GENERAL COMMENTS ON THE RESTRICTION PROPOSAL ON ALL PFAS SUBSTANCES

Daikin Chemical Europe GmbH

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Daikin Chemical Europe GmbH (DCE) is the German subsidiary of the Chemicals Division of Daikin Industries, Ltd, headquartered in Osaka, Japan. Daikin Industries is one of the world's leading producers of fluorochemicals.

DCE has several subsidiaries dedicated to the manufacture of different types of fluorochemicals in the EU, including:

- Daikin Chemical France, where PFAS are used as additives, monomers, as well as polymerisation aid (APFHx) in the production of fluoroelastomers (FKM).
- Daikin Compounding Italy, focused on PTFE micropowders, FEP, PFA, ETFE and recycled PTFE.
- Daikin Refrigerants Frankfurt GmbH, dedicated to the recovery and reclamation of used hydrofluorocarbons (HFCs) for resale on the EU market.

DCE welcomes the opportunity to reply to this consultation and submit its views on the proposal to restrict all PFAS substances under REACH.

DCE is a member of PlasticsEurope's Fluoropolymer Group, the Performance Fluoropolymer Partnership (PFP), the Alliance for Telomer Chemistry Stewardship (ATCS), as well as the CEFIC sector groups FluoroProducts and PFAS for Europe (FPP4EU) and European FluoroCarbons Technical Committee (EFCTC), the European Partnership for Energy and the Environment (EPEE), and Japan Business Council in Europe (JBCE). DCE supports the comments on the restriction proposal that these seven organisations have submitted to this public consultation.

In this contribution, DCE would like to share the serious concerns that the company holds about the restriction proposal's legal and scientific validity due to deficiencies in the dossier's risk justification. DCE has also identified significant gaps in the currently proposed exemptions, which demonstrate that the restriction proposal lacks an appropriate assessment of the dossier's socio-economic consequences and available alternatives.

1. Persistence does not necessarily represent a risk, especially where there is no evidence of adverse effects on human health and the environment

The Dossier Submitters indicate that persistence is a major concern and uses it as the main criterion for justifying the restriction. While DCE understands that persistent chemicals can be a possible concern under certain circumstances –due to the potentially increasing presence in the environment from emissions–, we would like to underline that persistence does not constitute a hazard *per se*. Furthermore, the persistence of a substance does not eliminate the need for a risk assessment based on evidence of adverse effects and environmental releases.

It should also be highlighted that persistence equals high stability, which is a crucial function of fluorochemistry, and allows the production of durable, resistant materials used in safety-critical applications, or in harsh environments. For instance, fluoropolymers contribute to achieving the EU's policy objectives in the field of climate change, helping it on its trajectory towards a carbon-neutral economy by reducing air pollution and allowing the development of e.g., semiconductors, lithium-ion batteries, fuel cells or large energy storage devices.

We believe that it is critical to work towards acceptable conditions for a continued use of PFAS substances. While certain responsible manufacturing requirements are already foreseen under paragraph 5a), which restricts the manufacturing of PFAS with PFAS polymerisation aids, we believe that the implementation of responsible manufacturing obligations based on monitoring and further reduction of emissions remains the most promising path forward.

For this purpose, the restriction proposal should provide for the possibility of implementing responsible manufacturing practices, notably for fluoropolymers and fluorinated gases, i.e., allowing production where emissions are proven to be negligible based on regular monitoring and reporting activities.

2. The pre-requirement of unacceptable risk is not fulfilled

Under Article 68 of the REACH Regulation, substances have to pose an "unacceptable risk to human health or the environment" in order to be restricted.

In the framework of Article 57(f) of REACH, the European Court of Justice determined the criteria that have to be fulfilled in order for a substance to be of an "equivalent level of concern" to PBT (persistent, bioaccumulative, toxic) or vPvB (very persistent, very bioaccumulative) substances. These criteria were further clarified in the T-636/17 case of 20 September 2019 concerning endocrine disruptors, in which the Court reiterated that the equivalent level of concern requires "an actual analysis of the hazards linked to the intrinsic properties of the substance under consideration" and "the demonstration that

the serious effects on human health or the environment of the substance under consideration"[1].

The REACH restriction proposal on all PFAS relies on the persistence of all PFAS, in combination with other hazardous properties such as mobility, and considers them in a similar manner to PBT/vPvB properties, with any release being a proxy for unacceptable risk:

> PFASs should be treated as non-threshold substances for the purpose of risk assessment in a **similar manner to PBT/vPvB substances**. Their releases can be accordingly used as a proxy for risk. [2]

In this regard, we would like to note that the proposed definition is based on the OECD Per- and Polyfluoroalkyl Substances (PFAS) project, which indicates that "[the general definition of PFAS] does not conclude that all PFASs have the same properties, uses, exposure and risks". In fact, it acknowledges that these substances vary widely in their physical and chemical properties[3].

