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

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Public consultation input provided by FPP4EU to the restriction on Per- and polyfluoroalkyl substances (PFAS)

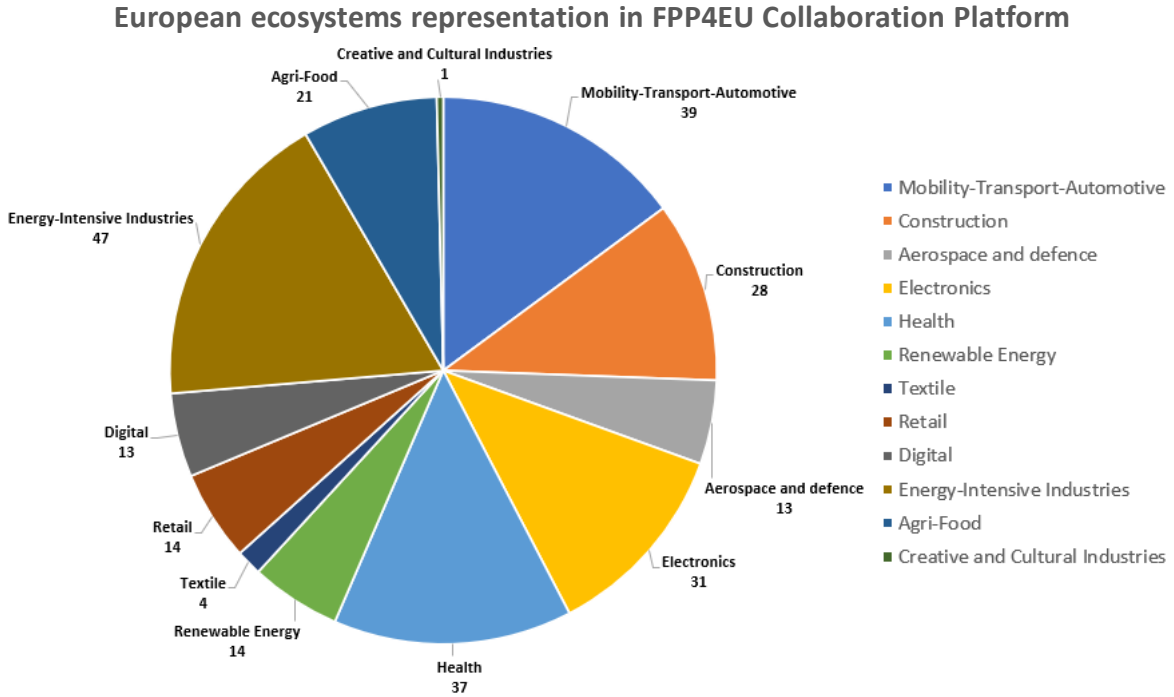
Introduction

FPP4EU, the FluoroProducts and PFAS for Europe Sector Group of Cefic, welcomes the opportunity to provide input to the public consultation on the universal REACH restriction on Per- and polyfluoroalkyl substances (PFAS). As a representative of producers, importers and users of the many potential substances that fall within the broad definition of PFAS, FPP4EU seeks to support EU policymakers and authorities in achieving the ambitions set out in the European Green Deal. As such, FPP4EU members understand and support the need for balanced regulatory action on PFAS. This submission focuses on the overall positions of the Sector Group.

Individual member companies of FPP4EU may provide more specific information and data on their own submissions.

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 as well as other parties with an interest in the Fluoroproducts and PFAS activities in Europe. FPP4EU represents 14 member companies and has also created the 'Collaboration Platform', where downstream users and other interested stakeholders are invited to exchange information, share useful documents, learn from each other. There are currently more than 150 parties participating in the Platform, including 13 national non-governmental federations representing the chemical industry in European countries. Participation continues to grow as industries become aware of the impact and their responsibilities under the restriction.



1. Not all PFAS are the same

The restriction proposal states that the proposed grouping "is based on structural similarity (common perfluoroalkyl moieties) that triggers equivalent hazards and risks among the substances covered". The main concern is their potential persistency. In many applications, PFAS are used because of their unique properties, namely their extreme durability under harsh conditions, thermal and chemical stability, fire resistance, and water and oil repellence.

