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

In this guide

158.   The EFSA Opinion (EFSA, 2020) states that "This TWI should prevent that mothers reach a body burden that results in levels in milk that would lead to serum levels in the infant associated with a decrease in vaccination response. As a result, the higher exposure of breastfed infants is taken into account in the derivation of the TWI and the intake by infants should therefore not be compared with this TWI".

159.   For the rest of the diet, UK Lower bound mean exposures for adolescents, adults, the elderly and the very elderly (3.2 - 5.6 ng/kg bw per week) are approximate to the TWI of 4.4 ng/kg bw per week. These exposures for other children are just double the value of the TWI, with a value of 9.7 ng/kg bw per week. Toddler exposures calculated using the NDNS survey data are approximately 4 fold the TWI. Infant and toddler exposures estimated using the DNSIYC survey data are approximately 14 and 7 fold the TWI.

160.   The UK lower bound 95th percentile exposures for adolescents, adults, the elderly and the very elderly exceed the TWI up to about 3-fold. For other children the exceedance is approximately 6 fold. Toddler exposures calculated using the NDNS survey data are about 10 fold. Infant and toddler exposures calculated using DNSIYC survey data are approximately 25 and 17 fold the TWI.

161.	UK upper bound mean exposures range from 97 to 590 ng/kg bw per week across the population groups, with infants having the highest exposures. These are 22 to 130 fold the TWI.

162.	UK upper bound 95th percentile exposures range from 200 to 870 ng/kg bw per week across the population groups, with infants having the highest exposures. These are 45 to 200 fold the TWI.

163.	Serum level modelling of the four PFASs indicates that the lower bound exposure is a more accurate prediction of the exposure than the upper bound estimates, which would lead to a much higher exceedance of the critical serum levels.

164.	With a PFAS concentration of 5 ng/L in drinking water derived from surface waters all calculated mean and 97.5th percentile exposures for all age groups were below the TWI of 4.4 ng/kg bw per week.

165.	For drinking water derived from ground water with a conservative concentration of 10 ng/L, mean exposures for all age groups were below the TWI. Exposures for 97.5th percentile consumers were below the TWI for all age groups except toddlers with a marginal exceedance of the TWI, with an exposure of 4.9 ng/kg bw per week.

166.	Exposures from household dust at average median PFASs concentrations for all UK populations range from 0.000051 to 2.1 ng/k bw per week across the four individual PFAS. For each of PFOS, PFOA, PFHxS and PFNA exposures from house dust are below the TWI.

167.	For conservative exposures calculated from average maximum PFASs concentrations in household dust, the values across all UK population groups across the four individual PFAS range from 0.0032 to 42 ng/kg bw per week. However, there is more uncertainty around the calculation of these values as discussed in Annex C and the uncertainties section. The TWI is exceeded for PFOS, PFOA and PFHxS by infants, toddlers and children. For all PFASs considered, infants had the highest exposures and teenagers, adults and seniors had the lowest exposures.

168.	For the individual PFASs, all exposures from indoor air calculated across all population groups for both average median and maximum concentrations, are below the TWI. For all PFASs considered, toddlers had the highest exposures via inhalation and seniors had the lowest exposures.

Uncertainty

Uncertainties in the exposure assessments

169.   Exposures for breast milk, dust, drinking water and indoor air were calculated for individual PFASs. Exposures for the rest of the diet were taken from the EFSA Opinion (2020) and were for a sum of the four PFAS. The majority of the studies used to calculate the exposures for breast milk, dust and indoor air did not provide individual sample data which could therefore not be assessed prior to the data analysis.

170.   UK bodyweights, inhalation rates and dust ingestion rates were selected to represent the greatest number of individuals (greatest age range) within that population group.

171.   The exposure calculations are likely to be conservative because generally all values reported were included in the analysis, including some reasonably high concentrations which were included in the average maximum calculations.

172.   All of the studies used to calculate exposures had sample numbers lower than 65. Most had 20 or fewer samples. This decreases the statistical reliability of the estimates.

173.   Studies were carried out in different years and in different countries which increased the likely variability within the samples between studies. Studies had different LODs/LOQs for the same PFASs for the same material of interest (breast milk, dust or indoor air). For some studies the data were available for the individual samples but in others only the outputs of the data analysis were available.

174.   Where branched and linear isomers of a specific PFASs were measured, where possible, the data were summed as suggested by Nyburg et al., (2018).

175.   In studies that included samples which were pooled prior to analysis, or only provided a summary of the information it is not known how the data from the individual samples compared and whether data are skewed by individual results.

176.   Uncertainties relating to specific exposure assessments are discussed in the following paragraphs.

Breast milk

177.   Data from the Nyberg (2018) study was available for individual samples. From these it was possible to calculate the average and median for individual PFASs and identify the minimum and maximum values. The data for PFOS and PFHxS were for both linear and branched isomers and these were summed for each PFAS to provide one value for each sample. For PFOS (for branched and linear), data were also reported for m/z 499/80 and 499/99 ions. These were averaged as suggested by Nyberg prior to use of the data for summing branched and linear values.

Rest of the diet

178.   The exposure calculations for the rest of the diet were from EFSA (2020) and as such, the uncertainties are as discussed in the EFSA Opinion.

Drinking water

179.   The uncertainties in the exposure assessment for drinking water include:

- The exposures calculated assumed that concentrations of 5 ng/L and 10 ng/L would be reasonably conservative scenarios for surface and ground water, respectively.
- Chemical concentrations were given in the units ng/L. Data in the NDNS is expressed in weight i.e., g or kg. Therefore, in the assessments these concentrations were assumed to be ng/kg. i.e., 1 L of water was assumed to equal to 1 kg of water.
- There were only limited numbers of infant/toddler consumers of water used as a diluent for infant foods.

Air (indoor)

180.   Only two studies were available for inclusion in the exposure calculations. The sample numbers for the studies are relatively small: 20 for the PFASs concentrations measured from Birmingham; and 57 from Kuopio, Finland. The detection frequencies are also low for PFHxS for samples from Kuopio. Therefore, there are only a limited number of measured data from which to calculate exposures.