SUPPLEMENTAL FILE 1:
HUMAN BIOMONITORING DATA

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The summaries below are taken from primary data sources with reliability ratings of 1, 2 or 4 (OECD, 2003).[1]

1 TBBPA

1.1 Measured Concentrations in Human Milk

Measured concentrations of TBBPA in human milk, extracted from four sources, are summarized below and tabulated in Table S1-1.

Europe

Pratt et al. (2013) investigated the levels of TBBPA and other brominated flame retardants in the human milk of 109 primiparous mothers in Ireland. Eleven pooled samples were collected in 2010 from the mothers at four collaborating centers across Ireland. The participants had a mean age of 32.7 years and a mean BMI of 23.3. All of the mothers had resided in Ireland for at least five years and the majority reported having a mixed diet. Data results were presented as upper-bound (UB) and lower-bound (LB) concentrations, which assumes non-detected compounds are present at the LOD or at zero, respectively. Investigators detected TBBPA above the LOD in two of the 11 pooled samples. Reported UB concentrations ranged from <0.29 to 0.17 ng/g fat weight (0.33 ng/g fat weight mean) and the LB mean concentration was reported as 0.05 ng/g fat weight (Note: possible reporting error in the UB concentrations for the highest value reported). Due to the limited dietary information collected from the mothers and because the samples were pooled, no direct relationship between the diet of the mothers and the occurrence of TBBPA or the other brominated flame retardants can be established.

TBBPA was measured in human milk and other biological samples (maternal and cord serum, and maternal adipose tissue) collected from 93 women (mean age 32.5 years) who had been hospitalized in Toulouse, France during the period November 2004 to September 2006 (Cariou et al., 2008). The milk was collected on the third and fourth day following childbirth at the hospital. Due to insufficient amount of sample for human milk, the experimenters analyzed 77 samples. In human milk, TBBPA was detected in 34 of the analyzed samples, at levels ranging from <LOD to 37.34 ng/g lipid weight (4.11 ng/g lipid weight mean; 0.48 ng/g lipid weight median).

Asia

Levels of TBBPA and other brominated flame retardants were measured in the human milk of primiparous mothers in two studies conducted in China. In the more recent study (Shi et al., 2013), 103 samples were collected within 3 to 40 weeks of childbirth by mothers living in urban and suburban

[1]For a rating of 1, the study should have a valid analytical method, data should be representative, statistical analysis could be conducted, and sampling (location, time period, matrix) should be adequate. For a rating of 2, three criteria from the rating of 1 should be met, excluding the requirement for conducting statistical analyses. A rating of 4 indicates that measurements are available but data are limited and reliability cannot be judged (OECD, 2003).

Beijing between January and August 2011. The mothers followed strict protocols when collecting their own samples. All mothers had resided in the area from half a year to more than 5 years. Ninety-five of the participants were primiparous and had a mean age of 30.1 years and a mean BMI of 22.7. Personal information such as dietary habits and socioeconomic and lifestyle factors was also recorded for all of the participants. None of the participants had occupational exposure to brominated flame retardants. TBBPA was found in 55 samples in concentrations ranging from <LOD to 12.46 ng/g lipid weight. The mean and median concentrations were 0.41 and 0.10 ng/g lipid weight, respectively. The authors found no significant correlation between brominated flame retardant levels in the milk and the mothers' diet, place of residence, smoking habit, nursing duration or computer use habit.

In an earlier study conducted by Shi et al. (2009), TBBPA and other brominated flame retardants were measured in 24 pooled human milk samples collected in 2007 from 12 provinces in China (12 urban and 12 rural areas). The samples were collected from 1,237 primiparous mothers within 3 to 8 weeks after childbirth. Each participant had resided in her home for more than five years. Similar to the later study, personal information such as occupation, diet, age, and smoking habits was also recorded. None of the participants had occupational exposure to brominated flame retardants. TBBPA was found in 10 of the urban pooled samples and in 9 of the rural pooled samples in concentrations ranging from <LOD to 5.12 ng/g lipid weight and <LOD to 4.46 ng/g lipid weight, respectively. The mean concentration for the urban pooled samples was 0.93 ng/g lipid weight and 0.96 ng/g lipid weight for the rural pooled samples.

