

# Annex XV Restriction Report Proposal for a restriction for per- and polyfluoroalkyl substances ("PFASs") - Submission to the public consultation

## "Legal flaws of the Proposal"

### 'Inconsistency of the Proposal with EU Strategic Policies'

#### on behalf of The Chemours Company ("Chemours")

## 1. 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 1907/2006<sup>1</sup> ("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 procedural and legal comments to the public consultation in relation to the Proposal in addition to considerations on the opportunity of the restriction as some aspects may directly contradict EU policy strategies and the Better Regulation concept. For the reasons set out in this paper, 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, ECHA, in particular RAC and SEAC, should acknowledge that the Proposal is **legally flawed** in their opinion development, among others, for the **12 reasons** set out below.

- i. The Proposal is unclear in its scope as it does not specify the identity of PFAS substances in sufficient detail
- ii. The Proposal arbitrarily relies on a non-legally binding accepted definition
- iii. The Proposal presents methodological flaws in the assessment of hazard and risks of PFAS substances
- iv. The Proposal presents insufficient information to allow an independent assessment of the hazard
- v. The Proposal presents insufficient information on the uses of the specific PFAS substance(s) and resulting emissions or exposure
- vi. The Proposal does not properly assess the information on alternatives

<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;

- vii. The Proposal does not properly assess the interplay with other EU legislation and does not sufficiently state reasons to support an action on an EU wide basis
- viii. The Proposal does not allow an evaluation of the assessment of the proposed restriction and other identified RMOs in relation to their effectiveness, practicality and monitorability
- ix. The Proposal presents inaccuracies on the conditions of the proposed restriction, in particular as regards proposed derogations
- x. The Proposal does not appropriately estimate on the "overall annual health costs following from exposure to PFAS in Europe" and of the costs to the society
- xi. The Proposal opposes the outlined principles of 'Better Regulation' and will render agreed upon policies such as the EU Green Deal and the EU Green Deal Industrial Plan obsolete
- xii. The Proposal will create illegal barriers to trade, causing the offshoring of companies from the EU and having a major socio-economic impact on the EU market

Furthermore, ECHA, in particular RAC and SEAC, should acknowledge in their opinion development that the Proposal is not appropriate as it would object to the EU concept of Better Regulation and would prevent the EU from achieving its decarbonisation objectives.

## 2. Legal flaws of the Proposal

- i. The Proposal is unclear in its scope as it does not specify the identity of PFAS substances in sufficient detail

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" property of the substances).<sup>2</sup>

However, with this approach, the Dossier Submitters indirectly assume that all PFAS share the same properties. Many PFAS substances, however, have different properties and should be differentiated one from another.

Combining 10,000 substances altogether appears scientifically incorrect. As a result, the scope of the restriction Proposal is not defined in sufficient detail neither in line with Annex XV to REACH, which requires to include the identity of the substance(s) under the restriction.<sup>3</sup> In that regard, it should be noted that RAC in its opinion to the PFAS restriction in fire-fighting foams, despite reaching a wrong conclusion, *i.e.* the justification of the grouping approach, recognized that "*due to the very large number of PFAS, the hazards are not homogeneous and there will always be some uncertainty regarding the hazards of the entire group*"<sup>4</sup> in contradiction with the wording of article 68 of REACH.

Furthermore, this approach runs counter one of the guiding principles for the preparation of Annex XV, *i.e.* enforceability<sup>5</sup>. Given the broadness of the definition, it would be difficult for relevant actors to comply with the restriction, and consequently, for the enforcement authorities to supervise and enforce the proposed restriction.

Additionally, given the large grouping of substances, the scope of the Proposal is unclear, as defined in by the Restriction Task Force of ECHA<sup>6</sup>. In particular, it might lead to difficulties for the Committees when analysing the stakeholder comments and preparing their opinions which may relate to specific PFAS substances rather than the whole group.

<sup>2</sup> Annex XV PFAS REACH restriction Proposal, p. 20;

<sup>3</sup> REACH Regulation, Annex XV, Section II, point (3);

<sup>4</sup> RAC opinion to the PFAS restriction in fire-fighting foams, p. 11;

<sup>5</sup> ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 66;

<sup>6</sup> [RESTRICTION EFFICIENCY TASK FORCE SETTING A CLEAR SCOPE, A common understanding for a clear scope of Annex XV restriction proposals, Version 3, Dec 2020](#);

ii. The Proposal arbitrarily relies on a non-legally binding accepted definition

In the Proposal, the Dossier Submitters do not specify the IUPAC name, nor EC number nor CAS number of PFAS substances. Instead, they use the following definition "*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)*", which resembles the 2021 OECD definition, with only an exception for fully degradable PFASs subgroups that only contain some specific structural elements.<sup>7</sup> In their view, this definition should cover more than 10,000 PFAS substances.<sup>8</sup>

The Dossier Submitters chose the 2021 OECD definition of PFAS,<sup>9</sup> while there is no legally binding accepted legal definition of PFAS. In that regard, it should be noted that the 2021 OECD report,<sup>10</sup> from where the definition was taken, was only conceived as a working paper in order "*to provide recommendations and practical guidance to all stakeholders with regard to the terminology of PFASs*"<sup>11</sup> and was not conceived for the purposes of "*regulatory and voluntary actions*".<sup>12</sup> Also, this report does not reach a definite solid and strong scientific conclusion, as it only identifies a standardized system for systematic characterization of different PFASs.<sup>13</sup> Furthermore, it also outlines several areas that warrant further work<sup>14</sup> in a constructive approach, which should be considered work in progress. Additionally, we also note that taking this definition for the purpose of the restriction is inconsistent with the criteria of the OECD for polymers of low concern.<sup>15</sup> In fact, the latter also recognizes that fluoropolymers are polymers of low concern and the [grouping] is not connected to decisions on how PFASs should be grouped in regulatory and voluntary actions.

