

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

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

In this guide

[In this guide](#)

1. [Introduction - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food](#)
2. [Background - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food](#)
3. [Summary of 2020 EFSA evaluation](#)
4. [Toxicity - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food](#)
5. [Exposures - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food](#)
6. [Critical effects, dose-response assessment and derivation of a health-based guidance value- Statement on the EFSA Opinion on the risks of perfluoroalkyl substances](#)
7. [Risk Characterisation - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food](#)
8. [Uncertainties in the critical effects, dose-response assessment and derivation of an HBG](#)
9. [COT Conclusions - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food](#)
10. [References - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food](#)
11. [Abbreviations - Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food](#)

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](#)

Abraham K, Mielke H, Fromme H, Volkel W, Menzel J, Peiser M, Zepp F, Willich SN and Weikert C. (2020). Internal exposure to perfluoroalkyl substances (PFASs) and biological marker in 101 healthy one-year old children: Associations between levels of perfluorooctanoic acid (PFOA) and vaccine response. Archives of Toxicology, 94(6): 2131-2147.

Available at: [Internal exposure to perfluoroalkyl substances \(PFASs\) and biological markers in 101 healthy 1-year-old children: associations between levels of perfluorooctanoic acid \(PFOA\) and vaccine response - PubMed \(nih.gov\)](#)

ANSES (French Agency for Food, Environmental and Occupational Health & Safety) (2015). OPINION of the French Agency for Food, Environmental

and Occupational Health & Safety on “the development of chronic reference values by the oral route for four perfluorinated compounds: perfluorohexanoic acid (PFHxA), perfluorohexane sulfonic acid (PFHxS), perfluorobutanoic acid (PFBA), and perfluorobutane sulfonic acid (PFBS).

Available at: [ANSES OPINION on the "development of chronic reference values by the oral route for four perfluorinated compounds: perfluorobutanoic acid \(PFBA\)](#)

Article 76(1)(e) of Regulation (EC) No 1907/2006.

Available at: [EUR-Lex - 02006R1907-20140410 - EN - EUR-Lex \(europa.eu\)](#)

ATSDR (Agency for Toxic Substances and Disease Registry) (2018). Draft Toxicological Profile for Perfluoroalkyls.

Available at: [Toxicological Profile for Perfluoroalkyls \(cdc.gov\)](#)

Bates, B, Lennox, A, Prentice, A, Bates, C, Page, P, Nicholson, S, Swan, G. (2014) National Diet and Nutrition Survey Results from Years 1, 2, 3 and 4 (combined) of the Rolling Programme (2008/2009 - 2011/2012) [Main heading \(publishing.service.gov.uk\)](#)

Bates B, Cox L, Nicholson S, Page P, Prentice A, Steer T, Swan G (2016). National Diet and Nutrition Survey Results from Years 5 and 6 (combined) of the Rolling Programme (2012/2013 - 2013/2014): [NDNS: results from Years 5 and 6 \(combined\) - GOV.UK \(www.gov.uk\)](#)

Budtz-Jorgensen E and Grandjean P (2018). Application of benchmark analysis for mixed contaminant exposures: Mutual adjustment of perfluoroalkylated substances associated with immunotoxicity. PloS ONE **13(10)**: e0205388. Doi: 10.1371/journal.pone.0205388. eCollection 2018. Available at: [Application of benchmark analysis for mixed contaminant exposures: Mutual adjustment of perfluoroalkylate substances associated with immunotoxicity - PubMed \(nih.gov\)](#)

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.
Available at: [EUR-Lex - 32011R0010 - EN - EUR-Lex \(europa.eu\)](#)

COT (2014). COT statement on the potential risks from perfluorooctane sulfonate (PFOS) in the infant diet.
Available at: [cotstatmpfos.pdf \(food.gov.uk\)](#)

COT (2018). First draft statement on the EFSA Opinion on “Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food” - RESERVED Business.
Available at: [\[ARCHIVED CONTENT\] UK Government Web Archive - The National Archives](#)

COT (2020). Minutes for an additional COT meeting on the EFSA draft opinion on PFAS currently out for public consultation.
Available at: [Minutes for an additional COT meeting on the EFSA draft opinion on PFAS \(food.gov.uk\)](#)

Danish Environmental Protection Agency (2015). Short-chain Polyfluoroalkyl Substances (PFAS). A literature review of information on human health effects and environmental fate and effect aspects of short-chain PFAS.
Available at: [978-87-93352-15-5.pdf \(mst.dk\)](#)

De Silva, A.O., Armitage, J.M., Bruton, T.A., Dassuncao, C., Heiger-Bernays, W., Hu, X.C., Kärrman, A., Kelly, B., Ng, C., Robuck, A. and Sun, M., 2021. PFAS exposure pathways for humans and wildlife: a synthesis of current knowledge and key gaps in understanding. *Environmental toxicology and chemistry*, 40(3), pp.631-657.

