FPP4EU
FluoroProducts and PFAS for Europe
A sector group of Cefic
European Chemical Industry Council - Cefic aisbl

POSITION PAPER

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FPP4EU views on the proposal for a restriction on per- and polyfluoroalkyl substances (PFAS)

Key elements

To achieve a practical, enforceable and workable Universal PFAS restriction, these key elements need to be addressed:

1) **Avoid missing PFAS uses:** all PFAS uses need to be assessed to avoid supply chain disruptions and to ensure that key applications are not unintentionally eliminated.

2) **Add a time unlimited derogation on PFAS used in industrial settings** to avoid banning the use of critical PFAS-containing pieces of equipment in industrial plants.

3) **Further reflect on the key fact that not all PFAS are the same,** with full appreciation of OECD assessments on the PFAS universe.

4) **Address primary and secondary financial impacts** of the proposal along the entire value chain.

5) Take into account **the drive for a competitive, resilient and sustainable Europe.**

6) Robustly **review the enforceability** of the proposal considering the sheer number of end products and substances that will have to be checked at EU borders.

Introduction

The association of PFAS producers and key users in Europe, FPP4EU, hopes that any Universal PFAS (U-PFAS) regulatory action is as practical, enforceable and workable as possible. To ensure this, industry is working to provide data supporting or challenging the assessment of the dossier that was published on 07 February by the European Chemicals Agency (ECHA) based on information provided by Germany, the Netherlands, Sweden, Norway, and Denmark (hereinafter "the proposal").

However, there are several elements that need to be addressed.

Avoid missing PFAS uses

Despite the level of detail in the current proposal, it reflects only a fraction of the current numerous uses of PFAS, including niche uses. The restriction will impact a huge number of products and value chains as many industries use PFAS in one way or another[i]. This is further complicated by the unprecedented number of substances covered. The combination of these makes the restriction unique and triggers its main challenge: a complete consideration of all PFAS uses. Therefore, all stakeholders need to be aware of the significant, and in some cases severe, consequences of this far-reaching proposal.

The two main elements can be explained thus:

- **The number of products that rely on PFAS,** either during their production phase and/ or in the final products is largely unknown. Indeed, many Downstream Users (DUs) may place on the market non-PFAS containing products that rely on PFAS in their production process at some point. Many of them may not realise PFAS have been involved.
- **The complexity of the supply chain**. Many supply chains involve multiple players. Whilst information flow is ensured between immediate parties involved in the supply (transmitter and receiver), there is currently no traceability system that ensures that complete information is received by the end user when multiple parties are involved in complex supply chains. This can be further exacerbated where parties are established in different (some non-EU) jurisdictions. This makes the mapping of the supply chains extremely complicated.

To improve the information flow through value chains, FPP4EU has consistently reached out to downstream sectors to support the dossier submitters in their two calls for evidence. This resulted in the creation of the FPP4EU Collaboration Platform ("the Platform") which aims to raise awareness of the PFAS regulatory action whilst building a broader understanding of the variety of PFAS uses for all stakeholders. There are currently more than 110 parties represented in the Platform and participation continues to grow as industries become aware of the impact and their responsibilities under the restriction. The Platform has enabled FPP4EU to find the significant number of industries and DUs that will be impacted but we predict that we are still not reaching everyone. This shows that more time is needed to completely map the PFAS universe and to identify the potential impact on some (currently unforeseen) critical uses.

Under the REACH restriction procedure, a six-month consultation started on 22 March. Its results will be assessed by ECHA's Committee for Risk Assessment (RAC) and Committee for Socio-Economic Analysis (SEAC). The input into the consultation will help identify or mitigate any risks and examine the benefits and costs of the proposed restriction. However there remains a growing concern within the Platform about the practicalities of contributing to this process. The legal six-month consultation period is short for a consultation on a restriction that covers 10,000 substances used in widespread value chains. In addition, not all parties have the resources to understand and assess the impact of this proposal, in particular SMEs at national level, EU wide and across regions.

During the RAC and SEAC meetings, there will also be limited industry seats to follow these discussions, creating an additional risk that many stakeholders will not have the opportunity to fully understand the process, to be heard and fully considered. Such stakeholders will need more time and guidance to be able to meaningfully respond or contribute.

