EU Focus Group Webinar:
"EU Green Deal in Need of Fluoropolymers"

(23 January 2023)

QUESTIONS & ANSWERS

1. GENERAL QUESTIONS

1.1. Where can I find recording to the event?

The recording of the entire Webinar is accessible through this link.

2. ABOUT PFAS & FLUOROPOLYMERS

2.1 What are PFAS?

Per- and polyfluoroalkyl substances (PFAS) are a large group of chemicals with widely different physical, chemical and biological properties. The general category PFAS is not based on the physiochemical or biological properties of the substances. Their legal definition varies by region. ECHA uses the following definition:

> *"PFAS are defined as substances that contain at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I atom attached to it).*
>
> *This definition is similar to the OECD definition, derived in 2021, which reads as: "PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS." [OECD. Series on Risk Management No. 61, 2021]. Substances meeting the chemical scope definition for this restriction proposal will therefore also meet the OECD PFAS definition".*

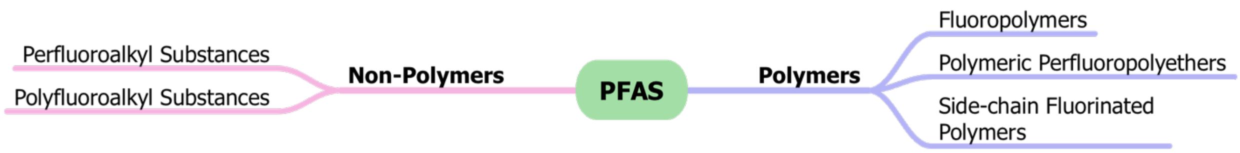
Thus, their only common denominator is that they include at least 1 perfluorinated methyl (-CF3-) or methylene (-CF2-) group.

2.2 What are Fluoropolymers?

Fluoropolymer are a polymer that has carbon backbone and contains fluorine to form strong carbon-fluoride bonds. This polymer performs well in extreme corrosive and high-temperature environments, and meets specific requirements to withstand extreme environments.

2.3 Are Fluoropolymers PFAS?

Yes. Chemically speaking, Fluoropolymers are a subgroup of PFAS since they include at least 1 perfluorinated methyl (-CF3-) or methylene (-CF2-) group.



2.4 How many Fluoropolymers are out there?

The Fluoropolymers class counts approximately a dozen of commercially relevant compounds. These include PTFE, PFA PVDF, FEP, PCTFE, ETFE etc. Notably, PTFE comprises over 60 % (by weight) of all fluoropolymers placed on the European market, the chemical and automotive industries being the strongest demand drivers.

3. INTRINSIC PROPERTIES OF FLUOROPOLYMERS

3.1 Are Fluoropolymers different from other PFAS?

Yes. While Fluoropolymers meet the broad structural definition of PFAS, they present completely different toxicological and ecotoxicological properties, environmental fate when compared to other PFAS.

For this reason, they should be considered as a separate class from any regulatory initiative on PFAS.

3.2 What makes Fluoropolymers unique?

The bond between fluorine and carbon, C-F, is the strongest chemical bond in organic chemistry characterized by its resistance to breaking when used, and are therefore, stable and durable.

Fluoropolymer's unique chemical property is, therefore, their stability, mechanical strength, inertness, thermal stability and resistance to chemical, biological and physical degradation. In practice, that translates into weather resistance, temperature resistance, chemical resistance, non-wetting and non-sticking properties and high-performance dielectric properties.

3.3 Where are Fluoropolymers used?

Fluoropolymers' unique combination of properties make them critical to modern life and a wide variety of sectors and industries including the Green Economy. Their applications span nearly every major sector of the European economy where products must meet specified performance and where failure is not an option.

Fluoropolymers are at the center of major technological advancements and will play a critical role in next wave of innovation such as 5G, green hydrogen, electric and autonomous vehicles, smart cities, and artificial intelligence. Here are but a few examples of their high societal value[1]:

- In the **transport industry**, fluoropolymers provide durable and effective protection against heat, aggressive fluids and fuels, humidity, vibrations and compressions. Fluoropolymers therefore **prolong the useful life of various components** critical for performance, emission control, and safety in both the automotive and aerospace industries, including lithium batteries.
- When it comes to the **chemicals industry**, fluoropolymers allow for the **safe storage and handling** of chemicals through protective equipment and linings. Their chemical stability allows them to be **resistant to some of the most corrosive substances** on the market, protecting works and equipment from harm.
- Fluoropolymers also play an important role in the **pharmaceutical and medical equipment industries**, preventing drug contamination and material failure. This **protects lives and saves costs** across the sector.
- In the **electronics industry**, fluoropolymers are critical to the semiconductor manufacturing process. Here various **fluoropolymer components can stand up to the aggressive etching chemicals** and provide the **necessary purity** required in the production of microchips and other electronics, where even trace contaminants can severely affect production yield.
- Fluoropolymers are an indispensable driver of the **European Green Deal –** for example, across **smart mobility, clean energy and sustainable industry** - and are used within various components of renewable energy installations, such as hydrogen and PV panels. In addition, they facilitate **advanced energy storage and conversion technologies** such as lithium-ion batteries.

3.4 Are Fluoropolymers toxic to human health?

No. According to the OECD, "*Polymers of low concern are those deemed to have insignificant environmental and human health impacts. Therefore, these polymers should have reduced regulatory requirements*[2]*.*

According to recent studies[3], the vast majority of fluoropolymers, including PTFE are considered to be of low concern. Fluoropolymers are, therefore, distinctly different from other polymeric and nonpolymeric PFAS and should be separated from them for hazard assessment or regulatory

[1] *Answer provided by https://fluoropolymers.plasticseurope.org/faq*

[2] *https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf*

[3] DOI: 10.1002/ieam.4035

purposes. Grouping fluoropolymers with all classes of PFAS for "read across" or structure–activity relationship assessment is not scientifically appropriate.

Fluoropolymers do not bioaccumulate (not B/vB) as the molecules insoluble in water and octanol and are too big to enter cells and they do not meet the criteria for being T (toxic).

3.5 Are Fluoropolymers toxic to the environment?

Fluoropolymers do not pose a significant risk to the environment in their intended use because of their thermal, chemical, photochemical, hydrolytic, oxidative, and biological stability. They are biologically stable and chemically inert (in presence of virtually any chemical) and do not dissolve in water. As such they are practically insoluble in water and not subject to long-range transport.

The only criterion that Fluoropolymers is persistency (P), which is the ecotoxicological definition of their durability.

3.6 Do Fluoropolymers meet REACH restriction criteria?

Article 68(1) of Regulation (EU) 1907/2006 (REACH) defines criteria for initiating a pan-European restriction procedure. A restriction may be initiated "when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis".

In other words, for a restriction to be adopted, there needs to be: (a) an unacceptable risk to human health or to the environment; (b) a causal link between that risk and the manufacture, use or placing on the market of the substance concerned; and (c) that risk needs to be addressed on a EU-wide basis.

Article 57 defines hazard classes for substances normally eligible for regulatory management measures under REACH. These include carcinogenicity, mutagenicity, reprotixicity (CMR) category 1A or 1B, persistent, bioaccumulative and toxic (PBT) or substances with "equivalent concern".

When it comes to Fluoropolymers, they meet Persistency (P) criterion. However, a persistency criterion alone has never been used as a ground for restricting substances under REACH Regulation so far.

3.7 Are Fluoropolymers in scope of the upcoming REACH PFAS Restriction?

Yes. As part of the upcoming PFAS restriction process, a group of five EEA countries have prepared a REACH dossier to ECHA with the proposal to restrict the manufacture, placing on the market and use of all PFAS substances.

PFAS are defined as "substances that contain at least one fully fluorinated methyl (CF3-) or methylene (-CF2) carbon atom (without any H/Cl/Br/I atom attached to it)".

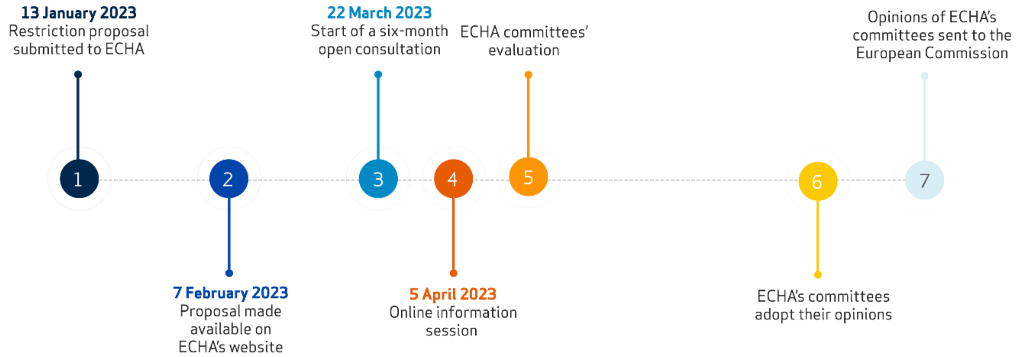
Fluoropolymers are a distinct class of PFAS. They are included in scope of restriction since their chemical structure includes at least 1 perfluorinated methyl (-CF3-) or methylene (-CF2) group.