There has been a lot of resistance against the grouping of all PFAS under the premise that common property is persistence. It has been stated that it is scientifically inaccurate because not all PFAS are persistent. In addition, just because a chemical is persistent, it does not mean it is hazardous.

Should the current scope of the restriction remain unchanged, diversification will then be needed at the level of the derogations. FPP4EU has developed a decision tree (see Annex II) that provides elements that can be considered when discussing those derogations.

The recently published report by UK's Health and Safety Executive, 'Analysis of the most appropriate regulatory management options (RMOA)' shows that UK Regulators have adopted a narrower working definition of PFAS[1], removing the criterion that a single isolated methylene group ($–CF_2–$) is sufficient for classification as a PFAS. It recommends action on specific uses, consumer articles from which PFAS are likely to be released, and potential UK REACH authorisation of PFAS used as processing aids in the manufacture and processing of fluorinated polymers. These actions are proposed pending further evaluation and investigation of substances of concern and support continued collaborative work across different government bodies and with external stakeholders. We believe that, given the lack of hazard information on a number of PFAS and on the extent of PFAS used across various value chains and downstream sectors, such an approach could be beneficial for the EU as well.

Furthermore, the US EPA's working definition, as it is outlined in its 'National PFAS Testing Strategy', identifies chemicals with at least two adjacent carbon atoms, where one carbon is fully fluorinated and the other is at least partially fluorinated. As there is a strong economic interdependence between the EU, UK, and US, it is suggested that a consistent approach is taken for the definition of PFAS, restriction and timing of implementation. Any inconsistency may result in economic disruptions.

2. Request for an exemption for the use of PFAS in the chemical industry's industrial settings

How they are used

PFAS are typically used in sealants, coatings on valves and piping, lining of vessels, gaskets, personal protective equipment/ clothing, refrigerants, filter materials and membranes, foams, greases/ lubricants, mould release, conveyor belts, O-rings, columns/ internals, diaphragms, processing aids, etc. These materials/ pieces of equipment are critical for industrial plants' safety.

[1] "PFAS are defined as fluorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), or two or more contiguous perfluorinated methylene groups (–CF2–)." Analysis of the most appropriate regulatory management options (hse.gov.uk)

The required key characteristics of PFAS, including durability, thermal and chemical stability, fire resistance, water and oil repellence, make them the material of choice in such applications. They are used in multiple sectors, ranging from the oil and gas industry, manufacturing and transporting of chemicals, and industrial cooling and heating systems among many others.

An exemption for PFAS used in industrial settings

In the European Commission's proposal for the synthetic polymer microparticles restriction, the microparticles are derogated for use at industrial sites, for manufacturers and industrial downstream users. This affects substances used on their own or in mixtures.

The text, recently approved by the REACH Committee, excludes them in those settings "because it is easier to control emissions from such uses than, for example, emissions from consumer or professional uses".[2] In the case of the silicones restriction proposal, the "Commission's request excludes the industrial uses of D4, D5 and D6 from the Annex XV investigation (such as formulation of mixtures, production of silicone polymers , or production of articles); industrial uses will therefore not be considered as candidates for restriction".[3]

It becomes evident that in both cases the European Commission did not want to target industrial uses, since it is easier to control emissions for such uses and they are already strictly regulated through different European legislation, such as the Industrial Emissions Directive.

During the ECHA's information session on the PFAS restriction, the dossier submitters acknowledged the fact that this is the broadest restriction proposal under REACH so far, with more than 10,000 substances in scope, as well as numerous uses and sub-uses. This raises the issue of an unprecedented impact on the industry with various unforeseen consequences. As outlined in the FPP4EU's decision tree (see Annex II), there is an important difference between industrial uses and consumer products, since the safety of industrial uses is regulated under dedicated legislation. The human health of workers is regulated via the EU Occupational Safety and Health legislation, whereas industrial emissions are regulated and controlled via the Industrial Emissions Directive.

Cefic has prepared a 'PFAS Inventory study', to investigate and map (sub-)uses of PFAS related to equipment and installations in the chemical industry - representing plants in its three industry sectors (specialty chemicals, petrochemicals and halogens), to look into potential non-PFAS alternatives, and to touch upon economic and operational impact of the restriction. This study can be found in Cefic's submission to the consultation.

