Annex A - Statement for use of the EFSA 2020 Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food in UK risk assessments

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Breast milk exposures

1. A literature search was carried out for concentrations of PFAS 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 show the studies and breast milk concentrations for PFOS, PFOA, PFHxS and PFNA, respectively.

Table 1. Concentrations of PFOS in breast milk in EU studies where breast milk samples were taken after 2008.

Region, country	Year of sampling	Number of samples	Mean LB-UB (SEM[a], SDb or 95% CI[c]) (ng/L)	Median (ng/L)	Range (ng/L)	LOD[a] LOQ[b] (ng/L)	Detection frequency (%)	Refe

Barcelona, Spain	2009	20	120[#]	84[#]	LOQ-870	3.5[a] 11.7[b]	95[#] (>LOQ)	Llorca al., 20
France	2010	30	78	74	24-170	2[a]	100	Kadar al., 20
Belgium	2009-2010	40 (P & M)	130 (90 - 130)[c]	100	70 - 220 (P10 - P90)	10[b]	100 (>LOQ)	Croes al., 20
Bologna, Italy	2010	21 (P)	57 (13[a])	NR		15[b]	90 (>LOQ)	Barba et al.,
Bologna, Italy	2010	16 (M)	36 (7[a])	NR		15[b]	63 (>LOQ)	Barba et al.,
France	2010-2013	61	40*			NR[a] 40[b]	82 (>LOD)	Cariou al., 20
Czech Republic	2010	50	53 (sum of linear and branched means 33 and 20, respectively)	30 (linear)	7-110	5[b]	100 (>LOQ)	Lanko al., 20
Czech Republic	2010	50	54 (sum of linear and branched means 33 and 20, respectively)	17 (branched)		10[b]	72 (>LOQ)	Lanko al., 20

Seine-Saint Denis, Ardèche, Isère, Loire and Savoie (France)	2007	48 (P)	92	79		50[a]	90 (>LOD)	Antig et al.,
Ireland	Not identified in paper	16 (P) pooled samples	38	20	20 - 120	20[b]	62 (>LOQ)	Abdal al., 20
Stockholm, Sweden	2012	20	51[#]	45[#]	16 - 96	0.5[a]	100 (linear) 92.5 (branched) (>LOD)	Nybu al., 20
Gothenburg, Sweden	2012	16	44[#]	38[#]	13 - 100	0.5[a]	100 (linear) 91 (branched) (>LOD)	Nybu al., 20
Stockholm, Sweden	2016	10	46[#]	45[#]	24 - 72	0.5[a]	100 (linear) 70 (branched) (>LOD)	Nybu al., 20

Values are given to 2 significant figures. P – primiparous; M – multiparous; SEM – standard error of the mean; LB - lower bound assigns the value of zero to non-quantified data; UB - upper bound assigns the value of the LOD/LOQ to non-quantified data; SD – standard deviation; 95% CI – 95th percent confidence interval; NR – not reported; LOD – limit of detection; LOQ – limit of quantification P10 – P90 – 10th to 90th percentiles. *identified by year; #calculated from individual data in the published paper.

Table 2. Concentrations of PFOA in breast milk in recent EU studies where breast milk samples were taken after 2008.

Region, country	Year of sampling	No. of samples	Mean LB-UB (SEMa, SDb or 95% CI[c]) (ng/L)	Median (ng/L)	Range (ng/L)	LOD[a] LOQb (ng/L)	Detection frequency (%)	Reference
Barcelona, Spain	2008	20	150-151[#]	#	LOQ-907	4.5[a] 15.2[b]	45 (>LOQ)	Llorca et al., 2010
France	2010	30	59	57	18-102	3[a]	100	Kadar et al., 2011
Belgium	2009-2010	40 (P & M)	80 (60 - 90)[c]	70	60 - 150 (P10 - P90)	10[b]	100 (>LOQ)	Croes et al., 2012
Bologna, Italy	2010	21 (P)	76 (14)[a]	NR	24 - 241	24[b]	81 (LOQ)	Barbarossa et al., 2013
Bologna, Italy	2010	16 (M)	43 (6)[a]	NR	24 - 100	24[b]	69 (>LOQ)	Barbarossa et al., 2013
France	2010-2013	61	41*			NR[a] 50[b]	77 (>LOD)	Cariou et al., 2015
Czech Republic	2010	50	50	44	12 - 128	6[b]	100 (>LOQ)	Lankova et al., 2013

