

FPP4EU: Ready to work with Europe to address PFAS

Cefic has formed a new Sector Group, Fluorinated Products and PFAS for Europe (FPP4EU), whose aim is to work together with all stakeholders on PFAS. Whilst these substances play many important roles in modern society, challenges with their emissions into the environment led to a proposal to restrict them as a group of substances under REACH.

FPP4EU stands ready to connect with authorities, NGOs, academics and the supply chain to work on the challenges ahead. It hopes to understand how:

- PFAS will be defined,
- REACH can efficiently regulate PFAS as a group,
- authorities intend to identify which PFAS are essential for society,
- PFAS grouping can be done on a scientific, pragmatic and enforceable basis,
- the latest science is employed to ultimately shape PFAS restrictions,
- responsible manufacturing processes and innovation can play a role.

FPP4EU is ready to work on PFAS with all stakeholders.

A new group on Fluorinated Products - A new valuable and active partner in discussions on PFAS

Cefic (the European Chemical Industry Association) has brought together interested producers, importers and users of fluorinated products in a new Sector Group called Fluorinated Products and PFAS for Europe (FPP4EU). This new group is unique as it addresses:

- an *unprecedented number of substances* in one Sector Group:
There are about 9000 PFAS when considering the definition of the 5 countries that initiated the REACH restriction (although the actual number of substances in commerce is likely to be a few hundred).
- an *unprecedented diversity of product uses*:
The group covers manufacturing, professional and consumer use, as well as industrial (which includes, *inter alia*, processing aids, intermediates) applications, for a variety of industries including polymers, transportation (automotive, aerospace, rail, as well as traffic safety infrastructure), electronics and semiconductor industries, heating and cooling, energy sector (utilities, renewables, batteries, hydrogen), construction sector, medical devices, personal protective equipment, (bio-)medicinal products and life sciences, petrochemicals, emergency response and fire-fighting foams, frying pans, paper food packaging, food industry, paints, cosmetics, textiles, agricultural chemicals and others.

Fluorinated Products and PFAS for Europe (FPP4EU)

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Individual user associations provide information on PFAS use in their products. For example, the Fluoropolymers Product Group under PlasticsEurope deals with the many uses of fluoropolymers (mainly from a manufacturers' perspective) whilst EFCTC (European FluoroCarbons Technical Committee) deals with HFCs and HFOs etc. With the upcoming REACH restriction on the wide group of PFAS, the Cefic membership decided to set up its own Sector Group to contribute to the European debate. It will not only cover the manufacturers but also the users (including several liaison members from various international PFAS user associations, in addition to those already mentioned).

A new challenge on PFAS

The PFAS chemistries contain properties that include stability in extreme environments and resistance to oil, water, temperature, friction, chemicals and fire, as well as electrical insulating properties. Such characteristics are critical for use in important product applications across many industries. They owe their properties to the strong carbon-fluorine bond, which also renders some PFAS highly resistant to breakdown in the environment. Some of them have been detected in groundwater, surface water and soil. Viewing that certain PFAS may cause adverse health effects when accumulating in the human body, the European regulatory authorities decided to take initiative in the form of a broad PFAS restriction proposal. The intention is to ban all PFAS unless their use can be proven to be essential for society. This introduces a new set of challenges:

- There is still much uncertainty about how the 'essential use' concept will be defined and whether this could be used in practice in this case. PFAS is used as a testing ground to introduce a new concept that has not been elaborated in REACH before.
- At this stage, it is not clear how it will be possible to group PFAS adequately. On the one hand, safety for people and the environment must be guaranteed for all substances in the same sub-group. On the other hand, the grouping paradigm should avoid restricting all PFAS simply for being 'part of the group' if some of them do not pose any unacceptable risk. Losing safe and valuable chemicals in useful applications should be avoided.
- Substituting those PFAS that may cause an unacceptable risk remains a priority for industry. For some applications, however, no alternatives exist yet. Often the properties required of the PFAS molecules in their applications, are the same properties that render them persistent in the environment.

FPP4EU will focus its activities on addressing the concerns expressed by society and in facing the challenges ahead, as well as raising awareness about the challenges faced by industry with the new regulatory approach. The group will build on actions already undertaken by our membership and their desire to engage further. For such a technically and legally complex topic, collaboration with all stakeholders will be key to ensure that the final restriction is proportionate, implementable and enforceable, whilst still enabling the EU to meet its Green Deal, economic and other policy objectives.

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A new set of questions on PFAS

PFAS discussions are complex. FPP4EU, as an industry sector, have questions that we would like to discuss with policy makers to help shape the future of any regulatory framework.

What are (relevant) PFAS?

In July 2020, Denmark, Germany, the Netherlands, Norway and Sweden launched a Call for Evidence to prepare for a REACH restriction proposal. They introduced a new definition: *PFAS are substances that contain at least one aliphatic -CF₂- or -CF₃ element*. With this, the list of 4730 PFAS under the OECD's definition was extended to about 9000 substances. However, the number of PFAS actually commercially available is unclear. A recent study suggests that this number is in the hundreds, rather than the thousands. There exist different subgroups of PFAS with vastly different structures and forms. Some are liquids, some gases and some are solid. Irrespective of whether the extended definition becomes the final one, it might be useful to identify how many of the targeted molecules are commercially sold and used, and how many are only used for Research and Development (R&D) purposes. FPP4EU will explore whether it is possible to focus only on commercially relevant PFAS and how some forms of R&D could still be allowed on any PFAS.

