



Brussels, **XXX**
[...] (2024) **XXX** draft

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

of **XXX**

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)

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

Article 1 of Regulation (EU) 2019/1021 on persistent organic pollutants ('POPs Regulation') establishes as the objective of that Regulation to protect human health and the environment from Persistent Organic Pollutants ('POPs') by, among others, 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.

Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds have been listed in Annex I to Regulation (EU) 2019/1021 by Commission Delegated Regulation (EU) 2020/784 ('PFOA entry') with specific exemptions. The specific exemption under paragraph 6 allows the use of PFOA, its salts and PFOA-related compounds in fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, including both mobile and fixed systems, subject to certain conditions. This exemption expires on 4 July 2025.

Some authorities and stakeholders have communicated to the Commission that many operators have difficulties to respect this deadline. This might be due to different reasons, including the difficulties in measuring PFOA-related compounds in the foams and underestimation of the volumes of foams containing PFOA. Moreover, because of on-going restriction processes under Regulation (EC) No 1907/2006 ('REACH'), it is expected that, as their outcome, companies will have to replace all PFAS-based fire-fighting foams with alternatives. An extension of the exemption would reduce the risk that companies, because of insufficient time, substitute foams containing PFOA with other PFAS based foams instead of fluorine-free ones.

The Commission proposes to extend the specific exemption until 3 December 2025, the latest possible date under the current specific exemption of 5 years in the Stockholm Convention.

The PFOA entry does not set a specific Unintentional Trace Contaminant (UTC) limit for PFOA, its salts and PFOA-related compounds in fire-fighting foams. The general UTC limits in paragraphs 1 and 2 apply. As PFOA-related compounds are reported to be present as unintentional trace contaminants in some foams above the limits set in paragraphs 1 and 2, it is appropriate to set a UTC limit for such compounds in fire-fighting foams in the PFOA entry for a period of 3 years.

When removing PFOA containing foams from the fire-fighting systems, even after cleaning, some of these substances can remain inside the system and could contaminate the new foams that are installed. It is then appropriate to set a UTC limit for fire-fighting foams installed after cleaning of the fire-fighting system to avoid that the new foams need to be replaced because of this contamination.

Paragraphs 3 and 10 of the PFOA entry set an obligation for the Commission to review some UTC limits for PFOA, its salts and PFOA-related compounds. There is currently no information supporting a change in those UTC limits. Considering that the Commission can amend the PFOA entry if new information becomes available, it is proposed to remove the two review clauses.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Experts designated by each Member State were consulted in the relevant expert group (the 'POPs CA meeting') on the draft delegated act and comments were taken into account.

A public consultation on the draft act was carried out through the public feedback mechanism portal **from to** and the comments have been taken into account.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act modifies the existing entry for PFOA, its salts and PFOA-related compounds in Annex I to Regulation (EU) 2019/1021 to adapt it to scientific and technical progress. The legal basis for the proposed delegated act is Article 15(1) of Regulation (EU) 2019/1021.

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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 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 ('the Convention') and under the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants³.
- (2) Annex A to the Convention contains a list of chemicals. Each Party to the Convention is required to prohibit the chemicals on the list 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) 2020/784⁴ amended Annex I to Regulation (EU) 2019/1021 to include perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds ('PFOA entry'). Subsequently, the PFOA entry has been amended by Commission Delegated Regulation (EU) 2021/115⁵ and Commission Delegated Regulation 2023/866⁶.

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¹ OJ L 169, 25.6.2019, p. 45, ELI: <http://data.europa.eu/eli/reg/2019/1021/oj>.

² Council Decision 2006/507/EC of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants (OJ L 209, 31.7.2006, p. 1, ELI: <http://data.europa.eu/eli/dec/2006/507/oj>).

³ Council Decision 2004/259/EC of 19 February 2004 concerning the conclusion, on behalf of the European Community, of the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants (OJ L 81, 19.3.2004, p. 35, ELI: <http://data.europa.eu/eli/prot/2004/259/oj>).

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 188I, 15.6.2020, p. 1, ELI: http://data.europa.eu/eli/reg_del/2020/784/oj).

⁵ 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 (OJ L 36, p. 7 ELI: http://data.europa.eu/eli/reg_del/2021/115/oj).

⁶ 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 (OJ L 113, 28.4.2023, p. 5, ELI: http://data.europa.eu/eli/reg_del/2023/866/oj).

- (4) Annex I to Regulation (EU) 2019/1021 contains a specific exemption for the use of PFOA, its salts and PFOA-related compounds in fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, including both mobile and fixed systems, subject to certain conditions. That exemption expires on 4 July 2025. Member States and stakeholders have reported difficulties for operators to comply with the deadline. This could be due to the difficulties in measuring PFOA-related compounds in the foams and underestimation of the volumes of foams containing PFOA-related compounds. The specific exemption should therefore be extended until 3 December 2025, which is the maximum extension possible under the Convention.
- (5) In point 2 of the PFOA entry, the unintentional trace contaminant (UTC) limit is set at 1 mg/kg for any individual PFOA-related compound or combination of PFOA-related compounds in substances, mixtures or articles. As recent analytical data from several Member States have shown that PFOA-related compounds can be present in higher concentrations as unintentional trace contaminants in fire-fighting foams and fire-fighting foam concentrates for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, a specific UTC limit should be set at 10 mg/kg for any individual PFOA-related compound or combination of PFOA-related compounds in such foams and foam concentrates for a period of three years. That period of time will allow operators to substitute foams and foam concentrates containing PFOA-related compounds above the current UTC of 1 mg/kg.
- (6) When removing foams containing PFOA, its salts and PFOA-related compounds from the fire-fighting systems, some of these substances can remain inside the system even after it has been cleaned and could contaminate the new foams that are installed. It is therefore appropriate to set a UTC limit for PFOA, its salts and PFOA-related compounds in fluorine-free fire-fighting foams installed after cleaning of the fire-fighting system to replace foams containing per- and polyfluoroalkyl substances. That limit should be set at 10 mg/kg for any individual PFOA-related compound or combination of PFOA-related compounds.
- (7) Article 3 of Regulation (EU) 2019/1021 prohibits the manufacturing, placing on the market and use of substances listed in Annex I to that Regulation whether on their own, in mixtures or in articles. Therefore, articles containing PFOA, any of its salts or PFOA-related compounds produced or placed on the market in accordance with an exemption laid down in Annex I to Regulation (EU) 2019/1021 are not allowed to be placed on the market after the relevant exemption expires. However, where articles that contain PFOA, its salts and PFOA-related compounds and that are produced or placed on the market under an exemption laid down in that Annex were already in use on the expiry date of the relevant exemption, they should be allowed to continue to be used after that date. This is to avoid the need to recall articles that were already in use by their final user at the expiry of the relevant exemption.
- (8) Points 3 and 10 of the PFOA entry set out an obligation for the Commission to review the UTC limits for PFOA, its salts and PFOA-related compounds with regard to certain medical devices and substances to be used as a transported isolated intermediate. There is currently no information supporting a change in such limits. Considering that the Commission can amend the PFOA entry if new information becomes available, the review clauses should be deleted,

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