from hexabromocyclododecanes (HBCDDs) in the diet of infants and 1 to 5 year old children

Statement on the potential risks from hexabromocyclododecanes (HBCDDs) in the infant diet

Available at:
http://cot.food.gov.uk/sites/default/files/HBCDDsstatementfinal.pdf

Secretariat
June 2016

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

Review of potential risks from hexabromocyclododecanes (HBCDDs) in the diet of infants and 1 to 5 year old children

ADME literature search terms

A literature search was run on PubMed using the terms HBCD OR HBCDD AND 'relevant term' AND 2015/01/01 – Present. 'Relevant term 'was absorption, distribution, metabolism, excretion or ADME

Toxicology literature search terms

Literature searches were made using PubMed on the following keywords: HBCD OR HBCDD OR hexabromocyclododecane AND 'relevant term ' AND 2015 – Present. The 'relevant term' was one of: milk, infant formula, baby food, food packaging, drinking water, air, dust or soil

Secretariat
June 2016

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

Review of potential risks from hexabromocyclododecanes (HBCDDs) in the diet of infants and 1 to 5 year old children

Exposures to hexabromocyclododecanes in infants and 1 to 5 year old children.

Secretariat
June 2016

Infant formula exposures

Food Group	Output	≥4 - <6 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	Mean	0	0	0	0
First Milk: From Birth (Powder)	Mean	0-0.00060	0-0.00060	0-0.00060	0-0.0018
Follow On Milk: 6 Months (Powder)	Mean	0	0	0	0
Growing Up Milk: 12 Months (Powder)	Mean	0	0	0	0
Goat Milk Formula	Mean	0	0	0	0
Hipp Organic	Mean	0	0	0	0
Soy	Mean	0-0.0011	0-0.0011	0-0.0011	0-0.0033
First Milk: From Birth (Ready to Feed)	Mean	0-0.57	0-0.57	0-0.57	0-1.7
Follow on: 6 Months (Ready to Feed)	Mean	0-0.15	0-0.077	0-0.077	0-0.30
Growing up Milk: 12 Months (Ready to Feed)	Mean	0	0	0	0
Total	Mean	0-0.73	0-0.65	0-0.65	0-2.0

Food Group	Output	≥4 - <6 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	P97.5	0	0	0	0
First Milk: From Birth (Powder)	P97.5	0-0.012	0-0.012	0-0.012	0-0.036
Follow On Milk: 6 Months (Powder)	P97.5	0	0	0	0
Growing Up Milk: 12 Months (Powder)	P97.5	0	0	0	0
Goat Milk Formula	P97.5	0	0	0	0
Hipp Organic	P97.5	0	0	0	0
Soy	P97.5	0	0	0	0
First Milk: From Birth (Ready to Feed)	P97.5	0-1.4	0-1.4	0-1.4	0-4.2
Follow on: 6 Months (Ready to Feed)	P97.5	0-1.6	0-0.80	0-0.80	0-2.4
Growing up Milk: 12 Months (Ready to Feed)	P97.5	0	0	0	0
Total	P97.5	0-1.9	0-1.4	0-1.4	0-4.7

Sum = sum of $\alpha + \beta + \gamma$

Food Group	Output	≥6 - <9 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	Mean	0-0.00020	0-0.00020	0-0.00020	0-0.00060
First Milk: From Birth (Powder)	Mean	0-0.00080	0-0.00080	0-0.00080	0-0.0024
Follow On Milk: 6 Months (Powder)	Mean	0-0.00050	0-0.00050	0-0.00050	0-0.0015
Growing Up Milk: 12 Months (Powder)	Mean	0	0	0	0
Goat Milk Formula	Mean	0-0.00030	0-0.00030	0-0.00030	0-0.00090
Hipp Organic	Mean	0-0.00010	0-0.00010	0-0.00010	0-0.00030
Soy	Mean	0-0.00060	0-0.00060	0-0.00060	0-0.0018
First Milk: From Birth (Ready to Feed)	Mean	0-0.24	0-0.24	0-0.24	0-0.72
Follow on: 6 Months (Ready to Feed)	Mean	0-0.56	0-0.28	0-0.28	0-1.1
Growing up Milk: 12 Months (Ready to Feed)	Mean	0-0.00050	0-0.00050	0-0.00050	0-0.0015
Total	Mean	0-0.80	0-0.52	0-0.52	0-1.8

