Exposures - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food

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92. Most of the exposures calculated in the sections below are for individual PFASs. Exposures for the rest of the diet were calculated by EFSA (2020) and are for a sum of the four PFASs (PFOS, PFOA, PFHxS and PFNA). The estimated exposures have been calculated from small datasets.

93. The COT noted that the estimates are conservative. Furthermore, the dataset from Spain may have skewed overall estimates.

Dietary

Breast milk

Exposure calculation by EFSA (EFSA, 2020)

94. EFSA calculated exposures from breast milk. Infants with the greatest exposures via breast milk are those less than 6 months of age. EFSA used a median age of 3 months with an equivalent body weight of about 6.1 kg. Estimated average and high daily milk consumption of about 800 mL and 1,200 mL; respectively were used. Levels in milk have been investigated but were often below the LOQs of the method.

95. However, some studies determined the ratio between milk levels and maternal serum levels. These were approximately 0.015 for PFOS and 0.03 for PFOA. Based on the mean serum levels in adults of 7.5 ng/mL for PFOS and 2.1 ng/mL for PFOA, this would result in milk levels of 0.113 and 0.063 ng/mL,

respectively.

96. For PFOS, a daily average and high consumption of 800 or 1,200-mL milk (EFSA NDA Panel, 2013) would result in an intake of 90 and 135 ng PFOS per day or, respectively, 15 and 22 ng/kg bw per day (103 and 155 ng/kg bw per week). For PFOA, the daily intake for average and high consumers would be 50 and 76 ng, or, respectively, 8 and 12 ng/kg bw per day (58 and 87 ng/kg bw per week).

Exposure calculation by the COT

97. A literature search was carried out for concentrations of PFASs in human breast milk. There were no UK data. Only data from countries in the EU with breast milk samples taken after 2008 were considered. Only those that had median and/or maximum values were included in the exposure calculations. Tables 1 to 4 in Annex A show PFOS, PFOA, PFHxS and PFNA breast milk concentration data and study information. Averages of the median and maximum values were calculated for each of the 4 PFASs (Tables 5 and 6, Annex B) which were used to calculate exposures for infants aged 0 - 4 months and 4 - 6 months (Table 1).

98. For the average median PFASs concentrations in breast milk the following ranges of exposures were calculated which included average and high consumers:

- PFOS: 38 – 75 ng/kg bw per week
- PFOA: 40 – 80 ng/kg bw per week
- PFHxS: 12 – 24 ng/kg bw per week
- PFNA: 14 – 27 ng/kg bw per week

99. For the average maximum PFASs concentrations in breast milk the following ranges of exposures were calculated which included average and high consumes:

- PFOS: 20 – 240 ng/kg bw per week
- PFOA: 30 – 260 ng/kg bw per week
- PFHxS: 22 – 43 ng/kg bw per week
- PFNA: 37 – 73 ng/kg bw per week

100. The average exposures were similar to those calculated by EFSA from serum levels. Exposures for high concentrations of PFOS and PFOA in breast milk were not calculated by EFSA because the available data were deemed

insufficient to estimate exposures (EFSA, 2020).

Table 1. Estimated PFOS, PFOA, PFHxS and PFNA exposure (ng/kg bw per week) in 0 to 6-month-old infants from breast milk.

Exposure (ng/kg bw/week)	**0 to 4 months (800 mL)**	**0 to 4 months (1,200 mL)**	**4 to 6 months (800 mL)**	**4 to 6 months (1,200 mL)**
PFOS concentration 53 ng/L	50	75	38	57
PFOS concentration 170 ng/L	160	240	120	180
PFOA concentration 56 ng/L	53	80	40	60
PFOA concentration 180 ng/L	170	260	130	190
PFHxS concentration 17 ng/L	16	24	12	18
PFHxS concentration 30 ng/L	28	43	22	32
PFNA concentration 19 ng/L	18	27	14	20
PFNA concentration 51 ng/L	48	73	37	55

Exposure values were calculated based on default consumption values of 800 and 1200 mL for average and high-level exclusive consumption of breast milk and expressed on a bodyweight (5.9 kg for infants aged 0-4 months and 7.8 kg for infants aged 4 to 6 months) basis.

Rest of the diet

101. The EFSA Opinion included UK data both on occurrence and consumption. The UK specific data and exposures for the sum of the four PFASs (Table 1 and Annex B) are within, and towards the lower end of the range of data from the EU. The data for the UK use the National Diet and Nutrition Survey (NDNS) data (years 1-3) for consumption data for toddlers, other children, adolescents, adults, elderly and the very elderly. Consumption data from the Diet and nutrition survey in infants and young children (DNSIYC) was used to calculate exposures for infants and toddlers. The calculated exposures are shown in Table 2.