In addition to the above, the application of this definition would include substances whose properties significantly differ from one to another and would be inconsistent with their risk assessment, e.g. trifluoroacetic acid ("TFA").<sup>16</sup>

Furthermore, the absence of CAS numbers and/or EC numbers and the grouping solely based on structural similarity triggers enforcement issues. In fact, contrary to what ECHA suggests,<sup>17</sup> it would not be feasible to require each actor to refer to the definition to verify compliance with the proposed restriction. In that regard, it should be noted that in global conventions like the Stockholm Convention,<sup>18</sup> implemented in the EU with the POPs Regulation,<sup>19</sup> there is an indicative list of substances which is regularly reviewed (e.g. PFOA and related substances indicative list).<sup>20</sup> In the Proposal, the Dossier Submitters failed to provide an analogous list.

<sup>7</sup> Annex XV PFAS REACH restriction Proposal, p. 4 Column 1;

<sup>8</sup> *Ibid.*, p. 21, p.181;

<sup>9</sup> 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) (OECD, 2021, Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris. [https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO\(2021\)25&docLanguage=En](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLanguage=En);

<sup>10</sup> *Ibid.*;

<sup>11</sup> *Ibid.* p. 7;

<sup>12</sup> *Ibid.* p. 8;

<sup>13</sup> *Ibid.* p. 8, 29;

<sup>14</sup> *Ibid.* p. 8, 33;

<sup>15</sup> Henry BJ, Carlin JP, Hammerschmidt JA, Buck RC, Buxton LW, Fiedler H, Seed J, Hernandez O. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag. 2018 May;14(3):316-334. doi: 10.1002/ieam.4035; Korzeniowski SH, Buck RC, Newkold RM, Kassmi AE, Laganis E, Matsuoka Y, Dinelli B, Beauchet S, Adamsky F, Weilandt K, Soni VK, Kapoor D, Gunasekar P, Malvasi M, Brinati G, Musio S. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag. 2023 Mar;19(2):326-354. doi: 10.1002/ieam.4646;

<sup>16</sup> Montreal Protocol On Substances that Deplete the Ozone Layer UNEP 2022 Assessment Report of the Environmental Effects Assessment Panel on , p. 25: <https://ozone.unep.org/system/files/documents/EEAP-2022-Assessment-Report-May2023.pdf>

<sup>17</sup> ECHA Webinar: Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH Questions and answers, p. 14, reply to question 1.4.1;

<sup>18</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>19</sup> Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

<sup>20</sup> Updated indicative list of substances covered by the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds;

Another deficit of this chemically structural grouping approach is the inclusion of a hypothetical group of unknown substances, some of which may not even be commercially relevant.<sup>21</sup> Furthermore, in order to be able to enforce the proposed restriction, competent authorities would need a profound chemical scientific knowledge, which could not simply be solved with the adoption of guidance on analytical methods as RAC suggests in its opinion to the PFAS in fire-fighting foams restriction.<sup>22</sup> Again, this approach runs counter one of the guiding principles for the preparation of Annex XV, *i.e.* enforceability.<sup>23</sup>

iii. The Proposal presents methodological flaws in the assessment of hazard and risks of PFAS substances

The Dossier Submitters failed to explain which hazard properties pose specific PFAS and in turn, which properties lead to risks for specific PFAS substances and related uses.

For instance, similarly to the restriction of PFAS in fire-fighting foams,<sup>24</sup> it is stated that "all" PFAS" are persistent, while "some" or "most of" are mobile/accumulate in biota/carcinogenic/endocrine disruptors, etc<sup>25</sup>. These statements are vague, general in nature and unrelated to specific case-by-case assessments of the various PFAS substances and, as pointed out above, this leads to uncertainty regarding the hazards of the entire group.

In reality, the data demonstrating adverse effects on human health and on the environment used in the Annex XV report relate principally to a few PFAS (most notably PFOA and PFOS).<sup>26</sup>

However, these concerns, which are specific for PFOA and PFOS, have been unduly extended by the Dossier Submitters to all other PFAS using a "specific-to-general" approach, which does not appear scientifically and legally sound.<sup>27</sup> Stated differently, the use of few examples on selected substances to support a concern for all PFAS substances fails to be scientifically and legally sound.

Besides, the risks deriving from these properties are combined without a clear link between the alleged hazard properties and derived risks. Indeed, the Dossier Submitters rely on a "combined effect" approach, which is not in line with the requirements for the preparation of an Annex XV dossier.<sup>28</sup>

iv. The Proposal presents insufficient information to allow an independent assessment of the hazard<sup>29</sup>

The Dossier Submitters have justified the grouping based on structural similarities of the substances related to alleged "very persistency" criterion, to avoid the regrettable substitution and prevention of future exposure of those PFAS, which are not currently in use.<sup>30</sup>

In doing so, different substances have been unduly and/or arbitrarily grouped together, without a proper case-by-case assessment as required under REACH.<sup>31</sup>

In that regard, such a large grouping under the REACH restriction process is legally questionable. Indeed, the grouping of substances is only foreseen under REACH for purposes of fulfilling data requirements of registered substances. While practice leans towards grouping for REACH restriction purposes, this appears to be driven mostly by reasons of efficiency but is not necessarily scientifically

