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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	6 March 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances

Delegations will find attached document [...](2024) XXX draft - D 090483/6 ANNEX.

Encl.: [...](2024) XXX draft - D 090483/6 ANNEX



EUROPEAN
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Brussels, XXX
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ANNEX

ANNEX

to the

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

**amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament
and of the Council as regards undecafluorohexanoic acid (PFHxA), its salts and PFHxA-
related substances**

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entry is added:

‘... [PO please insert the next consecutive number after the final entry]. Undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances: (a) having a linear or branched perfluoropentyl group with the formula C₅F₁₁- directly attached to another carbon atom as one of the structural elements; or (b) having a linear or branched perfluorohexyl group with the formula C₆F₁₃-. The following substances are excluded from this designation: (a) C₆F₁₄; (b) C₆F₁₃-C(=O)OH, C₆F₁₃-C(=O)O-X' or C₆F₁₃-CF₂-X' (where X' = any group, including salts); (c) any substance having a perfluoroalkyl group C₆F₁₃- directly attached to an oxygen atom at one of the non-terminal carbon atoms.	1. Shall not, from [PO: please insert the date = 24 months from the date of entry into force of this Regulation] be placed on the market, or used, in a concentration equal to or greater than 25 ppb for the sum of PFHxA and its salts, or 1000 ppb for the sum of PFHxA-related substances, measured in homogeneous material, in the following: (a) textiles, leather, furs and hides in clothing and related accessories for the general public; (b) footwear for the general public; (c) paper and cardboard used as food contact materials within the scope of Regulation (EC) No 1935/2004; (d) mixtures for the general public; (e) cosmetic products as defined in Article 2(1), point (a), of Regulation (EC) No 1223/2009. 2. Shall not, from [PO: please insert the date = 36 months from the date of entry into force of this Regulation] be placed on the market, or used, in a concentration equal to or greater than 25 ppb for the sum of PFHxA and its salts, or 1000 ppb for the sum of PFHxA-related substances, measured in homogeneous material, in textiles, leather, furs and hides, other than in clothing and related accessories referred to in paragraph 1, for the general public. 3. Paragraphs 1 and 2 shall not apply to the following: (a) personal protective equipment intended to protect users against risks within the scope of risk category III, points (a), (c) to (f), (h), and (l) of Annex I to Regulation (EU) 2016/425; (b) devices within the scope of Regulation (EU) 2017/745; (c) devices within the scope of Regulation (EU) 2017/746; (d) textiles used as construction textiles. 4. Shall not, from [PO: please insert the date = 18 months from the date of entry into force of this Regulation] be placed on the market, or used, in a concentration equal to or greater than 25 ppb for the sum of PFHxA and its salts, or 1000 ppb for the sum
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	of PFHxA-related substances, in: (a) firefighting foams and firefighting foam concentrates for training and for testing, except functional testing of the firefighting systems provided that all releases are contained; (b) firefighting foams and firefighting foam concentrates for public fire services, except where those services intervene at industrial fires at establishments covered by Directive 2012/18/EU of the European Parliament and of the Council* and they use the foams and the equipment for that purpose only. 5. Shall not, from [PO: please insert the date = 5 years from the date of entry into force of this Regulation] be placed on the market, or used, in firefighting foams and firefighting foam concentrates for civil aviation (including in civilian airports) in a concentration equal to or greater than 25 ppb for the sum of PFHxA and its salts, or 1000 ppb for the sum of PFHxA-related substances. 6. Paragraphs 1, 2, 4 and 5 shall not apply to substances having a perfluoroalkyl group C₆F₁₃-directly attached to a sulphur atom that are prohibited in Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council². 7. By way of derogation from paragraph 1, that paragraph shall not apply to articles and mixtures which were placed on the market before [PO: please insert the date = 24 months from the date of entry into force of this Regulation]. 8. By way of derogation from paragraph 2, that paragraph shall not apply to articles which were placed on the market before [PO: please insert the date = 36 months from the date of entry into force of this Regulation]. 9. For the purposes of this entry, PFHxA-related
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* Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1, ELI: <http://data.europa.eu/eli/dir/2012/18/oj>).

* ² Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45, ELI: <http://data.europa.eu/eli/reg/2019/1021/oj>).

	substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to PFHxA.’
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