

COMMISSION REGULATION (EU) 2022/2388
of 7 December 2022
amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkyl substances in certain foodstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽¹⁾, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006 ⁽²⁾ sets maximum levels for certain contaminants in foodstuffs.
- (2) Perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA) and perfluorohexane sulfonic acid (PFHxS) are perfluoroalkyl substances (PFASs), which are, or were used in numerous commercial and industrial applications. 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 the diet is the major source of PFASs exposure. However also the use of food contact materials containing PFASs is likely to contribute to human exposure to them.
- (3) On 9 July 2020, the European Food Safety Authority ('the Authority') adopted an opinion on the risk to human health related to the presence of perfluoroalkyl substances in food ⁽³⁾. The Authority concluded that PFOS, PFOA, PFNA and PFHxS can cause developmental effects and may have adverse effects on serum cholesterol, the liver and the immune system and birth weight. It considered the effects on the immune system as the most critical effect and it established a group tolerable weekly intake (TWI) of 4,4 ng/kg body weight per week for the sum of PFOS, PFOA, PFNA and PFHxS, which is also protective against the other effects of those substances. It concluded that the exposure of parts of the European population to those substances exceeds the TWI, which is of concern.
- (4) Maximum levels in food for those substances should therefore be set to ensure a high level of human health protection.
- (5) A reasonable period should be provided to allow for the food business operators to adapt to the maximum levels set out in this Regulation.
- (6) Taking into account that certain foodstuffs covered by this Regulation have a long shelf life, foodstuffs that were lawfully placed on the market before the date of application of this Regulation, should be allowed to remain on the market.
- (7) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 37, 13.2.1993, p. 1.

⁽²⁾ 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).

⁽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, <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.6223>

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

Article 2

Foodstuffs listed in the Annex, lawfully placed on the market before 1 January 2023, may remain on the market until their date of minimum durability or use-by date.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Regulation (EC) No 1881/2006, the following section is added:

'Section 10: Perfluoroalkyl substances

| Foodstuffs ⁽¹⁾ | | Maximum Levels µg/kg wet weight | | | | |
|---------------------------|---|---------------------------------|--------|--------|---------|---|
| | | PFOS * | PFOA * | PFNA * | PFHxS * | Sum of PFOS, PFOA, PFNA and PFHxS *. ** |
| 10.1 | Eggs | 1,0 | 0,30 | 0,70 | 0,30 | 1,7 |
| 10.2 | Fishery products ²⁶ and bivalve molluscs ²⁶ | | | | | |
| 10.2.1 | Fish meat ^{24, 25} | | | | | |
| 10.2.1.1 | Muscle meat of fish, except those listed under 10.2.1.2 and 10.2.1.3. Muscle meat of fish listed in 10.2.1.2 and 10.2.1.3, in case they are intended for the production of food for infants and young children. | 2,0 | 0,20 | 0,50 | 0,20 | 2,0 |
| 10.2.1.2 | Muscle meat of the following fish, in case they are not intended for the production of food for infants and young children: Baltic herring (<i>Clupea harengus membras</i>) Bonito (<i>Sarda</i> and <i>Orcynopsis</i> species) Burbot (<i>Lota lota</i>) European sprat (<i>Sprattus sprattus</i>) Flounder (<i>Platichthys flesus</i> and <i>Glyptocephalus cynoglossus</i>) Grey mullet (<i>Mugil cephalus</i>) Horse mackerel (<i>Trachurus trachurus</i>) Pike (<i>Esox</i> species) Plaice (<i>Pleuronectes</i> and <i>Lepidopsetta</i> species) Sardine and pilchard (<i>Sardina</i> species) Seabass (<i>Dicentrarchus</i> species) Sea catfish (<i>Silurus</i> and <i>Pangasius</i> species) Sea lamprey (<i>Petromyzon marinus</i>) Tench (<i>Tinca tinca</i>) Vendace (<i>Coregonus albula</i> and <i>Coregonus vandesius</i>) Silverly lightfish (<i>Phosichthys argenteus</i>) Wild salmon and wild trout (wild <i>Salmo</i> and <i>Oncorhynchus</i> species) Wolf fish (<i>Anarhichas</i> species) | 7,0 | 1,0 | 2,5 | 0,20 | 8,0 |

| | | | | | | |
|----------|---|------|------|------|------|-----|
| 10.2.1.3 | Muscle meat of the following fish, in case they are not intended for the production of food for infants and young children: Anchovy (<i>Engraulis</i> species) Babel (<i>Barbus barbus</i>) Bream (<i>Abramis</i> species) Char (<i>Salvelinus</i> species) Eel (<i>Anguilla</i> species) Pike-perch (<i>Sander</i> species) Perch (<i>Perca fluviatilis</i>) Roach (<i>Rutilus rutilus</i>) Smelt (<i>Osmerus</i> species) Whitefish (<i>Coregonus</i> species) | 35 | 8,0 | 8,0 | 1,5 | 45 |
| 10.2.2 | Crustaceans ^{26,47} and bivalve molluscs ²⁶ . For crustaceans the maximum level shall apply to muscle meat from appendages and abdomen ⁴⁴ . In case of crabs and crab-like crustaceans (<i>Brachyura</i> and <i>Anomura</i>) muscle meat from appendages. | 3,0 | 0,70 | 1,0 | 1,5 | 5,0 |
| 10.3 | Meat and edible offal ⁶ | | | | | |
| 10.3.1 | Meat of bovine animals, pig and poultry | 0,30 | 0,80 | 0,20 | 0,20 | 1,3 |
| 10.3.2 | Meat of sheep | 1,0 | 0,20 | 0,20 | 0,20 | 1,6 |
| 10.3.3 | Offal of bovine animals, sheep, pig and poultry | 6,0 | 0,70 | 0,40 | 0,50 | 8,0 |
| 10.3.4 | Meat of game animals, with the exception of bear meat | 5,0 | 3,5 | 1,5 | 0,60 | 9,0 |
| 10.3.5 | Offal of game animals, with the exception of bear offal | 50 | 25 | 45 | 3,0 | 50 |

* The maximum level applies to the sum of linear and branched stereoisomers, whether they are chromatographically separated or not.

** For the sum of PFOS, PFOA, PFNA and PFHxS, lower bound concentrations are calculated on the assumption that all the values below the limit of quantification are zero.'