Table S1-1. Measured Concentrations of TBBPA in Human Milk

Location	Population	Year	N (# of ND)[a]	TBBPA Concentration (ng/g lipid weight)		Comments	Reference (Reliability Rating[d])
				Range[b]	Central Tendency[c]		
Europe							
Ireland; (Four collaborating centers across country)	109 Primiparous-mothers with a mean age of 32.7 years, BMI of 23.3, the majority with a mixed diet, and at least 5 years residence.	2010	11 (9) (pooled samples)	<0.29 – 0.17[e] (upper bound)	0.33[e] mean (upper bound) 0.05[e] mean (lower bound)	Due to limited dietary information and the pooling of samples, no direct relationship between occurrence and diet can be established.	Pratt et al. (2013) (4)
France; Toulouse hospital	93 Women with a mean age of 32.5 years.	2004 - 2006	77 (43)	<LOD – 37.34	4.11 mean; 0.48 median	Samples collected 3rd and 4th day following childbirth. LOD not reported.	Cariou et al. (2008) (4)
Asia							
China; Beijing (Urban and suburban)	103 Mothers (95 primiparous) with a mean age of 30.1 years, BMI of 22.7, mixed diet, and 6 months to more than 5 years residence.	2011	103 (48)	<LOD – 12.46	0.41 mean; 0.10 median 5th, 25th, 75th, and 95th percentiles also reported.	Samples collected within 3 to 40 weeks after childbirth. Mothers had no occupational exposure to BFRs and followed strict protocols when collecting samples at home. Personal information such as dietary habit and socioeconomic and lifestyle factors was recorded. LOD reported in supplemental information as 0.06 ng/g (unadjusted for lipid weight).	Shi et al. (2013) (1)
China; 12 provinces (Urban and rural areas)	1237 Primiparous mothers with more than 5 years residence	2007	Urban: 12 (2) Rural : 12 (3) (pooled samples)	Urban: <LOD – 5.12 Rural: <LOD – 4.46	Urban: 0.93 mean Rural: 0.96 mean	Samples collected within 3 to 8 weeks after childbirth. Mothers had no occupational exposure to BFRs. Personal information such as occupation, diet, and smoking habits was recorded. LOD not reported.	Shi et al. (2009) (2)

[a] N refers to the number of samples, unless otherwise noted. The number of non-detect values is reported in parenthesis. Values "<X" are assumed to be non-detect.

[b] The range is the minimum and maximum values reported. Non-detect values are shown as less than the detection limit.

[c] The central tendency values shown are as reported in the reference.

[d] Reliability rating: 1 = valid without restrictions; 2 = valid with restrictions; 4 = not assignable.

[e] Potential error in values reported in published article.

1.2 Measured Concentrations in Human Adipose Tissue, Blood and Hair

Measured concentrations of TBBPA in human adipose tissue, blood and hair were extracted from twelve sources and are summarized below and tabulated in Table S1-2.

North America

Johnson-Restrepo et al. (2008) investigated the concentrations of TBBPA (and HBCDs) in human adipose tissue, as well as in the tissues of dolphins and sharks from the United States (see Appendix E). The human adipose tissues were collected in New York City during 2003-2004 from twenty patients (16 women and 4 men) who had undergone liposuction surgery. The participants had a mean age of 32.5 years and were of various ethnicities (10 Caucasians, 9 Hispanics, and 1 African American). TBBPA was above the limit of quantification of 0.0033 ng/g lipid weight in 69% of the samples analyzed. Concentrations ranged from <0.0033 to 0.464 ng/g lipid weight (0.0479 ng/g lipid weight mean; 0.0152 ng/g lipid weight median). The authors found no significant correlation between concentrations of TBBPA and the age, gender or ethnicity of the participants. However, it should be noted that the number of samples analyzed is small.

