PlasticsEurope Fluoropolymer Products Group (FPG)

Socioeconomic Impact Assessment for fluoropolymers

FPG response to the PFAS draft restriction proposal – Analysis of alternatives

15 September 2023

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Acronyms and Abbreviations

Name	Description
AEMEL	Anionic exchange membrane electrolysers
API	Active pharmaceutical ingredient
CfE	Call for Evidence
CSS	Chemicals Strategy for Sustainability
ECHA	European Chemicals Agency
ECTFE	Ethylene chlorotrifluoroethylene
EEA	European Economic Area (EU plus Norway, Iceland and Liechtenstein)
EPDM	Ethylene propylene diene terpolymer
ETFE	Ethylene tetrafluoroethylene
e-VTOL	Electrical vertical take-off and landing
FCM	Food contact materials
FDA	Food and Drug Administration
FEPM	1-Propene, polymer with 1,1,2,2-tetrafluoroethene
FEVE	Fluoroethylene vinyl ether
FEP	Fluorinated ethylene propylene
FFF	Fire-fighting foams
FFKM	Copolymer of tetrafluoroethylene and perfluoromethylvinylether
FP	Fluoropolymers
FPG	Fluoropolymers Product Group of PlasticsEurope
GDL	Gas diffusion layer
HEPA	High-efficiency particulate air
HNBR	Hydrogenated nitrile butadiene rubber
LNG	Liquefied natural gas
MDD	Medical Devices Directive 76/764/EEC
MDI	Metered dose inhalers
MDR	Medical Devices Regulation (EU) 2017/745
MEA	Membrane electrode assemblies
NBR	Nitrile butadiene rubber
OEM	Original Equipment Manufacturer
PA	Polyamide
PCTFE	Polychlorotrifluoroethylene
PEEK	Polyether ether ketone
PEMEL	Proton exchange membrane electrolysers
PEMFC	Proton exchange membrane fuel cells
PET	Polyethylene terephthalate
PFA	Perfluoroalkoxy polymer
PFAS	Per- and polyfluoroalkyl substances
PFCA	Perfluorocarboxylic acids
PFHxA	Undecafluorohexanoic acid
PFHxS	Perfluorohexane-1-sulphonic acid
PFOA	Perfluorooctanoic acid
PFPE	Perfluoropolyether
PP	Polypropylene

Name	Description
PPAP	Production part approval process
PPE	Personal protective equipment
PTFE	Polytetrafluoroethylene
PVC	Polyvinylchloride
PVDF	Polyvinylidene fluoride
SEA	Socioeconomic analysis
SOP	Start of production
TULAC	Textiles, upholstery, leather, apparel and carpets
VOC	Volatile organic compounds
XLPE	Cross-linked polyethylene

1. EXECUTIVE SUMMARY

1.1 Background information

On March 22, 2023, ECHA formally published the Annex XV report for the EU REACH restriction proposal and kicked off the six-month open public consultation giving all stakeholders the opportunity to submit information on their PFAS uses and the availability of alternatives. The public consultation is going to last until 25 September 2023.

The Fluoropolymers Product Group of PlasticsEurope (FPG) has prepared this report to participate in the public consultation on the proposal for a restriction of PFAS, by providing relevant data on the uses / applications of fluoropolymers in the EU, including information on, tonnages of fluoropolymers used, the availability of suitable alternatives, and the socioeconomic benefits of the continued use of fluoropolymers for the EU society. Within this report, the aim is to highlight the broad range of fluoropolymer uses in the EU and their significance for the EU society and economy.

The information presented in this report was collected via literature review of publicly available sources and through an extensive survey with FPG member companies, i.e., the fluoropolymer manufacturers, and downstream users of fluoropolymers, which received responses from over 130 companies in total.

It should be noted that FPG will submit an updated and expanded report by the end of the public consultation. Whilst this first document manly focuses on the uses / applications of fluoropolymers, tonnages of fluoropolymers used in the EU and the availability of suitable alternatives, the second report will contain more information on the socioeconomic arguments and the importance and societal benefits of the use of fluoropolymers for the EU.

1.2 Applications of fluoropolymers

Fluoropolymers are a versatile and durable group of materials, which are used in a very broad range of industry sectors, primarily for professional and industrial applications. They can be grouped in three main categories, namely fluoroplastics (PTFE, ETFE, PVDF, PFA, etc.), fluorinated elastomers (FFKM, etc.), and specialty fluoropolymers (PFPE as lubricant, amorphous fluoropolymers, fluorinated ionomers).

Fluoropolymers exhibit a combination of properties that make them the only suitable material for a broad range of applications, where durability to extreme temperatures, aggressive chemical agents and mechanical stress is essential, together with oil- and water-resistance, non-stick properties and / or low coefficient of friction. As a result, they are often the only type of materials suitable for use in applications where such harsh, extreme conditions are expected to be present.

Their versatility allows them to be used in different forms, such as:

- Coatings to protect a substrate from water, oil, chemicals or UV radiation, or to offer a low-friction surface in construction and transportation.
- Moulded sealing components to prevent leakage of hazardous or infectious agents in processes.
- Filter membranes, ensuring removal of all potential contamination in ultraclean manufacturing environments (e.g., in semiconductor manufacturing) or in the treatment of drinking water and wastewater.
- Ion-exchange membranes that are used in electrochemical processes, in the chemical industry and for power generation (e.g., fuel cells, hydrogen generation).
- Lubricants or lubricant additives in very demanding transport and industrial applications.

According to information provided by FPG members, in 2022 the quantities of fluoropolymers manufactured and imported in the EU were in the range of 40,000 – 95,000 tonnes. This indicates an increase to the volumes declared for 2020 in a previous SEA document on fluoropolymers, but it is within the range of fluoropolymer usage assumed in the PFAS restriction proposal. Transport (road, off-road and aerospace) applications accounted for the highest usage of fluoropolymers, followed by the chemical processing industry. Other critical sectors of fluoropolymer applications are energy (including power generation, Li-ion batteries, and hydrogen technologies), electronics and semiconductors, food processing (food contact and processing materials, cooking surfaces, packaging), medical devices, petroleum and mining, military and defence, technical and non-technical textiles, and water and wastewater treatment.

1.3 Analysis of alternatives

The fields of application for fluoropolymers are variable, but one common parameter is that fluoropolymers are chosen due to their superior performance in applications where other solutions are not available or would have significantly worse performance, leading to significant safety concerns, and need for more frequent maintenance or replacement due to failures. In some cases, such reduced performance would not be accepted by the final users of an article or the operators of a process.

Many of the fluoropolymer applications are in sectors that are governed by strict industry standards and regulatory processes, to ensure a high level of safety and performance, for the benefit and protection of the public. Such sectors are aerospace and transportation, construction, medical devices, electronics, food processing, and water and wastewater treatment.

Other manufacturing processes also need to ensure a high level of cleanliness and / or safety for both the workplace and the environment. For example, the chemical processing sector needs to prevent leakage of hazardous chemicals from transfer and processing equipment, such as piping, vessels, pumps and valves. Fluoropolymer linings, coatings and sealing is often the only suitable option. Furthermore, semiconductor, pharmaceutical, medical device and some fine chemical manufacturing processes need very clean environments, which can only be achieved through the use of fluoropolymer coating or membranes in filters. Fluoropolymer lubricants are also used in a broad range of applications where harsh conditions are expected and other materials cannot meet the performance and safety requirements.

In this broad range of applications, fluoropolymers are the material of choice, and, in many cases, required by the industry standards. Alternative materials cannot provide the combination of properties exhibited by fluoropolymers, as they cannot display the required resistance to a wide range of temperatures, degrade in presence of aggressive chemicals (e.g., petroleum products, caustic chemicals) or other contamination.

It must also be noted that fluoropolymers are usually more expensive than the potential alternative materials. The fact that they are preferred over cheaper materials, especially in some very cost-sensitive industries, such as chemical processing and transportation, is a strong indication that the potential alternatives are not suitable for the particular uses.

1.4 Conclusion

Overall, fluoropolymers are materials with a unique combination of properties that are used in a broad range of applications where harsh conditions are expected. They are critical for the safe use of equipment, and for maintaining ultra clean manufacturing and operating environments, with no leakage or contamination, over very long life spans. Their continued use in those applications is necessary, as they are outperforming alternatives and substitution may not be feasible, without several years of testing and qualification.

While work on substitution is ongoing, and potential alternatives have been identified for some applications, it is unlikely that it will be possible to replace fluoropolymers in all applications they are currently used in. The demanding specifications in these sectors mean that substitution will be achieved only through a long, structured process, and via rigorous testing. Considering the current status of alternatives and the unique combination of properties exhibited by fluorolymers in demanding applications, where safety and performance are a priority, it is very likely that fluoropolymers will need to continue being used for more than 10 or 15 years.

Table 1.1 Summary of fluoropolymer applications, status of alternatives, and substitution potential

Application	Indicative uses	Fluoropolymers used (not exhaustive)	Status of alternatives	Substitution potential
Transport, including automotive and aerospace	Fuel tubing and hose, engine oil and drivetrain seals (O-rings, gaskets), O-rings, seals, gaskets, ice-phobic coatings on helicopter rotor blades, window shades Exhaust gas pipes. Fuel cell membranes Oxygen, NO_x sensors, emission control systems. Pedal, battery, oil, radar, rain-light sensors Transmissions seals, thermal management systems Transfer or compression moulded automotive fuel Wires and cables Signal, control and power wires and cables insulated with fluoropolymers in military and civil aviation. Foams in aircraft insulation Electroluminescent lamps	Poly(TFE-ter-VDF-ter-PMVE), Poly(TFE-ter-PMVE-ter-VDF), Copolymers of tetrafluroethylene and propylene, FKM, FFKM, PVDF, PTFE, ETFE, FEP	Technical requirements and OEM specifications do not allow use of alternatives in harsh conditions (e.g., temperatures above 200°C, exposure to oils and fuel). Alternative rubbers cannot meet resistance to broad range of temperatures and to chemical agents in applications such as cable jacketing (for power transfer and sensors) and sealing.	The extreme performance requirements and specifications, combined with long qualification and certification processes make substitution of fluoropolymers in transport applications extremely difficult. Alternative development and qualification, process validation and certification and subsequent scale up and commercialisation of the alternative can be as long as 10 – 15 years or even longer in some cases (e.g., in aviation applications), even considering that a potential alternative has been identified.
Chemical processing	Fluid handling systems, Pipes (solid pipes and pipe linings), flue duct expansion joints. Seals, gaskets, valves, fittings, linings, filters, O-rings. PTFE-thread sealing tape. Tanks, lining of reaction vessels. Ion-exchange membranes (e.g., for chloralkali production). Wire and cable coatings for sensors, flowmeter tubes, and other electrical and electronic sensing and control equipment. Extrusion and moulding aids.	PTFE, FEP, PFA, ECTFE, EFPM, PVDF, fluorinated ionomers (ion exchange membranes), ETFE, FKM, and FFKM	Sealing from alternative rubbers cannot meet performance requirements for temperature (-40°C to 270°C), gas and chemical resistance. Chemical resistance is a main criterion, as alternative materials in pump, piping, etc. components cannot handle aggressive chemicals. Broad temperature compatibility is also essential for applications in flexible hoses and cryogenic media seals. These requirements	Alternative materials used in chemical processing cannot meet the high stability and performance requirements in chemical processes. In addition, any change in material requires long R&D, qualification, validation and commercialisation procedures before a suitable alternative is Industry stakeholders expect that such procedures can take several years, depending on the application, provided that a

Application	Indicative uses	Fluoropolymers used (not exhaustive)	Status of alternatives	Substitution potential
			can only be met by fluoropolymers. The alternatives to PEM cells in the essential chloralkali manufacturing industry use very hazardous materials (asbestos and mercury) and are also less energy efficient than membrane cells.	suitable alternative has been identified.
Construction	Wire & cable insulation, plenum cable insulation, Architectural protective and decorative coatings (e.g., on bridges), laminates, resistant paints, anti-graffiti and antifouling coatings, surface treatment in natural stone, metal, glass, plastic Bridge and offshore pad bearings Greenhouse films PTFE-thread seal tapes for pipes	PTFE, PVDF, PEF, PFA, ETFE	Potential alternatives in construction and architectural applications have worse performance than fluoropolymers and would be unsuitable where harsh conditions (environmental, mechanical) are expected. Alternative agricultural coatings have lower durability than fluoropolymers, which would require more frequent re-coating or replacements, with higher environmental load.	Substitution for construction and architectural applications, including PTFE-thread seal tapes depends heavily on stability testing over several years (6 to 12).
Energy, batteries and hydrogen	Solar panel coatings, O-rings, seals, gaskets, proton exchange membranes in fuel cells, in alkaline electrolysers and for hydrogen production via electrolysis, binder materials in the electrodes, both anode and cathode, and as a component of the gas diffusion layers (GDLs). Infrastructure for transport and storage of hydrogen (lining materials, seals etc.), seals in liquid organic hydrogen carrier technologies.	PVDF, Poly(TFE-ter-PMVE-ter-VDF), PTFE, ETFE, FKM, FFKM, other fluorinated elastomers, FEP	Some low energy alternatives for batteries are available, but they are not suitable for all applications, especially those that have space limitations, such as in transportation. In general, for Li-ion battery binders, the potential alternatives will require further testing and development before they can meet the performance requirements.	The limited suitability of potential alternatives (due to durability and performance) for these applications and the long R&D and qualification procedures make substitution of fluoropolymers very difficult. For hydrogen applications (e.g., electrolysis membranes), alternatives may not be available for the next 10 years at least.

Application	Indicative uses	Fluoropolymers used (not exhaustive)	Status of alternatives	Substitution potential
	Potentially in turbines in flanged connections in order to mitigate leakages, in power generation using H_2. Binders in electrodes of batteries, separator coatings, additives in the electrolyte, gaskets/seals, pipes, valves and sealings in the battery itself, manufacturing of positive electrodes for Li-ion cells Solar panel and wind turbine blade coatings.		For ion-exchange and electrolysis membranes used in hydrogen production, non-fluorinated alternatives still have worse durability and much shorter lifetimes than fluoropolymers. Sealing and cable jacketing alternative materials have lower resistance to temperature and chemicals than fluoropolymers, which make them unsuitable for use in applications with harsh conditions present.	For other applications, which also depend on meeting high performance requirements, substitution can also take many years.
Petroleum and mining	Chemical resistant components (e.g., seals) and coatings for extraction, transport and processing of petroleum and ores. Wire and cable insulation and covering Coating for sensors	FEP, PVDF, FFKM, FEP	Alternatives for applications in the petroleum and mining sector cannot meet the very high performance requirements for temperature (as high as 270°C), chemical and mechanical resistance. This appears to be recognised by the restriction proposal dossier submitters, who proposed a derogation for such uses. However, these performance requirements also extend to transport and processing of these chemicals and ores, with very extreme conditions often present.	The extreme performance requirements and specifications, combined with long R&D and qualification make substitution of fluoropolymers in petroleum and mining applications extremely difficult. Stakeholders expect that substitution can take as long as 10 years, provided that an alternative is available, which is not the case.
Food contact materials and packaging	Industrial, commercial and consumer cookware and bakeware Water and oil-repellent coating on paper products and packaging (cans, bags, etc.) Conveyor belts for cooking and drying foodstuff	PTFE, PFPE, FEPM, PVDF	Alternative materials for cook- and bakeware do not have the combination of properties that fluoropolymers offer and may fail in durability, non-stick, and temperature, chemical and abrasion resistance.	Food contact materials are heavily regulated and any FCM must meet several quality and safety standards. Any change would include identifying an approved FCM and

Application	Indicative uses	Fluoropolymers used (not exhaustive)	Status of alternatives	Substitution potential
	Processing / polymerisation aids for plastic film production Process lubricants		In addition, no suitable alternatives are available in the EU for processing aids.	running a series of durability and migration tests. The overall process can take at least three years, provided that the selected alternative is successful at all stages. High performance and safety requirements for FCM and the current status of alternatives means that substitution would take significant longer than that.
Electronics and semiconductors	Components of electronic devices (e.g., Hard disk drives), Semiconductor manufacturing (e.g., HEPA filters, wet processing equipment components) O-rings, seals, gaskets, parts and tubing used in the semiconductor processing industry, Welding and soldering agent, Insulation in wires and cables, Coatings, batteries and smart devices Powder coating for phone and tablet screens. Anti-reflective coatings for semiconductors Sensor applications (industrial, automotive, measuring and analytical)	PVDF, PFA, PFPE, PTFE FKM, FFKM, ECTFE, FEP	Alternatives for electronics and semiconductor applications cannot fulfil the temperature and chemical resistance required. The semiconductor industry in particular requires ultra-high purity and thermal resistance, which cannot be met by alternatives. Non-fluoropolymer alternatives are likely to cause contamination to products. Alternatives do not have the combination of properties offered by fluoropolymers and fail in temperature, chemical or mechanical resistance requirements. Analytical instruments and sensors also require high precision and cleanliness, and only fluoropolymers can offer the required level of purity.	The lack of alternatives for semiconductor applications, together with long R&D and qualification procedures make substitution in these applications extremely difficult. It can take as long as 10-15 years to develop an alternative to fluoropolymers, assuming that a suitable alternative is identified and there are no setbacks during the qualification and verification. Electronic equipment also has to carry out lengthy verification and validation testing to meet the very high performance and safety requirements by customers. This process can also take several years, especially considering that for many applications there are no alternatives. In addition, some products (e.g., cables and other electrical / electronic equipment) may need to receive third party approvals for CE Mark or other certifications

Application	Indicative uses	Fluoropolymers used (not exhaustive)	Status of alternatives	Substitution potential
				by independent third parties, which is a process that can take several years, subject to the third party's availability.
Water and wastewater treatment	Hollow fibre micro- and ultra-filtration water & wastewater treatment membranes Water piping	PTFE, PVDF	Experience with other materials such as polyether sulfone or chlorinated polyethylene have shown that the lack of flexibility, cleanability and chemical resistance result in short life expectancy and high operating cost for municipal and industrial users. Such materials may be in use for some low risk applications, but not for water with high levels of contamination such as surface water, urban WWTP and industrial wastewater. Fluoropolymers enable these waters to be used or reused for drinking water, utility water, process water or irrigation Ceramic based membranes are not suitable for large scale water and wastewater applications with space constraints.	Potential alternatives are not suitable for demanding water and wastewater applications where high levels of contamination are present and any substitution could take several years (as long as 5-10, but most likely over 15). Substitution is made even more difficult as the alternatives would require more space, which is not possible for most current installations, and many more frequent replacements.
Lubricants	High performance Lubricants (stable and inert) for applications in the aerospace, military, automotive, electronics, semiconductor, textile, chemical, paper, plastic and nuclear industries. High performance lubricants for engines and machinery. Lubrication for vacuum pumps, high-pressure oxygen equipment.	PFPE, PTFE	Alternatives cannot meet the high performance requirements in the various applications (automotive, chemical processing industry, food processing, drinking water treatment), as they have worse durability against chemicals and temperature and are dependent on the temperature, which is not the case for fluoropolymer-based lubricants.	Lack of high-performance alternatives for most applications makes substitution difficult. Furthermore, qualification and testing requirements for each application can take several years, depending on the industry sector.

Application	Indicative uses	Fluoropolymers used (not exhaustive)	Status of alternatives	Substitution potential
	Non-stick coatings as dry film lubricants in baked goods production, food processing, automotive and transportation, high-temperature kitchen equipment, medical equipment.			
Medical devices and pharmaceuticals	Biomedical devices Other medical devices, e.g., catheters, stents, heart patches, sutures, seals, lubricants, filters or surface treatment Coating in primary packaging components, coating for metered dose inhalers Analytical equipment and laboratory applications.	PTFE, ETFE, PVDF, FEP, FKM	Alternatives do not have the combination of thermal, chemical and mechanical resistance, together with the biocompatibility, offered by fluoropolymers. Particularly for cables used in medical equipment and in invasive procedures (e.g., endoscopy, surgeries), alternative rubbers are not conducive to the miniaturised equipment needed to perform them (e.g., endoscopy cables, guiding wires). Sealing and filtering equipment, relevant to the sensitive and low contamination tolerant manufacturing processes in these sectors, also do not have suitable alternatives, as discussed in sections on semiconductors, chemical processing, and petroleum and mining.	Medical devices and pharmaceuticals are heavily regulated products and any change in the product or the manufacturing process must undergo lengthy testing and qualification procedures and receive approval and certification from competent third parties. These processes could take 10-15 years to develop an alternative to fluoropolymers, but that could depend on the application, and on no unacceptable results during validation and approval.
TULAC	Waterproof and stain repellent clothing Chemical resistant PPE, fabrics, and high-performance textiles Membranes used as filtering media in applications with very low contamination tolerance (e.g., semi-conductors, pharmaceuticals, medical devices, chemical processing)	PTFE	Alternatives for filtering media cannot meet the performance and safety requirements, as discussed in other applications (e.g., semiconductors, chemical industry).	Substitution in demanding applications may not be possible in the short term, due to non-availability of suitable alternatives. For some applications, e.g., in pharmaceutical and medical devices, this can take much

Application	Indicative uses	Fluoropolymers used (not exhaustive)	Status of alternatives	Substitution potential
	Coated fabrics for architectural applications, tents and furniture		Alternatives do not appear to be available for more demanding applications (e.g., heavy rain resistance or dynamic water repellence, and high alcohol repellence needed in medical uses), where only the superior performance of fluoropolymers is suitable.	longer, as explained in the relevant section.
Metal plating and manufacturing of metal products	Noise suppression, anti-foam agent Electrical insulation and sealing in metal heating processes. Noise reduction and as dry bearings in metal product manufacturing processes.	PTFE	As per the information in the annexes to the restriction proposal, there is limited information available on alternatives for hard chrome plating.	Substitution activities for such applications would relate to the end product, which could be used in the transport, chemical, etc. sectors. Considering the discussion for the relevant applications, substitution of fluoropolymers in hard chrome plating applications can be long.
Cosmetics, consumer mixtures, ski wax and other uses	Polishes and waxes for stone surfaces for consumers and professionals Cosmetic applications (dental floss, perfume dip tips) Ski waxes	PTFE, FFKM	The dossier submitters mentioned strong evidence for the presence of technically feasible alternatives for consumer mixtures (e.g., for cleaning mixtures, waxes and polishes, dishwashing products, windscreen fluids for cars, and guitar strings), cosmetics and ski waxes. The stakeholder survey carried out for this report did not produce any additional information.	Considering the status of alternatives for these uses, as identified in the annexes to the restriction proposal, it is expected that substitution will be possible for most, if not all the applications.

2. BACKGROUND INFORMATION

2.1 Regulatory background on PFAS and fluoropolymers

On 14 October 2020, as part of the EU's zero pollution and circular economy ambitions (which in turn are a key commitments of the European Green Deal), the European Commission published its Chemicals Strategy for Sustainability (CSS). The strategy contains several 'key actions', one of which is to phase out per- and polyfluoroalkyl substances (PFAS) in the EU, unless their use is proven essential to society.

More specifically, with regard to PFAS, the strategy highlights the following:

"*Per- and polyfluoroalkyl substances (PFAS) require special attention, considering the large number of cases of contamination of soil and water - including drinking water - in the EU and globally, the number of people affected with a full spectrum of illnesses and the related societal and economic costs. That is why the Commission proposes a comprehensive set of actions to address the use of and contamination with PFAS. Those aim to ensure, in particular, that the use of PFAS is phased out in the EU, unless it is proven essential for society.*

The Commission will:

- *Ban all PFAS as a group in fire-fighting foams as well as in other uses, allowing their use only where they are essential for society;*
- *Address PFAS with a group approach, under relevant legislation on water, sustainable products, food, industrial emissions, and waste;*
- *Address PFAS concerns on a global scale through the relevant international fora and in bilateral policy dialogues with third countries;*
- *Establish an EU-wide approach and provide financial support under research and innovation programmes to identify and develop innovative methodologies for remediating PFAS contamination in the environment and in products;*
- *Provide research and innovation funding for safe innovations to substitute PFAS under Horizon Europe".*[1]

A Commission Staff Working Document[2] on PFAS accompanied the CSS. This further detailed the possibility for future regulatory initiatives concerning PFAS to address them as a group, primarily due to the prevalence of regrettable substitution as seen in the case of long-chain PFAS[3].

Meanwhile, the EU has been actively working to restrict the manufacture, use and placing on the market of PFAS in the EU.

- Entry 68 of Annex XVII of REACH (Restriction List) restricts the manufacture, use and placing on the market of C9-C14 perfluorocarboxylic acids (PFCAs), including their salts and any combinations thereof above a certain concentration in the mixture or article. The restriction includes derogations until July 2025 for uses in semi-conductor manufacturing, photographic coatings in films, invasive and implantable medical devices and in some fire-fighting foams[4]. This restriction originally also included

[1] European Commission (2020a): Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. Available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf (accessed 31 October 2022).

