

COMMISSION DELEGATED REGULATION (EU) 2023/866**of 24 February 2023****amending 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 contains a list of chemicals for which each Party to the Convention is required to prohibit 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) Annex I to Regulation (EU) 2019/1021 contains an unintentional trace contaminant (UTC) limit for PFOA and its salts in polytetrafluoroethylene (PTFE) micropowders of 1 mg/kg, to be reviewed by 5 July 2022.
- (5) The Risk Assessment Committee and the Committee for Socioeconomic Analysis of the European Chemicals Agency (ECHA) adopted an opinion ⁽⁵⁾ ('ECHA's opinion'), which included the assessment of two UTC limits set for PFOA, its salts and PFOA-related compounds.
- (6) ECHA's opinion concluded that processes have been developed to reduce the concentration of PFOA to a level below the generic UTC limit of 0,025 mg/kg set out in Regulation (EU) 2019/1021. Those processes have been successfully implemented by most polytetrafluoroethylene (PTFE) micropowder manufacturers. The remaining manufacturers would be able to comply with the limit of 0,025 mg/kg by 5 July 2022. Therefore, the current specific UTC limit for PFOA and its salts in PTFE micropowders of 1 mg/kg is no longer needed and should expire at the date of application of this Regulation.
- (7) Regulation (EU) 2019/1021 refers to Article 3(12) and (24) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽⁶⁾ to define 'placing on the market' and 'use'. The treatment of PTFE micropowders would qualify as 'use' and the transfer to a different legal entity for treatment would qualify as 'placing on the market'.

⁽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).

⁽⁵⁾ https://echa.europa.eu/documents/10162/13579/art77_3c_pfoa_pfca_derogations_compiled_rac_seac_opinions_en.pdf/6582d9a1-56b2-3e88-a70f-cdf3ab33d421

⁽⁶⁾ 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 (OJ L 396, 30.12.2006, p. 1).

- (8) In at least one case there is a need to transport the PTFE micropowders to a different facility for treatment in order to reduce the concentration of PFOA and its salts to comply with the UTC limit of 0,025 mg/kg. Therefore, the current specific UTC limit of 1 mg/kg should be maintained to cover manufacture, placing on the market and use of PFOA and its salts in PTFE micropowders only for the purpose of transport and treatment of PTFE micropowders to reduce the PFOA concentration.
- (9) PFOA-related compounds are present as an impurity in transported isolated intermediates used in the manufacturing of fluorochemicals with a perfluorocarbon chain length equal to or shorter than six atoms. To allow the manufacture and use of such transported isolated intermediates, Regulation (EU) 2019/1021 sets a UTC limit of 20 mg/kg, to be reviewed no later than 5 July 2022.
- (10) ECHA's opinion concluded that the present UTC level is the lowest that can be complied with, taking into account the available technological solutions. Therefore, the review of the UTC limit should be postponed.
- (11) C9-C14 PFCAs are also present as impurities in transported isolated intermediates used in the manufacturing of fluorochemicals with a perfluorocarbon chain length equal to or shorter than six atoms ('C6 alternatives'). Commission Regulation (EU) 2021/1297 ⁽⁷⁾ provides for a restriction under Regulation (EC) No 1907/2006 that sets a limit on their concentration, which is to be reviewed no later than 25 August 2023. The timing of the review of the UTC for PFOA-related compounds in intermediates used for the production of C6 alternatives under Regulation (EU) 2019/1021 should be modified to align it with the review foreseen in the restriction for C9-C14 PFCAs under Regulation (EC) No 1907/2006.
- (12) Annex I to Regulation (EU) 2019/1021 includes an exemption for the use of PFOA, its salts and PFOA-related compounds in the manufacture of PTFE and polyvinylidene fluoride (PVDF) for the production of several products.
- (13) During the public consultation for the preparation of ECHA's opinion, fluoropolymers producers commented that PFOA, its salts and PFOA-related compounds are no longer used for the manufacture of PTFE and PVDF in the Union. Based on this information, that specific exemption is no longer needed and should therefore be deleted.
- (14) The application of this Regulation should be deferred to provide the concerned stakeholders with sufficient time to adapt to the new requirements.
- (15) 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*.

⁽⁷⁾ Commission Regulation (EU) 2021/1297 of 4 August 2021 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances (OJ L 282, 5.8.2021, p. 29).

It shall apply from 18 August 2023.

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

Done at Brussels, 24 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Regulation (EU) 2019/1021, Annex I, Part A, in the table, in the entry 'Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds', the fourth column is amended as follows:

(1) in point 3, the second sentence is replaced by the following:

'This exemption shall be reviewed and assessed by the Commission no later than 25 August 2023.';

(2) point 4 is replaced by the following:

4. For the purposes of this entry, Article 4(1), point (b), 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 until 18 August 2023. All emissions of PFOA during the manufacture and use of PTFE micropowders shall be avoided and, if not possible, reduced as far as possible. The limit of 1 mg/kg (0,0001 % by weight) shall apply only to manufacture, placing on the market and use of PFOA and its salts where they are present in PTFE micropowders that are transported or treated for the purpose to reduce the concentration of PFOA and its salts below the limit of 0,025 mg/kg (0,0000025 % by weight).';

(3) in point 5, subpoint (e) is deleted.
