EUROPEAN
COMMISSION

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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 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)

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(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, mixtures or articles, and did not propose exemptions except for second-

1 OJ L 396, 30.12.2006, p 1.

2 PFOA-related substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to PFOA.

3 http://echa.europa.eu/documents/10162/e9cddee6-3164-473d-b590-8fcf9caa50e7

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 1000 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 socio-economic benefits and socio-economic 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 socio-economic 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 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.

[4] https://echa.europa.eu/documents/10162/2f0dfce0-3dcf-4398-8d6b-2e59c86446be

(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.

(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,

For the Commission
The President
Jean-Claude Juncker

[5] Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7).