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To the ECHA Secretariat:

In 2020, the Competent Authorities of Germany, Sweden, the Netherlands, Denmark and Norway agreed to prepare a joint Restriction Proposal ("the Proposal") aimed at restricting a wide range of PFAS under Regulation (EC) No 1907/2006[1] ("REACH Regulation" or "REACH"). Between 2020 and 2021, the four Member States and Norway ("the Dossier Submitters") conducted two calls of evidence to gather views from different stakeholders to contribute to the finalization of the Proposal.

On 13 January 2023, the Dossier Submitters submitted their Proposal to ECHA, which was published on its website on 7 February 2023.

The ECHA's Committee for Socio-Economic Analysis ("SEAC") and Committee for Risk Assessment ("RAC") will respectively meet on 10 March and on 15 March 2023. During their plenary meetings, they will vote on the conformity of the Proposal with the requirements set in Annex XV of REACH Regulation.

In the event of an agreement on the conformity of the Proposal during those meetings, it will move to ECHA's scientific committees for opinion making and will be subject to public consultation from 22 March 2023 to 22 September 2023.

Within this context, the Proposal **should not move forward** in the REACH restriction procedure in its current form, as it contains a series of **legal flaws,** for the reasons set out below (each legal flaw is related to a specific point of the conformity check template document).

[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;

1. Legal flaws of the Proposal

(i) The scope of the restriction is unclear as it lacks details to differentiate PFAS substances.

(**Points A1 and A2 of the Conformity Check**[2]).

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)[3].

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 and is not in line with the requirements of Annex XV.

Furthermore, this approach runs counter one of the guiding principles for the preparation of Annex XV, *i.e.* enforceability[4]. 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[5]. In this regard, 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.

(ii) Methodological flaws in the assessment of hazard and risks of PFAS substances.

(**Point B in general of the Conformity check**).

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

For instance, it is stated that "*all*" PFAS" are persistent, while "*some*" or "*most of*" are mobile/accumulate in biota/carcinogenic/endocrine disruptors, etc[6]. These statements are vague and tend to be general in nature and unrelated to specific case-by-case assessments of the various PFAS substances.

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).

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[7]. Stated differently, the use of few examples on selected substances to support a concern for all PFAS substances fails to be scientifically and legally rigorous.

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[2] REST_ECHA_PreCCrep_finalv2 (europa.eu)

[3] Annex XV PFAS REACH restriction Proposal, p. 21

[4] ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 66

[5] https://echa.europa.eu/documents/10162/13641/restriction_setting_a_clear_scope_en.pdf/36045edb-5135-f188-265b-b641a4177c93

[6] Annex XV PFAS REACH restriction Proposal, p. 13

[7] Annex XV PFAS REACH restriction Proposal, p. 14; 33

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 does not appear in line with the requirements for the preparation of an Annex XV[8].

(iii) Insufficient information to allow an independent assessment of the hazard[9].

(**Point B3 of the Conformity Check**).

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[10].

In doing so, different substances have been unduly and/or arbitrarily grouped together, without a proper case-by-case assessment as required under REACH[11].

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 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.

Moreover, the specific justification provided by the Dossier Submitters to group all 10,000 PFAS altogether is questionable. On one hand, persistency as a standalone criterion to justify a restriction is debatable[12]. The latter may only operate in combination with other criteria, such as bioaccumulation ("B") or toxicity ("T). The Dossier Submitters failed to clarify which specific PFAS are either PB or PT or PBT.

Further, the inclusion of PFAS that have no, or negligible, uses and thus no exposure, seems to breach on the requirements set out in article 68 of REACH, *i.e.* the presence of an "*unacceptable risk*"[13]. Indeed, if some PFAS are not in use, there is no exposure, and thus no risk. 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[14].

(iv) Insufficient information on the uses of the specific PFAS substance(s) and resulting emissions or exposure.

(**Point B4 of the Conformity Check**).

The Dossier Submitters claim to have covered rather exhaustively all PFAS uses, but they 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 and valves. 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*"[15].