[2] European Commission (2020b): Commission Staff Working Document on Poly- and perfluoroalkyl substances (PFAS). Available at https://op.europa.eu/en/publication-detail/-/publication/2614f1f2-0f02-11eb-bc07-01aa75ed71a1/language-en (accessed 31 October 2022).

[3] As noted within the RfP "*the EU has been regulating certain PFASs under the EU REACH Regulation as well as proposing regulation of the group of substances under the UN Stockholm Convention (Persistent Organic Pollutants). The most notable regulatory activity was to get PFOA, its salts and related substances ('C8 chemistry') under the EU REACH Restriction scheme. The industry moved on from 'C8 chemistry' to alternatives such as the so-called short-chain chemistry, incl. perfluorohexanoic acid (PFHxA), its salts and related substances ('C6 chemistry'). A REACH Restriction proposal for PFHxA and C9-C14 substances was submitted in late December 2019. ECHA's opinion was finalized in mid-2022.*"

[4] See https://echa.europa.eu/documents/10162/f9e7b269-87cd-fc26-1a8e-b8c8b6e40c08

perfluorooctanoic acid (PFOA), its salts and PFOA-related substances, but the scope was narrowed down to C9-C14 acids after the inclusion of PFOA in Annex I (prohibition) of the POP Regulation in 2020.

- Perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances was also included in Annex IV (waste management provisions) of the POP Regulation in 2022.
- Undecafluorohexanoic acid (PFHxA), its salts and related substances are in the process of being restricted in the EU. The proposed restriction includes a number of timed derogations, such as for chrome-plating, in some fire-fighting foam applications, in protective garments, medical devices and in filtration and separation media. ECHA's committees have issued their final opinions and the restriction proposal will be decided by the European Commission[5].
- PFAS in fire-fighting foams (FFF)

It must be noted that the restriction initiatives listed above are all very specific, in that they define a narrow scope, either by listing specific substances of known risk (PFCAs, PFHxA) or a well-defined application (FFF).

Nevertheless, at the time of publication of the CSS, the REACH competent authorities for Denmark, Germany, the Netherlands, Norway and Sweden had already initiated preliminary work on the (now published) broad (universal) restriction, covering all uses of PFAS:

- A regulatory management option analysis conclusion document was published by the aforementioned authorities in June 2021[6]. The document concluded that "*a broad restriction under REACH covering all PFAS as a group would be the preferred option in order to limit as many (non-essential) uses as practically possible. This would have the greatest impact on minimising human and environmental exposure to PFAS, would also include currently unknown PFAS and uses, would prevent regrettable substitution of restricted PFAS by other PFAS";*
- The registry of restriction intentions until outcome was subsequently updated on 15 July 2021, with a scope for a "*restriction on manufacture, placing on the market and use of PFAS*"[7];
- A consultation was held between 19 July 2021 and 17 October 2021[8] whereby the authorities also presented multiple summary reports associated with EEA-based uses, tonnages and emissions. The purpose of the consultation was for stakeholders to check the presented data and provide feedback to support that the correct information is used for the assessment and preparation of the REACH Annex XV Restriction Dossier;
- Upon the submission of a formal restriction intention, the responsible competent authority has 12 months to submit its dossier to ECHA. However, the relevant authorities announced (in February 2022) a 6-month delay in submission, with an updated expected date of submission to ECHA of 13 January 2023.; and
- On February 7, 2023, ECHA pre-published the full restriction report for the EU REACH restriction proposal, which aims to ban the uses of more than 10,000 PFAS.
- On March 22, 2023, ECHA formally published the Annex XV report for the EU REACH restriction proposal and kicked off the six-month open public consultation (closing on 25 September 2023) giving all stakeholders the opportunity to submit information on their PFAS uses and the availability of alternatives.

The universal PFAS restriction proposal focuses on the manufacture, placing on the market and use of PFAS, including polymeric PFAS (fluoropolymers). The restriction proposal defines PFAS as "*Any substance that*

[5] See https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d

[6] See https://echa.europa.eu/documents/10162/a59647fb-fcc5-869b-10d4-c14258bbea1d.

[7] See https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b.

[8] See https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Downloads/DE/REACH/Verfahren/Beschr%C3%A4nkung/Consultation-PFAS.pdf?__blob=publicationFile&v=1.

contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).", though there are exceptions.

The scope of the proposal includes all uses of PFAS, regardless of whether they are specifically assessed or mentioned in the restriction proposal, unless a specific derogation applies. Figure 2.1 below reproduces Table A.1 from Annex A to the restriction proposal, which lists the PFAS applications and the level of scrutiny they received in the restriction proposal development process[9].

PFAS applications			
PFAS manufacture	Textile, upholstery, leather, apparel and carpets (TULAC)	Food contact materials and packaging	Metal plating and manufacture of metal products
Consumer mixtures	Cosmetics	Ski wax	Applications of fluorinated gases
Medical devices	Transport	Electronics and semiconductors	Energy sector
Construction products	Lubricants	Petroleum and mining	Waste stage PFAS applications
Laboratory equipment & filtration	Plant protection products and biocides	Chemical industry	Firefighting foam
Medicinal products	Plastics (other than packaging) and rubber/elastomer production (including flame retardants)	Pyrotechnics	Personal care products other than cosmetics
Fracking (currently hardly applicable in EEA)	Immersion cooling (currently hardly applicable in EEA)	Defence industry	Printing inks
Cement industry	Professional cleaning and polishing	Other niche applications	Uses (yet) unknown

- Green uses are researched in detail
- Blue uses are researched in general
- Orange uses not researched in detail
- Purple use: Separate restriction proposal

Figure 2.1 Overview of PFAS applications and the level at which they were researched (reproduced from Annex A to the PFAS restriction proposal)

The restriction proposal includes a number of proposed derogations and derogations under reconsideration. These are for most of the uses and applications of PFAS that were researched in detail. The broadness of their scope varies, from very specific single applications to broader sectors (e.g., for petroleum and mining industries).

2.2 Aim of the report

The Fluoropolymers Product Group of PlasticsEurope (FPG) intends to participate in the public consultation on the proposal for a restriction of PFAS, which was initiated by ECHA and runs until 25 September 2023. As part of their response, FPG wants to present relevant data on the uses / applications of fluoropolymers in the EU, including information on, tonnages of fluoropolymers used, the availability of suitable alternatives, and the socioeconomic benefits of the continued use of fluoropolymers for the EU society.

FPG intends to submit this information in two phases. In the first submission, which is the current document, the aim is to highlight the broad range of fluoropolymer uses in the EU and their significance for the EU society

[9] Annex A to the Annex XV Restriction report for Per- and poly-fluoroalkyl substances. Available online at: https://echa.europa.eu/documents/10162/f71f3bed-e48d-5004-d195-e293c38d0602, accessed on 29 May 2023

and economy. The report also aims to provide a high-level overview of the necessity of the use of fluoropolymers in the identified applications, where suitable alternatives are not yet available.

FPG will submit a more comprehensive report by the deadline of the public consultation, which will expand on the suitability of known alternatives for each identified application of fluoropolymers, and will examine the potential socioeconomic impacts of the proposed restriction.

2.3 Scope of the report

The restriction proposal defines PFAS as "*Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).*" There are many families of polymeric PFAS (fluoropolymers) manufactured and used in the EU as compounds or as fully formed articles. They can be largely grouped under fluoroplastics such as PTFE and fluorinated elastomers, while perfluoropolyethers is another family of FP with wide use.

As part of the public consultation, ECHA is requesting any data that could help them and the dossier submitters to inform their opinions and amend the restriction proposal. There are also more specific information requests, including:

1. Emissions in the end-of-life phase.
2. Impacts on the recycling industry.
3. Tonnage and emissions on the proposed derogations.
4. Information on alternatives, substitution potential and timelines, and socioeconomic impacts of non-use for uses that are not examined in detail in the restriction proposal.
5. Information on alternatives, substitution potential and socioeconomic impacts of non-use for the potential derogations that are marked for reconsideration.
6. Similar information as items 3 and 4 for any other use of PFAS, including fluoropolymers.
7. Degradation potential of specific PFAS groups

This report will mainly focus on points 3-6 above, and more specifically on outlining the extensive uses and applications of fluoropolymers, as well as on the assessment of potential alternatives and the possibility of substitution for the identified applications. High-level socioeconomic information will also be presented, mainly on the quantities of fluoropolymers used in each application in the EU.

The geographical scope of this document will be the EEA, as the area where the PFAS restriction will apply. The report will apply to fluoropolymers manufactured, imported and used in the EU, either as such, in mixtures or in/on articles, by the members of FPG that participated in the provision of information.

- It should be noted again that this is only the first of two reports on fluoropolymers. The second report, intended to be submitted in August or early September 2023, will contain information on the importance of uses of fluoropolymers for the EU economy and society and an assessment of the impacts of a no-derogation scenario. It may also contain updated and more specific information on alternatives and substitution that became available after this report was finalised, information on uses, functions and potential alternatives of fluoropolymers.
- An expansive stakeholder survey, covering the FPG member companies participating in the study and downstream users of fluoropolymers in the EEA. ERM prepared two questionnaires, one for FPG members and one for downstream stakeholders. The questionnaires included questions on the uses of fluoropolymers, their function, assessment of potential alternatives and the socioeconomic impacts in case no derogation was granted for the uses. The survey received a total of 144 responses, eight from FPG members and the remaining 136 from downstream stakeholders. The responses were collated and the aggregated information is included in the report.

3. ANALYSIS OF ALTERNATIVES TO FLUOROPOLYMERS

3.1 Identification of fluoropolymers produced by FPG members

Fluoropolymers are high MW polymers with fluorine atoms directly attached to their carbon-only backbone. Based on their properties and functions, fluoropolymers can be distinguished as fluoroplastics, fluorinated elastomers and specialty fluoropolymers[10].

- Fluoroplastics are the more populous category and include (full names in the Acronyms and Abbreviations table) PVDF (homopolymer and copolymer), PTFE, PCTFE. FEVE, ETFE, ECTFE, FEP, EFEP, etc. They can be further distinguished as non melt-processible (PTFE) and melt-processible fluoroplastics[11].
- Fluorinated elastomers include rubbers such as FKM, FEPM and FFKM. designed for demanding service applications in hostile environments characterized by broad operating temperature ranges in contact with industrial chemicals, oils, or fuels. These are typically used as raw materials for applications where elastomers with enhanced heat resistance, chemical resistance, resistance to aging and oxidation are required[12].
- Specialty fluoropolymers include:
  - amorphous fluoropolymers with very good optical processes, used for example in photolithography for semiconductor manufacturing,
  - fluorinated ionomers used primarily in electrochemical processes, such as hydrogen production by electrolysis, and the chloralkali industry,
  - perfluoropolyethers (PFPE), which are used as lubricants in a broad range of applications

Table 3.1 shows the fluoropolymers manufactured and imported in the EU by FPG members, as determined through the survey.

Table 3.1 Non-exhaustive list of fluoropolymers

Fluoropolymer	Type
PTFE	Fluoroplastic
FKM	Fluoroelastomer
FFKM	Fluoroelastomer
ECTFE	Fluoroplastic
ETFE	Fluoroplastic
PVDF	Fluoroplastic
FEP	Fluoroplastic
PFA	Fluoroplastic
FEVE	Fluoroplastic
PFPE	Specialty
FEPM	Fluoroelastomer
MFA	Fluoroplastic
Amorphous fluoropolymers	Specialty
Fluorinated ionomers	Specialty
Other specialty fluoropolymers	

[10] Korzeniowski, S.H. *et al*. (2022) Critical Review A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers Integr Environ Assess Manag. Available online at: https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646, accessed on 29 May 2023

[11] Drobny J.G, Applications of fluoropolymer films – Properties, processing and products. Copyright © 2020 Elsevier Inc. All rights reserved., DOI: https://doi.org/10.1016/C2017-0-04740-7

[12] Ibid.

3.2 Volumes of fluoropolymers in the EEA

For the purposes of this report, volumes of fluoropolymers used in different applications were collected by the participating FPG members. For confidentiality reasons, and to ensure protection of trade information among the members, the information was provided in the form of ranges. Table 3.2 presents the range of sales of fluoropolymers by FPG members in 2022, broken down by sector of use.

Table 3.2 Volumes and value of fluoropolymers sold in the EU in 2022 per sector of use

Sector of use	Fluoropolymers sold in EU in 2022 (in t)	Comments
Cosmetics and personal care	100 – 1,000	
Food contact materials and packaging	2,500 – 6,000	Not including lubricants
Construction materials and products	5,000 – 10,000	
Lubricants	500 – 2,500	
Medical devices	300 – 2,000	
Metal plating and manufacturing of metal products	20 – 200	
Ski treatment (waxes)	0 – 20	
TULAC (Textiles, upholstery, leather, apparel and carpets)	800 – 2,000	
Petroleum and mining	2,500 – 10.000	
Electronics and semiconductors	2,000 – 6,000	
Energy applications	5,000 – 10,000	Including batteries and hydrogen. Not including lubricants
Transportation	11,000 – 20,000	Not including lubricants
Waste and recycling	10 – 100	
Consumer mixtures	1 -100	
Aerospace	300 – 1,200	Not including lubricants
Industrial applications (chemical industry)	8,000 – 16,000	Not including lubricants
Water and wastewater treatment	1,000 – 6,000	
Other	1,000 – 2,000	
Total	**40,000 – 95,000**	

In a previously prepared SEA document, the total amount of fluoropolymers sold in the EU in 2020 was estimated to be approximately 40,000 tons. That value is still accurate and provides a good indication of the usage of fluoropolymers, even if it appears to be closer to the lower end of the range in Table 3.2. It should be noted that 2020 sales were likely affected by the lockdown and temporary recession caused by the Covid-19 pandemic, and it is natural to expect that sales have increased in the years that followed.

Fluoropolymer manufacturers all expect that overall demand for their materials to increase in the short- to mid-term, as demand for the specialised applications they are used in is also expected to increase. Some sectors of use, particularly those mostly related to consumers, are expected to contract. On the other hand, the manufacturers expect a healthy growth in sectors such as electronics and semiconductors and energy. It is possible that, where non-FP alternatives are developed, demand for fluoropolymers will drop, but, as will be discussed in the following sections, for most of their uses, fluoropolymers appear to be the only suitable material and substitution by alternatives can take several years.

3.3 Applications and products using fluoropolymers

Fluoropolymers are a versatile group of substances, which are preferred for their high performance with regards to their chemical resistance, thermal stability and water and oil repellence, as well as very low coefficient of friction for some fluoropolymers.

Fluoropolymers can be used in a number of ways. Most commonly, they can be found as:

- **Articles used to prevent egress of fluids from a piping or container**, e.g. seals, O-rings, gaskets, fittings. There is a broad range of sealing components, each having a different critical role in the equipment it is used, be it in chemical or oil & gas industry, in transport equipment or in electronics and energy applications.

- Anti-Extrusion Ring/Backup Ring (PTFE or FKM or FFKM) - A ring which is installed on the low-pressure side of a seal or packing, in order to prevent extrusion of the sealing material.
- Gasket (PTFE or FKM or FFKM) - A device which is used between two relatively static surfaces to prevent leakage.
- Bellows (PTFE or FKM) - Eliminates the need for a secondary dynamic seal.
- Wedge (PTFE) - Locates the rotating face against the stationary face.
- Primary Ring/Sealing Ring (PTFE, PFA Coating, PCTFE, FKM) - The seal between the rotating and stationary faces.
- Packing (PTFE) - It prevents product leakage and extends the lives of pumps, valves and other rotating equipment.
- Valve Seat/Seat Ring (PTFE or FKM) - A device which maintains the strength of the seal within the valve & facilitates a seal that is free of leaks.
- Sleeve (PVDF) - A device which maintains the strength of the seal within the valve & facilitates a seal that is free of leaks.
- Pumping Ring (PVDF) - A simplified impeller within a chamber, which circulates fluid through a closed loop for cooling purposes.
- O-Ring (FEP or PFA Coating or FKM or FFKM) - Creates a seal preventing liquids or gases escaping to atmosphere.
- Coating (PFA) – Provides a non-porous film and increased permeation resistance to many aggressive chemicals and highly corrosive atmospheres.
- Seat/Mating Ring (PCTFE) - A disc or ring-shaped member, mounted either on a shaft or in a housing, which provide the primary seal when in proximity to the face of an axially adjustable face-seal assembly.
- Bushing (PCTFE or FKM) - A type of bearing used to reduce friction between two surfaces sliding against each other.
- Cup Ring/Lip Seal (FKM) - A rotary shaft sealing device equipped with a sealing lip on both the inside & outside edges in order to exclude contaminants while retaining lubricants. In contrast to an O-ring, cup rings create less friction & will therefore wear more slowly.
- V-Ring (FKM) - Serves as an axial shaft seal to exclude contaminants while retaining lubricants.
- Gland Plate (PVDF or FKM) - Adaptive hardware designed to simplify the incorporation of the primary ring & mating ring into the equipment which requires the mechanical seal.

- **Coatings that protect surfaces from water and other aggressive chemicals** (e.g., petroleum products, fluorinated gases and other chemicals)
  - Lining and moulding of vessels (tanks, scrubbers), valves, bellows and containers (ETFE, PFA, FEP, PVDF, ECTFE, PTFE)[13].
  - Lining of pipes used to transfer aggressive chemicals or foodstuff (PTFE, PFA, MFA, FEP, PVDF, ETFE and ECTFE).
  - Lining of other chemical processing components, such as valves and pumps (PTFE)

[13] Ebnesajjad, S., (2016). Fluoroplastics, Volume 2. Copyright © 2015 Elsevier Inc. All rights reserved., ISBN: 978-1-4557-3199-2, DOI: https://doi.org/10.1016/C2012-0-05997-2

- **Membranes to facilitate filtering or ion exchange:**
  - Wastewater and potable water filtration membranes
  - Pharmaceutical filtration membranes
  - Electrolysis membranes, e.g., for hydrogen generation
  - HEPA filters for use in clean environments such as the pharmaceutical industry, and for ultrapure water systems in semiconductor manufacturing
  - Ion exchange membranes in inorganic chemical manufacturing, e.g., in chloralkali plants
- **Additives in formulations, such as high-performance lubricants**
  - PFPE based formulations (oils and greases, such as non-PFAS/PFPE based greases, PFPE/PTFE greases or pastes),
  - dry-film lubricants (PTFE), and
  - anti-rust formulations for bearings (PFPE). PFAS-based solvents as carrier/deposition are used in combination with PFPE oils.

The uses described above can be found in numerous, diverse applications. FPG considers that the list of uses and applications presented in the restriction proposal can be expanded, as several critical applications of fluoropolymers have been under-described or omitted. The restriction proposal captures the main types of use of fluoropolymers, as described in the set of bullet points above, but the range of their applications is wider than that. Table 3.3 presents a non-exhaustive list of fluoropolymer applications that were identified through literature review and the stakeholder (FPG members and downstream users) survey. Each application / use will be discussed separately in following sections.

Table 3.3 Non-exhaustive list of fluoropolymer applications

Application	Description of uses and products	Known fluoropolymers used	Source
Chemical processing	Fluid handling systems, Pipes (solid pipes and pipe linings), flue duct expansion joints Seals, gaskets, valves, fittings, linings, filters, O-rings, Tanks, lining of reaction vessels, Ion-exchange membranes (e.g., for chloralkali production), Wire and cable coatings for sensors, flowmeter tubes	PTFE, FEP, PFA, ECTFE, EFPM, PVDF, fluorinated ionomers (ion exchange membranes), ETFE, FKM, and FFKM	[1], [5], [6], [10]
Construction, architecture	Wire & cable insulation, plenum cable insulation, Architectural protective and decorative coatings (e.g., on bridges), laminates, resistant paints, anti-graffiti and antifouling coatings, surface treatment in natural stone, metal, glass, plastic Bridge and offshore pad bearings Greenhouse films PTFE-thread seal tapes for pipes	PTFE, PVDF, PEF, PFA, ETFE	[1], [5], [7], [8], [9], [10]
TULAC	Waterproof and stain repellent clothing, Chemical resistant PPE, fabrics, high-performance textiles	PTFE,	[1]
Food contact materials and packaging	Industrial, commercial and consumer cookware, Lubricants, Water and oil-repellent coating on paper products and packaging	PTFE, PFPE, FEPM, PVDF	[1], [10]

Application	Description of uses and products	Known fluoropolymers used	Source
	Conveyor belts for cooking and drying foodstuff		
Medical devices (and pharmaceuticals)	Biomedical devices Other medical devices, e.g., catheters, stents, heart patches, sutures, seals, lubricants, filters or surface treatment Coating in primary packaging components, coating for metered dose inhalers Analytical equipment and laboratory applications.	PTFE, ETFE, PVDF, FEP	[1], [3], [8], [9]
Water and wastewater treatment	Hollow fibre micro- and ultra-filtration water & wastewater treatment membranes, Water piping	PTFE, PVDF	[1]
Energy, including batteries and hydrogen	Solar panel coatings, O-rings, seals, gaskets, proton exchange membranes in fuel cells, in alkaline electrolysers and for hydrogen production via electrolysis, binder materials in the electrodes, both anode and cathode, and as a component of the gas diffusion layers (GDLs) Infrastructure for transport and storage of hydrogen (lining materials, seals etc.), seals in liquid organic hydrogen carrier technologies. Potentially in turbines in flanged connections in order to mitigate leakages, in power generation using H_2. Binders in electrodes of batteries, separator coatings, additives in the electrolyte, gaskets/seals, pipes, valves and sealings in the battery itself, manufacturing of positive electrodes for Li-ion cells Solar panel and wind turbine blade coatings.	PVDF, Poly(TFE-ter-PMVE-ter-VDF), PTFE, ETFE, FKM, FFKM, fluorinated elastomers, FEP	[1], [2], [4], [5]
Electronics and semiconductors	Electronic components, semiconductor manufacturing, O-rings, seals, gaskets, parts and tubing used in the semiconductor processing industry, welding and soldering agent, insulation in W&C, coatings, batteries and smart devices Powder coating for phone and tablet screens. Anti-reflective coatings for semiconductors	PVDF, PFA, PFPE, PTFE FKM, FFKM, ECTFE, FEP	[1], [5], [8], [9]
Petroleum and mininig	Chemical resistant components (e.g., seals) and coatings, wire and cable insulation and covering, coating for sensors	FEP, PVDF, FFKM, FEP	[1]

Application	Description of uses and products	Known fluoropolymers used	Source
Transportation, including automotive	Fuel tubing and hose, engine oil and drivetrain seals (O-rings, gaskets), Exhaust gas pipes. Fuel cell membranes Oxygen sensors, emission control systems. Transmissions seals, thermal management systems Transfer or compression moulded automotive fuel, Wires and cables	Poly(TFE-ter-VDF-ter-PMVE), Poly(TFE-ter-PMVE-ter-VDF), Copolymers of tetrafluroethylene and propylene, FKM, FFKM, PVDF, PTFE, ETFE, FEP	[1], [8], [10]
Aerospace	O-rings, seals, gaskets, ice-phobic coatings on helicopter rotor blades, window shades Signal, control and power wires and cables insulated with fluoropolymers in military and civil aviation. Foams in aircraft insulation Electroluminescent lamps	Poly(TFE-ter-PMVE-ter-VDF), fluorinated elastomers in general , ECTFE, PTFE, FEP	[1], [8], [9], [10]
Lubricants	High performance Lubricants (stable and inert) for applications in the aerospace, military, automotive, electronics, semiconductor, textile, chemical, paper, plastic and nuclear industries, high performance lubricants for engines and machinery, corrosion inhibitor	PFPE, PTFE	[1], [9]
Cosmetics and personal care	Limited uses identified, e.g., dental floss, perfume dipping tip	PFPE, PTFE	[1], survey
Metal plating and manufacturing of metal products	Noise suppression, anti-foam agent Electrical insulation and sealing in metal heating processes. Noise reduction and as dry bearings in metal product manufacturing processes.	PTFE	

Sources:
[1] https://one.oecd.org/document/env/cbc/mono(2022)1/en/pdf
[2] https://hydrogeneurope.eu/wp-content/uploads/2023/02/Hydrogen-Europe-position-paper-on-PFAS-ban_v12_FINAL.pdf
[3] https://www.efpia.eu/media/636866/pfas-position-_-efpia-and-animalhealtheurope-january-2022.pdf
[4] https://rechargebatteries.org/wp-content/uploads/2022/09/Call-for-Evidence_RECHARGE-_-PFAS-restriction-V1.pdf
[5] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/per-and-polyfluoroalkyl-substances-alternatives-in-coatings-paints-varnishes.pdf
[6] https://pubs.acs.org/doi/10.1021/acs.chemrev.6b00159
[7] https://www.sciencedirect.com/science/article/abs/pii/S0950061814002104, https://www.sciencedirect.com/science/article/abs/pii/S136403211731211X
[8] https://www.elsevier.com/books/fluoroplastics-volume-1/ebnesajjad/978-1-4557-3199-2
[9] https://www.elsevier.com/books/fluoroplastics-volume-2/ebnesajjad/978-1-4557-3197-8
[10] https://www.sciencedirect.com/book/9780128161289/applications-of-fluoropolymer-films - Chapter 11

3.3.1 Transport, including automotive and aerospace

3.3.1.1 Description of applications

A very large number of parts used in transport vehicles, passenger cars and motorbikes and airplanes either contains or is coated with fluoropolymers. They include sealing components, such as gaskets and O-rings, seals and guide elements for hydraulic cylinders, hoses and cables with fluoropolymer insulation. They are also used as dry lubricants and lubricant additives.

