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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	14 April 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.:	C(2025) 2189 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 14.4.2025 amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards perfluorooctane sulfonic acid and its derivatives

Delegations will find attached document C(2025) 2189 final.

Encl.: C(2025) 2189 final



Brussels, 14.4.2025
C(2025) 2189 final

COMMISSION DELEGATED REGULATION (EU) .../...

of 14.4.2025

amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards perfluorooctane sulfonic acid and its derivatives

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

The objective of Regulation (EU) 2019/1021 is to protect human health and the environment from persistent organic pollutants ('POPs') by prohibiting, phasing out as soon as possible, or restricting the manufacturing, placing on the market and use of substances subject to the Stockholm Convention on POPs.

Perfluorooctane sulfonic acid and its derivatives (PFOS) is listed in Annex I to Regulation (EU) 2019/1021 ('PFOS entry'). Following Article 4(1)(b) of Regulation (EU) 2019/1021, the PFOS entry in Annex I includes Unintentional Trace Contaminant (UTC) limit values in substances, mixtures and articles in points 1 and 2 of the fourth column and a specific exemption for the use as mist suppressant for non-decorative hard-chromium plating in point 4. Following Article 15(1) of Regulation (EU) 2019/1021, the Commission can modify existing entries in order to adapt them to scientific and technical progress.

PFOS was the first per- and polyfluoroalkyl compound (PFAS) that was regulated in the EU, and the UTC limit values were set a long time ago. Therefore, it is very unlikely that PFOS is still present in substances and mixtures at the level of the current UTC limit value (10 mg/kg). ECHA did a screening of the REACH registration dossiers and did not find any indication of PFOS being present as impurity in substances or mixtures.

Concerning the UTC limit value for articles, PFOS uses were very similar to those of PFOA, another PFAS listed in Annex I to Regulation 2019/1021 (for example, coating of textiles and leather, use in semiconductors, etc). There is no indication that a limit for PFOS that is different from that for PFOA is needed.

Moreover, the terminology used to identify PFOS in the entry in column 1 of Part A of Annex I is different from the terminology used in the PFOA entry, as it says 'PFOS and its derivatives', while for PFOA it says 'PFOA, its salts and PFOA-related compounds'. The intention is in both cases to cover the whole group of substances including PFOS/PFOA, their salts and the substances that degrade to PFOS and PFOA.

Finally, the PFOS entry, in its point 5, refers to the availability of analytical methods, while no other entry in the POPs Regulation specifies such details.

For these reasons, the following modifications should be made:

- aligning the terminology of the substance identification for the entry of PFOS with the terminology used for PFOA;
- introducing a UTC limit value for PFOS and its salts of 0,025 mg/kg (in line with the one for PFOA);
- reducing the UTC limit value for PFOS-related compounds in substances, mixtures and articles to 1 mg/kg (in line with the one for PFOA);
- deleting point 5.

Concerning the specific exemption for the use as mist suppressant for non-decorative hard-chromium plating, the Commission consulted the POPs competent authorities expert group in a meeting (the 'POPs CA meeting') on 2 June 2022 and there was no objection to the proposal to delete this specific exemption, which indicates that it is no longer needed in the EU.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Experts designated by Member States were consulted in a meeting of the relevant expert group on the draft delegated act and comments were taken into account. Relevant stakeholders, including the chemicals industry and the civil society, also took part in the discussions on the amendment of the listing of PFOS in Annex I to Regulation (EU) 2019/1021 in the ‘POPs CA meeting’ and comments were taken into account.

A public consultation was carried out for the draft act from 4 December 2023 to 1 January 2024. Three comments were received from EU citizens supporting the initiative. Two comments from stakeholders underlined the possible difficulties in measuring very low levels of PFOS in specific products and waste. Two comments referred to the possible presence of PFOS in fire-fighting foams, as an impurity or deriving from contamination of fire-fighting equipment that contained PFOS-based fire-fighting foams. One of the two comments suggested introducing a transitional period for the new UTC limit value for PFOS aligned with the one foreseen for the ban of PFOA, its salts and PFOA related compounds in fire-fighting foams, that applies as from 5 July 2025. The Commission has proposed extending this deadline for the phase-out of PFOA in fire-fighting foam to 3 December 2025. As both groups of substances are probably present in the same legacy fire-fighting foams, the Commission decided to delay the application of the new UTC limit value for PFOS to 3 December 2025.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends the list of chemicals in Annex I on the basis of scientific and technical progress, as required by Article 15(1) of Regulation (EU) 2019/1021.

COMMISSION DELEGATED REGULATION (EU) .../...

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amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards perfluorooctane sulfonic acid and its derivatives

(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 pollutants¹, 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 Pollutants² and under the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants³.
- (2) Annex I to Regulation (EU) 2019/1021 contains unintentional trace contaminant (UTC) limit values for perfluorooctane sulfonic acid and its derivatives (PFOS).
- (3) PFOS was the first per- and polyfluoroalkyl compound regulated in the Union, and the UTC limit values were set a long time ago. More recently, a similar group of substances, perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, with very similar uses to PFOS, was included in Annex I to Regulation (EU) 2019/1021 with a much lower UTC limit value. That indicates that lower levels of contamination with those chemicals are technically feasible today.
- (4) The UTC limit values for PFOS should therefore be reviewed, to bring them in line with those specified for PFOA, its salts and PFOA-related compounds.
- (5) In order to have a full alignment between the entries on PFOS and PFOA in Annex I to Regulation (EU) 2019/1021, the wording of the first column of the entry on PFOS should be modified by replacing ‘Perfluorooctane sulfonic acid and its derivatives (PFOS)’ with ‘Perfluorooctane sulfonic acid (PFOS), its salts and PFOS-related compounds’.
- (6) Annex I to Regulation (EU) 2019/1021 includes an exemption for the use of PFOS as mist suppressant for non-decorative hard chromium (VI) plating. The information collected at Member State level on the substances used as mist-suppressants in hard chromium plating confirms that PFOS has been substituted for that use in the Union. Therefore, that specific exemption is no longer needed and should be deleted.

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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.

- (7) The entry on PFOS in Annex I to Regulation (EU) 2019/1021, in its point 5, refers to the availability of analytical methods. As no other entry in the POPs Regulation specifies such details, point 5 should be deleted.
- (8) It is appropriate to provide for a reasonable period of time for interested parties to take the measures necessary to comply with certain elements of this Regulation and for Member States to take the measures necessary for their implementation.
- (9) 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*.

Point 2 and point 3 of the Annex shall apply from 3 December 2025.

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

Done at Brussels, 14.4.2025

For the Commission
The President
Ursula VON DER LEYEN