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

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

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

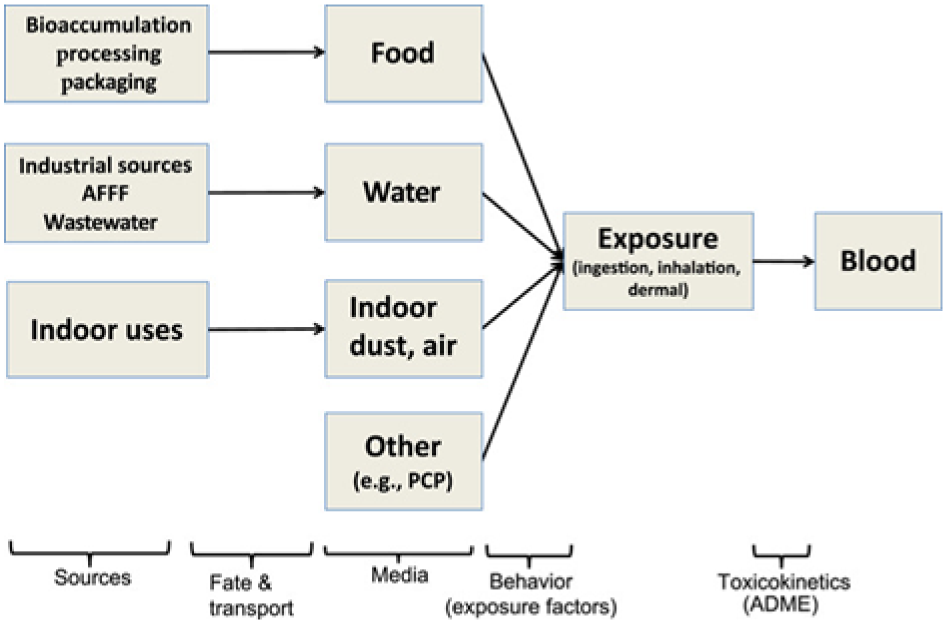

Figure one shows a diagram of cream coloured boxes and black text with black directional arrows. below these boxes are a diagonal list of 5 poly- and perfluoroalkyl substance (PFAS) sources.

Figure 1. Schematic of exposure assessment steps for humans that relates poly- and perfluoroalkyl substance (PFAS) sources to exposure media and internal concentrations of PFAS in blood. Not all possible exposure routes (e.g., outdoor air) or arrows are shown. ADME = absorption, distribution, metabolism and excretion. AFFF = aqueous film-forming foam; PCP = personal care product. (Figure taken from de Silva 2021)

5. There are differing definitions for PFASs but in the 2020 EFSA opinion they are defined as (R-X) substances where R is a hydrophobic alkyl chain of varying length (typically C4-C16) and X is a hydrophilic end group. The hydrophobic part (R) may be fully or partially fluorinated. The PFASs are highly persistent due to the strong covalent C-F bond. Many PFASs are potential precursors of other PFASs (EFSA, 2018). These precursors are not usually environmentally persistent but may be transformed to more persistent PFASs, in the environment through biodegradation (EFSA, 2020).

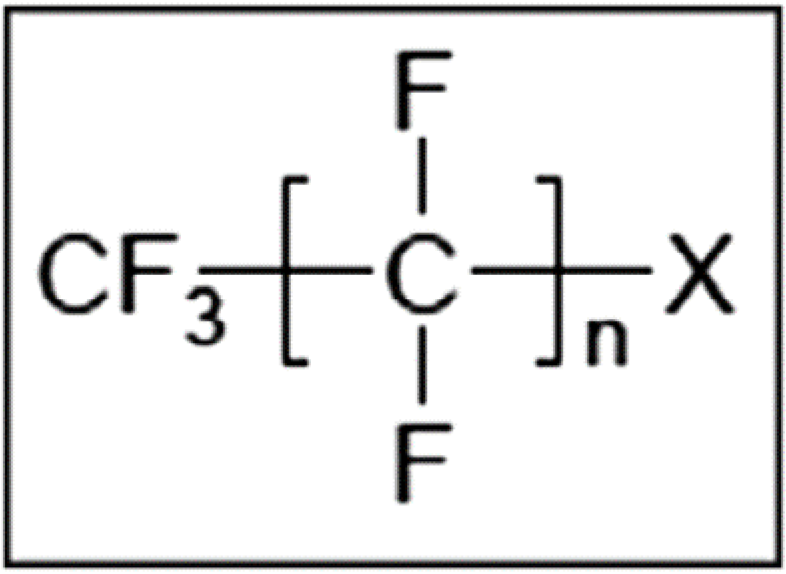

Figure 2 is an image of the general structure of PFASs. It has dark grey text on a white background in a box with a dark outline.

