

## SUBMISSION TO ECHA PUBLIC CONSULTATION

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

*"Overlapping of PFAS substances in the process of being regulated in two different REACH restrictions – (i) coherence and consistency of proposed conditions, in particular as regards derogations or (ii) exemption in accordance with the principle of over regulation or double regulation"*  
Chemours Belgium B.V. ("Chemours")

## Introduction

We refer to the "Annex XV Restriction Report Proposal for a restriction for per- and polyfluoroalkyl substances (PFAS)" and its Annexes ("the PFAS restriction proposal") aimed at restricting a wide range of PFAS under Regulation (EC) No 1907/2006<sup>1</sup> ("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 the PFAS restriction proposal to ECHA on 13 January 2023 and that a pre-publication version 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 PFAS restriction 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 the PFAS restriction 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) the conditions of the PFAS restriction proposal, in particular as regards derogations, should be aligned to the ones set in the Bisphenols restriction proposal, or in alternative (ii) BPAF should be simply exempted from the scope of the PFAS restriction proposal, in application of the principle of overregulation or double regulation.

## General Comments

The substance 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol ('Bisphenol AF', BPAF, EC 216-036-7) also called "BPAF" or "bisphenol AF" and its salts, happen to be included in the scope of two forthcoming restrictions under REACH: the Bisphenol A and Bisphenols of similar concern ("BoSC") for the

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<sup>1</sup> 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;

environment; proposed restriction ("Bisphenols restriction proposal")<sup>2</sup> and the per- and polyfluoroalkyl substances ("PFAS") , proposed restriction ("PFAS restriction proposal")<sup>3</sup>.

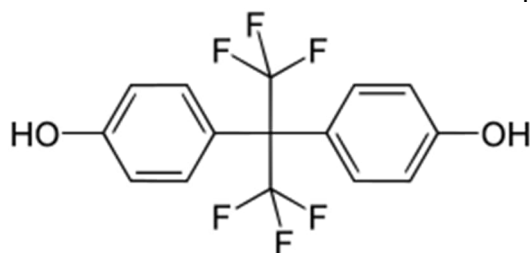
Given that the Bisphenols restriction proposal states that a derogation of 10 years for fluoroelastomers ("FKM") produced with BPAF is needed,<sup>4</sup> this derogation or any other condition proposed by the ECHA Committees should be the same in the PFAS restriction proposal.

Indeed, we believe that the derogations proposed by the Dossier Submitter and the ECHA scientific opinions in the Bisphenols restriction proposal should not be undermined by any other proposed condition in the PFAS restriction proposal. On top of these considerations, it should be noted that Chemours has already submitted comments on the overlapping of restrictions related to PFAS. First, Chemours outlined that PFAS substances already regulated or in the process of being regulated under other restrictions should be explicitly exempted from the scope of the PFAS restriction proposal. Second, Chemours suggested that 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"*<sup>5</sup> shall be deleted.

In particular, in this submission, Chemours considered that (i) the conditions of the PFAS restriction proposal, in particular as regards derogations, should be aligned to the ones in the Bisphenols restriction proposal, or in alternative (ii) BPAF should be simply exempted from the scope of the PFAS restriction proposal, as both proposed restrictions aim to reduce environmental emissions in application of the principle of overregulation or double regulation.

#### Key Takeaways and Arguments:

- BPAF is a substance which is both a bisphenol and a PFAS



Given the above structure of BPAF, this substance meets the definition of PFAS used in the proposed PFAS restriction proposal, i.e. *"Any substance that contains at least one fully fluorinated methyl (CF<sub>3</sub>-) or methylene (-CF<sub>2</sub>-) carbon atom (without any H/Cl/Br/I attached to it)[...]"*<sup>6</sup>

Germany ('the Dossier Submitter') has submitted to ECHA a restriction proposal on BPA & BoSC (BPA: Bisphenol A, BPB: Bisphenol B, BPS: Bisphenol S, BPF: Bisphenol F and BPAF: Bisphenol AF) and its salts

<sup>2</sup> Bisphenols with endocrine disrupting properties for the environment and their salts [Submitted restrictions under consideration - ECHA \(europa.eu\)](#)

