# Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds (Text with EEA relevance)

## COMMISSION DELEGATED REGULATION (EU) 2020/784

## of 8 April 2020

## amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

## (Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants[(1)], and in particular Article 15(1) thereof,

Whereas:

(1) Regulation (EU) 2019/1021 implements the commitments of the Union under the Stockholm Convention on Persistent Organic Pollutants[(2)] ('the Convention') and under the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants[(3)] ('the Protocol').

(2) Annex A to the Convention ('Elimination') contains a list of chemicals for which each Party to the Convention is required to prohibit and/or take the legal and administrative measures necessary to eliminate their production, use, import and export.

(3) The Conference of the Parties to the Convention has, pursuant to Article 8(9) of the Convention, decided in its ninth meeting to amend Annex A to the Convention in order to include perfluorooctanoic acid ('PFOA'), its salts and PFOA-related compounds in that Annex. That amendment contains various specific exemptions.

(4) Part A of Annex I to Regulation (EU) 2019/1021, which contains a list of the substances listed in the Convention and in the Protocol as well as substances listed only in the Convention, should therefore also be amended to include PFOA, its salts and PFOA-related compounds.

(5) PFOA, its salts and PFOA-related compounds are listed in Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(4)], subject to certain derogations. Those derogations were assessed by the Persistent Organic Pollutants Review Committee ('POPRC') with the result that not all of them were recommended to the Conference of the Parties. Consequently, the decision adopted by the Conference of the Parties (SC-9/12) contains some but not all derogations previously granted under Regulation (EC) No 1907/2006. Considering that the POPRC assessment was based

on more recent information and considering Council Decision (EU) 2019/639[(5)], it is appropriate to allow in Annex I to Regulation (EU) 2019/1021 only those specific exemptions that are granted under the Convention and needed in the Union.

(6) The Conference of the Parties to the Convention decided in its ninth meeting on a specific exemption that is not included in Annex XVII to Regulation (EC) No 1907/2006. It concerns the use of perfluorooctyl bromide containing perfluorooctyl iodide for the purpose of producing pharmaceutical products. Considering that information on this use was not available at the time of the listing of PFOA, its salts and PFOA-related compounds in Annex XVII to Regulation (EC) No 1907/2006 and considering the subsequent assessment by the European Chemicals Agency[(6)], it is considered appropriate to include that specific exemption in Annex I to Regulation (EU) 2019/1021.

(7) In order to reinforce the application and enforcement in the Union of Article 3 of Regulation (EU) 2019/1021, a limit value should be set for PFOA, its salts and PFOA-related compounds occurring as an unintentional trace contaminant in substances, mixtures and articles. That limit value should be set at 0,025 mg/kg for PFOA including its salts, and at 1 mg/kg for the individual PFOA-related compounds or a combination of those compounds. For applications where those concentration limits cannot currently be met, higher concentration limits should be established, subject to review by the Commission within 2 years with a view to lowering the limits.

(8) Regulation (EU) 2019/1021 should therefore be amended accordingly.

(9) Considering that some derogations previously granted in the restriction on PFOA, its salts and PFOA-related compounds in Annex XVII to Regulation (EC) No 1907/2006 are still needed by industry for a transitional period but are not among the specific exemptions in Annex I to Regulation (EU) 2019/1021, such derogations should apply until 3 December 2020, which is the date of entry into force of the amendment of Annex A to the Stockholm Convention concerning PFOA, its salts and PFOA-related compounds.

(10) The restriction on PFOA, its salts and PFOA-related compounds in Annex XVII to Regulation (EC) No 1907/2006, which the Commission now plans to delete, would normally start to apply on 4 July 2020. For reasons of coherence and to facilitate the implementation of Regulation (EU) 2019/1021, this Regulation should apply from the same date,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EU) 2019/1021 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*.

It shall apply from 4 July 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 April 2020.

*For the Commission*

*The President*

Ursula VON DER LEYEN

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/784. (See end of Document for details)*

ANNEX

In Part A of Annex I to Regulation (EU) 2019/1021, the following entry is added:

| **Substance** | **CAS No** | **EC No** | **Specific exemption on intermediate use or other specification** |
|---|---|---|---|
| ‘Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds<br>“Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds” means the following:<br>(i) perfluorooctanoic acid, including any of its branched isomers;<br>(ii) its salts;<br>(iii) PFOA-related compounds which, for the purposes of the Convention, are any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety $(C_7F_{15})C$ as one of the | 335-67-1 and others | 206-397-9 and others | 1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA or any of its salts equal to or below 0,025 mg/kg (0,0000025 % by weight) where they are present in substances, mixtures or articles.<br>2. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of any individual PFOA-related compound or a combination of PFOA-related compounds equal to |

**a** 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.”.

| | | | |
|---|---|---|---|
| structural elements.<br>The following compounds are not included as PFOA-related compounds:<br>(i) $C_8F_{17}$-X, where X = F, Cl, Br;<br>(ii) fluoropolymers that are covered by $CF_3[CF_2]_n$-R', where R'=any group, n> 16;<br>(iii) perfluoroalkyl carboxylic acids (including their salts, esters, halides and anhydrides) with ≥ 8 perfluorinated carbons;<br>(iv) perfluoroalkane sulfonic acids and perfluoro phosphonic acids (including their salts, esters, halides and anhydrides) with ≥ 9 perfluorinated carbons;<br>(v) perfluorooctane sulfonic acid and its derivatives (PFOS), as listed in this Annex. | | | or below 1 mg/kg (0,0001 % by weight) where they are present in substances, mixtures or articles.<br>3. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA-related compounds equal to or below 20 mg/kg (0,002 % by weight) where they are present in a substance to be used as a transported isolated intermediate within the meaning of Article 3 point 15(c) of Regulation (EC) No 1907/2006 and fulfilling the strictly controlled conditions set out in Article 18(4)(a) to |

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