3. Avoid missing PFAS uses

Despite the level of detail in the current restriction 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[4]. This is further complicated by the unprecedented number of substances covered, which, due to their non-hazardous status, were

[2] Commission Regulation (EU) …/… of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles (p.4).
[3] Proposal for an Annex XV restriction on Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6) (p.8).
[4] NCM (2022): Analytical Methods for PFAS in Products and the Environment. TemaNord 2022:510. Nordic Council of Ministers. DOI: 10.6027/temanord2022-510 (p. 10).

not covered by any reporting requirements under EU law, thus far. To improve the information flow through value chains, FPP4EU decided to consistently reach 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 150 parties represented in the Platform and participation continues to grow as industries become aware of the likely impact of the restriction proposal.

FPP4EU has compiled a non-exhaustive list of PFAS missed uses and uses partially covered in the restriction proposal submitted by the competent authorities in January 2023. This is the result of a survey completed by parties represented in the FPP4EU Collaboration Platform. Downstream users of PFAS were asked to complete two different templates and report on 'Missed uses' and 'Partially covered uses'. More than 590 PFAS missed uses were reported and over 290 PFAS uses were considered as only partially covered. The survey is attached as Annex I to this submission. The answers received were not filtered, therefore duplications and inaccuracies may occur. In order to preserve confidentiality, the sequence of the answers has been randomised and anonymised. It is also important to note that the survey is only a sample and does not represent a complete survey of PFAS uses/ applications.

4. Lack of currently available analytical methods to detect PFAS can hamper the enforcement of the restriction

The PFAS restriction proposal acknowledges that "the enforceability is partly dependent on the availability of sufficiently efficient and effective analytical methods for monitoring, which are in rapid development."[5] A recently published PFAS report by the US National Science and Technology Council also acknowledges the issue with analytical methods when it comes to PFAS testing and outlines a series of actions in order to address research gaps.

A report commissioned by the 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 organic fluorine methods or the total organic precursor assay.
- Total fluorine methods will not provide concentration for single substances. This will depend very much on either the manufacturer of the substance or the users and the matrices in which the substance will be found.
- There are currently no standard methods found to measure specific 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) there are no suitable standards available to ensure equipment functionality and inter-laboratory comparability.
- Whilst new methods are coming out every day, some PFAS can only be detected by laboratories with very specialised equipment meaning delays are possible in any assessment.

[5] U-PFAS restriction proposal (p. 181).

Time may also need to be spent on developing 'standard operating procedures' for the harmonised assessment of PFAS across the EU.

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 above);
- Requesting detection limits for 'any PFAS' generates analytical challenges because 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;
- Currently there is not a complete overview of products containing PFAS available. To make enforcement practicable, an overview of banned products containing PFAS would need to be prepared, maintained and expanded by Member States to allow the identification of potentially suspected products by the customs authorities. It is highly unlikely that this is feasible, though.

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

- Laboratory capabilities/ capacities and the availability/ applicability of analytical methods and equipment when proposing the timings and transition periods of the restriction;
- Challenges when requesting detection limits for 'any PFAS'.
- Standardisation of analytical methods and allocation of 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.

5. Need for longer transition periods

The proposed general transition period of 18 months is the same as in previous proposals for PFAS restrictions under REACH. The same timeframe was proposed for the PFOA restriction as well as the one on PFHxA. However, in both cases SEAC recommended the need for the transition period to be doubled:

- In the case of the PFOA restriction (where the 36-month general transition period was later incorporated in the Commission's proposal), SEAC proposed[6] a longer transition period to allow diffusion of information in numerous and complex (often at global scale) supply

[6] RAC & SEAC Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (p.53).

chains, more time for R&D and progress in various monitoring related challenges among others.

- In the case of the PFHxA restriction, SEAC proposed[7] to double the proposed 18 months general transition period, stating that this would balance on one hand the need for emission reduction without further delay and on the other hand the need for producers, importers and users of substances to have more time to comply and accelerate substitution activities wherever it is possible.