Figure 2. General structure of PFASs.

6. In their current Opinion, EFSA considered 27 PFASs covering several different groups.

7. Perfluoroalkyl carboxylic acids (PFCAs): Perfluorobutanoic acid (PFBA), Perfluoropentanoic acid (PFPeA), Perfluorohexanoic acid (PFHxA), Perfluoroheptanoic acid (PFHpA), Perfluorooctanoic acid (PFOA), Perfluorononanoic acid (PFNA), Perfluorodecanoic acid (PFDA), Perfluoroundecanoic acid (PFUnDA), Perfluorododecanoic acid (PFDoDA), Perfluorotridecanoic acid (PFTrDA), Perfluorotetradecanoic acid (PFteDA), Perfluoropentadecanoic acid (PFPeDA), Perfluorohexadecanoic acid (PFHxDA), Perfluorooctadecanoic acid (PFODA).

8. Perfluoroalkane sulfonic acids (PFSAs): Perfluorobutane sulfonic acid (PFBS), Perfluorohexane sulfonic acid (PFHxS), Perfluoroheptane sulfonic acid (PFHpS), Perfluorooctane sulfonic acid (PFOS), Perfluorodecane sulfonic acid (PFDS).

9. 7 others groups, which include respectively: Perfluorooctane sulfinic acid (PFOSI), 8:2 Fluorotelomer alcohol (8:2 FTOH), 8:2 Fluorotelomer phosphate monoester (8:2 monoPAP), 8:2 Fluorotelomer phosphate diester (8:2 diPAP), Perfluorooctane sulphonamide (FOSA), N-ethyl perfluorooctane sulphonamide (EtFOSA), N-ethyl perfluorooctane sulfonamidoethanol (EtFOSE) and Ammonium bis[2-[N-ethyl (hepatodecafluorooctane) sulphonylamino]ethyl]phosphate (FC-807).

10. PFASs are reported to be, or have been, used in a wide range of products including: “oil-, water- and stain resistant coatings for clothing, personal protective equipment, workwear, leather and carpets; oil-resistant coatings for food contact materials; aviation hydraulic fluids; fire-fighting foams; paints, adhesives, waxes and polishes; in industrial applications as surfactants, emulsifiers and coatings and personal care products including cosmetics”. The production volume for each of these uses is not publicly available. Their use in a wide range and numerous applications and products is predominantly due to their unique properties including: the ability to create stable foams, chemical resistance and surface tension lowering properties. (EFSA, 2020).

11. The 27 PFASs considered by EFSA in their 2020 Opinion are surfactants, intermediate environmental transformation products, surface protection products or major raw materials for surfactant and surface protection products. There are at least 3,000 PFASs on the global market, however, there is very little information on the production and use for most. Therefore, it is generally not known how much has been, or will be, released, transformed and accumulated in the environment. Due to their persistence and relatively water-soluble nature, many of these compounds may be transported long distances in water and also as aerosols (EFSA, 2020).

12. PFASs are present in food, mainly through two processes: accumulation in aquatic and terrestrial food chains and transfer from contact materials used in food packaging and processing. PFASs have been measured in ‘fish’, ‘eggs and egg products’, ‘livestock meat’, ‘fruit and fruit products’, drinking water’, ‘vegetable and vegetable products’, ‘alcoholic beverages’, ‘food for infants and small children’.

13. Releases to the environment occur during the production, use, and disposal of materials containing PFAS (de Silva 2021). Exposure pathways for PFAS can be considered as a chain of events, shown in Figure 1, linking sources to media (via fate and transport) to external exposure (via behavioural factors) to concentrations in blood, the body’s central compartment (via toxicokinetics). Exposure routes that are typically examined for PFAS include dietary ingestion, water ingestion (particularly in contaminated communities), and inhalation of air and dust particles. Hand-to-mouth contact and dermal absorption can also be relevant pathways.

