Commission Regulation (EU) 2017/1000 of 13 June 2017 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/1000

of 13 June 2017

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-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/EC[(1)], and in particular Article 68(1) thereof,

Whereas:

(1) Perfluorooctanoic acid ('PFOA'), its salts and PFOA-related substances[(2)] have some specific properties such as high friction resistance, dielectricality, resistance to heat and chemical agents, and low surface energy. They are used in a wide variety of applications such as in the fluoropolymer and fluoroelastomer production, as surfactants in fire-fighting foams, and in textile and paper production to provide water, grease, oil and/or dirt repellency.

(2) On 14 June 2013, the Member State Committee, referred to in Article 76(1)(e) of Regulation (EC) No 1907/2006, identified PFOA as a persistent, bioaccumulative and toxic substance ('PBT') in accordance with Article 57(d) of that Regulation. On 20 June 2013, PFOA was included in the Candidate List of Substances of Very High Concern ('SVHC') for possible inclusion in Annex XIV to Regulation (EC) No 1907/2006.

(3) On 17 October 2014, Germany and Norway submitted to the European Chemicals Agency ('the Agency') a dossier[(3)] pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'), proposing to restrict the manufacture, placing on the market and use of PFOA, its salts and PFOA-related substances, in order to address the risks to human health and the environment. Germany and Norway proposed a concentration limit of 2 ppb for the presence of these substances in other substances,

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/1000. (See end of Document for details)*

mixtures or articles, and did not propose exemptions except for second-hand articles for which an end-use in the Union can be demonstrated before the date of application of the restriction.

(4) On 8 September 2015, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion concluding that subject to modification of the scope and conditions proposed in the Annex XV dossier, a general restriction on manufacture, use and placing on the market of PFOA, its salts and PFOA-related substances, is the most appropriate Union-wide measure to address the identified risks in terms of effectiveness in reducing those risks. RAC proposed two different concentration limits, namely 25 ppb for PFOA and its salts and 1 000 ppb for one or a combination of PFOA-related substances, in other substances, mixtures or articles, reflecting the possible presence of unavoidable impurities and unintended contaminants, and taking account of the capabilities of analytical methods. RAC proposed to exempt from the restriction photographic coatings applied to films, papers or printing plates, implantable medical devices and substances or mixtures used in semiconductor and photolithography processes, considering the relatively low environmental impact and long substitution timeframes. RAC also proposed to exempt the use of substances as transported isolated intermediates in order to allow the manufacture of alternatives, as well as the placing on the market of second-hand articles.

(5) On 4 December 2015, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion, indicating that the restriction proposed in the Annex XV dossier, as modified by RAC and SEAC, is the most appropriate Union-wide measure to address the identified risks in terms of its socioeconomic benefits and socioeconomic costs.

(6) SEAC agreed with the exemptions proposed by RAC. In addition, SEAC suggested a three year deferral of the restriction, instead of the eighteen months proposed in the Annex XV dossier, to allow stakeholders to take the necessary compliance measures. Based on socioeconomic considerations, such as high costs, significant economic burden, lack of alternatives, relatively low emissions to the environment, critical uses with high societal benefits, SEAC suggested longer deferrals of the restriction for latex printing inks, textiles for the protection of workers, membranes intended for medical textiles, filtration in water treatment, production processes, and effluent treatment, certain plasma nano-coatings and non-implantable medical devices.

(7) SEAC also suggested to exempt from the proposed restriction fire-fighting foams already placed on the market before the date of application of the restriction, and semiconductor manufacturing equipment.

(8) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1)(f) of Regulation (EC) No 1907/2006, was consulted during the restriction process and its opinion has been taken into account.

(9) On 12 January 2016, the Agency submitted the opinions of the RAC and the SEAC[(4)] to the Commission.

(10) Based on those opinions, the Commission concluded that an unacceptable risk to human health and the environment arises from the manufacture, use or placing on the market

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2017/1000. (See end of Document for details)*

of PFOA, its salts and PFOA-related substances on their own, as a constituent of other substances, in mixtures and in articles. The Commission considers that those risks need to be addressed on a Union wide basis.

(11) Perfluorooctane sulfonic acid ('PFOS') and its derivatives should be exempted from the proposed restriction, since those substances are already regulated by Regulation (EC) No 850/2004 of the European Parliament and of the Council[(5)]. The unavoidable production of PFOA during the manufacture of fluorochemicals with a carbon chain equal to or shorter than six atoms should also be exempted from the proposed restriction.

(12) As advised by SEAC, the application of the restriction should be deferred generally for a period of three years and for longer periods in relation to specified sectors in order to enable stakeholders to comply with the proposed restriction. While a standard analytical method is available for the determination of extractable PFOS in coated and impregnated solid articles, liquids and firefighting foams (CEN/TS 15968:2010), which most likely can be adjusted to also include PFOA and PFOA-related substances with a relevant detection limit, at present no such standard method is available for extraction and chemical analysis of those substances. The deferral period for the restriction should allow the further development of suitable analytical methods that can be applied to all matrices.

(13) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(14) 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.

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, 13 June 2017.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/1000. (See end of Document for details)*

ANNEX

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

68. Perfluorooctanoic acid (PFOA) CAS No 335-67-1 EC No 206-397-9 and its salts. Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula C_7F_{15}- directly attached to another carbon atom, as one of the structural elements. Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C_8F_{17}- as one of the structural elements. The following substances are excluded from this designation: — C_8F_{17}-X, where X = F, Cl, Br. — C_8F_{17}-C(=O)OH, C_8F_{17}-C(=O)O-X′ or C_8F_{17}-CF_2-X′ (where X′ = any group, including salts).	1. Shall not be manufactured, or placed on the market as substances on their own from 4 July 2020. 2. Shall not, from 4 July 2020, be used in the production of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, in a concentration equal to or above 25 ppb of PFOA including its salts or 1 000 ppb of one or a combination of PFOA-related substances. 3. Points 1 and 2 shall apply from: (a) 4 July 2022 to: (i) equipment used to manufacture semi-conductors; (ii) latex printing inks. (b) 4 July 2023 to: (i) textiles for the protection of workers from risks to their health and safety; (ii) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment; (iii) plasma nano-coatings. (c) 4 July 2032 to medical devices other than implantable medical devices within the scope of Directive 93/42/EEC. 4. Points 1 and 2 shall not apply to any of the following: (a) perfluorooctane sulfonic acid and its derivatives, which are listed in Part A of Annex I to Regulation (EC) No 850/2004; (b) the manufacture of a substance where this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 6 atoms;