The components relevant to the transport sector are primarily safety components and, in general, operate at harsh conditions, such as high temperatures and pressures, in presence of chemical agents (oil, fuel, coolants, etc.), water. With regards to automotive, many components based on fluoropolymers are instrumental to the vehicle emission control (CO_2 and NO_x) and to the reduction of the fuel consumption in compliance with the latest standards of Euro6 and Euro7. A non-exhaustive list of applications for fluoropolymers in the transport and aerospace sector is below:

- Components of electrical vehicles, such as electric motors, cables for electrical gears and Li-ion batteries, which are essential for the EU to meet its decarbonisation goals until 2050.
- In every Li-Ion battery, PVDF is used as binder in the cathode and separator coating and often even as key material for the separators and FKM gaskets are largely used as well.
- Wires and cables for energy and data distribution (for communication and systems' control) in land vehicles and aircraft. Cables for Aircrafts, flight commands for Aircrafts, Satellites, e-VTOL, Drones, communication applications, radars, optronics systems
- Cables in land vehicle catalysts and NO_x, oxygen and lambda sensors which monitor the vehicles emissions and carbon footprint, contributing to emission control.
- Magnet wire wrap in traction motors and associated powertrain.
- Safety wires used in aircraft engines in high temperature areas. In addition, conventional manual flight controls have been replaced by an electronic system which has as primary benefit weight reduction. PTFE as insulation provides excellent electrical resistance combined with fire resistance and low smoke.
- Components such as seals, hoses and wiring needed to withstand extreme temperatures and aggressive chemicals in aircraft. Chemicals that the equipment must be durable against include jet fuel, engine lubrication oils, hydraulic fluids, rocket propellants and oxidizers. They must be able to do so at extreme (both very high and very low) temperatures. Fluoroelastomer seals have facilitated increase in engine temperature, which has improved engine efficiency by 40%, resulting in lower emissions.
- Aircraft interior may also be coated with fluoropolymer film, to facilitate safety, cleaning and anti-fouling over a long life span. The fluoropolymer coating also offers fire-retardant properties.
- Land vehicle and railway wheel bearing seals and in general seals protecting automotive bearings.
- FKM seals in combustion engines, water and oil filters, shock absorbers, cooling systems, turbochargers, gearboxes and transmissions, E-axles, crankshafts, clutches
- Low permeability FKM layers in the Fuel hoses and filler neck hoses, air Ducts (Turbo chargers) and Exhaust gas recirculation hoses used for the engine efficiency and the emission reduction. Both systems need FKM as the inner layer.
- Perfluorinated ionomers are used as membrane and electrode binder materials in fuel cell catalyst coated membranes (CCMs) and membrane electrode assemblies (MEAs) which are components in fuel cell stacks in fuel cell engines-in automotive
- Sensors (pedal, battery, oil, radar, rain-light, ABS NOx, Oxygen, Temperature)
- Propulsion, stern tube and thruster seals in marine vessels
- Special applications such as optical, probes, detection and embarked systems monitoring.
- Ionomers, specialized fluoropolymers with ionic properties, are used in ion exchange membranes (IEMs) that provide mechanical and chemical stability while delivering high proton conductivity. IEMs are critical components in fuel cells, while other FPs find use in batteries, sensors and circuits that are enabling the evolution of the transportation industry.

Fluoropolymers are used in the transport sector primarily due to their resistance and low friction properties, as well as due to their resistance to swelling and permeability. Fluoropolymers reduce evaporative emissions contributing to cleaner environment. In addition, PFPEs, which are mainly used as lubricants, are non-flammable, with very good chemical compatibility and thermal stability, while providing excellent lubricity at temperature extremes.

- Heat resistance and temperature stability are essential properties for automotive applications, where the parts are exposed to very high temperatures.
- Similarly for aerospace applications, wire insulation jackets must remain flexible and functional throughout their service lives (lasting more than 30 years) at temperatures that cycle from -50°C to +200°C. The wire insulation must exhibit abrasion and fire resistance so that short-circuits cannot develop into fires.
- In rail transport, fluoropolymers incorporated into wire wraps enables the high voltage, high current density motor designs used in high-speed rail motors. It provides insulation resistance around the magnetic wires in motor cores that are able to withstand the high electric field strengths in those applications where motors are running at voltages of up to 2000V AC and 3300V DC. Motors operate continuously at temperatures above 200°C, and so the wire jacket properties must be maintained in this temperature range.
- In addition, the fluoropolymer components are also exposed to harsh chemicals, such as oils and fuels, including biofuels which may contain high level of alcohol (methanol, ethanol) and environmental conditions (humidity, soil / dirt). Their high chemical compatibility ensures the right level of performance and safety of all the critical parts (engine, fuel systems, emission control systems, thermal management, transmissions). Moreover, they also protect the metal and plastic surfaces of the vehicle components.
- Hybrid vehicles technologies combine both the combustion engine technology and the Battery technology and fluoropolymers like FKM and PVDF are critical to ensure the needed level of performance and safety in the key components.
- The low coefficient of friction is an essential property for moving parts, as it contributes to increased durability of the parts and reduces energy and fuel use.
- Fluoropolymers are widely used in commercial and military airplanes, due to their excellent thermal stability that helps insulate the cables that run through the aircraft, their superior resistance to aging, radiation and fire and their chemical compatibility, which allows the safe and durable flow of fuel and other aircraft fluids.
- Beyond the earth’s atmosphere, fluoropolymer components are essential for the functioning of satellites and spacecraft, due to their durability, reliability and conductivity. For example, fluoropolymers used in the construction of the Mars Exploration Rover, Opportunity, helped reduce the risk of component failures owing to their superior thermal stability (up to 300 °C), lasting bend / twist flexibility and best-in-class dielectric properties. Thanks in large part to the durability of its components, Opportunity’s mission broke the record for travel in another planetary body by rolling more distance than a 26-mile marathon and operating for nearly 15 years.

It should be noted that the transport and aerospace sectors must meet very demanding standards with regards to part and vehicle performance and safety (as listed in Section 3.3.1.4, in the EU and globally. Fluoropolymers are critical in helping part and vehicle manufacturers in meeting these safety standards.

3.3.1.2 Status in the restriction proposal

Fluoropolymers are used in most of the transport applications identified in Annex A of the restriction proposal. The different components of vehicles and vessels using fluoropolymers are essential for their proper functioning and for the safety of passengers.

The restriction proposal lists the following proposed derogations for transport applications:

- Additives to hydraulic fluids for anti- erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry
- Refrigerants in mobile air conditioning (MAC)-systems in combustion engine vehicles with mechanical compressors
- Refrigerants in transport refrigeration other than in marine applications

As can be seen, the proposed derogations only cover a limited set of applications, focusing a lot on the defence and aerospace sector. The more numerous automotive applications may be covered by additional derogations, which are currently under consideration, as below:

- Applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods.

The scope of the above considered derogation can be rather broad, but it would require more specific criteria for both the users of fluoropolymers and the competent authorities to agree on whether an application is safety-critical of a vehicle.

3.3.1.3 Discussion on alternatives

As noted above, the restriction proposal lists multiple proposed derogations for transport applications. Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters, which also includes an assessment of alternatives. Concluding relevant remarks concerning each of the sub-uses are summarised below.

- The dossier submitters recognised the importance of the numerous fluoropolymer applications in transportation, as these components are necessary to ensure a high level of safety in all modes, including automotive, aircraft, rail, marine, and aerospace. They mention that in several of those applications, the use of a PFAS (which is most likely going to be a fluoropolymer) ensures the proper functioning of the vehicle. They also mention that identification of alternatives may not be easy, due to the various properties of fluoropolymers. Nevertheless, they only suggest the 12-year derogation for reconsideration.
- The dossier submitters recognise the difficulty in identifying alternatives and substitution in hydraulic fluids for the aviation and aerospace sector, due to the high requirements for anti-erosion and anti-corrosion purposes in hydraulic systems, such as landing gears. As a conclusion, they propose a 12-year derogation. Use of hydraulic fluids in other, non-aerospace applications is not mentioned.

At present, limited information has been forthcoming from consultation activities with regard to the ongoing criticality of fluoropolymers in transport applications. With this said, general statements have been provided with regard to e.g., extreme performance requirements in some applications, and the long certification processes which hinder prompt substitution activities within both the automotive and aerospace sectors. It is also indicated that high performance requirements in these industry sectors also mean that alternatives do not perform well enough to meet the required specifications.

Downstream users and FPG members commented in the survey that technical requirements and specifications from OEMs for cables do not allow for use of alternative materials in specific cases, such as high temperature operations (e.g., near the engine) or in areas exposed to fluids (fluid container, gearbox). Alternative materials for wire jacketing, such as XLPE cannot meet these specifications in all cases. The alternative material is cheaper as well, which means it would be preferred over fluoropolymers if they could meet the technical performance specifications.

In general, it has been commented that it is difficult to find performing alternatives for cable jacketing, where resistance to broad range of temperatures, as well as resistance to chemical agents, are required. Most materials, including PP, PVC, Polyethylene sulphone, polyimide and several rubbers, have lower resistance to heat and to aggressive chemicals, while they also have lower mechanical durability. PP, for example is not sufficiently stable in temperatures above 90°C and usually has a melting point below the temperatures where FP are normally used, and the same can be said for PVC. The different rubbers assessed have low temperature stability and would require thicker layers to achieve a comparable result, which would increase the weight and may require further design changes.

It was also noted that, for jacketing and sealing applications, alternative rubbers, apart from their stability in a narrow range of temperatures, also tend to swell excessively when in contact with fuel. Silicone rubbers and PEEK show better thermal stability compared to other plastics and rubbers (up to 180 and 220°C respectively), but this may still not be sufficient in some highly demanding applications, which may consistently reach temperatures of over 200°C. The alternatives also have moderate to low chemical resistance. Silicone also has poor abrasion resistance, making it unsuitable for dynamic sealing applications, while PEEK is less flexible than fluoropolymers.

It was mentioned that sensor cables with a mica coating for oxygen and nitrogen sensors can be used in transport applications, but mica has a high risk of cracking. To prevent that, they would need more copper and heavier insulation, which would increase the total weight of the component and the vehicle.

Given that the dossier submitters have marked the proposed derogation for 'PFASs in applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods, to the extent not addressed under other parts of this proposed restriction' for reconsideration, any FPG members supporting the proposed derogation are encouraged to provide significant additional information on the (lack of) technical and economic feasibility of potential alternatives will be required.

3.3.1.4 Substitution

As discussed in the previous section, there are no technically and economically feasible alternatives available for the various fluoropolymer applications in harsh conditions. While alternative materials exist, e.g., for some cable jacketing or sealing, these cannot meet the customer and regulatory specifications.

All components manufactured for transportation and aerospace applications must meet a series of very strict specifications. Those specifications arise from the customers, i.e., the vehicle manufacturers, and wider industry or regulatory standards. In fact, customer specifications often stem from industry standards. These can refer to safety and performance features. Table 3.4 shows a non-exhaustive list of industry standards that different components made containing fluoropolymers need to meet. Each component needs to meet a different set of these, depending on its function.

Table 3.4 Indicative list of standards for the transportation and aerospace sectors

Standard No	Standard description	Sector of relevance
NSA 935805	Flexible electrical conduits	Aerospace
Dornier-Werke GmbH DOL 90	Materials requiring chemical inertness	Aerospace
BOEING BMS 8-121D	Materials requiring chemical inertness	Aerospace
EN 45545-2	Fire protection	Railway
FAR/CS 25.853(d)	Heat release and smoke density	Aerospace
ISO 19642	Automotive cables	Automotive
AS22759/xy, MIL W16878 and EN 2267, ESC/SCC No. 3901/001		Aerospace
Euro 6 (EU Regulation 2017/1151)	Emission standards	Automotive
ISO 6722	Under hood cables for road vehicles	Automotive
SAE AS22759	Wire, Electrical, Fluoropolymer-Insulated, Copper or Copper Alloy	Aerospace

Furthermore, introducing a new component or material in any of these production lines needs to go through a very rigorous validation and qualification process, before it is accepted by the final manufacturer. A high-level description of this process includes:

- Development potential alternative materials and designs, including R&D, and iterative formulation and laboratory testing.
- Qualification and validation procedures, including the Customer Production Part Approval Process (PPAP), which includes testing of the part by the customer in real or simulated environments:

- Iterative general laboratory and component-specific testing.
- Engine or other equipment testing for qualification.
- Validation test plan creation and approval
- Engine or component testing and review of test results for approval
- Once approved, technical documentation must be updated.

- Certification, Process verification and start of production (SOP), involving another series of testing, scaling up and, where necessary, receive regulatory approval.

The duration of this substitution procedure may vary, depending on the actual application and sector. For example, it is expected that aviation and space applications will have longer qualification times, as they have more demanding specifications and a longer list of required validation tests. A typical time for the whole R&D and substitution process can be as long as 10-15 years in some cases, provided that the selected alternative is suitable and there is no need for iterations.

3.3.1.5 Conclusion on application

As recognised by the dossier submitters, the very high durability of fluoropolymers makes them critical safety materials in the whole transportation sector, including automotive, rail, marine, aviation and aerospace. Fluoropolymers are used in a broad range of applications in transportation ensuring that vehicles continue to operate without breakdowns or critical, and potentially life-threatening, failures throughout their intended service life.

The excellent chemical compatibility of fluoropolymers makes them highly resistant to fuel, oils and cooling or other fluids, and they can maintain their function over a very long life span. Alternatives are under examination and some may be available in the market, but these are mostly for lower end applications, as it is not easy to meet customer specifications and industry standards, such as Euro6 and Euro7 specifications.

Also, as mentioned elsewhere in the document, fluoropolymers are usually more expensive than alternative materials. Nevertheless, they are still preferred by the industry for their performance and for ensuring that the vehicle will operate safely for the passengers or goods carried.

3.3.2 Chemical processing

3.3.2.1 Description of applications

The chemicals industry is using fluoropolymers in manufacturing processes and equipment, to prevent leaks of hazardous fluids (gases and liquids) and to protect critical manufacturing equipment from aggressive chemicals. They can also be used in filters and other auxiliary equipment, such as heat exchangers and scrubbers.

These components are essential where corrosive chemicals are used or to reduce the health and environmental risk from emissions of hazardous substances, due to the broad chemical compatibility and durability of fluoropolymers. In addition, fluoropolymer components and coatings are commonly used in high-temperature processes, because of their excellent stability in high temperatures.

Fluoropolymers are widely used across the chemical processing industry, but some chemical industry sub-sectors for which their use is essential are polymer manufacturing, textiles, paper and pulp, and also manufacturing of fluoropolymers themselves, due to the presence of strong acids such as HCl and HF in the process.

Chloralkali manufacturing also relies heavily on fluoropolymers, as the process uses perfluorinated ionomers in diaphragms and ion exchange membranes used for the electrolysis of brine.

The survey of FPG members and downstream users of fluoropolymers has identified the following specific applications of fluoropolymers in chemical processing:

- Sealing material for rotating and other equipment, such as gaskets, sealing rings (O-rings), rotary seals, shaft seals, flanges, used in practically all equipment responsible for the transfer of fluids in a chemical plant. This includes pipes/tubes, connectors, pumps (including plunger and diaphragm pumps[14]), valves, dosing pumps and suction lances, (screw and piston) compressors and other machine tools, and mixers. Seals for cryogenic use were also mentioned in the downstream user survey. A broad range of FP has been reported to be used, mainly PTFE, FKM, FFKM and PVDF, while PFA, FEP, PCTFE, ETFE were also mentioned by respondents.
- Lining of piping, rection vessels, storage tanks and other fluid-handling components (e.g., flowmeters, sampling tubes) which would come in repeated and prolonged contact with aggressive chemicals. Use of fluoropolymers prevents corrosion and leakage and extends the lifetime of equipment. For example, unlined metal piping carrying acidic fluids can only last a couple of months, while a fluoropolymer lining can extend that lifetime to more than 20 years.
- Specific applications mentioned include a positive liquid tight seal preventing lubricant leakage and the ingress of contaminants in both static and dynamic conditions on horizontal and vertical equipment.
- In electronic equipment used in chemical processes. The electronic equipment can provide remote sensing (e.g., for pH, chlorine, ozone, fluorine concentrations, temperature) and control / automation functions.
- Primary insulation and jacket of electrical wiring and cables used in sensor systems, for general power supply and in applications with very high ambient temperatures, such as steel mills, but also for cryogenic applications, such as LNG storage and transport. The thermal stability and excellent chemical compatibility of fluoropolymers used (PTFE, FP, FEP, ETFE, PFA, PVDF, FKM) ensures longevity of the equipment and reduces the need for maintenance and the risk of failures.
- Non-adhesive PTFE based thread seal tapes for sealing of threaded pipes (metal, plastic, composites).
- Masterbatches, thermoplastics and elastomer, grease and oil additives, mould release
- Ion-exchange membranes (made out of fluorinated ionomers, often reinforced by PTFE fibres) and diaphragm technologies (mainly PTFE) are used in plants carrying out electrolysis[15]. Chloralkali plants in particular are a major industry using such membranes, especially as the older mercury- and asbestos-based (diaphragm) technologies are considered much more hazardous, considering the neurotoxic properties of mercury and the carcinogenic properties of asbestos. Membrane technique (using fluorinated ionomers) shows reduction of chlorate and chloride emissions, and reduction of salt and water consumption. It requires low investment and operating costs and produces high purity caustic. As cited by Eurochlor (CEFIC), it produces higher concentration of sodium hydroxide than diaphragms consisting of PTFE[16].

  It should be noted that chlorine is an important building block of chemistry, which can impact several downstream sectors, such as plastics (e.g., PVC, polyurethanes), epoxy resins, solvents, etc. Sodium hydroxide is also essential for the manufacturing of various organic and inorganic chemicals (e.g., detergents).
- PVDF membranes are also used for industrial water and wastewater filtration.
- Fluorinated elastomers allow stable extrusion and moulding processes for every type of technical rubber part and fitting in a wide range of polymerization constraints, reducing the risk of failures, and increasing product output.

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[14] Diaphragm pumps are tight pumps typically using a PTFE diaphragm, which separates the transported fluid from the environment. Fluoropolymers are often used as additional sealing.

[15] European Commission (2014). Best Available Techniques (BAT) Reference Document for the Production of Chlor-alkali. Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control). Available online at: https://eippcb.jrc.ec.europa.eu/reference/production-chlor-alkali-0, accessed on 29 May 2023

[16] Eurochlor (2020). The use of fluoropolymers in European chlor-alkali production. Available online at: https://www.eurochlor.org/wp-content/uploads/2020/07/11-Use-of-fluoropolymers-in-chlor-alkali.pdf, accessed on 29 May 2023

- PTFE is sometimes used as a filter medium and/or casing to ensure high chemical resistance in filtering particulate from fluids, such as, e.g., in the cement production industry.
- In lubricants used in chemical processes. In particular, PTFE is added as a powder lubricant in the matrix of various materials to reduce surface friction and mechanical wear. The applications identified include thermoplastics and elastomers, lithographic, flexographic, and gravure inks, greases, coatings and paints.

3.3.2.2 Status in the restriction proposal

The use of fluoropolymers in the chemical processing sector is not explicitly covered in the restriction proposal and not explicitly reflected in the proposed and considered derogations. The variety of applications of fluoropolymers in the chemical sector, as described in the previous section looks similar to applications in other sectors, such as petroleum and mining and food processing industries, but it should be noted that this is only part of the expansive applications. However, this does not appear to be recognised in the proposal.

The petroleum and mining applications in particular bear many similarities to the chemical processing sector, as they are used in harsh environments, with high temperatures and pressures and exposed to aggressive chemical agents. Similarly, manufacturing of electronics and semiconductors, as well as the pharmaceutical and medical device industries need to operate in environments with very low risk of leakage, because of the very low tolerance to contamination. The energy and transportation sector also use fluoropolymers in electrochemical applications, such as in fuel cells and PEM and electrolysis cells for hydrogen production.

3.3.2.3 Discussion on alternatives

As there was no section on chemical processing in the restriction proposal, there was no discussion on alternatives to PFAS / fluoropolymers for this group of applications in Annex E. Some of the uses (e.g., sealing, coating for tubing, pipes and reaction vessels, cables and wires) have been assessed under different uses (e.g., petroleum mining, electronics and semiconductors and medical devices), but this was done so under the specific conditions of the particular applications. The chemical sector, which also uses aggressive chemical agents and extreme temperature and pressure operational conditions, or need to transfer extremely pure water and reagents was not considered separately. Furthermore, the chloralkali manufacturing process, which relies extensively on membrane electrolysis, is not mentioned at all in the annexes to the proposal.

The broad range of fluoropolymer applications in the chemical industry is possible because of their unique combination of properties, as identified by FPG members and downstream users of fluoropolymers.

- Broad chemical compatibility, which allows it to be used in harsh environments and come in contact with aggressive, corrosive chemicals, maintaining its integrity and, therefore, protecting the equipment used in the process. Sealing equipment made of fluoropolymers exhibit low permeability to a broad range of fluids and chemicals including gases, oils, lubricants, fuels, and additives and are fire resistant. The chemical compatibility makes fluoropolymers reliable materials for use in dosing pumps that need to withstand high pressures and heavy loads.
- Non-stick properties allow easy cleaning and decontamination of surfaces of vessels and other equipment used in chemical processes. This can be of particular importance in tubes and seals used in paint, lacquer and coating industry. As this equipment is used for a large variety of products, each coloured differently, the fluoropolymer coating enables much faster cleaning with solvent, and potentially reduced use of solvent (VOC) in the process. The fluoropolymers' very low water solubility also ensures that coatings will not wash off during use.
- Resilience in a very broad temperature range, which allows fluoropolymers to be used in such diverse applications from cryogenic conditions (e.g., in LNG storage and transport) to high-temperature ones (e.g., steel mills).
- In addition to the above, resilience to the conditions of sterilisation has also been mentioned by several respondents. This is particularly important for equipment used in food processing and pharmaceutical or medical device equipment manufacturing, where the equipment must be regularly sterilised to avoid contamination.

- Very good electrical resistance, making fluoropolymers well suited for use as electrical insulators. Combined with their chemical compatibility, they become the first choice for applications in harsh environments.
- Low coefficient of friction makes fluoropolymers (and PTFE more specifically) effective solid lubricants in a variety of applications.
- Mechanical properties, such as fatigue strength, flexibility and bending strength of membranes and diaphragms made of fluoropolymers ensure that the components will not need to be replaced as often and will maintain their functionality for a longer period.

In the absence of fluoropolymer use in harsh conditions, materials that withstand these conditions less well may be used, but they would have a higher rate of failure. This will result in more frequent shutdowns of complicated processes, which is inherently unsafe and may cause unwanted spills and accidents. An alternative, in some cases, is the use of high-end alloys, which significantly drives costs up, and in extreme cases even exotic alloys won't have the required corrosion resistance.

There are several attempts to develop sealing (O-rings, various seals, gaskets) for use in the chemical sector. For example, O-rings and gaskets can be made out of EPDM, nitrile rubber and hydrogenated nitrile rubber. However, they cannot meet the customer specifications for temperature (which may range from -40°C to 270°C), as they cannot be used in temperatures above 200°C. In addition, they have poor gas or chemical resistance. It is the combination of durability under such harsh conditions that require the use of fluoropolymers such as PTFE, FFKM, and FKM and make their substitution so difficult. In general, while alternative materials are in use in seals for various equipment (pumps, pistons, etc.), where contact with highly aggressive chemicals is expected, these materials are not suitable, mainly due to poor chemical resistance. According to downstream stakeholders, alternative rubbers have been reported to have inferior physical and mechanical performance to fluoropolymers. Polyoxymethylene is not yet suitable due to plastic deformation.