TBBPA and other brominated organic compounds were measured in human hair samples, as well as environmental samples, obtained from approximately 40 individuals at three barber shops in El Dorado, Arkansas in 1977 (Pellizzari et al., 1978). Composites of human hair from each of the barber shops were analyzed as three separate samples in order to obtain enough material for analysis. At the time of this study, El Dorado was located in a geographic area associated with organo-bromide production facilities. TBBPA was confirmed in one of the three composite samples at a concentration of 2.0 ng/g. Interferences prevented confirmation of TBBPA in either of the other two composites.

The blood serum of pregnant women living in all regions of Alberta, Canada was monitored in 2005 for priority environmental contaminants, including TBBPA (Alberta_Health_Wellness, 2008). The objective was to examine the influence of age, geographic location, and seasonality on maternal serum concentrations of chemicals that women may be exposed to from food, drinking water, air, soil, household dust, or commercial products. A total of 28,484 individual samples were randomly selected from 44,584 samples stratified by geographic region, age group, and month of receipt. The samples were then pooled (n=158) before analysis. TBBPA concentrations were <0.03 ng/g serum (LOD) in all of the samples analyzed.

In 2004, Dallaire et al. (2009) determined the concentrations of TBBPA and other compounds (PFOS and brominated organic compounds) in the blood plasma of 883 Nunavik Inuit adults living in the Canadian Arctic (northern region of Quebec). Demographic, lifestyle, and dietary information were also collected. The participants (men and women) had a mean age of 38 years and a BMI of 27.4. Most of the participants were smokers (83%), overweight (55%), and had consumed marine mammals (97%) during the preceding year. TBBPA was detected in a small proportion (5%) of the 771 samples analyzed at concentrations ranging from <LOD to 82.6 ng/g lipid weight The authors concluded that that the

geographical location and traditional lifestyle of the Nunavik Inuit population do not protect them from exposure to emerging POPs, particularly PFOS, which was found in 100% of the samples analyzed.

Europe

Kicinski et al. (2012) investigated the levels of TBBPA and other brominated flame retardants in the blood serum of 515 high school students (13.6 to 17 years of age) as part of a biomonitoring program for environmental health surveillance in Flanders, Belgium. The participants were recruited between 2008 and 2011 in two industrial areas using a random sampling design. TBBPA concentrations in blood serum samples ranged from <LOQ (<0.015 µg/L) to 0.186 µg/L (weight type not reported). Both median and 75th percentiles were below LOQ; the 95th percentile was 0.022 µg/L.

Dirtu et al. (2008) optimized and validated an analytical method for simultaneous determination of TBBPA, bisphenol A (BPA) and triclosan (TCS) in human serum using solid-phase extraction (SPE) and gas chromatography coupled to electron-capture negative-ionization mass spectrometry (GC-ECNI/MS). The method was applied to 21 serum samples collected in Belgium. All samples were collected as part of other studies, and consisted of seven individual serum samples collected in 2007 (three males and four females, age 23 to 45 years) and fourteen pooled serum samples collected in 1999 (all females, age 55 to 60 years). All samples were assumed to be from background exposed individuals. TBBPA was detected at median concentrations of 0.08±0.02 µg/L serum in the seven individual samples and 0.09±0.03 µg/L serum in the fourteen pooled samples. The authors did not present concentration ranges. The limit of detection was 0.05 µg/L. Acceptable method recovery was achieved.

In the Cariou et al. (2008) study conducted between 2004 and 2006 in Toulouse, France. The investigators collected biological samples from women who were hospitalized following child birth. TBBPA levels were below the LOD to 93.22 ng/g lipid weight in maternal blood (N=91), <LOD to 649.45 ng/g lipid weight in cord blood (N=90), and all <LOD in adipose tissue (N=44). The limit of detection was not reported. Reported mean and median concentrations, respectively, were 19.87 and 16.14 ng/g lipid weight for maternal blood and 103.52 and 54.76 ng/g lipid weight for cord blood. The mean and median values appear to be calculated only from detected levels of TBBPA (29 of 91 maternal blood samples and 27 of 90 cord blood samples).