4. REACH PFAS RESTRICTION PROCESS

4.1 What is the REACH PFAS Restriction timeline?

The five EEA Member States submitted their intention on 15 July 2021. The latest Call for Evidence closed on 17 October 2021. The countries submitted the proposal to ECHA on 13 January 2023 (originally planned for 15 July 2022). The conformity check has been concluded on February 7, 2023. After the proposal is presented, checked for conformity, a six-month Stakeholder Consultation will start on March 22, 2023.

Next steps will include an Opinion by the Risk Assessment Committee (RAC) and a Draft Opinion by the Committee for Socio-Economic Analysis (SEAC), followed by an additional 60-day stakeholder consultation and a final ECHA Opinion. The ECHA Opinion will then be submitted to the European Commission who will prepare a Draft Annex XVII sometime end of 2024-beginning 2025, submitting it to a vote by the REACH Committee.



4.2 What are possible restriction scenarios?

Potential restriction measures in Annex XVII can include a total ban on certain substance, setting limits on the amount of PFAS that can be found in certain products, banning certain products or components (restriction) containing PFAS, introducing labelling requirements for products containing PFAS, or the obligation to provide training to workers or information to consumers.

Product labelling is one of the most comment options. Product labels can provide consumers with information about the amount of PFAS present in the product and whether or not the product contains any known hazardous materials. Labelling is a useful tool for informing consumers about potential risks associated with the use of a product and can help to reduce exposure to PFAS.

Setting limits on the amount of PFAS that can be used in certain products is another potential regulatory measure. This measure is often used when existing bans are deemed to be insufficient. Limits on the amount of PFAS that can be used in products can help to reduce exposure to these substances, as well as provide clarity for manufacturers who are trying to comply with regulations.

Finally, governments can introduce mandatory testing requirements for products that contain PFAS. This can help to ensure that products are compliant with regulations and that the amount of PFAS present in the product is within acceptable levels.

More information on the official ECHA homepage: https://echa.europa.eu/regulations/reach/restriction

4.3 Should we expect derogations for Fluoropolymers?

The restriction proposal is set to be published on 7 February 2023 outlining the initial approach by the five EEA Member States. ECHA committees will then have to decide whether Fluoropolymers use meets conditions of "unacceptable risk" within the meaning of REACH Article 68(1).

In the worst-case scenario, partial derogation for a limited use of Fluoropolymers could be considered for instance in semiconductor, hydrogen economy, medical devices, automotive if they are used responsibly by the whole value chain.

A total ban on Fluoropolymers will have devastating effects on the European economy and European society.

4.4 What is the difference between a derogation and an exemption?

A derogation usually applies under to certain uses and applications of a substance. There are roughly six different types of derogation foreseen: Lack of information; Lack of suitable alternatives; EU overlapping legislation; Substances pose no risk; Socio-economic impacts; Other rules regulating further stages of the substance.

Some substances are totally exempted from REACH, such as radioactive substances, non-isolated intermediates, waste – but not products recovered from waste. In addition, partial exemption may be granted for food and feedstuff, medicinal products (e.g. for Registration and authorisation)

4.5 What is "essential use"? Will it apply to Fluoropolymers?

As part of the EU Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (CSS), the Commission commits to "*define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health".*

At this moment, it is not yet decided how and when the essential use concept will be applied to ongoing and future REACH Restriction process. As such, regulators need to rely on existing tools available to them, to assess the essentiality of a substance (e.g. The SEAC Committee evaluates the socio-economic impact of the proposed restriction on manufacture, placing on the market or use of a substance. This includes the assessment of comments and socio-economic analyses submitted by third parties.

Either way, the "essential use" concept is to apply to the "most harmful chemicals which are a priority for phasing out", as referred to in the CSS. Clearly, Fluoropolymers do not meet the latter definition.

Finally, the concept will be only introduced into the REACH Regulation after the upcoming legislative review and, hence will not be part of the current restriction proposal on PFAS.