Available at : [PFAS Exposure Pathways for Humans and Wildlife: A Synthesis of Current Knowledge and Key Gaps in Understanding - De Silva - 2021 - Environmental Toxicology and Chemistry - Wiley Online Library](#)

Department of Environmental Protection (New Jersey, US). New Jersey Drinking Water Quality Institute Health Effects Subcommittee (2017) health-based maximum contaminant level support document: perfluorooctanoic acid (PFOA). Available at: [HEALTH-BASED MAXIMUM CONTAMINANT LEVEL SUPPORT DOCUMENT - PFOA - APPENDIX A \(nj.gov\)](#)

Dinsmore KJ. (2020). Forever chemicals in the food aisle: PFAS content of UK supermarket and take away food packaging. Available at: [\(PDF\) Forever chemicals in the food aisle: PFAS content of UK supermarket and takeaway food packaging \(researchgate.net\)](#)

DH (Department of Health) (2013). Diet and nutrition survey of infants and young children, 2011. Available at: [Diet and nutrition survey of infants and young children, 2011 - GOV.UK \(www.gov.uk\)](#)

DWI (Drinking Water Inspectorate). (2021). Guidance on the Water Supply (Water Quality) Regulations 2016 specific to PFOS (perfluorooctane sulphonate) and PFOA (perfluorooctanoic acid) concentrations in drinking water. Available at: [PFOS-PFOA-guidance-2021.pdf \(dwi.gov.uk\)](#)

EFSA (2008). Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts Scientific Opinion of the Panel on Contaminants in the Food chain. The EFSA Journal. **653**: 1-131. DOI:

10.2903/j.efsa.2008.653.

Available at: [Perfluorooctane sulfonate \(PFOS\), perfluorooctanoic acid \(PFOA\) and their salts Scientific Opinion of the Panel on Contaminants in the Food chain \[1\] | EFSA \(europa.eu\)](#)

EFSA (2018). Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food. EFSA Journal. **16(12)** :5194. DOI :

10.2903/j.efsa.2018.5194.

Available at : [Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food | EFSA \(europa.eu\)](#)

EFSA (2019). Genotoxicity assessment of chemical mixtures. EFSA Journal. **17(1)** :5519. Doi : 10.2903/j.efsa.2019.5519.

Available at: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5519>

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Schrenk D, Bignami M, Bodin L, Chipman JK, del Mazo J, Grasl-Kraupp B, Hogstrand C, Hoogenboom LR, Leblanc J-C, Nebbia CS, Nielsen E, Ntzani E, Petersen A, Sand S, Vleminckx C, Wallace H, Barregard L, Ceccatelli S, Cravedi J-P, Halldorsson TI, Haug LS, Johansson N, Knutsen HK, Rose M, Roudot A-C, Van Loveren H, Vollmer G, Mackay K, Riolo F and Schwerdtle T. (2020). Scientific Opinion on the risk to human health related to the presence of perfluoroalkyl substances in food. EFSA Journal 2020 ;18(9) :6223, 391 pp. Available at: <https://doi.org/10.2903/j.efsa.2020.6223>

EFSA/CONTAM/3503 (2018). Minutes of the expert meeting on perfluorooctane sulfonic acid and perfluorooctanoic acid in food assessment. Available at: [\[PDF\] Minutes of the expert meeting on perfluorooctane sulfonic acid and perfluorooctanoic acid in food assessment | Semantic Scholar](#)

Ericson Jogsten I, Nadal M, van Bavel B, Lindström G and Domingo JL, 2012. Per- and polyfluorinated compounds (PFCs) in house dust and indoor air in Catalonia, Spain: implications for human exposure. Environment

International, 39, 172-180.

Available at : [Per- and polyfluorinated compounds \(PFCs\) in house dust and indoor air in Catalonia, Spain: Implications for human exposure - ScienceDirect](#)

Food Safety Australia New Zealand (FSANZ) (2017). Hazard assessment report – Perfluorooctane Sulfonate (PFOS), Perfluorooctanoic Acid (PFOA), Perfluorohexane Sulfonate (PFHxS).

Available at: [Department of Health and Aged Care | Sorry, we cannot find that page...](#)

Fromme H, Dreyer A, Dietrich S, Fembacher L, Lahrz T and Volkel W, 2015. Neutral polyfluorinated compounds in indoor air in Germany-the LUPE 4 study. Chemosphere, 139, 572-578.

