



Council of the
European Union

041629/EU XXVII. GP
Eingelangt am 27/11/20

Brussels, 27 November 2020
(OR. en)

13455/20

ENV 753
ENT 139
COMPET 603
IND 229
SAN 432
CONSOM 203
MI 531
CHIMIE 59
DELECT 155

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 November 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2020) 7980 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 27.11.2020 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

Delegations will find attached document C(2020) 7980 final.

Encl.: C(2020) 7980 final



EUROPEAN
COMMISSION

Brussels, 27.11.2020
C(2020) 7980 final

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

of 27.11.2020

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 1 of Regulation (EU) 2019/1021 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 with Commission Delegated Regulation (EU) 2020/784. At the time of the adoption of this act, the medical devices industry informed the Commission that some of the articles they manufacture (including some critical to treat patients) contain PFOA and its salts above the limit of 25 ppb (0,025 mg/kg, 0,0000025 % by weight) set in the Commission delegated act. This is not due to an intentional use of PFOA in the production of the articles, but it is most probably linked to the presence of PFOA impurities in the short-chain PFAS alternatives used to manufacture the medical devices. These medical devices are non-implantable and non-invasive and, since they do not benefit from an exemption, their production would be prohibited after 3 December 2020. To allow the continuation of production of these medical devices, the Commission proposes to amend the entry on PFOA, its salts and PFOA-related compounds in Annex I to Regulation (EU) 2019/1021 by introducing an Unintentional Trace Contaminant (UTC) level of 2 ppm (2 mg/kg, 0,0002 % by weight) for medical devices other than implantable devices and invasive devices, subject to review after two years.

After the adoption of the delegated act, the Commission was also informed by some stakeholders that the conditions linked to the UTC for polytetrafluoroethylene (PTFE) micropowders were too specific when mentioning that the production process by ionising irradiation needs to take place with up to 400 kilograys. In addition, it is now considered impossible for enforcement authorities to determine if PTFE micropowders have been produced with irradiation up to 400 kilograys. For this reason, it is appropriate to delete the reference to 400 kilograys, while waiting for the on-going assessment of ECHA of this UTC.

In accordance with the second subparagraph of Article 15(1) of Regulation (EU) 2019/1021, a delegated act amending Annex I to Regulation (EU) 2019/1021 should be adopted to introduce these changes in the entry on PFOA.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The draft amendment was consulted with an expert group (the 'POP CA meeting') on 9 June 2020 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 1 to 29 September 2020. All comments received supported the amendment. Some comments asked to introduce additional amendments in the entry on PFOA, its salts and PFOA-related compounds in Annex I to

Regulation (EU) 2019/1021 or referred to the on-going legislative processes on a different substance. Such comments were not considered relevant.

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 27.11.2020

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

(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 ('Elimination') contains a list of chemicals for which each Party to the Convention is required to prohibit and/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) Article 15(1) of Regulation (EU) 2019/1021 empowers the Commission to adopt delegated acts to modify existing entries of Annex I to adapt them to scientific and technical progress.
- (5) After the adoption of Delegated Regulation (EU) 2020/784, the Commission was informed of the presence of unintentional impurities of PFOA and its salts above the

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).

limit of 0,025 mg/kg (0,0000025 % by weight) laid down in that Regulation in some medical devices other than implantable devices and invasive devices.

- (6) In order to avoid the prohibition of manufacturing of such medical devices after 3 December 2020 and in order to give manufacturers enough time to reduce the level of the impurities, an Unintentional Trace Contaminant (UTC) limit of 2 mg/kg (0,0002 % by weight) should be set for PFOA, its salts and PFOA-related compounds, subject to a review.
- (7) Delegated Regulation (EU) 2020/784 introduced a UTC limit for PFOA and its salts in polytetrafluoroethylene (PTFE) micropowders produced by ionising irradiation of up to 400 kilograys.
- (8) After the adoption of Delegated Regulation (EU) 2020/784, the Commission was informed that the requirement for the production process by ionising irradiation to take place with up to 400 kilograys was too specific for the operators to comply with and for the authorities to check compliance. The reference to 400 kilograys should therefore be deleted.
- (9) Delegated Regulation (EU) 2020/784 introduced a UTC limit for PFOA-related compounds where they are present in a substance to be used as a transported isolated intermediate for the production of fluorochemicals with a carbon chain equal to or shorter than 6 atoms.
- (10) The UTC limit was meant to cover intermediates used for the production of alternatives to PFOA with 6 or less fully fluorinated carbon atoms. For sake of clarity, the word “perfluoro” should be added before “carbon chain”.
- (11) Delegated Regulation (EU) 2019/1021 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Delegated 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, 27.11.2020

For the Commission
The President
Ursula VON DER LEYEN