Peters (2005) investigated the concentrations of TBBPA and other environmental contaminants in maternal and cord blood serum samples. Forty-two maternal blood samples and 27 cord blood samples were obtained from the Academic Hospital of Groningen in the Netherlands and analyzed for TBBPA, phthalates, musk compounds, alkylphenols, organochlorine pesticides, triclosan and perfluorinated compounds. No information was provided on sampling procedures or the volunteers who provided the blood samples. TBBPA was detected above the MDL (0.05 ng/g) in 9 samples of maternal blood at concentrations ranging from 0.06 to 0.19 ng/g serum. TBBPA was found in only one cord blood serum sample at a concentration of 0.05 ng/g.

In 2003, blood samples were collected from 47 volunteers living in 17 European countries (WWF, 2004). The samples were analyzed for 101 predominantly persistent, bioaccumulative and toxic man-made chemicals, including TBBPA. All of the volunteers were citizens of European countries and lived and worked in Europe. The volunteers included men (51%) and women (49%) who had a median age of

52 years. Lifestyle and personal data were also collected such as nationality, weight change, and recent purchase of consumer products likely to contain brominated flame retardants. TBBPA was detected in 27 of the 40 samples. The range of concentrations was <LOD to 0.33 ng/g blood (0.036 ng/g blood median). The author reported that the maximum concentration of TBBPA was roughly 10 times higher than that found in previous studies in Europe. In addition, the authors found no significant correlation between concentrations of TBBPA and lifestyle and personal data. A significant correlation was found for other chemicals.

To evaluate temporal trends and the role of age and gender on concentrations of TBBPA and other brominated flame retardants, Thomsen et al. (2002) analyzed archived serum samples collected from men aged 40-50 years between 1977 and 1999 and from different gender and age groups in 1998. The serum samples, obtained from a serum bank at the National Institute of Public Health in Norway, had been collected from patients at five county hospitals and stored at -20 °C until analysis. The serum samples from the 40- to 50-year old men, collected at six time periods from 1977 to 1999, were pooled into six samples, one for each sampling period, for analysis. The 1998 serum samples had been divided into eight gender/age groups at the serum bank. For the study, samples from 10 to 14 individuals from each gender/age group were pooled into one sample for a total of eight pooled samples.

The results show that TBBPA concentrations in serum from men aged 40-50 years increased during the sampling period 1977 to 1999 (Thomsen et al., 2002). TBBPA was not detected in the pooled samples collected in 1977 and 1981. The pooled samples from men aged 40-50 years collected in 1986, 1990, 1995, and 1999 had TBBPA concentrations of 0.44, 0.42, 0.59, and 0.65 ng/g (lipid weight), respectively. In the 1998 pooled serum samples, the concentration of TBBPA in the serum from the group aged 0-4 years was higher (0.71 ng/g lipid weight) than that of the other age groups (range: 0.31-0.65 ng/g lipid weight). For the age groups 15-24 years and 25-59 years, TBBPA concentrations in serum were lower in women (0.34-0.40 ng/g lipid weight) than in men (0.56-0.65 ng/g lipid weight). Men older than 60 years of age had lower TBBPA serum concentrations (0.31 ng/g lipid weight) compared to the corresponding group of females (0.42 ng/g lipid weight).

Concentrations of TBBPA and other brominated flame retardants were measured in three occupational groups in Norway: electronic dismantlers, circuit board producers, and laboratory personnel (Thomsen et al., 2001). The group of five female laboratory personnel (mean age 46 years) was designated as the non-occupationally exposed group. Even though their daily routine involved computer work, their contact time with computers was assumed to be comparable to that of the general Norwegian population. TBBPA concentrations in blood plasma samples obtained from laboratory personnel ranged from <LOQ (0.0004) to 0.52 ng/g lipid weight; the mean plasma concentration of TBBPA was 0.34 ng/g lipid weight. In the electronics dismantlers, TBBPA in plasma ranged from 0.64 to 1.8 ng/g lipid weight, with a mean concentration of 1.3 ng/g. In the circuit board producers, TBBPA was < LOQ to 0.80 ng/g lipid weight, and the mean value was 0.54 ng/g.