<sup>21</sup> Buck, R.C., Korzeniowski, S.H., Laganis, E. and Adamsky, F. (2021), Identification and classification of commercially relevant per- and poly-fluoroalkyl substances (PFAS). Integr Environ Assess Manag, 17: 1045-1055. doi:[10.1002/ieam.4450](https://doi.org/10.1002/ieam.4450);

<sup>22</sup> RAC opinion to the PFAS restriction in fire-fighting foams, p. 55;

<sup>23</sup> ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 66;

<sup>24</sup> RAC opinion to the PFAS restriction in fire-fighting foams, p.9;

<sup>25</sup> Annex XV PFAS REACH restriction Proposal, p. 13;

<sup>26</sup> Annex B to XV PFAS REACH restriction Proposal;

<sup>27</sup> Annex XV PFAS REACH restriction Proposal, p. 13, p. 33;

<sup>28</sup> ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 33; 34;

<sup>29</sup> ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 23;

<sup>30</sup> Annex B to the Annex XV PFAS REACH restriction Proposal, p. 5;

<sup>31</sup> ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 32;

justified. In fact, the clustering of many (and different) substances into a group would make the restriction difficult to meet and falls short to comply with some general REACH and EU principles, such as the One Substance One Registration ("OSOR") principle, proportionality, due process, precautionary, equal treatment and legal certainty. As such, grouping cannot be justified by reference to the literature,<sup>32</sup> let alone to working papers that do not reach a definitive scientific position much less one that is not accepted as legally binding, in particular the 2021 OECD report<sup>33</sup> and 2018 Ritscher Zurich Statement.<sup>34</sup> In that regard, the fact that RAC in the PFAS restriction in fire-fighting foams refers to such papers does not mean that such definitions are legally sound and definitive.

Moreover, the specific justification provided by the Dossier Submitters to group all 10,000 PFAS altogether is questionable. Indeed, relying on persistency as a standalone criterion to justify a restriction is debatable<sup>35</sup>. Persistency may indeed only operate in combination with other criteria, such as bioaccumulation ("B") or toxicity ("T") or mobility ("M"). This is confirmed both by the text of REACH and Regulation 1272/2008 ("CLP"). On one hand, Annex XIII to REACH lays down the criteria for the identification of persistent, bioaccumulative and toxic substances ("PBT"), and very persistent and very bioaccumulative substances ("vPvB"). On the other hand, the CLP Regulation was recently amended to reflect the publication of Commission Delegated Regulation EU 2023/707 introducing new hazard classes and related criteria.<sup>36</sup> In fact, this lays down criteria for Persistent, Bioaccumulative and toxic substances ("PBT"), Very Persistent, Very Bioaccumulative substances ("vPvB"), Persistent, Mobile and Toxic substances ("PMT"), very Persistent, very Mobile substances ("vPvM"). These criteria should be taken into account in the Proposal.

Such approach would be in line with past grouped restrictions where substances were deemed to be persistent, the justification for restriction was given on the basis of a combination of these criteria. For instance, in the PFHxA restriction, RAC considered that the substances constitute intrinsic hazards due to their *"extreme persistence combined with mobility"*<sup>37</sup>. Similarly, in the microplastics restriction, RAC noted that although microplastics did not meet the PBT and vPvB criteria, *"the long-term persistence in the environment of microplastics could raise an equivalent level of concern to PBT/vPvB, as established in REACH Article 57(f)"*.<sup>38</sup>

Taking all of this into account, it should be noted that the Dossier Submitters failed to clarify which specific PFAS are either PBT, vPvB, PMT or vPvM in the Proposal. In fact, ECHA is wrong in stating that the Proposal *"does not only rely on persistence"*,<sup>39</sup> as the Dossier Submitters failed to explain the combination of persistency with other concerns and relied on the literature supporting the P-sufficient approach.<sup>40</sup>

Further, the inclusion of PFAS that have no or negligible uses, thus no exposure, seems to breach the requirements set out in article 68 of REACH, *i.e.* the presence of an *"unacceptable risk"*<sup>41</sup>: indeed, if some PFAS are not in use, there is no exposure, and therefore no risk.<sup>42</sup> In that regard, it should be

<sup>32</sup> For instance, Cousins I.T., DeWitt J.C., Gluge J., Goldenman G., Herzke D., Lohmann R., Miller M., Ng C.A., Scheringer M., Vierke L., and Wang Z. (2020a): Strategies for grouping per- and polyfluoroalkyl substances (PFAS) to protect human and environmental health. Environmental science. Processes & impacts 22 (7), 1444-1460. [doi: 10.1039/d0em00147c](https://doi.org/10.1039/d0em00147c);

<sup>33</sup> OECD, 2021, Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris. [https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO\(2021\)25&docLanguage=En](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLanguage=En);

<sup>34</sup> Ritscher A, Wang Z, Scheringer M, Boucher JM, Ahrens L, Berger U, Bintein S, Bopp SK, Borg D, Buser AM, Cousins I, DeWitt J, Fletcher T, Green C, Herzke D, Higgins C, Huang J, Hung H, Knepper T, Lau CS, Leinala E, Lindstrom AB, Liu J, Miller M, Ohno K, Perkola N, Shi Y, Småstuen Haug L, Trier X, Valsecchi S, van der Jagt K, Vierke L. Zürich Statement on Future Actions on Per- and Polyfluoroalkyl Substances (PFASs). Environ Health Perspect. 2018 Aug;126(8):84502. [doi: 10.1289/EHP4158](https://doi.org/10.1289/EHP4158);

