

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

**SANTE 11183-2018 Rev.4.**

**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 food<sup>1</sup>, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006<sup>2</sup> 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 have been 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 also the use of PFASs-containing food contact materials is likely to contribute to the human exposure to PFASs.
- (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

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<sup>1</sup> OJ L 37, 13.2.1993, p. 1.

<sup>2</sup> 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).

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in food.<sup>3</sup> PFOS, PFOA, PFNA and PFHxS can cause developmental effects, adverse effects on the serum cholesterol, the liver, the immune system and affect birth weight. EFSA 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 bw per week for the sum of PFOS, PFOA, PFNA and PFHxS, which is also protective for the other effects. EFSA concluded that the exposure of parts of the European population exceeds the TWI, which is of concern.

- (4) Taking into account the Authority's opinion and in order to ensure a high level of human health protection, for these substances maximum levels in food need to be set.
- (5) Taking into account that certain foodstuffs covered by this Regulation have a long shelf life, it is appropriate to provide that foodstuffs not complying with the new maximum levels and lawfully placed on the market before the date of application of this Regulation, may remain on the market.
- (6) Food business operators should be allowed time to adapt to the new requirements set out in this Regulation. The date of application of the maximum levels of perfluoroalkyl substances in food should therefore be deferred.
- (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 to this Regulation, that were lawfully placed on the market before the date of application may continue to be marketed until their date of minimum durability or use-by date.

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<sup>3</sup> 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>.

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### *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 [*Publication office please introduce date 6 months after entry into force*].

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

*Draft*