Murcia, Spain	2014	67 (P & M)	54 (54)[b]	26		10[b]	60 (>LOQ)	Guzman et al., 2016
Seine-Saint Denis, Ardèche, Isère, Loire and Savoie (France)	2007	48	82	75		50[a]	98 (>LOD)	Antignac et al., 2013
Ireland	Not identified in paper	16 (P) pooled samples	130	100	16 - 350	20[b]	100 (>LOQ)	Abdallah et al., 2020
Stockholm, Sweden	2012	20	53[#]	45[#]	23 - 102	2[a]	100 (>LOD)	Nyburg et al., 2018
Gothenburg, Sweden	2012	16	53[#]	49[#]	21 - 104	2[a]	100 (>LOD)	Nyburg et al., 2019
Stockholm, Sweden	2016	10	44[#]	42[#]	3 - 83	2[a]	100 (>LOD)	Nyburg et al., 2020

Values are given to 2 significant figures. P – primiparous; M – multiparous; SEM – standard error of the mean; LB - lower bound assigns the value of zero to non-quantified data; UB - upper bound assigns the value of the LOD/LOQ to non-quantified data; SD – standard deviation; 95% CI – 95th percent confidence interval; NR – not reported; LOD – limit of detection; LOQ – limit of quantification P10 – P90 – 10th to 90th percentiles. *identified by year; $^{\#}$calculated from individual data in the published paper.

Table 3. Concentrations of PFHxS in breast milk in recent EU studies where breast milk samples were taken after 2008.

Region, country	Year of sampling	No. of samples	Mean LB-UB (SEMa, SDb or 95% CI c) (ng/L)	Median (ng/L)	Range (ng/L)	LOD[a] LOQb (ng/L)	Detection frequency (%)	Reference
Belgium	2009-2010	40 (P & M)	NC			10[b]	20 (>LOQ)	Croes et al., 2012
France	2010-2013	61	26*			10 - 30[a] 30[b]	15 (>LOD)	Cariou et al., 2015
Czech Republic	2010	50	NC	NC	6 - 12	6[b]	8 (>LOQ)	Lankova et al., 2013
Seine-Saint Denis, Ardèche, Isère, Loire and Savoie (France)	2007	48	49	50	40 - 66	NR[a,b]	100 (>LOD)	Antignac et al., 2013
Ireland	Not identified in paper	16 (P) pooled samples	40	40	40 - 87	40[b]	31 (>LOQ)	Abdallah et al., 2020
Stockholm, Sweden	2012	20	8.38	7.55	0.8 - 25.4	0.8[a]	95 (linear) 0 (branched) (>LOD)	Nyburg et al., 2018

Gothenburg, Sweden	2012	16	5.60625	4.1	1.4 - 14.4	0.8[a]	94 (linear) 6 (branched) (>LOD)	Nyburg et al., 2019
Stockholm, Sweden	2016	10	7.63	8.2	0.8 - 13.4	0.8[a]	80 (linear) 30 (branched) (>LOD)	Nyburg et al., 2020

Values are given to 2 significant figures. P – primiparous; M – multiparous; SEM – standard error of the mean; LB - lower bound assigns the value of zero to non-quantified data; UB - upper bound assigns the value of the LOD/LOQ to non-quantified data; SD – standard deviation; 95% CI – 95th percent confidence interval; NC not calculated; NR – not reported; LOD – limit of detection; LOQ – limit of quantification P10 – P90 – 10th to 90th percentiles. *identified by year; $^{\#}$ calculated from individual data in the published paper.

Table 4. Concentrations of PFNA in breast milk in recent EU studies where breast milk samples were taken after 2008.