5. MANUFACTURING FLUOROPOLYMERS

5.1 Are PFOA/PFOS emitted during manufacturing of Fluoropolymers?

No. PFOA and PFOS are banned in the EU. The have been under the EU's Persistent Organic Pollutants (POPs) Regulation. The Stockholm Convention also regulates the global elimination of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds. As such, these substances are no longer used in the EU in the manufacturing of Fluoropolymers.

5.2 What can we do to eliminate PFAS emissions from Fluoropolymers manufacturing process?

The release of fluorinated substances to air and water can be controlled at site level by putting in place state-of-the-art abatement technologies subject to local approvals and permits. By doing so, emissions may be reduced by 50-80%, however an emission reduction of 99% may depend on additional technologies, which are still in the early phases of development, thus cannot be installed (yet) at industrial scale. Some players are planning to achieve a 99 % emissions reduction level by 2030.

6. USES & APPLICATIONS OF FLUOROPOLYMERS

6.1 What are the uses of Fluoropolymers in the renewable energy industry?

Fluoropolymers play a significant role in the renewable energy industry such as:

- **Wind turbines:** Fluoropolymers are used in paints and coatings on the towers and blades of wind power generators because they provide high weather resistance and increased service life. They are also used a durable lubricants.
- **Solar installations:** Fluoropolymers are used in coatings for solar thermal installations as a protective armor from harsh environmental conditions, including extreme heat and moisture. Fluoropolymers also provide electrical insulation in the wiring of many critical components that are contained within solar panels, extending the lifetime of solar panels by up to 25 years.

- **Energy Storage Systems:** Fluoropolymers are a crucial component of energy storage systems like lithium-ion batteries and PEM fuel cells which comprise an increasing share of renewable energy.

6.2 What are the uses of Fluoropolymers in medical devices?

Some example applications include:

- **Surgically implantable medical devices:** Fluoropolymers are used in implantable medical devices like vascular grafts, stent-grafts, and surgical mesh to reduce the risk of failure, infections, medical complications, and replacements as well as to increase the lifetime of implants.
- **Heart patches:** Fluoropolymers are used to make various layers of heart patches to reduce the risk of complications associated with tissue attachment and equipment failure.
- **Catheters:** Fluoropolymers are used to make low-friction and clot-resistant coatings for catheters to support patient safety and comfort.
- **High Dielectric Insulators:** Fluoropolymers make possible high dielectric insulators in defibrillators, pacemakers, and CRT, PET, and MRI imaging devices.
- **3D printing:** Fluoropolymers are used in 3D printing applications that are supplementing supply chain disruptions for personal protective equipment like certified face masks.
- **COVID-19 testing and treatment:** Fluoropolymers are used to make ventilators and COVID-19 test kits that are critical in fighting the global pandemic.

6.3 What are the uses of Fluoropolymers in the automotive industry?

Fluoropolymers are widely used in the automotive sector. This includes conventional internal combustion engines powered cars as well as electric vehicles and cars which operate on hydrogen. As such they are also dependent on semiconductors, and other parts to operate them. Some examples:

- Fuel lines, fuel hoses, turbocharger hoses and hoses in hydraulic systems: Fluoropolymers are used for their resistance to high temperatures, helping prevent leaks and breakdowns.
- ABS brake lines: Fluoropolymers provide better brake efficiency and help absorb pressure.
- O-rings: Fluoropolymers are used as seals in fuel containment systems and fuel injectors.
- Shaft seals and valve stem seals: Fluoropolymers are used as a sealing component to protect from dust and aggressive lubricants.
- Air intake manifold and cylinder head gaskets: Fluoropolymers as used to provide essential heat and stress resistance to sealant beads that prevent gas and other liquid leakages.
- Greenhouse emission controls: Fluoropolymers are used to lower exhaust emissions, which reduces a vehicle's carbon footprint.
- Fuel cells and batteries in electric vehicles: Fluoropolymers are utilized in newer fuel cells and batteries, providing extra safety while maintaining high voltages.

7. ALTERNATIVES TO FLUOROPOLYMERS

7.1 Are alternatives to Fluoropolymers in SEMICONDUCTORS INDUSTRY?

As of today, it is estimated to no technical and economically feasible alternatives exist for fluoropolymers

More precistly, none of the potential alternatives to fluoropolymers used in semiconductor manufacturing had the required properties, including chemical resistance and purity, to successfully enable the process. Traditional metal options such as stainless steel and copper risk contamination and polyvinyl chloride and polypropylene do not have the chemical resistance, while polyether ether ketone is prone to kinking and has absorptive qualities. As such, the production of semiconductors is directly dependent on the overall availability of fluoropolymers and a potential restriction could cause the EU semiconductor industry to collapse.