102. Exposures of infants were calculated to be 61 and 590 ng/kg bw per week for LB and UB mean consumers and 110 and 870 for LB and UB 95th percentile consumers. There are 2 sets of data for toddlers, one set using NDNS data and the other data from DNSIYC. Using the DNSIYC data toddler exposures were calculated as 29 and 460 ng/kg bw per week for LB and UB mean consumers and 74 and 770 ng/kg bw per week for LB and UB 95th percentile consumers, respectively. Generally, exposures calculated from the NDNS data are lower than those calculated from the DNSIYC data. Exposure estimates are 17 and 450 ng/kg bw per week for LB and UB mean consumers and 45 and 850 ng/kg bw per week for LB and UB 95th percentile consumers.

103. Exposures for other children were calculated to be 9.7 and 330 ng/kg bw per week for LB and UB mean consumers and 27 and 640 ng/kg bw per week for LB and UB 95th percentile consumers.

104. Adolescent exposures had been calculated and were 3.2 and 150 ng/kg bw per week for LB and UB mean consumers and 10 and 350 ng/kg bw per week for LB and UB 95th percentile consumers.

105. Exposures had also been calculated for adults, the elderly and the very elderly. Ranges for LB and UB mean consumers were 4.3 – 5.6 and 97 and 110 ng/kg bw per week, respectively. For LB and UB 95th percentile consumers, exposures were calculated as 13 – 15 and 200 – 220 ng/kg bw per week, respectively.

Table 2. Mean and 95th percentile(a) chronic exposures to the 4 PFASs (ng/kg bw per week) for total population.

Survey	Age	Number of subjects	LB Mean exposure	UB Mean exposure	LB 95th Exposure	UB 95th Exposure
NDNS years 1-3	Toddlers	185	17	450	45	850
NDNS years 1-3	Other children	651	9.7	330	27	640
NDNS years 1-3	Adolescents	666	3.2	150	10	350
NDNS years 1-3	Adults	1266	4.3	97	13	200
NDNS years 1-3	Elderly	166	5.5	100	14	210
NDNS years 1-3	Very elderly	139	5.6	110	15	220
DNSIYC 2011	Infants	1369	61	590	110	870

DNSIYC 2011	Toddlers	1314	29	460	74	770

Drinking water

106. Drinking water is not routinely monitored for PFASs, but the Drinking Water Inspectorate (DWI) specifies that water companies should ensure that PFOS and PFOA are adequately addressed in their risk assessments, and that if appropriate, they should consider initiating monitoring for PFASs at their works. The DWI has established a tiered approach for monitoring levels of PFOS and PFOA in drinking water. The DWI have considered other PFAS, however based on occurrence data and modelling, the main conclusion was that it was unlikely that individual PFAS would be detected at concentrations greater than 0.1 µg/L. If a water company detects PFAS other than PFOS or PFOA it is expected that a precautionary approach be adopted and the DWI informed (DWI, 2021).

107. The recently revised guidance on the Water Supply Regulations, 2016 established updated guidance levels which have been set for water companies to take increasing action for both PFOS and PFOA levels >0.01 µg/L, >0.1 µg/L and >1.0 µg/L (DWI, 2021). The value of 0.1 µg/L has been established as a trigger level for further action to reduce concentrations. It is a pragmatic value that is broadly in line with assessments made by other developed countries based on animal data. The corresponding previous values from 2009 were PFOS 1.0 µg/L and PFOA 5.0 µg/L and were based on the 2009 COT TDIs. The value of 0.01 µg/L is a concentration that can be reliably and accurately measured using modern analytical techniques and is a trigger for further monitoring (DWI, 2021).

108. In discussions with the DWI, it was suggested that the concentrations that should be used for PFOS and PFOA for drinking water derived from surface and ground water are:

- 5 ng/L for drinking water derived from surface water. This is about the typical level found in river water, which will of course be subject to treatment. Most surface water will receive granular activated carbon (GAC) treatment which is likely to reduce the concentration. 5 ng/L is therefore reasonably conservative.
- 10 ng/L PFOS and PFOA in ground water derived drinking water. There are fewer data, and some will receive GAC treatment. Companies have reported that currently all supplies are below 100 ng/L which would be very

conservative. Therefore, 10ng/L is reasonably conservative.

109. For other PFAS at present the data are relatively limited.

110. Chronic exposures were calculated with drinking water (including all tap and bottled water) using the values of 5 and 10 ng/L. Consumption data from NDNS years 1-8 (Bates et al., 2014; Bates et al., 2016; and Roberts et al., 2018) and DNSIYC (DH, 2013) were also used in the exposure calculations. All age groups were considered and include infants (4 - 18 months), toddlers (18 months – 3 years), children (4 – 10 years), adolescents (11 – 18 years), adults (19 – 64 years) and the elderly (65+ years).