Food Group	Output	≥6 - <9 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	P97.5	0	0	0	0
First Milk: From Birth (Powder)	P97.5	0	0	0	0
Follow On Milk: 6 Months (Powder)	P97.5	0	0	0	0
Growing Up Milk: 12 Months (Powder)	P97.5	0	0	0	0
Goat Milk Formula	P97.5	0	0	0	0
Hipp Organic	P97.5	0	0	0	0
Soy	P97.5	0	0	0	0
First Milk: From Birth (Ready to Feed)	P97.5	0-1.1	0-1.1	0-1.1	0-3.3
Follow on: 6 Months (Ready to Feed)	P97.5	0-1.9	0-0.97	0-0.97	0-3.8
Growing up Milk: 12 Months (Ready to Feed)	P97.5	0	0	0	0
Total	P97.5	0-1.9	0-1.1	0-1.1	0-4.1

Sum = sum of $\alpha + \beta + \gamma$

Food Group	Output	≥9 - <12 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	Mean	0-0.00070	0-0.00070	0-0.00070	0-0.0021
First Milk: From Birth (Powder)	Mean	0-0.00020	0-0.00020	0-0.00020	0-0.00060
Follow On Milk: 6 Months (Powder)	Mean	0-0.00080	0-0.00080	0-0.00080	0-0.0024
Growing Up Milk: 12 Months (Powder)	Mean	0	0	0	0
Goat Milk Formula	Mean	0	0	0	0
Hipp Organic	Mean	0	0	0	0
Soy	Mean	0-0.00060	0-0.00060	0-0.00060	0-0.0018
First Milk: From Birth (Ready to Feed)	Mean	0-0.10	0-0.10	0-0.10	0-0.30
Follow on: 6 Months (Ready to Feed)	Mean	0-0.55	0-0.27	0-0.27	0-1.1
Growing up Milk: 12 Months (Ready to Feed)	Mean	0-0.0078	0-0.0078	0-0.0078	0-0.023
Total	Mean	0-0.66	0-0.39	0-0.39	0-1.4

Food Group	Output	≥9 - <12 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	P97.5	0	0	0	0
First Milk: From Birth (Powder)	P97.5	0	0	0	0
Follow On Milk: 6 Months (Powder)	P97.5	0-0.0057	0-0.0057	0-0.0057	0-1.7
Growing Up Milk: 12 Months (Powder)	P97.5	0	0	0	0
Goat Milk Formula	P97.5	0	0	0	0
Hipp Organic	P97.5	0	0	0	0
Soy	P97.5	0	0	0	0
First Milk: From Birth (Ready to Feed)	P97.5	0-0.66	0-0.66	0-0.66	0-2.0
Follow on: 6 Months (Ready to Feed)	P97.5	0-1.8	0-0.88	0-0.88	0-3.6
Growing up Milk: 12 Months (Ready to Feed)	P97.5	0	0	0	0
Total	P97.5	0-1.8	0-0.91	0-0.91	0-3.6

Sum = sum of $\alpha + \beta + \gamma$

Food Group	Output	≥12 - <15 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	Mean	0	0	0	0
First Milk: From Birth (Powder)	Mean	0	0	0	0
Follow On Milk: 6 Months (Powder)	Mean	0	0	0	0
Growing Up Milk: 12 Months (Powder)	Mean	0-0.00030	0-0.00030	0-0.00030	0-0.00090
Goat Milk Formula	Mean	0	0	0	0
Hipp Organic	Mean	0	0	0	0
Soy	Mean	0-0.00020	0-0.00020	0-0.00020	0-0.00060
First Milk: From Birth (Ready to Feed)	Mean	0-0.015	0-0.015	0-0.015	0-0.045
Follow on: 6 Months (Ready to Feed)	Mean	0-0.13	0-0.067	0-0.067	0-0.26
Growing up Milk: 12 Months (Ready to Feed)	Mean	0-0.069	0-0.069	0-0.069	0-0.21
Total	Mean	0-0.22	0-0.15	0-0.15	0-0.52