Asia

In a Japanese study, Nagayama et al. (2000) analyzed 14 blood samples collected in 1998 from a pool of 24 men and women with a mean age of 43.9 years. The authors detected TBBPA in 8 samples, with levels that ranged from ND to 3.70 ng/g lipid weight. Reported mean and median concentrations were 1.352 and 0.915 ng/g lipid weight, respectively.

Table S1-2. Measured Concentrations of TBBPA in Human Adipose Tissue, Blood and Hair

Location	Population	Year	Media	N (# of ND)[a]	TBBPA Concentration		Comments	Reference (Reliability Rating[d])
					Range[b]	Central Tendency[c]		
North America								
United States New York City (Urban)	16 Women and 4 men with a mean age of 32.5 years and various ethnicity (10 Caucasian, 9 Hispanic, and 1 African American)	2003-2004	Adipose Tissue	20 (31%)	<0.0033-0.464 ng/g lw	0.0479 ng/g lw mean; 0.0152 ng/g lw median	Samples collected from patients who had undergone liposuction surgery. Personal information such as ethnicity and occupation was recorded.	Johnson-Restrepo et al. (2008) (1)
United States El Dorado, AR (Industrial)	Approximately 40 individuals at 3 barber shops	1977	Hair	3 (2)[e] (composite samples)	2.0 ng/g[e]	NR	Samples collected in vicinity of organo-bromide production facilities.	Pellizzari et al. (1978) (2)
Canada Alberta	28,484 Pregnant women with ages ranging from <25 to >31 years	2005	Blood serum	158 (158) (pooled samples)	<0.03 ng/g	--	A total of 28,484 samples was randomly selected from 44,584 samples stratified by geographic region, age group, and month of receipt. Samples were then pooled.	Alberta_Health_Wellness (2008) (2)
Canada 14 communities in Nunavik, northern region of Quebec (Canadian Arctic)	883 Inuit adults (men and women) with a mean age of 38 years, BMI of 27.4, smokers (83%), and marine mammal consumers (97%)	2004	Blood plasma	771 (95%)	<LOD – 82.6 ng/g lw	NR	Personal information such as demographics, lifestyle habits, and nutrition was recorded. LOD=10 ng/L	Dallaire et al. (2009) (4)
Europe								
Belgium; Flanders	515 Adolescents, age 13.6 to 17 years	2008-2011	Blood serum	NR	<0.015-0.186 µg/L	<0.015 µg/L median (75th and 95th percentiles of <0.015 and 0.022 µg/L, respectively)	Samples collected in two industrial areas. No association between TBBPA levels and performance in neurobehavioral tests.	Kicinski et al. (2012) (2)

Table S1-2. Measured Concentrations of TBBPA in Human Adipose Tissue, Blood and Hair