111. Chronic mean exposures calculated for a PFAS concentration of 5 ng/l, as derived from surface water, across both NDNS and DNSIYC, ranged from 0.29 ng/kg bw per week (0.041 ng/kg bw per day) for consumers aged 65+ to 0.86 ng/kg bw per week (0.12 ng/kg bw per day) for toddlers (Table 3). Exposures calculated for 97.5th percentile consumers ranged from 0.85 ng/kg bw per week (0.12 ng/kg bw per day) for consumers aged 65+ to 2.5 ng/kg bw per week (0.35 ng/kg bw per day) for toddlers (Table 3).

112. Chronic mean exposures calculated with a PFAS concentration of 10 ng/L, as derived from ground water, across both NDNS and DNSIYC, ranged from 0.57 ng/kg bw per week (0.081 ng/kg bw per day) for consumers aged 65+ to 1.7 ng/kg bw per week (0.25 ng/kg bw per day) for toddlers (Table 4). Exposures calculated for 97.5th percentile consumers ranged from 1.7 ng/kg bw per week (0.24 ng/kg bw per day) for consumers aged 65+ to 4.9 ng/kg bw per week (0.71 ng/kg bw per day) for toddlers (Table 4).

Table 3. Exposure estimates (ng/kg bw per week) calculated with a PFAS concentration of 5 ng/L.

Age groups	**Mean**	**97.5th percentile**
Infants (4-18 months)	0.59	2.1
Toddlers (18 months – 3 years)	0.86	2.5

4 – 10 years	0.61	1.7
11 – 18 years	0.34	1.1
19 – 64 years	0.37	1.1
65+ years	0.29	0.85

Table 4. Exposure estimates (ng/kg bw per week) calculated with a PFAS concentration of 10 ng/L.

Age groups	**Mean**	**97.5th percentile**
Infants (4-18 months)	1.2	4.2
Toddlers (18 months – 3 years)	1.7	4.9
4 – 10 years	1.2	3.3
11 – 18 years	0.68	2.2
19 – 64 years	0.75	2.3
65+ years	0.57	1.7

Non-dietary

Dust and soil

113. No data were available on measured levels of PFOS in soil in the UK.

114. Levels of PFOS, PFOA, PFHxS and PFNA have been measured in indoor dust in UK (Birmingham) and European homes and was used to calculate exposures (Annex C).

115. Exposures from dust ingestion were calculated for median and high concentrations of PFOS, PFOA, PFHxS and PFNA and mean ingestion rates, for each UK population group (infants, toddlers, children, adolescents, adults and seniors).

116. For the average median PFASs concentrations in dust, the following ranges of exposures were calculated for all UK population groups for each of the compounds (Table 5):

- PFOS (59 ng/g): 0.014 – 1.9 ng/kg bw per week
- PFOA (66 ng/g): 0.015 – 2.1 ng/kg bw per week
- PFHxS (55 ng/g): 0.013 – 1.8 ng/kg bw per week
- PFNA (0.22 ng/g): 0.000051 – 0.0071 ng/kg bw per week

117. For the average maximum PFASs concentrations in dust, the following ranges of exposures were calculated for all UK population groups for each of the compounds (Table 5):

- PFOS (1300 ng/g): 0–30 – 42 ng/kg bw per week
- PFOA (660 ng/g): 0.15 – 21 ng/kg bw per week
- PFHxS (910 ng/g): 0.21 – 29 ng/kg bw per week
- PFNA (14 ng/g): 0.0032 – 0.45 ng/kg bw per week

118. For all PFASs considered, infants had the highest exposures and teenagers, adults and seniors had the lowest exposures.

Table 5. Estimated exposures for PFOS, PFOA, PFHxS and PFNA (ng/kg bw per week) for UK population groups.

Exposure (ng/g bw/week)	**Infants**	**Toddlers**	**Children**	**Teenagers**	**Adults**	**Seniors**
PFOS (59 ng/g)	1.9	1.1	0.43	0.014	0.014	0.014

PFOS (1300 ng/g)	42	23	9.4	0.32	0.30	0.31
PFOA (66 ng/g)	2.1	1.2	0.48	0.016	0.015	0.016
PFOA (660 ng/g)	21	12	4.8	0.16	0.15	0.16
PFHxS (55 ng/g)	1.8	0.99	0.40	0.013	0.013	0.013
PFHxS (910 ng/g)	29	16	6.6	0.22	0.21	0.22
PFNA (0.22 ng/g)	0.0071	0.0039	0.0016	0.000054	0.000051	0.000052
PFNA (14 ng/g)	0.45	0.25	0.10	0.0034	0.0032	0.0033

Mean dust ingestion rates: infants 36 mg/day; toddlers 41 mg/day; children 32 mg/day; teenagers 2.2 mg/day; adults and seniors 2.6 mg/day. Values are to 2 significant figures.