<sup>35</sup> Annex XV PFAS REACH restriction Proposal, p. 1;

<sup>36</sup> Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, OJ L 93, 31.3.2023, p. 7–39;

<sup>37</sup> PFHxA REACH restriction, combined RAC and SEAC opinion p. 29;

<sup>38</sup> *Ibid.*, p. 56

<sup>39</sup> ECHA Webinar: Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH Questions and answers, p. 14, reply to question 1.4.4;

<sup>40</sup> Annex XV PFAS REACH restriction Proposal, p. 24;

<sup>41</sup> REACH Regulation, article 68;

<sup>42</sup> RAC opinion to the PFAS restriction in fire-fighting foams, p. 14;

noted that RAC erred when stating in its opinion to the PFAS in fire-fighting foams restriction that *"If certain PFAS are not suitable, they are not impacted by this restriction and the effort required to identify such groups and substances would not be justified"*.<sup>43</sup> Indeed, in that case, the ECHA Committee was wrong in targeting the whole PFAS class, rather than specific PFAS or groups of related PFAS, as the given justification, *i.e. "the precise identities of the PFAS currently used in firefighting foams are largely unknown due to manufacturer confidentiality"*,<sup>44</sup> does not appear legally sound. This last point, *i.e. including in scope PFAS of no or negligible use*, seems also to run counter the principle of effectiveness, which is a guiding principle in the preparation of Annex XV<sup>45</sup>.

v. The Proposal presents insufficient information on the uses of the specific PFAS substance(s) and resulting emissions or exposure

The Dossier Submitters claim to have covered rather exhaustively all PFAS uses, but in fact, they only covered 14 uses and 78 sub-uses as indicated in Table 2 of the Proposal.<sup>46</sup>

However, it seems that the Dossier Submitters arbitrarily chose to focus on these specific uses while stating that *"all uses of PFASs are covered by this restriction proposal, regardless of whether they have been specifically assessed by the Dossier Submitters and/or are mentioned in this report or not, unless a specific derogation has been formulated"*.<sup>47</sup>

In addition to the above, it appears that the Dossier Submitters did not take into consideration some of the feedback submitted during the calls for evidence concerning chemical industry large uses, such as notably pipes, lining, valves and two-phase-immersion cooling applications. In addition, they concede that, for some PFAS uses, *"no detailed assessment"* was carried out since *"they concerned niche applications or because the applications are currently of little relevance in the EU"*<sup>48</sup>. Furthermore, the Dossier Submitters do not seem to have provided an explanation of what constitutes *"niche applications"* and *"uses of little relevance in the EU"*.<sup>49</sup>

However, this approach is not in line with the requirements set out for the preparation of an Annex XV, *i.e. providing deep analysis of the information of the use of the substances*.<sup>50</sup>

vi. The Proposal does not properly assess the information on alternatives

The Dossier Submitters allege that there is *"sufficiently strong evidence"* that technically and economically feasible alternatives exist for non-polymeric PFAS as polymerisation aids in the production of PTFE, PVDF and FKM.<sup>51</sup> In that regard, the following should be noted.

Firstly, in order to qualify evidence as *"sufficiently strong"*, it is clear that information should not come only from one source as this approach is not reflective and representative of the market.

Secondly, Annex E to the Proposal contains a contrary statement. Specifically, this annex states that *"it is not clear whether all PTFE, PVDF and FKM can already be produced without PFAS polymerisation aids at industry level"*.<sup>52</sup>

In certain cases (such as commercial HVACR), the Dossier Submitters acknowledge that *"the sector is still dominated by using fluorinated gases, and the assumption that alternatives are ready to replace*

<sup>43</sup> RAC opinion to the PFAS restriction in fire-fighting foams, p. 14;

<sup>44</sup> *Ibid.*, p. 13;

<sup>45</sup> ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 64;

<sup>46</sup> Annex XV PFAS REACH restriction Proposal, p. 53 Table 2;

<sup>47</sup> *Ibid.*, p. 2;

<sup>48</sup> Annex A to the Annex XV PFAS REACH restriction Proposal, p. 4;

<sup>49</sup> *Ibid.*;

<sup>50</sup> ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 108;

<sup>51</sup> Annex XV PFAS REACH restriction Proposal, p. 81 Table 8;

<sup>52</sup> Annex E to the Annex XV PFAS REACH restriction Proposal, p. 2;

*them is premature*<sup>53</sup> or that “Air cooled CO<sub>2</sub> AC systems are available in capacities from 3kW to 300kW, though systems become inefficient at high ambient temperatures”,<sup>54</sup> but still propose that no derogation is needed for this application.

In addition, quantitative assessment is not available in the text of the Proposal. As regards the availability of alternatives, the Dossier Submitters recognise that *“there remain uncertainties in the dossier that may affect the quality of conclusions reached on specific sectors and applications”*<sup>55</sup>.

As such, it can be concluded that a thorough analysis of the possible alternatives was not conducted, in breach of one of the requirements set out in the Guidance for the preparation of Annex XV.<sup>56</sup>

- vii. The Proposal does not properly assess the interplay with other EU legislation and does not sufficiently state reasons to support an action on an EU wide basis

The Dossier Submitters have failed to analyze other RMOs by inadequately assessing the EU regulatory framework applicable to PFAS.