Food Group	Output	≥12 - <15 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	P97.5	0	0	0	0
First Milk: From Birth (Powder)	P97.5	0	0	0	0
Follow On Milk: 6 Months (Powder)	P97.5	0	0	0	0
Growing Up Milk: 12 Months (Powder)	P97.5	0	0	0	0
Goat Milk Formula	P97.5	0	0	0	0
Hipp Organic	P97.5	0	0	0	0
Soy	P97.5	0	0	0	0
First Milk: From Birth (Ready to Feed)	P97.5	0-0.28	0-0.28	0-0.28	0-0.84
Follow on: 6 Months (Ready to Feed)	P97.5	0-1.1	0-0.57	0-0.57	0-2.2
Growing up Milk: 12 Months (Ready to Feed)	P97.5	0-0.55	0-0.55	0-0.55	0-1.7
Total	P97.5	0-1.2	0-0.69	0-0.69	0-2.6

Sum = sum of $\alpha + \beta + \gamma$

Food Group	Output	≥15 - <18- HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	Mean	0	0	0	0
First Milk: From Birth (Powder)	Mean	0	0	0	0
Follow On Milk: 6 Months (Powder)	Mean	0-0.00010	0-0.00010	0-0.00010	0-0.00030
Growing Up Milk: 12 Months (Powder)	Mean	0-0.00010	0-0.00010	0-0.00010	0-0.00030
Goat Milk Formula	Mean	0	0	0	0
Hipp Organic	Mean	0	0	0	0
Soy	Mean	0-0.00010	0-0.00010	0-0.00010	0-0.00030
First Milk: From Birth (Ready to Feed)	Mean	0-0.0034	0-0.0034	0-0.0034	0-0.010
Follow on: 6 Months (Ready to Feed)	Mean	0-0.069	0-0.034	0-0.034	0-0.14
Growing up Milk: 12 Months (Ready to Feed)	Mean	0-0.045	0-0.045	0-0.045	0-0.14
Total	Mean	0-0.12	0-0.083	0-0.083	0-0.29

Food Group	Output	≥15 - <18 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Comfort	P97.5	0	0	0	0
First Milk: From Birth (Powder)	P97.5	0	0	0	0
Follow On Milk: 6 Months (Powder)	P97.5	0	0	0	0
Growing Up Milk: 12 Months (Powder)	P97.5	0	0	0	0
Goat Milk Formula	P97.5	0	0	0	0
Hipp Organic	P97.5	0	0	0	0
Soy	P97.5	0	0	0	0
First Milk: From Birth (Ready to Feed)	P97.5	0	0	0	0
Follow on: 6 Months (Ready to Feed)	P97.5	0-0.74	0-0.37	0-0.37	0-1.5
Growing up Milk: 12 Months (Ready to Feed)	P97.5	0-0.43	0-0.43	0-0.43	0-1.3
Total	P97.5	0-0.74	0-0.50	0-0.50	0-1.7

Sum = sum of $\alpha + \beta + \gamma$

Commercial Infant Foods

Food Group	Output	≥4 - <6 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	Mean	0-0.014	0-0.014	0-0.014	0-0.042
Dairy Based Dishes	Mean	0-0.012	0-0.012	0-0.012	0-0.036
Fruit Based Dishes	Mean	0-0.018	0-0.018	0-0.018	0-0.054
Meat Based Dishes	Mean	0-0.027	0-0.027	0-0.027	0-0.081
Drinks	Mean	0-0.014	0-0.014	0-0.014	0-0.042
Other savoury based dishes	Mean	0-0.012	0-0.012	0-0.012	0-0.036
Snacks - sweet and savoury	Mean	0-0.0027	0-0.0027	0-0.0027	0-0.0081
Total	Mean	0-0.10	0-0.10	0-0.10	0-0.30

