Statements

Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances (PFASs) in food: Lay Summary

1. The European Food Safety Authority (EFSA) was asked, by the European Commission, to prepare an Opinion on the risks to human health related to the presence of perfluoroalkylated substances (PFASs) in food, and to consider existing hazard assessments and available occurrence data. The statement was published in September 2020.

2. The Committee on Toxicity of Chemicals in Food, Consumer products and the Environment (COT) have reviewed the “EFSA Opinion Risk to human health related to the presence of perfluoroalkyl substances in food” (2020) alongside UK exposure data to assess the potential risks to the UK population from PFASs (predominantly through exposure via the diet).

3. Per- and polyfluoroalkyl substances (PFASs) with a minimum of six carbons in their backbone, are a class of over 12,000 fluorinated substances (US EPA CompTox Dashboard 2022). They have been produced since the 1940s and are, or have been, used in a broad range of consumer products and industrial applications (Glüge *et al*., 2020). Their structure enhances their utility in a variety of applications including the production of water- and oil-resistant clothing, electronics, non-stick cookware, carpets, and food packaging materials.

4. Many PFASs are environmentally long-lived and individuals are exposed to them through all environmental sources, i.e. drinking water, air, dust, and the diet and through the placenta and breastfeeding for developing offspring (Sunderland *et al*., 2019).

5. The tolerable weekly intake (TWI) was established by EFSA based on epidemiological studies of an effect on the immune system, as this was considered, by the EFSA CONTAM Panel, to be the critical effect. Two studies on this (Abraham *et al*., 2020 and Grandjean *et al*., 2012) were considered by EFSA as suitable for hazard characterisation. One of these studies, Abraham *et al.* (2020), was amenable to dose-response modelling (i.e. analysis of the response of an organism, as a function of exposure (or doses) to a chemical after a certain exposure time); which resulted in a benchmark dose limit value (BMDL10) for blood serum of 17.5 ng/mL for the sum of the four main PFASs present. This value was then used as the reference point to calculate the corresponding tolerable daily intake for a mother, to protect their offspring, considered the most sensitive population, which was 0.63 ng/kg body weight (bw) per day. This was then converted to a weekly value, because of the long persistence of PFASs in the body, the TWI, of 4.4 ng/kg bw per week for the sum of the four PFASs PFOS, PFOA, PFHxS and PFNA, for use as the health-based guidance value.

6. 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 that was selected. However, the COT agreed that the critical study was the best available; and, in the absence of more appropriate studies, its use was understandable. Therefore, it was not unreasonable that this study was selected.

7. The COT had significant reservations about the dose-response model used, including the modelling approach, and the TWI which had been established, due to the uncertainties and the caveats involved.

8. The COT agreed that the use of the sum of the four PFASs was acceptable as a first approximation for exposures of PFASs but had reservations about the calculations due to the uncertainties.

9. The diet is the predominant route of exposure to PFASs, however, other possible sources of exposure include dust by ingestion and indoor air by inhalation, and these exposures = have been considered. There may also be some exposure via the skin, however these have not been calculated.

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

11. Estimated breast milk exposures for UK infants all exceed the TWI of 4.4 ng/kg bw per week. However, EFSA cautions that “the higher exposure of breastfed infants is taken into account in the derivation of the TWI (i.e. it is assumed that those later exposed have already received this exposure) and the intake by infants should therefore not be compared with this TWI”.

12. Blood serum level modelling of the four PFASs indicates that the lower bound estimates of exposure (assuming that levels below detection are zero) is a more accurate prediction of the exposure than the upper bound estimates (assuming that levels below detection are present at that level), which would lead to a much higher exceedance of the critical blood serum levels. Lower bound mean estimated dietary exposures for adolescents, adults, the elderly and the very elderly approximate the TWI, that for other children is approximately twice the TWI, and for infants and toddlers are several times the TWI.

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

14. The EFSA CONTAM Panel, in their evaluation of PFASs, assessed exposure both to individual compounds and using a mixtures approach (i.e. a probabilistic model for representing the presence of subpopulations within an overall population, without requiring that an observed data set should identify the sub-population to which an individual observation belongs) for the sum of four PFASs: PFOS, PFOA, PFHxS and PFNA. All exposure estimates were compared to the TWI of 4.4 ng/kg bw per week. 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.

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

16. Whilst the COT is unable to suggest an alternative TWI at this time due to the lack of data, 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.

17. 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.

18. The full statement can be found at: Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food.

Lay summary to COT Statement 04/22
November 2022

References

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