FPP4EU believes that these same issues will have to be addressed in the current restriction, but at a much greater scale. During the past two years, our interactions with various downstream users through the FPP4EU's Collaboration Platform have showcased the lack of awareness in the supply chains when it comes to PFAS. Industries showed that in many applications where harsh conditions are the norm and there is need for high level performing properties, it is not possible to replace PFAS at the moment. As alternatives will also have to be characterised by the combination of properties like resistance to harsh chemicals, harsh temperatures etc., to provide the same properties under these conditions, there is the danger of regrettable substitution by non PFAS. The characteristics required to achieve this level of performance means that any possible alternative will also have similar properties to those that are deemed problematic for PFAS, namely persistence.

Taking into account the fact that, as it has been stated by the dossier submitters, the U-PFAS restriction is the broadest restriction proposal under REACH so far, with more than 10,000 substances in scope, as well as numerous uses and sub-uses, we believe that a 36-month transition period should be the starting point when assessing the necessary length of the transition period. In previous restrictions, which covered only a few substances, SEAC proposed the 36-month transition period as an adequate time for companies to comply and develop alternatives. In this case, where we have thousands of substances in scope, and various sectors that will be impacted, it will be necessary to have a general transition period which will provide the right balance of reducing emissions while also making the restriction enforceable and avoid jeopardising a series of objectives outlined in the European Green Deal and other European legislations.

The proposed general transition period of 18 months is also not feasible in an industrial setting for several reasons:

- Even for applications where alternatives already exist, the replacement procedure can be very difficult and requires time. Replacement of equipment in plant operations occurs at regular intervals and are planned far ahead to reduce downtime. The inspection of equipment, ensuring all parts are available for repairs, and any changes of equipment (which need to be designed and checked from a process safety perspective, prior to ordering the parts, and planning installation) is usually a multi-year program for higher risk operations and these shutdowns occur every 1-3 years. This means that an 18-month transition period will never be feasible even for changing simple flanges, piping, replacing a PFAS lined pump, or other equipment. If the risks to the operation are increased this may mean changes to the permit or revision or preparation of SEVESO plans (for higher risk sites).
- In cases where alternatives do not yet exist, this may take even longer than indicated above.

[7] RAC & SEAC Opinion on an Annex XV dossier proposing restrictions on undecafluorohexanoic acid (PFHxA), its salts and related substances (p.15).

- For an industrial application of PFAS, linked to products that require certification such as PPE (Personal Protective Equipment), medical devices, pharmaceuticals manufactured under GMP (Good Manufacturing Practice), car parts, aeroplane parts, etc., the product certification and recertification can take up to a decade if an alternative exists. Without an alternative, R&D must be performed to find one prior to product certification. This is irrespective of whether the PFAS is in the final product or not.

6. The impact of the restriction on various goals outlined in EU legislation

As outlined previously, the current proposal for a universal restriction on PFAS will have many consequences and a great impact in most sectors of the EU economy. As the substances in scope are used in many important applications (batteries, fuel cells etc.), it is certain that various strategies that the EU has put forward in recent years will be heavily impacted as well. We would therefore like to stress the need for regulatory authorities to ensure that the EU will have access to the technologies and materials necessary to achieve the goals outlined in these strategies. Especially in the case of the EU's Green Deal and the overall efforts towards an autonomous and resilient Europe. Whilst the search for alternatives should continue, progress to achieve the targets cannot be stalled.

For critical applications, additional derogations could be envisaged, all the while being mindful that regrettable substitution can also occur when replacing a PFAS with another substance. The current proposal risks losing large parts of the European industrial manufacturing and runs against the ambition to strengthen the 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.

6.1 EU Strategy on hydrogen

The EU strategy on hydrogen puts forward a vision for the creation of a European hydrogen ecosystem for research and innovation, in order to scale up production and infrastructure to an international dimension. The rapid development of hydrogen is key to meet the EU's climate and energy security objectives and a key priority to achieve the goals of the European Green Deal. The European Commission has proposed to produce 10 million tonnes of renewable hydrogen by 2030 and to import 10 million tonnes by 2030. Recently, the Commission also set out new plans to stimulate and support investment in sustainable hydrogen production through a European Hydrogen Bank (EHB), accompanying the legislative proposal for a Net-Zero Industry Act, which aims to boost EU manufacturing of clean technologies.