<sup>3</sup> Per- and polyfluoroalkyl substances (PFAS) [Submitted restrictions under consideration - ECHA \(europa.eu\)](#)

<sup>4</sup> Annex XV 4,4'-isopropylidenediphenol (Bisphenol A) and bisphenols of similar concern for the environment restriction, p. 6, Appendix Y

<sup>5</sup> Annex XV PFAS REACH restriction Proposal, Column 2, paragraph 9, p. 8

<sup>6</sup> Annex XV PFAS REACH restriction Proposal, Column 1, p.4

("Bisphenols restriction proposal"), which is also under the process of ECHA public consultation for the formation of a scientific opinion. In that respect, it should be noted that the six-month consultation period ended on 22 June 2023.

BPAF is used as a crosslinker in fluoroelastomer ("FKM") pre-compounds and FKM products produced with pre-compounds<sup>7</sup>. The Dossier Submitter has proposed a derogation for BPAF in FKM articles,<sup>8</sup> which allows a higher residual BPAF content of 50 ppm for 10 years instead of a general threshold content of 10 ppm provided in the Bisphenols restriction proposal.

Given that BPAF meets the definition of PFAS substance provided in the PFAS restriction proposal, we consider that the derogation for FKM articles as well as any other derogation or condition of restriction provided in the Bisphenols restriction proposal should be reflected in the PFAS restriction proposal to ensure coherence and consistency between the different REACH restrictions. Indeed, this principle has already been applied in past examples where substances considered similar.

For instance, in the perfluorinated carboxylic acids (C9-C14 PFCAs), their salts and C9-C14 PFCA- related substances ("C9-C14 PFCAs") REACH restriction,<sup>9</sup> the same derogations granted as in Persistent Organic Pollutants Regulation ("POPs") restriction<sup>10</sup> of perfluorooctanoic acid ("PFOA")<sup>11</sup>.

These derogations included, *inter alia*, allowing the manufacturing, placing on the market and use of PFOA/C9-C14 PFCAs for the following purposes: photolithography or etch processes in semiconductor manufacturing; photographic coatings applied to films; invasive and implantable medical devices; textiles for oil- and water-repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety; the manufacture of polytetrafluoroethylene ("PTFE") and polyvinylidene fluoride ("PVDF"); and fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems.

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<sup>7</sup> Precompound: an initial formulation based on FKM fluoropolymer resin, to which general ingredients are added like the crosslinker (which is often BPAF), accelerator, and possibly others

<sup>8</sup> Annex XV 4,4'-isopropylidenediphenol (Bisphenol A) and bisphenols of similar concern for the environment restriction, p. 6, Appendix Y

<sup>9</sup> [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](#)

<sup>10</sup> [Regulation \(EU\) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants](#).

<sup>11</sup> [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](#).

In fact, the Commission Regulation amending REACH with the new entry for C9-C14 PFCAs recognized that C9-C14 PFCAs are strictly linked to PFOA. First, they mainly occur as unintended by-products of PFOA; secondly, they can be used as a substitute of PFOA; thirdly, the manufacturing process is similar.<sup>12</sup>

Indeed, this coordination between the regulation of C9-C14 PFCAs substances under REACH and of PFOA substances under POPs is clearly related to the principle which ensures consistency and coherence across different EU legislation, based on the similarity of the substances. This principle is further confirmed in the Common Understanding Paper on the relationship between REACH and POPs, which states that when a substance is already restricted under REACH and it is subsequently listed under the Stockholm Convention, the POPs Regulation should be amended "*to cover at least the bans under the Stockholm Convention*<sup>13</sup> and existing restrictions in Annex XVII to the REACH Regulation."<sup>14</sup> In this case, "the bans" should be read as "the restrictions" entailing the full text of the restriction, with concentration limits, conditions of restrictions and possible derogations.

