September 2022

Public consultation input provided by FPP4EU to the PFAS in firefighting foams restriction

Introduction

FPP4EU, the FluoroProducts and PFAS for Europe Sector Group of Cefic welcomes the opportunity to provide input to the public consultation on the restriction on PFAS in firefighting foams (FFF). In response to the statements made by Environment Commissioner Sinkevičius and P. Simpson (ECHA) that the FFF file was a 'learning file' and that the basic elements of the hazard assessment would also be used for the wider PFAS restriction[1], FPP4EU is providing comments on key assumptions made by the ECHA Secretariat in the dossier rather than on the specific provisions on firefighting foams.

As representative of producers, importers and users of the many potential substances that fall within the broad definition of PFAS, the Cefic sector group FluoroProducts and PFAS for Europe (FPP4EU) seeks to aid EU policymakers in achieving the ambitions set out in the EU Green Deal. As such, FPP4EU members understand and support the need for balanced regulatory action on PFAS.

To jointly come to a final regulatory measure which is science-informed, implementable, and enforceable, whilst still enabling the EU to meet its Green Deal, economic and other policy objectives, we envision:

- A common understanding of what a PFAS restriction under REACH may look like.
- Collaboration and constructive dialogues with all EU stakeholders – from policymakers to downstream users – to be able to address health and environmental concerns whilst ensuring that safe and critical applications of PFAS remain available for the future of Europe.
- To support to further research and data generation to fill potential data gaps.

Annex I: Detailed explanation on the decision tree developed by FPP4EU

About FPP4EU

Cefic established a new Sector Group in March 2021, the group was set up to represent the views of producers, importers, and users of Fluoroproducts and PFAS and other parties with an interest in the Fluoroproducts and PFAS sector group activities in Europe. Members include: 3M Belgium NV (Belgium), AGC Chemicals Europe (Netherlands), Arkema (France), BASF SE (Germany), Bayer AG (Germany), Chemours (Belgium), Daikin Chemical Europe GmbH (Germany), DuPont De Nemours Inc. (Belgium), ExxonMobil Petroleum and Chemical BV (Belgium), Gujarat Fluorochemicals GmbH, Merck Life Science (Germany), Omnova Solutions/Synthomer (USA), W.L. Gore (USA).

[1] High-Level-Conference: "Forever? No More! Phasing out "forever chemicals" PFAS in Europe, 2 May 2022, hosted by MEP Jutta Paulus

Please note that comments in light blue are literally copied and pasted from the proposal on the restriction on PFAS in firefighting foams

The group's main purpose is to understand what the wider restriction could look like, given the complexity of the PFAS universe – thousands of substances with very different properties and a multitude of applications – as well as the expected focus of the restriction being on exposure and accumulation. Given the potential impact of the PFAS restriction on many key EU industries, it is crucial for all stakeholders to have the opportunity to engage in the process and to provide data that will lead to a balanced and science-informed restriction. Therefore, our group calls for a series of technical workshops and dialogues with the authorities and all concerned stakeholders to discuss the "PFAS universe". During these workshops, authorities could further clarify their expectations, and manufacturers could provide targeted data and help authorities better understand the differences in fluorinated chemistries and their critical applications across numerous industries, including those that enable the ambitions of the Green Deal, such as electrical vehicles and wind turbines.

1. Grouping & Scope

To summarise, the grouping is based on structural similarity (common perfluorinated moieties) that triggers equivalent hazards and risks among the substances covered, primarily related to the very persistent property of the substances.

All PFASs are very persistent in the environment. This is the key hazardous property common to all PFASs.

We support the need for balanced regulatory action on PFAS. We use the term balanced because properties vary greatly among PFAS. It is an oversimplification to imply that all PFAS have multiple or adverse effects.

OECD has clearly stated the need to recognise the diversity of PFAS as they are a chemical class with diverse molecular structures and physical, chemical and biological properties[2]. This view is also reflected in a recent expert panel on PFAS where *"Most experts agreed that "all PFAS" should not be grouped together, persistence alone is not sufficient for grouping PFAS for the purposes of assessing human health risk, that subgroups are appropriate, and that the nature and definition of the subgroups can only be defined on a situation-dependent and case-by-case manner. No single grouping strategy was agreed on that would be sufficient for all regulatory or public health risk assessment purposes."* [3]

In the EU, grouping and read-across is a common practice for filling data gaps when registering substances under REACH. The proposed 'restriction' of PFAS as one group is not following the same alternative approach for filling data gaps for registration purposes using relevant information from analogous substances as required by ECHA through their Read Across Assessment Framework.[4] This approach is chosen to avoid additional animal testing of every individual substance, in accordance with the conditions outlined in REACH Regulation, Annex XI, section 1.5 for using grouping and read-across approaches and corresponding ECHA guidelines and the Read Across Assessment Framework.

