

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2022/1431

of 24 August 2022

on the monitoring of perfluoroalkyl substances in food

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Perfluoroalkyl substances (PFASs) were and some of them still are widely used in industrial and consumer applications including stain-resistant coatings for fabrics and carpets, oil-resistant coatings for paper and board food contact materials, firefighting foams, mining and oil well surfactants, floor polishes and insecticide formulations. Their widespread use, together with their persistency in the environment has resulted in a widespread environmental contamination. Contamination of food with these substances is mainly the result of bioaccumulation in aquatic and terrestrial food chains, and of the use of food contact materials containing PFASs. Perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) and their salts are the PFASs which are found in food and in humans in the highest concentrations.
- (2) The European Food Safety Authority ('the Authority') therefore asked its Scientific Panel on Contaminants in the Food Chain to prepare an opinion on the importance of food and the relative contribution of the different foodstuffs and food contact materials to the human exposure to PFOS, PFOA and their salts and to advise on further steps in relation to the risk assessment of PFASs.
- (3) The Scientific Panel on Contaminants in the Food Chain adopted a scientific opinion on PFOS, PFOA and their salts on 21 February 2008 ⁽¹⁾, stating that further data on PFASs levels in food and in humans would be recommended, particularly with respect to monitoring trends in human exposure.
- (4) Additional occurrence data on various PFASs in food were gathered under Commission Recommendation 2010/161/EU ⁽²⁾.
- (5) In 2020, at the request of the Commission, the Authority updated its risk assessment of PFOS and PFOA and extended it to perfluorononanoic acid (PFNA) and perfluorohexane sulfonic acid (PFHxS), taking into account the most recent scientific information and the occurrence data gathered under Recommendation 2010/161/EU. In its opinion on the risk to human health related to perfluoroalkyl substances ⁽³⁾, it concluded that parts of the European population exceed the tolerable weekly intake. However, the Authority noted that a representative set of occurrence data are still lacking for many foods and, therefore, recommended to gather such data for a wide range PFASs in a broad range of widely consumed foods. Furthermore, since the measured concentrations of PFASs in certain foods were only obtained with very sensitive analytical methods, which are currently not achievable for the majority of the laboratories, it recommended to implement sensitive analytical methods for the analyses of PFASs.

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

⁽²⁾ Commission Recommendation 2010/161/EU of 17 March 2010 on the monitoring of perfluoroalkylated substances in food (OJ L 68, 18.3.2010, p. 22).

⁽³⁾ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific opinion on the risk to human health related to the presence of perfluoroalkyl substances in food, *EFSA Journal* 2020;18(9):6223.

- (6) In light of the opinion by the Authority, occurrence data for a wide range of PFASs should be gathered in foods which are relevant for the human exposure to PFASs in order to support a dietary exposure assessment and assess the need to regulate these substances in specific commodities. To this end, specific foods from specific production types or with specific characteristics, for which data are lacking, should be monitored and an estimate of the processing factors for various processed products provided.
- (7) Follow-up investigations towards the sources of contamination are required to allow the implementation of follow-up measures to avoid the occurrence of PFASs in food. In order to provide guidance in this regard, it is appropriate to set indicative levels of concentrations of PFASs in food. Those levels should not affect the possibility to place on the market any food, but investigations should be carried out when the concentration of PFASs in a foodstuff exceeds those levels. In order to quantify concentrations of PFASs in the quantities in which they occur, sufficiently sensitive methods should be used. This should be encouraged by recommending target limits of quantification.
- (8) Food of animal origin is an important contributor to the human exposure to PFASs. The Authority concluded that PFASs transfer from feed to animal derived food, with clear differences between species and the type of PFASs. Such PFASs transfer may also occur from soil ingested by foraging farm animals and from drinking water for animals. Therefore, for the follow-up investigations aiming at determining the causes of contamination, where the maximum levels of PFASs in food of animal origin set out in Commission Regulation (EC) No 1881/2006 ⁽⁴⁾ are exceeded, it is important that laboratories are able to also control feed, animal drinking water and the soil on which animals live. However, only few data are currently available concerning the occurrence of PFASs in Union feed and allowing to study feed as a source of PFASs in food of animal origin. As only a limited number of laboratories is able to analyse PFASs in feed, further work is being undertaken by the European Reference Laboratory for halogenated persistent organic pollutants in feed and food, to help the laboratories to develop such capability. While that work should allow for the adoption in the future of further recommendations concerning PFASs in feed, once there is a sufficient analytical capability among the laboratories, in the meanwhile, those Member States, whose laboratories are already able to analyse PFASs in feed, should be recommended to already do so and, in those Member States which do not have the required analytical capability yet, the laboratories should already validate analytical methods for PFASs in feed.
- (9) In order to ensure that the samples are representative for the sampled lot, the sampling procedures as laid down in the Annex to Commission Implementing Regulation (EU) 2022/1428 ⁽⁵⁾ laying down methods of sampling and analysis for the control of perfluoroalkyl substances in certain foodstuffs should be followed,

