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

of **XXX**

**laying down methods of sampling and analysis for the control of perfluoroalkyl
substances in certain foodstuffs**

(Text with EEA relevance)

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laying down methods of sampling and analysis for the control of perfluoroalkyl substances in certain foodstuffs

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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of 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 (Official Controls Regulation)¹, and in particular Article 34(6) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006² sets out maximum levels for perfluoroalkyl substances (PFASs) in certain foodstuffs and Commission Recommendation **2022/XXXX**³ lists indicative levels beyond which the Commission recommends that Member States investigate the causes of PFASs contamination in foodstuffs with high concentrations of PFASs. In order to ensure the reliability and consistency of official controls on the maximum levels for PFASs in certain foods, detailed requirements should be set for the methods used for sampling and for laboratory analyses.
- (2) 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 95, 7.4.2017, 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 [Publication office please insert reference to SANTE 2021/10010]

HAS ADOPTED THIS REGULATION:

Article 1

For the purposes of this Regulation, the definitions and abbreviations set out in this article shall apply.

- (1) 'lot' means an identifiable quantity of food delivered at one time and determined by the competent authority to have common characteristics, such as origin, variety, species, catch area, type of packing, packer, consignor or markings;
- (2) 'sublot' means a physically separated and identifiable part of a large lot, designated to apply the sampling method;
- (3) 'incremental sample' means a quantity of material taken from a single place in the lot or sublot;
- (4) 'aggregate sample' means the combined total of all the incremental samples taken from the lot or sublot;
- (5) 'laboratory sample' means a representative part or quantity of the aggregate sample intended for the laboratory;
- (6) 'comparable size or weight' means a difference in size or weight that does not exceed 50 %;
- (7) 'precision' means the closeness of agreement between independent test results obtained under stipulated conditions. Precision is expressed as the standard deviation or coefficient of variation of the test results;
- (8) 'within laboratory reproducibility or intermediate precision (RSD_R)' means precision under a set of within-laboratory conditions in a specific laboratory;
- (9) 'limit of quantification ('LOQ')' means the lowest content of the analyte which can be measured with reasonable statistical certainty, i.e. the lowest concentration or mass of the analyte that has been validated with acceptable accuracy by applying the complete analytical method and identification criteria;
- (10) 'combined standard measurement uncertainty ('u')' means a non-negative parameter associated with the result of measurement, which characterises the dispersion of values that could reasonably be attributed to the measurand based on the information used. It is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model;
- (11) 'expanded measurement uncertainty ('U')' means the value which is obtained using a coverage factor of 2 which gives a level of confidence of approximately 95 % ($U = 2u$);
- (12) 'trueness' means the closeness of agreement between the average value obtained from a large series of test results and an accepted reference value. This value can be estimated from regular analysis of certified reference materials, fortification experiments or participation in inter-laboratory studies and is expressed as apparent bias.

Article 2

Sample preparation and analyses for the official control of the levels of PFASs in foodstuffs for which maximum levels have been established by Regulation (EC) No 1881/2006 shall be carried out in accordance with the methods set out in the Annex to this Regulation.

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*.

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