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

of XXX

**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**

(Text with EEA relevance)

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

of **XXX**

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 68(1) thereof,

Whereas:

- (1) Undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances² have a combination of hazardous properties. PFHxA by far exceeds the ‘very persistent’ criterion set out in point 1.2.1 of Annex XIII to Regulation (EC) No 1907/2006, is mobile in the aquatic environment and has potential adverse effects on human health and the environment. PFHxA itself is not registered or used in the Union. Several PFHxA-related substances as well as the ammonium salt of PFHxA are registered in the Union with tonnage bands from 1 to more than 100 tonnes per annum. PFHxA-related substances and the ammonium salt of PFHxA are widely used in many sectors, with large quantities used in paper and cardboard for use as food contact materials, in textiles and in firefighting foams. The continued use of PFHxA salts and PFHxA-related substances in particular in wide dispersive uses will lead to an increasing environmental stock and further environmental and human exposure.
- (2) On 20 December 2019, Germany submitted to the European Chemicals Agency (‘the Agency’), a dossier³ pursuant to Article 69(4) of Regulation (EC) No 1907/2006 (‘the Annex XV dossier’) proposing to restrict the manufacture, use and placing on the market of PFHxA, its salts and PFHxA-related substances on their own, and to restrict their use in the production of and placing on the market in another substance, as a constituent, in a mixture or in an article or their use in another substance, in a mixture or in an article, with a general transition period of 18 months. In order to address the

¹ OJ L 396, 30.12.2006, p 1.

² PFHxA-related substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to PFHxA. A non-exhaustive list of substances belonging to the scope of the restriction proposal is available on the website of the European Chemicals Agency: <https://echa.europa.eu/documents/10162/7da473c1-7f27-df34-9e6a-46152ef10d4b>

³ <https://echa.europa.eu/documents/10162/c4e04484-c989-733d-33ed-0f023e2a200e>

risks to human health and the environment, Germany proposed concentration limits of 25 ppb for the sum of PFHxA and its salts, and 1000 ppb for the sum of PFHxA-related substances.

- (3) In addition, both time-limited and non-time-limited derogations were proposed by Germany for certain uses taking into account the socio-economic impact and the availability of alternatives. For the use of PFHxA, its salts and PFHxA-related substances in firefighting foams, Germany proposed a reporting obligation for a natural or legal person benefitting from the proposed derogations.
- (4) On 3 June 2021, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion concluding that it has not been demonstrated that the restriction on PFHxA, its salts and PFHxA-related substances as proposed by Germany is the most appropriate Union-wide measure to address the identified risks. Nevertheless, RAC considers that a broad Union-wide restriction with carefully considered targeted derogations and transition periods is the most appropriate Union-wide measure to address the identified risks in terms of effectiveness, practicality and monitorability.
- (5) RAC supported the restriction as proposed by Germany regarding the uses where it is not possible to implement risk management measures to minimise emissions, especially wide dispersive consumer uses in food contact materials, in textiles as well as in firefighting foams used for municipal firefighting, which comprise three major emission sources. However, based on the limited information available on the conditions of use and the effectiveness of risk management measures, RAC could not conclude on whether certain other uses contribute to the identified risks, such as chrome plating and firefighting foams used at industrial installations. For those other uses, the uncertainties around the current conditions of use and effectiveness of risk management measures are too large to conclude that the restriction as proposed by Germany was the most effective risk management option.
- (6) Furthermore, RAC did not support the justification for most of the derogations as proposed by Germany as there was insufficient information available to conclude that releases from those uses were minimised. However, in the event that a restriction would be imposed, RAC supported derogations for the following uses as credible information on the minimisation of releases from those uses was available: semiconductors and semiconductor related equipment, epilame in watches, coating for hearing devices, implantable medical devices and transported isolated intermediates.
- (7) RAC agreed with the concentration limits and general transition period as proposed by Germany. RAC also noted that standard analytical methods for the substances and matrices within the scope of restriction as proposed by Germany are required to be developed. However, RAC concluded that, in general, analytical methods are commercially available to monitor exposures and the implementation of the restriction as proposed by Germany.
- (8) On 8 December 2021, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion concluding that it has not been demonstrated that the restriction on PFHxA, its salts and PFHxA-related substances as proposed by Germany is the most appropriate Union-wide measure to address the identified risks, taking into account its socio-economic benefits and costs. SEAC considered that a restriction on PFHxA, its salts and PFHxA-related substances is, in general, an appropriate measure to address the identified risks. However, based on the limited available information on socio-economic impacts and emission estimates, SEAC could not conclude whether the conditions of the restriction, as modified by SEAC, are, as a

