

TECHNICAL REPORT:

Analysis of alternatives to fluoropolymers and potential impacts related to substitution in different sectors of use

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Executive Summary

This report describes in detail a selection of specific applications in which different fluoropolymers are used. The objective of the report is twofold; on one side, it intends to highlight the key combination of properties that fluoropolymers provide in a selection of high technology industries. On the other side, a detailed description of possible alternatives to fluoropolymers is given, and expected trade-offs related to a hypothetical substitution of fluoropolymers by such alternatives are described and justified. This aims at explaining what could be the consequences that should be expected (not only for direct industrial users, but for the European society as a whole) if the use of fluoropolymers was to be discontinued due to a potential regulatory ban that could be derived from the inclusion of fluoropolymers in the scope of the upcoming PFAS restriction under REACH.

It is worth highlighting that the scope of this report is limited to fluoropolymers as a clearly separate family of substances within the broad group of PFAS, including other polymeric PFAS such as perfluoropolyethers and side chain fluorinated polymers, which should not be confused with fluoropolymers and are definitely not in the scope of the present report.

The case studies that are described in this report are based on specific applications as reported by a selection of downstream users of fluoropolymers. Those downstream users were requested to provide information via a detailed questionnaire developed specifically for this project. Where relevant, one-to-one conferences with the respondents were set-up in order to expand on the replies provided, in order to refine and expand on the information provided. This information has been complemented with publicly available literature or references with the objective to further clarify the application described.

Where available, information on expected socio-economic impacts related to a potential substitution (or lack of availability) of fluoropolymers has been provided. Information in this case has been usually sought from industry associations involved in some of the specific industrial sectors covered.

It should be noted that the applications described in this report should be considered as a reduced sample of the broad industrial sectors that rely on fluoropolymers today. Further work is expected to be developed in order to add further cases, and to expand on the socio-economic impacts of fluoropolymers for critical industrial sectors in Europe.

Table of contents

Executive Summary	iii
Table of contents	iv
List of abbreviations and acronyms	vi
1. Introduction	1
2. Properties of fluoropolymers and socio-economic importance.....	3
3. Case studies evaluated	4
3.1. Sector of use 1: Industrial uses.....	4
3.1.1. Application 1.1: Use of PTFE, PFA and ETFE in the production of lined equipment in the chemical processing industry.....	4
3.1.2. Application 1.2: Use of PFA, PTFE, FKM in the production of lined pumps in the chemical processing industry.....	9
3.1.3. Application 1.3: Use of PTFE matrix composites in the production of seals and gaskets for industrial machines.....	11
3.1.4. Application 1.4: Use of PSEPVE and PTFE matrix composites in the production of membranes for electrochemical processes	14
3.1.5. Application 1.5: Use of PTFE, PVDF, PFA in the production of filter systems for waste treatment in the chemical processing industry, power plants and other sectors	16
3.2. Sector of use 2: Energy production.....	18
3.2.1. Application 2.1: Use of PTFE, PVDF and FKM in the production of lithium-ion batteries	18
3.2.2. Application 2.2: Use of PSEPVE and PTFE in the production of proton exchange membranes for hydrogen production.....	20
3.2.3. Application 2.3: Use of PTFE and FEP in the production sealing systems for storage, transport and production of green hydrogen	24
3.3. Sector of use 3: Semiconductors and electronics.....	26
3.3.1. Application 3.1: Use of PTFE and PFA in the production of pipes and tubes for ultra-high purity requirements in the semiconductor industry.....	26
3.3.2. Application 3.2: Use of PTFE, FEP and ETFE in electrical cabling for various industrial sectors	29
3.4. Sector of use 4: Automotive and aerospace	31
3.4.1. Application 4.1: Use of PTFE and FEP in the production of electrical cabling for use in aircrafts	31
3.4.2. Application 4.2: Use of PTFE in the production of lambda sensor for the automotive industry.....	34
3.4.3. Application 4.3: Use of PTFE in the production of control cable liners for the transport industry	36
3.4.4. Application 4.4: Use of PTFE and ETFE in the production of different auxiliary components for the automotive industry	38
3.4.5. Application 4.5: Use of FKM for sealing applications in the automotive industry	41

3.5. Sector of use 5: Food and water processing	43
3.5.1. Application 5.1: Use of modified PTFE, PFA and FEP in the production of systems used for food processing.....	43
3.5.2. Application 5.2: Use of PVDF in the production of membranes for water treatment	46
3.6. Sector of use 6: Medical and pharma	49
3.6.1. Application 6.1: Use of PTFE in the production of equipment to be used in vaccine preparation requiring ultra-high purity media	49
3.6.2. Application 6.2: Use of PTFE and FPE in the production of implants for the medical device sector...	51
3.7. Sector of use 7: Construction.....	54
3.7.1. Application 7.1: Use of PVDF in the production of pipe fittings and manifolds for plumbing in the construction sector.....	54
3.7.2. Application 7.2: Use of PVDF in façade and infrastructure protection for the construction sector....	57
3.7.3. Application 7.3: Use of PTFE, ETFE, FEP, PFA in the production of sealing systems in compressors used for heating and air conditioning equipment	60
3.8. Sector of use 8: Cookware	63
3.8.1. Application 8.1: Use of PTFE in cookware	63
4. Conclusions	65
5. References	67
Annex I: Questionnaire for downstream users of fluoropolymers	70
Annex II: Main fluoropolymers covered in this report.....	79

List of abbreviations and acronyms

ACEA	European Automobile Manufacturer's Association
ACM	Acrylic Rubber
AEM	Ethylene acrylate copolymer
ASTM	American Society for Testing and Materials
BAT	Best Available Techniques
BPA	Bisphenol A
BPS	Bisphenol S
C/A	Chlor/Alkali
CMR	Carcinogenic, mutagenic, or toxic for reproduction
COM	European Commission
DHBP	4,4'-dihydroxybiphenyl
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EL	Electrolyser
EPDM	Ethylene propylene diene rubber
EPR	Ethylene propylene rubber
ETFE	Ethylene tetrafluoroethylene
ESIA	European Semiconductor Industry Association
EU	European Union
EV	Electric vehicles
FEP	Fluorinated ethylene propylene
FKM	Vinylidene fluoride-hexafluoropropylene copolymer
FPG	Fluoropolymers Product Group - PlasticsEurope
GDP	Gross domestic product
GHG	Greenhouse Gases
JRC	Joint Research Centre
HFC	Hydrofluorocarbons
HFFR	Halogen free flame retardants

HFO	Hydrofluoro-olefins
HNBR	Hydrogenated nitrile butadiene rubber
HVACR	Heating, Ventilation, Air Conditioning and Refrigeration
ISO	International Organization for Standardization
MBR	Membrane bioreactor
MDI	Methylene diphenyl isocyanate
MLD	Minimal Liquid Discharge
MNB	Mononitrobenzene
MVQ	Methyl Vinyl Silicone Rubber
NBR	Nitrile butadiene rubber
NSF	National Sanitation Foundation (USA)
OECD	Organisation for Economic Co-operation and Development
PAG	Polyalkylene glycol
PAI	Polyamideimide
PBI	Polybenzimidazole
PE	Polyethylene
PEEK	Polyether ether ketone
PEI	Polyetherimide
PEM	Proton Exchange Membrane
PES	Polyether sulfone
PET	Polyethylene Terephthalate
PFA	Perfluoroalkoxy polymer
PFAS	Per- and polyfluoroalkyl substances
PLC	Polymer of Low Concern
POE	Polyester oil
POM	Polyoxymethylene
PP	Polypropylene
PPSU	Polyphenyl sulfone
pro-K	German Association for Semi-Finished Plastics and Consumer Products

PTFE	Polytetrafluoroethylene
PU/TPE-U	Thermoplastic Polyurethane
PVC	Polyvinyl chloride
PVDF	Polyvinilidene fluoride
PVE	Polyvinyl ether oil
RACHP	Refrigeration, Air Conditioning, and Heat Pump
REACH	EU Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RES	Renewable energy sources
R&D	Research and Development
SME	Small and medium enterprise
UHMWPE	Ultra-high molecular weight polyethylene
UV	Ultraviolet radiation
VoP	Velocity of Propagation

1. Introduction

Fluoropolymers are a separate family of fluorinated polymers, which can be clearly differentiated from other substances typically included in the Per- and polyfluoroalkyl substances (PFAS) group of chemicals. In fact, they can also be further differentiated from other polymeric fluorinated substances, such as side-chain fluorinated substances or perfluoropolyethers (FPG, 2022a). Fluoropolymers are structurally characterised by having fluorine atoms directly attached to their carbon-only backbone.

Existing scientific data demonstrates that, because of their unique characteristics such as the negligible solubility in water or the high molecular weight, fluoropolymers cannot enter or accumulate in the human bloodstream, and cannot degrade into other PFAS under intended use conditions, nor under environmental conditions at the end-of-life phase of their applications. Therefore, it is considered that fluoropolymers do not impact water quality, and do not pose a significant risk human health, or the environment (Henry et al., 2018). This allows the conclusion that by far most fluoropolymers meet the Organisation for Economic Co-operation and Development (OECD, 2009) criteria to be identified as Polymers of Low Concern (PLC). While originally the focus was placed on a set of 4 fluoropolymers, more recent research has expanded these conclusions to cover a larger number of substances, reaching an estimate of >96% volume of fluoropolymers in the global market (Korzeniowski et al., 2022).

However, since fluoropolymers match the OECD definition of PFAS, they could be included in the scope of the restriction proposal that five Competent Authorities from Member States of the European Economic Area¹ (EEA) have announced on the broad PFAS group of chemicals under the REACH Regulation². Therefore, fluoropolymers could face market restrictions in the EEA if their differentiated properties are not clearly highlighted in such restriction proposal. This could even lead to a ban on the uses of these high value materials in the different applications in which they are used.

While the uses of fluoropolymers are primarily related to industrial applications, these substances are involved in value chains that have a strong impact in many sectors and articles that will eventually reach end-users. Fluoropolymers also play a key role in enhancing key avenues of progress that have been highlighted as extremely relevant to ensure environmental objectives and industrial autonomy in the EEA, such as transport, semiconductors, telecommunications, renewable energy, or chemical processing industries.

Fluoropolymers have unique physicochemical properties which render them specialty plastics that are virtually chemically inert, non-wetting, non-stick, and highly resistant to temperature variability, fire, and weather and exhibit low flammability. They also display features such as low coefficient of friction, dielectric strength, and flexibility. These properties, and particularly the joint combination of all of them in single products, make them irreplaceable in many

¹ European Union (EU) 27 + Iceland, Norway, and Liechtenstein

² Regulation (EC) No 1907/2006

applications, and it is commonly accepted that their unique set of properties cannot be matched by alternative materials, particularly in the wide range of operability they offer. In fact, fluoropolymers are frequently the high-cost option in many industries, being the material of choice only when other products are known to fail to provide the required properties for the desired application.

The objective of this report is to highlight specific examples of uses of fluoropolymers, with details on how the benefits that these materials provide to the use are related to the combination of properties they offer. In addition, an evaluation of potential alternative substances that could be used to replace fluoropolymers in each use has been performed. Potential trade-offs that could be expected due to substitution have been highlighted, not referring to impacts on the direct uses, but on potential consequences that could be expected down the value chain and which could affect the general population, as well as broader environmental and innovation expectations within the EEA.

Information on the case studies that are described in this report has been collected via questionnaires that were delivered to a set of downstream users involved in primary handling of fluoropolymers. The questionnaire was also shared with a number of associations representing different industrial sectors involved in the use of fluoropolymers. Since some of these associations delivered the questionnaire to their members, it is not possible to establish the number of users that received it. A total of 27 responses were collected, which were then filtered in terms of quality of the information provided. Where deemed useful for a better understanding of the case, one-to-one videoconferences were organized with the respondents. It should be noted that due to time constraints and complexity issues, most of the cases described have been built with feedback from only one responding company. Efforts have been made to reassure the reliability of replies received (with cross-checking information from public literature), and final versions of the cases have been double-checked with experts from the German Association for Semi-Finished Plastics and Consumer Products (pro-K) for final validation. A copy of the questionnaire that was delivered to the downstream users can be found in **Annex I**.

Where available, information on the relevance of each sector of use in terms of socio-economic importance for the European society has been highlighted. This information has been provided by the sectorial associations that could be impacted due to a ban on the use of fluoropolymers. However, most of the respondents were primary users of the fluoropolymer substances in very complex value chains. For this reason, the potential impact of a restriction on the use of fluoropolymers in each application may be difficult to quantify. In any case, it is clear that the socio-economic importance of fluoropolymers increases significantly through the different steps in the multiple value chains in which they are involved.

The list of fluoropolymers covered in this report can be found in **Annex II**.

2. Properties of fluoropolymers and socio-economic importance

The key properties that fluoropolymers provide to a wide variety of industrial applications can be summarised as follows (FPG, 2021):

- Inertness and non-reactivity; high resistance to corrosion and chemical attack.
- Low and high temperature resistance: with a range as large as -263°C to +260°C for PTFE.
- Very low coefficient of friction to any solid.
- Low and ultra-low permeation rates.
- Ultraviolet radiation (UV) resistance.
- Excellent electrical insulation, low dielectric constant, low variations of conductivity.
- High level of fire safety; no flame propagation and low smoke generation.
- High and ultra-high purity with extremely low leach out properties.
- Stress-crack and cut-through resistance.
- Flex fatigue properties enabling thermal expansion/contraction in temperature cycles.
- Biocompatibility.
- High Flex life
- Durability.
- Hydrophobicity; neither water nor water-containing substances wet fluoropolymers, providing excellent repellent properties to many chemicals.
- Non-stick, and consequently non-fouling properties, along with sufficient bonding in certain multilayer applications.

In terms of socio-economic value of fluoropolymers, the Fluoropolymer Group of PlasticsEurope (FPG) has currently updated information (FPG, 2022b) from a previous socio-economic analysis that was performed on these substances (FPG, 2017). However, it is worth noting that this information is limited to the production, employment and revenue values of the fluoropolymer manufacturers and importers in the European Union (EU). While relevant, the importance of these figures is clearly minimised in comparison of the value that fluoropolymers enable downstream for end use applications. For example, while total revenue obtained from the whole fluoropolymer industry in the EEA in 2020 was of 740 million EUR (with 70 million EUR directly sold to the electronics industry), the revenue reported by the European Semiconductor Industry Association for the same year was 32.85 billion EUR (ESIA, 2020). As reported by downstream users, modern semiconductors cannot be produced without the use of fluoropolymers in the process, as will be explained in one of the case studies covered in this report. This means that fluoropolymers can multiply their direct value by nearly 500 times in the applications in which they are used, which gives a clear indication of their critical relevance for many important industries in Europe.

3. Case studies evaluated

3.1. Sector of use 1: Industrial uses

3.1.1. Application 1.1: Use of PTFE, PFA and ETFE in the production of lined equipment in the chemical processing industry

Description of the application

Polytetrafluoroethylene (PTFE), Perfluoroalkoxy polymer (PFA), and Ethylene tetrafluoroethylene (ETFE) are used in pipes, expansion joints, vessels, and fittings for the chemical processing industry, with the objective to protect equipment from direct contact at high temperatures (up to 230°C) and very aggressive media, such as hydrochloric acid (HCl), sulfuric acid (H₂SO₄) or hydrofluoric acid (HF). Other highly aggressive substances may be sodium hydroxide (NaOH), potassium hydroxide (KOH), or sour gases.

As an example, desorption columns lined with PTFE are used in the recycling process of hydrochloric acid in the chemical industry. Streams with low acid concentrations are treated in these desorption columns, resulting in more concentrated streams that are then reused in the initial or further processes within chemical plants.

When there is no need to protect equipment or chemical products from the effect of corrosion, black steel piping and fitting systems are currently used by the chemical processing industry. An example of this could be the mineral oil industry. Such unprotected steel constructions are however limited to situations in which:

- Chemicals are not corrosive (or less corrosive) to steel.
- Processes in which short system lifetime (e.g., cycles of 2 years) is acceptable.
- Metallic ion impurities in the streams handled in the relevant processes do not raise situations of concern, neither from a quality nor from a safety perspective.
- Additional cleaning steps are available, that can remove the above-mentioned impurities. However, such systems add costs to the process.