HEREBY RECOMMENDS:

1. Member States, in collaboration with food business operators, should monitor during the years 2022, 2023, 2024 and 2025 the presence of PFASs in food.

Member States should test for the presence in food of the following PFASs:

- (a) Perfluorooctane sulfonic acid (PFOS);
- (b) Perfluorooctanoic acid (PFOA);
- (c) Perfluorononanoic acid (PFNA);
- (d) Perfluorohexane sulfonic acid (PFHxS).

Member States should, if possible, test also for the presence of compounds which are similar to PFOS, PFOA, PFNA and PFHxS, but have a different alkyl chain and with relevant occurrence in food, drinking water and/or human serum such as:

- (a) Perfluorobutanoic acid (PFBA);
- (b) Perfluoropentanoic acid (PFPeA);

⁽⁴⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

⁽⁵⁾ Commission Implementing Regulation (EU) 2022/1428 of 24 August 2022 laying down methods of sampling and analysis for the control of perfluoroalkyl substances in certain foodstuffs (see page 66 of this Official Journal).

- (c) Perfluorohexanoic acid (PFHxA);
- (d) Perfluoroheptanoic acid (PFHpA);
- (e) Perfluorodecanoic acid (PFDA);
- (f) Perfluoroundecanoic acid (PFUnDA);
- (g) Perfluorododecanoic acid (PFDoDA);
- (h) Perfluorotridecanoic acid (PFTrDA);
- (i) Perfluorotetradecanoic acid (PFTeDA);
- (j) Perfluorobutane sulfonic acid (PFBS);
- (k) Perfluoropentanesulfonic acid (PFPS);
- (l) Perfluoroheptane sulfonic acid (PFHpS);
- (m) Perfluorononane sulfonic acid (PFNS);
- (n) Perfluorodecane sulfonic acid (PFDS);
- (o) Perfluoroundecane sulfonic acid (PFUnDS);
- (p) Perfluorododecane sulfonic acid (PFDoDS);
- (q) Perfluorotridecane sulfonic acid (PFTrDS);
- (r) Perfluorooctane sulphonamide (FOSA).

Member States should also consider testing for the presence in food of emerging PFASs, such as:

- (a) 2-[(6-chloro-1,1,2,2,3,3,4,4,5,5,6,6-dodecafluorhexyl)oxy]-1,1,2,2-tetrafluoroethansulfonic acid (the acid form of F53B);
- (b) 2,3,3,3-tetrafluor-2-(heptafluorpropoxy)-propanoic acid (the acid form of GenX);
- (c) (2,2,3-Trifluor-3-[1,1,2,2,3,3-hexafluor-3-(trifluoromethoxy)propoxy]-propionic acid (the acid form of ADONA);
- (d) 1-Propanaminium, N,N-dimethyl-N-oxide-3-[[[3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulfonyl]amino]-, hydroxide (Capstone A);
- (e) 1-Propanaminium, N-(carboxymethyl)-N,N-dimethyl-3-[[[3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulfonyl]amino]-, hydroxide (Capstone B);
- (f) Fluorotelomer alcohols and sulfonates.

2. The monitoring should include a wide variety of foodstuffs reflecting consumption habits, including fruits, vegetables, starchy roots and tubers, seaweed, cereals, nuts, oilseeds, food for infants and young children, food of animal origin, non-alcoholic drinks, wine and beer.

Data should be collected for the following range of production types or product characteristics:

- (a) for products from different production types, including organic production;
- (b) for animal products, for products from animals with outdoor access to soil or water and for products from animals with no outdoor access to soil or water;
- (c) for animal products, for products from a wide range of farmed and wild species, which are representative of the national consumption habits;
- (d) for potatoes, for peeled potatoes or, for potato varieties, which are consumed with the peel, for unpeeled potatoes, provided that this is clearly indicated during the data submission;
- (e) for fungi, for wild and farmed fungi.