There is no proper and exhaustive assessment of the overlap between the restriction proposal and other existing EU legislation<sup>57</sup>. For instance, the restriction of PFOS and PFOA under the Stockholm Convention and Regulation 1021/2019 (“POPs”) is not considered in Table 5 of the Proposal,<sup>58</sup> while in points 2.2.1.1. and 2.2.1.2. of the Proposal it is only superficially addressed.<sup>59</sup> Indeed, a proper analysis of the interaction between REACH and POPs would remove these two substances from the Proposal, as they are already regulated. This would prevent the application of over regulation, a principle according to which double regulation should be avoided.<sup>60</sup> Therefore, in the present case, the ECHA Committees should acknowledge that PFOS and PFOA should be excluded from the scope of this Proposal.

Without the intention of being exhaustive, there are other examples in which the Dossier Submitters failed to fully address the interplay with other EU legislation. For instance, as regards the F-gas Regulation, the Proposal states that this regulation *“does not per se restrict the use of the substances but rather aims for a reduction of their use”*.<sup>61</sup> However, the Dossier Submitters also explicitly recognize that there might be an overlap with between the Proposal and *“section 2 [of Annex I the current F-gas Regulation]”*.<sup>62</sup>

In addition to that, the Dossier Submitters seem to not have taken into account the inclusion of PFHxS into the Stockholm Convention which will lead to the consequent update of the POPs Regulation.

As such, the Proposal does not properly assess the interplay with other EU legislation and ECHA errs when stating that *“the proposal is not meant to interfere with any existing regulations and ensures that the strictest EU regulation (including REACH restrictions) applies”*.<sup>63</sup>

Finally, the Proposal considers that some uses should be in scope even though they are currently of *“little relevance in the EU”*<sup>64</sup>. This is contrary to the principle of subsidiarity according to which the EU should act only if the objectives of the measure taken at EU level are of EU relevance and cannot be sufficiently achieved at Member State level.

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<sup>53</sup> *Ibid.*, p. 248;

<sup>54</sup> *Ibid.*, p. 263;

<sup>55</sup> Annex XV PFAS REACH restriction Proposal, p. 189;

<sup>56</sup> ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 69;

<sup>57</sup> *Ibid.*, p. 70;

<sup>58</sup> Annex XV PFAS REACH restriction Proposal, p. 70, 71;

<sup>59</sup> Annex XV PFAS REACH restriction Proposal, p. 63, 64;

<sup>60</sup> [Commission understanding paper on the relationship between REACH and POPs](#);

<sup>61</sup> Annex XV PFAS REACH restriction Proposal, p. 10;

<sup>62</sup> Annex XV PFAS REACH restriction Proposal, p. 66;

<sup>63</sup> ECHA Webinar: Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH Questions and answers, p. 16, reply to question 1.4.11;

<sup>64</sup> Annex A to the Annex XV PFAS REACH restriction Proposal, p. 4;

- viii. The Proposal does not allow an evaluation of the assessment of the proposed restriction and other identified RMOs in relation to their effectiveness, practicality and monitorability

The Proposal does not meet the requirements of *effectiveness* and *enforceability*, for the following reasons:

- first, it includes PFAS of no or negligible use;
- second, it aims to cover more than 10,000 PFAS relying on the 2021 OECD definition, which is inherently inconsistent; and
- third, it acknowledges a series of data gaps on health and environmental impact.

The Proposal is also *inadequate*, as there is insufficient data to enable detailed modelling of costs to industry, etc. and/or of benefits via reduced impacts to ecosystems and human health.<sup>65</sup>

In particular, as regards health and environmental impacts, the Dossier Submitters recognise that for most PFAS, there are insufficient data to adequately assess their effects on human health and the environment<sup>66</sup>. For example, the Proposal does not provide specific data as regards the emissions of PFAS processors<sup>67</sup>, emissions in the waste phase<sup>68</sup>, or from the article production<sup>69</sup>.

The Dossier Submitters recognise that, for a large part of the chemicals covered by the restriction, the available information is incomplete<sup>70</sup>. Therefore, the Proposal in our opinion does not comply with the *effectiveness* criterion<sup>71</sup>, as it is not targeted at the effects or exposures that cause the identified risk, but broadened also to the unidentified or non-assessed risks.

Additionally, the Proposal regards the possibility to have PFAS being controlled at EU level at the "end-of-pipe" as being not achievable without clearly assessing the possible measures.<sup>72</sup> In fact, the Proposal only focuses on the need to tackle the issue regarding PFAS at the source and does not assess other means to control the risk at the "end-of-pipe". In turn, the resulting conclusion is at odds with the principle of *proportionality*.

- ix. The Proposal presents inaccuracies on the conditions of the proposed restriction, in particular as regards proposed derogations

The Dossier Submitters distinguish between "*sufficiently strong evidence*", "*weak evidence*" and "*inconclusive evidence*" for each of the proposed derogations.

The methodology followed is questionable in as much as those levels of evidence are arbitrary and were not used equally to support the restriction.

In addition, the Dossier Submitters have proposed a derogation for fluoropolymers used in the proton-exchange membrane ("PEM") into fuel cells applications for 6.5 years after the entry into force.<sup>73</sup> However, they have not considered the derogation for PEM in electrolyzers for hydrogen production. Without the latter, the derogation may be deprived of its *effet-utile*, namely devoid of its practical application. A similar reasoning can be applied to several granted derogations, which depend on the availability of PTFE, manufactured with fluorinated polymerisation aids, e.g. implantable medical

<sup>65</sup> Annex XV PFAS REACH restriction Proposal, p. 189;

<sup>66</sup> *Ibid.*, p.13;

<sup>67</sup> *Ibid.*, p.39;

<sup>68</sup> *Ibid.*, p.43;

<sup>69</sup> *Ibid.*, p.44;

<sup>70</sup> *Ibid.*, p.49;

<sup>71</sup> ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 57;

<sup>72</sup> Annex XV PFAS REACH restriction Proposal, p. 2;

<sup>73</sup> *Ibid.*, p.7 Column 2, paragraph 6(e);

devices, or the derogation of PFPE oils, which depend on fluorine-based solvents, which are the only carrier fluid to effectively dissolve PFPE lubricants.

