# 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

## In this guide

# 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 (%) | Refer |
|---|---|---|---|---|---|---|---|---|

| Location | Year | N | | | | | | Reference |
|---|---|---|---|---|---|---|---|---|
| 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 |

| Location | Year | N | | | | | | Reference |
|---|---|---|---|---|---|---|---|---|
| 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., 2 |
| Gothenburg, Sweden | 2012 | 16 | 44[#] | 38[#] | 13 - 100 | 0.5[a] | 100 (linear) 91 (branched) (>LOD) | Nybu... al., 2 |
| Stockholm, Sweden | 2016 | 10 | 46[#] | 45[#] | 24 - 72 | 0.5[a] | 100 (linear) 70 (branched) (>LOD) | Nybu... al., 2 |

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 (SEM[a], SD[b] or 95% CI[c]) (ng/L) | Median (ng/L) | Range (ng/L) | LOD[a] LOQ[b] (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 |

| Location | Year | N | | | Range | LOD/LOQ | Detection | Reference |
|---|---|---|---|---|---|---|---|---|
| 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 (SEM[a], SD[b] or 95% CI[c]) (ng/L) | Median (ng/L) | Range (ng/L) | LOD[a] LOQ[b] (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 |

| Region, country | Year | No. of samples | Mean | Median | Range | LOD/LOQ | Detection frequency | Reference |
|---|---|---|---|---|---|---|---|---|
| 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 (SEM[a], SD[b] or 95% CI [c]) (ng/L) | Median (ng/L) | Range (ng/L) | LOD[a] LOQ[b] (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 |

| Location | Year | | | | Range | | Detection | Reference |
|---|---|---|---|---|---|---|---|---|
| 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 ng/L | 51 | 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**

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