



Council of the
European Union

Brussels, 1 September 2022
(OR. en)

11658/1/22
REV 1

DENLEG 61
FOOD 50
SAN 477

COVER NOTE

From:	European Commission
date of receipt:	25 August 2022
To:	General Secretariat of the Council

No. Cion doc.:	D082175/04
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkyl substances in certain foodstuffs

Delegations will find attached document D082175/04.

Encl.: D082175/04



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/11183/2018 Rev.2
(POOL/E2/2018/11183/11183R2-
EN.docx) D082175/04
[...](2022) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkyl
substances in certain foodstuffs**

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

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 food¹, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006² 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.

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>.

- (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,

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,

For the Commission
The President
Ursula VON DER LEYEN