Region, country	**Year of sampling**	**No. of samples**	**Mean LB-UB (SEMa, SDb or 95% CI[c]) (ng/L)**	**Median (ng/L)**	**Range (ng/L)**	**LOD[a] LOQb (ng/L)**	**Detection frequency (%)**	**Reference**
Belgium	2009-2010	40 (P & M)	NC			10[b]	43 (>LOQ)	Croes et al., 2012
France	2010-2013	0/61 quantified	11*			NR[a] 50[b]	0 (>LOD)	Cariou et al., 2015

Czech Republic	2010	50	NC	NC	6 - 15	6[b]	48 (>LOQ)	Lankova et al., 2013
Murcia, Spain	2014	67 (P & M)	41 (29)[b]	40	15 - 70	10[b]	6 (>LOQ)	Guzman et al., 2016
Seine-Saint Denis, Ardèche, Isère, Loire and Savoie (France)	2007	Detected 1/48	NC	NC		50[a]	2 (>LOD)	Antignac et al., 2013
Ireland	Not identified in paper	16 (P) pooled samples	26	14	10 - 100	10[b]	69 (>LOQ)	Abdallah et al., 2020
Stockholm, Sweden	2012	20	15	15	3 - 30	2[a]	100 (>LOD)	Nyburg et al., 2018
Gothenburg, Sweden	2012	16	17	16	5 - 38	2[a]	100 (>LOD)	Nyburg et al., 2019
Stockholm, Sweden	2016	10	9.3	10	1 - 18	2[a]	70 (>LOD)	Nyburg et al., 2020

Values are given to 2 significant figures. P – primiparous; M – multiparous; SEM – standard error of the mean; LB - lower bound assigns the value of zero to non-quantified data; UB - upper bound assigns the value of the LOD/LOQ to non-quantified data; SD – standard deviation; 95% CI – 95th percent confidence interval; NC not calculated; NR – not reported; LOD – limit of detection; LOQ – limit of quantification P10 – P90 – 10th to 90th percentiles. *identified by year; #calculated from individual data in the published paper.

2. In the absence of a suitable UK study of PFAS in breast milk, data from EU studies for which all samples were taken after 2008 have been used to calculate

exposures to PFAS from breast milk in this paper. The exposure estimates are based on concentrations derived as an average of the median (Table 5) or maximum (Table 6) values reported in the literature.

Table 5. Concentrations (ng/L) derived as an average of the median values reported in the literature.

Chemical	Average of reported median values (ng/L)	References
PFOS	53	Llorca et al., 2010; Kadar et al., 2011; Croes et al., 2012; Lankova et al., 2013; Antignac et al., 2013; Abdallah et al., 2020; and Nyburg et al., 2018
PFOA	56	Kadar et al., 2011; Croes et al., 2012; Lankova et al., 2013; Guzman et al., 2016; Antignac et al., 2013; Abdallah et al., 2020; and Nyburg et al., 2018
PFHxS	17	Antignac et al., 2013; and Nyburg et al., 2018
PFNA	19	Guzman et al., 2016; Abdallah et al., 2020; and Nyburg et al., 2018

Table 6. Concentrations (ng/L) derived as an average of the maximum values reported in the literature.

Chemical	Average of reported maximum values (ng/L)	References

PFOS	170*	Llorca et al., 2010; Kadar et al., 2011; Croes et al., 2012; Barbarossa et al., 2013; Cariou et al., 2015; Lankova et al., 2013; Antignac et al., 2013; Abdallah et al., 2020; and Nyburg et al., 2018
PFOA	180	Llorca et al., 2010; Kadar et al., 2011; Croes et al., 2012; Barbarossa et al., 2013; Cariou et al., 2015; Lankova et al., 2013; Guzman et al., 2016; Antignac et al., 2013; Abdallah et al., 2020; and Nyburg et al., 2018
PFHxS	30	Antignac et al., 2013; and Nyburg et al., 2018
PFNA	51	Guzman et al., 2016; Abdallah et al., 2020; and Nyburg et al., 2018

*The maximum PFOS value in the Llorca et al., (2010) study was from an individual and was approximately 5 – 30-fold higher than all other measure values. Therefore, the second highest value from this study was used.

3. No consumption data were available for exclusive breastfeeding in infants aged 0 to 6 months. Therefore, the default consumption values used by the COT in other evaluations of the infant diet of average (800 mL) and high-level (1200 mL) consumption have been used to estimate exposures to PFOS and PFOA from breast milk. Bodyweights of 5.9 and 7.8 kg were used for infants aged 0 - 4 and 4 - 6 months, respectively.

4. 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

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

consumers:

- PFOS: 120 - 240 ng/kg bw per week
- PFOA: 130 - 260 ng/kg bw per week
- PFHxS: 22 - 43 ng/kg bw per week
- PFNA: 37 - 73 ng/kg bw per week

Table 7. Estimated PFOS, PFOA, PFHxS and PFNA exposure (ng/kg bw per week) in 0 to 6-month-old infants and from breast milk

PFOS concentration ng/L	**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.