Available at: [Neutral polyfluorinated compounds in indoor air in Germany - The LUPE 4 study - ScienceDirect](#)

Frisbee, S.J., Brooks Jr, A.P., Maher, A., Flensburg, P., Arnold, S., Fletcher, T., Steenland, K., Shankar, A., Knox, S.S., Pollard, C. and Halverson, J.A., 2009. The C8 health project: design, methods, and participants. *Environmental health perspectives*, 117(12), pp.1873-1882.

Available at: <https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.0800379>

Gallo V, Leonardi G, Genser B, Lopez-Espinosa MJ, Frisbee SJ, Karlsson L, Ducatman AM and Fletcher T. (2012). Serum perfluorooctanoate (PFOA) and perfluorooctane sulfonate (PFOS) concentrations and liver function

biomarkers in a population with elevated PFOA exposure. *Environmental Health Perspectives*. **120**: 655–660.

[German Human Biomonitoring Commission (2017). Fortschreibung der vorläufigen Bewertung von per- und polyfluorierten Chemikalien (PFC)

im Trinkwasser Empfehlung des Umweltbundesamtes nach Anhörung der Trinkwasserkommission. *Bundesgesundheitsblatt*. **60**:350-352.

Available at: [fortschreibung_der_uba-pfc-bewertungen_bundesgesundheitsbl_2017-60_s_350-352.pdf](https://www.umweltbundesamt.de/foerderung/publikationen/fortschreibung-der-uba-pfc-bewertungen-bundesgesundheitsbl-2017-60-s-350-352.pdf)
([umweltbundesamt.de](https://www.umweltbundesamt.de))

Glüge, J., Scheringer, M., Cousins, I.T., DeWitt, J.C., Goldenman, G., Herzke, D., Lohmann, R., Ng, C.A., Trier, X. and Wang, Z., 2020. An overview of the uses of per-and polyfluoroalkyl substances (PFAS). *Environmental Science : Processes & Impacts*, 22(12), pp.2345-2373.

Available at : [An overview of the uses of per- and polyfluoroalkyl substances \(PFAS\) - Environmental Science: Processes & Impacts \(RSC Publishing\)](https://pubs.rsc.org/en/content/articlelanding/2020/ps/c9ps00011a)
[DOI:10.1039/D0EM00291G](https://doi.org/10.1039/D0EM00291G)

Grandjean P, Andersen EW, Budtz-Jorgensen E, Nielsen F, Molbak K, Weihe P and Heilmann C. (2012). Serum Vaccine antibody concentrations in children exposed to perfluorinated compounds. *JAMA*. **307** : 391-397. Doi : 10.1001/jama.2011.2034.

Available at: [Serum vaccine antibody concentrations in children exposed to perfluorinated compounds - PubMed \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov/22111111/)

Grandjean P, Heilmann C, Weihe P, Nielsen F, Mogensen UB, Timmermann A and Budtz-Jorgensen E (2017). Estimated exposures to perfluorinated compounds in infancy predict attenuated vaccine antibody concentrations at age 5-years. *J Immunotoxicol*. **14(1)** :188-195. Doi : 10.1080/1547691X.2017.1360968.

Available at: [Estimated exposures to perfluorinated compounds in infancy predict attenuated vaccine antibody concentrations at age 5-years - PubMed \(nih.gov\)](#)

Goosey E and Harrad S. (2012). Perfluoroalkyl substances in UK indoor and outdoor air: spatial and seasonal variation, and implications for human exposure. *Environment International*. **45** : 86-90.

Available at: [Perfluoroalkyl substances in UK indoor and outdoor air: spatial and seasonal variation, and implications for human exposure - PubMed \(nih.gov\)](#)

Gyllenhammar, I., Berger, U., Sundström, M., McCleaf, P., Eurén, K., Eriksson, S., Ahlgren, S., Lignell, S., Aune, M., Kotova, N. and Glynn, A., 2015. Influence of contaminated drinking water on perfluoroalkyl acid levels in human serum—A case study from Uppsala, Sweden. *Environmental research*, 140, pp.673-683.

Available at: [Influence of contaminated drinking water on perfluoroalkyl acid levels in human serum - A case study from Uppsala, Sweden - ScienceDirect](#)

Harrad S, de Wit CA, Abdallah MA, Bergh C, Bjorklund JA, Covaci A, Darnerud PO, de Boer J, Diamond M, Huber S, Leonards P, Mandalakis M, Ostman C, Haug LS, Thomsen C and Webster TF, 2010. Indoor contamination with hexabromocyclododecanes, polybrominated diphenyl ethers, and perfluoroalkyl compounds: an important exposure pathway for people? *Environmental Science & Technology*, 44, 3221–3231.