[2] Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance1 (page 8)
[3] Anderson JK, Brecher RW, Cousins IT, DeWitt J, Fiedler H, Kannan K, Kirman CR, Lipscomb J, Priestly B, Schoeny R, Seed J, Verner M, Hays SM. Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts. Regul Toxicol Pharmacol. 2022 Jul 8;134:105226. doi: 10.1016/j.yrtph.2022.105226. Epub ahead of print. PMID: 35817206.
[4] Read-Across Assessment Framework (RAAF), March 2017, ECHA-17-R-01-EN, 614e5d61-891d-4154-8a47-87efebd1851a (europa.eu)

Grouping of PFAS specifically, requires careful, informed attention to ensure regulatory coherence and to enhance implementation. PFAS – as defined by the dossier submitter – is grouping a large and very diverse selection of chemicals with different hazard and risk profiles. Properties vary greatly among PFAS and that is why it will be challenging to regulate these substances as a single class.

The U.S. EPA appears to intend to ultimately regulate PFAS as various classes or groups based on similarities in the chemical structures of the various PFAS[5].

To conclude, Cefic has outlined some of the considerations to grouping in general in its position paper. Regardless of how grouping is used, Cefic believes it needs to be based on the following key principles:

- The grouping process should be transparent for all stakeholders;
- Grouping should consider risk and hazard profiles in addition to structural similarity;
- Similar family name or backbone should not be confused with similar hazard profile;
- Identification of substances in a group should be based on a unique substance ID to facilitate digitalisation;
- A proposed regulatory measure should be enforceable.

It is critical that grouping is based on solid scientific standards and applied coherently across REACH independently of its purpose.

Given that not all PFAS are the same and many may be used safely with the right measures to control emissions during production, use and end-of-life phases. Whereas we can understand that the grouping presents a potential regulatory approach, it is important to ensure that the groupings are sufficiently granular to address the different hazard and risk profiles of individual PFAS. Grouping should therefore also allow for separate evaluation based on their specific toxicological and environmental profiles. Viewing that the dossier submitter groups all PFAS in the same entry, diversification will need to be done at the level of the derogations. FPP4EU developed a decision tree (see Annex I) that provides elements that can be considered when discussing those derogations.

2. Hazard assessment

FPP4EU would like to provide initial comments on some of the key statements made in the hazard assessment section, due to its relevance for the wider PFAS restriction. We are preparing an informative summary of those available ecotoxicological and toxicological data of a number of FPP4EU types of substances (typically making use of reference molecules) from scientific literature. We expect results to be available in January 2023 (tbc). Individual member companies may provide comments and / or data on specific PFAS that they manufacture or use for firefighting foams specifically. A lot of this data has been provided in previous consultations related to the wide PFAS restriction.

Even though extrapolating data on properties of some individual PFAS to all PFAS may be convenient for regulatory purposes, it hampers the required differentiation between the very diverse group of substances. The addition of degradation products (the arrowhead approach) adds to the complexity. Many PFAS provide value to consumers and industry (see point 5 for a non-exhaustive list) and can be safely handled with the appropriate risk management measures.

[5] EPA PFAS Grouping Regulations Gather Additional support, the national law review, Volume XI, number 363.

For some PFAS, safe use is regulated by sector specific or other legislation, for instance active substances in the pharmaceuticals and pesticides, but also via REACH restrictions and the POPs Regulation. This element is also incorporated in the aforementioned decision tree (Annex I).

- *Due to the above-mentioned hazardous properties, a quantitative risk assessment is not appropriate, but releases of PFASs should be minimised in accordance with paragraph 0.10 of Annex I to REACH* (case-by-case approach).

From a practical point of view, also in light of the upcoming wide PFAS restriction which is to be based on the same group wide hazard assessment, we are wondering how SEAC and RAC are expected to handle the large amount of case-by-case potentially very specific and technical derogations.