It should be noted that such cases are not frequent in the chemical process industries, and that some sort of corrosion protection on the equipment to be used is typically required.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Flexibility
- Resistance to harsh chemicals
- Resistance to high temperature
- Resistance to low temperatures
- Wide temperature range of operation, between (-250°C to + 230°C)
- Barrier properties (low permeation of process media through fluoropolymer liner)

- Non-stick properties
- Flex fatigue properties to enable thermal expansion/contraction during temperature cycles

General description of alternatives and comparison with fluoropolymers

Some alternatives that could be considered for these applications are:

- Polypropylene (PP) lining systems
- Rubber lining systems
- Tantalum-based piping
- Stainless steel (V2, V4, 316 L, Hasteloy, Inconel) and some precious metals
- Enamel / glass lining systems

PP and rubber lining systems

These alternatives could work only under a narrower range of operating conditions. PP or rubber-based systems would only withstand temperatures up to 100-120°C without degradation, in comparison to higher temperatures (230°C) that are required for some processes, in which fluoropolymers are effective. Furthermore, the lifetime and duration of these lining systems is lower than 5 years.

These alternatives are sufficiently available and at a competitive price in comparison with fluoropolymers. In fact, where the process conditions do not require the use of fluoropolymers, they are already implemented by industry as the material of choice. However, it needs to be considered that due to much shorter lifetimes, PP or rubber lined equipment for the chemical industry would need to be frequently replaced if these systems were to be used under aggressive conditions, and therefore costs would be significantly increased.

Tantalum based piping

In principle, tantalum may offer similar performance as compared to fluoropolymers in the chemical process industry.

However, tantalum is more expensive and not competitive when compared to fluoropolymers. In addition to this, it is highly unlikely that tantalum supply could cover the demand that would be required to completely replace fluoropolymers in this application for the whole European chemical industry. Furthermore, tantalum is ranked as a conflict mineral which is frequently mined under unclear conditions. Therefore, supply (as well as prices) of this metal could be subject to significant constraints and result in business uncertainty in the future.

Stainless steel (V2, V4, 316 L, Hasteloy, Inconel) and some precious metals

Stainless steel offers similar chemical resistance like PTFE or PFA. Harsh, corrosive chemicals may extract metal ions in low concentration from the steel. While this could be acceptable in

some applications, it renders this alternative not feasible for use in cases in which high purity would be required.

This alternative is much more expensive compared to the combination black steel + PTFE/PFA used in current piping systems. The costs of using this alternative may go up to 5 times higher than the use of fluoropolymer lined systems. In special cases, metals like silver or even gold may be considered; in such cases, the cost of the alternative options could be 10 times higher, or more.

Enamel / glass lining systems

Enamel or glass based lined pipes could work under certain conditions, but not reaching the wide range of temperatures and aggressive media that fluoropolymers can withstand. These materials are brittle and could break easily when subject to temperature changes or acid attack. Service life of piping systems would be much shorter than with the use of fluoropolymers (perhaps reaching 5 years, but certainly below 10 years, in comparison to fluoropolymers that can last decades in operation).

Enamel glass linings are also more expensive than fluoropolymers (estimated at twice the price). Again, the need for further maintenance and higher replacement rates of these systems renders them as a non-viable option as an alternative to fluoropolymers in this application.

Potential impacts related to substitution

Use of PP, rubber or enamel/glass lined piping and fitting systems could create high risks situations for workers and the environment. The probability of cracking and integrity failure would be significantly increased in the process industry. This would be particularly critical when strong acids such as hydrochloric acid, sulfuric acid or hydrofluoric acid are used, which are highly corrosive and could generate great damage on workers and the environment.

Related to the hydrochloric acid example, PTFE linings are used to protect steel shell, pipes, and other equipment from direct contact to hot, concentrated hydrochloric acid. PTFE linings are critical for safe operation since they eliminate or minimize corrosion. Corrosion on equipment results in risk of leakage and severe accidents. Depending on process conditions, corrosion can appear within hours of operation and can have sudden, unpredictable effects, potentially leading to serious injuries to workforce, contamination of the environment and operational downtime. Hence, PTFE liners allow for the safe production of high-quality hydrochloric acid.

Many chemical establishments in the EU are multi-purpose plants, which means that they can run different processes at different times. For example, one process may be run for which P systems could be effective, but after a few weeks, a new process could be undertaken in which the combined properties that fluoropolymers provide are required. A scenario in which fluoropolymers would not be available for use in the process industry would create a significant challenge in terms of restructuring and reorganizing chemical establishments and in the end, it is likely that companies would decide to run their processes involving harsh

conditions (e.g., involving strong acids at high temperatures) in other locations outside the EEA where the use of fluoropolymers would still be allowed. This could result in the loss of a significant part of basic chemicals production within the EEA and severely damage the objectives of developing a stronger industry.

The possibility to replace fluoropolymer-based lining systems with stainless steel or other metals, which could work from a technical perspective in certain cases, would likely generate significant market distortions. This is because only the larger chemical companies may afford replacing the piping, vessels and fitting systems lined with fluoropolymers, and still this could also reduce the flexibility of those companies to run certain processes. Small and Medium Enterprises (SMEs) in the EU would be significantly impacted if they were forced to substitute fluoropolymers with metal-based alternatives.

It should also be noted that the use of PP or rubber lined piping systems would lead to the need of more frequent maintenance and replacement. This would significantly increase the amount of these products that would need to be disposed. For PP, recycling options are not identified, therefore the amount of waste of this material would increase dramatically, and therefore objectives related to a circular economy in the EEA would be jeopardized. Moreover, if fluoropolymers were to no longer be used in chemical plants, this could imply the need to take down such installations and subsequently starting them up again, which are two high risk instances that should be avoided

Regarding the hydrochloric acid example, it should be noted that this is a main chemical base material (~20 million tonnes produced per year worldwide) which is used in the production of further essential chemical base materials. For example, hydrochloric acid is used for the production of polysilicon materials (wafer, computer chips and connected markets), in the steel industry (refining ore, pickling and cleaning of metal, etc.), for food production, in the oil industry, for production of pulp and paper, and other industries, all of which would be directly impacted if fluoropolymer lined piping and fitting systems would not be available.

In addition to these end users, a significant number of companies supplying using fluoropolymers for the production of this kind of systems to the general chemical industry would face significant challenges, since they have developed high technical expertise on fluoropolymer-based piping equipment. Continuity of all these business in the EEA would be at risk.

Conclusions on the application

Single alternatives could eventually cope with some of the requirements required in the chemical industries, in terms of equipment protection. However, it is the combination of properties that fluoropolymers provide, particularly high resistance to chemical attack and wide range of temperature of operation, combined with low permeation and non-stick properties for a smooth development of chemical processes, which render them as the material of choice for many chemical industries in the EEA. Substitution by the limited set of

alternative materials would create a wide variety of problems both for the industries directly involved (e.g., suppliers and users of piping and fitting systems), as well as for the European society as a whole. On one hand, high risk situations for workers and the environment may be created, involving processes dealing with strong acids at high temperature. On the other hand, the use of alternatives could lead to situations in which conflict minerals would be required (tantalum), with significant ethical constraints as well as economic ones (related to volatile pricing and supply uncertainty), or to significant increase of waste streams of other plastics or rubber that could pose a challenge to the circular economy objectives. Ultimately, it is reasonable to assume that, should fluoropolymers not be available for this application, significant relocation outside the EEA of a large number of companies (mostly, but not only, SMEs) may occur, not only of direct downstream users of fluoropolymers, but of end-use industries that work with fluoropolymer based piping and fitting systems in the chemical industry.

In conclusion it can be stated that, evaluating jointly the benefits of continued use of fluoropolymers, as well as the negative effects that could be generated for the European society if fluoropolymers were not available for these applications, the continued use of fluoropolymers in lined piping and fitting systems for the chemical industry should be granted to ensure a safe, sustainable, and competitive chemical industry.

3.1.2. Application 1.2: Use of PFA, PTFE, FKM in the production of lined pumps in the chemical processing industry

Description of the application

PFA and PTFE are used for lining pumps in the chemical processing industry, with the objective to avoid corrosion under specific conditions of chemical attack. In addition, vinylidene fluoride-hexafluoropropylene copolymer (FKM) based seals such as o-rings are used in those processes to avoid releases of hazardous materials.

An example that can be highlighted of this use is related to chemicals involved in the manufacture of polyurethane foams, which are used for example in building insulation. mononitrobenzene (MNB) is used for the production of methylene diphenyl isocyanate (MDI), which is a raw material for the production of polyurethane. In the process, sulfuric acid is diluted with nitric acid (HNO₃) to produce MNB. The use of nitrosulfuric acid leads to a highly corrosive environment.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical properties, e.g., flexibility (ASTM D2176 - Test Method for Folding Endurance of Paper and Plastics Film by the MIT tester, with MIT > 1 million)
- Resistance to harsh chemicals
- Resistance to high temperature
- Resistance to low temperatures
- Wide temperature range of operation (between (-60°C to + 200°C)
- Barrier properties (minimum wall thickness 3.5 mm)

General description of alternatives and comparison with fluoropolymers

Chrome/Nickel alloys are usually considered as possible alternatives for this use. While these materials can be used for lining in pumps to operate certain chemical processes, and are still in use today, they are not able to cope with every specific anti-corrosion situation. In fact, those alloys were used for the lining of pumps and seals used for the MNB plants in the 1970s, however this led to frequent failure of the equipment, resulting in significant challenges in terms of maintenance and safety, related to corrosion and leakage from mechanical seals.

The introduction of PFA/PTFE lined pumps in the 1980s solved safety (related to unexpected releases of highly corrosive material that could reach operators) as well as environmental issues (due to release of ecotoxic mixtures). These systems offer a much higher protection against corrosion in this chemical process and minimise the need for replacement of the equipment, resulting in higher efficiency but also in increased worker and environmental protection. Particularly, PTFE-based systems (magnetic coupling pumps with stationary sealing) replaced mechanical sealed (rotating sealing) pumps which are more effective to avoid leakage to the environment.

It should be noted that in the past, other materials such as those described in **Application 1.1** (enamel/glass or rubber-based lined pumps) were used for this application, however corrosion always led to significant difficulties for developing the process in a safe and reliable way.

Potential impacts related to substitution

Returning to the use of chrome/nickel alloys would significantly damage the efficiency of the MNB/MDI process in the production of polyurethane foams. More importantly, it would increase risk of corrosion in processing plants and increase risk of damage to humans and the environment, not to mention the reduction in efficiency of the process and higher costs related to the need for more frequent maintenance and replacement of equipment. It is to be expected that such increases in costs would be transferred through the supply chain, reaching the end users of polyurethane foams. Replacement by other materials such as rubber or enamel is not considered as they are of even inferior performance compared to chrome/nickel alloys for this application.

Conclusions on the application

Industrial equipment based on chrome/nickel alloys is still in place and used nowadays to provide for corrosion protection in certain chemical plants. Corrosion guides are available for critical fluids and conditions which describe the corrosion resistance. The selection of the adequate material for key industrial equipment such as pumps must be done on a case-by-case basis, however frequently mixed fluids (e.g., sulfuric acid and nitric acid) are not always described in those guides, and therefore the company developing specific processes needs to test the specific material of choice on a case-by-case basis.

Removing fluoropolymer lined pumps and seals from the market would push technology back to levels of the 1970s and reduce the choice of materials for extremely corrosive chemical processes, which would result in a decrease of safety and environmental standards, as well as a reduction of the competitiveness of the European industry. Processes that today are run using fluoropolymer-based solutions (which occurs only when other materials that continue to be available on the market, such as chrome/nickel alloys, do not perform properly) would likely be moved to other countries where fluoropolymers are still allowed, and products manufactured in such processes would likely need to be imported rather than manufactured in the EEA.

3.1.3. Application 1.3: Use of PTFE matrix composites in the production of seals and gaskets for industrial machines

Description of the application

PTFE-based materials are essential components of highly reliable sealing mechanisms. These mechanisms are applied in a wide variety of industrial sectors, such as the chemical processing industry, automotive, aviation, food processing, and power generation.

Gaskets are a typical system to keep two pieces of an equipment together. They are defined as a mechanical seal which fills the space between two or more mating surfaces, generally to prevent leakage from or into the joined objects while under compression. It is a deformable material that is used to create a static seal and maintain that seal under various operating conditions in a mechanical assembly.

PTFE based seals and gaskets are used across a broad range of industries that require processing harsh chemicals. They are used in the vast majority of manufacturing plants involving chemical processes. One example is the Chlor/Alkali (C/A) process in which chlorine, sodium hydroxide and hydrogen are produced via electrolysis. These chemicals are then used in a broad range of applications. This process requires highly reliable sealing systems which are based on PTFE to guarantee adequate performance.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength (15-40 MPa)
- Flexibility
- Low coefficient of friction (maximum 0.2)
- Resistance to harsh chemicals
- Resistance to high temperature
- Resistance to low temperatures
- Wide temperature range of operation (-100°C to + 250°C)
- Weather resistance
- Non-stick properties
- Fire retardancy / smoke suppression
- Low bacterial / algae growth

General description of alternatives and comparison with fluoropolymers

Asbestos fibre gaskets have been highlighted as potential replacements for PTFE-based sealing systems. These systems were used in the past and they could have satisfactory performance but certainly not at the levels that fluoropolymers provide, particularly in extreme conditions of mechanical strength required, variability of temperatures and chemical conditions. Other elastomers such as hydrogenated nitrile butadiene rubber (HNBR) and plastic materials, such

as polyethylene (PE) or PP, could eventually be used but providing limited mechanical strength and chemical resistance.

Potential impacts related to substitution

Ensuring proper sealing systems is a critical feature in the chemical processing industry. Failure in these systems could result in the release of hazardous materials and pose a risk to workers and the environment. Furthermore, the lower performance of alternatives would result in the need for increased maintenance procedures, resulting in additional costs for companies as well as an increase of waste material. Materials such as polyurethane, PP or HNBR, are expected to have a lifetime of 50% compared to PTFE based seals and gaskets. PTFE-based solutions are frequently more expensive and are used only when it is known that other materials will not provide the desired performance, to a point in which the application may result not viable.

Looking at the C/A example, according to the Best Available Techniques (BAT) for this process (JRC, 2014), the development of non-asbestos sealing systems started in the 1970s, taking about 10-15 years until viable alternatives to asbestos were introduced. These alternatives are all based on PTFE-based sealing systems. According to the Joint Research Centre (JRC), "With its superior characteristics regarding stability against chlorine, caustic soda, and other chemicals, as well as its dimensional stability, it was considered an ideal alternative to asbestos. Asbestos swells during operation in a diaphragm cell and this increases the energy demand. PTFE does not show this swelling effect, and therefore the energy demand would be lower. In addition, the high stability against chlorine and caustic soda should result in the diaphragm having a very long lifetime."

In terms of economic relevance, it is estimated that the C/A process covers approximately 25% of the EU specialty chemical industry which has a revenue of roughly 225 million EUR³. C/A is a good proxy for harsh chemicals because it tracks with the key processing attributes that rely on PTFE sealing solutions. These processes outstand for their reduced risks of leaks which protect safety of people and the environment. Harsh chemical processing has an essential function for the EU chemical manufacturing industry, and it is interlinked with a large number of downstream industries. Just to name a few, the following very different sectors can be considered:

- Agriculture: 178.4 billion EUR turnover and 9.7 million jobs in 2020³.
- Chemical manufacture: 588.88 billion EUR turnover and 1.2 million jobs in 2019³.
- Semiconductors: 40.43 billion EUR turnover and 200,000 jobs in 2021 (ECIA, 2022)

The economic impact of disruption in EU chlorine production would flow from initial production through all end use applications of the material, amplifying the effect. The propagation of the impact would be similar for other harsh chemicals such as sulfuric acid.