The need for liners or body components in industrial equipment (e.g., pumps, shaft seals) to withstand very aggressive chemicals has been mentioned by several stakeholders. Any alternative material should be resistant to these chemicals, as per the requirements of the customers. In some cases, alternatives from glass or ceramics are already in use, but they may develop cracks under sudden outer forces or temperature stress. In general, fluoropolymers appear to be the only chemically compatible material to handle aggressive fluids. Most alternatives do not have good corrosion resistance. It should be noted that most alternatives are cheaper than PTFE and FFKM, so if they were suitable, they would be bound to be used in pumps or valves. In diaphragm pumps, stainless steel sheets could replace PTFE diaphragms, but it cannot be used in all applications as it has much lower flexibility. High nickel alloys may also be used in pipes, tubes, pumps, valves and vessels, due to their good corrosion resistance and high melting points, but their performance is still worse than fluoropolymers. In addition, they do not allow for design flexibility when used in sealing applications.

Gold-plated steel has been used in the past, before the introduction of fluoropolymers, in piping and chemical reactors, to prevent corrosion. However, this would significantly increase the demand for gold and it would increase the costs significantly, especially as the price of gold could increase as a result of this high demand.

Flexible hoses (and pipes) that are used to transport aggressive agents in the chemical industry usually have a liner that protects the equipment from the chemical. Thermoplastics, such as PP and PVC cannot meet the temperature requirements. Furthermore, rubbers (such as EPDM and HNBR) are used for some applications, but not when certain chemicals are transferred or there are high temperatures. Chemical resistance appears to be a major disadvantage of rubbers for flexible hoses. Metal alternatives (stainless steel, and nickel alloys) do not have good corrosion resistance and are less flexible. Furthermore, while the raw material is cheaper, the end product may be more expensive. PA has been mentioned as an alternative for hoses, but they need more frequent flushing, as their anti-adhesive properties are worse than FP.

Another specific application mentioned by stakeholders is in seals for cryogenic media, which cannot use metallic materials, as there is a high risk of spark generation, which could cause ignition. Safety valves from alternative (non-fluoropolymer) rubbers would have low resistance to the very low temperatures in cryogenic processes (e.g., handling liquefied gases). A stakeholder mentioned that, for industrial applications, nitrile or EPDM rubber could replace fluoropolymers, though it was also noted that new R&D would be needed.

For chloralkali manufacturing, the membrane cell has the lowest toxicity potential from all the available technologies. It was developed in Japan in the 1970s, as a result of the environmental pressures that arose from the incident in Minamata and the need to eliminate the use of mercury in the industry[17]. Mercury is highly toxic and has also been phased out in Europe since 2017 due to health and environmental concerns and as part of the EU's commitment to the Minamata Convention[18, 19]. Asbestos, which is used in diaphragm cells, is a known carcinogen, and causes asbestosis and pleural thickening (lining of lung thickens and swells)[20].

In addition, there is a much higher energy consumption with diaphragm and mercury-based technologies than with fluoropolymer membranes. Asbestos based diaphragm technology has been replaced by PTFE diaphragms however this is still a PFAS. From the BREF document it can be seen that membrane cells use the lowest amount of electrical energy and have many advantages[21].

- The mercury cell technique had the highest electrical energy consumption with 3,000 to 4,400 AC kWh/t Cl_2 produced. The electrical energy consumption of a mercury cell is relatively constant over time, however it changes at the end of the lifetime of the anode coatings.
- The electrical energy consumption of diaphragm cells ranges from approximately 2 600 to 3 100 AC kWh/t Cl_2 produced. Energy consumption however increases with the lifetime of the diaphragms.
- The electrical energy consumption of membrane cells ranges from approximately 2 300 to 3 000 AC kWh/t Cl_2 produced however it raises with lifetime of membranes and electrodes.

3.3.2.4 Substitution

Manufacturers of equipment that is used in the chemical industry need to comply with customer specifications and industry standards. These relate to performance and, importantly, safety of the equipment. Table 3.5 lists some of the international standards that manufacturers of equipment for chemical processing need to comply with.

Table 3.5 Indicative list of standards for the chemical processing industry

Standard No	Standard description	Relevant equipment
ISO 10931:2005	Plastics piping systems for industrial applications	
ISO 9080	Determination of the long-term hydrostatic strength of thermoplastics materials in pipe form by extrapolation	Plastics piping and ducting systems
DVS 2205-1 Beiblatt 4:2012	Calculation of tanks and apparatus made of thermoplastics	Tanks, vessels
ISO 4433-1:1997	Resistance to liquid chemicals	Thermoplastic pipes
ISO 11925-2	Reaction to fire tests	All
EN 13823	Single Burning Item (SBI) test	All
API 610	Centrifugal pump standard	Centrifugal pumps

Introducing a change in a chemical process, in the form of a new material (instead of fluoropolymers) requires a series of steps. Each of these steps need to be completed before the alternative part or material is accepted

[17] European Commission (2014). Best Available Techniques (BAT) Reference Document for the Production of Chlor-alkali. Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control). Available online at: https://eippcb.jrc.ec.europa.eu/reference/production-chlor-alkali-0, accessed on 29 May 2023

[18] European Commission website – Mercury. Available online at: https://environment.ec.europa.eu/topics/chemicals/mercury_en, accessed on 29 May 2023

[19] Thomas W. Clarkson & Laszlo Magos (2006) The Toxicology of Mercury and Its Chemical Compounds, Critical Reviews in Toxicology, 36:8, 609-662, DOI: 10.1080/10408440600845619

[20] European Environment Agency website – Asbestos. Available online at: https://www.eea.europa.eu/publications/environmental-burden-of-cancer/asbestos, accessed on 29 May 2023.

[21] European Commission (2014). Best Available Techniques (BAT) Reference Document for the Production of Chlor-alkali. Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control). Available online at: https://eippcb.jrc.ec.europa.eu/reference/production-chlor-alkali-0, accessed on 29 May 2023

by the customer or placed in the market. Similar to the automotive and aerospace sectors, the change process includes:

- Identification of alternative materials and designs and selection of most suitable ones. This includes a comprehensive literature review to identify potential alternatives and then forming a partnership with a third party, such as a university or chemical manufacturer, to develop a new polymer that would meet the use specifications. If no suitable alternatives are available, as appears to be the case for most applications of fluoropolymers, such a process could take as long as 10 years, as per the comments of downstream users.
- Validation of design against customer specifications
  - Initial project review to identify what will be needed to produce the potential alternative (e.g., facilities, equipment, raw materials and logistics)
  - Design review, including reviews of processes, inspection techniques, and similar products and reproducibility, risk assessment of the selected product and manufacturing processes, potential modifications in the process, availability of raw materials, etc.
  - Product verification, with identification of manufacturing sites, identification of operational constraints and risks, preliminary design of the manufacturing processes, and a general understanding of the process and product capabilities. This is followed by a series of analyses and assessments to determine the resources needed for manufacturing a prototype and scaling up to commercial production. In the end, a manufacturing process and a manufacturing control plan should be drawn, with sufficient confidence and understanding of the risks and any limitations.
  - Product validation (including pilot production), which refines the conclusions of the previous phase with regards to the raw materials (and associated costs and lead times), the manufacturing processes, any new equipment and tools needed, timelines for commercialisation, and any health, safety and environmental concerns and risks. During this phase pilot / low volume manufacturing begins, and design of the new product freezes, provided that it meets the specifications.
- Customer approval may also be required in some cases, for any product undergoing redesign. This can take place at the product verification or validation phases and could add additional time to the process (up to one year in some cases).
- Product commercialisation takes place once the product and process design have been decided upon and any required customer approvals have been received. This phase includes scaling up of the production by setting up the necessary workstations at production sites, with suitable trained personnel in place. Manufacturing programmes and procedures are also finalised and implemented. Any product standards requiring fluoropolymers will also need to be revised and this is also a process that can take several months, if not years.

This process can take several years to complete, once a suitable alternative is identified. As discussed in the previous sector, for applications with harsh conditions (e.g., wide range of temperature, high pressure, aggressive chemicals, electrical currents) there are no suitable alternatives and further R&D, and further testing will be needed before one is identified.

3.3.2.5 Conclusion on application

The chemical processing sector is among the major users of fluoropolymers in the EU. The excellent durability of those materials in presence of extreme (both high and cryogenic) temperatures, aggressive chemical agents and high pressure potentials, together with good flexibility, abrasion resistance and non-stick properties, make fluoropolymers the material of choice for several demanding industrial processes. Among such processes are petrochemicals (in distilleries and synthesis plants), manufacturing of polymers (including fluoropolymers), as well as electrochemical processes, such as chloralkali manufacturing.

Available potential alternatives cannot meet the performance of fluoropolymers and usually fail in one or more resistance requirements, e.g., corrosion, or heat resistance over a broad temperature range.

Development of those alternatives would require several years of research and validation, so that they become suitable across the whole range of applications in the chemical industry. As such, the chemical processing sector must continue the use of fluoropolymers for their demanding processes, to ensure minimal leakage of hazardous chemicals and uninterrupted manufacturing of thousands of chemicals.

The chloralkali manufacturing process is also notable, as the ion-exchange membrane technology is the least hazardous of the alternatives, which include mercury and asbestos. In addition, the output of the process, namely chlorine and sodium hydroxide are building blocks for the wider chemical industry. Chlorine, in particular, is necessary for the manufacture of some of the alternatives to fluoropolymers that are discussed in the restriction proposal and in this document, such as PVC and polyurethanes.

3.3.3 Construction materials

3.3.3.1 Description of applications

The construction sector is using a broad range of fluoropolymer-based construction materials and coatings, because of their versatility, light weight and resistance to wear and corrosion from exposure to harsh conditions, as well as because of their resistance to fire. Architectural materials very often have a fluoropolymer coating or use films and other components made of fluoropolymers, typically PTFE, ETFE and PVDF.

More specific construction applications of fluoropolymers, collected from literature and the FPG and downstream user surveys, are listed below. It should be noted that the list is not exhaustive, but it is expected to cover the vast majority of fluoropolymers in construction and architecture.

- Coatings for a broad range of materials, including concrete, metal, wood, marble and stone. Those coatings usually have oil- and / or water-repellent function on all these surfaces, thus protecting the building material from water and other harsh chemicals, and also protecting from ingress of water. Such coatings include FP-based paints, coatings and varnishes, which can be applied in a variety of ways[22]. Powder coatings are used on the exterior surfaces of bridges and buildings. Anti-graffiti coatings used on the surfaces of buildings and walls (as well as in public transport) allow for easier cleaning of those surfaces. Aerosol spray and water- and solvent-based paints are also used on bridges and building construction. Finally, varnishes are used on a variety of surfaces (e.g., stone, tiles, work surfaces, kitchen surfaces) to protect the surface from wear and corrosion.
- Architectural coatings, usually made of PVDF, ETFE and FEVE. Architectural films (typically PVDF and, primarily, ETFE) are applied on various surfaces in buildings as protective coating in applications where a lifespan of several decades is needed. These coatings protect the substrate, which can be any material, from weather and environmental conditions. Applications include coatings of bridges and other industrial structures, as well as large constructions, such as roofs of stadiums and domes. They can be transparent, allowing natural light in the building and reducing the need for artificial lighting, and consequently energy usage. FEVE is commonly used in paints and coatings for buildings and bridges[23].
- Bridge and offshore pad bearings. Fluoropolymers are used as seals to protect the bearings from the harsh environmental conditions. In some applications, fluoropolymers are used as coating of the bearings, both to protect from corrosion, as well as because of their low friction coefficient, which reduces wear.
- Ultra-thin ETFE films (ETFE foil) are used to substitute traditional glass roofs in greenhouses. Also used as building structures of stadium, as domes e.g., Allianz Arena in Munich, Rotterdam Floating Pavilion in Rotterdam. They are treated with an anti-drip coating, designed to increase the yields of plants, flowers, fruits and vegetables grown inside commercial greenhouses. ETFE foils allows maximum UV light

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[22] OECD, 2022. Per- and Polyfluoroalkyl Substances and Alternatives in Coatings, Paints and Varnishes (CPVs). Available online at: https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/per-and-polyfluoroalkyl-substances-alternatives-in-coatings-paints-varnishes.pdf, accessed on 29 May 2023.

[23] Hintzer, K., Zipplies, T., Carlson, D. P., & Schmiegel, W. (2013). Fluoropolymers, Organic. In Ullmann's Encyclopedia of Industrial Chemistry. Wiley. https://doi.org/10.1002/14356007.a11_393.pub2

transmission to ensure early blooms and higher quality fruit and vegetables. PTFE is used in architectural fabrics (PTFE coated glass cloth). It is resistant to UV light, waterproof, windproof and chemically inert. Translucent coated glass cloth allows natural light to pass through onto the pitch of the stadium.

- Sealings, O-rings and gaskets for hydraulic devices, pipes, joints, water and gas conveyors. They are also used in seals, vents, pistons, manifolds.
- Wiring and cables used in the building may also have fluoropolymer insulation and / or jacketing to protect it from aggressive chemical agents. As fluoropolymers are also fire-resistant, they reduce the fire risk in the building.
- Non adhesive PTFE based thread seal tapes for sealing of threaded pipes (metal, plastic, composites).

The durability of fluoropolymers are among the main reasons that the construction industry uses them extensively. Fluoropolymer-based coatings are used in settings where the longest lifespans are required to provide superior substrate protection, including exterior finishes on buildings, bridges and other industrial structures. In particular, the combination of chemical and thermal resistance has been claimed by the industry to be unique and cannot be found in the alternative materials. More specifically, fluoropolymers are known to exhibit:

- Long durability to weather and environmental conditions, as well as to chemical agents, making them suitable for construction projects in demanding / harsh environments, such as offshore platforms and bridges. Fluoropolymers also have high UV resistance, which contributes to their durability.
- Resilience in a very broad temperature range. This is important for outdoor applications where large temperature swings are expected through the year, but also for cables used in construction, which may be exposed to very high temperatures.
- Low flammability and no flame propagation, acting as effective fire retardants. Fluoropolymers used in construction have low smoke generation as well.
- Low surface tension, which minimises staining, thus maintaining the visual characteristics of the substrate. Its water- and oil-repellence properties are also highly desirable in applications such as anti-graffiti coatings, among others.
- Low coefficient of friction, which is an important property for bearings used in bridge and offshore pads.

Overall, the higher durability of fluoropolymers results in fewer materials usage from a lifecycle perspective. They also require less maintenance and energy, thus contributing to a lower carbon footprint.

3.3.3.2 Status in the restriction proposal

Construction product applications are extensively described in the restriction proposal, but none of the assessed sub-uses were proposed or are considered for a derogation.

Within the restriction proposal, construction products are broken down into the following sub-uses:

- Architectural coatings and paints
- Wind turbine blade coating
- Coil coating
- Architectural membranes (composite membranes with top coating)
- Architectural membranes (pure fluoropolymers)
- ETFE film/foil for greenhouses
- Windows frames (laminated with fluoropolymers)
- Bridge and building bearings
- PTFE thread sealing tape

- Polymeric PFASs used as processing aids for production of non-PFAS polymers/plastics
- Side-chain fluorinated polymers used for surface protection/sealants
- Fluorosurfactants as wetting/ levelling agents in e.g. coating, paints and adhesives
- Non-polymeric PFAS as processing aids
- Window film manufacturing

Comparing the restriction proposal document with the information received from FPG members and downstream users of fluoropolymers, it appears that the restriction proposal covers the uses and applications of fluoropolymers in the construction sector accurately.

3.3.3.3 Discussion on alternatives

As noted above, none of the sub-uses are currently considered for a derogation within the restriction proposal. For most sub-uses, the restriction report currently notes that there is sufficiently strong evidence that technically and economically feasible alternatives exist and that there is a high-substitution potential anticipated by the anticipated EiF of the restriction.

Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters, which also includes an assessment of alternatives. Concluding relevant remarks concerning each of the sub-uses are replicated in the following table.

The dossier submitters concluded that, for the majority of sub-uses, there are suitable alternatives available in the market.

- For architectural coatings and paints, the dossier submitters mention polyurethane coatings among other alternatives, recognising their shorter life span, but proceed to consider it of low importance.
- For wind turbine blade coatings, the dossier submitters also list a number of potentially suitable alternatives, such as polyester/PVC membranes with TiO_2 and fiberglass fabric coated with silicone, but they also note that they are worse performing than fluoropolymers.
- The same arguments as above are used for architectural membranes, either with or without top coating).
- The same arguments were also made on the use as a binder in coil coating. Alternatives are likely to have a shorter life span under harsh environmental conditions compared to fluoropolymer binders (PTFE). Despite that, they conclude that technically and economically feasible alternatives are available.
- For ETFE film and foil for greenhouses, the dossier submitters also consider that there are technically and economically feasible alternatives available, even though they have worse performance than ETFE, as far as durability over time and the need for cleaning are concerned.
- The dossier submitters also concluded that, for bridge and building bearings, there is weak evidence that no alternatives are available. They mention comments from one stakeholder that steel rollers cannot be considered as drop-in alternatives to fluoropolymers, as the buildings and bridges will have to be designed differently to accommodate the larger space requirements of steel rollers.
- PTFE thread sealing tapes appear to have available alternatives, mainly for permanent applications, with liquid or paste pipe thread used. For non-permanent pipe seals, they cannot conclude that technically and economically feasible alternatives are available, but do not propose a derogation.
- For fluoropolymers used as processing aids for non-PFAS polymers, the dossier submitters mention boron nitride and siloxanes and point to absence of information that they have worse performance than fluoropolymers.

In the FPG member and stakeholder survey, the importance of fluoropolymers in demanding applications and in meeting construction standards was pointed out. While alternatives in some applications are available, these alternatives tend to have worse performance, as pointed out by the dossier submitters, and this would make unsuitable for some of the applications where harsh conditions are expected.

It should be noted, however, that some of these alternatives, such as PVC and TiO_2, are subject to regulatory scrutiny so there is still much uncertainty about their future use and the potential for regrettable substitution.

Downstream users have commented that alternative coatings do not deliver the durability and longevity that fluoropolymer-based architectural coatings provide to building products. As a result, alternatives would require multiple re-coatings or replacements and more frequent manufacture throughout the construction products value chain, increasing potential negative environmental footprints. Polyester and polyurethane coatings cannot achieve EN 10169 UV classification RUV5 (the highest one for UV resistance), as they have much lower lifespan compared to PVDF. In addition, more layers of an alternative coating would ned to be applied to achieve the same performance as with fluoropolymers.

Downstream manufacturers of sealing tapes have also commented that, while alternatives are available in the market, they are not always suitable for use in extreme conditions, as they have lower chemical and temperature resistance and lower pressure tolerance than PTFE (e.g., they are not suitable for plastic pipes).

3.3.3.4 Substitution

Fluoropolymers are essential for meeting industry and regulatory standards in construction. An indicative list of such standards is presented in Table 3.6.

Table 3.6 Indicative list of standards for the construction industry

Standard No	Standard description	Relevant application
EN 1337-2:2004	Structural bearings – Part 2: sliding elements	Bridge bearings and anti-seismic devices PTFE is currently the only sliding material required by the EU legislation
Qualicoat class 3	Specifications defining minimum requirements for plant and equipment, coating materials and finished products.	Architectural coatings
AAMA 2605, AAMA 625	Voluntary specifications, performance requirements and test procedures for performing coatings	Coil coatings on aluminium Coatings on fibre-reinforced thermoplastics
EN 10169	Continuously organic coated (coil coated) steel flat products	Coatings for UV protection Fluoropolymers can achieve the highest classification RUV5 on UV resistance

Timeline for substitution in construction applications varies, but, considering the very long expected service lives of construction materials and coating, it is important to carry out careful long-duration testing. For example, PTFE glass fabrics, which show very high durability in architecture, are expected to have a service life exceeding 40 years, and none of the known alternatives can achieve the same performance for that long.

In general, when a potential alternative is proposed, all products that currently contain fluoropolymers must be reformulated and tested for stability over their expected lifetime. For coatings intended to be used in hundreds of different surface materials (e.g., different stones, marble, concrete, plastic, etc.) stability testing must be carried out in as many as possible, and they must be monitored for a period of 6 to 12 years (but can be even longer), as requested by customers. This intends to show that the new coating can meet stability expectations against atmospheric agents and food, and also mechanical resistance. Flame spread testing is also requested for many architectural applications of fluoropolymers, according to EN ISO 13501 and other standards mentioned in Table 3.6.

In addition, for PTFE-thread tapes or yarns, extensive tests is needed for tightness check, temperature tolerance, pressure tolerance and chemical resistance. Threaded joints which are sealed with PTFE-thread seal tape must stay sealed for several years (more than 20 years in some cases). To ensure the same performance, alternative materials must provide results from lifetime tests. Accelerated tests are possible but could still take as long as 5-10 years.

It should be noted that any alternative material may also need to receive approval for contact with for example drinking water, oxygen and natural gas as required by relevant national regulations. Typical approval time for these is usually 6-12 months.

3.3.3.5 Conclusion on application

Even though the dossier submitters consider that there is no need for any derogation on use of fluoropolymers in construction products, from the information collected during the stakeholder survey, this cannot be the case for all applications.

For several of the sub-uses, primarily architectural membranes and greenhouse film, the restriction proposal submitters mention that the known alternatives have shorter lifetime than fluoropolymer products, but this is not considered significant. However, a long life span for the coating ensures that there will be low need for maintenance or restoration activities, e.g., to apply additional protective coatings.

Architectural coatings must be able to meet certain construction standard classifications, e.g., with regards to UV protection. This appears not to be possible without the use of fluoropolymers.

In other specific applications, a number of downstream users mentioned the use in bearings in bridges or offshore wind turbine beds. The restriction proposal cites limited information received from a single stakeholder during the call for evidence during its preparation. If this sub-use is considered significant, arguments on the substitution challenges and any shortcomings of alternatives will need to be developed.

Another sub-use for which the substitution potential is unclear is on PTFE thread sealing tapes, particularly for non-permanent sealing. While alternatives may be available in the market, they have worse performance than fluoropolymer tapes and, for some applications, they cannot be used at all.

Overall, the use of fluoropolymers in construction is broad and, for many of the applications described, necessary. The available alternatives cannot replicate the long-term performance of fluoropolymers in architectural films and in paints and coatings, as well as in sealing tapes and greenhouse films. They protect the building surface from UV radiation and offer high corrosion protection in harsh environments, such as offshore installations and bridges. These functions are achieved through the combination of resistance properties of fluoropolymers, which make them suitable for use in a variety of environments.

3.3.4 Energy, including batteries and hydrogen

3.3.4.1 Description of applications

Fluoropolymers are extensively used in the energy sector, covering a wide field of applications, including conventional energy generation, renewables and hydrogen technologies.

Components, such as sealing, wires and cables, and protective (conformal) coating, are used in conventional energy generation (e.g., thermal or nuclear power plants, industrial heat generation). Some examples of conventional energy applications are:

- As dielectric layer in high performance communication cables and connectors used in nuclear research and production and in the hydrogen market.
- As primary insulation and jacketing on electrical cables used in power generation, e.g., in gas turbines, transformers and batteries. This can also include cables used in control rooms and as sensor cables in nuclear plants.
- In pump elements, injectors and injection holders for marine, locomotive and stationary power generation
- In heat exchanger tubing in power plants
- In general, various sealing components, such as gaskets, O-rings and seals are used in large power generation installations, e.g., in steam turbines.

- As binders in lithium primary and secondary batteries for various long-term applications. Fluoropolymer solutions are also part of the chemistry of Li-ion cells and lithium primary battery cells. Those batteries can be found in diverse applications, such as metering, tracking, alarm systems, medical devices and aerospace.
- Insulation discs in Li-ion batteries also use glass fabric coated with PTFE as an industry standard, due to the chemical, electrochemical and thermal stability of the PTFE and the additional stabilization of the glass fibre. This is a critical safety application for users such as medical devices and aerospace.
- Fluoropolymer membranes are used in flow batteries. These are electrochemical devices used to store electricity in liquid electrolytes that are stored in tanks and pumped through the cell in charge and discharge cycles. The ion exchange membrane allows the transfer of ions between the anode and cathode of the cell, providing ionic resistance, mechanical properties, durability, and chemical stability.
- PFPEs are also used to lubricate surfaces or sub-components such as bearings, valves and slideways. These can find application, for example, in electric motor bearings, steam flow control valves and steam turbine frame expansion bearings.