Similarly, the Dossier Submitters have not proposed a derogation for transported isolated intermediates. Although not explicitly provided in REACH, practice leans towards allowing for this derogation. In fact, there are examples for which RAC proposed to exempt from a restriction transported isolated intermediates used under strictly controlled conditions (e.g. PFOA<sup>74</sup> and PFHxA<sup>75</sup>).

On top of all these considerations, it should be noted that in the Foresight for Chemicals Report, recently published by the Commission, PFAS have been included among the twenty Critical Chemicals ("CCs"), i.e. chemicals that are economically and strategically important for the EU economy, and the need for their derogation has been emphasized.<sup>76</sup> In fact, the authors of this report have underlined the importance of considering derogations to allow the continued use of PFAS as "*there are in some cases no suitable alternatives for its role in certain parts of the value chain*".<sup>77</sup>

Overall, we believe that the public consultation is the right place to insist on the fact that the Dossier Submitters did not properly assess the conditions of the proposed derogations as "*the consultation is about providing ECHA's committees with all available information that helps them form scientifically sound opinions on the proposed restriction*".<sup>78</sup> As such, we believe that the Committees should reflect this in their respective opinions. In fact, the same reasoning should apply to all sections of this legal paper.

- x. The Proposal does not appropriately estimate on the "overall annual health costs following from exposure to PFAS in Europe"<sup>79</sup> and of the costs to the society

The Dossiers Submitters make unsubstantiated assumptions and fail to adequately support the estimates with sufficient data to enable detailed modelling of costs to the industry<sup>80</sup>.

- xi. The Proposal opposes the outlined principles of 'Better Regulation' and will render agreed upon policies such as the EU Green Deal and the EU Green Deal Industrial Plan obsolete

'Better regulation' aims to design and prepare EU policies and laws in the most efficient way to achieve their objectives. It involves working in an open and transparent manner, informed by the best available evidence, and involving stakeholders to ensure that the EU acts in line with the principles of subsidiarity and proportionality.<sup>81</sup>

The guidelines rightly state that EU Laws and regulation cannot be adopted in isolation and must be consistent with the high-level and long-term policy objectives.<sup>82</sup> Such examples of long-term policy

<sup>74</sup> Commission Regulation (EU) 2017/1000 of 13 June 2017 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances, OJ L 150, 14.6.2017, p. 14–18. As PFOA, its salts and any related substance are now included in Annex I to Regulation (EU) 2019/1021, the PFOA entry has been removed from Annex XVII to REACH;

<sup>75</sup> See RAC Opinion in PFHxA restriction, page 64;

<sup>76</sup> European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Hafner-Zimmermann, S., Jagaciak, M., Kolos, N., et al., *Chem4EU : foresight for chemicals : final report*, Publications Office of the European Union, 2023, [doi/10.2873/574731](https://doi.org/10.2873/574731);

<sup>77</sup> *Ibid.*, p. 11;

<sup>78</sup> ECHA Webinar: Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH Questions and answers, p. 10, reply to question 1.3.2;

<sup>79</sup> Annex XV PFAS REACH restriction Proposal, p. 2;

<sup>80</sup> *Ibid.*, p. 189;

<sup>81</sup> Communication from the Commission to the European Parliament, the Council, the European and Social Committee and the Committee of the Regions Better Regulation: Joining forces to make better laws;

<sup>82</sup> *Ibid.*, p. 22;

objectives are outlined in the broad policy framework of the EU Green Deal<sup>83</sup> aimed at achieving climate neutrality and sustainability and the concrete actions of the EU Green Deal Industrial Plan<sup>84</sup>.

Concretely, the proposed PFAS Restriction would, at least, be in contradiction with the following legislation:

#### a) The 2020 EU Strategy for Hydrogen

The Hydrogen Strategy<sup>85</sup> emphasizes the need for renewable hydrogen production through electrolysis and the use of renewable electricity. This is because conventional methods of producing hydrogen from fossil fuels are not sustainable in the long run, due to their high carbon emissions. Only green hydrogen generation is advocated vs grey/blue/pink and other types.

Although the Proposal clearly outlines the potential for growth of PFAS (e.g. PTFE) uses in the energy sector with a foreseen annual growth rate of 10% to accomplish the 2030 EU hydrogen Strategy goal of 40 GW electrolysis capacity within the EU,<sup>86</sup> it does not draw the appropriate conclusion, i.e. that an indefinite exemption is needed and not a 'delayed' ban. An increase in the use of PFASs to be used in PEM electrolysis technology (proton exchange membrane – a fuel cell) is essential to meet the objectives of the strategy. However, the Proposal does conclude that there are enough alternatives for membrane applications in PEM fuel cells but that those are less performant and durable.<sup>87</sup> Commercial availability will not start before 10 years from 2022, eventually. However, a delayed ban is proposed in 5 years or 12 years from entry into force,<sup>88</sup> impacting, as a result, all investments in this technology at this precise time, rendering any business assessment impossible.