³ Data provided by responses to the questionnaire based on information from Statista and Eurostat.

The use of asbestos fibre gaskets as an alternative to fluoropolymers would result in an increased risk of cancer due to the well-known carcinogenic properties of this material. Because of this, disposal of materials containing asbestos is complex and regarded as a hazardous activity, which needs to be considered as sealing systems using asbestos in the chemical industry would need to be more frequently replaced.

Conclusions on the application

Ensuring adequate sealing of machinery and equipment used by a wide variety of industries is of outmost importance. Materials used for this function need to be reliable and frequently withstand extreme conditions in terms of temperature, mechanical strength, and chemical attack. If those industries are not able to provide the required performance, significant impacts would be expected in terms of malfunctioning of such equipment, which could result in damage to people and releases of chemicals to the environment. Furthermore, inefficient sealing systems would result in sub-optimal operating conditions which could result in increased energy consumption leading to higher emissions of greenhouse gases (GHG), which could have a negative impact on the overall environmental objective established in the Green Deal.

Downgraded performance would imply reduce competitiveness of the European industry in many sectors. Industrial companies based in the EEA would face significant issues to maintain their high levels of performance and efficiency, so it is quite possible that those companies would eventually relocate their production to non-EU countries where the use of fluoropolymer-based seals and gaskets may still be allowed (even more so if the restrictions are expanded to other components that would also require fluoropolymers, see case 1.1). This situation will imply also that the technology will be transferred to the non-EU area so a loss of knowledge will occur.

Removal of PTFE-based seals and gaskets would kick technology backwards by 50 years, since technical solutions to asbestos in sealing systems in, for example, the C/A process were initiated in the 1970s. The use of PTFE for this process is currently considered Best Available Technique and removing it from the market would go against significant achievements made in the field of chemical process innovation, in addition to having replaced a well-known human carcinogen substance, a feature that is not shared by PTFE which is regarded as a Polymer of Low Concern (PLC) due to the lack of hazardous properties for human health and the environment.

3.1.4. Application 1.4: Use of PSEPVE and PTFE matrix composites in the production of membranes for electrochemical processes

Description of the application

Sulfonated tetrafluoroethylene (PSEPVE) is used in the production of membranes used in the C/A process. PTFE matrix is used to reinforce those membranes. In the C/A process, chlorine and its co-products are created by electrolysing a salt solution with a direct electric current that ultimately converts chloride ions into chlorine.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength (15-40 MPa)
- Flexibility
- Resistance to harsh chemicals
- Resistance to high temperature
- Wide temperature range of operation (-100°C to + 250°C)

General description of alternatives and comparison with fluoropolymers

The manufacture of chlorine is an industrial process that has been on-going for more than 100 years. Traditionally, the only two alternatives to the use of membrane cells are mercury cells and diaphragm cells. In the mercury cell process, sodium forms an amalgam (a 'mixture' of two metals) with the mercury at the cathode. This amalgam reacts with the water in a separate reactor called a decomposer where hydrogen gas and caustic soda solution at 50% are produced.

The diaphragm cell process works with a combination of water and sodium chloride to create a brine solution, which is processed and filtered to remove impurities. Heat is applied to the solution and more salt is added until the purified brine solution is prepared for the electric current. In this case, an asbestos diaphragm is usually used to separate the cathode and anode, which will create the current (Mesothieloma, 2017).

Potential impacts related to substitution

Both mercury and asbestos are toxic materials and could generate significant issues to human health. In fact, according to Eurochlor (2022), the mercury cell system for the C/A process has been discontinued in Europe since 2017. As per asbestos, indications provided in the application described previously (**Application 1.3** describing gaskets and sealing systems) remain valid. Socio-economic relevance of the C/A process described previously can also be considered relevant for the production of membranes for C/A cells.

Conclusions on the application

In addition to safety considerations, the membrane cell system to produce chlorine via the C/A process is much more effective, and it requires less energy to produce the same quantity of product (at a higher purity), than the two alternatives (mercury and diaphragm cells). There is currently no other alternative known that would work in this process, which would withstand the combination of chemical aggressive environment of operation and very high temperatures that can be achieved in the process. This is a perfect example to demonstrate how the use of fluoropolymers has allowed for innovation and improved safety conditions of operation, removing the use of well-known hazardous materials from a very important industrial use and replacing them by materials that meet the conditions of PLC. For this application, different types of fluoropolymers are relevant, such as sulfonated TFE (for the production of the membrane itself) and PTFE matrix composites (to protect and reinforce durability of the membrane).

3.1.5. Application 1.5: Use of PTFE, PVDF, PFA in the production of filter systems for waste treatment in the chemical processing industry, power plants and other sectors

Description of the application

PTFE, PFA and Polyvinilidene fluoride (PVDF) are used in filter bags and filter systems which are needed to convert predominantly toxic or hazardous components, such as gaseous dioxins and furans or nitrous oxides from highly aggressive and corrosive gas streams, bringing concentrations of those chemicals below established regulatory limits. Furthermore, PTFE is used in large heat exchangers that enable the desulphurisation process at power plants by maintaining required temperature conditions of treated streams.

Typical sectors involved are chemical processing industries, but also waste incineration, metallurgical processes, cement manufacturing and power plant flue gas cleaning, which have stringent environmental requirements in terms of limiting emissions to air.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength
- Wear resistance
- Flexibility
- Low coefficient of friction
- Resistance to harsh chemicals
- Resistance to high temperature
- Resistance to low temperatures
- Wide temperature range of operation
- Barrier properties
- Non-stick properties

General description of alternatives and comparison with fluoropolymers

There are potential alternatives materials such as fibre threads available from different suppliers. In the past, some of these contained asbestos, which needs to be taken into account from an overall safety perspective. Currently, these fibres provide lower performance, which results in higher power consumption and shorter lifespan of these materials (resulting in higher replacement rates, adding costs to the process and the value chain).

Such fibres are less resistant to higher temperatures, they have limited ability to incorporate catalysts and other active components which destroy or capture harmful emissions. Lower chemical resistance results in higher filter failures, increased emissions, and more frequent replacement.

Other materials such as PP and polyether sulfones (PES) can also be used for filter systems, but again they are not expected to perform at the same demanding conditions under which fluoropolymer-based filter pieces can provide reliable operation.

Potential impacts related to substitution

Emission control in harsh and aggressive environments is an essential function across many industries (e.g., construction, manufacturing of petroleum products, metallurgy, etc.) and is interlinked with many downstream industries. Filters containing fluoropolymers are used in the most demanding applications such as hazardous waste incinerators, to prevent toxic pollutants from being released to the environment. Products containing fluoropolymers have a common benefit of reducing risk of emissions, which protect health and safety for people and the environment. They are necessary for many industries to meet existing environmental emissions regulations.

Filters made with fluoropolymers also provide necessary cooling and cleaning for advanced electrical products to avoid overheating. It is assumed that nearly all the advanced semiconductor chip sets and memory devices imported into the EU use filters containing fluoropolymers. Semiconductors and memory devices are essential devices for the function of many end-uses across many industries. Likewise, the pharmaceutical industry may also require high levels of performance for filtering systems, which can only be achieved with the use of fluoropolymers.

Furthermore, when alternatives are evaluated, their potential toxicological and ecotoxicological impacts should be taken into consideration. In the case of PES, publications suggest that they may have potential endocrine disrupting properties and may actually be considered of equivalent concern to bisphenol A – BPA (Kang et al., 2014), and based on recent research, they are related to generation of other bisphenols during degradation (Li et al., 2022), therefore this and similar materials may not be considered a suitable alternative from a safety perspective, as this could lead to regrettable substitution.

Conclusions on the application

Fluoropolymers such as PTFE, PFA and PVDF are key components of filtering systems that are required in several industries in which hazardous chemicals are handled. The efficiency of such filtering systems is crucial to ensure adequate environmental protection, and operation within predefined regulatory limits. If fluoropolymers were not available for use in such applications, the possibility to comply with such limits could be impaired and operation in a number of sectors and industries may have to be discontinued due to failure to comply with existing regulatory standards. This would effectively force shutdowns and relocation of industries. In some processes with less demanding conditions, alternative materials may be used but this could imply more frequent demands, higher replacement rates and ultimately increased costs, which could be transferred through the value chains reaching the end users. More important, if substitution is forced with some alternative materials such as PES, there may be a risk of introducing potentially hazardous materials that could be related to endocrine disrupting effects.

3.2. Sector of use 2: Energy production

3.2.1. Application 2.1: Use of PTFE, PVDF and FKM in the production of lithium-ion batteries

Description of the application

PTFE and PVDF are used as electrode binders and separator coatings in lithium-ion (Li-ion) batteries, providing interconnectivity within each electrode. This facilitates electronic and ionic conductivity, increasing the cell manufacturing productivity and the cell safety. PVDF offers unparalleled cohesive and adhesive properties under high voltage, allowing for closely packed cathode active materials for high density electrodes. Thanks to PVDF, different battery components can be packed more closely together, improving the energy efficiency of a single unit, and helping reduce overall size.

In parallel to PVDF, FKM is used for the production of cell gaskets used in Li-ion batteries, improving the electrolyte containment efficiency and safety of each cell.

Fluoropolymers also offer high durability, flexibility and other exceptional mechanical properties when used in separators and gaskets, helping resist the harsh conditions faced within a Li-ion battery. This dramatically improves performance, as well as the lifespan of batteries, which are increasingly used in applications that require a guaranteed and dependable level of output.

In this application, the fire retardancy property offered by fluoropolymers also plays a critical role, as the use of these materials allows for the creation of a non-flammable matrix that prevents batteries to catch fire due to overheating, which is a well-known concern related to these batteries.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength
- Wear resistance
- Flexibility
- Low coefficient of friction
- Resistance to harsh chemicals
- Resistance to high temperature
- Resistance to low temperatures
- Wide temperature range of operation
- Barrier properties
- Non-stick properties
- Fire retardancy / smoke suppression

General description of alternatives and comparison with fluoropolymers

Other polymeric materials could be used for the application such as PE or Polyethylene Terephthalate (PET). Alternatives to Li-ion batteries are lead acid batteries, which do not contain fluoropolymers.

Potential impacts related to substitution

The use of PE or PET in Li-ion batteries would not be a sustainable solution, as these materials would not offer the combined set of properties that fluoropolymers provide, particularly in terms of both fire retardancy and battery efficiency.

In the case of replacement of Li-ion batteries with lead-acid batteries, it needs to be noted that these batteries offer reduced performance notably in terms of energy efficiency because a lower proportion of the energy stored in lead acid batteries. In addition, lead-acid batteries are heavier resulting in reduced functionality and increased energy consumption compared to Li-ion batteries. In addition, it needs to be considered that lead acid batteries involve the use of a known carcinogenic, mutagenic, or toxic for reproduction (CMR) substance (lead) which is a known human reprotoxicant, with additional hazards related to neurotoxicity and environmental damage.

Conclusions on the application

In the automotive sector, batteries are being increasingly used to power up electric vehicles (EV). And this number is only set to grow, with predictions that by 2030 EV sales will reach nearly 60% of the total car sales (Bloomberg NEF, 2021). In order to achieve the objectives of the EU Green Deal, the development of Li-ion batteries particularly in the transport sector is expected to play a key role. Those batteries could not perform at optimal level if fluoropolymer-based solutions (including PTFE and PVDF as electrode binder and FKM in sealing gaskets) were not available.

3.2.2. Application 2.2: Use of PSEPVE and PTFE in the production of proton exchange membranes for hydrogen production

Description of the application

Electrolysers (EL) and fuel cell membranes are used in the production of green hydrogen (H_2) by an electro-chemical reaction. To enable the movement of protons from the anode to the cathode side of the fuel cell, a Proton Exchange Membrane (PEM) made of sulfonated TFE and reinforced with PTFE is used due to the efficiency and unique durability, chemical and temperature resistance properties that fluoropolymers offer for this application. The technical principles behind this case are similar to those described in **Application 1.4**.

The membrane is the core component in ELs as well as in fuel cells. In the former, the electric current and the catalyst coated membrane split water into hydrogen and oxygen, hence hydrogen is produced, with oxygen obtained as a by-product. In the latter, the membrane separates protons and electrons by using a catalyst, and it provides proton conductivity (thereby producing electric current) while separating hydrogen and oxygen.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength (<12 MPa)
- Mechanical properties (E-Modulus <500 MPa)
- Low coefficient of friction (0.05-0.1)
- Wear resistance (<5E-7 mm³/N·m)
- Resistance to high pressure (250°C)
- Resistance to harsh chemicals
- Resistance to high temperatures
- Resistance to low temperatures (-263°C)
- Wide temperature range of operation (-263°C to +250°C)
- High limiting oxygen index
- Ionic conductivity
- Barrier properties

General description of alternatives and comparison with fluoropolymers

Hydrocarbon-based ionomers / sulfonated polymers

Some existing hydrocarbon-based ionomers and hydrocarbonated sulfonated polymers could be considered as alternatives to sulfonated TFE for the PEM production, however they offer significantly lower ionic conductivity, especially at low humidity and they are not sufficiently stable against chemical and mechanical degradation to be used in reliable and efficient fuel cell applications. The life span of alternatives is significantly shorter than fluoropolymers implying a higher maintenance cost and probability of failure, therefore resulting in an

increase in the risk of accidents. Furthermore, the likelihood of replacement is substantially higher as well, leading to higher waste generation.

Polyether ether ketone (PEEK)

Research work has been ongoing for PEEK membrane development. Usually, the properties and performance of these materials can be reasonably good whereas the durability is often poor, as oxidation by oxygen radicals, which are inevitably generated at the cathode electrode, occurs. Activities to replace the conventional fluorinated ionomers with fluorine-free materials have existed for the last 25 years but so far, no commercial product has been released due to poor stability against oxidation.

Switch to other hydrogen-based energy solutions

Production of grey or blue hydrogen comes with carbon emissions as well, as those forms of hydrogen are based on the reformation of natural gas and release carbon (CO_x), that either get emitted into the environment or are questionably captured underground.

Potential impacts related to substitution

Alternatives do not meet the performance required for hydrogen-based energy production as they fail to achieve the demanding conditions in terms of flexibility, stability, resistance to chemicals and performance (superior ion conductivity) under the ranges of temperature variability that are required in the process, therefore the durability and reliability is significantly reduced along with an increased rate of potential failure. If such failure occurs during e.g., use of a hydrogen vehicle, this could result in accidents and risk for population.

Fuel cell manufacturers are in close contact with the suppliers of components, establishing collaborations to test new materials at a relatively early stage. They are thus able to identify and qualify promising options, promote their industrialisation, and introduce the use of innovative materials, as early as possible. However, building from past experience, at present time it is not possible to establish when a validated alternative material may be available in sufficient volume and with equivalent performance compared to fluoropolymers.

Conclusions on the application

In the case of a ban on fluoropolymers for this use, ELs and PEM for green hydrogen production may no longer be available, at least not in the parameters that modern technology involving the use of sulfonated TEF and PTFE allows. It is possible to produce hydrogen by using combustion engines, but this option will result in an increase in GHG emissions and carbon footprint, therefore the decarbonization objectives planned in the European Green Deal and sustainability policies would be jeopardized, and the transition to cleaner energies would be significantly delayed, if at all possible.

Hydrogen has seen unprecedented development over the last years. Starting as an innovative niche technology, it is fast becoming a systemic element in the European efforts to transition to a climate-neutral society in 2050. It will become a crucial energy vector and the other leg

of the energy transition, alongside renewable electricity, by replacing coal, oil, and gas across different segments of the economy. The rapid development of hydrogen is not only important for meeting the EU's climate objectives but also for preserving and enhancing the EU's industrial and economic competitiveness.

A very large proportion of planned projects involving ELs and fuel cells (and in some applications 100%) are based on this PEM technology. Amongst tracked water electrolysis projects to be completed by 2030 in EU/EEA/UK for which information is available, PEM electrolysis accounts for 53% of the projects and 13% of the capacity. PEM are a non-replaceable and high-priority component enabling this fuel cell technology. Without these membranes, the roll-out of such high-performance fuel cell and water electrolysis applications would be delayed by 10-15 years, thereby impacting a wide range of industries.