Protective coating and other structural components in renewable energy sources:

- Solar panel front sheet laminates for lightweight and flexible photovoltaics. Also as back sheet layer of full sheet for bifacial photovoltaic panels.
- Perfluorinated ionomers can be used as an organic passivation layer for crystalline silicon heterojunction (HJN) and tunnel oxide passivated contact (TOPCON) n-type solar cells. Solar PV market industry is dominated by crystalline silicon and the technology trend is towards n-type HJN or TOPCON solar cell technology.
- Offshore wind turbine installations also need components that can withstand harsh conditions, such as saltwater and the presence of oil. Such components can be cable insulation and sleeving and microswitches.
- As mentioned in section 3.3.1 on construction materials, wind turbine blades often use a fluoropolymer coating. Furthermore, wind turbine base bearings may be made of or be coated by fluoropolymers (primarily PTFE).

The emerging hydrogen technologies rely heavily on fluoropolymers, including membranes used in electrolysis (proton exchange membranes – PEM, alkaline electrolysers – AEL, anionic exchange membrane electrolysers – AEMEL), compressors used in biomass gasification and biogas or methane reforming, as well as in hydrogen storage and transport applications (valves, sealing and pipes). More specifically, applications of fluoropolymers in hydrogen technologies include:

- As membrane in Membrane Electrode Assembly (MEA), as binder material, bipolar plates, ionomer and membrane support in proton exchange membrane electrolyser (PEMEL) stacks, gas drying units in H_2 conditioning, electrolyte pumps and valves in a PEMEL system.
- As seals, membranes, diaphragms in AEL stacks and gas drying units in H_2 conditioning, electrolyte pumps and valves in an AEL system.
- As membrane in MEA in AEMEL stacks, as membrane ionomer, cell frames and seals in stacks and also in the gas drying unit.
- In air or oxygen compression units and CO_2 separation units used in biogas or methane reforming and biomass or waste gasification units.
- In several applications in storage (compressed or storage) and transport of gaseous and liquid hydrogen. Fluoropolymers can be used as liners of pressurised cylinders, as pipe seals and fittings, as sealing in hydrogenation and dehydrogenation systems, in pumps, in transfer arms in liquid hydrogen transfer systems, etc.

- Membranes, ionomer, membrane support in PEM fuel cell (PEMFC) MEA; ionomer in PEMFC catalyst layer; Gas diffusion layer (GDL), bipolar plates and seals in PEMFC stack; diaphragms and seals in liquid pumps.
- As components and sealing in turbines, burners and boilers using hydrogen fuel.

The hydrogen applications listed above are indicative of the versatility of fluoropolymers and their importance in the emerging hydrogen technology. Membranes are critical components of the MEA for both fuel cell and electrolysis applications, as they electrically isolate the electrodes, preventing short-circuits, they act as electrolytes and provide a mechanical barrier to the MEA, preventing the mixing of hydrogen and oxygen. The high proton conductivity offered by fluoropolymer ionomers used in manufacturing these membranes is among the main properties needed by the industry. The hydrophobic PTFE backbone provides effective mechanical stability, whereas the pendant sulfonic acid groups form interconnected domains with the absorbed water and are responsible for the conduits for proton transport.

3.3.4.2 Status in the restriction proposal

As seen in the section above, the energy and battery section, including the emerging hydrogen technologies, uses fluropolymers in a diverse set of applications. The uses described in the Annexes of the restriction proposal include[24]:

- Solar array bearings in solar collectors
- Film / coating and tape on photovoltaic cells
- Wind blade protection coating, release film for wind turbines, cables and lubricant for wind energy installations
- Heat exchanger tubing and filters in coal power plants
- Gaskets in nuclear power plants
- PEM fuel cells, including MEAs, GDLs and sealing components, and PEM electrolysers
- Other, non-PEM electrolysis technologies
- Binders and ion exchange membranes in batteries
- Others, including switchgears, high-voltage DC converter valves

Nevertheless, the only energy-related proposed derogation in the restriction proposal is on the use of PFAS in PEM for fuel cells. The other uses are not covered by a derogation, mainly due to the inconclusive evidence on availability of suitable alternatives. According to Annex E of the restriction proposal[25]:

> "A general derogation for all uses is likely to be not justified, as there are alternatives for some uses. A derogation could (most likely) be justified for specific uses where alternatives are not technically feasible, but this would rely on more detailed information on the specific uses."

3.3.4.3 Discussion on alternatives

Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters, which also includes an assessment of alternatives. The assessment of alternatives highlights the following key concluding remarks:

- Only limited information has been submitted on possible alternatives.

[24] Annex A to the Annex XV Restriction report for Per- and poly-fluoroalkyl substances (Table A.54). Available online at: https://echa.europa.eu/documents/10162/f71f3bed-e48d-5004-d195-e293c38d0602, accessed on 29 May 2023

[25] Annex E to the Annex XV Restriction report for Per- and poly-fluoroalkyl substances (Section E.2.12.5). Available online at: https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea, accessed on 29 May 2023

- Generally, or at least broadly applicable alternatives are not available, and stakeholders do not foresee any changes in the future.
- Some stakeholders therefore conclude that alternatives are not available at all.
- However, other stakeholders reported that substitution is possible for some application.
- Limiting factors are R&D costs, time needed for substitution, uncertainty regarding future success in finding suitable alternatives, assessment of functional losses and the resulting assessment of applicability.
- Some alternatives, notably for uses of polymers, are already available. Nevertheless, stakeholder information on current substitution potential is inconclusive. Some stakeholders agree that users need to analyse all their uses in detail to identify less demanding uses where alternatives suffice. Other stakeholders argue that there is no potential for substitution, citing that PFAS-based materials are more expensive than the available alternatives and therefore are only used when they are indispensable.

The dossier submitters also highlight that, based on information submitted in various stakeholder consultations, some specific alternatives have been identified that are available for the energy industry but several of them might have limitations regarding properties such as weather resistance, heat resistance or chemical resistance that may cause a decrease in lifetime and/or instability in the systems.

Within the Annex XV dossier, considering the energy sector – as noted above – only a single derogation is proposed (a 5-year derogation for PEMFC). It should be noted, however, that this proposed derogation does not cover the use of fluoropolymers in electrolysis membranes, which are an essential application in hydrogen generation.

Within questionnaire responses it was highlighted that low energy alternatives for batteries may be available, but they are not suitable for all uses and some specific ones (e.g., in automotive / transportation applications) have no alternatives. Alternatives in these applications would not fit in the space available and the use of non-fluorinated polymers could lead to higher rates of failure due to lower chemical compatibility.

Downstream stakeholders have commented that battery manufacturers need to meet with strict specifications on capacity, electrical behaviour during use and lifetime from their customers. While not explicitly stated, these specifications cannot be met by alternative binders, as their low chemical resistance would lead to decomposition and battery failure. In addition, for Li-ion manufacturing, transferring of the electrolyte requires materials very resistant to chemical agents, due to the potential formation of aggressive chemicals.

PTFE provides a unique combination of properties that make it indispensable for use as binder. It has excellent chemical compatibility with the organic solvents in the electrolyte, it is electrochemically stable and can withstand the high voltage in the battery cell, it is resistant to the high temperature necessary for drying the cathodes and provides stability in high temperature applications, it has good adhesion properties to the substrate material and good dispersion properties, to ensure uniformity of the electrodes. In addition, its unique fibrillation properties mean that very low concentrations are sufficient to bind the substrate in place, without covering the active surface. Finally, it has good flexibility, to allow winding of the electrode during assembly. The combination of those properties leads to very long life spans of up to 20 years, which cannot be met by alternative materials.

Several polymers, including polyacrylic acid, sodium alginate, polyurethane, and catechol-bearing polymers have been assessed as cathode binders for Li-ion batteries. However, while initial tests showed they had good adhesion properties, additional research and development will be needed to determine whether they have adequate chemical, mechanical and electrical properties to substitute fluoropolymers.

For insulation discs, it is understood that PP and PET-based are used instead. These are cheaper materials as well, but it has been commented by downstream users that they may have lower product safety and may not currently meet customer specifications and industry standards for some applications, such as in aerospace. Other shortcomings of alternative materials, such as PP, PVC and elastomers (EPDM, HNBR, NBR, acrylic and ethylene-acrylic) is that they are not performing as well against radiation or outgassing. In addition, PVC contains chlorine, which could be emitted during operation.

Work on alternatives for ion-exchange and electrolysis membranes, which are essential for hydrogen and electrolytical applications, has identified non-fluorinated ionomers. The properties and performance of those materials may be comparable to fluoropolymers, but their overall durability is still much worse, as they are not as resistant to oxidation from oxygen radicals that are generated in the cathode. According to a downstream stakeholder, available non-fluorinated membranes have a very short life span, orders of magnitude below the industry requirements of more than 25,000 hours. Using these membranes would mean much more frequent replacement, which would increase costs, and waste, substantially.

Other energy and hydrogen related applications, such as in membrane reinforcement materials and as binders in electrodes or catalyst layers have some potential alternatives, but these do not always meet the high requirements. Alternative PBI-type materials are used in membrane reinforcement and, according to one downstream stakeholder, they have acceptable mechanical properties. However, they are still mainly at experimental level and commercial use is not expected in the next 5-10 years. As mentioned above for batteries, non-fluorinated ionomers are examined for use as binders. However, their low gas permeability makes them less suitable than fluoropolymers.

As discussed by the dossier submitters, there are no suitable alternatives for gas diffusion layers, as their water repellence is applied via PTFE impregnation. It is expected that more than 10 years of R&D would be required to identify and switch to an alternative.

Alternatives for sealing materials are also not as performing as fluoropolymers, as they cannot resist the harsh environments and the contamination of the MEA. Therefore, the need to identify durable materials, which also have dimensional stability without mechanical reinforcement is essential. Graphene and flexible graphite have been mentioned as potential sealing materials, but they are not durable enough without the use of a metal sheet, which itself raises chemical resistance issues. Furthermore, these are still at the developmental stage and would be much more expensive, even than fluoropolymers.

Finally, for sealing and cable jacketing applications, the same arguments as those mentioned in other sections apply here as well. In summary, the combination of chemical, heat and mechanical durability of fluoropolymers, together with their flexibility, is not easily found in alternative materials. Thus, alternatives cannot be used in highly demanding applications, where harsh conditions are expected.

3.3.4.4 Substitution

As discussed in the previous section, the suitability of potential alternatives to fluoropolymers is limited. For several of the uses, where harsh conditions are present (e.g., in fossil fuel or nuclear power plants, in onshore and offshore wind turbines), the alternatives cannot meet the requirements for durability and resistance to heat and chemicals. For hydrogen applications, alternatives to fluoropolymer PEM and GDL are expected to be more than 10 years in the future.

In addition, any alternative will need to meet the very demanding specifications in national and international standards. An indicative list of such standards is presented in Table 3.7.

Table 3.7 Indicative list of standards for the energy sector

Standard No	Standard description	Relevant application
10 CFR part 21 (US)	Reporting of defects and of non-compliance for nuclear power plants.	Nuclear power plants
ASME NQA-1	Certification of the quality assurance program for organizations that supply items or services that provide a safety function for nuclear facilities	Nuclear power plants

For applications such as sealing and cable jacketing, as well as coatings, which have to meet very high performance requirements, substitution may also take several years, as discussed in the respective sections of other applications (e.g., transport, chemical processing and electronics).

3.3.4.5 Conclusion on application

Use of fluoropolymers in the energy sector is widespread, covering conventional power generation facilities, renewable energy sources, as well as storage (batteries). They also extensively used in developed and emerging hydrogen technologies, which are expected to play a significant role to the EU meeting its climate targets for 2050.

The only derogation in the restriction proposal refers to PEM for fuel cells, but it appears that this does not include the fluoropolymer membranes' use in other electrolysing, catalysing or energy applications.

Furthermore, other critical uses of fluoropolymer coatings and components (e.g., seals, wire and cable insulation and jacketing) are not consider for derogation, despite their superior performance over alternatives at the harsh conditions that they are required for (e.g., temperature, radiation, chemical agents).

Overall, alternatives for the several important fluoropolymer applications are either not available or cannot meet the high requirements of specialised uses, such as battery binders, ion-exchange membranes and even cable jacketing for applications where extreme conditions are anticipated.

Therefore, ECHA should focus on expanding the scope of derogations in the energy sector, to include those sub-uses for which a technically and economically feasible alternative is not expected to be available at the time the restriction enters into force.

3.3.5 Petroleum and mining

3.3.5.1 Description of applications

Fluoropolymers are widely used in the oil and gas industry, which involves the transfer of aggressive chemical agents, such as oils, acids and petroleum and gas products, and is also exposed to harsh environmental conditions. Oil and gas drilling requires the use of "downhole" fluids that contain aggressive additives. In addition, the pumped liquids contain a broad mix of compounds that can degrade piping and pumping equipment. The drilling equipment can also be exposed to high temperatures and pressures.

- Fluoropolymers are used in sealings for pipes, valves and joints and as inner liners and coatings for piping and high-pressure hoses, due to their high chemical and heat resistance. Other examples of equipment using fluoropolymers includes exploration seals, on/off and control valves for fluids, pumps, actuators and control accessories.
- Their low permeation rate also makes fluoropolymers an ideal material for sealings, valves and pumps for gas transfer and storage equipment, as it minimises leakage.
- They are also used as insulation and jacketing of cables used in drilling and prospecting tools and equipment, as well as in surface and downhole cables and subsea cables for offshore installations. Use of fluoropolymers in cables allows for the cables' downsizing, making them more suitable for downhole applications (e.g., data logging, trace heating and ESP power cables).

3.3.5.2 Status in the restriction proposal

The applications of fluoropolymers in the petroleum and mining industry have received a wide-scope derogation in the restriction proposal. The uses mentioned in the section above are also covered by the applications of fluoropolymers, as discussed in the relevant chapters of the restriction proposal Annexes A and E.

3.3.5.3 Discussion on alternatives

Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters, which also includes an assessment of alternatives. The assessment of alternatives highlights the following key concluding remarks regarding petroleum (as well as mining):

- For non-polymeric PFAS the Dossier Submitters conclude based on information from CfE, literature review and stakeholder consultations, that the evidence is sufficiently strong that technically and economically feasible alternatives are available for the quantities required for use in oil and gas tracers and anti-foaming agents and that the substitution potential is high. The Dossier Submitters note that one stakeholder claims that a transition period of up to 4 years might be required. The assessment of the Dossier Submitters is that this claim will need further justification (in the Annex XV report consultation) to be considered; and
- For fluoropolymers, the Dossier Submitters conclude based on information from CfE and literature review and stakeholder consultations, that the evidence is sufficiently strong that technically and economically feasible alternatives are not generally available for fluoropolymer applications in the petroleum and mining sectors and that the substitution potential is uncertain.

Based on the above, within the Annex XV restriction report, no derogation is proposed for non-polymeric PFAs in petroleum and mining applications whereas a 12-year derogation is proposed for respective fluoropolymer applications. It is anticipated that the proposed 12-year exemption for fluoropolymers will be welcomed by FPG members.

The excellent chemical and heat resistance of fluoropolymers make them the ideal material to use in the petroleum and mining sector, where the presence of aggressive chemicals and high temperatures are encountered. This has been noted by the downstream stakeholders and the FPG members who responded to the survey.

As noted elsewhere in this report, O-rings and gaskets may be made by materials such as EPDM and (hydrogenated or not) nitrile rubber, but they do not meet customer expectations for temperature (sometimes being as high as 270°C) and gas or chemical resistance, especially as far as the petroleum and mining industries are concerned. It should be noted that the combination of chemical and heat resistant exhibited by fluoropolymers such as PTFE and FKM are very difficult to be found in alternative materials. This comment has been repeated by several downstream users manufacturing sealing products and other technical articles.

Furthermore, flexible hoses that are used to transport aggressive agents in the chemical industry usually have a liner that protects the hose from the chemical. Thermoplastics, such as PP and PVC cannot meet the temperature requirements. Furthermore, rubbers (such as EPDM and HNBR) are used for some applications, but not when certain chemicals (e.g., petroleum products, acidic sludges) are transferred or there are high temperatures.

In general, flexible pipes are preferred over steel pipes for two main reasons. First, the flexible structure allows for permanent connection between a floating support vessel with large motions and subsea installations. Secondly, transport and installation is significantly simplified due to the possibility for prefabrication in long lengths, which can be stored on limited sized reels for ease of handling. Reeling is also possible with steel pipes. However, the reeling process involves plastic yielding and ovalisation of the pipe, and the requirements to the handling equipment are high. Flexible riser systems have become a standard solution for permanent connection of subsea systems to floating vessels. Its flexibility means it can spool pipe on reel or carousel for efficient and quick transportation, and ease to lay on difficult seabed conditions.

3.3.5.4 Substitution

Operations in the petroleum (oil and gas) and mining industries take place under very harsh conditions, with the equipment being exposed to high temperatures, chemical agents such as fuels, oils and acids, and undertaking severe mechanical stress. In oil extraction, piping and cables may be inserted deep into the earth. These environments generate very high requirements from the materials used in the equipment, and there are several international standards that these materials and equipment must meet. Table 3.8 lists some of these standards.

Table 3.8 Indicative list of standards for the oil and gas sector

Standard No	Standard description	Relevant application
SAES-X-400	ARAMCO standard for cathodic protection of buried pipeline	Cables
ASTM D8436	Specification for Fluoropolymer-based Materials for Use for Encapsulation of Downhole Cable	Downhole cables
NORSOK M-710	Resistance to Rapid Gas (explosive) Decompression – safety standard	Elastomer O-rings and seals

Due to the extreme conditions present, potential alternatives need to undergo rigorous testing by the manufacturers and the end users, to ensure they are safe to use over a long service life. Stakeholders estimate that the time to develop an alternative in the oil and gas sector, assuming that the alternative meets all the specifications discussed above, can be as long as 5-10 years. However, due to the absence of technically and feasible alternatives, as also discussed in the restriction proposal, alternatives may not be available until much later.

3.3.5.5 Conclusion on application

Fluoropolymers are critical materials for the petroleum and mineral extraction and processing industries. The heavy contamination from petroleum products and the harsh conditions, both environmental and mechanical, present in extraction and processing sites require highly durable materials, and at the moment only fluoropolymers can meet all the requirements.

Their use is critical not only for downhole applications, where cables and hoses are lowered in the earth in survey and extraction processes, but also for transfer, storage and transportation of the products.

Alternative materials do not have the combination of chemical, heat, pressure and mechanical durability of fluoropolymers and are not in use in those applications. Considering the demanding nature of these processes and the pollution potential, e.g., in case of a leaking valve seal or gasket, development of alternative materials is something that could take several years if not decades.

3.3.6 Food contact materials and packaging

3.3.6.1 Description of applications

This use category can be split in the following broad applications:

- Kitchen equipment, which includes industrial, professional and consumer equipment used in preparing and cooking food. Such kitchen articles can include:
  - Cookware (e.g., pots, pans), bakeware (e.g., trays), knives, other kitchen utensils and small electric kitchen devices.
  - Household coffee-machines or other appliances may contain hoses made of FEP, FPA, PTFE or ETFE, seals and gaskets (FKM) coming in contact with food.
  - Plate heat exchanger gaskets, piping, tubing and membranes for drinking water/beverage applications, flow meters and pumps.
- Food packaging, such as cans, paper bags, etc. More specific applications include:
  - Inner layer on paper-aluminium heat-sealed laminates or paper-mPET/silicone laminates. The end use of such products is by consumers.
  - Co-extruded and laminated packaging films
  - Metal can coating.

- Food processing and packaging equipment which come in contact with food, and materials used therein (e.g., printing inks for food packaging)). More specific applications identified during the FPG member and Downstream User consultations include:
  - Printing inks applied to food packaging via an industrial printing process may contain PTFE
  - Fluoropolymers (primarily fluorinated elastomers) are used as processing aids in the manufacturing of blown polyethylene, polypropylene and polyamide (nylon) film, by release and deposition on the extruder surface.
  - Equipment used in handling of foodstuff, which come in contact with the foodstuff and must meet high requirements for food safety (e.g., 3A Sanitary Standard, FDA and EU regulations and EHEDG guidelines) are coated with a fluoropolymer layer or use fluoropolymer seals to protect the food, from contamination. Such equipment may include seals, membranes, bellows, pumps, tubes, process valves, filling valves, closures and applicators, etc.
  - Fluoropolymers (mainly PFPE or PTFE) are used as lubricants in the processing equipment

Fluoropolymers exhibit the following properties which make them highly suitable for use in food contact materials and packaging:

- High temperature resistance and stability, allowing safe use of cooking equipment at high temperatures, without breaking down or releasing any hazardous substances to the oil or water. This is also important for fluid handling equipment in the food and drink industry, which are exposed to hot temperatures (e.g., during sterilisation with steam).
- Pressure stability ensures that, where fluoropolymer seals are used, they maintain tightness and do not deform or break.
- The chemical resistance of fluoropolymers also protects the equipment from corrosion, and the products from contamination. This is important as the cleaning detergents and descaling agents used can be corrosive.
- Oil- and water-repellence and anti-stick properties are important for all applications, and for food processing equipment in particular. They facilitate cleaning of the equipment (e.g., tubes, vessels, pumps) and reduce the risk of flavours from one product being carried over to another.
- The transparency and the mechanical properties of fluoropolymers are desirable properties for food packaging, such as films and coated cans and packaging paper.
- Use of fluoropolymers in coatings and lacquers provides the desirable slip properties and sufficient abrasion resistance, as well as cohesive strength and surface wettability, which allow the packaging to comply with the requirements of legislation.
- In polyethylene film production, use of fluoropolymers as a processing aid minimises defective products and waste during the process. The fluoropolymer is deposited on the extruder walls, thus improving polymer flow during production. This avoids melt fracture and build-up of polymer in the die. It also contributes to a smoother surface, high transparency and avoids leakage of the product while on the shelf.
- Resistance to radiation was also mentioned by downstream users, as sterilisation via radiation is a common modality.
- PTFE lubricant powders are ideal as additives because they can influence the behaviour of many hosting materials without reacting with them. Moreover, they ensure the benefit of reducing the coefficient of friction, increasing wear resistance, improving non-stick properties and enhancing anti-dripping properties.

Any material that comes into contact with food must comply with the EU Regulation 1935/2004 on Food Contact Materials (FCM). In addition to that, all FCM must be manufactured according to Good Manufacturing Practices (as per Commission Regulation (EC) 2023/2006) and other specific EU and national legislations. This is to ensure that FCM and food packaging pose no risk to public health. Fluoropolymers are currently approved as food contact materials in the EU and have been used as such for decades. Any alternative material for FCM and packaging applications must also meet all the specifications arising from EU and national legislations.

3.3.6.2 Status in the restriction proposal

The restriction proposal identified the same food contact material and food processing applications as those reported by FPG members and downstream users. The proposed derogations focus on industrial and professional applications, while any use that may reach consumers, such as food packaging and consumer cook- and bakeware were not deemed justifiable for a derogation.

The proposed and considered derogations for food contact material applications are:

- Proposed derogation for food contact materials used in food and feed production at industrial and professional settings – there has been large number of comments during earlier consultations for these uses.
- Considered derogation for non-stick coatings in industrial and professional bakeware.

It is understood that the proposed derogation on food and feed production covers the industrial applications identified (e.g., use of fluoropolymers in seals, tubing etc. in production equipment exposed to high temperature or harsh cleaning agents).

Several downstream users mentioned packaging applications and the difficulty of moving to alternative materials, so this should be taken into consideration in the response. It should be noted, however, that the restriction proposal did not propose derogations for packaging materials and processing aids due to “sufficiently strong evidence” that alternatives are available.

3.3.6.3 Discussion on alternatives

Annex E to the restriction proposal identified and assessed the following sub-uses for food contact materials and packaging.

- Paper and board packaging: several technically and economically feasible alternatives are mentioned in the Annex, such as uncoated paper, biopolymers and petroleum- or bio-based waxes. The assessment concluded that substitution is feasible and no derogation was proposed on that basis.
- Plastic packaging: there is uncertainty on the suitability of alternatives and the substitution potential for the use of PFAS as polymer processing aids in assisting in the extrusion of plastic film and sheet and to provide moisture protection. Qualitative information was provided during the call for evidence by stakeholders, which has resulted in a considered derogation for this sub-use.
- Consumer cookware: technically and economically suitable alternatives were identified, such as ceramic or silicon coatings, stainless steel, bakeware out of silicone and, finally, anodised aluminium, with some of them already having a significant market share. As such, no derogation was proposed.
- Industrial applications: the dossier submitters considered a number of alternative coatings for the use in seals, tubing, etc., where the components are exposed to high temperatures and pressures, strong cleaning agents, high material throughput and automated production. In conclusion, substitution potential in this sub-use is expected to be low, and the dossier submitted to propose a derogation for industrial and professional food and feed production.
- Non-stick coatings in industrial and professional bakeware: there were contrasting responses from stakeholders during the call for evidence about the suitability of alternative coatings. There were varying views during the call for evidence, with some respondents claiming that alternative materials were less performing than fluoropolymer coatings and materials. Furthermore, fluoropolymers were preferred in certain demanding applications, despite their higher cost. Other parameters, such as the size of the company and the necessary investment to move to alternatives, the different cooking processes and conditions may also affect substitution. For that reason, a considered derogation was included in the restriction proposal.