As regards PEM membranes for the generation of Green hydrogen, the Proposal does not offer an exemption which would mean, a ban as from the entry into force. In that respect, the Proposal only refers to the fact that several stakeholders point out that it is likely that alternatives are already available or might be found for a lot of components depending on concrete circumstances for each use.<sup>89</sup>

As such, the proposal is in contradiction with the objectives of the 2020 EU Strategy for Hydrogen.

#### b) The 2023 Green Deal Industrial Plan

The Green Deal Industrial Plan<sup>90</sup> is based in four pillars: a predictable and simplified regulatory environment, faster access to sufficient funding, skills and open trade for resilient supply chains.

Among the measures outlined, the European Commission proposes to create a more coherent regulatory framework by aligning policies across different sectors.<sup>91</sup> It also suggests greater predictability for businesses by setting clear targets and timelines for emissions reductions.<sup>92</sup> This includes setting binding targets for reducing greenhouse gas emissions across various sectors and providing long-term funding commitments for sustainable projects. This is achieved with the

<sup>83</sup> [COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS The European Green Deal](#);

<sup>84</sup> [COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A Green Deal Industrial Plan for the Net-Zero Age \(2023\)](#);

<sup>85</sup> [COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A hydrogen strategy for a climate-neutral Europe](#);

<sup>86</sup> Annex XV PFAS REACH restriction Proposal, p. 60;

<sup>87</sup> *Ibid.*, p. 106, 107, 108;

<sup>88</sup> *Ibid.*, p. 7, Column 2, paragraph 6(e);

<sup>89</sup> *Ibid.*, p. 106, 107, 108;

<sup>90</sup> [COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A Green Deal Industrial Plan for the Net-Zero Age \(2023\)](#);

<sup>91</sup> *Ibid.*, p. 3;

<sup>92</sup> *Ibid.*, p. 4;

development of the green hydrogen, decarbonization of heating and cooling, increasing energy performance of buildings, solar panels, windmills, electrification of cars with performant batteries and requiring thousands of microchips needing fluoropolymer and fluorinated gases.

It should be noted that the Proposal concludes that several stakeholders point out that that it is likely that alternatives are already available or might be found for a lot of components depending on concrete circumstances for each use.<sup>93</sup> In other words, the wind and solar renewable energy development or the pace of deployment of energy efficient heat pumps will slow down, because of the uncertainty brought forward by the Proposal, without valid proof of said alternatives. The length of the process is therefore, a cause of serious concern.

Finally, the plan insists on the need to promote international cooperation on climate change by working with other countries to develop common standards and regulations (with UN Framework Convention on Climate Change ("UNFCCC"))<sup>94</sup> to develop common reporting standards for greenhouse gas emissions). The new HFOs have a very low warming potential and facilitated the booming of heat pumps, alternative to fossil fuels energies but, those are at risk with the Proposal.

Also, a ban is proposed for PFAS used in HVACR, 12 years after the entry into force.<sup>95</sup> This risks to slow down the recent development of alternatives to coal and gas heating, further to the Ukraine war and the surge in energy prices.

As such, the Proposal appears in contradiction with the 2023 Green Deal Industrial Plan.

#### c) The 2023 Net 0 Industry Act

The 2023 Net 0 Industry Act<sup>96</sup> supports the manufacturing of net-zero technologies and increase the competitiveness of the net-zero tech industrial base. It does so by simplifying the regulatory framework and improving the investment environment for the Union's manufacturing capacity of technologies that are key to meet the Union's climate neutrality goals. The goal of this initiative is to reduce dependencies on fossil fuels and seize economic opportunities stemming from the global market for net-zero industry technologies, which is expected to reach an annual worth of around EUR 600 billion a year by 2030 according to the International Energy Agency. Net-zero technologies such as solar panels, wind turbines or heat pumps are also strongly promoted by this new policy initiative and those depend, in terms of durability, from PFAS, to protect them from very high/low temperature, UV light, wind, rain, etc.<sup>97</sup>

This initiative foresees the review of critical European legislation which would help to address the issue of PFAS emissions during the end of life phase. Though the largest emissions are at the manufacturing phase and those can be addressed by abatement technologies, the use and end of life phase are also relevant. In that respect, the coming reviews of the Electric and Electronic Waste Directive<sup>98</sup> and the End of Life of Vehicles Directive<sup>99</sup> should be considered as a support to the development of electric cars and an opportunity to ensure recycling including of fluoropolymers. These legislations could address easily the issue of PFAS at the end of life. A formal obligation could be made to collect all PFAS from a car and collect all WEEE containing PFAS with a view to recycle. Given the very high value of PFAS, an obligation to recycle would further develop the circular economy and avoid emissions from waste into the environment.

<sup>93</sup> Annex XV PFAS REACH restriction Proposal, p. 81 to 138;

<sup>94</sup> [UN Framework Convention on Climate Change 1992](#);

<sup>95</sup> Annex XV PFAS REACH restriction Proposal, p. 5, Column 2, paragraph 5(i);

<sup>96</sup> [Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem \(Net Zero Industry Act\)](#);

<sup>97</sup> *Ibid.*, Annex I;

<sup>98</sup> [Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment \(WEEE\)](#);

<sup>99</sup> [Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles - Commission Statements](#);

The revision of the F-gas Regulation will address containment of F-gases throughout their life cycle, via a broader application of leak detection systems harmonized training and certification of maintenance technicians and proper end of life disposal of F-gases.