Food contact materials

119. EFSA concluded that “PTFE cookware may contain residual PFOA in the low µg/kg range, and food packaging may contain PFASs where they are used because of their grease-resistant properties. Studies conducted to date continue to support the conclusions reported in the previous Opinion (EFSA CONTAM Panel,

2018) that the use of this type of material is likely to contribute to human exposure to PFASs, but that the contribution is small compared with other sources of exposure.” (EFSA, 2020).

120. Some testing was carried out on total fluorinated content of selected UK supermarket and takeaway food packaging, by the environmental charity Fidra (Dinsmore, 2020). The specific test method used to determine the total fluorinated content of the selected packaging samples does not reflect the potential migration of the substance into the food it is in contact with. “To fully understand the direct health implications of PFAS in food packaging, more information is needed on the chemical migration levels, i.e., how much of the PFAS from food packaging is transferred to the food itself. This has not been addressed in this study and requires further resource to quantify” (Dinsmore, 2020).

121. The Food Standards Agency (FSA) has recently been made aware that the vast majority of paper packaging manufactured in the UK by Confederation of Paper Industry member companies does not use PFASs. PFASs are now predominantly used only in specialist packaging which has particular technical requirements such as moisture or grease resistance, like microwavable popcorn bags.

Air (indoor)

122. Concentrations of PFASs in indoor air generally exceed those of outdoor air and therefore exposure via inhalation is mainly due to indoor air (Harrad et al., 2010). Concentrations of PFASs in indoor air have been found to vary greatly between homes. (EFSA, 2020; Ericson Jogsten et al., 2012; Fromme et al., 2015, Haug et al., 2011). There are only 2 studies which have measured samples of PFOS, PFOA, PFHxS and/or PFNA in homes in the UK or Europe since 2008 (Winkens et al., 2017; Goosey and Harrad, 2012). Measurements of PFNA were only available from Winkens et al., 2017. Exposures were calculated even though the data from the two studies were dissimilar.

123. A number of studies published since 2008 have measured the PFAS precursors and some of these have then calculated predicted exposures to PFOS and PFOA using factors to take into account the biotransformation. However, there is a lack of biotransformation data for PFAS precursors to PFOS, PFOA and PFNA in humans, although certain biotransformation factors have been assumed previously (Poothong et al., 2020; Padilla-sanchez et al., 2017; Fromme et al., 2015; Schlummer et al., 2013).

124. For the average median PFASs concentrations in indoor air in homes, the following ranges of exposures were calculated for all UK population groups for each of the compounds (Table 6):

- PFOS (6.4 pg/m^3): 0.0085 – 0.027 ng/kg bw per week
- PFOA (20 pg/m^3): 0.027 – 0.083 ng/kg bw per week
- PFHxS (12 pg/m^3): 0.016 – 0.050 ng/kg bw per week
- PFNA (2.4 pg/m^3): 0.0032 – 0.010 ng/kg bw per week

125. For the average maximum PFASs concentrations in indoor air in homes, the following ranges of exposures were calculated for all UK population groups for each of the compounds (Table 6):

- PFOS (200 pg/m^3): 0.27 – 0.83 ng/kg bw per week
- PFOA (270 pg/m^3): 0.36 – 1.1 ng/kg bw per week
- PFHxS (220 pg/m^3): 0.29 – 0.91 ng/kg bw per week
- PFNA (17 pg/m^3): 0.023 – 0.070 ng/kg bw per week

126. For all PFASs considered, toddlers had the highest exposures via inhalation and seniors had the lowest exposures.

Table 6. Estimated exposures for PFOS, PFOA, PFHxS and PFNA (ng/kg bw per week) from indoor air for UK population groups, based on average and maximum indoor air concentrations for each of the PFASs, respectively.

Exposure (ng/kg bw/week)	**Infants**	**Toddlers**	**Children**	**Teenagers**	**Adults**	**Seniors**
PFOS 6.4 pg/m^3	0.020	0.027	0.017	0.012	0.0093	0.0085
PFOS 200 pg/m^3	0.61	0.83	0.53	0.38	0.29	0.27
PFOA 20 pg/m^3	0.061	0.083	0.053	0.038	0.029	0.027
PFOA 270 pg/m^3	0.83	1.1	0.71	0.51	0.39	0.36
PFHxS 12 pg/m^3	0.037	0.050	0.032	0.023	0.017	0.016

PFHxS 220 pg/m^3	0.68	0.91	0.58	0.42	0.32	0.29
PFNA 2.4 pg/m^3	0.0074	0.010	0.0063	0.0046	0.0035	0.0032
PFNA 17 pg/m^3	0.052	0.070	0.045	0.032	0.025	0.023

Mean inhalation rates: infants 3.4 m^3/day; toddlers 9.3 m^3/day; children 12 m^3/day; teenagers 17 m^3/day; adults 16 m^3/day and seniors 15 m^3/day.