Viewing the unprecedented character of this restriction (as further exemplified in Annex 1), we ask the regulatory authorities to consider:

- Special measures (potentially even deviating from the framework regulation) to enable the participation of all parties to the restriction process, for example, by exceptionally organising longer/ additional consultations and/ or permitting delayed submissions of information;
- Additional meetings (RAC, SEAC…) to assess, as fully as possible, the different uses covered by the restriction;
- Guidance on data requirements, including which specific data are needed to show that alternatives are unavailable, ideally in multiple EU languages;
- Transparency on how conflicting submissions will be resolved;
- Enhanced communication on data gaps to ensure that all uses and potential derogations can be considered.

Add a time unlimited derogation on PFAS used in industrial settings

The proposal only derogates (for a limited period of time) few PFAS uses in industrial settings. PFAS are typically used in sealants, coatings on valves and piping, gaskets, personal protective equipment/ clothing, refrigerants, membranes, filter materials and membranes, foams, greases/ lubricants, mould release, conveyor belts, O-rings, columns/ internals, diaphragms, processing aids, etc. Without these materials/ pieces of equipment, industrial plants can no longer operate. The required key characteristics of PFAS, including durability, thermal and chemical stability, fire resistance, water and oil repellence, make them indispensable.

Therefore, the current proposal will have a significant impact on industry settings, which are already subject to strict regulations to ensure safety of operational conditions and emission control. Interestingly, ongoing discussions in the microplastics and the silicones group restrictions include derogations for industrial settings.

We therefore ask the regulatory authorities to consider:

- A derogation on PFAS used in industry settings, potentially with additional reporting and waste management plan obligations to ensure emissions from the use of PFAS are minimised.

Further reflection on the key fact that not all PFAS are the same

It is widely understood that chemical, physical and (eco-)toxicological properties can vary greatly between the more than 10,000 PFAS. OECD recognises the diversity of PFAS as a chemical class with diverse molecular structures and physical, chemical and biological properties[ii]. They state that their proposed PFAS definition "*is based only on chemical structure, and the decision to broaden this definition compared to Buck et al. (2011) is not connected to decisions on how PFASs should be grouped and managed in regulatory and voluntary actions*"[iii].

The current restriction proposal groups all PFAS under the premise that they share a common property (persistence). From a risk assessment point of view, this broad grouping is questionable. PFAS can be gaseous, liquid or solid; some are water-soluble and scientific literature confirms that not all PFAS are (equally) persistent, toxic, mobile or bio accumulative. As such they will have varied risk profiles.

As for other chemical classes it is critical that PFAS grouping is based on solid scientific standards and applied coherently across REACH, independent of its purpose.

Given that not all PFAS are the same, and many may be used safely (as long as the correct measures to control emissions during production, use and end-of-life phases are applied), it remains important to ensure that any groupings are sufficiently granular to address the different hazard and risk profiles of individual PFAS. Grouping should therefore allow for separate evaluation based on specific toxicological, ecotoxicological and environmental fate profiles. Viewing that the dossier submitters group all PFAS in the same entry, 'group splitting' will be needed under the derogations. To assist this, FPP4EU have developed a decision tree that provides elements that can be considered when discussing those derogations.

Regarding these we ask the regulatory authorities to consider:

- The FPP4EU decision tree as they prepare any derogations to:
  - Assess whether the substance meets the PFAS definition
  - Consider other EU product-specific legislation
  - Make a clear separation between 'industrial use only' and 'consumer uses'
  - Assess safety and how vital the PFAS-containing application is for society;
- The societal need for materials that are durable;
- Excluding from the proposal those PFAS that are not persistent or do not show additional properties of concern.

Address primary and secondary economic impacts of the proposal along the entire value chain

For any restriction, unintended economic impacts should be considered, not only the consequences of a restriction on most of the industrial uses, but also the losses from one specific (larger volume) use. This may result in the remaining derogated uses becoming no longer viable from an overall volume perspective within the EU. Subsequently the derogated use would also disappear, along with entire value chains (regardless of whether the involved products are essential or not). This could impact downstream users who are currently unaware of the PFAS in their supply chain, meaning they may suddenly no longer be able to manufacture a product (which may itself not even contain a PFAS). In this situation this user will go out of business in the EU whilst non-EU competition will still be able to import the non-PFAS product that relies on (unrestricted) PFAS in their production process.