whole, the most appropriate measures to address the identified risks. Nevertheless, SEAC concluded on the socio-economic benefits and costs of a restriction for certain uses, where information on socio-economic impacts was less uncertain. SEAC took into account RAC's conclusions on effectiveness of risk management measures and the minimisation of emissions, the irreversibility of emissions of PFHxA to the environment, the information available on alternatives, the possible functional losses and socio-economic impacts. SEAC concluded that restricting the uses in consumer apparel textiles, firefighting foams in municipal and mobile firefighting, paper and cardboard as food contact materials and consumer mixtures is likely not an inappropriate measure, in terms of its socio-economic benefits and its costs, to address the risk, and that restricting the use in cosmetic products is likely an appropriate measure, in terms of its socio-economic benefits and its costs, to address the risk.

- (9) SEAC did not agree with the proposed general transition period of 18 months. SEAC considered that the transition period should be long enough to ensure that producers, importers and users of substances, mixtures and articles are able to comply with the restriction and adapt their operations to allow for the phasing-out and substitution of PFHxA, its salts and PFHxA-related substances and to allow for adaptations within the affected supply chains. Therefore, SEAC proposed a general transition period of 36 months.
- (10) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1), point (f), of Regulation (EC) No 1907/2006, was consulted during the restriction process and its opinion has been taken into account. SEAC noted the Forum's opinion that the restriction as proposed by Germany can be regarded as enforceable, as long as it is clear which substances are in the scope of the restriction and that reliable normative test methods are defined covering all types of regulated substances.
- (11) On 10 May 2022, the Agency submitted the opinions of RAC and SEAC⁴ to the Commission.
- (12) Taking into account the Annex XV dossier and the opinions of RAC and SEAC, the Commission considers that an unacceptable risk to human health and the environment arises from the use and placing on the market of PFHxA, its salts and PFHxA-related substances in certain mixtures and in certain articles, which needs to be addressed on a Union-wide basis.
- (13) The Commission considers that it is not demonstrated that the proposed restriction, as modified by RAC and SEAC, is the most appropriate Union-wide measure to address the identified risks, taking into account that the data presented on emissions, risk reduction and socio-economic impacts are uncertain. RAC clearly indicated that the reported quantitative release estimates are unreliable due to numerous inconsistencies between different sections of the Background Document to the Opinion on the Annex XV dossier⁵, insufficient justifications for the assumptions made and significant gaps in the information presented or in the reporting of the underlying calculation methodology for the different use sectors.
- (14) Despite the existing uncertainties on the data available, the Commission concurs with RAC that releases to the environment and exposure to humans have been confirmed

⁴ <https://echa.europa.eu/documents/10162/97eb5263-90be-ed5-0dd9-7d8c50865c7e>

⁵ <https://echa.europa.eu/documents/10162/5c011606-5891-d26a-03e7-ceba0a35126f>

by a large set of environmental and human monitoring data, and that the manufacture of PFHxA, its salts and PFHxA-related substances, and the uses of those substances that result in releases to the environment that are not adequately controlled, should be minimised. Instead of a broad restriction, the Commission considers a targeted restriction as the most appropriate Union-wide measure to address the identified risks. The Commission considers that the restriction should be targeted to those uses for which RAC concluded that it is not possible to implement risk management measures to minimise emissions and SEAC concluded that restricting that specific use is likely appropriate or likely not inappropriate in terms of socio-economic benefits and costs. For those uses, the Commission considers that the risk is not adequately controlled, alternatives are available and socio-economic costs are likely to be limited in comparison to the human health and environmental benefits.