- *All PFASs are very persistent in the environment. This is the key hazardous property common to all PFASs.*

Grouping all PFAS under the premise that their common hazard is persistence is scientifically not accurate, not all PFAS are persistent. Highly stable molecules will, by definition, be more likely to be persistent in the environment, however, this does not mean that all PFAS either show the same level of persistence as, e.g. PFOA, or break down into persistent PFAS. Persistency of individual PFAS should be assessed with appropriate tests.

It should be noted that there are non-persistent PFAS.

- Examples of non-persistent PFAS which also do not break down into persistent molecules are HFOs: R1132E and R1234ze (CAS 29118-24-9).
- Some PFAS are mineralisable (e.g., a CF3 attached to a heteroatom (O, S, N)) and are not persistent.[6]
- Some PFAS, which have a OCF3 or >NCF3 moiety will directly hydrolyse (see contribution by CropLife Europe for details).

More elaborate information on this may be submitted by individual member companies where relevant in this or during the upcoming public consultation on the wide PFAS restriction.

Persistence is not, however, a guarantee of long-range transport potential or ability to partition to air, water, sediment or soil. Persistence in the environment does not equate to toxicity, bioaccumulation and mobility. Persistence does mean a substance could be in the environment for a relatively long time, potentially leading to longer term exposure, only adverse if the substance is also bioavailable.

The strong carbon-fluorine bond makes PFAS substances stable. This stability is often needed to enable the durability that is requested from them in their use. Indeed, durable, highly resistant materials are indispensable for use in protective equipment, and in many situations where heat-resistance and chemical resistance are required. We refer to our website and submission by

[6] Cousins, I.T., DeWitt, J.C., Glüge, J., Goldenman, G., Herzke, D., Lohmann, R., Ng, C.A., Scheringer, M., Wang, Z., 2020b. The high persistence of PFAS is sufficient for their management as a chemical class. Environ. Sci.: Process. Impacts 22, 2307–2312. https://doi.org/10.1039/D0EM00355G.

Singh, R.R., Papanastasiou, D.K., 2021. Comment on "scientific basis for managing PFAS as a chemical class. Environ. Sci. Technol. Lett. 8, 192–194. https://doi.org/ 10.1021/acs.estlett.0c00765

downstream users for a non-exhaustive list of applications and examples to illustrate this. for a non-exhaustive list of applications and examples to illustrate this.

In case, a specific PFAS is persistent, other factors will need to be taken into account, like their individual environmental and human health hazard profiles, mobility and bioaccumulation, and potential emissions into the environment throughout their life cycle. A narrow regulatory focus on persistence will undermine innovation, especially when fulfilling the need to produce durable, high performing and critical materials and products. It is important to keep in mind that the property of durability may only be replaced with another chemical that could be also classified as persistent or by an altogether different process.

In addition, a lot of research is currently being undertaken to develop novel ways to break down PFAS which may reduce the relevance of persistency in the environment in combination with appropriate risk management measures. A recent example is perfluoroalkyl carboxylic acids (PFCAs) mineralization through a sodium hydroxide–mediated defluorination pathway.[7]

3. PFAS and Water & Environment

On the topics of drinking water (de)contamination, accumulation in plants, mobility and long range transport, individual member companies may provide comments and / or data on specific PFAS that they manufacture or use. A lot of this data has been provided in previous consultations related to the wide PFAS restriction.

Generally, it is important to point out that not all PFAS come in direct contact with water and or soil during their life cycle, this is especially true for many industrial applications and uses. This is very dependent on the specific use or application of an individual PFAS.

4. Regulatory findings to consider

> ***PFASs can be divided with regard to the hazard assessment into "precursors" and "arrowheads". The precursors are known or expected based on modelling to degrade on a timescale from hours to years to the arrowheads, such as PFCAs, PFECAs and PFSAs (p.18).*** *RAC supported the proposal to restrict microplastics based on a closely similar case-by-case hazard and risk assessment approach (ECHA, 2020). Analogously, a specific case for excluding a PFAS from the scope of the proposed restriction could be made if sufficient evidence is provided that the specific PFASs is not very persistent itself and does not degrade into a very persistent PFASs* (p.37).