We therefore ask the authorities to consider:

- Indirect economic impacts of the restriction proposal when evaluating its proportionality.

Take into account the need for a competitive, resilient and sustainable Europe

Certain PFAS are indispensable to reach the objectives set out in various EU policy initiatives, such as the EU Pharmaceuticals Strategy, the EU Industrial Strategy, the European Chips Act, the EU Renovation Wave and the EU Green Deal (e.g.: Fit for 55, Smart and Sustainable Mobility, Batteries Regulation and the EU Strategy on Hydrogen). Whilst the search for alternatives should continue, progress to achieve the targets cannot be stalled. For critical applications, additional time-limited derogations could be envisaged, all the while being mindful that regrettable substitution can also occur when replacing a PFAS by another substance.

Multiple sectors already indicated that the derogation timelines are too short in view of the required discovery and implementation of viable alternatives. The lack of a revision clause (e.g.: to evaluate progress after 5 years), also creates uncertainty and shifts investments away from the EU.

The restriction proposal also needs to consider the EU's renewed focus on competitiveness and resilience. The current proposal risks losing large parts of European industrial manufacturing and runs against the ambition to strengthen European industry in light of recent crises. For example, by not exempting intermediates, processing aids (etc.), that are relevant for the production of derogated uses, the EU becomes dependent on imports and thus significantly decreases its strategic autonomy (e.g. searched for under the EU pharmaceutical strategy, EU Chips Acts etc.). Product and Process Orientated Research and Development (PPORD) derogations may also be needed to keep Research and Development activities of derogated industry sectors within Europe.

We therefore ask the authorities to consider:

- The different wider needs of Europe when evaluating the derogations requested by the different parties;
- Departing from legislation proposals that allow the import of PFAS contained products into Europe but not their manufacture.

Robust review of the enforceability of the proposal

One aim of the U-PFAS restriction is to ban products containing PFAS. Such products will therefore become illegal and must not be placed or imported into the EU market[iv]. National authorities will need to enforce and ensure compliance with their market surveillance obligations. This will include market surveillance and controls, organising recalls and stopping products banned by the restriction at their borders.

The restriction could establish a concentration limit for PFAS in different products, meaning there must be an analysis, detection and potentially identification of the different PFAS therein via a range of analytical methods in specialised laboratories. The wide number of substances under assessment here could lead to challenges with enforcement due to:

- Limitations of analytical methods and laboratory capacity. There is a widely understood lack of standardised analytical methods to detect the large number of PFAS covered by the restriction. Existing standards tend only to be available for a targeted subset of PFAS (mostly 10-30 individual substances as detailed in Annex 2);
- Requesting detection limits for 'any PFAS' generates analytical challenges due to the fact that new PFAS may be detected during any measurement. These 'newly detected peaks' may need further identification and their quantification will need further analyses;
- Local customs departments will need sufficient enforcement tools and resources to implement the restriction;
- There is no register of products containing PFAS available in Europe. To make enforcement practicable, a register of banned products containing PFAS will need to be prepared by Member States to allow the identification of potential suspected products by the customs authorities.

There is currently sufficient evidence that the vast majority of goods containing banned or restricted chemicals come from outside the EU[v] (RAPEX). It showcases that the enforcement of the current restrictions is an issue, to which the PFAS challenge, with such a broad scope, still needs to be added.

Considering these constraints and to help ensure a level playing field we ask the regulatory authorities to consider:

- Lab capabilities/ capacities and the availability/ applicability of analytical methods when proposing the timings and transition periods of the restriction;
- Consider challenges when requesting detection limits for 'any PFAS'.
- Standardisation of analytical methods and allocating additional EU research funds to enable the development of adequate methodologies to monitor PFAS;
- Measures/ processes to improve the enforcement of the restriction at the border, including cooperation with enforcement authorities and customs. Additional control of e-commerce may be needed.