- (15) Therefore, the Commission considers it necessary to adopt a Union-wide restriction for placing on the market or use of PFHxA, its salts and PFHxA-related substances in textiles, leather, furs and hides in clothing (such as outdoor clothing like rain jackets); related accessories (such as handbags) and footwear for the general public; paper and cardboard used as food contact materials; mixtures for the general public; cosmetic products; and some firefighting foams applications.
- (16) Although SEAC could not conclude on the magnitude of socio-economic costs in relation to the benefits for textiles, leather, furs and hides other than in clothing and related accessories for the general public, the Commission considers that the use in those materials should also be restricted because there are indications that considerable amounts of PFHxA-related substances might be used; it is a wide dispersive use where the risk is not adequately controlled; emissions cannot be minimised by the application of risk management measures, as concluded by RAC; and alternatives for water repellent properties appear to be available. The product types concerned include carpets, rugs, curtains, blinds, upholstery, textile wall covers and other textile-based coverings (such as tablecloths or bed linen). This includes product types concerned in transport and public places, as well as in offices as it can be assumed that those offices are visited by the general public. For those restricted product types, it has not been well established that the lack of oil and stain repellent properties would lead to functional losses with significant negative impacts. Given the possible socio-economic impacts related to functional losses where alternatives do not provide sufficient oil and stain repellence, a longer transition period for textiles other than in clothing and related accessories for the general public is considered to be justified.
- (17) Despite their wide-dispersive use, certain textiles, leather, furs and hides and related accessories and footwear where specific requirements to the technical performance cannot be met otherwise, should be exempted from this restriction, because of the need for such materials to fulfil specific requirements in terms of safety or functionality. These exemptions take into account the expected socioeconomic impacts and apply to uses for which alternatives appear currently not available. Exempted articles are textiles, leather, furs and hides and related accessories and footwear used as (parts of) personal protective equipment within the scope of risk category III (a), (c), (d), (e), (f), (h), (l) of Annex I of Regulation (EU) 2016/425 of the European Parliament and of the Council⁶, medical devices and medical textiles within the scope of Regulation (EU)

⁶ Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

2017/745 of the European Parliament and of the Council⁷, in vitro diagnostic medical devices within the scope of Regulation 2017/746⁸ and construction textiles, like membranes for light shoring or surface structure, reinforcement fabric, textile façade substructures, insulate material against cold and heat and textile roofing systems. These exemptions do not apply to textiles intended for private use. This is the case if they are intended for use by the consumer within the meaning of Article 2 (2) of Directive (EU) 2019/771⁹. Accordingly, a consumer is any natural person who uses textiles outside their trade, business, craft or profession. The general public does not include the use of products by consumers for which an EU conformity assessment procedure is required following Annex II Module B of Decision No 768/2008/EC¹⁰. Products subject to EU-type examination are only intended for a narrowly defined range of consumers who require particularly stringent authorisation due to the level of risk involved.

- (18) On 14 January 2022, the Agency submitted on behalf of the Commission a dossier¹¹ pursuant to Article 69(1) of Regulation (EC) No 1907/2006, proposing to restrict the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS) in firefighting foams (both concentrates and the ready to use mixture of firefighting foam). PFHxA, its salts and PFHxA-related substances are in the scope of that restriction proposal. The Commission considers that a decision on restricting the use of PFHxA, its salts and PFHxA-related substances in most firefighting foams uses is more appropriately reached based on the restriction dossier for all PFAS in firefighting foams. However, given that alternatives are widely available and already in use for PFHxA, its salts and PFHxA-related substance in firefighting foams used for training and testing, for public fire services and for civil aviation, the Commission considers that restricting those uses should not be delayed.
- (19) The Commission agrees with the concentration limits as proposed by Germany, RAC and SEAC.
- (20) [On duty, public fire services may face different types of fires and establishments. To take into account the variability in the organisation of public fire services in all Member States and to ensure a high level of fire safety, the placing on the market and use of of PFHxA, its salts and PFHxA-related substances in firefighting foams and firefighting foam concentrates shall be derogated for use in industrial settings by those public fire services.]
- (21) The Commission notes that uses of PFHxA, its salts and PFHxA-related substances not covered by this targeted restriction, are also included in two other pending restriction dossiers, notably per- and polyfluoroalkyl substances (PFAS) in firefighting

⁷ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁸ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176–332).

⁹ Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC

¹⁰ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

¹¹ <https://echa.europa.eu/documents/10162/4524f49c-ae14-b01b-71d2-ac3fa916c4e9>

foams¹² and PFAS in all other uses¹³. The need to restrict those uses will therefore be further considered based on the justification and information provided in those dossiers.