Legislation

14. The legal status of PFOS and PFOA has been summarised in the 2018 EFSA Scientific Opinion (EFSA, 2018). In brief, PFOS, including its salts and perfluorooctane sulfonyl fluoride (PFOSF), is now listed in Annex I of the persistent organic pollutants (POP) regulation (Regulation (EU) 2019/1021) and added to Annex B (Restriction) of the Stockholm Convention. PFOS is not allowed for use in the production of plastics food contact materials (FCM) Commission Regulation (EU) No 10/2011. Under Commission Regulation (EU) 2019/1021 the use of PFOS and PFOS related substances is prohibited. There is only one time-limited exemption remaining: the use of PFOS as a mist suppressant for non-decorative hard chromium (VI) plating in closed loop systems (EA).

15. PFOA also has a number of restrictions placed on it within the European Union Article 76(1)(e) of Regulation (EC) No 1907/2006.

16. Currently, no other PFASs addressed in the EFSA 2020 Opinion have been legally restricted in Europe with respect to production, marketing or use. There are a number of initiated or ongoing activities which aim to reduce human and environmental risk connected to a number of the PFASs discussed in the 2020 EFSA Opinion (EFSA, 2020).

Previous evaluations

17. EFSA considered evaluations on PFOS and PFOA that had been carried out since their Opinion from 2018 and previous risk assessments for PFASs other than PFOS and PFOA.

18. The 2018 EFSA Opinion (EFSA, 2018) included tolerable weekly intakes (TWIs) of 13 and 6 ng/kg bw per week for PFOS and PFOA, respectively. These were based on human epidemiological studies. For PFOS, the increase in serum total cholesterol in adults, and the decrease in antibody response at vaccination in children were identified as the critical effects. Increase in serum total cholesterol was the critical effect identified for PFOA. Reduced birth weight was also considered a critical effect for both compounds and increased prevalence of high serum levels of the liver enzyme alanine aminotransferase (ALT) for PFOA.

19. Risk assessments have also been carried out by:

i. the Swedish Environmental Protection Agency (2012) which assessed 23 PFASs (PFBS, PFPS, PFHxS, PFHpS, PFOS, PFOSi, PFOSA, EtFOSA, PFDS, PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA, PFPeDA, PFHxDA, 6:2 FTSA) in Sweden (Swedish Environmental Protection

Agency, 2012).

ii. the Danish Environmental Protection Agency (2015) which reviewed FOSA (Danish EPA, 2015).

iii. the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) published an opinion on PFBA, PFHxA, PFBS and PFHxS (ANSES, 2015).

iv. The German Human Biomonitoring (HBM) Commission established drinking water guide values for PFBA, PFHxA, PFHpA, PFOA, PFNA, PFBS, PFHxS, PFOS and Health-based orientation values for PFPeA, PFHpA, PFDA, PFHPs and FOSA (Bundesgesundheitsblatt 2017, 60:350-352).

v. Food Safety Australia New Zealand (FSANZ) published a hazard assessment report for PFOS, PFOA and PFHxS (FSANZ, 2017).

vi. The Department of Environmental Protection (New Jersey, US) developed a Health-based Maximum Contaminant level for PFOA (DEP, 02/2017), PFOS (DEP, 11/2017) and PFNA (DEP, 10/2017).

vii. The ATSDR (2018) has prepared a draft for public comment on the Toxicological profile of 14 PFASs (PFOS, PFOA, PFBA, PFHxA, PFHpA, PFNA, PFDA, PFUnDA, PFDoDA, PFBS, PFHxS, FOSA, 2-(N-methyl-erfluoroocatanesulfonamido) acetic acid and 2-(N-ethyl-perfluorooctane-sulfon-amido) acetic acid.

viii. RIVM (2018) published a Relative Potency Factor approach for 19 PFASs (PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA, PFHxDA, PFODA, PFBS, PFPeS, PFHxS, PFHpS and PFOS.

ix. Michigan Science Advisory Workgroup Recommended Health-based Drinking Water Values for six PFASs (PFHxA, PFOA, PFNA, PFBS, PFHxS and PFOS). (Michigan Science Advisory Workgroup71, 2019)