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[8] ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 33; 34

[9] ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 23

[10] Annex B to the Annex XV PFAS REACH restriction Proposal, p. 5

[11] ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 32

[12] Ibid., p. 4

[13] Article 68 of REACH

[14] ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 64

[15] Annex A to the Annex XV PFAS REACH restriction Proposal, p. 4

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[16]. 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".

(v) Improper assessment of the information on alternatives.

(**Point C1 of the Conformity Check**).

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.

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 A to the Proposal contains a contrary statement. Specifically, this annex states: "*it is not clear whether all PTFE, PVDF and FKM can already be produced without PFAS polymerisation aids at industry level*"[17].

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*"[18].

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[19].

(vi) Insufficient reasons to support an action on an EU wide basis.

(**Point D1 of the Conformity Check**).

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

There is no assessment of the overlap between the restriction proposal and other existing EU legislation[20]. For instance, the restriction of PFOS and PFOA under the Stockholm Convention and Regulation 1021/2019 ("POPs") is not considered although this would remove these two substances from the REACH restriction, thereby avoiding over regulation or double regulation[21]. Similarly, the inclusion of PFHxS into the Stockholm Convention in 2022 and consequent update of the POPs Regulation does not seem to have been taken into account

Furthermore, the Proposal considers that some uses should be in scope even though they are currently of "*little relevance in the EU*"[22]. 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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[16] ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 108

[17] Annex A.2.1 to the Annex XV PFAS REACH restriction Proposal, p. 2

[18] Annex XV PFAS REACH restriction Proposal, p. 177

[19] ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 69

[20] *Ibid*., p. 70

[21] Commission understanding paper on the relationship between REACH and POPs

[22] Annex A, page 4

(vii) 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.

(**Point E1 of the Conformity Check**).

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 impacts.

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[23].

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[24]. For example, the Proposal does not provide specific data as regards the emissions of PFAS processors[25], emissions in the waste phase[26], or from the article production[27].

The Dossier Submitters recognise that for a large part of the chemicals covered by the restriction the information in this regard is incomplete[28]. Therefore, the Proposal may not comply with the *effectiveness* criterion[29], as that 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[30]. 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*.

(viii) The Proposal does not give sufficient background on the defined scope and conditions of the proposed restriction, in particular as regards proposed derogations.

(**Point E2 of the Conformity Check**).

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

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

Moreover, the Dossier Submitters failed to take into account the concept of "*essential use*", as this was announced in the 2020 Chemical Strategy for Sustainability ("CSS"), and the PFAS restriction was envisaged there as a kind of case study for the concept[31].

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[23] Annex XV PFAS REACH restriction Proposal, p. 177

[24] *Ibid*., p.13

[25] *Ibid*., p.39

[26] *Ibid*., p.43.

[27] *Ibid*., p.44.

[28] *Ibid*., p.49.

[29] ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 57

[30] Annex XV PFAS REACH restriction Proposal, p. 1

[31] 2020 CSS, p. 13

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. However, they have not considered the derogation for PEM in electrolyser for hydrogen production. Without the latter, the derogation may be deprived of its *effet-utile*, namely devoid of its practical application.

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 and PFHxA).

(ix) Inappropriate and unsubstantiated estimate on the "overall annual health costs following from exposure to PFAS in Europe"[32] and of the costs to the society

(**Point E3 of the Conformity Check**).

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[33].

2. 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. In turn, the Proposal is not compliant with the requirements set out in Annex XV and is unfit, in its current form, to constitute the basis for further decision-making.

We ask the ECHA Secretariat to share this document and related concerns with the RAC and SEAC members ahead of their respective meetings.

In order to ensure due process, it is of particular importance that the RAC and SEAC of ECHA carefully consider the points set out in this document.

If the RAC and SAC members consider that the Proposal does not conform, they should specify the reasons set out in this white paper and send the Proposal back to the Dossier Submitters so that the latter may bring it in compliance within 60 days of receipt.

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[32] Annex XV PFAS REACH restriction Proposal, p. 2

[33] *Ibid*., p. 177