



Council of the
European Union

Brussels, 6 May 2021
(OR. en)

8228/21

COMPET 294
ENT 77
ENV 265
SAN 248
CONSOM 101
MI 291
CHIMIE 52

'I/A' ITEM NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

No. Cion doc.: ST 7043/21 - D 071310.03

Subject: COMMISSION REGULATION (EU) .../... of XXX 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
- Decision not to oppose adoption

1. On 12 March 2021, the Commission submitted the above draft Regulation to the Council, which amends Annex XVII of Regulation (EC) 1907/2006¹ (REACH) in accordance with its Articles 68(1) and 133.

¹ Regulation (EC) 1907/2006 of the European Parliament and of the Council on 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);

The above-mentioned PFCA substances and others that are derivative, occur as by-products during manufacturing. They are included in the Candidate List of Substances of Very High Concern to be potentially included in Annex XIV of REACH as toxic for reproduction, in accordance with Article 57(c) of REACH. They are also included in Part 3 of Annex VI of Regulation (EC) No 1272/2008² as carcinogenic and toxic to reproduction.

2. The Commission considers that there is an unacceptable risk to human health and the environment from the manufacture, use or placing on the market of these PFCA and related products and mixtures, and that the risk should be addressed on EU-wide basis.
3. The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of REACH.
4. Pursuant to the procedure in Article 5a of Council Decision 1999/468/EC³, such draft measures, before being formally adopted by the Commission, are submitted for scrutiny to the European Parliament and the Council. If neither the Parliament nor the Council have opposed the envisaged measures, the draft Regulation shall be adopted by the Commission.
5. On 10 March 2021, the Committee, established under REACH, voted for the draft measures with 26 delegations in favour and 1 delegation abstained, in accordance with Article 5a(2) of Council Decision 1999/468/EC.

² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1–1355): Current consolidated version is of 1 May 2020.

³ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23); Current consolidated version is of 23/07/2006.

6. On 15 March 2021, delegations were asked by 23 April 2021 to indicate their possible opposition to the draft Regulation. No delegation raised any relevant grounds for opposition. The Commission will formally adopt the draft measures after the three month deadline expires on 12 June 2021.

 7. Against this background, the Permanent Representatives Committee is invited to recommend to the Council to confirm its non-opposition to the above draft Regulation, as set out in document ST 7043/21 + ADD 1 as an item without discussion at one of its forthcoming meetings.
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