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

In this guide

12. Technical Information - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food
13. 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
14. Annex B - Statement for use of the 2020 EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food in UK risk assessments
15. Annex C - Statement for use of the 2020 EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food in UK risk assessments
16. Annex D - 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

194. The TWI was calculated based on studies of epidemiological studies of immune effects as this was considered, by the CONTAM Panel, to be the critical effect. Two studies on this (Abraham et al., 2020 and Grandjean et al., 2012) were considered by EFSA. The predominant study used was that by Abraham et al. (2020). From this study a BMDL10 of 17.5 ng/mL was calculated, for the sum of the four PFASs in serum. This value was then used as the reference point for PBPK modelling. From the PBPK model the daily intake calculated for a mother was 0.63 ng/kg bw per day. This was then converted to a weekly value of 4.4 ng/kg bw per week, for use as the health-based guidance value.

195. The COT agreed that, on the basis of the information reviewed by EFSA, qualitatively the appropriate health endpoint had been selected but quantitatively, questioned the calculations. Overall, there were some reservations about the choice of the critical study (Abraham et al., 2020) and the specific effect selected. However, the COT agreed that the critical study was the best available. It was not unreasonable that this study was selected, and, in the absence of more appropriate studies, its use was understandable.

196. The COT had significant reservations about the model used, including the BMD approach, and the TWI which had been established, due to the uncertainties and the caveats involved. The concerns related to both the study and thus the data used in the modelling, and the modelling itself.

197. The COT agreed that the use of the sum of the four PFASs was acceptable as a first approximation for exposures of PFAS but had reservations

about the calculations due to the uncertainties.

198. The values for the BMDL and TWI were low and there was a lot of uncertainty surrounding the data used by EFSA.

199. Estimated breast milk exposures for UK infants all exceed the TWI of 4.4 ng/kg bw per week. However, EFSA (2020) stated that “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”. Important to note is that estimates of breast milk exposures were very conservative and that the Spanish data set could have skewed the results.

200. For the rest of the diet, EFSA had calculated UK exposures. UK Lower bound mean estimated exposures for adolescents, adults, the elderly and the very elderly approximate the TWI of 4.4 ng/kg bw per week. The exposures for other children are approximately 2 fold the TWI. Toddler exposures estimated 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.

201. The UK lower bound 95th percentile estimated 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 estimated 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, respectively.

202. UK upper bound mean estimated exposures across the population groups, with infants having the highest estimates are approximately 22 to 130 fold the TWI.

203. UK upper bound 95th percentile estimated exposures across the population groups, with infants having the highest estimates, are approximately 45 to 200 fold the TWI.

204. Serum level modelling of the four PFASs indicates that the lower bound estimate 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.

205. Estimated exposures from household dust at average median PFASs concentrations for all UK populations for individual PFASs are below the TWI.

206. For exposures estimated from average maximum PFASs concentrations in household dust the TWI is exceeded for PFOS, PFOA and PFHxS by infants, toddlers and children.

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

208. For drinking water derived from ground water with a conservative concentration of 10 ng/L, mean estimated exposures for all age groups were below the TWI. Estimates 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.

209. For the individual PFASs, all estimated exposures from indoor air calculated across all population groups for both average median and maximum concentrations, are below the TWI.

210. Due to high numbers of results below the LOD/LOQ for food samples, these estimated chronic exposures should be viewed as indicative of the range of exposures and therefore, interpreted with caution. The same caution should be used when considering the estimated household dust and indoor air exposures and also taking into account the additional uncertainties around these, discussed previously.

211. The diet is the predominant route of exposure to PFASs, however, other routes of exposure may include dust ingestion and indoor air, for which exposures have been considered. There may also be some exposure from the dermal route, however these have not been calculated in this statement.

212. The EFSA CONTAM Panel, in their evaluation of PFASs have used a mixtures approach and established a TWI of 4.4 ng/kg bw per week, based on the sum of four PFASs: PFOS, PFOA, PFHxS and PFNA. The CONTAM Panel considered that the impact of the uncertainties on the risk assessment for the sum of PFOA, PFNA, PFHxS and PFOS is high.

213. The exceedances of the TWI at lower bound exposure estimates indicate a potential health concern.

214. Whilst the COT is unable to suggest an alternative TWI at this time, there are strong caveats when comparing the exposure estimates with the TWI established by EFSA. There is considerable uncertainty as to the appropriateness

of the derivation of the TWI, and of the biological significance of the response on which it is based, which complicates interpretation of the possible toxicological significance of exceedances.

215. The COT suggested that in future reviews it could use the averages for exposures for the four PFASs added together to provide a reasonable estimation of combined PFASs exposure for comparison to the TWI.

COT
October 2022
Statement Number 04/22