7.2 Are there alternatives to Fluoropolymers in MEDICAL DEVICES INDUSTRY?

Fluoropolymers such as PTFE are used to insulate medical devices and protect them also from corrosion.

Due to their inert status and lack of bioavailability, provided by their high grade, they are excellent in providing the needed functions, providing unmatched qualities. As such, there are no known technically and economically feasible alternatives for many technical functions. Furthermore, it is not warranted that alternatives, if available, could comply with existing regulations such as the medical device regulation.

7.3 Are there alternative to Fluoropolymers in HYRDOGEN ECONOMY?

According to various industry estimates, no alternatives to currently used fluoropolymers in membranes used for the generation of hydrogen could replace fluoropolymers due fluoropolymers' high mechanical and chemical stability.

Alternative fuel cell and water electrolyser technologies that do not use fluoropolymer membranes were too large and heavy or are not commercially viable. Alkaline water electrolysers (AWEs) currently dominate the water electrolysis market, but their large size means they cannot meet the future demand for hydrogen in metropolitan areas. Anion electrolyte membrane electrolysers (AEMs) might provide an alternative, but this technology is currently in its infancy, and its potential is unclear.

8. ESSENTIALITY OF FLUOROPOLYMERS

8.1 Are Fluoropolymers essential for EU decarbonization goals?

Yes. Fluoropolymers are essential to meeting the EU's decarbonization goals, such as those from the Renewable Energy Directive and Hydrogen Strategy.

This is achieved through efficiency and protection of photovoltaics and solar thermal installations, wind turbines, hydrogen electrolysers, fuel cells, flow batteries, and lithium-ion batteries. They also help reduce GHG emissions in cars and other road transport carriers, and enable 5G data transfer speeds and digitalization.

Fluoropolymers are used in various components of renewable energy installations and are instrumental in meeting the EU's target of renewable energy consumption, as aimed at in the Renewable Energy Directive (REDIII). In photovoltaics and solar thermal installations, the energy generation is directly dependent on the right exposure to the sun and are fully exposed to the elements. The protection by fluoropolymers shields them effectively from heat, water, UV abrasion and chemical stress. They increase the efficiency and coating results in decreased need of mechanical cleaning. Like PV, wind farms are directly exposed to the environment. FPs ensure the smooth and safe operation of wind turbines and decrease their overall downtime through specialized coating and lubricants.

Fluoropolymers also help enable the recently published Hydrogen Strategy, which sets an ambitious target for renewable clean 'green' hydrogen in the energy mix by 2050, since they are added to membranes in hydrogen electrolysers, fuel cells and flow batteries so that charged particles can travel and prevent cross-contamination. Without them, newer generations of electrolysers for the cheap and safe generation of hydrogen would be unthinkable and we would have to resort back to more expensive and unreliable forms of hydrogen generation by using fossil fuels.

(Lithium-Ion) batteries could not be used on a large scale without Fluoropolymers making them flame retardant, thermally stable and extending lifetime, thus lowering the levelized cost of energy.

For the next generation of decarbonised cars and other road transport carriers, fluoropolymers are utilized in automobile components such as fuel lines, fuel hoses, O-rings, turbocharger hoses, and hoses in hydraulic systems, as well as electric vehicles, for their unique combination of properties. They help prevent leaks and breakdowns, while reducing GHG emissions – especially important given Euro 7 emission standard with a CO_2 emission target of 95 grams per kilometer, as well as the Zero Emissions cars foreseen in the current proposal of legislation.

Finally, fluoropolymers are critical in enabling 5G data transfer speeds and digitalization – which is a key requirement to making the EU a world leader for fully automated and connected mobility systems, as outlined in the European Commission's Digital Strategy. Fluoropolymers are used in the production of semiconductors that are needed to continue to enable technology and systems, and which are supported by the recently released European Chips Act.

9. EDUCATING ABOUT FLUOROPOLYMERS

9.1 How can Fluoropolymers' Downstream Users educate the society that Fluoropolymers are not problematic from an environmental standpoint?

In the context of the ongoing REACH Restriction process, ECHA will launch two public consultations – one on the Annex XV Proposal and another one on the Draft SEAC Opinion. All interested parties are encouraged to submit their comments.

Particular attention will be paid to the way Fluoropolymers are manufactured, used, whether or not they end up in the environment and socio-economic costs in case of a total ban.

More information will be published here.