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COMPET 149
IND 72
SAN 107
CONSOM 56
MI 142
CHIMIE 12
DELECT 34

COVER NOTE

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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 24.2.2023 amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

Delegations will find attached document C(2023) 1151 final.

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Brussels, 24.2.2023
C(2023) 1151 final

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

of 24.2.2023

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)

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 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'). Following Article 4(1)(b) of the POPs Regulation, the PFOA entry in Annex I includes Unintentional Trace Contaminant (UTC) limits for PFOA, its salts and PFOA-related compounds in some substances, mixtures and articles. Following points 3 and 4 of the fourth column of the PFOA entry, such UTC limits are subject to review.

In 2020, ECHA's Scientific Committees adopted an opinion¹, which included the assessment of the two UTC limits set for PFOA in:

- polytetrafluoroethylene (PTFE) micropowders,
- intermediates used in the production of C6 alternatives.

Annex I to the POPs Regulation includes a UTC limit for PFOA and its salts in PTFE micropowders of 1 mg/kg, to be reviewed by 5 July 2022. ECHA's Committees concluded that processes have been developed to reduce the concentration of PFOA to below the generic UTC level of 0,025 mg/kg (25 ppb) set out in the POPs Regulation. These processes have been successfully implemented by most PTFE micropowder manufacturers. The remaining manufacturers would be able to comply with the limit of 0,025 mg/kg by 5 July 2022. For this reason, the Commission proposes that the specific UTC limit for PTFE micro powders should expire at the entry into force of this delegated act.

This change would have an impact on transport and treatment processes to make PTFE micropowders compliant with the limit of 0,025 mg/kg. Transport to and treatment in a different site are needed for at least one manufacturer of PTFE micropowders.

The POPs Regulation refers in its Article 2, points 1 and 6 to Article 3, points 12 and 24 of the REACH Regulation 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". Pursuant to Article 3(1) of the POPs Regulation, use and placing on the market of PFOA and its salts present in PTFE micropowders not compliant with the new UTC limit of 0,025 mg/kg will be prohibited.

To avoid such a situation, the Commission proposes keeping the UTC limit of 1 mg/kg to cover manufacture, placing on the market and use only for the purpose of transport and treatment of PTFE micropowders to reduce the PFOA concentration. The existing generic

¹

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

UTC limit of 0,025 mg/kg would then apply to PFOA and its salts present in PTFE micropowders that are placed on the market for their final use.

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 ('C6 alternatives'). To allow the production and use of such transported isolated intermediates, point 3 of the fourth column of the PFOA entry sets a UTC limit of 20 mg/kg (20 ppm).

The ECHA Committees concluded that the present limit value is the lowest that can be complied with, taking into account the available technological solutions. The implementation of strictly controlled conditions (as set out in Article 18 of the REACH Regulation and also required in the POPs Regulation pursuant to point 3 of the fourth column of the PFOA entry in Annex I) should ensure that releases are minimised as far as possible during the manufacture and use of the substances.

The intermediates also contain C9-C14 PFCAs as impurities. The restriction on C9-C14 PFCAs that was recently adopted under REACH² foresees a derogation for use as intermediate in the production of C6 alternatives, to be reviewed no later than 25 August 2023. The Commission proposes aligning the timing of the review of the UTC limit for PFOA in intermediates used for the production of C6 alternatives under the POPs Regulation with the review foreseen in the REACH restriction for C9-C14 PFCAs.

Annex I to the POPs Regulation includes an exemption for the use of PFOA to produce PTFE and polyvinylidene fluoride (PVDF) for several applications (exemption in point 5e of the fourth column of the PFOA entry).

During the public consultation for the preparation of the ECHA opinion on C9-C14 PFCAs and on PFOA UTCs, some stakeholders submitted comments also on this exemption. Fluoropolymer manufacturers have developed alternatives to PFOA and related long-chain polymerisation aids that can be used for the production of all types of fluoropolymers, regardless of their final application. Additionally, there are no fluoropolymer manufacturers in the EU that still use PFOA as a polymerisation aid.

In the light of the above information, the Commission considers that this exemption for the use of PFOA to produce PTFE and PVDF for several applications is no longer needed. Consequently, the Commission proposes deleting this exemption.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The draft amendment was consulted with an expert group (the 'POP CA meeting') on 23 November 2021 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 17 May to 14 June 2022 and 10 comments were submitted. Two stakeholders supported the proposed changes concerning the UTC limit for PTFE micropowders. One stakeholder asked for a higher UTC limit and for a grace period for products already in stock. Considering that most producers can comply with

² Commission Regulation (EU) 2021/1297

the new limit, as confirmed in ECHA's opinion, the Commission confirms that the generic UTC limit of 0,025 mg/kg will apply to the PTFE micropowders placed on the market for their final use. A stakeholder expressed concern on the potential impact of the changes, especially for complex supply chains. In order to allow producers that have not yet adapted their processes to comply with the new rules, the Commission proposes that the delegated act enters into application 3 months after its publication. A stakeholder reported the possibility that PTFE micropowders may be exported outside the Union for treatment, leading to potential emissions in non-Union countries, and asked for a phase-out of the irradiation technology in the Union. The Commission notes that such a situation was not reported during the public consultation for the preparation of ECHA's opinion and the potential impacts of a phase-out of that technology were not assessed. This option could be assessed during a future review of the PFOA entry. Finally, some citizens asked for a phase-out of PFOA and per- and polyfluoroalkyl substances (PFAS) in general.

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 in order 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 24.2.2023

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 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 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) 2020/784⁴ 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 Socio-economic Analysis of the European Chemicals Agency (ECHA) adopted an opinion⁵ ('ECHA's opinion'),

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_ra_c_seac_opinions_en.pdf/6582d9a1-56b2-3e88-a70f-cdf3ab33d421

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 Council⁶ 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".
- (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) 2021/1297⁷ 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

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).

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)

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*.

It shall apply from [*OP please insert the date = 90 days after the date of entry into force of this Regulation*].

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

Done at Brussels, 24.2.2023

For the Commission
The President
Ursula VON DER LEYEN