Electrolysers and fuel cell membranes, the hydrogen industry's fundamental technologies, are heavily reliant on fluoropolymers. Polytetrafluoroethylene (PTFE) and Fluorinated ethylene propylene (FEP) are materials of choice for sealing components used in production, transport and storage of renewable hydrogen. This application is challenging particularly from the temperature perspective. On one hand, cryogenic conditions (e.g., close to -268°C) are involved during storage of hydrogen. On the other hand, hydrogen is one of the few gases that actually heat up when expanded. Fluoropolymers are well suited to cope with increased temperatures that may occur during hydrogen production. The proposed restriction, as it stands right now, will jeopardise these objectives and make the EU vulnerable to future geopolitical changes.

Relevant case study: If climate neutrality requires hydrogen, we cannot rule out PFAS - FPP4EU

6.2 REPowerEU plan

According to the REPower EU Plan, the European Union should aim at doubling the current deployment rate of individual heat pumps, resulting in a cumulative 10 million units by 2027.

Heat pumps are used in buildings to regulate the temperature, humidity, and purity of the air. The working process for heat pumps is based on the refrigeration cycle. Some gases that allow the refrigeration cycle to work in a safe and efficient manner are F-Gases. F-Gases possess unique characteristics that enable heat pumps to operate despite the complexity of the parameters that need to be taken into account – mainly harsh climate conditions, containment of hazards from flammable and toxic environments, and energy efficiency. The dossier submitters have acknowledged the lack of alternatives for refrigerants used in heat pumps and air conditioning and have thus proposed a 12-year derogation for maintenance and refilling of existing HVACR equipment without drop-in alternative(s).

Relevant case study: Heat Pumps: A future-proof solution for sustainable heating and cooling - FPP4EU

6.2.1 Energy Efficiency Directive

The energy consumption of EU data centres is projected to increase by almost 30% by 2030. The European Digital strategy[8] has therefore highlighted the need for data centres and telecommunications to become more energy efficient, reuse waste energy, and use more renewable energy sources.

Maintaining a cooling system is vital for the safety of all electronic equipment but these systems can account for almost 40% of the total electricity consumption. Immersing IT hardware in a non-conductive fluorochemical liquid, however, can reduce the cooling system's energy consumption by 95% and minimises water use[9].

The dossier submitters have identified[10] this market as one with strong growth potential for the coming years and as such it is essential for the EU to make sure that it has the necessary technologies and materials to keep up with demand.

6.2.2 EU Solar Energy Strategy

As part of the REPowerEU plan, the EU Solar Energy Strategy aims to bring online over 320 GW of solar photovoltaic (PV) by 2025 (more than double compared to 2020) and almost 600 GW by 2030[11]. The EU solar PV sector employed 357,000 full-time equivalent (direct and indirect) jobs in 2020 and this figure is expected to at least double by 2030, based on the European Commission's renewable targets[12]. Solar energy technologies have relatively high upfront costs, compared to other sources of energy, but low operational costs. This is also reflected in the distribution of jobs created, with the vast majority of them (80%) associated with solar deployment activities, whereas operation

[8] Shaping Europe's digital future (COM(2020) 67 final)
[9] Pérez, S., Arroba, P., & Moya, J. M. (2021). Energy-conscious optimization of Edge Computing through Deep Reinforcement Learning and two-phase immersion cooling. Future Generation Computer Systems, 125, 891-907.
[10] Annex XV restriction report. Proposal for a restriction on Per- and polyfluoroalkyl substances (PFASs) (p.57)
[11] EU solar energy strategy, COM(2022)
[12] SolarPower Europe, EU Solar Jobs Report 2021 (p.3)

and maintenance jobs represent a much smaller percentage (10%). Solar energy is one of the most job intense power technologies, creating huge amounts of local jobs, which are essential for many Member States dealing with rising unemployment rates.

In frontsheets, PFAS are used to increase the amount of light reaching the solar panel, whereas in backsheets they protect the PV modules from moisture, UV degradation and act as an electrical insulator. Fluoropolymer films in the front and backsheets of solar panels have been used to improve the performance of solar panels because of their hydrophobic properties. The build-up of dust, dirt or air pollution impacts the ability of light to reach the photovoltaic cells, therefore reducing energy output. In PFAS coatings, water is repelled by the surface of the solar panels and washes away along with dust and dirt[13]. They can be used in a wide range of sizes of solar panels, from grid-connected systems to portable units.