Food Group	Output	≥4 - <6 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	P97.5	0-0.070	0-0.070	0-0.070	0-0.21
Dairy Based Dishes	P97.5	0-0.12	0-0.12	0-0.12	0-0.36
Fruit Based Dishes	P97.5	0-0.14	0-0.14	0-0.14	0-0.42
Meat Based Dishes	P97.5	0-0.17	0-0.17	0-0.17	0-0.51
Drinks	P97.5	0-0.14	0-0.14	0-0.14	0-0.42
Other savoury based dishes	P97.5	0-0.081	0-0.081	0-0.081	0-0.24
Snacks - sweet and savoury	P97.5	0-0.017	0-0.017	0-0.017	0-0.051
Total	P97.5	0-0.46	0-0.46	0-0.46	0-1.4

Sum = sum of $\alpha + \beta + \gamma$

Food Group	Output	≥6 - <9 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	Mean	0-0.017	0-0.017	0-0.017	0-0.051
Dairy Based Dishes	Mean	0-0.012	0-0.012	0-0.012	0-0.036
Fruit Based Dishes	Mean	0-0.026	0-0.026	0-0.026	0-0.078
Meat Based Dishes	Mean	0-0.044	0-0.044	0-0.044	0-1.3
Drinks	Mean	0-0.018	0-0.018	0-0.018	0-0.054
Other savoury based dishes	Mean	0-0.018	0-0.018	0-0.018	0-0.054
Snacks - sweet and savoury	Mean	0-0.0041	0-0.0041	0-0.0041	0-0.012
Total	Mean	0-0.14	0-0.14	0-0.14	0-0.42

Food Group	Output	≥6 - <9 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	P97.5	0-0.085	0-0.085	0-0.085	0-0.26
Dairy Based Dishes	P97.5	0-0.11	0-0.11	0-0.11	0-0.33
Fruit Based Dishes	P97.5	0-0.15	0-0.15	0-0.15	0-0.45
Meat Based Dishes	P97.5	0-0.22	0-0.22	0-0.22	0-0.66
Drinks	P97.5	0-0.18	0-0.18	0-0.18	0-0.54
Other savoury based dishes	P97.5	0-0.10	0-0.10	0-0.10	0-0.30
Snacks - sweet and savoury	P97.5	0-0.021	0-0.021	0-0.021	0-0.063
Total	P97.5	0-0.53	0-0.53	0-0.53	0-1.6

Sum = sum of $\alpha + \beta + \gamma$

Food Group	Output	≥9 to <12 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	Mean	0-0.012	0-0.012	0-0.012	0-0.036
Dairy Based Dishes	Mean	0-0.0075	0-0.0075	0-0.0075	0-0.023
Fruit Based Dishes	Mean	0-0.025	0-0.025	0-0.025	0-0.075
Meat Based Dishes	Mean	0-0.041	0-0.041	0-0.041	0-0.12
Drinks	Mean	0-0.016	0-0.016	0-0.016	0-0.048
Other savoury based dishes	Mean	0-0.019	0-0.019	0-0.019	0-0.057
Snacks - sweet and savoury	Mean	0-0.0040	0-0.0040	0-0.0040	0-0.012
Total	Mean	0-0.12	0-0.12	0-0.12	0-0.36

Food Group	Output	≥9 to <12 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	P97.5	0-0.076	0-0.076	0-0.076	0-0.23
Dairy Based Dishes	P97.5	0-0.078	0-0.078	0-0.078	0-0.23
Fruit Based Dishes	P97.5	0-0.13	0-0.13	0-0.13	0-0.39
Meat Based Dishes	P97.5	0-0.21	0-0.21	0-0.21	0-063
Drinks	P97.5	0-0.14	0-0.14	0-0.14	0-0.42
Other savoury based dishes	P97.5	0-0.13	0-0.13	0-0.13	0-0.39
Snacks - sweet and savoury	P97.5	0-0.021	0-0.021	0-0.021	0-0.063
Total	P97.5	0-0.51	0-0.51	0-0.51	0-1.5

Sum = sum of $\alpha + \beta + \gamma$

Food Group	Output	≥12 - <15 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	Mean	0-0.0050	0-0.0050	0-0.0050	0-0.015
Dairy Based Dishes	Mean	0-0.0039	0-0.0039	0-0.0039	0-0.12
Fruit Based Dishes	Mean	0-0.015	0-0.015	0-0.015	0-0.045
Meat Based Dishes	Mean	0-0.024	0-0.024	0-0.024	0-0.072
Drinks	Mean	0-0.0078	0-0.0078	0-0.0078	0-0.023
Other savoury based dishes	Mean	0-0.0075	0-0.0075	0-0.0075	0-0.023
Snacks - sweet and savoury	Mean	0-0.0029	0-0.0029	0-0.0029	0-0.0087
Total	Mean	0-0.067	0-0.067	0-0.067	0-0.20