How can REACH be best used?

Currently, it could be argued that the existing regulatory framework and assessment guidance may not be in place to address such a vast and complex set of substances. By ensuring that PFAS are addressed correctly and collaboratively, Europe could set a precedent for other complex chemical groups with a strong scientific, legal and harmonised basis. Nevertheless, a couple of questions will need to be answered:

- How do we avoid double regulation when considering such large groups (e.g. F-gases)?
- How to deal with already approved actives covered by existing specialized and targeted provisions in sectorial legislation including (e.g.) Regulation (EU) 1107/2009 for plant protection products and Regulation (EC) No. 726/2004 & Directive 2001/83/EC for medicinal products that provide robust and effective control of active substances in relation to the environment?
- The Chemicals Strategy for Sustainability introduces new instruments for regulating chemicals under REACH, such as essentiality, pre-defined grouping (etc.) and puts PFAS forward as a test case. How can we ensure that parallel discussions on the new concepts and the PFAS restrictions take place in a coordinated way, involving all stakeholders?
- How should the Zero Pollution Action Plan be leveraged, to seize opportunities to further limit emissions in production, including for PFAS?
- Can critical industrial and consumer applications be safeguarded?

How can grouping be done in a scientific, pragmatic and enforceable way?

Substances falling under the current scope of the restriction are very diverse. As a result, a differentiated approach could be applied. Some PFAS are already controlled as they pose an unacceptable risk to the environment or health based on scientific evidence. Others may be safely handled and provide value to consumers and industry. Splitting them into sub-families could be done, taking into consideration a risk-based approach, and according to:

- chemical structure,

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- physical-chemical properties,
- (eco-)toxicological properties,
- pieces of legislation that already cover subsets of PFAS,
- any combination of the above.

Grouping of PFAS will require careful, informed attention to ensure regulatory coherence and to enhance implementation.

Properties vary greatly among PFAS and that is why it will be challenging to regulate these substances as a single class. Of the 9000 PFAS chemicals, it is estimated that less than 10% are related to commercial use. Buck *et al.* (2021) propose that *“grouping and categorizing PFAS using fundamental classification criteria based on composition and structure can be used to identify appropriate groups of PFAS substances for risk assessment, thereby dispelling assertions that there are too many PFAS chemistries to conduct proper regulatory risk assessments for the commercially relevant substances.”*¹

How can the latest science be employed across the EU regulatory framework?

PFAS substances are diverse and there is a great deal of analytical, human/ environmental health and epidemiological scientific information that can help inform any discussions on them. Especially in the areas of risk assessment, grouping, emission reduction and emission control, decisions should be informed by the latest science. This places responsibility on industry to share available scientific information with the authorities and on authorities to include the most recent scientific developments in their decision-making processes. Constructive dialogues can lead to identification of data gaps and further research and data generation. Using the latest science will certainly assist in ensuring that PFAS-involving innovative technologies that are (e.g.) contributing to decarbonisation of Europe, remain available.

How can responsible manufacturing processes and innovation help?

FPP4EU will engage with its value chain to work towards further reducing PFAS emissions (via air, water or waste) to the environment in all stages of the life cycle, including remediation.

Innovation will certainly also consist of finding alternatives to many of the PFAS in use at present, starting with the most harmful ones used in critical applications. Carefully performed life-cycle assessments and detailed reviews of the proposed alternatives in their intended uses will be needed to avoid regrettable substitution or other unintended consequences.

A new open collaboration opportunity

Fluorinated products play a key role in meeting various sustainability-driven regulatory priorities, including ensuring process safety, food safety, and waste reduction as part of a circular economy, protecting the health and well-being of European citizens via personal protective equipment, medical devices, medicinal products, medical imaging and other devices, and contributing to various strategic value chains such as aerospace, automotive, electronics and construction.

Viewing the importance of the value chain, FPP4EU extended the group with a Collaboration Platform enabling downstream users to connect with manufacturers and importers and other users. The so-called

¹ [R. Buck et al, \(2021\) Identification and Classification of Commercially Relevant Per- and Poly-fluoroalkyl Substances \(PFAS\)](#)

Observers of the FPP4EU populating the Platform will bring the highly needed added value to the discussions.

FPP4EU Members and Observers are ready to engage and to invite authorities, NGOs and academia to workshops dedicated to specific PFAS-related topics, such as:

- Addressing multiple uses under a single restriction whilst avoiding double regulation: how to make it work in the current EU regulatory framework.
- Grouping: discussing options and an optimal strategy for Europe.
- Analytics: available analytical methods and areas where (further) development is needed.
- Safe use of PFAS and opportunities for alternatives in different uses and applications.
- Health and environmental science: discussing and evaluating the scientific evidence

By working with all stakeholders, FPP4EU will be able to address health and environmental concerns whilst ensuring that the safest and critical applications of PFAS remain available for the future of Europe.

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About Cefic
Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.1 million jobs and account for 15% of world chemicals production

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