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COVER NOTE

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 8 April 2020

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
the European Union

No. Cion doc.: C(2020) 1973 final

Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 8.4.2020
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

Delegations will find attached document C(2020) 1973 final.

Encl.: C(2020) 1973 final



Brussels, 8.4.2020
C(2020) 1973 final

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

of 8.4.2020

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

(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. At the ninth Conference of the Parties to the Stockholm Convention, which took place in Geneva, Switzerland from 29 April to 10 May 2019, decisions were taken to include further chemicals in Annex A to the Convention. Those regulatory actions and decisions should be reflected in Annex I to Regulation (EU) 2019/1021. This delegated act implements decision SC-9/12 on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds. In accordance with the second subparagraph of Article 15(1) of Regulation (EU) 2019/1021, separate delegated acts will be adopted for the other decisions of the Conference of the Parties concerning inclusion of chemicals in Annex A.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The draft amendment was consulted with an expert group (the 'POP CA meeting') on 26 November 2019 and comments were taken into account as far as possible. 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 7 November 2019 to 5 December 2019. Several comments were received from stakeholders, mostly concerning the discrepancies between the derogations in the existing restriction on PFOA, its salts and related compounds in the REACH restriction (entry 68 of Annex XVII to Regulation (EC) No 1907/2006) and the exemptions in the draft act. The Commission included in the proposal the exemptions that are included in both decision SC-9/12 under the Stockholm Convention and the REACH restriction. Concerning the duration, the Commission chose 5 years for those exemptions that had no time limit in the REACH restriction and the time limit of the REACH restriction for those exemptions with a shorter time limit than 5 years. For the derogations that were granted under the REACH restriction but not included in decision SC-9/12 under the Stockholm Convention, the Commission proposes that such derogations will be applicable until the date of entry into force of decision SC-9/12 (3 December 2020). This will allow the industries that were benefitting from the derogations of the REACH restriction more time to complete the phase-out of PFOA, still respecting the timeline for implementation of decision SC-9/12. Other comments concerned Unintentional Trace Contaminant (UTC) limits of PFOA in specific substances, mixtures and articles. The Commission has decided to increase some UTC limits but to ask ECHA for a detailed scientific assessment with a view to review such limits as soon as possible.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends the list of chemicals in Annex I on the basis of developments under the Convention, as required by Article 15(1) of Regulation (EU) 2019/1021.

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

of 8.4.2020

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

(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 ('the Protocol').
- (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.
- (3) The Conference of the Parties to the Convention has, pursuant to Article 8(9) of the Convention, decided in its ninth meeting to amend Annex A to the Convention in order to include perfluorooctanoic acid ('PFOA'), its salts and PFOA-related compounds in that Annex. That amendment contains various specific exemptions.
- (4) Part A of Annex I to Regulation (EU) 2019/1021, which contains a list of the substances listed in the Convention and in the Protocol as well as substances listed only in the Convention, should therefore also be amended to include PFOA, its salts and PFOA-related compounds.
- (5) PFOA, its salts and PFOA-related compounds are listed in Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁴, subject to certain derogations. Those derogations were assessed by the Persistent Organic Pollutants Review Committee ('POPRC') with the result that not all of them were recommended

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 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).

to the Conference of the Parties. Consequently, the decision adopted by the Conference of the Parties (SC-9/12) contains some but not all derogations previously granted under Regulation (EC) No 1907/2006. Considering that the POPRC assessment was based on more recent information and considering Council Decision (EU) 2019/639⁵, it is appropriate to allow in Annex I to Regulation (EU) 2019/1021 only those specific exemptions that are granted under the Convention and needed in the Union.

- (6) The Conference of the Parties to the Convention decided in its ninth meeting on a specific exemption that is not included in Annex XVII to Regulation (EC) No 1907/2006. It concerns the use of perfluorooctyl bromide containing perfluorooctyl iodide for the purpose of producing pharmaceutical products. Considering that information on this use was not available at the time of the listing of PFOA, its salts and PFOA-related compounds in Annex XVII to Regulation (EC) No 1907/2006 and considering the subsequent assessment by the European Chemicals Agency⁶, it is considered appropriate to include that specific exemption in Annex I to Regulation (EU) 2019/1021.
- (7) In order to reinforce the application and enforcement in the Union of Article 3 of Regulation (EU) 2019/1021, a limit value should be set for PFOA, its salts and PFOA-related compounds occurring as an unintentional trace contaminant in substances, mixtures and articles. That limit value should be set at 0,025 mg/kg for PFOA including its salts, and at 1 mg/kg for the individual PFOA-related compounds or a combination of those compounds. For applications where those concentration limits cannot currently be met, higher concentration limits should be established, subject to review by the Commission within 2 years with a view to lowering the limits.
- (8) Regulation (EU) 2019/1021 should therefore be amended accordingly.
- (9) Considering that some derogations previously granted in the restriction on PFOA, its salts and PFOA-related compounds in Annex XVII to Regulation (EC) No 1907/2006 are still needed by industry for a transitional period but are not among the specific exemptions in Annex I to Regulation (EU) 2019/1021, such derogations should apply until 3 December 2020, which is the date of entry into force of the amendment of Annex A to the Stockholm Convention concerning PFOA, its salts and PFOA-related compounds.
- (10) The restriction on PFOA, its salts and PFOA-related compounds in Annex XVII to Regulation (EC) No 1907/2006, which the Commission now plans to delete, would normally start to apply on 4 July 2020. For reasons of coherence and to facilitate the implementation of Regulation (EU) 2019/1021, this Regulation should apply from the same date,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) 2019/1021 is amended in accordance with the Annex to this Regulation.

⁵ Council Decision (EU) 2019/639 of 15 April 2019 on the position to be taken on behalf of the European Union at the ninth meeting of the Conference of the Parties as regards amendments to Annexes A and B to the Stockholm Convention on Persistent Organic Pollutants (OJ L 109, 24.4.2019, p. 22).

⁶ <https://echa.europa.eu/documents/10162/c9666f21-532b-49a0-ace3-c843b7b8e5b0>

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 4 July 2020.

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

Done at Brussels, 8.4.2020

For the Commission
The President
Ursula VON DER LEYEN