Moreover, the Restriction Dossier does not derive a conclusion on bioaccumulation, toxicity and/or mobility criteria for each substance or subgroup of substances.

Fluoropolymers, for example, are generally very high molecular weight polymers, non-toxic, not bioavailable, non-water soluble and non-mobile molecules, and are deemed as such to have no significant environmental and human health impacts[4].

In the case of the F-gases in scope of the restriction proposal, these were only included because they degrade to Trifluoroacetic acid (TFA). However, TFA has biological properties that differ significantly from the longer chain PFAS (e.g., PFOS, PFOA, PFHxS or C9–C14 PFCAs). [5] Although TFA salts are persistent in the environment, this persistence does not represent a major concern because TFA does not react with

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[1] Judgment of the General Court (Fifth Chamber) of 20 September 2019, PlasticsEurope v European Chemicals Agency, https://curia.europa.eu/juris/document/document.jsf?text=&docid=217994&doclang=EN.

[2] European Chemicals Agency (ECHA), Annex XV Restriction Report on Per- and polyfluoroalkyl substances (PFAS), https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49, p. 48.

[3] OECD, the Environment Directorate, Chemicals and Biotechnology Committee, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*, July 9, 2021, ENV/CBC/MONO(2021)25, No.61, Paris.

[4] Henry B. J., Carlin P. J., Hammerschmidt J. A., Buck, R. C., Buxton W., Fiedler H., Seed J., Hernandez O, (2018), *A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers*, Integr Environ Assess Manag 2018:316–334, https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4035; Korzeniowski S.H., Buck, R. C., Newkold R. M., El kassmi A., Laganis E., Matsuoka Y., Dinelli B., Beauchet S., Adamsky F., Weilandt K. ,Soni V., Kapoor D., Gunasekar P., Malvasi M., Brinati G., Musio S, (2022), *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*, Integr Environ Assess Manag 2022:1–30, https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4646

[5] UNEP EEAP 2022 Assessment Report, p. 25, https://ozone.unep.org/system/files/documents/EEAP-2022-Assessment-Report-May2023.pdf.

biomolecules. As TFA and its salts are easily excreted by animals and plants, therefore, they do not bioaccumulate in food chains. Next to their low toxicity to animals and plants, there are wide margins between current/ projected exposures and toxicity values.[6]

Furthermore, the hazard assessment covers substances that are already restricted or banned under REACH and for which it has been demonstrated that they do pose concerns for human health and/or the environment, e.g., PFOS, PFOA, PFHxS[7]. As these compounds do not fall within the scope of the restriction proposal, in line with its paragraph 9, their specific hazard properties shall not be used to justify the need for a restriction on additional PFAS or PFAS groups. Most importantly, it should not be assumed that all PFAS have an **"**equivalent hazard and risk", as indicated in the Restriction Dossier[8]. The hazard assessment should, instead, provide a more detailed analysis of the substances that are specifically targeted by this restriction. This has also been highlighted by the ruling of the European Court of Justice in the C-144/21 case, which underlined the obligation to demonstrate that the socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies.[9]

Based on all the above, we believe that there is no sufficient scientific basis to refer to the potential "irreversible adverse effects on the environment and on human health over time"[10], especially not for fluoropolymers and F-gases. Such vague assumptions do not constitute a demonstration of unacceptable risk as required by REACH. Therefore, we request that additional data is provided to adequately assess the effects of fluoropolymers and F-gases on human health and the environment, and that such assessment is carefully reviewed by the Risk Assessment Committee (RAC).

3. The Restriction Dossier is based on far too many uncertainties for crucial aspects to justify the use of the precautionary principle

The application of the precautionary principle requires some minimum scientific and objective justification. The preliminary conditions for it to be applied are stated in the Commission's Communication from 2 February 2000, including (1) identification of

[6] UNEP EEAP 2022 Assessment Report, p. 292.

[7] The first non-polymer, long-chain perfluoroalkyl substance to be restricted was perfluorooctane sulfonate, PFOS (Annex I, Part A. Regulation (EU) 2019/1021 of the European Parliament and the Council), followed by perfluorooctanoic acid, PFOA (Commission Regulation (EU) 2017/1000). Additionally, long-chain (C9-C14) perfluorocarboxylic acids, and perfluorohexane sulfonate (PFHxS) have been restricted under REACH after having been identified as Substances of Very High Concern (SVHCs).