Location	Population	Year	Media	N (# of ND)[a]	TBBPA Concentration		Comments	Reference (Reliability Rating[d])
					Range[b]	Central Tendency[c]		
Belgium	Adults, age 23 to 45 years	2007	Blood serum	7 (NR)	NR	0.08±0.02 µg/L median	Background exposed. Individual samples collected from other studies.	Dirtu et al. (2008) (4)
	Females, age 55 to 60 years	1999	Blood serum	14 (NR)	NR	0.09±0.03 µg/L median	Background exposed. Pooled samples collected from other studies.	
France; Toulouse hospital	93 Women with a mean age of 32.5 years	2004 - 2006	Maternal blood serum	91 (62)	<LOD-93.22 ng/g lw	19.87±24.15 ng/g lw mean; 16.14 ng/g lw median[f]	Volunteers were hospitalized for caesarean deliveries. LOD not reported.	Cariou et al. (2008) (4)
			Cord blood serum	90 (63)	<LOD-649.45 ng/g lw	103.52±149.73 ng/g lw mean; 54.76 ng/g lw median[f]		
			Adipose tissue	44 (44)	All <LOD	--		
The Netherlands	NR	2005	Maternal blood serum	42 (33)	<0.05-0.19 ng/g	<0.05 ng/g median	Samples were obtained from the Academic Hospital of Groningen; no information was provided on sampling procedures or the population sampled.	Peters (2005) (2)
			Cord blood serum	27 (26)	<0.05-0.05 ng/g	<0.05 ng/g median		
Europe (17 countries)	40 Volunteers (51% men and 49% women) with a median age of 52 years[g] and a median BMI of 24.8	2003	Blood (whole)	40 (13)	<LOD – 0.33 ng/g	0.036 ng/g median	Personal information such as nationality, diet, residence, and recent purchase of consumer products likely to contain BFRs was recorded. Countries include: Austria, Belgium, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, the Netherlands, Poland, Spain, Sweden, and the UK. LOD not reported. 25th and 75th percentiles also reported.	WWF (2004)(4)
Norway, five county hospitals	Males, age 40-50 years	1977-1999	Blood serum	6 (2)	<LOD – 0.65 ng/g lw	NR	Samples were collected at six time periods; serum samples from between 17 to 34 individuals for	Thomsen et al. (2002) (2)

Table S1-2. Measured Concentrations of TBBPA in Human Adipose Tissue, Blood and Hair

Location	Population	Year	Media	N (# of ND)[a]	TBBPA Concentration		Comments	Reference (Reliability Rating[d])
					Range[b]	Central Tendency[c]		
							each time period were pooled into one sample for a total of 6 samples. LOD not reported.	
	Various gender/age groups[h]	1998	Blood serum	8 (0)	0.31-0.71 ng/g lw	NR	Samples from 10 to 14 individuals from each gender/age group were pooled into one sample for a total of eight samples.	
Norway	Laboratory personnel; females with a mean age of 46 years	2001	Blood plasma	5 (NR)	<0.0004 - 0.52 ng/g lw	0.34 ng/g lw mean	Designated as non-occupationally exposed; contact time with computers was assumed to be comparable to that of the general Norwegian population	Thomsen et al. (2001) (2)
Asia								
Japan	24 Adults (12 male and 12 female) with a mean age of 43.9 years.	1998	Blood	14 (6)	ND-3.70 ng/g lw	1.352 ng/g lw mean; 0.915 ng/g lw median	Detection limit not reported.	Nagayama et al. (2000) (4)

NR=Not reported

[a] N refers to the number of samples, unless otherwise noted. The number of non-detect values is reported in parenthesis. Values reported as "<X" are assumed to be non-detect.

[b] The range is the minimum and maximum values reported. Non-detect values are shown as less than the detection limit.

[c] The central tendency values shown are as reported in the reference.

[d] Reliability rating: 1 = valid without restrictions; 2 = valid with restrictions; 4 = not assignable.

[e] Concentration confirmed for one sample; unconfirmed levels in remaining two samples due to interferences.

[f] The mean and median values reported in Cariou et al. (2008) appear to be based on the quantifiable levels only.

[g] Age based on total number of volunteers studied (47), of which 24 were male and 23 female.

[h] Eight gender/age groups: males/females 0-4 years old; males/females 4-14 years old; females 15-24 years old; males 15-24 years old; females 25-59 years old; males 25-59 years old; females >60 years old; and males >60 years old.

2 TBBPA-bis(methyl ether)

EPA/OPPT identified only one reference to biomonitoring data in a Japanese study of TBBPA-bis(methyl ether). The compound was not detected in five adipose tissue samples in Japan in 1989, with a detection limit of 20 µg/kg, as cited in EC (2008a).

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