As such, the Proposal appears in contradiction with the objectives of the 2023 Net 0 Industry Act.

d) The 2022 European Chips Act

The Chips Act proposal aims to establish a framework of measures for strengthening Europe's semiconductor ecosystem. This proposal is in response to the increasing demand for semiconductors, which are essential components in many electronic devices, including smartphones, computers, and cars. The COVID-19 pandemic has further highlighted the importance of semiconductors as they are used in medical equipment and devices.

This initiative also aims to address disruptions in chip supply by improving the availability of critical raw material and prevent potential societal consequences. The strategic objective is to strengthen Europe's semiconductor ecosystem by enlarging its resilience and increasing its global market share. It will facilitate early adoption of new chips by European industry and increase its competitiveness.

It should be noted that the Proposal provides for a 12 year derogation from the entry into force,<sup>100</sup> despite not having demonstrated that semiconductors can function without fluoropolymers. Given the extreme implications of such a ban, it is of utmost importance that ECHA acknowledges the need for an indefinite exemption for fluoropolymers needed for the manufacturing of semiconductors. Without fluoropolymers, there is no future, in the EU, for the semiconductors industry and therefore, all developments and investments will happen outside the EU, increasing our dependence from China, Taiwan, South Korea and the US.

As such, the Proposal appears in contradiction with the objectives of the 2022 European Chips Act.

xii. The Proposal will create illegal barriers to trade, causing the offshoring of companies from the EU and having a major socio-economic impact on the EU market

The Proposal only foresees an exemption for fully degradable PFAS<sup>101</sup> and a limited number of derogations. When proposing these exceptions, the Dossier Submitters did not only fail to ensure the *effet-utile* of some derogations (*see point ix of this submission*), but did not consider the low hazard and/or safe uses of certain PFAS.<sup>102</sup>

In that regard, it should be observed that under UK REACH, the regulatory management option analysis ("RMOA") for PFAS, supported by the UK competent authorities in their regulatory decision making, has recognized that "*exemptions could also be considered for PFAS (as individual substances or groups) for which comprehensive reliable evidence of low hazard or safe use can be provided or consideration may be given to exemption on socioeconomic grounds and subject to the availability of alternatives*".<sup>103</sup> Furthermore, in full consistency with the criteria of the OECD for polymers of low concern,<sup>104</sup> the UK RMOA has recognized that fluoroplastics or fluoroelastomers represent low hazard groups and should be exempted from the restrictions,<sup>105</sup> along with "*intermediates, uses in*

<sup>100</sup> Annex XV PFAS REACH restriction Proposal, p. 7, Column 2, paragraph 5(ee);

<sup>101</sup> Annex XV PFAS REACH restriction Proposal, p. 4 Column 1;

<sup>102</sup> *Ibid.*, p. 4,5,7, 8 Column 2;

<sup>103</sup> UK HSE Analysis of the most appropriate regulatory management options (RMOA) for PFAS, p. 174;

<sup>104</sup> Henry BJ, Carlin JP, Hammerschmidt JA, Buck RC, Buxton LW, Fiedler H, Seed J, Hernandez O. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integr Environ Assess Manag.* 2018 May;14(3):316-334. doi: [10.1002/ieam.4035](https://doi.org/10.1002/ieam.4035); Korzeniowski SH, Buck RC, Newkold RM, Kassmi AE, Laganis E, Matsuoka Y, Dinelli B, Beauchet S, Adamsky F, Weilandt K, Soni VK, Kapoor D, Gunasekar P, Malvasi M, Brinati G, Musio S. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. *Integr Environ Assess Manag.* 2023 Mar;19(2):326-354. doi: [10.1002/ieam.4646](https://doi.org/10.1002/ieam.4646);

<sup>105</sup> *Ibid.*;

*sealed/contained systems (including use as heat exchange fluids in heat pumps and refrigeration systems), (low risk uses)".<sup>106</sup>*

It should be noted that the disparities between the UK RMOA and the EU restriction, if adopted as they currently stand, will likely create illegal barriers to trade in the future, in breach of the international trade rules laid down in the General Agreement on Tariffs and Trade ("GATT"),<sup>107</sup> the Agreement on Technical Barrier to Trade ("TBT")<sup>108</sup> and the Agreement on Sanitary and Phytosanitary Measures ("SPS").<sup>109</sup>

In practical terms, this would mean that companies will be incentivized to move their business abroad (e.g. to the UK) where less restrictive measures will apply. This would have a major impact from a socio-economic point of view in the EU market. As such, the ECHA Committees, in particular SEAC, should take these aspects into account when evaluating if the net benefits to human health and the environment outweigh the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole in accordance with the REACH rules.<sup>110</sup>

### 3. Conclusion

In light of all the above, there is enough evidence that the REACH restriction Proposal presents serious flaws in terms of methodology, legal principles and scientific rigour for the reasons presented in this paper in addition to being in breach with the principle of Better Regulation.

**We ask ECHA, in particular RAC and SEAC members, to carefully take this information into account and reflect it in their opinions, in accordance with articles 70 and 71(1) REACH as well as the general principles of EU law, such as due process, right of good administration and right of defence.**

\* \* \*

Yours sincerely,



**Claudio Mereu**  
Partner

<sup>106</sup> *Ibid.*;

<sup>107</sup> GATT Agreement, articles Art. I, III, XI, XX;

<sup>108</sup> TBT Agreement, article 2;

<sup>109</sup> SPS Agreement, articles 2, 3 and 5;

<sup>110</sup> REACH, article 71; Annex XV and Annex XVI.