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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	5 May 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 5.5.2025 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

Delegations will find attached document C(2025) 2566 final.

Encl.: C(2025) 2566 final



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C(2025) 2566 final

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

of 5.5.2025

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)

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 such 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 Member States were consulted in a meeting of the relevant expert group (the 'POP MS-CA 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 PFOA, its salts and PFOA-related compounds in Annex I to Regulation (EU) 2019/1021 in the ‘POPs CA meeting’ and comments were taken into account.

A public consultation on the draft act was carried out through the public feedback mechanism portal from 8 November to 6 December 2024 and the comments have been taken into account as follows.

Some comments were supporting the proposal to defer the expiry of the specific exemption for the use of PFOA, its salts and related compounds in fire-fighting foams for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems. They were also supporting the introduction of a UTC limit for PFOA, its salts and PFOA related compounds in fire-fighting foams. Such changes would provide operators still using foams that contain those substances above the current UTC limit more time for substitution. Concerning the proposed UTC limit for PFOA-related compounds in fluorine-free fire-fighting foam installed in fire-fighting equipment which has undergone cleaning, some comments asked to include a specific UTC limit also for PFOA in such fire-fighting foams.

Some other comments were not supporting the Commission proposal for new UTC limits, as this would lead to additional exposure to PFOA and because cleaning techniques and fluorine-free foams are available.

The Commission considers that it is justified to provide more time for substitution of fire-fighting foams containing PFOA, its salts and PFOA related compounds, so that operators would move to fluorine-free foams rather than replacing them with other PFAS-based foams. Such substitution requires more time as fluorine-free foams are not a drop-in alternative and fire-fighting systems need to be adapted to the use of such foams. The Commission considers also appropriate to set a specific UTC limit for PFOA, its salts and PFOA-related compounds in fluorine-free fire-fighting foam installed in fire-fighting equipment which has undergone cleaning, to avoid generating large amounts of liquid waste or premature disposal of fire-fighting equipment.

Some comments were proposing to define cleaning standards, to gradually lower the proposed UTC limit for fire-fighting foams and to set a review clause. Concerning the suggestions to define cleaning standards, a guidance document is currently being developed. The Commission does not consider appropriate to gradually lower the UTC as such foams will be substituted over time with fluorine-free ones, considering also the on-going restriction under REACH Regulation. Concerning the review, the Commission can review the entry in Annex 1 at any time if additional relevant information becomes available.

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.

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

of 5.5.2025

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 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.

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

- (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 1 of the PFOA entry in Annex I to Regulation (EU) 2019/1021, the unintentional trace contaminant (UTC) limit is set at 0,025 mg/kg for PFOA or any of its salts, where they are present in substances, mixtures and articles. In point 2 of that entry, the UTC limit is set at 1 mg/kg for any individual PFOA-related compound or a combination of PFOA-related compounds, where they are present in substances, mixtures or articles. As recent analytical data from several Member States have shown that PFOA or its salts and 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 1 mg/kg for PFOA or any of its salts and 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 sufficient time to substitute foams and foam concentrates containing PFOA or any of its salts and PFOA-related compounds above the current UTC limits.
- (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 PFOA, its salts and PFOA-related compounds. That limit should be set at 10 mg/kg for the sum of PFOA, its salts and PFOA-related compounds.
- (7) To ensure clarity on the foams, concentrates or solutions covered in Annex I to Regulation (EU) 2019/1021, a definition is added clarifying that the term ‘Fire-fighting foam’ covers any mixture to fight fires with foam as well as firefighting foam concentrates and firefighting foam solutions to produce the foam.
- (8) 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. In this regard, it should be clarified that 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 I to that Regulation and that were already in use on the expiry date of the relevant exemption, are allowed to continue to be used after that date.
- (9) 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

salts and PFOA-related compounds (OJ L 113, 28.4.2023, p. 5, ELI: http://data.europa.eu/eli/reg_del/2023/866/oj).

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.

- (10) The first column of the PFOA entry, under point (v), refers to ‘Perfluorooctane sulfonic acid and its derivatives (PFOS)’. As the wording of the first column of PFOS entry has been changed to ‘Perfluorooctane sulfonic acid (PFOS), its salts and PFOS-related compounds’, the reference in the PFOA entry should be changed 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, 5.5.2025

For the Commission
The President
Ursula VON DER LEYEN