Available at: [Indoor contamination with hexabromocyclododecanes, polybrominated diphenyl ethers, and perfluoroalkyl compounds: an important exposure pathway for people? - PubMed \(nih.gov\)](#)

Haug LS, Huber S, Schlabach M, Becher G and Thomsen C, 2011. Investigation on per- and polyfluorinated compounds in paired samples of house dust and indoor air from Norwegian homes. *Environmental Science &*

Technology, 45, 7991–7998.

Available at: [Investigation on per- and polyfluorinated compounds in paired samples of house dust and indoor air from Norwegian homes - PubMed \(nih.gov\)](#)

Meng, Q., Inoue, K., Ritz, B., Olsen, J. and Liew, Z., 2018. Prenatal exposure to perfluoroalkyl substances and birth outcomes; an updated analysis from the Danish National Birth Cohort. *International journal of environmental research and public health*, 15(9), p.1832.

Available at: [IJERPH | Free Full-Text | Prenatal Exposure to Perfluoroalkyl Substances and Birth Outcomes; An Updated Analysis from the Danish National Birth Cohort \(mdpi.com\)](#)

Michigan Science Advisory Workgroup (2019). Health-based drinking water value recommendations for PFAS in Michigan.

Available at: [Health-Based Drinking Water Value Recommendations for PFAS in Michigan Report](#)

Padilla-Sánchez JA, Papadopoulou E, Poothong S, and Haug LS. (2017). Investigation of the Best Approach for Assessing Human Exposure to Poly- and Perfluoroalkyl Substances through Indoor Air. Environmental Science and Technology. **51**: 12836 – 12843.

Poothong S, Papadopoulou E, Padilla-Sánchez JA, Thomsen C and Haug LS. (2020). Multiple pathways of human exposure to poly- and perfluoroalkyl

substances (PFASs): From external exposure to human blood. Environment International. **134**: 105244.

Available at: [Multiple pathways of human exposure to poly- and perfluoroalkyl substances \(PFASs\): From external exposure to human blood - ScienceDirect](#)

RIVM (National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport) (2018). Mixture exposure to PFAS: A Relative Potency Factor approach.

Available at: [Mixture exposure to PFAS: A Relative Potency Factor approach \(rivm.nl\)](#)

Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

Available at: [EUR-Lex - 32019R1021 - EN - EUR-Lex \(europa.eu\)](#)

Roberts C, Steer T, Maplethorpe N, Cox L, Meadows S, Nicholson S, Page P, and Swan G. (2018). National Diet and Nutrition Survey. Results from Years 7 and 8 (combined) of the Rolling Programme (2014/2015 to 2015/2016): [National Diet and Nutrition Survey \(publishing.service.gov.uk\)](#)

Schlummer M, Gruber L, Fiedler D, Kizlauskas M and Müller J. (2013). Detection of fluorotelomer alcohols in indoor environments and their relevance for human exposure. Environment International. **57-58**: 42-49

Sunderland, E.M., Hu, X.C., Dassuncao, C., Tokranov, A.K., Wagner, C.C. and Allen, J.G., 2019. A review of the pathways of human exposure to poly-and perfluoroalkyl substances (PFASs) and present understanding of health effects. Journal of exposure science & environmental epidemiology, 29(2), pp.131-147.

Available at: [A review of the pathways of human exposure to poly- and](#)

[perfluoroalkyl substances \(PFASs\) and present understanding of health effects | Journal of Exposure Science & Environmental Epidemiology \(nature.com\)](#)

Swedish Environmental Protection Agency (Borg D and Håkansson H) (2012). Environmental and Health Risk Assessment of Perfluoroalkylated and Polyfluoroalkylated Substances (PFASs) in Sweden. Available at: [Vi hittar inte sidan... \(naturvardsverket.se\)](#)

Vaccine Knowledge Project

Available at: [Diphtheria | Vaccine Knowledge \(ox.ac.uk\)](#)

Winkens K, Koponen J, Schuster J, Shoeib M, Vestergren R, Berger U, Karvonen A., Pekkanen J, Kiviranta H and Cousins IT. (2017). Perfluoroalkyl acids and their precursors in indoor air sampled in children's bedrooms. Environmental Pollution. **222**: 423-432.

Available at: [Perfluoroalkyl acids and their precursors in indoor air sampled in children's bedrooms - ScienceDirect](#)

WHO/IPCS (World Health Organization/International Programme on Chemical Safety) (2012). Guidance for immunotoxicity risk assessment for chemicals.

Available at: [Harmonization Project Document No. 10: Guidance for Immunotoxicity Risk Assessment for Chemicals \(inchem.org\)](#)