COMMISSION DELEGATED REGULATION (EU) 2021/115

of 27 November 2020

amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards 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]).

(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, taking into account applicable specific exemptions laid down in that Annex.

(3) Commission Delegated Regulation (EU) 2020/784 ([4]) amended Annex I to Regulation (EU) 2019/1021 to include perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds.

(4) Article 15(1) of Regulation (EU) 2019/1021 empowers the Commission to adopt delegated acts to modify existing entries of Annex I to adapt them to scientific and technical progress.

(5) After the adoption of Delegated Regulation (EU) 2020/784, the Commission was informed of the presence of unintentional impurities of PFOA and its salts above the limit of 0,025 mg/kg (0,0000025 % by weight) laid down in that Regulation in some medical devices other than implantable devices and invasive devices.

(6) In order to avoid the prohibition of manufacturing of such medical devices after 3 December 2020 and in order to give manufacturers enough time to reduce the level of the impurities, an Unintentional Trace Contaminant (UTC) limit of 2 mg/kg (0,0002 % by weight) should be set for PFOA, its salts and PFOA-related compounds, subject to a review.

(7) Delegated Regulation (EU) 2020/784 introduced a UTC limit for PFOA and its salts in polytetrafluoroethylene (PTFE) micropowders produced by ionising irradiation of up to 400 kilograys.

(8) After the adoption of Delegated Regulation (EU) 2020/784, the Commission was informed that the requirement for the production process by ionising irradiation to take place with up to 400 kilograys was too specific for the operators to comply with and for the authorities to check compliance. The reference to 400 kilograys should therefore be deleted.

(9) Delegated Regulation (EU) 2020/784 introduced a UTC limit for PFOA-related compounds where they are present in a substance to be used as a transported isolated intermediate for the production of fluorochemicals with a carbon chain equal to or shorter than 6 atoms.

([1]) OJ L 169, 25.6.2019, p. 45.
([2]) OJ L 209, 31.7.2006, p. 3.
([3]) OJ L 81, 19.3.2004, p. 37.
([4]) 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 (OJ L 188 I, 15.6.2020, p. 1).

(10) The UTC limit was meant to cover intermediates used for the production of alternatives to PFOA with 6 or less fully fluorinated carbon atoms. For sake of clarity, the word 'perfluoro' should be added before 'carbon chain'.

(11) Regulation (EU) 2019/1021 should therefore be amended accordingly,

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*.

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

Done at Brussels, 27 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Part A of Annex I to Regulation (EU) 2019/1021, in the table, the fourth column ('Specific exemption on intermediate use or other specification') of the entry for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds is amended as follows:

(1) the first sentence of point 3 is replaced by the following:

'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 (f) of that Regulation for the production of fluorochemicals with a perfluoro carbon chain equal to or shorter than 6 atoms.';

(2) the first sentence of point 4 is replaced by the following:

'4. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA and its salts equal to or below 1 mg/kg (0,0001 % by weight) where they are present in polytetrafluoroethylene (PTFE) micropowders produced by ionising irradiation or by thermal degradation as well as in mixtures and articles for industrial and professional uses containing PTFE micropowders.';

(3) the following point 10 is added:

'10. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA and its salts and/or PFOA-related compounds equal to or below 2 mg/kg (0,0002 % by weight) where they are present in medical devices other than invasive devices and implantable devices. This exemption shall be reviewed and assessed by the Commission no later than 22 February 2023'.