[8] ECHA, Annex XV Restriction Report on Per- and polyfluoroalkyl substances (PFAS), p. 21.

[9] Judgment of the General Court (Fourth Chamber) of 20 April 2023, Parliament v Commission, https://curia.europa.eu/juris/document/document.jsf;jsessionid=0530C1616E39D3668F8DBFDCCE7EAD49?text=&docid=272682&pageIndex=0&doclang=FR&mode=lst&dir=&occ=first&part=1&cid=2500189.

[10] ECHA, Annex XV Restriction Report on Per- and polyfluoroalkyl substances (PFAS), p. 50.

potentially adverse effects, (2) evaluation of scientific data available, and (3) extent of scientific uncertainty[11].

It is concerning that large parts of the Restriction Dossier are based on assumptions about possible future effects that are not corroborated by scientific evidence and data.

The Restriction Dossier provides some quantitative assessment of expected releases by sector. However, it fails to provide evidence that would support the claim that emissions could reach a level of concern that could represent a risk. In fact, the Dossier Submitters indicated that "uncertainty in the quantities of PFASs used increases over time"[12].

Moreover, the Restriction Dossier does not sufficiently address the technologies that are commercially available and increasingly in use to minimise emissions to the environment, and the amounts of releases that result and could result in the future with these technologies. For instance, DCE has introduced wastewater treatment best available techniques (BAT) that have proven to be very effective in minimising emissions from fluoropolymers' production. Further information on these technologies is provided in a separate report.

In addition, it is worth noting that there is targeted legislation already in place to deal with F-gases, including the Montreal Protocol (Kigali Amendment) and the EU F-Gas Regulation, which will be reinforced by its revision expected to enter into force on 1st January 2024. This legislation adequately addresses concerns in terms of containment, leakage management, proper handling, reporting, end-of-life procedures (including provisions and incentives for recovery and reclamation operations, which will be extended to hydrofluoroolefins (HFOs) in the revised legislation); and provides an ambitious schedule for the phasing-down of hydrofluorocarbons (HFC). It is absolutely necessary that risk management measures under REACH are compatible with parallel environment-related legislation, avoiding conflict of any type.

Based on this, we believe that the assumptions on which the Restriction Dossier relies do not constitute a sufficient basis to justify such a broad use of the precautionary principle, especially not for fluoropolymers and F-gases. At least some additional quantitative assessment should be conducted in order to reduce the uncertainties in the Restriction Dossier's assumptions about an increasing and long-term exposure and the resulting adverse effects, which are all crucial elements that have to be assessed in order to justify a restriction.

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[11] European Union: European Commission, *Communication from the Commission on the precautionary principl*e, 2 February 2000, COM(2000) 0001 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52000DC0001&from=EN.

[12] ECHA, Annex XV Restriction Report on Per- and polyfluoroalkyl substances (PFAS), p. 188.

4. Reflections on the PFHxA restriction proposal

4.1. Focus on consumer uses

The European Commission recently published the legislative draft for the REACH restriction on PFHxA, its salts and related substances.[13] As DCE, we support the Commission's approach which, in contrast with the initial proposal, targets well-defined categories of products intended for the general public, those that historically lead to the highest potential exposure. This generally leaves out fluoropolymers, which are mainly used for professional and industrial applications and have a better environmental profile compared to C6 side-chain fluorinated polymers.

In this regard, we believe that a similar approach could be implemented in the context of the restriction proposal on all PFAS, as it would allow to accelerate the restriction process and encourage an earlier transition for consumer applications, where alternatives are in most cases available.

4.2. Responsible manufacturing principles

As shown by paragraphs 5a) and 8), as well as by previously adopted REACH restrictions, REACH can set requirements in the field of responsible manufacturing along the supply chain. This would allow the continued production and use of fluoropolymers while ensuring responsible manufacturing principles are being implemented along the supply chain, as relevant. FPG, Daikin is member of, supports a comprehensive approach to responsible manufacturing.

5. Thresholds should be set considering the availability of analytical methods to ensure product compliance and enforceability

It has to be stressed that there is currently no harmonised/established analytical method to measure PFAS impurities in products and articles. Different analytical methods are used by different laboratories for measuring PFAS in different media, such as water,[14] but there are currently no validated methods that can reliably measure PFAS impurities in many product groups (e.g., articles, gas matrixes).