Food Group	Output	≥12 - <15 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	P97.5	0-0.050	0-0.050	0-0.050	0-0.15
Dairy Based Dishes	P97.5	0-0.054	0-0.054	0-0.054	0-0.16
Fruit Based Dishes	P97.5	0-0.11	0-0.11	0-0.11	0-0.33
Meat Based Dishes	P97.5	0-0.17	0-0.17	0-0.17	0-0.51
Drinks	P97.5	0-0.12	0-0.12	0-0.12	0-0.36
Other savoury based dishes	P97.5	0-0.073	0-0.073	0-0.073	0-0.22
Snacks - sweet and savoury	P97.5	0-0.019	0-0.019	0-0.019	0-0.057
Total	P97.5	0-0.36	0-0.36	0-0.36	0-1.1

Sum = sum of $\alpha + \beta + \gamma$

Food Group	Output	≥15 - <18 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	Mean	0-0.0020	0-0.0020	0-0.0020	0-0.0060
Dairy Based Dishes	Mean	0-0.0014	0-0.0014	0-0.0014	0-0.0042
Fruit Based Dishes	Mean	0-0.0095	0-0.0095	0-0.0095	0-0.029
Meat Based Dishes	Mean	0-0.012	0-0.012	0-0.012	0-0.36
Drinks	Mean	0-0.0070	0-0.0070	0-0.0070	0-0.021
Other savoury based dishes	Mean	0-0.0037	0-0.0037	0-0.0037	0-0.011
Snacks - sweet and savoury	Mean	0-0.0018	0-0.0018	0-0.0018	0-0.0054
Total	Mean	0-0.038	0-0.038	0-0.038	0-0.11

Food Group	Output	≥15 - <18 Months - HBCDD Exposure (ng/kg bw/d) (LB-UB)			
		α	β	γ	Sum
Cereal Based Dishes	P97.5	0-0.022	0-0.022	0-0.022	0-0.066
Dairy Based Dishes	P97.5	0-0.021	0-0.021	0-0.021	0-0.063
Fruit Based Dishes	P97.5	0-0.082	0-0.082	0-0.082	0-0.25
Meat Based Dishes	P97.5	0-0.099	0-0.099	0-0.099	0-0.29
Drinks	P97.5	0-0.084	0-0.084	0-0.084	0-0.25
Other savoury based dishes	P97.5	0-0.056	0-0.056	0-0.056	0-0.17
Snacks - sweet and savoury	P97.5	0-0.011	0-0.011	0-0.011	0-0.033
Total	P97.5	0-0.22	0-0.22	0-0.22	0-0.66

Sum = sum of $\alpha + \beta + \gamma$

TDS Exposure Food Groups

Food Group	≥12 - <15 Months – HBCDD Exposure (ng/kg bw/d) (UB)							
	α		β		γ		Sum	
	Mean	97.5	Mean	97.5	Mean	97.5	Mean	97.5
Bread	0.076	0.21	0.051	0.14	0.076	0.21	0.20	0.55
Canned veg	0.017	0.087	0.017	0.087	0.017	0.087	0.050	0.26
Carcase meat	0.24	1.2	0.010	0.049	0.010	0.049	0.26	1.3
Dairy products	0.30	1.6	0.20	1.1	0.20	1.1	0.70	3.7
Eggs	0.0068	0.036	0.0068	0.036	0.0068	0.036	0.020	0.11
Fats and oils	0.042	0.17	0.0080	0.032	0.013	0.054	0.064	0.26
Fish	0.074	0.34	0.0093	0.043	0.0093	0.043	0.093	0.43
Fresh fruit	0.057	0.19	0.057	0.19	0.057	0.19	0.17	0.58
Fruit products	0.074	0.53	0.037	0.27	0.056	0.40	0.17	1.2
Green veg	0.010	0.045	0.010	0.045	0.010	0.045	0.031	0.14
Meat products	0.096	0.51	0.019	0.10	0.019	0.10	0.13	0.71
Milk	0.26	0.75	0.26	0.75	0.26	0.75	0.79	2.2
Miscellaneous cereals	0.18	0.58	0.12	0.39	0.12	0.39	0.42	1.4
Nuts	0.0046	0.020	0.0077	0.033	0.0046	0.020	0.017	0.073
Offal	0	0	0	0	0	0	0	0
Other veg	0.037	0.13	0.037	0.13	0.037	0.13	0.11	0.39
Potatoes	0.035	0.13	0.035	0.13	0.035	0.13	0.11	0.39
Poultry	0.010	0.045	0.010	0.045	0.010	0.045	0.031	0.14
Sugars	0.0076	0.046	0.0038	0.023	0.0076	0.046	0.019	0.12
Total	1.53	3.2	0.90	1.8	0.95	1.8	3.4	6.8

