

Annex XV Restriction Report Proposal for a restriction for per- and polyfluoroalkyl substances ("PFASs")

Submission to the public consultation *"Overlapping of PFAS substances already regulated or in the process of being regulated in other restrictions"*

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Key Issue Addressed (include Annex or Question references): General comments, Overlap of PFAS restrictions, Annex XV restriction report, principle of over-regulation, Column 1 "exemptions", Column 2, Condition of Restriction 9

Introduction

We refer to the *"Annex XV Restriction Report Proposal for a restriction for per- and polyfluoroalkyl substances (PFASs)"* and its Annexes ("the Proposal") aimed at restricting a wide range of PFAS under Regulation (EC) No 1907/2006¹ ("REACH Regulation" or "REACH"), submitted to ECHA by the competent authorities of Germany, Sweden, the Netherlands, Denmark and Norway ("the Dossier Submitters").

We understand that the Dossier Submitters sent their Proposal to ECHA on 13 January 2023 and that a pre-publication version of the Proposal was made available on ECHA's webpage as of 7 February 2023. Subsequently, the ECHA's Committee for Socio-Economic Analysis ("SEAC") and Committee for Risk Assessment ("RAC") confirmed that the Proposal met the requirements set in Annex XV of REACH during their respective voting meetings on 10 March and on 15 March 2023, in accordance with article 69(4) of REACH.

Consequently, in accordance with article 69(6) of REACH, ECHA re-published an updated version of the Proposal indicating the official date of publication, *i.e.* 22 March 2023 and inviting interested parties to submit comments within six months, *i.e.* until 25 September 2023.

Within this context, we hereby submit legal comments to the public consultation outlining that (i) PFAS substances already regulated or in the process of being regulated under other restrictions should be explicitly exempted from the scope of the Proposal and (ii) the condition of restriction stating that the Proposal shall apply without prejudice to the application of any restrictions set out in this Annex or to other applicable Union legislation shall be deleted.

Key Takeaways and Arguments

¹ Regulation (EC) N° 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1;

- Some PFAS have been regulated and are being regulated in restrictions in Europe and internationally, most notably under the REACH Regulation and the Stockholm Convention,² which is implemented in Europe through the POPs Regulation;³
- Examples of PFAS substances already regulated under other restrictions include but are not limited to the following examples: PFOA⁴, PFOS⁵ and C9-C14 PFCAs;⁶
- Likewise, examples of substances, which are under the process of being regulated include but are not limited to the following examples: PFHxA,⁷ which appears in preparation under a Commission proposal, and PFHxS,⁸ that has been included under the Stockholm Convention, which will lead to the consequent update of the POPs Regulation;
- In the case where the same substance is regulated under two REACH restrictions or under a REACH restriction and a POPs restriction, the principle of *over-regulation*, according to which double regulation should be avoided, applies. This principle appears in line with the overall EU principle of Better Regulation,⁹ which aims to design and prepare EU policies and laws in the most efficient way to achieve their objectives;
- The principle of over-regulation between REACH and POPs Regulation has been further clarified by the Commission in its Common Understanding Paper.¹⁰ This paper states that authorities can proceed with a REACH restriction even when in the knowledge that a proposal for listing a substance under the POPs Convention has been submitted in order to benefit from an earlier time period of restriction.¹¹ However, the paper clarifies that ultimately "*the REACH restriction should - in principle - be removed*".¹² This confirms that there is an overlap between the POPs Regulation and REACH, eventually resolved with POPs Regulation 'overruling' any REACH restriction, which is thus consequently removed.
- Therefore, it is clear that PFAS already regulated or in the process of being regulated in other REACH or POPs restrictions should not fall under the scope of the Proposal;

² The Stockholm Convention on Persistent Organic Pollutants, *opened for signature* May 23, 2001, UN Doc. UNEP/POPS/CONF/4, App. II (2001), *reprinted in* 40 ILM 532 (2001);

³ [Regulation \(EU\) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants](#);

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](#);

⁵ [Commission Regulation \(EU\) No 757/2010 of 24 August 2010 amending Regulation \(EC\) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III Text with EEA relevance](#);

⁶ [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](#);