According to the Hydrogen Council (2021), there are 200 hydrogen fuel cell projects currently announced in Europe, with investments focussed across multiple industries, from transport to heavy industry. In fact, according to this source, the majority of global hydrogen-related investments expected for this decade will be made in Europe. If the use of fluoropolymers in this sector was to be banned, companies will relocate such investments to non-EEA countries where these restrictions do not apply. This situation will imply also that the technology will be transferred outside of the EEA so a loss of knowledge and competitiveness will occur.

Hydrogen is essential to the production of green energy and will be critical in the achievement of the EU Green Deal objectives as well as the objectives set out at COP21. It is estimated that by 2030, 110,000 fuel cell trucks and busses could be on the road (Ruf et al., 2020), and fuel cell EVs could account for 1 in 22 passenger vehicles; in the construction sector, hydrogen could replace an estimated 7% of natural gas by volume (Hydrogen Roadmap Europe, 2019).

Moreover, based on input provided by Hydrogen Europe (2022), the following impact assessment on a potential ban that could cover fluoropolymers in the EEA can be anticipated:

a) In 3 years

Banning materials under a restriction would slow down deployment of clean hydrogen technology in several markets, as it will effectively eliminate PEM ELs and PEM fuel cells from the market.

An analysis of the current pipeline of renewable hydrogen production projects shows ca. 25% all ELs capacity in projects under current development in the EU rely on PEM technology. Taking the EU hydrogen strategy targets as a predictor of future investments (EU-wide target of 6 GW of ELs capacity by 2024), a ban on key products would jeopardise investments worth ca. 1.125 billion EUR by 2024 in ELs only.

It is worth stressing that PEM ELs (due to capacity for flexible load operation) are best suited for coupling with variable renewable energy sources (RES) and are therefore an indispensable technology for large scale RES integration with power grid. Hence a ban would not only jeopardize green hydrogen markets, but it could also significantly affect

the EU's ability to deploy needed RES generation and make reaching decarbonisation targets practically impossible for 2030 and 2050.

b) In 10 years

Based on same strategy's 2030 target of 40 GW of EL, a ban would: jeopardise investments worth 7.5 billion EUR in ELs only (and total estimate of EL capacity in the EU project pipeline is even greater than strategy targets: 141 GW with 35 GW in PEM ELs, worth an estimate of 18 billion EUR). In summary, bans on fluoropolymers may put at risk a total investment estimate value in clean hydrogen sector of 26-36 billion EUR. In terms of employment and put between 84,000 and 140,000 direct jobs at risk, with an estimation of potentially 242,000-261,000 indirect jobs impacted, resulting in a total potential negative impact of 326,000-401,000 full time employees.

3.2.3. Application 2.3: Use of PTFE and FEP in the production sealing systems for storage, transport and production of green hydrogen

Description of the application

PTFE and fluorinated ethylene propylene (FEP) are materials of choice for sealing components used in production, transport and storage of green hydrogen. This application is challenging particularly from the temperature perspective. On one hand, cryogenic conditions (e.g., close to -268°C) are involved during storage of hydrogen. On the other hand, hydrogen is one of the few gases (with helium and neon) that actually heat up when expanded. Fluoropolymers are well suited to cope with increased temperatures that may occur during hydrogen production.

Fluoropolymer based sealing systems can be involved in many steps in the hydrogen process involving cryogenic conditions, for example for rotatory swivels for loading arms at transport of liquid hydrogen, during storage for hydrogen liquefaction or at pumps and valves used at fuelling stations.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical properties ($<12\text{ MPa}$)
- Wear resistance ($<5\text{E-}7\text{ mm}^3/\text{N}\cdot\text{m}$)
- Flexibility (E-Modulus $<500\text{ MPa}$)
- Low coefficient of friction ($0.05 - 0.1$)
- Resistance to harsh chemicals: for example, carbon dioxide (CO_2) acts as a solvent for many polymers in cryogenic stage, also for hydrogen or methane (CH_4).
- Resistance to high temperature
- Resistance to low temperatures
- Wide temperature range of operation (between -263°C to $+250^{\circ}\text{C}$)
- Barrier properties (No swelling when exposed to carbon dioxide, hydrogen, methane)
- Vibration dampening: >0.9
- Impact resistance (IZOD Shrinkage: $>8\text{ kJ/m}^2$)

General description of alternatives and comparison with fluoropolymers

Steel seals and other rubber materials such as nitrile butadiene rubber (NBR) may be seen as potential alternatives

Potential impacts related to substitution

Steel seals would eventually fail because they could not provide the reliability required during the hydrogen cycle. Flanges and bolts to be used in the process require significantly stronger materials during harsh temperature conditions and steel solutions would eventually break leading to releases and significant risks for the operators and the environment.

Similarly, NBR is a material that cannot resist temperatures below -70°C, which is significantly far from the lowest possible temperature during the hydrogen storage and transport processes, which can go as low as -263°C.

Conclusions on the application

A significantly innovative and modern process to generate clean energy such as hydrogen production could be put at risk if fluoropolymers were to be banned for use in the EEA. Because fluoropolymers existed before this technology was developed, these materials have been essential in facilitating this promising energy source, and therefore it cannot be expected that this may continue without the use of PTFE or FEP sealing systems, even if lower performance with the use of other materials was possible. Put simply, the technology could not exist without the use of fluoropolymers.

There are high hopes placed on hydrogen currently as a key vector to support the achievement of a carbon-free energy mix in Europe, as an essential component of the EU Green Deal objectives. Removing fluoropolymers from the EU market could lead to significant damage to those objectives. References to the impact of such a ban on the EEA society are the same as those described for **Application 2.2**.

Conclusions on this application could be extrapolated to other energy considerations such as offshore windmill shafts (involving complex maintenance operations, therefore requiring maximum reliability of components).

3.3. Sector of use 3: Semiconductors and electronics

3.3.1. Application 3.1: Use of PTFE and PFA in the production of pipes and tubes for ultra-high purity requirements in the semiconductor industry

Description of the application

Similar to **Application 1.1**, PTFE and PFA are used in vessels, pipes, fitting systems (e.g., diaphragms in valves) and related infrastructure for the semiconductor industry, with the objective to protect equipment under very aggressive media while granting an extremely high purity of the materials involved in the process. A relevant example of this application would be the use of PTFE or high purity PFA lined columns and tanks to produce high purity sulfuric acid for etching silicon wafers to manufacture electronic chips. This technology allows for larger wafers and ultimately, a more efficient microchip production process. However, it needs to be stressed that most piping and tubing systems used in the semiconductor industry are not lined systems, but the 100% based on fluoropolymer material, as this is the most effective solution to adequately design piping systems in environments that require very high chemical and temperature resistance with flexibility and other properties.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength (<10 MPa)
- Flexibility (E-module <500 MPa)
- Resistance to harsh chemicals
- Resistance to high temperature (250°C)
- Wide temperature range of operation
- Barrier properties (low permeation of process media through fluoropolymer liner)
- Non-stick properties
- Flex fatigue properties to enable thermal expansion/contraction during temperature cycles
- Extremely high product purity

General description of alternatives and comparison with fluoropolymers

Some alternatives that could be considered for these applications are:

- PP lining systems
- Rubber lining systems
- Tantalum-based piping
- Stainless steel: V2, V4, 316 L, Hasteloy, Inconel
- Enamel / glass lining systems

For the semiconductor industry it is absolutely essential to guarantee that the streams treated within the vessels, piping and fitting systems will stay at the highest possible purity levels. For this industry, levels of purity of part per trillion (and even beyond) are required to ensure the highest possible quality, and to reduce production scrap rates for the user of high purity sulfuric acid. For this reason, any material to be used within this process must ensure an extremely low level of impurities, as well as a low level of leaching of the material used for the piping system into the product. In this particular case, even the use of stainless steel or tantalum would not be viable as these materials would not meet the high demand for product purity. Indeed, no metals are allowed to come into contact with chemicals involved in production of semiconductors, as they would act as ion implants in monocrystalline silicon and change its semiconductor properties in an undesired way. The same would apply to tantalum or enamel-based solutions, which would ultimately not guarantee the need for ultra-high purity values. Likewise, materials like PP or rubber would lead to faster degradation and contamination.

Safety considerations of alternatives would be equivalent those presented for **Application 1.1** since this use would also involve the use of highly corrosive acids like sulfuric acid. The same would apply to economic feasibility of alternatives.

Potential impacts related to substitution

In order to maintain and enhance a competitive semiconductor industry in Europe, there is currently no option to replace the use of fluid systems made from fluoropolymers. Even a slight change in the semiconducting properties, which could be generated due to the use of metal-based materials, would not allow the EU semiconductor manufacturing industry to reach the high standards of efficiency and sophistication that are demanded by the modern downstream user sectors (e.g., telecommunications and electronics).

The semiconductor industry has invested heavily to increase the wafer size during the last 30 years. While foundries used to produce 1-inch wafers in the past, currently common wafer size is 300mm. Larger wafer sizes enable the production of more semiconductors from a single wafer, enhancing productivity and efficiency. By replacing fluoropolymer solutions in this industry, a drastic reduction in product quality would have to be accepted, which would bring the European industry to levels of quality that were acceptable only decades ago (in terms of size, precision and reliability of the articles produced), preventing the possibility to supply to increasingly demanding products such as smartphones, tablets, and personal computers, and thus rendering the European industry as non-competitive in front of companies based in other regions of the world.

According to information from the European Semiconductor Industry Association (ESIA, 2022), in 2021 this industry reached sales for a value of 40.43 billion EUR. Being ranked as the most research and development (R&D) intensive sector by the European Commission (COM), the European semiconductor ecosystem supports approximately 200,000 jobs directly and up to 1,000,000 induced jobs in systems, applications and services in Europe. Overall, micro- and

nano-electronics enable the generation of at least 10% of gross domestic product (GDP) in Europe and the world.

Furthermore, highly efficient semiconductors will play a critical role in the achievement of the objectives of the EU Green Deal, as they are a key enabler of low carbon and energy efficient innovative solutions by optimising energy usage in transportation, manufacturing, consumer products and services. Any negative impact on this industry could seriously hamper the development of such solutions.

Conclusions on the application

For most applications dealing with fluoropolymers, the general principle is that it is the combination of properties they offer that make them highly valued materials. While for semiconductors this principle is still valid, there is one property that clearly stands out, which is the ability of fluoropolymers to grant extremely high level of purity for the aggressive chemicals that are required. Certainly, fluoropolymers add the benefit of also granting high durability and reliability which are critical properties in terms of safety considerations during operations.

Modern (and competitive) microchip technology relies heavily on the possibility to use fluoropolymers in the manufacturing process of semiconductors. Without these materials, the European industry would take a step back of around 30 years, which would leave companies based in the EEA at a clear disadvantage in front of the already dominating industries based in other regions. A ban on the use of fluoropolymers would be in contradiction with the plans expressed by the European Commission to thrive in the global microchip race (European Commission, 2021).

Semiconductors are indispensable in today's modern society, related to consumer electronics and communications. In practice, it is thanks to the availability of microchip miniaturisation that mobile phones have reached the level of (reduced) size and sophistication that enable their functionalities. Removing fluoropolymers from the market would result in loss of these features and make it impossible to maintain the technological levels that have been obtained.

3.3.2. Application 3.2: Use of PTFE, FEP and ETFE in electrical cabling for various industrial sectors

Description of the application

PTFE, FEP and ETFE are used in electrical cabling for various industrial sectors. These fluoropolymers are used because of their exceptional electrical and resistance properties, as well as to provide fire and flame retardancy, which are features required in many industrial applications. In addition, fluoropolymers have a high dielectric strength which means that cables insulated with these materials can be thinner than those manufactured with other materials. On the other hand, due to the dielectric properties, fluoropolymers are widely used for cables and wires for communication facilities as insulators for high-frequency electronics.

LAN cables of category 4 or higher are made with FEP to allow for optimum data transmission properties, which is measured as Velocity of Propagation (VoP).

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Flexibility
- Resistance to high temperature (>200°C)
- Resistance to low temperature
- Resistance to chemicals
- Wide temperature range of operation
- Fire retardancy/smoke suppression
- Electrical insulator (high data transmission range)
- Low arc-tracking
- Barrier properties (low permeation of process media through fluoropolymer liner)

General description of alternatives and comparison with fluoropolymers

Engineering plastics, such as polyvinyl chloride (PVC) or PE combined with halogen free flame retardants (HFFR) could be considered as alternatives, however none of them meet the combination of properties that lead to superior performance of fluoropolymers, such as high flexibility, resistance to harsh chemicals and resistance to high temperatures (>200°C), which are frequently required for many industrial applications.

PEEK and ceramic based cable insulations may also be considered, but again these materials would not bring the combined set of properties that fluoropolymers offer and would not perform under the full set of required situations and process conditions.

A critical property in modern electronics which is required to any material that may be used for data transmission cables is minimum signal disruption. If other plastics such as PE are used in LAN cables, VoP is significantly reduced, resulting in less efficient performance. The use of PE would also result in thicker LAN cables.

Potential impacts related to substitution

While alternative materials could be used in industrial cables under conditions that require minimum performance levels (e.g., moderate temperature ranges, low flexibility needs, absence of harsh chemicals or limited voltage), it is often the case that many industries need to cope with very demanding conditions in relation to those properties. A wide variety of end-sectors depend on availability of cables that are able to perform under harsh conditions of use, from coffee machines to switch pumps placed under water, from data processing cables to control systems in industrial processes.

For example, alternative plastics described earlier will typically have a higher minimum working temperature than fluoropolymers, therefore performance will be significantly reduced particularly in cases where coolants are used to decrease temperature, which is typical in data processing systems. In addition, flame retardants increase dielectric constant and dielectric loss, which reduce data communication rates. The use of alternative plastics combined with other flame retardants will result in weaker data processing and slower signal return, reflecting inferior properties if compared to those obtained with the use of fluoropolymers.

The need to provide additional insulation due to the use of degraded performance by the use of alternatives would result in increased weight and size of cables, which would also be more rigid and brittle. Therefore, electrical installations would become bigger and more complex. Furthermore, performance in high-tech properties such as data transmission via LAN cables would be significantly reduced as well.

Conclusions on the application

Fluoropolymers provide a unique combination of properties that are not met by the alternatives, reaching extreme conditions that cannot be achieved with the use of alternatives. If fluoropolymers are not available in electrical cables, performance of a wide variety of industrial applications would be seriously downgraded, resulting in increased maintenance costs, lower reliability, and eventually higher risks for human health (fires) and the environment (increased replacement of other plastics leading to generation waste).

Ordinary wires are not equipped to handle the high-power consumption and high frequencies of e.g., 5G radios and cells. Fluoropolymers increase 5G reliability by insulating and protecting riser cables from fire and heat and allowing for quick data transmission and flexibility.

Under this situation, many industries based in the EEA would face significant issues to maintain their high levels of performance and efficiency, which could result in a significant decrease of competitiveness of those industries. The example that has been provided on reduced performance of data transfer technologies is illustrative of how European based companies could be challenged by competition in other regions of the world if they were forced to transition to lower performance alternatives.

3.4. Sector of use 4: Automotive and aerospace

3.4.1. Application 4.1: Use of PTFE and FEP in the production of electrical cabling for use in aircrafts

Description of the application

This case is a specific example related to the general case of electrical cables described in **Application 3.2**, describing the use of PTFE, FEP and ETFE in industrial machines.

PTFE and FEP are used in electrical cabling for the aerospace industry (aircrafts, but also outer space vehicles), where there is an essential requirement for high-performance under very demanding conditions. Fluoropolymers offer property retention under a wide range of temperatures and exposure to specialty fuels that may be chemically aggressive.