Conclusion

FPP4EU wants to ensure that any U-PFAS regulatory action is as practical and workable as possible and will continue to work with all stakeholders to keep them informed of the process. However, there are challenges with the process that should be addressed to ensure that interested parties can effectively participate and that ECHA and the Commission take account of and examine carefully and impartially all information that may have bearing on the decision to be adopted.

Annex 1 – Unprecedented restriction

As many stakeholders compare this restriction with the one on microplastics, below for information the PFAS Categories compared with the microplastics restriction ones:

FPP4EU have compared the uses covered by both restrictions via the use categories in the study by Glüge et al. (2020)[vi] and those product groups listed in the microplastics restriction[vii]. Glüge et al. estimate that PFAS are used in 64 use categories cross 21 Industry branches and 43 Other use categories. Contrary to PFAS, microplastics are not used in 13 of these Industry branches including: Aerospace, Biotechnology, Chemical industry, Electroless plating, Electroplating (metal plating), Electronic industry, Machinery and equipment, Manufacture of metal products, Mining, Nuclear sector, Semiconductors, Watchmaking, and Wood. Additionally, microplastics are not used in 22 of the Other use categories including: Aerosol propellants, Air conditioning, Antifoaming agents, Ammunition, Conservation of books and manuscripts, Cook- and baking ware, Dispersions, Electronical devices, Fire-fighting foams, Flame retardants, Floor coverings, Leather, Musical Instruments, Paper and packaging, Particle physics, Personal care products, Pipes, pumps, fittings and liners, Refrigerant systems, Sealants and adhesives, Soldering, Soil remediation, and Tracing and tagging.

The microplastics restriction however lists 19 product groups with PFAS being used in all of them apart from substances or mixtures used for glass sheet transportation, and granular infill material for synthetic sports surfaces. It should be noted though, as admitted by Glüge et al. also, that the PFAS uses are likely far from being complete. As such it is safe to say that compared to other group restrictions the U-PFAS restriction potentially has a significant impact on far more use categories.

Number of substances covered by the U-PFAS restriction

Over 10,000 substances have been identified[viii] as PFAS but theoretically there may be many more. For example the PFAS PubChem Tree estimates that there are more than 6 million entries matching the OECD PFAS definition.

Annex 2 – Limitations on analytical method and laboratory capacity

There are different analytical methods available to measure PFAS; indirect (focusing on measuring the total organic or extractable fluorine content present in samples), targeted (for specific substances) and suspect or non-target methods (for broader screening and the identification of unexpected or previously unknown PFAS).

A recent report commissioned by Norwegian Environment Agency looked into the available analytical methods for 17 specific uses/ matrices and showed the current limitations of the standard methods available for measuring PFAS. It concluded, amongst others, that:

- *There are no standards available for total fluorine methods or the total organic precursor assay.*
- *There are currently no standard methods found to measure PFAS in some uses including electronics and electronic equipment incorporating semiconductors, F-Gases and refrigerants, medical devices and medicinal products, cosmetics, oil gas and mining, metal plating, flame retardants and resins.*
- *For some matrices (e.g. water/air/soil/people or animal body parts and liquids) where there are no suitable standards available to ensure equipment functionality and inter-lab comparability.*
- *Whilst new methods are coming out every day, some PFAS can only be detected by labs with very specialised equipment meaning delays are possible in any assessment. Time may also need to be spent on developing 'standard operating procedures' for the harmonised assessment of PFAS across the EU.*

Additionally, some PFAS are difficult to 'get out' of the matrix they are in so there may be a tendency to 'under/ over report' the concentration present. Finally, some PFAS may be overlooked (i.e. when a sample is tested) as due to the method employed you may only see some of the ones that are present (if you use certain methods).

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About FPP4EU

FluoroProducts and PFAS for Europe (FPP4EU) is a sector group of Cefic (the European Chemical Industry Council). The group was set up to represent the views of producers, importers, and users of fluorinated products and PFAS and other parties with an interest in the fluorinated products and PFAS sector group activities in Europe. Our members produce, import and use over 300 PFAS in nearly all subgroups as defined by the OECD. FPP4EU does not represent individual PFAS substances, but represents the group as a whole.

References

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