⁷ [COMMISSION REGULATION \(EU\) .../...of ...amending Annex XVII to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council as regards undecafluorohexanoic acid \(PFHxA\), its salts and PFHxA-related substances](#)

⁸ [COMMISSION DELEGATED REGULATION \(EU\) .../... amending Annex I to Regulation \(EU\) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorohexane sulfonic acid \(PFHxS\), its salts and PFHxS-related compounds](#);

⁹ [COMMISSION STAFF WORKING DOCUMENT Better Regulation Guidelines](#), p. 40;

¹⁰ [Common understanding paper - REACH and Regulation \(EC\) 850/2004 on persistent organic pollutants \('the POP Regulation'\)](#);

¹¹ *Ibid.*, p. 3;

¹² *Ibid.*, p. 3;

- As such, the Dossier Submitters should have "exempted" these PFAS substances by adding specific exemptions for these substances under Column 1 of the Proposal, page 4;¹³
- In that regard, paragraph 9 of the Conditions of the restriction set out in Column 2 of the proposed restriction table (Option 2), stating that "*Paragraphs 1 and 2 shall apply without prejudice to the application of any restrictions set out in this Annex or to other applicable Union legislation*",¹⁴ should be deleted as this is legally wrong and does not provide clarity for stakeholders and enforcement authorities. Furthermore, it appears in breach of the principles of effectiveness¹⁵ and enforceability,¹⁶ which are considered guiding principles for the preparation of Annex XV. In addition to that, this appears also in breach of legal certainty, which is a general principle of EU law.
- In any event, it should be recalled that it is for the Commission to clarify the relationship between different EU legislations, as in the example of the above-mentioned Commission Common Understanding Paper.¹⁷
- We finally believe that the Dossier Submitters should not usurp this role by stating that the Proposal "*shall apply without prejudice to the application of any restrictions set out in this Annex or to other applicable Union legislation*".¹⁸

Supporting Information

The analysis above demonstrates that any overlapping of legislations on the same substances should be avoided. In that respect, the Dossier Submitters should explicitly exempt the PFAS substances already restricted or in the process of being restricted by other EU – restrictions. Furthermore, the condition of restriction stating that the Proposal shall apply without prejudice to the application of any restrictions set out in this Annex or to other applicable Union legislation shall be deleted.

In support of these arguments, it should be recalled that in the proposed restriction of PFAS used in Fire-Fighting Foams,¹⁹ RAC recommends that "*the overlap with related restrictions be reviewed, and steps taken to avoid conflicting requirements*".²⁰ Also, it should be noted that SEAC "*agrees with RAC concerning the recommendations to the Commission to provide guidance and review the overlap with related restrictions*".²¹

Therefore, we believe that paragraph 9 of the Conditions of the restriction set out in Column 2 of the proposed restriction table (Option 2) should be deleted and the above recommendations from the ECHA Scientific Committees should be also taken into account in the Proposal. It would help the Commission to propose a text of the Proposal legally correct, *i.e.* explicitly exempting from the scope of the restrictions PFAS already regulated or in the process of being regulated under other restrictions.

¹³ Annex XV PFAS REACH restriction Proposal, Column 1, p.4;

¹⁴ *Ibid.*, Column 2, paragraph 9, p. 8;

¹⁵ ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 64;

¹⁶ ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 66;

¹⁷ [Common understanding paper - REACH and Regulation \(EC\) 850/2004 on persistent organic pollutants \('the POP Regulation'\)](#);

¹⁸ Annex XV PFAS REACH restriction Proposal, Column 2, paragraph 9, p. 8;

¹⁹ Annex XV PFAS REACH restriction Proposal in fire-fighting foams;

²⁰ RAC opinion to the PFAS restriction in fire-fighting foams, p. 55;

²¹ SEAC opinion to the PFAS restriction in fire-fighting foams, p. 54.

We also refer to the EU Better Regulation – *Please see above*.

Conclusion

We believe that ECHA, in particular RAC and SEAC, should take into account the information submitted during this public consultation and reflect it in their opinions, in accordance with articles 70 and 71(1) of REACH as well as the general principles of EU law, such as due process, right of good administration and right of defense.