The aerospace industry also relies on fluoropolymers due to their exceptional electrical properties at high voltage and high signal frequencies and resistance properties, as well as fire and flame retardancy and reduced smoke generation.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength: SPE-J-920-A-0061⁴ torsion
- Wear resistance: SPE-J-920-A-0061 wire to wire abrasion
- Mechanical properties: SPE-J-920-A-0061 room temperature bend
- Low coefficient of friction: SPE-J-920-A-0061 Pliability
- Resistance to harsh chemicals: SPE-J-920-A-0061 Resistance to aircraft fluids
- Resistance to high temperature: SPE-J-920-A-0061 accelerated ageing (operating temperature may reach 260°C)
- Resistance to low temperature: SPE-J-920-A-0061 cold bend (operating temperature may reach -70°C)
- Wide temperature range of operation: SPE-J-920-A-0061 Climatic
- Dielectric strength: SPE-J-920-A-0061 High voltage test, spark test, surface resistance, overload resistance, resistance to wet arc tracking, resistance to dry arc tracking
- Fire retardancy/smoke suppression
- Low arc-tracking
- Electrical insulator
- Barrier properties

⁴ SPE-J-920-A-0061 refers to specifications for wires to be used in Eurofighter type aircrafts

General description of alternatives and comparison with fluoropolymers

Similar to **Application 3.2**, engineering plastics (such as PVC and PE) combined with HFFR could be considered as alternatives, however as discussed previously these materials will not meet the combination of properties that lead to superior performance of fluoropolymers, which are highly needed in aircrafts. Polymeric materials could give some chemical and electrical protection but would fail to perform under the required set of temperature ranges.

PEEK is able to resist up to 260°C, however this material is significantly rigid which greatly impacts on the design of the electrical systems. On the other hand, chemical resistance and electrical properties are inferior to fluoropolymers.

Ceramics could also be an alternative and provide protection against some (not all) chemicals, but flexibility requirements are again not fulfilled, and they would be significantly heavier.

Potential impacts related to substitution

The aerospace industry requires high insulation performance in aircrafts, this is amplified by the need of higher voltages (>230V) at higher altitudes with partial vacuum conditions and where vibrations can lead to product failure, which is not the case if fluoropolymers are used. Furthermore, cables need to be flexible and resistant to high as well as low temperatures, which can go as low as -70°C; if the flexibility requirements are not met, cables will turn rigid and there could be a breakdown risk that may result in a system failure, thus compromising aircraft safety. In addition, most of the alternatives cannot work at 260°C, this temperature may be reached in aircraft engines where high reliability is critical to guarantee safety during flight. PEEK could be an exception in terms of resistance to higher temperatures but again the lack of other properties like flexibility turns this into a non-viable alternative.

Being fluoropolymers resistant to the action of harsh chemicals, their use in cabling is particularly useful in areas of the aircraft where exposure of the cabling system to specialty fuels that may be chemically aggressive could occur. On the other hand, in the event of a fire incident during flight, fluoropolymers are able to provide fire retardancy and reduced smoke generation suppression properties with better performance compared to alternative materials, which is another critical element to ensure safety of passengers and the crew.

The exceptional dielectric properties provided by fluoropolymers allows for cables insulated with these materials to be thinner than those produced with other materials. Less weight improves the agility and speed of aircrafts and reduces the amount of fuel required.

Conclusions on the application

A typical modern aircraft may contain between 150 and 250 km of cables installed (specific models such as the Airbus 380 have > 500km of installed cables). Aerospace companies use fluoropolymers because they provide outstanding performance under highly demanding environments, which cannot be compromised due to safety issues. High durability and reliability of the materials used in aircrafts are required, this poses significant challenges when

those materials need to withstand temperature variability or chemical attack, while offering sufficient flexibility and other properties such as dielectric strength or flame retardancy. Fluoropolymers are the only materials that offer outstanding properties in relation to those properties, all in one single material type.

If fluoropolymers were to become not available for electrical cables used by the aerospace industry, performance of the aviation in general would be seriously downgraded, resulting in increased maintenance costs, lower reliability, and eventually higher risks for safety of passengers and workers.

In addition to these considerations, it is necessary to highlight that the airspace industry has extremely demanding validation procedures for new materials. The approval could take at least ten years, therefore if changes were to be introduced in the systems used in aircrafts, lengthy and costly procedures for certification would need to be taken into account.

3.4.2. Application 4.2: Use of PTFE in the production of lambda sensor for the automotive industry

Description of the application

PTFE is used in lambda sensor cables due to its resistance to high temperatures and chemicals, dielectric strength, flexibility, and electrical insulator properties. Lambda sensors essentially consist of three parts: wiring, grommet and sleeve. PTFE is used throughout these components with the objective to protect the sensor which is directly exposed to exhaust gases.

In vehicles, lambda sensors adjust the fuel amount that is sent to the engine cylinders by optimizing the air and fuel mixture, which in turn will make the engine work properly. Lambda sensors allow for this control system via measurement of oxygen in exhaust fumes. This is a critical element in cars and vehicles to control the rate of gas emissions by ensuring that the catalytic converter works in an efficient way. Lambda sensors ensure that the car complies with the European regulations on pollution and carbon emissions.

To allow for a better control of emissions, it is common that gasoline injection systems in vehicles feature at least two lambda sensors. The air/fuel mixture is optimized by a control sensor upstream of the catalytic converter. Taking the engine load into consideration, the fuel quantity injected is controlled in a manner that an optimum air/fuel ratio is ensured, thus creating ideal conditions for exhaust-gas treatment at the catalytic converter. In case of rich mixtures, the amount of fuel is reduced. With lean mixtures, it is increased. The second lambda sensor downstream of the catalytic converter (the diagnostic sensor) checks if the control sensor works optimally. If there are any deviations, they can be compensated by the control unit.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical properties (tensile and elongation)
- Resistance to high temperature: ISO 6722 long term heat ageing (operating temperature 280°C)
- Resistance to chemicals: ISO 6722 fluid compatibility
- Resistance to low temperature: ISO 6722 low temperature winding, cold impact
- Weather resistance: ISO 6722 temperature and humidity cycling
- Electrical insulator: ISO 6722 withstand voltage
- Dielectric strength: ISO 6722 withstand voltage
- Fire retardancy/smoke suppression: ISO 6722 resistance to flame propagation

General description of alternatives and comparison with fluoropolymers

Silicon, ethylene propylene rubber (EPR) and ethylene propylene diene rubber (EPDM) could be considered as alternatives, but they are able to operate at maximum temperatures ranging between 150°C and 180°C (specifically, 150°C EPDM, 160°C EPR, and 180°C rubber), therefore

they are not able to work at the required operating temperature of around 250°C, which is frequently encountered in car engines where lambda sensors are installed. In addition to this, alternatives do not meet the mechanical properties (elongation) required by the automotive sector for these critical components.

In addition, EPR and EPDM are resistance to some acids and alkalis, but they are not recommended for petroleum fluids or diester lubricants, products that may eventually become in contact with lambda sensors at some point while in operation.

Potential impacts related to substitution

As mentioned above, alternative materials do not meet the performance required for the adequate functioning of lambda sensor, mainly related to the maximum operating temperature required, which for alternative materials is lower than the maximum temperature that can be achieved with the use of PTFE. This would result in downgraded performance and reduced efficiency to control gas emissions and fuel consumption. This would not be aligned with the decarbonization and sustainability policies that are being promoted by the European Union through the Green Deal.

Alternative materials such as silicon, EDR and EPDM also offer reduced performance on other relevant parameters such as chemical resistance to lubricants or elongation, which are important to ensure adequate fitting and performance in car engines.

Conclusions on the application

Lambda sensors are an essential component that optimizes the functioning of combustion engines to guarantee that gas emissions from vehicles are kept within adequate parameters and fulfil the limits established in the relevant European regulations. The adequate functioning of these components is an essential element to ensure that the objectives to reach net zero carbon emissions by 2050 will be achieved. In order to ensure such adequate performance, PTFE will be required for the production of lambda sensors. While it is expected that combustion engines will be replaced by EVs in the coming years, vehicles based on combustion engines will still be in operation likely until 2050 and, considering the need to provide spare parts for vehicles that will still be operational within approximately 30 years, it can be concluded that PTFE has a key role to play in ensuring the Green Deal objectives in the described application.

3.4.3. Application 4.3: Use of PTFE in the production of control cable liners for the transport industry

Description of the application

PTFE is used in control cable linings for vehicles and aircrafts due to its low coefficient of friction and durability properties, which in combination with some abrasion resistant fillers enable metal wires to slide through the liner as the inner part of cable construction. Control cable liners ensure the well-functioning and safety of vehicles and aircrafts (including spaceships). They are used in many applications such as speedometer cables, hand brake and accelerator cables, gear shift and clutch cables, parking brake and fluid lid opener cables, etc. Control cables are also applied for outdoor power equipment, such as light duty throttle cables or heavy-duty transmission and brake cables. They are even involved in the adequate function of key components related to safety such as wing flaps required to ensure reliability during take-off and landing of aircrafts. Ultimately, these cables are used in any general systems that may require movements in the order of millions of cycles in a lifetime.

These cables need to perform under very demanding and highly variable conditions, e.g., in terms of temperature changes (from cables close to engines to external equipment at high altitude and therefore very low temperatures), resistance to harsh chemicals (fuels and other liquids in vehicles) with no tolerance to failure, situations under which PTFE provides outstanding properties.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength (> 40 MPa)
- Wear resistance (>1 million cycles)
- Mechanical properties (elongation break)
- Low coefficient of friction (max 0.2)
- Resistance to chemicals (hydraulic fluids, oils, acidic aqueous solutions)
- Resistance to high temperature (> 250°C)
- Resistance to low temperature (-70°C)
- Wide temperature range of operation
- Fire retardancy/smoke suppression

General description of alternatives and comparison with fluoropolymers

PEEK could be seen as an alternative to PTFE for cable liners. This material offers stability at higher temperatures and can allow for some protection of cables under certain conditions; however, it is not expected to provide the same combination of properties that PTFE offers in one single product.

Potential impacts related to substitution

PEEK is not expected to match the performance required for the lining of control cables intended to be used in the automotive and aerospace industries. Even if additional additives for lubrication were to be used, the results of the application on demand could not be compared with the low coefficient of friction, resistance to chemicals, lifespan, and wide range of operation that PTFE offers, particularly for critical safety systems that need to perform at extremely high cycles in a lifetime. Again, PEEK may prove to be efficient in some cases (e.g., resistance to only some (not all) foreseeable chemical environments in the application, or adequate performance up to +250°C, but not at low temperatures expected in high altitude during flight operation), but not in the broad range of scenarios that can be expected in the automotive and aerospace industries. For this reason, any initiative that could push for replacement of PTFE in control cable liners could create high risk situations for the population, since safety performance of critical transport systems would be downgraded.

Conclusions on the application

Fluoropolymers and in particular PTFE provide a unique combination of properties and remains the best (if not the only) option to facilitate adequate and reliable performance of control systems in land vehicles and aircrafts. If PTFE were not allowed to be used in control cable lining, the performance of these essential components would be seriously downgraded, resulting in a clear compromise to safety of passengers and the population in general. PTFE can be regarded as the top technology option today for these cable liners and removing it from these applications would bring control systems in vehicles to their technological infancy.

Under this circumstance, the whole transportation sector in the EEA, including vehicle and aircraft manufacture, could face an uncertain future and relocation to other countries, mainly in the Americas and the Asia-Pacific region could benefit from technology transfer to guarantee continued availability of highly reliable land vehicles and aircrafts. In addition to the safety considerations, impacts on standards of living of the general population (not only related to massive employment losses in these sectors, but also to affordability of e.g., cars and airplane travel) would need to be carefully evaluated.

3.4.4. Application 4.4: Use of PTFE and ETFE in the production of different auxiliary components for the automotive industry

Description of the application

PTFE and ETFE are used for the manufacture of different parts of car equipment, such as door hinges and seat height adjustment bearings. These parts can be regarded as pivot points which are subject to sporadic demand while cars are running, requiring high reliability and very low friction conditions.

Technical properties required for the material of choice

For these applications, the following properties are relevant for the material of choice:

- Mechanical strength (<12 MPa)
- Tensile strength (>40 MPa)
- Wear resistance (<5E-7 mm³/Nm)
- Flexibility (E-Modulus <500 MPa)
- Resistance to high temperatures (>250°C)
- Resistance to low temperatures (-30°C)
- Wide temperature range of operation
- Vibration dampening (>0.9)
- Impact resistance (IZOD impact test >8kJ/m²)

General description of alternatives and comparison with fluoropolymers

Some alternatives that could be considered for these applications are:

- Steel/Steel
- High temperature polymers
- Ultra-high molecular weight polyethylene (UHMWPE)

Steel/steel solutions and high temperature polymers

These alternatives require re-greasing the system in very short time frame (e.g., every two weeks) in order to avoid continued squeaking of the systems. Other high temperature polymers also require additional lubrication either like the steel/steel contact or solid lubricants like PTFE.

High temperature polymers

These polymers are so rigid that a press fit assembly is not possible, which in turn requires additional sealing and causes door drop issues due to wear, because wear particles can easily fall out the contact. Furthermore, in relation to seat-height adjustment bearings, the lack of press fit assembly will make it impossible to remove rattling noises from unoccupied seats, making the car noisier.

UHMWPE

UHMWPE has good mechanical, physical and tribological properties, such as: extreme hardness and durability, good chemical resistance, abrasion resistance, impact resistance, being easy to fabricate, a very low coefficient of friction and being a non-polarity polymer, which would have no additional lubrication requirements. However, UHMWPE causes rigidity issues. In addition, this material has a very low temperature resistance, with a melting point of 125°C -132°C, in contrast with PTFE which has a melting point of 327°C.

Potential impacts related to substitution

For door hinges, good lubrication is essential which can be achieved via the use of fluoropolymer-based systems. Alternatives resulting in higher friction would require significant amount of additional lubrication, this would have to be done via the use of oils which would result in environmental impacts. For example, the use of steel/steel systems in door hinges with frequent re-greasing was a feature of the old (and iconic) Volkswagen Beetle model launched in the 1940s.

From an economic perspective, while the steel-steel contact solution may be cheaper in the creation phase, regreasing efforts should be taken into account when evaluating this possibility. In a broader service life consideration of cars, the final outcome would result in higher costs, particularly if the car owner is not able or willing to take care of the service on his own.

In relation to UHMWPE, it is relevant to note that its low temperature resistance would create significant problems to the car manufacturing industry. This would force the complete redesign of the assembly process of cars (a quite complex one), which involves painting at high temperatures. Doors and hoods would have to be painted separately from the car body and assembled later, in contrast with modern technology (i.e., involving the use of fluoropolymers) which allows for the homogenous painting of the car body together with doors and hoods. This would result in significant impact to the car industry. Indeed, while the UHMWPE solution is also more economic (if focus is placed only on direct comparison one-to-one with the fluoropolymers), the fact that this solution would require major technical changes to the car industry could lead to investments for car manufacturers which could be expected to reach amounts near 100 million EUR.

In addition, alternatives must be tested to check that the performance and safety requirements are fulfilled. The substitution must be also approved by the manufacturers of the different applications. This process takes time, depending on the sector the time frame to consider could be in the range of 5-10 years.

Conclusions on the application

The alternatives previously described will likely result in higher maintenance costs and lower car reliability due to the lower quality of the material replacements. As a result, car production could remain in Europe, but cars produced outside the EEA will be more comfortable, less

noisy and they will require less maintenance. Altogether, the competitiveness of the automotive industry in the EEA will be compromised, as manufacturers based outside the EEA will have opportunities for more cost-effective design solutions.

According to information from the European Automobile Manufacturer's Association (ACEA, 2022), in 2018 the automotive industry was responsible for 12.6 million jobs in the EU, including manufacturing, services and construction. This corresponds to 6.6% of the total EU employment. Direct manufacture of motor vehicles employs 2.6 million people. In terms of trade, a positive balance 76.3 billion EUR was achieved in 2020 in the trade of motor vehicles, with 134.1 billion EUR of exports. The automotive industry contributed to 398.4 million EUR in fiscal income from motor vehicles in 2020 (data from EU14). In the same year, the sector of automobiles and parts invested 58.8 billion EUR in research and innovation related activities.