Following clarification from ECHA, we understand that non-persistent PFAS may not be in scope of the wide restriction or may be derogated. Decisions on this are to be made by RAC and SEAC who will assess the justifications for non-persistence on a case by case basis. We would appreciate further

[7] BRITTANY TRANG, XIAO-SONG XUE, MOHAMED ATEIA, K. N. HOUK AND WILLIAM R. DICHTEL,, Low-temperature mineralization of perfluorocarboxylic acids *SCIENCE*, 18 Aug 2022, Vol 377, Issue 6608, pp. 839-845, DOI: 10.1126/science.abm8868

clarification which kind of persistence tests would be acceptable to prove non persistency, due to the wide physio-chemical divergences of the substances that fall under the proposed definition of PFAS. We would also like to highlight that not for all types of PFAS such tests or standards exist or that not all relevant environmental compartments may be suitable for such testing. For example, there is no "persistency" in air compartment, but long-range transport through air particles and fugacity.

> *A distinct PFAS subgroup are the trifluoroacetic acid (TFA) precursors. They are a special subclass of PFASs often containing only a single –CF3 group. Most of these occur – in addition to TFA itself- in gaseous form. Such fluorinated gases or "F-gases" are treated as a distinct group in this report due to their distinct properties.*(p.13).

When reviewing the proposal as prepared by the dossier submitter and in the context of the wide PFAS restriction, FPP4EU kindly requests the members of the RAC to consider the following questions:

- How do you foresee the treatment of TFA precursors and F-Gases as a distinct group during the restriction process and will the F-gas Regulation revision proposal measures be taken into account? For details on F-gases please see the contribution of EFCTC.
- Taking into account that TFA is both a naturally occurring substance and a degradation product of specific PFASs and feedstock material, how will the different sources of TFA be considered when addressing the TFA emissions? In particular, how are you going to consider the different quantities of TFA produced by the breakdown products of the different F-Gases? We would also draw your attention to the paper prepared by EFCTC, on natural occurring TFA, which has been previously submitted to this public consultation.
- How should dispersion and TFA deposition rate and precipitation concentrations be modelled and determined?
- How will the extensive data on the environmental, ecological effects and no observable effects concentrations of TFA be taken into account? See individual members contribution for data on this point.

> *Considering these elements, the Dossier Submitter proposes a concentration threshold of 1 ppm. [total PFAS]*

When reviewing the proposal (which recommended RO3 as the preferred approach) and in the context of other restrictions, FPP4EU highlights that the 1ppm limit has the following note:

- '…use in firefighting foam concentrates where the concentration of total PFASs is greater than 1 ppm[10] 10 years after entry into force'. We highlight there is no Explanatory Note 10.

FPP4EU would like to highlight the varied and diverse concentration limits, for example the PFHxA restriction proposal foresees a lower limit value, than proposed here. If implemented as proposed, it should be clear to users and producers which concentration applies to ensure effective enforcement. FPP4EU members believe, the concentration proposed in this restriction is implementable. Individual member companies may have submitted detailed comments on the specificities.

5. PFAS are enabling the Green Deal

The PFAS' C-F bond results in a combination of desirable and unique chemical and physical properties[8]. It is key to the high performance and durability of the products involved. Other types of chemicals, which lack the strong C-F bond, may not bring the combination of functionalities and therefore may perform less effectively. A detailed life cycle assessment would be needed to evaluate the potential impact of any replacement substance on the environment. While some alternative materials might match selected properties of PFAS substances, it is the combination of properties present in PFAS-based materials that makes them so ideal for many applications and critical for some medical, health and safety purposes.

A ban of all PFAS would eliminate a wide variety of important products that enable many aspects of modern society and would be detrimental to the EU's climate, circular, digital and resilient-health objectives.

Below a few examples of industries that use PFAS. A more comprehensive list is available in the Benefits & Applications section of the FPP4EU website:

- For the topic of this consultation - for **firefighting across the Military, Aviation, Chemical and Oil & Gas sectors**, for the most significant fire scenarios – PFAS compounds in firefighting foam provide performance capabilities that provide critical life-saving benefits to society for emergency use in major flammable liquid fires.
- In the **transport/automotive industry**, PFAS improve performance of electric car batteries, contribute to keeping vehicles' emissions in check and are used in fire-repellent materials.
- In the **chemicals industry**, PFAS enable the safe handling of chemicals by shielding workers and equipment from highly corrosive substances.
- In the **pharmaceutical industry**, PFAS make patients' lives safer by preventing drug cross-contamination, providing inertness to medicines, supporting machine sterilisation, ensuring low friction for catheters, and developing Active Pharmaceutical Ingredients (APIs) essential for treating diseases such as cancer and depression.
- In the **laboratory and life science**, PFAS are used in analytical procedures. They contribute to sterile environments including in vaccine production and act as reagents and catalysts in chemical manufacturing.
- In **medical devices**, PFAS are used as sealing agents and are included in lubricants for minimally invasive medical robots. They are also an integral part of many implantable medical devices, such as synthetic vascular grafts and surgical meshes for hernia surgical interventions.
- In the **personal protection equipment sector**, PFAS provide the fluid and particle repellent properties to personal protective masks (FPP2, FPP3), enhancing their filtration capacity.
- In the **electronics industry**, PFAS components can stand up to the aggressive etching chemicals, provide heat resistance up to 300°C and the necessary purity required in the production of semiconductors, such as microchips.
- In the **energy sector**, PFAS enhance energy storage in photovoltaic panels and facilitate energy conversion in lithium-ion batteries and are key for the hydrogen economy including fuel cells and electrolysers.
- In the **aviation and the space/defense** sectors PFAS are used in electronic applications, seals and gaskets ensuring both safety and functionality.