One consultee provided information on suitability of alternatives to cook- and bakeware coatings, which seem to agree with the information collected by the dossier submitters during the call for evidence. It is mentioned that ceramics can meet temperature resistance requirements, but their non-stick performance and durability deteriorate over time, requiring more frequent replacement. Furthermore, they are not suitable for coil coating, which is typically used to produce lower-end pans. Silicone coatings also appear to have lower thermal, abrasion and chemical resistance to fluoropolymer coatings. The alternative, non-coating options, such as aluminium and stainless steel would not have durability concerns as there would be no coating. Using them, however, could result in higher cost for the final users.

For food-contact tubing, use of alternative coatings would be expected to result in higher rate of defects in the processing machines, increasing maintenance and also replacement costs. Other alternatives, such as silicones are also regulated under REACH, which could lead to regrettable substitution.

Downstream users have commented that alternative processing aids are not available for use in the EU at the moment. Food contact materials are highly regulated and must go through a rigorous approval process before they can be used. Nevertheless, for one of the potential alternatives, siloxanes, it has been reported that hazardous substances may be released during extrusion of films. It should also be noted that silicon-based chemistries have also been under regulatory scrutiny in the EU, with silanes and siloxanes being considered for regulatory action.

Furthermore, it was reported that sealing components (O-rings, gaskets), used in bottle-filling equipment and piping and made of alternative materials (rubbers), tend to have shorter service life than fluoropolymers and tend to negatively affect the quality of the filled products. In general, it should be noted that the combination of chemical and heat resistance exhibited by fluoropolymers such as PTFE and FKM are very difficult to find in alternative materials. This comment has been repeated by several downstream users manufacturing sealing products and other technical articles.

3.3.6.4 Substitution

Currently, all materials coming in contact with foodstuff in the EU must comply with the provisions of the EU Framework Regulation EC 1935/2004, and the Regulation (EC) on Good Manufacturing Practices for articles intended to come in contact with food, 2023/2006.

The Framework Regulation sets the general principles of safety and inertness for all FCM. According to it, FCM should not release their constituents into food at levels harmful to human health, and should not change food composition, taste and odour in an unacceptable way. It also provides powers to enact additional EU measures for specific materials. Commission Regulation (EU) No. 10/2011 on plastic materials and articles sets out rules on the composition of plastic FCM and establishes a list of substances that are permitted for use in the manufacture of plastic FCM.

Use of a new FCM is only allowed after the interested companies obtain an authorisation according to the provisions of Article 9(1) of the FCM Regulation 1935/2004 (as amended). The authorisation application involves the preparation of a technical dossier with information on the material’s identity, physicochemical and toxicity properties, as well as migration studies. Approval of the application can be lengthy, with the competent authorities given between six and twelve months to form an opinion, which they forward to the Commission, which will need to prepare the respective legislative act.

The authorisation procedure above must be considered when estimating the potential for substitution of fluoropolymers, in case the potential alternatives are not authorised FCM.

A typical substitution process for FCM can be described as below:

- Identification of a potentially suitable material that fulfils all mechanical requirements and only used approved FCM. This is the most difficult phase and can take at least one, and most likely several, years, considering the excellent performance of fluoropolymers.
- Durability and stability tests, which typically take one year. If these tests fail with the new material the process moves back at the beginning, with the identification of a new potential alternative.

- Migration tests to ensure compliance with food contact legislations (for every single relevant country worldwide), which can also take approximately one year. Again, if the material fails the migration tests the process moves again back to the identification phase.

An indicative list of legislation relevant to FCM are shown in Table 3.10.

Table 3.9 Indicative list of standards and regulations for FCM

Legislation / Standard	Description	Region
CFR Title 21		USA
EC Regulation 1935/2004	Framework Regulation on FCM	EEA
EC Regulation 2023/2006	Good Manufacturing Practices	EEA
EU Regulation 10/2011	Plastic FCM	EEA
Directive 84/500/EEC	Ceramics	EEA
EC Regulation 282/2008	Recycled plastic materials	EEA
NSF/ANSI 51	Standard for materials and finishes used in the manufacture of food equipment and components such as plastic materials, tubing, sealants, gaskets, valves and other items intended for various food equipment and food contact applications	USA

3.3.6.5 Conclusion on application

The use of fluoropolymer in industrial production of food and feed as sealing material and coating of equipment is proposed for a time-limited derogation.

It is important to note that, at the moment there are no alternatives able to perform at the required level in equipment at food processing plants and meet the necessary industry and regulatory specifications. Stakeholders have mentioned that, as far as food processing equipment is concerned, alternative processing aids, such as siloxanes, are not available for use in the EU currently.

Fluoropolymers are highly performing materials and are essential for the food processing industry, as they can be used in a broad range of extreme conditions and come in contact with harsh (e.g., acidic) fluids without degradation or corrosion. This allows for safer and more efficient production of foodstuffs. Furthermore, their very good non-stick properties ensure that fewer cleaning cycles will be necessary, thus reducing the use of solvents and other potentially hazardous chemicals. Notably, and in agreement with the EU Green Deal, fluoropolymers allow high durability of materials and therefore, a lower amount of breakdowns and unusable material is expected.

The combination of these properties, together with the absence of suitable alternatives for the whole range of applications, especially where extreme temperature and chemical conditions are present, highlights the importance of fluoropolymers for a critical industrial sector. Safety in the processing and production of foodstuffs is a primary concern for that industry and for EU society and it can be achieved consistently and efficiently through the targeted use of fluoropolymers.

Here it should also be noted that fluoropolymers are preferred over potential alternatives, despite their higher unit costs. This indicates that the industry does not consider that other materials perform as well as fluoropolymers, otherwise a cheaper option would be preferred. In fact, as mentioned above, use of a lining with worse non-stick properties than PTFE could result in higher risk of contamination and would need more frequent cleaning and maintenance with the use of aggressive cleaning agents and solvents. This could also lead to a shorter life span of the lining (or other sealing components) and even a shorter life span of the processing equipment itself.

3.3.7 Electronics and semiconductors

3.3.7.1 Description of applications

The electronics industry, including the critical semiconductor manufacturing sector, uses fluoropolymers to improve their products' durability, service life and overall performance. Fluoropolymers are used in these applications in the following forms:

- As formative / protective coating on electronic parts and semiconductors to protect from harsh conditions. Printed circuit boards is an example, with numerous extensions, of where such a coating can be applied.
- Fluoropolymer components in hard disk drives can also extend the life of those parts that need a high dielectric strength.
- In vapour phase soldering equipment where PFPE fluids bring precise temperature control, thus increasing yield and also enabling replacing lead-based technologies.
- In sealing that can protect sensitive electronic components from external agents, such as moisture, acids or alkalis. This use also includes gaskets, O-rings and other sealing equipment or lining of tubing / pipes and other fluid-handling equipment, e.g., in *in vitro* diagnostic devices or cooled / refrigerated devices, to prevent leakage that could impair the function of the electronic component.
- As insulation and jacketing of cables used in devices, allowing these to operate at higher temperatures and harsher conditions for longer.
- In manufacturing processes where a high degree of cleanliness and precision is required. This is particularly important for semiconductors, as they are particularly sensitive to contamination by particles and chemical agents, which could adversely affect the product's performance.

Manufacturers and users of fluoropolymers have mentioned a number of electronic equipment that relies on the use of fluoropolymers. The list below is non-exhaustive, but it is indicative of the broad range of affected applications and of the important equipment affected by the proposed restriction.

- Voltage testers, radars, wiring systems, gateways and connectors.
- Current transmission, signal transfer, sensors and safety systems in automotives and industrial applications (robotics). Fluoropolymers also provide very low dielectric constant that minimises signal losses at high frequencies.
- Other sensor applications, such as measuring devices using microwaves, process and hydrostatic pressure measuring devices and various probes for liquid level measurement.
- Level-controlled condensate drains (typically electronically controlled) in several industrial and professional applications also use fluoropolymer components. Other components and devices of such systems designed for drying of compressed air, such as measuring devices, also use fluoropolymer components, such as membranes.
- High-efficiency and HEPA air filters to capture particles in ventilation of clean industrial environments, such as in semiconductor manufacturing
- PTFE in plastics used in smoke detectors.
- As sealing and lubricants in screw-, piston- and turbo-compressors and refrigerant and desiccant dryers for industrial and medical applications.
- Wires, cables and connectors for semiconductor manufacturing for the defence market.
- Cables in automotive applications, e.g., in emission and other sensors, safety systems to warn a user that the brake pad needs replacement, in gearboxes, in the fuel pump, and in heating cables.
- In servomotors for medical devices and industrial applications

- Tools. A lot of jigs and tools in the production of sensors are based on PTFE: wafer carrier, sealing rings, handling tools in MEMS (micro electrical mechanical systems) processes in the production of pressure sensors or inertial sensors. Other components using fluoropolymers include inductors, laminated chokes, transformers, TVS diodes and membranes and sealings for thermomanagement modules.
- Testing of the semiconductor chips and sensors. Thermal shock testing of chips requires the chips or sensors to be immersed in a fluid in order to test their reliability (especially critical for automotive and aerospace). PFPE fluids are used because of dielectric properties, inertness and ability to stay pumpable at extreme temperatures.
- Amorphous fluoropolymers are used as 3D printer vat windows on account of high oxygen permittivity which facilitates a dead layer and thus easier printing.

The semi-conductor industry relies on precision processes and requires an ultra-clean environment where manufacturing takes place, as it has very low tolerance to contamination[26]. Therefore, the use of materials that contribute to minimising contamination is essential. As a result, the semiconductor industry has relied on fluoropolymers for wet processing equipment, fluid transport systems and wafer handling tools. Fluoropolymers are used in fluid handling part of the process where ultra-pure types are used with very low leachable content that can withstand the harsh chemicals used in the etching process. Reducing contamination from particles, metallic contaminants and outgassing caused by seal deterioration are major goals of semiconductor fabricators. Perfluoroelastomers (FFKMs) are used in deposition processes due to their extraordinary chemical resistance and thermal stability.

Plasma is a powerful tool for etching, cleaning, deposition, etc., which are processes commonly used in semiconductor manufacturing. Fluorine-containing plasmas, e.g., NF_3 and CF_4, are used for deposition process chamber cleaning due to their high reactivity towards materials to be removed. Since all materials are consumed in plasma, seals need to withstand plasma attack, i.e., exhibit low weight loss (erosion) and leave minimal particles behind after being etched. Plasma attack can be chemical (seal exposed to radicals), physical (seal subjected to ion bombardment) or both. In most seal locations on wafer processing equipment, the plasma attack mechanism is mainly chemical. Fluoroelastomers exhibit better resistance to such environments versus other elastomeric materials.

High purity PFA is also needed to keep fluids used in manufacturing ultra pure. It allows larger wafers and therefore ever improving and affordable microchips and LEDs due to higher production yields in semiconductor manufacturing.

In addition, the need to maintain a clean atmosphere in the processing areas urges the use of high-performance filters relying on fluoropolymer membranes, which minimise contamination by particulates, chemicals and metals (e.g., from piping or other equipment). Piping of ultra-pure water needed for semiconductor manufacturing is carried out using pipes, joints and processing tubes made of or coated with fluoropolymers, e.g., PVDF. For semiconductor manufacturing, combining cleanliness requirements with harsh conditions (extreme temperatures, vacuum, high intensity plasmas, harsh chemicals) often means fluoropolymers are required for sealing, heat transfer and pumps lubrication applications.

Finally, FP resins and coatings ensure communications equipment (i.e., cell towers, cabling) achieve speeds, capacity, and low latency that 5G requires. Fluoropolymers can also be found in seals in etching equipment and as protective film on photomasks in lithography processing.

3.3.7.2 Status in the restriction proposal

No derogation has been proposed for electronics applications in the restriction proposal. The uses described in Annex A of the restriction proposal seem to cover those identified in the surveys undertaken for this report. However, the assessment of alternatives carried out therein concluded that there are suitable alternatives for heat transfer fluid for immersion cooling and liquid crystal displays, while for the remaining applications more

[26] Ebnesajjad, S., (2016). Fluoroplastics, Volume 2. Copyright © 2015 Elsevier Inc. All rights reserved., ISBN: 978-1-4557-3199-2, DOI: https://doi.org/10.1016/C2012-0-05997-2 (Chapter 20)

evidence was needed to prove that there would be no suitable alternatives when the restriction will enter into force.

This report will further investigate whether a derogation for electronics applications of fluoropolymers in general, or more specific ones, should be considered in the restriction.

Many of the applications of fluoropolymers are relevant to semiconductor manufacturing processes, which require a very clean environment. These applications can partly be covered by the proposed derogation on filter media, but there are several other applications that require further investigation, to justify the considered derogation on semiconductor manufacturing. It is likely that fluoropolymers are used on semiconductors as well as in the manufacturing processes.

3.3.7.3 Discussion on alternatives

Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters, which also includes an assessment of alternatives. The assessment of alternatives highlights the following key concluding remarks regarding electronics and semiconductors:

- Only limited information has been submitted on possible alternatives for PFAS uses in the electronics and semiconductors and energy sectors.
- General or at least broadly applicable alternatives may not be available and stakeholders do not foresee any change in the future.
- Some stakeholders therefore conclude that alternatives are not available at all.
- Other stakeholders reported that substitution is possible for some applications.
- Limiting factors are R&D costs, time needed for substitution, uncertainty regarding future success in finding suitable alternatives, assessment of functional losses and the resulting assessment of suitability.
- Some alternatives, notably for uses of polymers, are already available. Nevertheless, stakeholder information on current substitution potential is inconclusive. Some stakeholders agreed that users need to analyse all their uses in detail to identify less demanding uses where alternatives suffice. Other stakeholders argue that there is no potential for substitution as PFAS-based materials are more expensive than the available alternatives and therefore are only used when they are indispensable.

Regarding the sub-uses electronics and semiconductors, it is noted that more detailed information on substitution potential for specific uses is scarce:

- For **electronics**, the dossier submitters highlight that in general, there are very few alternatives. The alternatives available might not fulfil the requirements e.g., thermal/chemical resistance or durability. Some stakeholders report that it is likely that alternatives can be found for a lot of smaller components, e.g., gaskets, wires, cables etc. as these components are used in many categories. For some uses, e.g., of fluorinated polymers, in electronics alternatives might be available.
- For **semiconductors**, the dossier submitters highlight that according to industry stakeholders, no non-PFAS technically feasible alternatives are available that can replace the properties necessary for semiconductor manufacturing process chemistries. No single “drop-in” replacement is possible for all semiconductor applications where substitutes exist. Almost every use has to be re-engineered to see if a replacement material will meet the technology requirements. Moreover, even within the semiconductor industry technologies are not consistent. Alternatives that work for one application or one company, will not necessarily work for another application or another company.

Based on the above, within the Annex XV restriction report, no derogations are proposed for electronics whereas a 12-year derogation is proposed for reconsideration for the semiconductor manufacturing process.

Within questionnaire responses it was highlighted that, generally speaking, the semiconductor industry is associated with a combination of very high purity and thermal resistance requirements. The requirement for an ultra-clean semiconductor manufacturing environment is also cited, with non-PFAS alternatives likely to cause contamination to products.

Downstream stakeholders have commented that it is very difficult to find highly performing alternatives for cable jacketing, where resistance to a broad range of temperatures, as well as resistance to chemical agents, are required. Most materials, including PP, XLPE and PE, PVC, Polyethylene sulphone, polyimide and several rubbers, have lower resistance to heat and to aggressive chemicals, while they also have lower mechanical durability. PP, for example is not sufficiently stable in temperatures above 90°C (DU 5.7) and usually has a melting point below the temperatures where FP are normally used, and the same can be said to apply to PVC. While polyolefins can be used in a narrow temperature range, they exhibit inconsistent electronic properties and flame propagation.

Ethylene-acrylic rubber may find some application as compound component, but it shows moderate service life length in extreme environments and has similarly moderate temperature range and chemical resistance, but would still need a thicker layer to be applied.

In general, it has been commented that fluoropolymers show better insulating properties compared to alternatives, such as vulcanised rubber film and polyimide foils, as the latter may have a higher risk of creepage current and electrical surge. Flyoropolymers do not absorb moisture, so the risk of overvoltage and electrical surge is reduced.

For sealing applications alternative materials such as EPDM and hydrogenated nitrile rubber are available. However, downstream users commented that these products do not meet customer requirements for temperature (which can range from -40°C to as high as 270°C) and gas or chemical resistance.

It should be noted that the combination of chemical and heat resistant exhibited by fluoropolymers such as PTFE and FKM are very difficult to be found in alternative materials. This comment has been repeated by several downstream users manufacturing sealing products and other technical articles. In general, while alternative materials are in use in seals for various equipment (pumps, pistons, etc.), where contact with highly aggressive chemicals is expected, these materials are not suitable, mainly due to poor chemical resistance. Various rubbers (e.g., EPDM, Nitrile, Hydrogenated NBR, acrylic and ethylene-acrylic) are not considered suitable for use in sealing, high frequency board, and greases and lubricants for cables, radars, wiring systems and connectors as they do not offer the required resistance over a broad temperature range.

In particular for semiconductor applications, one downstream user commented that using glass-fibre HEPA filters with a PFAS / FP binder makes the filter moisture-stable and oleophobic, reducing the risk of product leakage and contamination.

3.3.7.4 Substitution

As discussed in the previous section, there are no technically and economically feasible alternatives available for the various fluoropolymer applications in harsh conditions. While alternative materials exist, e.g., for some cable jacketing or sealing, these cannot meet the customer and regulatory specifications. For semiconductors in particular, the very high cleanliness and precision demands, require rigorous R&D to identify materials that will work equally well as fluoropolymers.

Table 3.10 below lists some standards that must be met in the electronics and semiconductor sectors.

Table 3.10 Indicative list of standards for the electronics and semiconductor sectors

Standard No	Standard description	Relevant application
SEMI F57	Specification for High Purity Polymer Materials and Components used in Ultrapure Water and Liquid Chemical Distribution Systems	Semiconductors
Semi F63	Guide for Ultrapure Water Used in Semiconductor Processing	Semiconductors
NEMA HP 3, HP 4	From US national electric manufacturers association	Electronics
DIN VDE 0250	Cables, wires and flexible cords for power installations	Electronics
IEC/UL/CSA 62638-1	Safety Requirements for Audio/video, Information and Communication Technology Equipment	Electronics
EU Directive 2014/35	Low voltage Directive	Electronics

RoHS Directive 2002/95/EC & 2011/65/EU & 2015/683/EU as amended	Restriction on the use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)	Electrical and electronic equipment

The substitution process in this sector mirrors closely those in other industries, in that the new material or component must undergo through a series of validation and qualification phases, with many tests, both by the manufacturer and the customer side.

- Identification of alternative materials and designs and selection of most suitable ones
- Validation of design and prototype manufacturing, also verifying adequate supply of raw materials to meet demand for the new product.
- Customer approval, where necessary
- Process validation and scale up / commercialisation

Qualification of a new filter medium includes testing of basic properties, such as filtration efficiency, pressure drop, emission behaviour, tensile strength, stiffness, water- and oil-repellence.

Once these properties are validated, the focus switches to the processability into folded filter packages and the assembly into a final filter element. Properties assessed at that phase include cutting behaviour, pleating properties, and compatibility with other materials, such as polyolefin and polyamide based hotmelts, and polyurethanes.

Following that, manufacturers verify the key performance parameters of the finished filter element must be verified, which include filtration efficiency, leak freeness, pressure drop, dust/oil holding capacity, energy consumption, gas emission and transportability.

In a final step, field tests are carried out to verify the suitability under real operating conditions and the long-term stability.

The industry estimates that the above process could take as long as 10-15 years to develop an alternative to fluoropolymers, but that could depend on the application, and on no unacceptable results during validation and approval.

In addition, some products (e.g., cables and other electrical / electronic equipment) may need to receive third party approvals for CE Mark or other certifications by independent third parties, before they can be placed in the EEA market. The timeline of these approvals and certifications depend on the availability of those approval bodies and can take several years.

3.3.7.5 Conclusion on application

Fluoropolymers are essential components for the electronics and semiconductor sectors, having several applications because of their durability in a broad spectrum of extreme conditions (temperature, pressure, chemicals, mechanical stress). They are considered essential by most manufacturers of electronic equipment, who claim that alternative materials cannot meet the necessary specifications and could have higher risks compared to fluoropolymers.

Fluoropolymers are broadly used in cables and wires, as they are the only ones that can withstand very high temperatures, exposure to chemicals, as well as mechanical stress. Their very good flexibility is another factor contributing to the popularity of fluoropolymers as cable jacketing. At the moment, alternative rubbers or other materials are not considered suitable by the manufacturers of electrical and electronic equipment where those harsh conditions are encountered.

Considering the number of important end uses of this equipment, which is only made possible through the use of fluoropolymers, the necessity of those materials for a wide range of industry sectors needs to be ensured.

For the semiconductor industry in particular, fluoropolymers exhibit several properties that make their use essential for the industry. They have excellent compatibility with all chemical agents used in the process, they have high oil and water repellence when used in filters to maintain an extremely clean environment and in semiconductor processing equipment (wet processing equipment, fluid transport systems and wafer handling tools).

Semiconductors are encountered in practically every aspect of life and are essential for the operation of a wide range of devices and equipment. If the semiconductor manufacturing industry is able to keep up with the ever-increasing demand for their products, it is through the use of semiconductors.

3.3.8 Water and wastewater treatment

Fluoropolymer (usually PVDF) membranes are an essential component of water and wastewater treatment technologies. Hollow fibre micro- and ultra-filtration membranes are manufactured having a very fine porous structure (on a size scale of nanometres), which allows the water to pass through, while blocking pollutants (such as particles and microplastics) and infectious agents. Water typically flows from the outside to the inside of the membrane lumen. They can be installed directly submerged in water, working under suction, or enclosed in a pressurised vessel and fed by pumps.

Applications of these membranes include industrial and municipal wastewater treatment plants, in drinking water treatment facilities and for industrial water filtration. Another use mentioned by a stakeholder in the survey is as pre-treatment of water in desalination processes. In comparison to conventional sand filtration, membranes form an absolute barrier to many unwanted and potentially harmful constituents present in untreated water and wastewater. Today, ultrafiltration membranes treat an estimated 25 gigalitres of water and wastewater daily in the European Union (with over 2,000 installations). Approximately 45 million people in Europe drink water treated with membranes and 35 million rely on membranes for their domestic wastewater treatment.

Additional uses of fluoropolymers include sealings, O-rings and gaskets for hydraulic devices, pipes, joints and water conveying systems. The benefits of these products have been discussed in previous sections (e.g., Section 3.3.1).

3.3.8.1 Status in the restriction proposal

The water and wastewater treatment section is not examined separately in the restriction proposal annexes. There is a single mention for application of lubricants in wastewater treatment. In addition, there is mention of PFAS applications in filtration and separation media, but their extensive use of fluoropolymer in water and wastewater treatment membranes, as described above, is not mentioned. The derogation on filtering and separation media specifies that combined oil- and water-repellence should be required from the filter material.

Considering the essential services provided in these applications, a derogation should be considered for these applications, either as a separate one or through extension of the scope of existing ones.

The application could fit under a derogation as follows: “Industrial use of PVDF-based ultrafiltration membranes for water and wastewater treatment plants”.

3.3.8.2 Discussion on alternatives

As there was no section on water and wastewater treatment in the restriction proposal, there was no discussion on alternatives to PFAS / fluoropolymers for this group of applications in Annex E.

The advantages of fluoropolymer membranes, as mentioned by downstream users, include:

- Very good flexibility, allowing them to be used in applications with high concentrations of solids.
- Easy to clean, due to their anti-stick properties and their oil- and water-repellence.
- Robustness / chemical and thermal resistance, which give a long lifetime to membranes, minimising the need and frequency of replacement.

- Their high efficiency, due to their large active area leads to smaller-sized membranes used in water and wastewater treatment facilities, resulting in more compact installations and lower costs overall.