The use of alternatives would bring certain parts of car technology to systems that were used 50+ years ago. In the event that fluoropolymers may not be available for the application described, it is difficult to assume that consumers would accept a recoil in car quality and comfort, particularly when non-EEA car manufacturers may continue to keep those standards at XXI century levels. Going back to noisy and squeaking car components would be considered a significant disadvantage from a competitive perspective, for a very relevant industry in the EEA.

3.4.5. Application 4.5: Use of FKM for sealing applications in the automotive industry

Description of the application

FKM-based fluoroelastomers are used by the automotive industry in various products such as o-rings, gaskets, shafts, joints, fuel and turbo charger hoses and other connector components that are subject to intense temperature, in order to provide highly reliable sealing systems.

With the development of modern and more fuel-efficient turbochargers involving high pressure direct fuel injection, technical performance required from such sealing systems has reached unprecedented levels. It is imperative that no leakage at high temperatures occurs in vehicles in order to ensure safety for passengers and the surrounding population. Moreover, this energy-efficient, highly powerful and complex engines require durable components that will operate for longer periods without requiring frequent maintenance or replacements.

This case may be expanded to other engine-based means of transport such as aircrafts and ships.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength ($> 8\text{MPa}$)
- Wear resistance
- Flexibility
- Low coefficient of friction
- Resistance to harsh chemicals, such as synthetic oils
- Resistance to high temperature ($> 200^{\circ}\text{C}$)
- Wide range of temperature operation (-40°C to 250°C)
- Barrier properties
- Non-stick properties
- Fire retardancy / smoke suppression

General description of alternatives and comparison with fluoropolymers

Other rubber or elastomeric materials such as acrylic rubber (ACM), ethylene acrylate copolymers (AEM), HNBR, UHMW-PE, Polyoxymethylene (POM), PU, PEEK or EPDM could be suggested as potential alternatives. However, they would fail to provide the same level of efficient performance that FKM-based sealing systems offer. Other elastomeric materials such as ACM, AEM or HNBR have much higher friction coefficients, which is not suited for materials that need to be in constant demand for interacting with other pieces of vehicles while in use. UHMW-PE, POM, PU fail in heat resistance as they cannot withstand the temperature ranges required by car engines. PEEK is too hard to perform adequately in the sealing function of highly demanding engines.

EPDM is a synthetic rubber material that can offer good resistance under certain chemical environments, mainly for outdoor applications. It offers a good range of temperature

resistance (-50°C to 150°C). Although EPDM offers good resistance to diluted acids, ketones and alkalis, it does not perform so well in case of fuels, oils and non-polar solvents. It certainly would not be a suitable choice for the automotive sector, or others in which harsh conditions are expected.

In summary, while there are low-cost alternatives to FKM for certain less demanding (e.g., outdoors) applications, for cases such as car engines where highest standards of chemical and thermal resistance are required, FKM is currently the only reliable option available on the market.

Potential impacts related to substitution

If FKM seals were to be replaced by alternatives from vehicle engines, these systems would become less reliable and subject to increased need for maintenance and replacement, because the alternatives described previously would not perform at an equivalent level. All of them would fail to provide the same technical performance as FKM at least in one key property. FKM is currently the only material available on the market that fulfills all the technical conditions that modern turbocharger engines require to operate vehicles in an efficient way.

Conclusions on the application

FKM seals are a good example of fluoropolymers offering not just one but a combination of different properties that are (all of them required) in high technology applications. While other materials are available on the market, and they could offer equivalent performance under one single property required, they would fail to provide the same performance as FKM sealing systems. This makes those alternatives as not suited to be used for sealing systems in the automotive sector. Beyond increased wear rates, maintenance costs and generation of waste from repairs, the critical trade-off that would be derived from the replacement of fluoropolymers from this application is the fact that safety of passengers and the general population would be compromised due to higher risk of unexpected failure of engine components.

3.5. Sector of use 5: Food and water processing

3.5.1. Application 5.1: Use of modified PTFE, PFA and FEP in the production of systems used for food processing

Description of the application

Modified PTFE is used in membranes and bellows for food and beverage processing systems, but also in many components used by this industry such as baking belts, baking trays, cooking liners etc. In addition, PFA and FEP can also be used for different components in food processing and packaging machines. Because of their superior mechanical and non-stick properties, as well as low coefficient of friction, durability, wide temperature range of operation, and chemical resistance, fluoropolymers are used by the food processing industry when harsh conditions of use are required, or when ultra-high levels of purity and quality are needed. Membranes are used to provide aseptic conditions during handling of food, and bellows are designed to provide a dynamic separation element to protect the product from contamination.

Specific European regulations are in place for materials intended to come into contact with food, with positive lists indicating authorised substances, as well as allowed migration limits.

Fluoropolymers offer the high purity and strictest hygienic requirements that the food industry requires. Those properties are crucial in food processing. Materials must also meet inertness and resistance to high-temperature properties to avoid the migration of hazardous substances into the food that would imply contaminations that could create significant problems related to human health. Furthermore, fluoropolymers allow a unique sealing due to their resistance to chemicals and temperature that provides very precise dosing of the components during the process.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength (>30 MPa)
- Wear resistance (min 1E-6 mm³/(N·m))
- Mechanical properties (min 3E6 cycles)
- Low coefficient of friction (max 0.2)
- Resistance to chemicals
- Resistance to high temperature (150°C)
- Biocompatibility (food approvals required, e.g., NSF – EU10/2011 and GB4806.1)
- Wide temperature range of operation (0°C to 150°C in several operational conditions)
- Non-stick properties
- Fire retardancy / smoke suppression
- Low bacterial/algae growth

General description of alternatives and comparison with fluoropolymers

Elastomers like EPDM, methyl vinyl silicone rubber (MVQ), or NBR could be considered as alternatives, however they can only be used for a limited life cycle (maximum 20,000 life cycles) so the durability of the application is drastically reduced. On the other hand, the combination of resistance to high temperatures and chemicals are not met at an equivalent level that are achieved with the use of PTFE.

Other materials like PVC, polystyrene or silicon could also be recommended but approval state for food contact, chemical resistance against cleaning agents and performance under changing temperatures are coming as trade-offs.

Potential impacts related to substitution

The substitution of PTFE membranes and bellows with a combination of alternative materials would be expected to result in more frequent replacement of the damaged components. It is estimated that this would be increased by a factor of 150, therefore maintenance costs will be significantly increased as well, in addition this would lead to the generation of more waste since materials would need to be disposed frequently. These repairs also mean production losses, lower reliability, reduced life span and efficiency and a higher risk of food contamination. In contrast, fluoropolymers provide a long-life span to the materials due to their resistance to fatigue.

Membranes and bellows functions to avoid contaminations from the equipment and/or the environment will not be achieved by the alternatives which is a critical point for food safety so human health could be compromised. In addition, it will be quite difficult to obtain the demanding cleaning conditions required by the food industry as the resistance to chemicals of the alternatives are lower than fluoropolymers so again, it would result in health issues. In addition, food and drink streams must not excessively stick to the thermocouples or other food quality sensing devices.

All possible alternatives come with significant shorter lifetime cycles. This requires regular repair cycles for the equipment due to failures, which are costly and produce more waste. For low-cost consumer products this would most likely result in that repair costs are higher than buying new product which results in immense waste and recycling challenges. For higher end products for industrial use, the cost of the final product produced will most likely be higher due to more maintenance and labour cost involved. Even here, the consumer buying the final product (coffee, juice, tomato puree, soups, etc.) will pay the higher price, generating increased inflation in the EU zone in the long term.

Europe would lose competitiveness, especially to Asia-Pacific countries where cost is not high and circular economy is not yet a prioritised topic. More low-cost problems would be imported, and the amount of waste would increase as cheaper products (like household coffee machines) will be disposed instead of putting them into service/repair. Trends will get

removed from circular economy back towards “use and trash – then buy new” as it was the case in the past.

Conclusions on the application

Fluoropolymers provide a unique combination of properties that allow food processing equipment to reach extreme conditions, which is not possible with the use of existing alternatives. If fluoropolymers were not available for use in the food industry, performance of those systems would be seriously downgraded, resulting in increased risk of food contamination or reduced food quality, which could in turn derive into serious health concerns for the general population.

Food and Beverage filling and packing is an extraordinarily relevant industry in EEA, all from dispensing fluids like coffee or juices to breweries or packing equipment. According to FoodDrinkEurope (2022), the EU food and drink industry employs 4.5 million people, generates a turnover of 1.1 trillion EUR and 222 billion EUR in added value, making it one of the largest manufacturing industries in the EU. These industries are in need of fluoropolymers as the non-stick properties in combination with chemical resistance makes advanced automation processes (with changing media/fluids and cleaning cycles in between) possible. Reducing these, the EEA will suffer a significant loss in both workforce but even more competitiveness towards other regions like Asia Pacific. Production would most likely be moved out of the EEA if product quality and safety would be downgraded due to the use of alternatives. Standard of living and choice of products would also be reduced, and increased waste generation due to disposal of more frequently replaced elements should also be taken into consideration. While this impact may not be as severe as others related to safety considerations, they should be taken into account as well when evaluating the regulatory future of fluoropolymers.

3.5.2. Application 5.2: Use of PVDF in the production of membranes for water treatment

Description of the application

PVDF is used in the production of hollow fibre membranes used in different subsegments of water ultrafiltration systems. For example, these membranes are relevant at industrial and municipal wastewater treatment plants in which treated water is expected to be returned to waterways (e.g., rivers). They are also used in drinking water at municipal water plants, and also at industrial sites (irrigation in agriculture, cooling towers in process industries, etc.).

Hollow fibre membranes are a class of artificial membranes containing a semi-permeable barrier in the form of a hollow fibre. Originally developed in the 1960s for reverse osmosis applications, hollow fibre membranes have since become prevalent in water treatment, desalination, and other applications⁵. Most commercial hollow fibre membranes are packed into cartridges which can be used for a variety of liquid and gaseous separations.

PVDF filtration membranes are used to filter out contaminants such as pathogens (parasites, bacteria, and viruses), micropollutants (such as pesticides, pharmaceuticals, personal care products, endocrine disruptors and microplastics for drinking water production. A membrane bioreactor (MBR) is a combination of membrane processes like ultrafiltration with a biological wastewater treatment process (activated sludge process).

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength: Tensile strength >45 MPa (ASTM D638).
- Wear resistance: 10 years accelerated test (internal standard test).
- Mechanical properties: Elongation at yield > 25% (ASTM D638); Tensile modulus <2200 MPa (ASTM D638).
- Resistance to harsh chemicals: 1,000,000 ppm·hours to sodium hypochlorite (NaOCl) exposure for membrane cleaning, which is a critical chemical used for removing organic constituents and disinfection.
- Non-stick properties: Resistance to fouling by organic constituents present in surface waters.

PVDF membranes are typically rigorously tested and meet drinking water standards throughout the world. Certifications include: NSF 61 and NSF 419 (USA), KTW (Germany), KIWA (Netherlands), ACS (France), DWI (UK), ICIM (Italy), MOH (China), or KWWA (Korea).

General description of alternatives and comparison with fluoropolymers

PES is the most common material that could be described as a potential replacement for PVDF for the production of membranes intended for water filtration. Other compounds such as PE

⁵ https://en.wikipedia.org/wiki/Hollow_fiber_membrane

and PP, or even ceramic based materials may be used in membranes, but PES stands out as the most typical option.

Where one-to-one replacements would not be considered, the only other alternative for water treatment would be to return to clarification methods based on the use of a wide variety of chemicals (e.g., flocculants, coagulants), as well as conventional gravity settling and sand filtration, which is a fairly old technology.

In relation to hollow fibre ultrafiltration membranes, it is critical to distinguish between inside-out type and outside-in type. For inside-out hollow fibre membranes, the feed water is fed to the inside bore of the hollow fibre and the clean water passes through the polymer matrix (the separation barrier) to the outside of the hollow fibre. This type of membrane is used on easier to treat applications (e.g., post treatment of potable water, low turbidity surface water). For inside-out hollow fibre membranes, PES can be used effectively. For outside-in hollow fibre membranes, dirty water is on the outside of the hollow fibre and the clean water is collected from the inside of the hollow fibre. Outside-in hollow fibre membranes are used on higher solids and more fouling feed waters (e.g., industrial applications, wastewater treatment, high turbidity surface water). Due to the challenging applications, outside-in hollow fibre membranes are subjected to more aggressive cleaning, including agitation with air scouring and use of high concentrations of cleaning chemicals (e.g., sodium hypochlorite and acids). For these reasons, outside-in hollow fibre membranes are almost exclusively made from PVDF (The MBR site, 2017).

Potential impacts related to substitution

As previously mentioned in the description of other cases, there are indications that PES may be related to equivalent concern as BPA due to potential endocrine disrupting properties (Kang et al., 2014). In addition to this PES-based membranes are known for exhibiting inferior performance compared to the PVDF equivalent. For example, while PES may provide equal mechanical properties (reaching tensile strength above 45 MPa), its elongation at yield is lower (6% compared to 25%), and the resistance to sodium hypochlorite is limited to 250,000 ppm hour. Their reduced flexibility and chemical resistance will make PES membranes brittle during product life, resulting in broken fibres and reduced life expectancy (5-7 years compared to nearly 20 years duration of PVDF membranes). Furthermore, changing existing PVDF-based systems to PES would require significant engineering studies and equipment changes to make PES membranes work. Because the solutions using PES membranes will be more complex with additional treatment steps, the cost of substitution is expected to be in the range of hundreds of millions EUR for making the necessary retrofits. Additionally, future membrane treatment plants will also be much more expensive to construct if PVDF membranes are no longer available.

The change to filtration systems based on non-membrane solutions would result in the need to use older technologies that imply the use of chemicals and less efficient water treatment processes which could seriously impact the quality of water that could return to humans or the

environment. Indeed, MBR technology using PVDF hollow fibre membranes replaced old conventional gravity settling and sand filtration, and it plays a critical role in providing the advanced wastewater treatment needed to allow municipal wastewater treatment plants to effectively comply with the Urban Wastewater Directive ⁶ (91/271/EEC), to which the protection of aquatic ecosystems, bathing water, and groundwater are closely related.

Membrane filtration also provides high-quality reclaimed water, helping cities to meet the EU Water Reuse Regulation⁷ as well as other legislations fostering the recycling of municipal and/or industrial wastewater. The potential role of treated wastewater reuse as an alternative source of water supply is now well acknowledged and embedded within European and national strategies. Water reuse is a top priority in the Strategic Implementation Plan of the European Innovation Partnership on Water, while maximization of water reuse is a specific objective in the Communication "Blueprint to safeguard Europe's water resources" (COM, 2022).

Many cases exist where membrane filtration was determined to be the best available technology (and in some cases the only viable technology) to protect ecologically sensitive water bodies. Examples include plants in Sweden, with 540 Minimal Liquid Discharge (MLD) and commissioned in 2008, which is the largest MBR in the world, Germany (47 MLD, commissioned in 2003), France (108 MLD, commissioned in 2013) and Belgium (86 MLD, commissioned in 2017).

The annual MBR market is estimated at around 5 billion EUR, solutions costing 50-100% more would result in 2.5-5 billion EUR per year additional investment to meet future wastewater treatment needs. For one single membrane producer in the EU, 1000 jobs would be expected to be lost, including high level manufacturing, engineering, and R&D jobs. Another 500-800 jobs could be lost in other functions within the EEA countries, with revenue losses for one company alone expected in the range of would be 250 - 350 million EUR per year.

Conclusions on the application

Fluoropolymers provide the best solution to allow high quality water ultrafiltration systems. Alternative materials or technologies will either imply the use of potentially hazardous chemicals (PES) or the return to technologies that were used decades ago, involving increased use of chemicals which may remain in water that will later return to the environment. Without this technology, more complex and expensive solutions will have to be employed to provide removal of these contaminants. For many of the more challenging surface water sources impacted by increasing weather events brought on by climate change, good alternative solutions are not feasible in practice.