Sum = sum of $\alpha + \beta + \gamma$

Food Group	≥15 - <18 Months – HBCDD Exposure (ng/kg bw/d) (UB)							
	α		β		γ		Sum	
	Mean	97.5	Mean	97.5	Mean	97.5	Mean	97.5
Bread	0.085	0.23	0.057	0.15	0.085	0.23	0.23	0.61
Canned veg	0.016	0.077	0.016	0.077	0.016	0.077	0.049	0.23
Carcase meat	0.30	1.5	0.012	0.060	0.012	0.060	0.32	1.6
Dairy products	0.26	1.1	0.17	0.75	0.17	0.75	0.61	2.6
Eggs	0.0070	0.037	0.0070	0.037	0.0070	0.037	0.021	0.11
Fats and oils	0.050	0.19	0.0095	0.035	0.016	0.058	0.076	0.28
Fish	0.070	0.35	0.0087	0.044	0.0087	0.044	0.087	0.44
Fresh fruit	0.070	0.20	0.070	0.20	0.070	0.20	0.21	0.60
Fruit products	0.085	0.56	0.042	0.28	0.064	0.42	0.19	1.3
Green veg	0.011	0.042	0.011	0.042	0.011	0.042	0.033	0.13
Meat products	0.12	0.54	0.024	0.11	0.024	0.11	0.16	0.76
Milk	0.26	0.64	0.26	0.64	0.26	0.64	0.79	1.9
Miscellaneous cereals	0.22	0.61	0.14	0.41	0.14	0.41	0.51	1.4
Nuts	0.0021	0.019	0.0035	0.032	0.0021	0.019	0.0077	0.071
Offal	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Other veg	0.038	0.13	0.038	0.13	0.038	0.13	0.12	0.38
Potatoes	0.033	0.11	0.033	0.11	0.033	0.11	0.10	0.32
Poultry	0.012	0.050	0.012	0.050	0.012	0.050	0.035	0.15
Sugars	0.011	0.057	0.0057	0.029	0.011	0.057	0.029	0.14
Total	1.6	3.1	0.93	1.6	0.99	1.7	3.6	6.4