Fluoropolymers (PVDF) have been used in outside-in type ultrafiltration membranes for more than 20 years and there is no direct replacement material available that has the unique combination of properties which provides the output, compactness, and long-life expectancy of PVDF in this application. Experience with other materials such as polyether sulfone or chlorinated polyethylene have shown that the lack of flexibility, cleanability and chemical resistance result in short life expectancy and high operating cost for municipal and industrial users. Ceramic based membranes are extremely costly and require approximately 5 times the footprint compared with PVDF-based membranes. This makes them unsuitable large-scale water and wastewater applications where land constraints exist (e.g., urban centres) or as replacements for existing membrane treatment systems.

According to downstream stakeholders, some alternative materials for filtration membranes for water treatment have been developed and are in use in some low-risk applications. These are usually made of PES, PAN, ceramic or chlorinated polyethylene. However, they are only suitable for applications without risks of high fouling and with no chemical compounds that could damage the membrane. Alternative solutions are limited in the scope of their applications and cannot replace PVDF membranes in applications such as drinking and process water, where high performance is required (high suspended solids and high organic content), MBR in urban WWTP and industrial wastewater for specific industries (petrochemical, cosmetic, textiles, pulp & paper, …).

3.3.8.3 Substitution

Any alternative that is developed must be able to meet all relevant health and environmental standards, considering the use of the ultrafiltration membranes in the production of drinking water and in treatment of wastewater before release to the environment.

Drinking water is regulated in the EU by the recast Drinking Water Directive (2020/2184). The Directive includes provisions on water quality standards and on tracking emerging pollutants, such as endocrine disruptors, PFAS and microplastics. It takes a preventative approach, with actions to reduce pollution at the source, using a risk-based approach. It also harmonised the standards for materials and products in contact with water. The Directive introduced stricter standards for water quality, which require high efficiency filtering to achieve.

Urban wastewater is regulated by Directive 91/271/EEC, which was recently revised to include higher standards on wastewater quality and pollution, among other measures.

Table 3.11 lists some of the water quality standards that must be met by water and wastewater treatment facilities.

Table 3.11 Indicative list of standards for the water and wastewater treatment sectors

Standard No	Standard description	Relevant application
DVGW W534:2015	Pipe connectors and pipe joints in drinking water installation	Drinking water
KTW-BWGL	Evaluation criteria for plastics and other organic materials in contact with drinking water, by the German Environment Agency	Drinking water
DVGW W 270:2007	Microbial enhancement on materials to come into contact with drinking water	Drinking water
NSF/ANSI 61	Materials or products that come into contact with drinking water, such as protective barrier and plastic materials, joining and sealing materials, pipes, mechanical devices and others, including process media.	Drinking water
UL-778	Standard for Safety Motor-Operated Water Pumps	Water pumps

In the responses from stakeholders, it was made clear that alternative filtering membrane materials are not as efficient as fluoropolymers and would require larger land usage and redesign of water and wastewater treatment facilities, along with more frequent replacement of the filters, due to contamination and degradation from pollutants. Such changes impact the planning of these facilities and could require several years to implement.

In addition, work on developing efficient alternatives to fluoropolymers needs several years of testing to ensure compliance with all the relevant safety and performance standards. Therefore, considering the current status of alternatives, substitution may take 15 years or longer.

3.3.8.4 Conclusion on application

Filtration membranes used in (drinking) water and wastewater treatment constitute a critical application of fluoropolymers, which are not assessed in detail in the restriction proposal. Their mechanical properties, combined with their durability and, importantly, their large active surface area make fluoropolymer membranes very efficient and with a long life span.

Using alternative materials could result in more frequent replacement of the membranes, due to damage from contaminants, and could also result in redesign of many facilities, as the alternative membranes would need to be larger to achieve the same results as fluoropolymer ones.

ECHA and the restriction dossier submitters need to consider the important applications of fluoropolymers in water and wastewater treatment and evaluate the possibility of adding a specific derogation on it, in line to other derogations in the restriction proposal (e.g., for textiles used in filters). A derogation for this application will be further supported by submissions from manufacturers and users of these fluoropolymer based water and wastewater treatment membranes.

3.3.9 Lubricants

3.3.9.1 Description of applications

Fluoropolymers are used in lubricant applications across various sectors, where the reduction of coefficient of friction is important for the machinery and other equipment to function as required. The fluoropolymers mainly used for lubrication purposes are PTFE micropowders and PFPE oils.

- PTFE micropowders (polymeric PFAS) are used as an additive to reduce friction and wear in lubricating greases and coatings. PTFE micropowders are used as the main thickener in PFPE-based grease formulations offering the unique combination of wide temperature range (very low and high), chemical inertness and friction & wear reduction. They can be used in thermoplastic compounds in components that need improved abrasion resistance or as processing aid in elastomer polymerisation. They can also be used in inks for various applications and in various coatings and paints, where abrasion resistance is required.

- PFPE is used as lubricating oil on its own, in combination with PFAS-based solvents as carrier/deposition or in greases/pastes formulations.
- Due to its compatibility/solubility in PFPE lubricants, functionalised PFPE is used as rust preventive additive in PFPE oil, PFPE based grease/paste or in combination with PFAS-based solvents as carrier/deposition to impart corrosion protection to metallic part such as, but not limited to, high temperature rolling bearings.

Fluoropolymers, including PFPE, are preferred for lubricant applications where other, non-PFAS alternatives cannot meet the requirements of the use. FP lubricants combine the low coefficient of friction with excellent resistance to chemical agents and extreme temperatures (-75°C to over 270°C), while at the same time being non-flammable, allowing for extended durability during their use at temperature extremes. In addition, PFPE-based lubricants are non-toxic, odourless, dielectric, and offer excellent compatibility with materials (plastics, elastomers) and resistance to high pressure oxygen (liquid & gas) provide safety in use in multiple sectors.

Compatibility with a broad range of materials used in manufacturing of equipment, vehicle and craft components is essential, as non-compatible materials could cause swelling, shrinking or softening of seals and gaskets, which could result to leakage and other, potentially catastrophic failures.

For those reasons, fluoropolymer lubricants are used across a broad range of applications, including the chemical sector, automotive and transportation in general, industrial machinery and the semiconductor industry, especially where high temperatures are expected, due to the high heat resistance of fluoropolymers. They can also be used as additives in waxes, inks, paintings, thermoplastics, elastomers, synthetic oils, and greases. Some important applications, as referenced by FPG members and downstream users in the survey include:

- Automotive and other transport applications use FP-containing oils and greases in various components, where low/high temperatures and other harsh conditions are expected, also resulting in reduced energy consumption. PFPE-based lubricants combining a unique set of properties in a wide temperature range offer lifetime lubrication and safety (e.g., non-flammable, no failure due to stress cracking of plastics or elastomers) for applications such as, not limited to, rolling bearings, actuators, plastic gear boxes, electrical contacts, sensors, sintered metal bearings, braking systems, car interior plastic lubrication and aid assembly during manufacturing.
- Vacuum pump lubrication using PFPE-based lubricants (oils and greases) for their chemical resistance, non-flammability (e.g., FM 6930 approved), low outgassing under vacuum conditions.
- High pressure oxygen equipment such as valves, pumps, compressors for the chemical industry but also the automotive, aeronautic, aerospace and the medical sectors, thanks to the inertness and the stability of PFPE-based lubricants (e.g., BAM institute certified)
- Roller bearing of corrugator paper machine using high temperature and corrosion resistance of PFPE-based grease.
- Tire mould lubrication with high temperature and corrosion resistance PFPE-based grease to reduce downtime, maintenance and adequate lubrication of the segments during the tire manufacturing / vulcanization step. Electrical connectors and similar technologies like circuit breakers also benefit from the lubricity offered by PTFE or PFPE-containing coatings, together with the temperature resistance. The higher lubricity offered by even a very thin coating allows for lower “press-in” force for the wire to make the connection and the overall durability of the coating ensures a longer service life for the connectors and lower failure rate for the equipment using it.
- A downstream user commented that FP lubricants (PTFE, PFPE) are also used to lubricate gearboxes in nuclear power plants.
- Applications where the parts and equipment are exposed to harsh chemicals (e.g., acids, alkalis), such as in the chemicals industry, food and feed industry or in oil and gas operations. Examples can be lubrication of oxygen valves and similar equipment.
- Wind power applications

- Non-stick coatings as dry film lubricants also have many industrial and professional applications, such as in baked goods production, food processing, automotive and transportation, high-temperature kitchen equipment, medical equipment, etc.
- PTFE is used as an additive for friction reduction in use of other polymers, flares for military, and pyrotechnics.

3.3.9.2 Status in the restriction proposal

Fluoropolymer-based or containing lubricants are used in a very broad range of applications, as shown in the section above. They can be found in the chemical and manufacturing industry, in electronic equipment, in the transport sector, as well as energy applications (e.g., wind power, nuclear and conventional power stations).

The proposed derogation refers to applications that take place “under harsh conditions” in uses “for safe functioning and safety of equipment”. Several of the applications of lubricants may not be covered by this if a narrow interpretation (e.g., use only in low and high temperatures and in presence of aggressive chemicals or under extreme pressure) is used. However, it can be seen that fluoropolymer lubricants are essential for electrical connectors, power generation and also as “dry-film” lubricants in a broad range of applications. It can be argued that all these applications are essential for the safe functioning and safety of equipment, but it is unclear whether they are covered by the proposed derogation.

3.3.9.3 Discussion on alternatives

Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters, which also includes an assessment of alternatives. The assessment of alternatives highlights the following key concluding remarks:

- PFAS-based lubricants are superior in terms of technical performance under harsh conditions (very high or low temperatures, very high or low pressure, strong chemical conditions like strong acids/bases or corrosive chemicals, oxidising or reducing substances, radiation etc.) compared to other lubricants and/or where other types of lubricants would not be technically feasible. Further, they are also used for safe functioning and safety in e.g., circuit breakers and switchgear (long lifetime) and according to stakeholders also in food industry (avoid chemical contamination due to inertness).
- No alternatives to the use of PFAS base oils and micro-powder PTFE under harsh conditions or for safe functioning and safety of equipment have been identified. As PFAS-additives (other than micro-powder PTFE) and PFAS-based solvents are the only additives and solvents that are compatible with PFAS-base oils, they must follow the PFAS base oils in terms of a ban or derogation.

Fluoropolymer-based lubricants combine a range of properties that make them suitable for use in the broad range of applications and conditions mentioned in Section 3.3.9.1[27].

- They retain their very low friction at extreme (both high and low) temperatures, and their resistance to oxygen, aggressive chemical agents and cryogenic gases.
- In addition, their viscosity is not affected significantly from changes in temperature, ensuring stable performance at a broad range of temperatures.
- They have excellent durability against liquid and highly pressurized and extremely reactive gaseous oxygen, acids, fluorine, which are needed for the synthesis of base chemicals.
- They have very good electrical resistance, making them suitable for high voltage applications.
- They are not soluble to water or hydrocarbons.

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[27] Meinert, H., Fluorchemie: zur Chemie und Anwendung, WTB.: Reihe Chemie, 1979, Akademie-Verlag, https://books.google.de/books?id=YguSMQAACAAJ
Ebnesajjad S. (2021): Introduction to Fluoropolymers: Materials, Technology, and Applications, 2nd Edition. ISBN: 9780128192993
Ebnesajjad S. & Morgan R (Eds.) (2019): Fluoropolymer Additives. 2nd Edition. William Andrew. ISBN: Hardcover 9780128137840
Rudnick L.R. (2020): Synthetics, Mineral Oils, and Bio-Based Lubricants: Chemistry and Technology, 3rd Edition. ISBN: 978-1-35-165574-3; 978-1-138-06821-6. ://WOS:000668149400068

- They have very good non-stick properties.
- They are compatible with a broad range of materials used to manufacture components, such as piping, hoses, seals and gaskets, hydraulic cylinders, etc.

Finding an alternative that has similar properties to fluoropolymers is not easy for many applications. Some downstream stakeholders commented that, even though lubricants not containing fluoropolymers are available, they are not suitable for the broad and high-performance range of applications of fluoropolymer lubricants such as PFPE and PTFE micropowder. Using the lower performing non-fluoropolymer lubricants would result in reduced lifetime of equipment and premature replacement, move from for-life-lubrication to time consuming, risky, costly relubrication maintenance, more frequent maintenance activities, higher energy consumption and in some cases significantly enhanced safety risks as well (leading to health hazards, environmental pollution, fatal accidents).

It has been commented that, while fluorosilicones could meet requirements on temperature resistance and material compatibility, it has low carrying load especially in metal-to-metal contact. A lubricant formulator would need to use other additives to improve this property, but the available additives are not soluble in silicones, significantly limiting the alternative’s applicability.

This performance is not acceptable in most of the applications where fluoropolymers are used as lubricants, including transportation (automotive and aviation), food processing industry, chemical industry and drinking water treatment. Each of these sectors has very high safety and performance requirements, which alternative lubricants cannot meet.

3.3.9.4 Substitution

Based on information from the Call for Evidence, literature review and stakeholder consultations, the dossier submitters conclude that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are unavailable for the quantities required for use in lubricants under harsh conditions or for safe functioning and safety of equipment and that the substitution potential is low. As noted above, a derogation (12-year timeframe) is proposed for such applications.

Lubricants are usually subject to very specific customer requirements, with performance specifications arising from national and international technical standards (e.g., ISO, DIN, ASTM) or test regimes (e.g., BAM (Federal Institute for Materials Research and Testing) safety tests). These specifications many times can only be met with the use of a fluoropolymer lubricant.

Substitution requirements vary across the different industry sectors using fluoropolymer based lubricants, but in all cases there will be a need for qualification of the new lubricant and validation of the manufacturing process and the affected components, before commercialisation is possible. Development of a completely new chemistry could take as long as 5-10 years and scaling up and commercialising it can add more to this time. It should be noted, as well, that any lubricant or additive must then be assessed and formulated by downstream users, which can take up to 7 years, depending on the application. Critical automotive and aerospace applications have higher performance and safety specifications which require long testing and are more difficult to be met by a new product. Formulators must also consider the compatibility of components or other lubricant additives with any new chemistry.

The length of the substitution process, assuming that a potential alternative is available, can take several years even assuming that a suitable alternative has already been identified, which is not the case. Work on identifying alternative lubricants is ongoing, but so far without success, for the reasons discussed above.

3.3.9.5 Conclusion on application

Fluoropolymer-based lubricants are used in a broad range of applications, such as transportation, aerospace, the chemical processing industry, the general manufacturing industry, construction, and also in power generation.

The proposed derogation refers to applications that take place “under harsh conditions” in uses “for safe functioning and safety of equipment”. The definition of harsh conditions is very vague at the moment and would need refinement to ensure that fluoropolymer applications are sufficiently covered.

It can be argued that all uses of FP-based lubricants are critical for the safe functioning and safety of the varied equipment that use them. Fluoropolymer lubricants display unique properties in liquid formulations, in pastes and as dry (powder) lubricants. They display consistent performance over a wide range of temperatures and chemical agents. PTFE also has a very low coefficient of friction and very high abrasion resistance.

The combination of those properties cannot easily be met by alternative substances, and this is also made evident by the fact that fluoropolymers are preferred over other lubricants (and additives), despite their higher price.

3.3.10 Medical devices and pharmaceuticals

3.3.10.1 Description of applications

The medical and diagnostic sector is heavily regulated, with medical devices, pharmaceuticals and even pharmaceutical packaging having to meet strict specifications to ensure high performance and minimal risk for patients and practitioners. Therefore, the use of high-quality materials is necessary, and fluoropolymers are often the choice for demanding applications, as they combine properties that alternatives do not have.

A non-exhaustive list of medical applications of fluoropolymers is below:

- In sealing components (e.g., seals, gaskets, O-rings) in medical and diagnostic devices, to protect the components and reagents in the device from contamination and to prevent leakage of potentially biohazardous fluids to the environment.
- In tubing and other equipment (e.g., tools and trays, seals, pipes, hoses, connectors) used in manufacturing of pharmaceuticals, where high temperatures and aggressive chemicals are expected. This equipment must neither leach nor contaminate the pharmaceuticals or intermediates.
- As primary insulation and jacketing of cables and wiring used in medical and analytical / diagnostic equipment, fluoropolymers allow the devices to meet specifications set in international standards (e.g., for FDA approval). Those cables can be found in:
  - Endoscopy equipment, which uses miniature cables with a diameter of 1.25µm
  - Imaging diagnostic devices, such as echography, radiography (X-ray sensors)
  - Other medical analyses (e.g., blood, tissue, urine)
  - Artificial hearts
  - Robots used in surgery
  - Implantable hearing aids
- FPs are used in surgically implantable medical devices, catheters, guide wires, filters and pumps to reduce the risk of failure, replacements, cross-infections, and clogging of medical equipment. Surgically implantable devices, such as vascular grafts and heart patches, stents, occluders, hernia (e.g., peritoneal) meshes, endoprosthetics, ligament replacement, tubes for dialysis and catheters. Use of fluoropolymers ensures the longevity of the implants and reduces the risk or frequency of the implant having to be replaced.
- PCTFE thermoform film is used in packaging of pharmaceutical products, nutraceuticals and medical devices. The film is typically laminated on other packaging materials to create a moisture barrier for the (usually solid) medicine. It ensures safety, efficacy, purity, product stability, tamper resistance, and extended shelf life for the medicinal product. The film is a critical and essential packaging material used by multiple therapeutic entities for disease management, prevention, and curative drug treatment regimens. Fluoropolymer laminated packaging also facilitates cryogenic drug and sample preservation.

- ETFE and PFA film and laminates are used as inert surfaces on caps and lids of medical vials and syringes.
- Fluoropolymers are also used in medical garments, because of their non-stick properties.
- High-efficiency air filters are used in ventilation and in maintaining clean industrial production environments, which are essential in drug production.
- PFPEs are also used as lubricants and filling liquids in oxygen management systems enabling safe use in hospitals and portable units.
- Biochips or analysis chips use amorphous fluoropolymers in a waveguide set up for analysis, commonly used in point of care diagnostics. This exploits the fact that amorphous fluoropolymer has low autofluorescence and has a refractive index close to that of water.
- PFPE is also mentioned to be used in easy to clean ophthalmic products (contact lenses?).
- Other uses of fluoropolymers mentioned in the survey are in cryogenic bags for blood and organs, in breathing air devices, medical ventilators and oxygen supply systems.
- A fluoropolymer coating is a critical component of Metered Dose Inhalers (MDI) and similar applications, where compatibility with a medicine and non-stick properties are required.
- In pharmaceutical applications, PVDF filtration membranes are used in sterilising grade and virus removal filters, ensuring the sterility of the final (bio)pharmaceutical product. PVDF is used in highly demanding applications, where no other efficient solutions exist.

Again, the unique combination of properties exhibited by the fluoropolymers is the main reason that they are preferred in demanding applications. It should be noted that, in most cases, the more expensive fluoropolymers are used when the alternatives cannot meet the requirements.

- Thermal and chemical resistance of fluoropolymers ensure that they will maintain their functionality after sterilisation (whether steam, chemical or radiation) and they will continue to operate under harsh conditions (e.g., acids, lubricants, oils in devices) and temperatures (ranging from cryogenic temperatures to over 250°C).
- Fluoropolymers have excellent biocompatibility and they do not react with drug components, biological fluids (e.g., blood, urine) or the human body. This biocompatibility ensures that the drugs in fluoropolymer packaging will not degrade, the biological fluid or tissue samples used for diagnostic analysis or research will not be affected and that human tissue in contact with implantable devices will not have an unwanted reaction to the fluoropolymer. Thus, biocompatibility is a major requirement by drug and medical device manufacturers, who carry out extensive testing to ensure the safety and long-term efficacy of a medicine, a medical device or a diagnostic.
- For cables, high insulation resistance together with good flexibility and extrudability of fluoropolymers allows for thinner layers to be used, thus reducing the mass and facilitating miniaturisation. The high dielectric strength and low loss provide good data transmission performance, which is required in imaging devices (e.g., endoscopes). Their fire-retardance also increases safety during the use of a medical device.
- Fluoropolymers with low coefficient of friction are also preferred for use in medical devices used in minimally invasive surgeries, where miniaturised equipment is used. These low friction materials, e.g., in miniaturised cables, guiding wires, etc., enable the surgeons to carry out such operations which have low stress for the patient.
- Pharmaceutical solid oral drugs are sensitive to moisture and can experience undesirable chemical reactions known as degradation. This process is accelerated with increased moisture absorption. When these reactions occur, the drug becomes unstable, rendering the active ingredient or formulation ineffective and potentially unsafe. Therefore, pharmaceutical and veterinary API efficacy and performance are protected and guaranteed only by the use of highly effective barrier materials.
- Sensitive solid oral formulations must be packaged in moisture resistant primary packaging materials to avoid the negative impact of high relative humidity. The clear polymeric structure of fluoropolymer

(PCTFE) film provides ultra-high protection against moisture ingress. An inadequate moisture barrier will render a drug API unstable, ineffective, and potentially dangerous. A fluoropolymer film layer possesses ultra-high, non-yellowing clarity essential for Child Resistant packaging, and patient access along with treatment adherence.

3.3.10.2 Status in the restriction proposal

The restriction proposal includes several derogations for medical devices, but the overall scope seems to be narrower than the broad range of applications discussed in this section. The proposed and considered derogations appear to cover mostly single-use or implantable medical devices (e.g., tubes and catheters, hernia meshes, wound treatment products (e.g., sutures) and coatings for medical devices, but only coatings for Metered Dose Inhalers have a proposed derogation. In addition, diagnostic laboratory testing is another proposed derogation.

A large number of medical devices that use fluoropolymers and do not appear to be explicitly covered are those that have electronic parts, such as endoscopy equipment, surgery robots, artificial hearts or implantable hearing aids. *In vitro* diagnostic systems are also a sector with many diverse products. Those devices must avoid contact of function-critical components and surfaces with moisture and also to prevent leaks of potentially hazardous or biohazardous fluids. The potential of a derogation for fluoropolymer sealings and coatings need therefore to be considered in more detail. The same applies to fluoropolymers used as primary insulation and jacketing of miniaturised cables used in endoscopes and other cables used in imaging diagnostic devices.

In the pharmaceutical and veterinary sectors, the active ingredients are exempt from the scope of the PFAS restriction, as they are regulated by Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC (paragraph 4 of the restriction proposal).

However, there are other, auxiliary uses of fluoropolymers in the pharmaceutical industry, which are not explicitly discussed in the restriction proposal and may not be covered by a derogation. The exemption only refers to the active ingredient and does not include other co-formulants or equipment used in the manufacturing process.

As discussed in the section on chemical processing (3.3.1), fluoropolymer sealing components and coatings are commonly used in applications where harsh conditions and agents are present. This may also be the case for the manufacturing of small molecule (synthetic) and biological medicines. Preventing contamination and leakages is essential in those processes, where purity of the final product is the primary goal.

Use of fluoropolymers in filter membranes may be covered by derogationon textiles used in filtration and separation media for high performance air and liquid applications, where a combination of oil and water repellence is required. However, this needs to be assessed further.

Finally, there is a considered derogation for the use of PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics (derogation 6(l)). This use has been mentioned by a number of FPG members and downstream users and should be explored further.

3.3.10.3 Discussion on alternatives

Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters, which also includes an assessment of alternatives. Summarised remarks concerning each of the sub-uses are provided below.

- The very good biocompatibility, heat resistance, combined with chemical compatibility and low friction are unique among fluoropolymers and they are preferred over alternatives, despite their higher costs. These properties contribute to increased lifetime of implants and reduce the risk of failure and need for replacement through surgery. It has been also noted that, where feasible, alternatives would have already been implemented. The long validation and qualification procedures for medical devices under the MDD (and now the MDR) are another factor that may delay substitution of fluoropolymers in those applications. Similar justification of the importance of using fluoropolymers in tubes and catheters, which reduce the need for more invasive operations.

- For hernia meshes and wound treatment products (e.g., bandages, surgical tapes and staples), potential alternatives may be available, but may not have the same performance as fluoropolymer ones. The dossier submitters commented that further justification would be needed for these.
- For coating applications, the dossier submitters recognised the very good compatibility of fluoropolymers with the medicine in MDI and that alternatives do not have sufficient durability in the environment in the inhaler. On the other hand, they did not conclude the same for other coating applications in medical devices.
- The important function of fluoropolymers for diagnostic laboratory applications was also recognised by the dossier submitters, as the chemical compatibility and overall durability of these coatings in place of chemical and biological agents are essential for their purpose. It was also noted that potential alternatives may also be persistent, which could lead to regrettable substitution.
- Ophthalmic and contact lenses also use fluoropolymers, due to their high water and oil repellence and their high durability. Alternatives, such as silicone and fluorinated methacrylate monomers may be available, but they still have lower performance than fluoropolymers in some applications and could lead to lower functionality for the users.
- Medical devices also use PTFE membranes for sterile venting (e.g., analytical devices, blood tube systems for dialysis, etc.). The dossier submitters list limited information on the availability of alternatives, requesting for additional information to support a derogation.
- Finally, Annex E to the restriction proposal discussed the limited availability of technically and economically feasible alternatives for use in different medical device packaging applications. In most cases, there are no alternatives to fluoropolymers (e.g., in packaging for medicinal preparations, medical devices and molecular diagnostics, in packaging of ophthalmic solutions, and in packaging of terminally sterilised medical devices). This was primarily based on comments received from stakeholders.

