



Brussels, **XXX**
[...] (2023) **XXX** draft

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

of XXX

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)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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) limits 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) to be regulated in the EU, and the UTCs were set a long time ago. Therefore, it is very unlikely that it is still present in substances and mixtures at the level of the current UTC (10 mg/kg). ECHA did a screening of the REACH registrations dossier and did not find any indication of PFOS being present as impurity in substances and mixtures.

Concerning the UTC 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 different from that for PFOA is needed.

Moreover, the way the PFOS entry is described in column 1 is different from the one of PFOA, 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 wording of the substance identification for the entry of PFOS with the one for PFOA;
- introducing a UTC level for PFOS and its salts of 0,025 mg/kg (in line with the one for PFOA);
- reducing the UTC for PFOS-related substances 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 an expert group (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

The 'POPs CA meeting' was consulted on the draft delegated act on 24 November 2022, 14 June 2023 and 29 November 2023 and comments were taken into account. The group is composed of all the relevant stakeholders - representatives of Member States, of the European Chemicals Agency, the chemicals industry and the civil society.

A public consultation was carried out for the draft act from [insert date] to [insert date] [summarise comments received and replies]

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.

DRAFT

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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 (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) limits for perfluorooctane sulfonic acid and its derivatives (PFOS).
- (3) PFOS was the first per- and polyfluoroalkyl compound regulated in the Union, and the UTC limits 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. 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 for PFOA, its salts and PFOA-related substances.
- (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 substances’.
- (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) 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,

For the Commission
The President
Ursula VON DER LEYEN