We would like to stress that while total fluorine detection techniques and methods, which are mentioned in the Restriction Dossier for the implementation of the 50 ppm threshold

[13] European Commission, 2023, *Draft Regulation 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*, https://ec.europa.eu/transparency/comitology-register/core/api/integration/ers/338585/090483/1/attachment.

[14] Interstate Technology & Regulatory Council (ITRC). 2020. PFAS Technical and Regulatory Guidance Document and Fact Sheets PFAS-1. Washington D.C.: Interstate Technology & Regulatory Council, PFS team: https://pfas-1.itrcweb.org/.

for polymeric PFAS[15], are useful for general screening, they are not suitable for compliance certification or enforcement unless they are validated and certified methods.[16] Furthermore, as indicated in the Restriction Dossier, it is currently not analytically possible to distinguish between PFAS substances and non-PFAS organofluorine substances when measuring the total fluorine content of a product[17]. This would require highly sophisticated procedures, including target and non-target analyses, that would be able to make the distinction which, to the best of our knowledge, are not yet available. This renders the ancillary requirement under paragraph 2(iii) virtually unusable.

With regards to the 250 ppb threshold, it should be noted that the Total Oxidizable Precursor Assay (TOPA) technique, a detection technique that uses oxidation and is mentioned in the Restriction,[18] is performed in laboratories but it is not a validated and certified method to measure and speciate PFAS. Moreover, the TOPA presents the following shortcomings:

- TOPA does not quantify nor identify the structures of individual fluorinated compounds and cannot be relied upon to quantify all of the fluorinated mass in a sample.
- TOPA is conducted under excessively harsh oxidative conditions and does not reflect real-world conditions. Therefore, the results of this technique are not indicative of the PFAS mass that is susceptible to oxidation in the natural environment[19].

Based on these analytical shortcomings, and given the already proposed limit of 25 ppb for individual non-polymeric PFAS, we question the added value of implementing the 250 ppb threshold for the sum of PFAS.

Furthermore, we would like to underline that the two proposed thresholds for non-polymeric PFAS (i.e., 25 ppb for individual compounds and respectively 250 ppb for sum of these) are impracticable for F-gases, as appropriate measurements can only be achieved by using analytical techniques that are only available at lab scale, but not on industrial level.
The purity level currently requested for all F-gases used as refrigerants worldwide is

[15] ECHA, Annex XV Restriction Report on Per- and polyfluoroalkyl substances (PFAS), p. 9.

[16] E. F. Houtz and D. L. Sedlak, Oxidative Conversion as a Means of Detecting Precursors to Perfluoroalkyl Acids in Urban Runoff, *Environmental Science & Technology 46*(17), 9342-9349, 2012, doi: 10.1021/es302274g.

[17] ECHA, Annex XV Restriction Report on Per- and polyfluoroalkyl substances (PFASs), p. 171.

[18] ECHA, Annex XV Restriction Report on Per- and polyfluoroalkyl substances (PFASs), p. 45.

[19] Dora Chiang, *What Total Oxidizable Precursor Assay Can and Cannot Tell Us about Precursors of Perfluoroalkyl Acids*, January 2019, https://www.semanticscholar.org/paper/What-Total-Oxidizable-Precursor-Assay-Can-and-Tell-Chiang/480762d58de0a62b5d137db7ad59f4be7882c500.

99.5% (without thresholds for individual substances) following the AHRI 700 Standard.[20] This includes virgin and reclaimed refrigerants and ensures equal product performance. While virgin refrigerants usually have a higher purity than reclaimed refrigerants[21], we support a common standard for both. We, therefore, support the request of EFCTC to increase the threshold to 5000 ppm for F-gases following the AHRI 700 Standard. Additionally, we would like to point out that the analytical methods included in Appendix E.4 of the Restriction Dossier to identify specific PFAS F-gases have no relevance for the F-gas industry procedures because they take ambient air as the matrix. However, in the context of the F-gas industry, the relevant matrix needs to be a non-PFAS F-gas with the aim to detect PFAS F-gas impurities in this non-PFAS F-gas.

Moreover, the fact that there is no harmonised analytical method will present both industry and regulators with serious implementation and enforceability challenges should the restriction proposal be adopted in its current form.

Reliable, preferably harmonised or widely recognized/available analytical methods should be provided to contribute to a level playing field within industry and effective enforcement by market surveillance authorities.

[20] https://www.fluorocarbons.org/wp-content/uploads/2020/09/AHRI_Standard_700_2019.pdf

[21] After reclamation, some minor traces of other F-gases in scope of the restriction may still be contained, that is why an impurity threshold of 5000ppm is needed.