Overall, the dossier submitters recognise the difficulty in identifying, and substituting with, technically and economically feasible alternatives for the very demanding medical device and pharmaceutical applications but require further justification for some of those applications.

Stakeholders that participated in the survey have highlighted additional applications in the pharmaceutical and medical device sectors, where fluoropolymers are used. These applications may overlap with similar ones in other demanding sectors, such as the chemical processing industry, oil and gas, and electronics and semiconductor manufacturing.

Medical devices need to use cables which are resistant to high temperature and biological and chemical agents and also have unique mechanical properties. It is difficult to find performing alternatives for cable jacketing, where resistance to broad range of temperatures, as well as resistance to chemical and biological agents, are required. Most materials, including PP, PVC, Polyethylene sulphone, polyimide and several rubbers, have lower resistance to heat and to aggressive chemicals, while they also have lower mechanical durability (compared, e.g., to FEP). In addition, it is possible that they contain additives that may leach into biological fluids or tissues.

Polypropylene, for example, is not sufficiently stable in temperatures above 90°C and usually has a melting point below the temperatures where FP are normally used. Similarly for PVC. PVC is also not an approved material for cable applications in medical devices. The different rubbers discussed have low temperature stability, and would require thicker layers to achieve a comparable result, which would increase the weight of the product. Ethylene-acrylic rubber may find some application as compound component, but it shows moderate service life length in extreme environments and has similarly moderate temperature range and chemical resistance but would still need a thicker layer to be applied.

One particular group of products that benefits from the use of fluoropolymers are the miniature endoscopy cables and other imaging and diagnostic equipment, due to the thinner jacketing that is needed. In addition, such medical devices, as well as other devices used in minimally invasive surgeries, need to have low friction, which is not achievable by non-fluoropolymer alternatives.

Furthermore, O-rings and gaskets, used in applications with high temperatures and aggressive chemical agents present, such as sterilising devices, may be made by materials such as EPDM and (hydrogenated) nitrile rubber, but they do not meet customer expectations for temperature and gas or chemical resistance. Sterilisation equipment often requires high temperatures (e.g., above 150°C). If the seal material is not resistant to these conditions, the medical device will fail. It should be noted that the combination of chemical and heat resistance exhibited by fluoropolymers such as PTFE and FKM are very difficult to be found in alternative materials.

3.3.10.4 Substitution

Medical devices and pharmaceuticals are highly regulated products in the EU. Both product groups need to carry out extensive testing to prove their efficacy and safety for the patient. Any medical device or pharmaceutical product must also be certified and registered with the respective competent authorities, after carrying out a long series of validation and testing. Medical devices in particular, according to the Medical Device Regulation (EU) 2017/745, need to receive CE certification by a Notified Body before they are placed on the EU market.

In the EU, the qualification and approval processes are clearly defined by the Pharmaceutical regulatory systems comprised of a decentralized body like the European Medicines Agency (EMA), Heads of Medicines Agencies (HMA), National Competent Authorities (NCAs) and the European Directorate for the Quality of Medicines EDQM). Eudralex is the collection of rules and regulations governing medicinal products in the EU. A medicinal product can only be sold in the EU by a Marketing Authorization Holder (MAH) after acquiring a marketing authorization in the EU, and the drug API, formulation, and primary packaging material are inextricably linked in that Marketing Authorization. The marketing authorization can be obtained by any of the four major procedures: centralised (CP), decentralised (DCP), mutual recognition (MRP), and national procedures. The authorisation applied under the centralised procedure is granted in all EU member states including the European Economic Area (EEA), whereas marketing authorisations under DCP and MRP are approved in EU members states selected by the applicant.[See footnote 18 in the questionnaire response] The impact on the Regulatory approval processes due to the significant number of new or amended registrations requiring review and approval is unknown; but will indeed add significant workload and burden to the agencies above and beyond their normal workloads.

Any change to the manufacturing process or to the materials or equipment used needs to be communicated to the competent authorities, so that they are approved for use. Depending on how big the change is, testing can take from a few months to several years, especially if clinical trials are required. Medical device companies estimate such a process to take 3-5 years or even longer, assuming that a suitable alternative is already identified.

It must be noted that drug APIs, formulations, and primary packaging structures are inextricably linked for market access and regulatory authorisations. Considering the number of drugs impacted, these efforts would require over 12-15 years to complete, due to the extensive qualification testing required. Such testing includes manufacturing and testing of packaging to evaluate moisture permeation and moisture resistance, drug degradation and stability analyses, impurity and degradation product testing, chemical analyses for API potency and drug excipients, quality testing over the prescribed shelf life of the drug package integrity testing, and patient use testing.

In addition, new manufacturing feasibility analysis would be required to assess accuracy and precision of thermoform moulds to ensure material performance as it relates to barrier properties if changes in primary packaging materials are made, and throughput efficiency, production capability quality, and operational utilities will undoubtedly be affected.

The medical device and pharmaceutical sectors also require very clean environments for manufacturing, which are achieved with the help of high-efficiency filters. Qualification of a new filter medium includes testing of basic properties, such as filtration efficiency, pressure drop, emission behaviour, tensile strength, stiffness, water- and oil-repellence.

Once these properties are validated, the focus switches to the processability into folded filter packages and the assembly into a final filter element. Properties assessed at that phase include cutting behaviour, pleating properties, and compatibility with other materials, such as polyolefin and polyamide based hotmelts, and polyurethanes.

Following that, manufacturers verify the key performance parameters of the finished filter element must be verified, which include filtration efficiency, leak freeness, pressure drop, dust/oil holding capacity, energy consumption, gas emission and transportability.

In a final step, field tests are carried out to verify the suitability under real operating conditions and the long-term stability.

The industry estimates that the above process could take 10-15 years to develop an alternative to fluoropolymers, but that could depend on the application, and on no unacceptable results during validation and approval. Furthermore, the competent authorities for these products, namely FDA in the USA and EMA in Europe, must be convinced of the suitability of the new HEPA filters, which is typically demonstrated by long-term stability tests, which could extend the substitution timeline beyond those 10-15 years.

3.3.10.5 Conclusion on application

While the restriction proposal contains several derogations for medical devices, some of the uses identified during the FPG member and downstream user surveys do not appear to be covered. Such uses could be medical devices having electrical or electronic components that must be protected from moisture, chemical or biological agents or temperature, co-formulants in pharmaceutical or diagnostic products and equipment (e.g., sealing or tubing) used in the medicine production process.

The importance of fluoropolymers for the medical device and pharmaceutical sectors must be highlighted to ensure that medical devices and medicines continue to be produced at the current high standards in the EU. However, whilst several derogations are recommended, should FPG members support further derogations for medical devices and pharmaceuticals additional information on the (lack of) technical and economic feasibility of potential alternatives will be required.

Further to the above, the currently proposed time-limited derogation for implantable medical devices presupposes that suitable alternatives would be made available by the time that the derogation will expire. Considering that some of the main obstacles to developing alternatives are the need for excellent biocompatibility and a long life span, if alternative materials cannot meet the performance of fluoropolymers, this could result in the need for more frequent replacement of the implant in the patient, which could mean several additional, unnecessary surgeries.

Overall, it is important to consider the huge benefits that the use of fluoropolymers imbues on a broad spectrum of different medical devices, ranging from implantable devices, to wound treatment articles, to endoscopy and imaging equipment, to analytical and diagnostic equipment and ophthalmic and contact lenses.

3.3.11 TULAC (textiles, upholstery, leather, apparel and carpets)

3.3.11.1 Description of applications

Historically, fluoropolymers have been widely used in fabrics as a result of their oil- and water-repellence, breathability and light weight compared to alternative materials. Fluoropolymer coatings can be found in a broad range of applications.

FPG members and downstream users of fluoropolymers have identified a number of such applications, as below:

- Waterproof clothing, such as raincoats, jackets, footwear etc. Most of the consumer products are expected to be moving to alternatives, but the high performance required in professional uses (e.g.

safety clothing such as military, firefighters, police, workers in industrial environment), such as high-visibility jackets and chemical resistant apparel, still requires the use of fluoropolymers. Another example of high-performance technical textile using fluoropolymers is for fire-fighting garments, in which expanded PTFE membranes are used to provide thermal protection, while at the same time maintaining breathability and waterproofness.

- Fabrics (textile or leather) used in applications where extensive outdoor use is expected (e.g., in motorcycles).
- Geomembranes and composting membranes, which require low-permeability materials and high resistance to chemicals. Geomembranes in particular are essential in protecting ground and groundwater from contamination from human activities (e.g., in mines, construction / demolition sites or in landfills).
- ePTFE sewing thread, fibres, and weaving yarn: Used for outdoor applications like awnings, umbrellas, furniture, boat covers, and sails, industrial filtration applications in demanding environments and high-performance ropes.
- Fluoropolymer-coated polyester fabrics are used to protect membranes used in several applications, such as in architectural materials for roofs or facades, as they provide extended lifetime due to their strong resilience to soiling. Such membranes can also be used in tents and furniture.
- Fluoropolymer (mainly PTFE) membranes are also used as filtering media in HEPA filters, as they can efficiently capture particles (soot, droplets, biological agents) at lower pressure drop, which translates into lower energy requirements. HEPA filters are essential in semi-conductor manufacturing to maintain the clean manufacturing environment, and they are also used in food processing plants.

As mentioned above, oil- and water-repellence together with breathability are the primary properties of fluoropolymers used in TULAC applications. Other relevant properties are fire-retardancy, weather and chemical resistance, thermal stability and heat resistance, as well as low friction and good lubricity. The expanded PTFE membranes typically used in these applications retain the properties of PTFE resin and can even be produced with a tailored pore size, that broadens their application range.

3.3.11.2 Status in the restriction proposal

The different TULAC applications were assessed in the restriction proposal and the following derogations were proposed:

- Personal protective equipment (PPE) for general risks and for professional fire-fighting activities (paragraphs 5b and 5c of the proposed restriction).
- Impregnation agents for such PPE
- [technical] textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence.

There is also a considered derogation on textiles used in engine bays in automotives, for noise and vibration insulation.

Consumer-related applications, such as home textiles, consumer apparel, leather and home fabric treatment sprays were not proposed for a derogation.

From the uses of fluoropolymers described in the previous section, it is unclear if some technical applications, such as for geomembranes and architectural applications are covered. That use does not seem to be adequately described in the restriction proposal currently.

Furthermore, it is not clear what the derogation for filtering material currently covers and what “high performance” could cover. HEPA filters, for example, are used in a broad range of industrial and professional applications, such as semiconductor manufacturing, food processing plants and, increasingly since the Covid-19 pandemic, to protect public health (e.g., in hospitals).

3.3.11.3 Discussion on alternatives

Within the restriction proposal, construction products are broken down into the following sub-uses:

- Home textiles
- Consumer apparel
- Professional apparel (including PPE)
- Technical textiles
- Leather
- Other: Home fabric treatments (sprays)
- Other: Textiles for use in engine bays in automotives (for noise and vibration insulation)

As noted above, a limited number of sub-uses are currently associated with potential derogations. Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters. For TULAC, the submitted impact assessment is particularly extensive (almost 140 pages), providing a cost-benefit analysis of each sub-use. Within the impact assessment, significant consideration is also given to potential alternatives. Substitution potential considerations for each sub-use can be summarised as below:

- Home textiles (curtains, carpets, textile coverings) and consumer apparel appear to have technically and economically feasible alternatives available and substitution is therefore feasible. Similar arguments were made for leather articles, though the evidence is considered to be somewhat weaker than for home textiles and consumer apparel due the existence of some conflicting evidence.
- For professional apparel, there is significant evidence that there are no technically and economically feasible alternatives for a number of PPE categories, i.e., where exposure to chemicals is expected, for protection against microorganisms, for firefighting and for care, and maintenance of such workwear.
- For technical textiles, the dossier submitters concluded that in outdoor applications, where only water repellence is required, there are technically and economically feasible alternatives, even though most of the alternative groups assessed still required further testing and may still require PFAS for their manufacturing.
- The dossier submitters recognised the high performance of fluoropolymer membranes in filters for industrial and professional air and liquid applications, where oil and water repellence are both required. This is essential for medical applications, but it should also be relevant for high-performance and high-cleanliness industrial applications, such as in semiconductor or other electronics manufacturing, in medical devices and in high purity (bio)pharmaceutical and chemical processes.
- Spray treatment of home fabrics was also assessed and the dossier submitters identified a number of potential alternatives, but mention only silicone-based alternatives as technically feasible. Nevertheless, based on the lack of conflicting information, they concluded that substitution should be feasible for this sub-use.
- Finally, the dossier submitters recognise that it may not be possible to substitute PFAS from textiles used in automotive engine bays, but more information would be needed to justify such a derogation.

Within questionnaire responses in the stakeholder survey, it was highlighted that water repellence by spray using alternative technologies can be achieved for lower specification applications (e.g., shower-resistant), but it becomes more difficult for more demanding ratings, e.g., heavy rain resistance or dynamic water repellence, In addition, it was mentioned that the high alcohol repellence required for medical use cannot be achieved with non-fluoropolymer coatings[28].

[28] Euratex Alliance (Schellenberger, S., et al., (2019). Highly fluorinated chemicals in functional textiles can be replaced by re-evaluating liquid repellency and end-user requirements. Journal of Cleaner Production, 217, 134–143. doi: 10.1016/j.jclepro.2019.01.160.)

One downstream user commented that using glass-fibre HEPA filters with a PFAS / fluoropolymer binder makes the filter moisture-stable and oleophobic, reducing the risk of product leakage and contamination.

3.3.11.4 Substitution

For surface finish of polyester or PVC fabrics, downstream stakeholders commented that reformulation can take at least 5 years of R&D development, provided that an alternative with suitable water- and oil-repellence had been identified.

3.3.11.5 Conclusion on application

The restriction proposal includes derogations for use of fluoropolymers in textiles used in PPE (including impregnation agents) and technical textiles used in filtration and separation media in high-performance industrial and professional applications where oil- and water-repellence is required. In addition, they have listed for reconsideration the use of technical textiles in automotive engine bays for noise and vibration insulation.

These derogations cover some of the uses of fluoropolymers supplied by FPG members. Annex E to the restriction proposal notes that there were no suitable alternatives mentioned for indoor technical textiles, but there is strong evidence for alternatives on outdoor ones (e.g., polyurethanes).

However, the dossier submitters do not seem to consider the importance of fluoropolymers for more demanding applications (e.g., heavy rain resistance or dynamic water repellence, and high alcohol repellence needed in medical uses). Substitution in these cases may not be possible in the short term, as new alternatives may need to be developed and tested. For medical applications, this could take several years, due to the regulatory validation and verification procedures in place.

3.3.12 Metal plating and manufacturing of metal products

3.3.12.1 Description of applications

Fluoropolymers are used in several metal treatment processes. Downstream users have reported its use as an antifoam additive in chromium plating baths and as electrical insulation and sealing in metal heating processes. Metal plated / coated parts for automotive applications were mentioned as final products of such processes, but these are dealt separately in the respective section.

In addition to anti-foam additive, fluoropolymers may also be used for noise reduction and as dry bearings in metal product manufacturing processes.

3.3.12.2 Status in the restriction proposal

The restriction proposal only has a derogation for reconsideration. The derogation refers to hard chrome plating specifically, with other processes, such as decorative chrome plating and other metal product manufacturing processes. The use of protective fluoropolymer layers on steel substrates in metal plating also appears to be out of scope of the considered derogation.

3.3.12.3 Discussion on alternatives

As noted above, considering metal plating and the manufacture of metal products, the restriction proposal lists only one potential derogation for reconsideration.

Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters, which also includes an assessment of alternatives. Concluding relevant remarks concerning each of the sub-uses are summarised below.

- The dossier submitters refer to mixed evidence on the availability of alternatives for hard chrome plating, possibly due to the different specifications among the various product lines requiring the use of fluoropolymers, which is why they have included a potential derogation for reconsideration for that specific sub-use.

- The dossier submitters concluded that there are suitable alternatives available for decorative chrome plating and plating on plastics with other metals.

At present, very little information has been forthcoming from consultation activities with regard to the ongoing criticality of fluoropolymers in metal plating and manufacture of metal products (not addressed elsewhere within the restriction proposal).

One downstream user of fluoropolymers as electrical insulation and sealing in metal heating processes, commented that use of PE is possible in some cases, but not for all applications.

3.3.12.4 Substitution

Metal plating is essential for manufacturing of components used in other sectors, such as transport (all modes), chemical industry, as well as electronics and water and wastewater processing. As such, substitution activities for such applications would relate to the end product. For example, a chrome-plated steel component of a passenger car or an airplane must meet the specifications set by industry standards and customer requirements, as discussed in Section 3.3.1.4. Any change in the process will need to be assessed to ensure that it does not impact the quality and performance of the final product.

Furthermore, as the most common use of fluoropolymers in metal plating is as an anti-foam agent, it has a critical function in reducing occupational risk from exposure to mist containing hexavalent chromium.

Considering the above, the time required for substitution of fluoropolymers in these applications is expected to be long and comparable to those required for substitution in transport or other applications, especially considering that, at the moment, there are no suitable alternatives available.

3.3.12.5 Conclusion on application

Information on the use of fluoropolymers in metal plating and manufacturing of metal products is limited, but it is understood that they are still considered important processing aids and component materials. Those manufacturing processes still require high temperatures and aggressive chemicals, so equipment such as pumps, seals and piping receive great benefit from the use of fluoropolymers.

Nevertheless, more information would need to be collected for a more thorough assessment of the substitution potential in this application.

3.3.13 Cosmetics, consumer mixtures and other applications not mentioned elsewhere

3.3.13.1 Description of applications

A number of other mixtures and applications of fluoropolymers were considered, but it appears that they are not very extensive:

- The only mixtures intended for direct use by consumers that may contain fluoropolymers that were mentioned in responses to the downstream user survey were polishes and waxes for stone surfaces. There are several more articles with fluoropolymer coatings that reach the consumers, such as electrical appliances, cars and motorbikes, high-pressure washers, coffee machines and food packaging.
- Fluoropolymer (Fluoroalkyl acrylate copolymer, Pure methacrylic polymer, (Meth)acrylic polymer, Fluoroalkyl silanes, Fluorosurfactant) containing polishes and waxes are used in professional and consumer products for various stone (marble, granite, natural stone) and wood surfaces, due to their good oil- and water-repellence, anti-stain and UV resistance properties.
- Cosmetic applications are mentioned in the restriction proposal, but they were not explicitly listed by any of the downstream users of fluoropolymers that responded to the survey. Some potential uses of fluoropolymers may include:

  - In dental floss
  - In perfume dip tips

- Similarly, for ski waxes, there were no responses by downstream users that decided to respond to the survey and FPG members only commented of very low quantities of fluoropolymers being used for this application.
- In F-gases uses, FFKM is a fundamental component in seals, tubes and valves where high temperatures and aggressive media show up.

3.3.13.2 Status in the restriction proposal

There are no proposed or considered derogations for uses of fluoropolymers that may end up in consumer mixtures or applications such as cosmetics, ski wax, cleaners, polishes and other surface care products.

Considering the widespread uses of such products, it is unlikely that a derogation will be proposed. Furthermore, during the FPG member and downstream user surveys, there were few respondents who mentioned such uses.

3.3.13.3 Discussion on alternatives

Considering consumer mixtures, cosmetics and ski waxes (identified as separate use categories within the restriction proposal), the restriction proposal concludes that sufficiently strong evidence points to the existence of technically and economically feasible alternatives.

Within Annex E to the Annex XV dossier, an impact assessment has been provided by the dossier submitters, which also includes an assessment of alternatives. Concluding relevant remarks concerning each of the uses are summarised below:

- For a variety of consumer mixtures, the dossier submitters mentioned strong evidence for the presence of technically feasible alternatives (e.g., for cleaning mixtures, waxes and polishes, dishwashing products, windscreen fluids for cars, and guitar strings). No comments were received for use of PFAS in pianos.
- The dossier submitters also consider that the potential for substitution in cosmetics is very high, based on the relatively small share of cosmetic products containing PFAS.
- Finally, they also concluded that there are technically and economically feasible alternatives for ski waxes.

At present, very little information has been forthcoming from consultation activities with regard to the ongoing criticality of fluoropolymers in this additional wide group of applications.

3.3.13.4 Conclusion on application

The use of fluoropolymers in mixtures mainly intended for consumers, such as cleaning products, waxes and polishes, cosmetics, and ski waxes, appears to be limited. For most of these products there appear to be suitable alternatives available in the market.

4. COLLECTED COMMENTS ON THE USES OF FLUOROPOLYMERS

The PFAS restriction proposal has made an impressive effort in capturing the widespread uses of PFAS, including fluoropolymers, in the EU. It also attempts to map the situation around the suitability and availability of potential alternatives in the different uses and sub-uses.

This report focused on a wide mapping of the uses of fluoropolymers specifically and highlight the reasons that make this group of materials a first choice in most, if not all of these uses.

- Fluoropolymers combine a range of properties that make them the only suitable material for several applications, in which there are extreme temperatures (both very high and very low), aggressive chemical agents (e.g., oils, fuel, acids) and / or mechanical stress. Fluoropolymers are highly suited for use in these harsh conditions due to their high durability to all the stress factors. In addition, they are easy to form and handle and are lightweight, allowing for more flexibility in the design of the components and processes that use them.
- Fluoropolymers are versatile materials and can be used in a variety of ways.
  - They can be applied as coatings to protect a substrate from water, oil, chemicals or UV radiation, or to offer a low-friction surface in construction and transportation,
  - They can be used as moulded sealing components to prevent leakage of hazardous or infectious agents in processes,
  - They can be formed into filter membranes, ensuring removal of all potential contamination in ultraclean manufacturing environments (e.g., in semiconductor manufacturing) or in the treatment of drinking water and wastewater
  - They can form ion-exchange membranes that are used in electrochemical processes, in the chemical industry and for power generation (e.g., fuel cells, hydrogen generation),
  - They can also be used as lubricants or lubricant additives in very demanding transport and industrial applications.
- The fields of application for fluoropolymers are variable, but one common parameter is that fluoropolymers are chosen where other solutions are not available or would have significantly worse performance, leading to increased costs and need for maintenance or replacement.
- Potentially suitable (technically and economically) alternatives exist for some, but not all of those applications. Where possible, these alternatives are already in use. This typically takes place in applications that are less demanding (e.g., operate at a narrower temperature range or there are no aggressive chemicals). However, practically all alternatives fail to meet at least one resistance criterion, thus making them unsuitable for most applications under harsh conditions.
- In general, the lifetime of a component made out of, or coated with, fluoropolymers is much longer than that of potential alternatives, ensuring that the equipment, vehicle or process can operate without breakdowns for several years, if not decades. As an example, use of piping with a fluoropolymer lining in a chemical process could have a service life of two decades or more. Use of an alternative lining or pipe material could mean that the piping would need to be replaced every few months.
- It must be noted that several stakeholders have commented that fluoropolymers are usually more expensive than the potential alternative materials. The fact that they are preferred over cheaper materials, especially in some very cost-sensitive industries, such as chemical processing and transportation, is a strong indication that the potential alternatives are not suitable for the particular uses. In general, the industry aims at minimising production costs and any contingencies arising from equipment failure. This is often assessed over the whole lifetime of a component or a plant. Materials with better performance and durability, such as fluoropolymers, have a very long lifetime and a much smaller rate of failure than alternative materials. This results in less frequent maintenance and replacement (e.g., for seals), which, over a 20-year period proves to be less costly for the user. As they are

less prone to failure than alternative components, it can reduce costs from equipment breakdowns, not counting the potential human and environmental cost from exposure to leaked chemicals or accidents.

- Most of the industry sectors discussed in this report place very high importance in the safety of their products and processes. Fluoropolymers are chosen by those sectors because they ensure a high level of safe operation and safety for their products and their customers or the final consumer.

Overall, fluoropolymers are materials with a unique combination of properties that are used in a broad range of applications where harsh conditions are expected. They are critical for the safe use of equipment, and for maintaining ultra clean manufacturing and operating environments, with no leakage or contamination, over very long life spans. Their continued use in those applications is necessary, as they are outperforming alternatives and substitution may not be feasible, without several years of testing and qualification.