We believe that the same rationale should apply *mutatis mutandis* to the case of BPAF. In fact, given that the substance falls within the scope of two different REACH restrictions there is no need to prove the requirement of "similarity". As such, in order to ensure full consistency and coherence across different EU legislation, we believe that the derogation for FKM articles as well any other derogation or condition of restriction given in the Bisphenols restriction proposal should be reflected in the PFAS restriction proposal.

In alternative, it should be noted that in the case where the same substance is regulated under two REACH restrictions, the principle of *over-regulation*, according to which double regulation should be avoided, should apply. This principle appears in line with the overall EU principle of Better Regulation,<sup>15</sup> which aims to design and prepare EU policies and laws in the most efficient way to achieve their objectives.

The principle of over-regulation has been further clarified by the Commission in its Common Understanding Paper on the relationship between REACH and POPs.<sup>16</sup> In essence, this paper explains this principle by stating that where the same substance is regulated both under REACH and POPs, ultimately "*the REACH restriction should - in principle - be removed*".<sup>17</sup> This rationale should be deemed to apply even when a substance is regulated under two different REACH restriction. In fact, both restrictions aim to reduce emissions, protecting the environment and human health in accordance with the objectives of REACH restrictions.<sup>18</sup>

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<sup>12</sup> [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](#) Recital 1; Recital 5; Recital 10.

<sup>13</sup> 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);

<sup>14</sup> [Common understanding paper - REACH and Regulation \(EC\) 850/2004 on persistent organic pollutants \('the POP Regulation'\)](#), p. 3

<sup>15</sup> [COMMISSION STAFF WORKING DOCUMENT Better Regulation Guidelines](#), p. 40

<sup>16</sup> [Common understanding paper - REACH and Regulation \(EC\) 850/2004 on persistent organic pollutants \('the POP Regulation'\)](#)

<sup>17</sup> *Ibid.*, p. 3;

<sup>18</sup> REACH, article 68(1); article 1(1)

In the case of bisphenols, this conflict between two different REACH restriction appears as the result of the grouping approach in the PFAS restriction proposal. Indeed, in the latter the Dossier Submitters decided to cover more than 10,000 PFAS substances by grouping PFAS substances on grounds of their structural similarities (primarily related to the alleged "very persistent" criterion) and failed to specify the identity of the substances in sufficient detail.

In fact, unlike in the POPs Regulation (e.g. PFOA and related substances indicative list),<sup>19</sup> there is no indicative list of substances in scope, which would allow the industry and enforcement authorities to refer to the PFAS definition to verify compliance with the proposed restriction, with enforcement issues and in violation of the principle of legal certainty.

To conclude, the proposed derogation for Bisphenols should not be undermined by a different derogation proposed under the scope of PFAS for the same substance BPAF and its salts. The conditions of the proposed restricted substance should be aligned in both restrictions. Alternatively, BPAF could be simply exempted from the scope of the PFAS proposed restriction, as both proposed restrictions aim to reduce environmental emissions.

## 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.

For the reasons set out in this paper, we kindly invite ECHA, in particular RAC and SEAC members, to consider the following options:

- (i) to align the conditions of restriction of the PFAS restriction proposal, in particular as regards derogations, to the ones of the Bisphenols restriction, or in alternative,
- (ii) to exempt BPAF from the scope of the PFAS restriction proposal, in accordance with the principle of double regulation or over regulation.

### Supporting Information:

Chemours has already submitted comments on 2/06/2023 on the overlapping of restrictions. (Receipt: bcb1bf8a-62ef-404e-932c-516af6d33528) related to the PFAS restriction as well as comments on 16/06/2023 related to the Bisphenols restriction (Receipt: 5dd4cf2d-9256-4886-9858-e96054bd9325).

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<sup>19</sup> [Updated indicative list of substances covered by the listing of perfluorooctanoic acid \(PFOA\), its salts and PFOA-related compounds;](#)

This specific one concerns derogation already proposed by the German DS. The final ECHA scientific opinion on this specific BPAF derogation should not be undermined by the PFAS restriction.

Example of similar approach: PFOA and C9-C14 PFCAs restrictions. The derogations given for the PFOA in the POPs derogations were aligned to the derogations given for the C9-C14 PFCAs restriction in order that the one restriction does not undermine the other.