Only the edible portion of the foodstuffs should be analysed. Fruits, vegetables, starchy roots and tubers should be washed prior to sampling, while ensuring not to introduce additional PFASs contaminations via the washing water. Food for infants and young children should be analysed dry or liquid, as marketed.

Data should be collected for foods produced in non-polluted regions, but also data from foods from polluted regions may be reported, provided that this is clearly indicated, when reporting the data to the Authority.

3. Member States, in collaboration with food business operators, should collect information on concentrations of PFASs in raw and processed products from the same batch of raw products and determine processing factors for various processed products, in particular, cheese, whey powder, egg yolk, fine bakery wares with a high egg content and meat products containing liver.
4. Member States, which have the analytical capability to analyse PFASs in feed, should also monitor PFASs in feed. Member States as yet lacking that required analytical capability should validate analytical methods for PFASs in feed.
5. Member States should follow the sampling procedures as laid down in the Annex to Commission Implementing Regulation (EU) 2022/1428 laying down methods of sampling and analysis for the control of perfluoroalkyl substances in certain foodstuffs.
6. The analyses should be carried out in accordance with Article 34 of Regulation (EU) 2017/625 of the European Parliament and the Council⁽⁶⁾ using a method of analysis that has been proven to generate reliable results. The limits of quantification of the analytical methods should be below or at:
 - (a) 0,002 µg/kg for PFOS, 0,001 µg/kg for PFOA, 0,001 µg/kg for PFNA and 0,004 µg/kg for PFHxS in fruits, vegetables, starchy roots and tubers and food for infants and young children;
 - (b) 0,010 µg/kg for PFOS, 0,010 µg/kg for PFOA, 0,020 µg/kg for PFNA and 0,040 µg/kg for PFHxS in milk;
 - (c) 0,10 µg/kg for PFOS, PFOA, PFNA and PFHxS in fish meat and meat of terrestrial animals;
 - (d) 0,30 µg/kg for PFOS, PFOA, PFNA and PFHxS in eggs, crustaceans and molluscs;
 - (e) 0,50 µg/kg for PFOS, PFOA, PFNA and PFHxS in edible offal of terrestrial animals and in fish oil.

Member States which use methods which cannot achieve these limits of quantification may submit results obtained with methods with higher limits of quantification. However, those Member States should take the necessary action to achieve the target limits of quantification as soon as possible.

7. Further investigation of the causes of the contamination should be carried out when the following indicative levels are exceeded:
 - (a) 0,010 µg/kg for PFOS, 0,010 µg/kg for PFOA, 0,005 µg/kg for PFNA and 0,015 µg/kg for PFHxS in fruits, vegetables (except wild fungi), starchy roots and tubers;
 - (b) 1,5 µg/kg for PFOS, 0,010 µg/kg for PFOA, 0,005 µg/kg for PFNA and 0,015 µg/kg for PFHxS in wild fungi;
 - (c) 0,020 µg/kg for PFOS, 0,010 µg/kg for PFOA, 0,050 µg/kg for PFNA and 0,060 µg/kg for PFHxS in milk;
 - (d) 0,050 µg/kg for PFOS, 0,050 µg/kg for PFOA, 0,050 µg/kg for PFNA and 0,050 µg/kg for PFHxS in baby food⁽⁷⁾.

⁽⁶⁾ Regulation (EU) 2017/625 of the European Parliament and The Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1).

⁽⁷⁾ Babyfood as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

8. Member States should provide the monitoring data to the Authority on a regular basis, together with the information and in the electronic reporting format as set out by the Authority, for compilation into one database. Member States should:
- (a) report data from regions with a known high environmental pollution as suspect samples, in particular for fish, game, free range and outdoor poultry, outdoor fruit and vegetables;
 - (b) specify the production type, in particular for animal products (wild, gathered or hunted versus farmed non-organic production or farmed organic production; free range or outdoor production versus indoor production methods) and fungi (wild or gathered versus farmed);
 - (c) for game meat and offal, report the age of the animals, where possible; and
 - (d) for food for infants and young children, report the main ingredients (cows' milk, soy beans, fish, meat of terrestrial animals, cereals, vegetables or fruits).

Done at Brussels, 24 August 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission
