Revised TWI for PFASs: rationale and consequences

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Previous EFSA assessment for PFOS

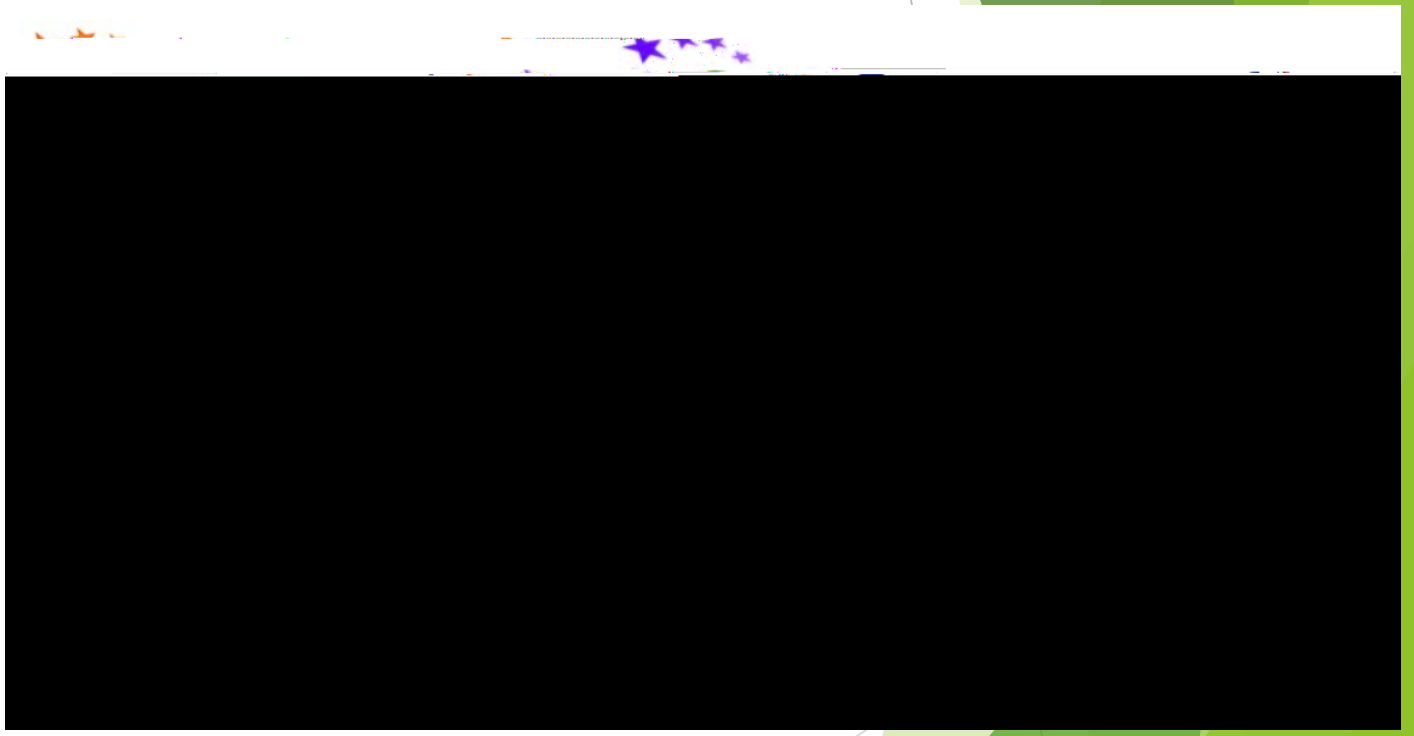
2008, EFSA established a tolerable daily intake (TDI) of 150 ng/kg bw per day for PFOS

Based on a lowest no-observed-adverse-effect-level (NOAEL) of 0.03 mg/kg bw per day derived from a sub-chronic study on cynomolgus monkeys, where a decrease in serum total cholesterol and high-density lipoproteins (HDL), increased TSH levels and lowered triiodothyronine (T3) concentrations were observed.

Uncertainty factor (UF) of 200 was applied to the NOAEL. A UF of 100 was used for inter and intra-species differences and an additional UF of 2 to compensate for uncertainties related to the duration of the key study and the elimination kinetics of PFOS. The EFSA CONTAM panel concluded that the exposure to the general population was well below the derived TDI

Previous EFSA assessment for PFOA

For PFOA a benchmark dose for a 10% increase in increased liver weight ($BMDL_{10}$) of 0.3 mg/kg bw per day based on studies in mice and rats was used to derive a TDI of 1.5 µg/kg bw per day applying a UF of 200 to the $BMDL_{10}$



Other risk assessments

All use animal studies and all present TDIs in broadly the same range and conclude no adverse health effects for most of population as a result of dietary exposure based on normal occurrence levels

- Federal Institute for Risk Assessment in Germany (BFR)
- Swedish Environmental Protection Agency
- United States Environmental Protection Agency (U.S. EPA)
- Danish Environmental Protection Agency

New Mandate of EFSA CONTAM Panel

ORIGINAL: to prepare an opinion on the risks to human health related to the presence of perfluoroalkylated substances (PFASs) in food

LATER: Following an agreement with EC, the CONTAM Panel decided to address the mandate in 2 separate opinions, one on

2020 opinion

2020 opinion takes into account:

- more recent scientific knowledge
- recent guidance for assessing combined exposure to multiple chemicals

HBGV based on sum of 4 PFASs - perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS).

Decreased response of the immune system to vaccination now considered to be the most critical human health effect

Draft 2020 opinion subject to public consultation which resulted in a lowering of the proposed TWI from 8 to 4.4 ng/kg body weight per week for sum of PFOA, PFNA, PFHxS and PFOS.

Rationale behind 4 PFASs chosen

- Similar effects in animals
- Toxicokinetics
- Observed levels in human blood
- These 4 PFASs make up half of the overall dietary exposure, remainder primarily from PFASs with short half-lives

Derivation of HBGV

Dietary exposure

Food can become contaminated through contaminated soil and water used to grow the food, through the concentration of these substances in animals via feed and water, through food packaging containing PFAS, or equipment that contained PFAS during food processing.

Foods that contribute most to dietary exposure to these four PFASs are

- drinking water,
- fish,
- fruit,
- eggs

Most exposed population groups

Infants, toddlers and other children have highest dietary exposure.

Basis for group TWI

EFSA's

Exposure

Previous data on food demonstrated that exposure was well below established (<2018) TDIs.

Some analytical methods that have been used to date lack sensitivity and many data are left censored (i.e. <LOD) but this was not so problematic because it was possible to show that exposure was well below any level of concern; i.e. was fit for purpose

To analyse food to demonstrate that exposure is below the new TWI means that this is no longer the case and more sensitive analytical methods are needed for measurement of PFASs

Knowledge gaps

- Occurrence data is needed for a broad range of food groups obtained with more sensitive analytical methods,
- More information on the relative of the 4 PFAS (they were equal)
- More information on other PFASs that are detected in food.

acknowledgements

Especially the WG on PFASs, and the CONTAM Panel

The Panel on Contaminants in the Food Chain (CONTAM) provides scientific advice on contaminants in the food chain and undesirable substances such as natural toxicants, mycotoxins and residues of unauthorised substances.