⁶ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment.

⁷ Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse

3.6. Sector of use 6: Medical and pharma

3.6.1. Application 6.1: Use of PTFE in the production of equipment to be used in vaccine preparation requiring ultra-high purity media

Description of the application

Similar to **Applications 1.1** and **3.1**, PTFE is used in vessels, pipes, and fitting systems (e.g., diaphragms in valves) for the pharmaceutical industry, with the objective to produce medicines and vaccines, requiring ultra-pure media and sterile conditions. In this industry, most of this equipment is not necessarily based on other materials lined with fluoropolymer, but the fluoropolymers are directly used for tubing and piping systems.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength (<10 MPa)
- Flexibility (E-module <500 MPa)
- Resistance to harsh chemicals
- Resistance to high temperature (250°C)
- High flex-life (>5E6 cycles)
- Extremely high product purity

General description of alternatives and comparison with fluoropolymers

Some alternatives that could be considered for these applications are:

- PP lining systems
- Rubber lining systems
- Tantalum-based piping
- Stainless steel: V2, V4, 316 L, Hasteloy, Inconel
- Enamel / glass lining systems

Similar to the case of the semiconductor industry (**Application 3.1**), the highest levels of purity of chemicals used in the production of vaccines or other medical products must be guaranteed. For this reason, elements of equipment in contact with chemicals used in the manufacture of these products have to ensure that no impurities will be generated during the process, which could alter the final composition of the medicines or vaccines.

Potential impacts related to substitution

The possible alternative materials listed previously have already been discussed in previous sections and will not be commented further. Due to potential degradation from rubber or other plastic solutions, and to the release of metals or migration of components from enamel elements, the use of these materials would not guarantee the highest purity demands that

the pharmaceutical industry requires, therefore those products could not be regarded as a viable alternative to fluoropolymers in this application.

Conclusions on the application

While fluoropolymers provide an outstanding combination of properties that are relevant for this use, the possibility to grant the highest possible purity levels and sterile conditions makes these materials the only real material of choice for production of vaccines and certain medicines, for which this property is absolutely essential. Failure in achieving this requirement may result in contamination of vessels and on the final vaccines delivered to the population, which would generate not only an obvious health concern, but also social distress and significant issues related to quality controls, tracking of contaminated vessels and eventually removal of a high number of vaccines that could have been marketed before identifying purity issues. In a situation that fluoropolymers would not be available for this use, production of vaccines requiring ultra-high purity conditions may become not viable within the EEA.

According to the European Federation of Pharmaceutical Industries and Associations (EFPIA, 2022), in 2016 the market value of the European pharmaceutical industry was 199,234 million EUR, with a production value of 248,053 million EUR. Investment in innovation for the same year was 33,949 million EUR, and total spending (public and private) on healthcare as a percentage of GDP at market prices of 2016 reached 8.8%. In terms of employment, the pharmaceutical industry contributed to 747,607 jobs, with additional 115,000 jobs focused on pharmaceutical R&D.

Other than the numbers displayed above, the recent crisis related to the Covid-19 pandemic has demonstrated that it is critical for the protection of the European population to keep a strong pharmaceutical sector ready to deal with immediate challenges from an ever-increasing complex health situation.

3.6.2. Application 6.2: Use of PTFE and FPE in the production of implants for the medical device sector

Description of the application

PTFE is used in interventional delivery devices (e.g., cardiovascular grafts, arteries, hernia mesh, stents, ligaments, etc.) due mainly to its inertness, non-toxicity, and biocompatibility properties, which allow for tissue attachment and cell adhesion without adverse reactions, infections, and rejection issues. In addition to that, PTFE coatings are used to enhance anti-friction properties and enable a smooth travel through blood vessels or other parts of the body.

Interventional delivery devices are crucial and, in many cases, the only solution to solve the malfunction or non-efficient behaviour of the human organs which can lead to very serious health issues. Medical devices are essential for saving lives and enhancing the life quality for millions of people who are suffering from certain illnesses.

PTFE etched liners are used as base for the implant construction, whereas the inner diameter of the PTFE is in direct contact with the media applied through the tubing (either inside the body or extraction from the body). For this application, a very low coefficient of friction is required to not disturb the flow and to not collect residue in the liner, which may impact the performance of the medical procedure. In addition, PTFE is able to withstand several sterilization methods. The etched outer surface is needed to bond the PTFE liner stable, yet flexible on another layer of the device construction.

Moreover, it is always necessary to hold all components of the device construction in place. For this functionality, an FEP heat shrink is always needed. FEP is here used for the shrink ratios 1.3:1 or 1.6:1 which are unique for fluoropolymers to be able to give the stability needed for the device.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical properties (moderate stiffness and high ultimate elongation)
- Low coefficient of friction
- Chemical inertness
- Resistance to harsh chemicals (chemical inertness to industrial chemical and solvents)
- Resistance to high temperatures (260°C)
- Resistance to low temperatures (-240°C)
- Weather resistance
- Biocompatibility
- Electrical insulator (high data transmission range)
- Dielectric strength (exceptional, stable with frequency and temperature)
- Barrier properties

- Non-stick/lubricant properties
- Low bacterial/algae growth (negligible moisture absorption)
- Gas exchange properties
- Non-aging characteristics

General description of alternatives and comparison with fluoropolymers

PP is one of the more widely used synthetic plastic materials. It is both strong and flexible, easily cut and can readily be integrated by surrounding tissues. Even though this is the most popular synthetic material on the market, it is associated with many complications, including infection issues.

Other polymers usually used in tubes like PVC, PE, thermoplastic polyurethane (PU/TPE-U), or silicone could be considered as alternatives, but they do not allow for the combination of low friction (without stick-slip), multiple use (cleanability and sterilization), high temperature resistance and dielectric strength (electrical surgery) that the various implant-related applications require.

The life span of alternatives is significantly shorter than that of fluoropolymers, implying a higher probability of failure and as a result a significant risk to human health. Furthermore, the likelihood of replacement is substantially higher as well, resulting in higher levels of waste that will need to be disposed of.

Potential impacts related to substitution

Alternatives do not meet the performance required by interventional delivery devices. The non-use of fluoropolymers would result in a severe decline in the life quality of people, or in the worst-case scenario, an increase in mortality because of the lower efficiency of medical devices and/or the rejection of the implant, therefore human health would be significantly compromised.

European companies manufacturing medical devices would most likely relocate outside of the EEA to other countries where such restrictions do not apply, which could result in an increase in health care tourism. Furthermore, it would have a severe economic impact on the healthcare sector, resulting in increased unemployment and dissatisfaction among the population.

Conclusions on the application

A ban on fluoropolymers for their use in medical devices would be expected to have a great impact on society because the European healthcare sector would be with all likelihood set back more than 50 years in terms of innovation, since the most modern technologies would not be available anymore.

Medical devices are regulated by specific regulations to guarantee human health. Material qualification and registration processes for medical devices are lengthy and costly processes. Depending on the application, approval of medical devices could take up to 12 years. These

procedures often involve significant efforts in terms of testing and changes to existing validated processes. To guarantee the adequate health care, the unique combination of properties offered by fluoropolymers to the interventional delivery devices becomes essential.

For many companies, the procedure to find suitable alternate materials, to re-design the components to accommodate new materials to meet the functional requirements and to change the tools for manufacturability will pose big challenges and make the products economically unviable.

Customers will generally use the most cost-effective solution that meets the needs of the application. It should be considered that the costs and time for research, development, testing, qualifications, and changes to processes would be significant even if suitable alternatives could be identified. Any changes would have to be evaluated, more complex environmental health and safety challenges would be created, and increased costs passed down to customers.

3.7. Sector of use 7: Construction

3.7.1. Application 7.1: Use of PVDF in the production of pipe fittings and manifolds for plumbing in the construction sector

Description of the application

PVDF is used in the production of pipe fittings and manifolds for plumbing systems in buildings, both residential and industrial. PVDF was introduced in the 1990s in this sector, due to its excellent resistance to chemicals and corrosion, resistance to high temperature, high compatibility with many chemical substances, stability, inertness, flame retardant and UV resistance properties. The main applications involve heating systems and sanitary water, related to delivery and transport of both gas and water.

PVDF is non-toxic and its smooth surface does not encourage the growth of microorganisms, therefore this anti-fouling property is helpful to prevent contamination of water or gas.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength
- Wear resistance
- Mechanical properties
- Low coefficient of friction
- Resistance to harsh chemicals
- Resistance to high temperature
- Resistance to low temperatures
- UV resistance
- Wide temperature range of operation
- High limiting oxygen index
- Weather resistance
- Low bacterial / algae growth

General description of alternatives and comparison with fluoropolymers

Brass

Brass was a typical material used for plumbing applications and in fact it can still be found today as a potential alternative. However, PVDF was introduced around 30 years ago to replace brass because it is a lighter material, offers better resistance to attack and is not impacted by corrosion, offering 50+years lifetime for the plumbing installation.

Polyphenyl sulfone (PPSU)

PPSU is an alternative material that can be found currently on the market and may be used for plumbing applications. However, replacement of PVDF with PPSU in plumbing applications

could result in several trade-offs, the most relevant ones being related to compatibility with other materials used in plumbing and reduced lifespan of the materials, along with some foreseeable supply issues.

Potential impacts related to substitution

Even if brass fitting systems are still available for plumbing applications today, it needs to be highlighted that this material is prone to corrosion under certain environments. Because small (yet significant) amounts of lead can be found in certain brass compositions, corrosion of brass-based plumbing materials could lead to release of lead and introduction of this hazardous metal into water systems, which can lead to significant issues from a health and environment perspective. The fact that this material is also heavier than PVDF and would eventually reduce the lifespan of the plumbing installations highlight that it is not a suitable replacement to PVDF fittings and manifold equipment.

In relation to PPSU, it needs to be highlighted that it is a polyether composed of bisphenol S (BPS) and 4,4'-dihydroxybiphenyl (DHBP), both of which have been related to potential endocrine disrupting properties (Eckardt et al., 2018). Indeed, PPSU has been associated to generation of BPS during degradation (Li et al., 2022), therefore selection of this material as a component of plumbing installations should be evaluated carefully, particularly as a replacement to PVDF in case of a ban on the use of fluoropolymers, as this could lead to regrettable substitution. PPSU is not resistant to UV radiation and therefore there could be a potential risk of decomposition and release of BPS during normal use of fitting systems produced with PPSU.

PPSU is also considered to be more fragile and not resistant to heat which makes this a less reliable material in comparison to PVDF. More significantly, PPSU is known for not being compatible with the typical glue composition (under a well-known commercial brand) that is frequently used by plumbers in their installations. Introducing PPSU for all plumbing solutions would thus create significant problems down the value chain of plumbing installations, in relation to the need to find alternative materials for sealing fittings and manifolds. In addition, new casts for fitting solutions would have to be developed, bringing significant additional costs (approximately 15 million EUR are estimated by one single company) to adapt to new standards having to switch from PVDF to PPSU based fittings.

In addition to this, it needs to be noted that water and gas pipe requirements are regulated by specific regulations, which means that new materials need to be approved for these uses. Such approval procedures may take up to 5 years, with obligations to demonstrate that the alternative is safe for use in water applications. This will involve the need for testing and additional research which can be estimated at about an extra 1 million EUR.

As of today, only two companies are identified as suppliers of PPSU in the EEA. This could point towards a supply issue in the case that replacement of PVDF by PPSU could be imposed due to regulatory restrictions on the use of PVDF, including potential price increases of the

alternative. Currently PVDF is a more expensive product compared to PPSU, but this could change if its use would be imposed in the context of a restriction impact on PVDF.

Companies involved in the production of PVDF based fittings and manifolds may consider taking production of these products outside of the EEA. Individual losses for companies in this sector are estimated at 200 million EUR revenue and 400 jobs terminated.

Conclusions on the application

The consequences of a ban on the use of PVDF in plumbing applications, related to the production of pipe fittings and manifolds for use in sanitary and heating systems (water and gas) could result in significant negative impact for the European society. Looking at alternative materials, the two main options available for substitution currently would entail potential issues human health or the environment, being related to higher corrosion risk from brass (and potential release and uptake of metals like lead in water streams), or to potential degradation of PPSU (e.g., via disposal of systems after end-of-life, or by degradation via exposure to UV radiation) resulting in potential release of hazardous chemicals like BPS. It needs to be noted that PVDF was introduced around 30 years ago as a replacement of brass-based solutions, therefore this change would push the European building sector a few decades backwards in terms of innovation.

Both solutions would bring additional negative situations to the broad value chain related to plumbing, from individual company losses in the range of hundreds of millions of EUR and hundreds of jobs at risk, with relocation of activities outside the EEA, to a need for plumbers to re-evaluate basic materials used in construction, such as typical gluing systems for sealing of fittings and re-shaping of casts for new pieces. This could be related to investments in the range of tens of millions of EUR, which would also include research and testing for verification of materials to be in contact with sanitary water. Relatively long time periods for obtaining approvals to use new materials would have to be foreseen as well.

The lack of availability of fluoropolymers in the plumbing sector will therefore imply a competitiveness decrease of the European companies, due to downgraded performance related to the alternatives not being able to match the combination of properties that PVDF provides. In addition to the negative impact on health and environment, and increased costs related to substitution, more frequent maintenance and increased disposal of materials related to shorter lifespans would need to be considered.

3.7.2. Application 7.2: Use of PVDF in façade and infrastructure protection for the construction sector

Description of the application

PVDF is used in coatings for the construction sector to protect and enhance the durability of critical infrastructure elements, especially for metal-based components. These protective coatings are used in, among others, bridges, pipelines, storage tanks, racks that support solar panels, buildings in housing, heavy industry, and airports.

PVDF is used for this application due to its excellent resistance to chemicals and corrosion, resistance to high temperature, high compatibility with many chemical substances, stability, inertness, durability, flame retardant and UV resistance properties. Its exceptional flexibility allows the use in the complex forming and bending of metal building panels. PVDF is also resistant to high humidity environments, non-toxic, and its smooth surface does not encourage the growth of microorganisms, therefore this anti-fouling property is helpful to prevent stains and dirtiness.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Wear resistance: PVDF meets or exceeds the standards for the building panel industry. AAMA 2605, EU equivalent to ASTM D968).
- Mechanical properties: The superior flexibility of PVDF allows for complex forming and bending of metal building panels AAMA 2605 EU equivalent to ASTM D4145, ASTM D522 and ASTM D2794.
- Resistance to harsh chemicals: EU equivalent to ASTM D1308.
- Weather resistance: Exceptional resistance to UV degradation during exterior exposure AAMA 2605 EU equivalents to ASTM G7, ASTM D2244 colour retention, ASTM D4214 chalk resistance and film erosion.
- Barrier properties: Provides enhanced corrosion and humidity resistance VDA 233-102 EU equivalents to ASTM B117, ASTM D2247 and ASTM D4585.
- Fire retardancy / smoke suppression: Exceptional flame spread resistance and smoke development EU equivalent to ASTM E84.
- Low bacterial / algae growth
- Low refractive index for optical effects: Compared to other coating types, the lower refractive index leads to lower pigment demand for film opacity. The use of less pigment supports sustainability initiatives.
- Other properties: These coatings have less tendency to collect dirt and reduced degradation due to UV exposure. This allows for a graffiti resistant coating. This also allows for the coating to maintain solar reflectance values longer. CRRC-1 Program, ASTM D7897 and ASTM E1918.

General description of alternatives and comparison with fluoropolymers

Silicon-modified polyester, polyurethane or high-performance polyester could be taken into account as alternatives. However, alternatives would potentially reduce the life expectancy of building panels from 40 to 50 years or even more down to 20 to 35 years or less, depending on the alternative technology used and the specific setting.

Potential impacts related to substitution

If alternative materials were to replace PVDF in coating applications for buildings, the reliability of coated surfaces would be expected to decline over time due to the reduced efficiency of such materials. This could lead to compromised safety where the coatings are used to protect elements of the critical infrastructure such as bridges and buildings.