Sum = sum of $\alpha + \beta + \gamma$

Food Group	≥18 - <24 Months – HBCDD Exposure (ng/kg bw/d) (UB)							
	α		β		γ		Sum	
	Mean	97.5	Mean	97.5	Mean	97.5	Mean	97.5
Bread	0.090	0.20	0.060	0.14	0.090	0.20	0.24	0.54
Canned veg	0.028	0.11	0.028	0.11	0.028	0.11	0.085	0.33
Carcase meat	0.33	1.7	0.013	0.068	0.013	0.068	0.36	1.8
Dairy products	0.29	1.3	0.19	0.88	0.19	0.88	0.67	3.1
Eggs	0.0052	0.029	0.0052	0.029	0.0052	0.029	0.016	0.088
Fats and oils	0.068	0.22	0.013	0.041	0.021	0.068	0.10	0.33
Fish	0.092	0.37	0.011	0.046	0.011	0.046	0.11	0.46
Fresh fruit	0.08	0.22	0.085	0.22	0.085	0.22	0.25	0.67
Fruit products	0.19	0.73	0.095	0.37	0.14	0.55	0.43	1.6
Green veg	0.010	0.057	0.010	0.057	0.010	0.057	0.029	0.17
Meat products	0.14	0.65	0.028	0.13	0.028	0.13	0.20	0.91
Milk	0.25	0.77	0.25	0.77	0.25	0.77	0.74	2.3
Miscellaneous cereals	0.23	0.46	0.16	0.30	0.16	0.30	0.55	1.1
Nuts	0.0011	0.0016	0.0019	0.0027	0.0011	0.0016	0.0041	0.0058
Offal	0.00	0.00	0.00	0.00	0.00	0.00	0.000	0.00
Other veg	0.024	0.070	0.024	0.070	0.024	0.070	0.071	0.21
Potatoes	0.034	0.070	0.034	0.070	0.034	0.070	0.10	0.21
Poultry	0.014	0.042	0.014	0.042	0.014	0.042	0.041	0.13
Sugars	0.013	0.064	0.007	0.032	0.013	0.064	0.034	0.16
Total	1.9	3.9	1.0	1.7	1.1	1.9	4.0	7.5

Sum = sum of $\alpha + \beta + \gamma$

Food Group	≥24 - <60 Months – HBCDD Exposure (ng/kg bw/d) (LB-UB)							
	α		β		γ		Sum	
	Mean	97.5	Mean	97.5	Mean	97.5	Mean	97.5
Bread	0.10	0.24	0.068	0.16	0.10	0.24	0.27	0.64
Canned veg	0.017	0.067	0.017	0.067	0.017	0.067	0.052	0.20
Carcase meat	0.20	1.1	0.0080	0.043	0.0080	0.043	0.22	1.2
Dairy products	0.17	0.61	0.11	0.41	0.11	0.41	0.39	1.4
Eggs	0.0054	0.030	0.0054	0.030	0.0054	0.030	0.016	0.091
Fats and oils	0.061	0.20	0.011	0.038	0.019	0.063	0.091	0.30
Fish	0.070	0.27	0.0088	0.034	0.0088	0.034	0.088	0.34
Fresh fruit	0.061	0.16	0.061	0.16	0.061	0.16	0.18	0.49
Fruit products	0.17	0.83	0.086	0.42	0.13	0.62	0.39	1.9
Green veg	0.010	0.040	0.010	0.040	0.010	0.040	0.029	0.12
Meat products	0.17	0.57	0.034	0.11	0.034	0.11	0.24	0.79
Milk	0.17	0.50	0.17	0.50	0.17	0.50	0.52	1.5
Miscellaneous cereals	0.19	0.45	0.13	0.30	0.13	0.30	0.44	1.1
Nuts	0.0034	0.048	0.0057	0.080	0.0034	0.048	0.012	0.17
Offal	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Other veg	0.027	0.087	0.027	0.087	0.027	0.087	0.080	0.26
Potatoes	0.032	0.090	0.032	0.090	0.032	0.090	0.10	0.27
Poultry	0.011	0.049	0.011	0.049	0.011	0.049	0.034	0.15
Sugars	0.019	0.082	0.010	0.041	0.019	0.082	0.049	0.20
Total	1.5	2.7	0.81	1.3	0.90	1.6	3.2	5.6

Sum = sum of $\alpha + \beta + \gamma$

TOX/2016/28 ANNEX D

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

Review of potential risks from hexabromocyclododecanes (HBCDDs) in the diet of infants and 1 to 5 year old children

Exposures to hexabromocyclododecanes in infants and 1 to 5 year old children.

Maurice N, Olry JC, Cariou R, Dervilly-Pinel G, le Bizec B, Travel a, Jondreville C and Schroeder H. Short term effect of a perinatal exposure to the HBCDD a-isomer in rats: Assessment of early motor and sensory development, spontaneous locomotor activity and anxiety in pups. Neurotoxicol Teratol. 2015 Nov-Dec:52(Pt B): 170-80. doi: 10.1016/j.ntt.2015.08.005. Epub 2015 Sep 5.

Sent as a separate file not for publication on the web.

Secretariat
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