COT
October 2022
Statement Number 04/22

References

Abdallah MA-E, Wemken N, Drage DS, Tlustos C, Cellarius C, Cleere K, Morrison JJ, Daly S, Coggins MA and Harrad S. (2020). Concentrations of perfluoroalkyl substances in human milk from Ireland: Implications for adult and nursing infant exposure. Chemosphere. **246:** 125724.

Antignac J-P, Veyrand B, Kadar H, Marchand P, Oleko A, Le Bizec B, and Vandentorren S. (2013). Occurrence of perfluorinated alkylated substances in breast milk of French women and relation with socio-demographical and clinical parameters: Results of the ELFE pilot study. Chemosphere. **91:** 802-808.

Barbarossa A, Masetti R, Gazzotti T, Zama D, Astolfi A, Veyrand B, Pession A, Pagliuca G. (2013). Perfluoroalkyl substances in human milk: a first survey in Italy. Environment International. 51:27-30.
Available at: Perfluoroalkyl substances in human milk: a first survey in Italy - PubMed (nih.gov)

Cariou R, Veyrand B, Yamada A, Berrebi A, Zalko D, Durand S, Pollono C, Marchand P, Leblanc JC, Antignac JP, Le Bizec B. (2015). Perfluoroalkyl acid (PFAA) levels and profiles in breast milk, maternal and cord serum of French women and their newborns. Environment International. 84:71-81.
Available at: Perfluoroalkyl acid (PFAA) levels and profiles in breast milk, maternal and cord serum of French women and their newborns - PubMed (nih.gov)

Croes K, Colles A, Koppen G, Govarts E, Bruckers L, Van de Mieroop E, Nelen V, Covaci A, Dirtu AC, Thomsen C, Haug LS, Becher G, Mampaey M, Schoeters G,

Van Larebeke N, Baeyens W. (2012). Persistent organic pollutants (POPs) in human milk: a biomonitoring study in rural areas of Flanders (Belgium). Chemosphere. 89(8):988-94.
Available at: Persistent organic pollutants (POPs) in human milk: a biomonitoring study in rural areas of Flanders (Belgium) - PubMed (nih.gov)

Kadar H, Veyrand B, Barbarossa A, Pagliuca G, Legrand A, Bosher C, Boquien CY, Durand S, Monteau F, Antignac JP, Le Bizec B. (2011). Development of an analytical strategy based on liquid chromatography–high resolution mass spectrometry for measuring perfluorinated compounds in human breast milk: Application to the generation of preliminary data regarding perinatal exposure in France. Chemosphere. 85(3):473-80.
Available at: Development of an analytical strategy based on liquid chromatography-high resolution mass spectrometry for measuring perfluorinated compounds in human breast milk: application to the generation of preliminary data regarding perinatal exposure in France - PubMed (nih.gov)

Lankova D, Lacina O, Pulkrabova J, Hajslova J. (2013). The determination of perfluoroalkyl substances, brominated flame retardants and their metabolites in human breast milk and infant formula. Talanta. 117:318-25.
Available at: The determination of perfluoroalkyl substances, brominated flame retardants and their metabolites in human breast milk and infant formula - PubMed (nih.gov)

Llorca M, Farré M, Picó Y, Teijón ML, Alvarez JG, Barceló D. (2010). Infant exposure of perfluorinated compounds: levels in breast milk and commercial baby food. Environment International. 36(6):584-92.
Available at: Infant exposure of perfluorinated compounds: levels in breast milk and commercial baby food - PubMed (nih.gov)

Guzmàn M, Clementini C, Pérez-Cárceles MD, Jiménez Rejón S, Cascone A, Martellini T, Guerranti C, Cincinelli A. (2016). Perfluorinated carboxylic acids in human breast milk from Spain and estimation of infant's daily intake. The Science of the Total Environment. 544:595-600.
Available at: Perfluorinated carboxylic acids in human breast milk from Spain and estimation of infant's daily intake - PubMed (nih.gov)

Nyberg E, Awad R, Bignert A, Ek C, Sallsten G and Benskin JP. (2018). Inter-individual, inter-city, and temporal trends of per- and polyfluoroalkyl substances in human milk from Swedish mothers between 1972 and 2016. Environmental Science: Processes and Impacts. **20:** 1136.