- (22) The Commission considers that a derogation for any substance having a perfluoroalkyl group C₆F₁₃-directly attached to a sulphur atom (PFHxS, its salts and related substances) should be provided for, since those substances are restricted by Regulation (EU) 2019/1021 of the European Parliament and of the Council¹⁴.
- (23) The Commission agrees with RAC and SEAC that substances having a perfluoroalkyl group C₆F₁₃- directly attached to an oxygen atom at one of the non-terminal carbons should be excluded from the scope of substances subject to the restriction since those substances cannot be transformed into PFHxA. Their chemical structure is such that a degradation to a carboxylic acid or to a carboxylate would form two separate shorter fluoroalkyl chains, the hazards and risks of which were not assessed in the Annex XV dossier.
- (24) Stakeholders and Member States should be allowed sufficient time to take appropriate measures to comply with the restriction. Therefore, taking into account the suggestions from the Annex XV dossier, as well as RAC's and SEAC's considerations, the application of the restriction should be deferred for 18 months for firefighting foams used in training, testing and public fire services [, except for use in industrial fires for establishments covered by the Directive 2012/18/EU (Seveso III)¹⁵, as regards the use in these establishments only and the use the equipment only for this purpose]; 24 months for textiles, leather, furs and hides in clothing and related accessories and footwear for the general public, paper and cardboard used as food contact materials, mixtures for general public and cosmetic products; 36 months for textiles, leather, furs and hides other than in clothing and related accessories for the general public; and 5 years for firefighting foams used in civil aviation.
- (25) The restriction should not apply to articles and mixtures placed on the market prior to the respective date of application of the restriction, for practicality and enforceability reasons.
- (26) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (27) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

¹² <https://echa.europa.eu/documents/10162/4524f49c-ae14-b01b-71d2-ac3fa916c4e9>

¹³ <https://echa.europa.eu/documents/10162/1c480180-ec99-1bdd-1eb8-0f3f8e7c0c49>

¹⁴ 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).

¹⁵ 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. 1–37).

Article 2

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



EUROPEAN
COMMISSION

Brussels, XXX
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[...] (2023) XXX draft

ANNEX

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to the

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and of the Council as regards undecafluorohexanoic acid (PFHxA), its salts and PFHxA-
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ANNEX

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

‘... [OP please insert the next consecutive number]. Undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances: - having a linear or branched perfluoropentyl group with the formula C₅F₁₁- directly attached to another carbon atom as one of the structural elements; or - 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 carbons.	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: - textiles, leather, furs and hides in clothing and related accessories for the general public; - footwear for the general public; - paper and cardboard used as food contact materials within the scope of Regulation (EC) No 1935/2004; - mixtures for the general public; - 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. Paragraphs 1 and 2 shall not apply to technical textiles¹⁶ for which one or both the following criteria can apply: - a maximum repellence to liquids and dust of 27.5 (mN/m) according to DIN EN ISO 14419:2010-08 - a minimum oil note 3 is required and the use has serious effects on the textile functionality and normative requirements for the safety and health of the consumer or other persons are mandatory. These derogation criteria apply but are not limited to: - personal protective equipment intended to
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¹⁶ Technical textiles. Reference CCMI/105-EESC-2012-01-01-1966.
The European Economic and Social Committee.

	protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council; - medical devices as specified in Regulation (EU) 2017/745 of the European Parliament and of the Council; woven, knitted and nonwoven medical textiles as specified in Regulation (EU) 2017/745 of the European Parliament and of the Council 3. 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 of PFHxA-related substances, in: - firefighting foams and firefighting foam concentrates for training and for testing (except testing of the firefighting systems for their functioning); - firefighting foams and firefighting foam concentrates for public fire services [except if also in charge of industrial fires for establishments covered by the Directive 2012/18/EU (Seveso III)¹⁷, as regards use in these establishments only and the use of the equipment only for this purpose]. 4. 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. 5. Paragraphs 1, 2, 3 and 4 shall not apply to substances having a perfluoroalkyl group C₆F₁₃- directly attached to a sulphur atom. 6. By way of derogation from paragraph 1, that paragraph shall not apply to articles and mixtures for which it can be demonstrated that these were placed on the market before [PO: please insert the date = 24 months from the date of entry into force
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¹⁷

OJ L 197, 24.7.2012, p. 1–37.

	<i>of this Regulation].</i> 7. By way of derogation from paragraph 2, that paragraph shall not apply to articles for which it can be demonstrated that these were placed on the market before <i>[PO: please insert the date = 36 months from the date of entry into force of this Regulation].</i> 8. For the purposes of this entry, PFHxA-related 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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