6.3 Batteries and waste batteries Regulation

In its proposal for the Batteries and waste batteries Regulation, the Commission outlined the importance of this initiative as an integral part of the European Green Deal. The EU Green Deal recognizes the importance of batteries in facilitating the transition to a sustainable, low-carbon economy and in the aim to enhance energy storage, promote electric mobility, support renewable energy integration, drive industrial transformation, and foster a circular economy. Already in October 2017, the European Commission launched the 'European Battery Alliance' and in 2018 put forward the Strategic Action Plan on Batteries, which states that "from 2025 onwards Europe could capture a batteries market of up to EUR 250 billion a year, served by at least 10 to 20 Gigafactories to cover EU demand".

The oxidation stability of fluorinated polymers enables their use in cathode materials. Electrode coatings with fluoropolymer binders ensure a longer use and better densification to achieve a higher energy density. Within the electrolyte, fluorinated materials are tailored to fit the application and allow the usage at low and high operational temperature or foster high power delivery. As it is highlighted by the dossier submitters, PFAS are not only used in lithium-ion batteries, but also in dry cell batteries[14]. Of course, lithium-ion batteries are used in most of today's all-electric and plug-in hybrid electric vehicles (PHEVs), making their continuous production an essential part of the EU's Green Deal.

Relevant case study: Powering electric vehicles with Lithium-ion batteries - FPP4EU

6.4 Pharmaceutical Strategy for Europe

In November 2020, following the outburst of the COVID-19 pandemic, the European Commission proposed a new pharmaceutical strategy for Europe, as a "patient-centred strategy that aims to ensure the quality and safety of medicines, while boosting the sector's global competitiveness". Shortages of medicines have been a serious concern in the EU for several years and both the

[13] OECD (2022), Per- and Polyfluoroalkyl Substances and Alternatives in Coatings, Paints and Varnishes (CPVs), Report on the Commercial Availability and Current Uses, OECD Series on Risk Management, No. 70, Environment, Health and Safety, Environment Directorate, OECD.
[14] Annex XV restriction report. Proposal for a restriction on Per- and polyfluoroalkyl substances (PFASs). Annex A (p.95)

European Parliament and Member States have called on the Commission to address this issue[15]. According to the strategy, the reasons for these shortages include among others "marketing strategies, parallel trade, scarce active pharmaceutical ingredients and raw materials".

In §4 c the restriction proposal includes a derogation on active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC. However, PFAS are also used in the production process of Active Pharmaceutical Ingredients and Medicinal products (for PFAS- and non-PFAS products), besides as Active Pharmaceutical Ingredients (API). Because of their combination of a set of properties (e.g., low protein binding, low leaching and chemical inertness), membranes made of fluoropolymers are used in many filtration steps during pharmaceutical production (bioburden, sterile filtration, virus filtration, ventilation). Further examples for fluoropolymer, including fluoroelastomers, applications are used in laboratory equipment as they are characterised by high resistance levels against chemicals and extreme purity. They are used in sampling and analysis equipment since they do not affect the parameters to be investigated and monitored, and do not interact with the chemicals or samples. PFAS are also used in vacuum technology because they are inert and do not react with aggressive chemicals or the processed media. The use of PFAS also leads to a massive increase in the service life and total life cycle of the vacuum pumps, resulting in less waste and therefore lower environmental impact.

Relevant case studies: Laboratory equipment is vital to making scientific advancements - FPP4EU

PFAS in the production process of medication and vaccines - FPP4EU

Multifunctional membrane – FPP4EU

6.5 Net Zero Industry Act

On the 16th of March, the European Commission put forward the Net Zero Industry Act, as part of the Green Deal Industrial Plan, with the goal of simplifying the regulatory framework, and improving the investment environment for the Union's manufacturing capacity of net-zero energy technologies. As it has been outlined both in this section and in the restriction proposal, almost all of the strategic net-zero technologies outlined in the Act[16] rely heavily on PFAS: Solar photovoltaic and solar thermal technologies, onshore wind and offshore renewable technologies, battery/storage technologies, heat pumps and geothermal energy technologies, electrolysers and fuel cells. The importance of PFAS in Europe's green and digital transition is further substantiated by a recent report conducted on behalf of the European Commission (DG GROW)[17]. The authors included PFAS in the top 20 Critical Chemicals, highlighting "the importance of considering derogations to allow continued use in the EU in potential future regulation to restrict its use".