[8] Huheey J. E., Keiter,, E. A. and. Keiter, R. L., 1993. *Inorganic Chemistry*, 4th ed.

- In **agricultural chemicals,** PFAS are used as active ingredients in Plant Protection Products.
- In **industrial processes,** PFAS are used in particle and / or gas filtration systems, contributing to emission measurement and control in manufacturing plants across many sectors.
- In the **refrigeration, air conditioning and heat pump (RACHP) sector**, F-gases show a low flammability and toxicity profile and provide functionality to a wide range of applications (e.g., food industry, automotive, building and construction), equipment types and variation of heating and cooling capacity, despite geographic and ambient temperature differences.

Transition periods will be critical to enable the various ambitions of the European Green Deal. Those currently outlined in the restriction are very optimistic, particularly for Seveso III facilities.

While some alternatives have started to emerge for certain applications, these may be specific to the application, as well as any risks being mitigated. Alternatives need to be proven sufficiently efficient without unacceptable risk for human health or the environment for each use. These alternatives must be widely available on the market for a successful transition process.

6. Cost considerations

To reach a threshold of 1ppm PFAS will not only require replacement with proper waste handling and disposal, but also cleaning of systems. Cleaning could be very costly, as it may require thorough procedures involving draining, washing with chemicals, flushing, monitoring, potentially dismantling the system. Limited data and cost are available for meeting residual thresholds, and estimated costs are likely underestimated. We ask that thresholds are considered separately for placing products on the market and for cleaning systems.

Annex I: Detailed explanation on the decision tree developed by FPP4EU

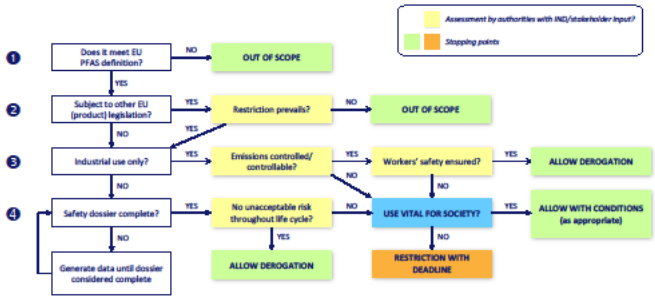
FPP4EU
FluoroProducts and PFAS for Europe

A decision tree for PFAS: Our potential solution to how this broad category of substances could be assessed in view of a REACH restriction

Some of the main concerns regulators have around PFAS is their ubiquitous presence in the environment, combined with their potential persistence. PFAS are a large group of molecules and not all have the same properties, yet as a group, PFAS are facing a restriction in the EU under REACH. A proposal by the competent authorities of Germany, Norway, the Netherlands, Denmark and Sweden ("the dossier submitters") is expected in January 2023. The proposal will then be assessed by the relevant scientific committees of the European Chemical Agency (ECHA), where stakeholders have the opportunity to provide input via two public consultations. Then the European Commission will draft a proposal, before it undergoes scrutiny by the co-legislators the European Member States and the European Parliament.

When we tried to find our way through the restriction, and what it could look like, we were challenged by the complexity created by the combination of such a large amount of substances with different hazard properties and some very diverse usages. FPP4EU designed a decision tree which offers a potential solution to how this broad category of PFAS substances could be assessed in view of a REACH restriction and help identify where derogations/exemptions may be allowed.

The version of the decision tree shared here, is the one approved by the FPP4EU Management Committee. We are eager to find the best approach. Therefore, our decision tree is continuously evolving, based on views shared by relevant stakeholders.



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