[15] European Parliament resolution of 17 September 2020 on the shortage of medicines — how to address an emerging problem (2020/2071(INI)) and European Council Conclusions of 2 October 2020 (EUCO 13/20).
[16] Annexes to the proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net Zero Industry Act)
[17] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Hafner-Zimmermann, S., Jagaciak, M., Kołos, N.et al., Chem4EU – Foresight for chemicals : final report, Publications Office of the European Union, 2023

7. Transported isolated intermediates

The restriction proposals for the PFHxA, and the C_9-C_{14} PFCAs, included specific exemptions for "a substance that is to be used, or is used as a transported isolated intermediate". In the case of the PFOA restriction, this text was added later, following the advice of RAC to allow the manufacturing of alternatives[18]. The exemptions were granted provided that these substances are transported and used under strictly controlled conditions and points (a) to (f) of REACH Article 18(4) are met. Since the registration process for transported isolated intermediates, as well as the strictly controlled conditions are already outlined under REACH (Article 18) and given the examples of previous restrictions of PFAS, we believe that a similar derogation should be provided under the U-PFAS restriction as well. Additionally, PFAS are needed as transported isolated intermediates to be able to manufacture derogated substances/ uses in the EEA (e.g. for active substances PFAS moiety needs to be introduced). If no derogation for transported isolated intermediates is included in the U-PFAS restriction only import of exempted substances/articles would be possible with severe disadvantages for EU based industries.

8. Alternatives

When it comes to alternatives, we believe that the framework of this consultation is not clear as to their assessment. Due to the diversity and broad scope of the restriction, more specific information requirements on alternatives by authorities would help avoid confusion amongst the downstream user community. Alternatives should also be subject to a thorough risk assessment exercise combined with efficiency tests and socio-economic analysis. This is the only way to avoid regrettable substitution with non PFAS. Individual members companies may provide examples of non PFAS alternatives not meeting safety and/or efficiency requirements

It should be considered that, as alternatives may need to showcase the same properties as PFAS, they have a high probability to be persistent, too.

Finally, in many sectors (e.g. aerospace, pharmaceuticals) the regulatory approval process is very strict and very long, in order to ensure the safety of the applications. Even if alternatives are already available, they will have to be rigorously tested to be approved, and thus will not be able to enter the market in a few months or years. In applications where alternative chemistry is still being researched without success for several years, it may take over two decades before the final approval of non-PFAS chemistry is completed (e.g.: aviation fluid technologies).

9. Review clauses

In their opinions on previous restriction proposals under REACH, such as the PFOA and the synthetic polymer microparticles, RAC, SEAC as well as ECHA (as the dossier submitter), proposed to include clauses for the European Commission to review the restrictions 5 years after they enter into force. Even though the Commission can review restrictions, without having a specific mandate, we believe that such a provision could be beneficial in terms of the U-PFAS restriction. As it was highlighted above, many goals outlined in European strategies depend on PFAS. The unprecedented scope of the restriction coupled with the lack of information on PFAS uses in various sectors highlights the unpredictability of the restriction's consequences for the European Union. Specific review clauses

[18] European Commission Regulation (EU) 2017/1000

should make sure that the aforementioned European strategies and legislation will not be compromised by the lack of the necessary technologies and materials.

In various cases, the dossier submitters have found that the use of PFAS is necessary and there are currently no available alternatives in the market. This is why they have provided longer transition periods, of 13,5 years after Entry into Force. We believe that in many of those cases it is very possible that further R&D will not provide solutions bringing the same unique combination of properties that PFAS have, while also being easy to break down. In these cases it will be necessary to have a possibility to review in order to extend these derogations.

10. The economic impact of the restriction on the EU's industry

Regarding the economic impact of the restriction on the European industry, we would like to refer to a study commissioned by Cefic. An external consultant, Ricardo, was asked to assess business and business-driven economic cost impacts of RO1 and RO2 of the restriction proposal. The study can be found in Cefic's submission.

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