The longer durability of fluoropolymer-based coatings results in a reduced environmental impact and maintenance cost over the lifetime of the building, since maintenance activities will be minimised; less removal and replacement of building panels will be required when PVDF is used in coatings compared to alternatives. The low surface energy and hydrophobicity of PVDF also results in reduced dirt, allowing the structures to remain cleaner for a longer time. Finally, PVDF is also resistant to UV radiation, a property that all the alternatives would not offer. This means that non-fluoropolymer coatings could break down through hydrolysis and photochemical reactions, resulting in increased degradation and reduction of protection objectives.

Conclusions on the application

The architecture and construction industries are not only challenged to build structures that withstand extreme weather conditions, but also maintain the exterior appearance for years to come. Consequently, building design teams are always looking for more durable solutions when envisioning projects that use architectural metal panels. This means they are increasingly turning to architectural metal coatings that offer longevity, lasting colour retention and superior protection from the elements.

It is important to highlight that trade-offs from the use of alternatives to PVDF in this application are not related to appearance or other aesthetics properties, but to safety and integrity of infrastructures, some of which are related to housing (buildings), but also to critical components for mobility (bridges), or even for renewable energy systems (solar panels). The use of high technology fluoropolymer-based coatings allows for enhanced fire protection and longer life of coated surfaces, which in turn reduces the need for material replacement and/or recoating. The reduction in waste and material consumption would be expected to result in lower carbon usage. PVDF is used as the back sheet in most solar panels. Furthermore, the use of painted metal structures is amenable to recycling as many metals such as steel and aluminium are recycled through melting in blast furnaces. In general, it is difficult to reuse or recycle applied organic coatings, but high-temperature incineration would be expected to

result in destruction of the PFAS molecular structure and vapor capture and processing is commonly used during recycling efforts.

The use of high-technology fluoropolymer-based coatings allows for the long life of coated surfaces, which in turn reduces the need for material replacement and/or recoating. The reduction in waste and material consumption would be expected to result in lower carbon usage. The extraordinary resilience of fluoropolymer-based coatings means that relatively little of the material would be expected to be released over the product's lifespan. The erosion of the coated film is minimal. This allows for a life cycle and product warranties of 40 years or more.

It should also be noted that the use of PVDF in the construction sector is limited to industrial applications, and that PVDF-based coatings are generally not available for the general public for use in lower value applications.

The lack of availability of fluoropolymers-based coatings for the construction sector will therefore imply a competitiveness decrease for the European companies, due to downgraded performance related to the alternatives not being able to match the combination of properties that PVDF provides. It would be expected that the sheets for coatings may be produced outside the EEA and/or they will be imported in the case the application would be still needed.

In addition to the negative impact on the environment and increased costs related to substitution, more frequent maintenance and increased disposal of materials related to shorter lifespans would need to be considered.

3.7.3. Application 7.3: Use of PTFE, ETFE, FEP, PFA in the production of sealing systems in compressors used for heating and air conditioning equipment

Description of the application

PTFE, ETFE, FEP and PFA (and their composites) are used in the production of seals, bearings, gaskets, and o-rings. These materials are then used in compressors that are installed mainly in houses for heating and air conditioning purposes. However, there are other applications that could be relevant for this use, for example installations destined for food preservation and maintenance (cooling) of medical products (vaccines, etc.).

The industry referred in this case is typically referred to as Heating, Ventilation, Air Conditioning and Refrigeration industry (HVACR) or Refrigeration, Air Conditioning, and Heat Pump (RACHP) industry.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Mechanical strength (Compressive and tensile strength, ductility, and modulus).
- Wear resistance (Wear rate, including no scuffing/galling, and ability to conform for high-speed sleeve bearings).
- Mechanical properties (Flexural strength, ability to deform/yield slightly to produce adequate sealing).
- Low coefficient of friction: 0.05 maximum dynamic friction coefficient.
- Resistance to harsh chemicals: must not excessively harden, soften, or crack in the presence of pressurized F-gases such as hydrofluorocarbons (HFC) or hydrofluoro-olefins (HFO) or hydrocarbon refrigerants and their oils, such as polyester oil (POE), polyalkylene glycol (PAG), or polyvinyl ether oil (PVE).
- Resistance to high temperature: temperatures of operation may reach 175°C.
- Resistance to low temperatures: certain HVACR applications (helium/cryogenic) can expose polymers to very cold temperatures (<-60°C) due to the cooling effect of the refrigerant.
- Wide temperature range of operation: Must not excessively harden, soften, or crack in the presence of refrigerants and oils under large temperature swings (-60°C to 175°C). This temperature range may come from the refrigerant effect as well as the winter ambient outside.
- Electrical insulator: The internal motors, wire insulation, relays, electrical protectors, etc., come in contact with refrigerant and oils and must maintain their insulative properties equivalent to current fluoropolymer material.
- Dielectrical strength.
- Explosive decompression: Due to the large cyclic variation in gas pressure and temperature in normal operation, the polymer must not absorb excess refrigerant with a corresponding fast release causing material "explosion".

General description of alternatives and comparison with fluoropolymers

Materials such as polyetherimide (PEI), polybenzimidazole (PBI), polyamideimide (PAI) or phenolic resins have been proposed as potential alternatives, however it should be highlighted that these materials have not been fully tested as replacements for fluoropolymers in the application.

Potential impacts related to substitution

None of the alternative materials that have been flagged as potential replacements for fluoropolymers in this application offer the same degree of chemical resistance. In addition, they are expected to offer inferior protection against friction in front of increased compressor power usage, leading to less reliability and service life (bearing failure rate increase, scuffing/galling rate increase), efficiency reduction (refrigerant leakage from less effective sealing causing capacity loss). In the case of flammable refrigerants (which are becoming more common as they are low global warming type refrigerants), leakage would be a safety concern.

Due to the previously mentioned inferior chemical resistance, alternative may lead to increased chemical degradation and higher chances of releases. This could be a safety concern, particularly as the use of flammable refrigerants is increasing, which are considered of lower global warming impact.

Other properties that would be downgraded are ductility, sealing effectiveness, yielding/conformability with bearings, or high temperature tolerance. All of this would make compressors less reliable, less energy efficient, not to mention the need to face higher product costs due to design changes which would likely become necessary.

It is important to understand that HVACR systems are very aggressive to polymers in the general sense. HVACR systems are hermetically sealed and normally last 15 or more years. Compression of the refrigerant causes high gas pressure and temperature swings. Temperatures can range from -60°C to 175°C. Under these conditions, the refrigerant can penetrate into the polymer components or coatings and cause several destructive events (brittleness, softness, and explosive decompression). Another unfortunate consequence is that the refrigerant acts like a solvent to some extent and dilutes the oil. Dilution of the oil causes the oil's viscosity to diminish which reduces the oil's ability to effectively lubricate. There are many moving parts inside a compressor and valves and fluoropolymers are used to help reduce friction and keep the refrigerant sealed. So, all these constraints and hardships make the conditions inside an HVACR system very unique and demanding. As a result, these hardships make choosing a polymer type very difficult. There are not many polymers that can withstand this environment. Fluoropolymers are one of the few classes of polymers that work well in these environments because of the combination of many beneficial properties as described earlier and certainly the ones that offer best performance and reliability. They have been approved for use in HVACR systems for many years.

Conclusions on the application

The HVACR industry represents over 30 billion EUR in turnover, over 200,000 direct jobs and millions of indirect jobs. Even a small perturbation in this industry due the unavailability of fluoropolymers would be fairly substantial. This industry plays a vital role in the EU society. It provides critical climate control and ventilation in homes, hospitals, schools, elder care facilities, and most buildings. The HVACR industry creates the environmental conditions necessary for the application by controlling and monitoring temperature, humidity, and air quality.

Electric heat pump compressors (for hot water and air heating) are vital to reduce Europe's reliance on oil and gas. These elements are expected to play a key role in the achievement of the Green Deal goals. Less reliable, less efficient, and shorter lasting heat pump compressors would be a detriment and slow down decarbonisation objectives. Finally, it should be considered that the incorporation of low global warming refrigerants is becoming an increasing trend in the sector. The fact that these refrigerants are flammable requires absolutely efficient sealing systems, which may not be possible if fluoropolymers are not available for this application.

The following are other important applications: transportation and storage of food and other perishables, reach-in food store display cases, walk-in coolers, computer rooms, breweries, liquid desiccant dehumidification, cannabis processing, ice machines, ultra-low temperature/cryogenic freezing, warehouse climate controlled storage, process chillers in industrial plants, indoor farming, shop air drying, dental air compression, ocean refrigeration containers, rail and bus air conditioning (and monitoring), truck/trailer refrigeration, controlled storage of medicines such as vaccines and laboratory specimens, industrial and commercial chillers. Reducing or eliminating HVACR products caused by premature elimination of fluoropolymers would likely cause a global societal crisis.

3.8. Sector of use 8: Cookware

3.8.1. Application 8.1: Use of PTFE in cookware

Description of the application

PTFE is used in cookware (e.g., frying pans and in bakery trays) due to its long-lasting non-stick performance. The main positive effects resulting from this use are related to safety (preventing metal migration into food), improved health conditions (less oil being used, less burned food), sustainability (less food waste due to burned food, longer life-time of articles which are as well easier to clean, resulting in lower carbon footprint due to less water and detergent usage for cleaning) and hygiene (articles are easier to clean).

It is relevant to highlight that decomposition of PTFE is expected at a temperature of 350°C. Above 260-270°C, slight degradation of PTFE coatings may begin. However, most food will be burned before reaching any of those temperature levels, in fact decomposition of frying oil starts at 180°C, with the Maillard reaction (browning of food) starting at 140°C. Therefore, it is not expected that any decomposition of PTFE would be involved in the cooking process.

It is the case that in the curing process of cookware (not in the end use by consumers), coatings are heated up to 420°C for a short time. Any release of volatile materials (which would in any case be minimal) will be collected and absorbed by abatement techniques that are currently present at any production facility.

Technical properties required for the material of choice

For this application, the following properties are relevant for the material of choice:

- Resistance to harsh chemicals (those that may be used for cooking but also for cleaning purposes)
- Resistance to high temperature
- Barrier properties
- Non-stick properties

General description of alternatives and comparison with fluoropolymers

Ceramic materials can be used as an alternative to coat cookware. The use of non coated stainless-steel articles for coating can also be used but these will obviously not provide the desired non-stick properties.

Potential impacts related to substitution

Non-stick properties of ceramic coated cookware are nowhere near to the levels that PTFE provides. This means that replacement needs to occur more frequently, which will result in higher cost for consumers. Furthermore, this solution is not valid in industrial kitchen appliances (e.g., cooking robots) which require very high performance. For this sector, no viable alternatives are considered to be available.

According to the Federation of European manufacturers of Cookware and cutlery (FEC), there are currently 600 million pieces of coated cookware in EU households. Assuming a replacement of coated cookware every 4 years, this results in 150 million pieces of coated cookware being sold in Europe on a yearly basis.

Conclusions on the application

PTFE shows unique long lasting non-stick performance not met by other metals or coating materials up to now.

It needs to be highlighted that PTFE is known as being a non-toxic material. The main concern related to the use of PTFE in cookware was the use of other PFAS surfactants as polymerisation aids during the manufacturing process, where small concentrations of such surfactants may remain in the final PTFE coat and thus be released during the use phase of cookware. However, industry has taken significant steps over the last years to remove the use of those surfactants. It is expected that in the near future, all PTFE grades may be available on the market without involving PFAS in the manufacture. The result of this will be that cookware will be coated with a non-hazardous material that contains no remaining of any other substance of concern. It would therefore be questionable that a non-hazardous product should be banned from applications in which it provides significant benefits to society, related not only to comfort levels, but also to safety and improved health conditions. Indeed, even before such technical developments occurred, release of such PFAS from coated cookware was nevertheless regarded as being improbable, as stated by the German Institute for Risk Assessment (BfR, 2019), which wrote that “toxicologically relevant migration of PFOA (one of the PFAS of highest concern) from non-stick coated cookware is unlikely to happen if the production is done under ‘Good Manufacturing Practice’”.

in 2017, the Danish Consumer Council THINK Chemistry selected 16 frying pans from the Danish market. These products were tested for the release of unwanted fluorine substances. In the test, the frying pans were first washed. They were then filled with olive oil and put in the oven at 200 degrees for 30 minutes. The olive oil was then tested for the content of 22 specific fluorine substances. It was also tested for so-called total organic fluorine, which is a broad term for fluorine substances. No release of fluorine substances was found in any of the frying pans. However, the test shows that the frying pans tested did not release these substances to food. If frying pan material contains fluorine substances in their non-stick coating, the substances are therefore well-bound in the pan's material (Danish Consumer Council, 2017).

4. Conclusions

The case studies described in this report are just a small sample of the many applications in which fluoropolymers are used. However, they can be considered as a good representation of the many key properties that fluoropolymers offer to a wide number of industrial sectors, and which enable highly valuable benefits that end-users in Europe enjoy.

Fluoropolymers are currently irreplaceable for many critical applications, and existing potential alternatives would be associated with significant trade-offs that could compromise safety of workers, general population, or the environment, either due to direct hazardous properties of the alternative, or by downgrading performance of key applications. As of today, it is not anticipated that viable alternatives offering equivalent performance could be developed in the near future.

Fluoropolymers were first discovered and developed in the late 1930s. Since then, many innovative processes have been developed which involve the use of these high-value materials. This has enabled sophisticated and high-performance technological systems that have resulted in the quality standards that the modern society has achieved. Fluoropolymers were frequently introduced in existing industrial sectors to improve safety and reliability conditions, replacing less efficient materials. Under a situation in which fluoropolymers may no longer be available and downstream users would be forced to switch to alternatives, a relevant number of applications could be pushed backwards 50 years or more, in terms of technologies that would have to be used. Clear examples of this would be the manufacture of semiconductors at modern technical standards, or the development of innovative green energy techniques.

On top of this, some of those applications are key enablers of strategic objectives that the European Union has established, in terms of energy and decarbonization (as indispensable components in lithium batteries or green hydrogen production), or related to innovative technology, such as data processing systems. Ultimately, the contribution of fluoropolymers to safety in many systems related to the chemicals industry, vehicles such as cars or airplanes, processing of water and food, or production of vaccines and medicines highlight the important contribution of these materials to the European society. While human safety and environmental protection, as well as contribution to development of clean energy sources have been highlighted as key benefits derived from the use of fluoropolymers, their contribution to the competitiveness of the European industry should also be taken into account. In fact, all the respondents to the questionnaire expressed concerns that a situation in which fluoropolymers may no longer be available for the specific application described could result in strong negative impact to many sectors and eventually relocation of a large number of stakeholders involved in the value chain of fluoropolymers. 100% of the replies obtained in the survey underlined the possibility that Europe would become a net importer of articles and goods manufactured with the aid of fluoropolymers in other regions of the world

that may continue to allow the use of these substances, in an ever increasingly competitive environment.

The vast majority of fluoropolymers have been proven to be polymers of low concern. Furthermore, industry continues to make progress to remove the use of other (small molecule-) PFAS as processing aids in their manufacture of fluoropolymers. In parallel, increasingly effective abatement techniques are able to adequately control industrial emissions. All of these initiatives, coupled to the high value that fluoropolymers bring to the progress, competitiveness, safety, protection, and well-being of the modern European society, suggest that the benefits of the continued use of fluoropolymers would largely outweigh potential risks (if any), related to the manufacture, use and disposal of fluoropolymers. In summary, it appears evident that any regulatory initiative that could impact fluoropolymers should look at establishing mechanisms that would ensure that these materials will continue to be available for the many critical industrial sectors in which they are currently used.

The case studies described have been grouped depending on the sector of use involved, with a description of the specific application in which the fluoropolymers are handled. It should be noted that frequently, the combination of properties offered by fluoropolymers could make the description of one case expandable others. For example, the combination of high range of operating temperature with resistance to harsh chemical environments is relevant for sectors such as the chemical processing industry, food and water treatment, semiconductors, or pharmaceuticals. Therefore, specific cases for those sectors have been described, which are equivalent between each other in terms of describing the benefits that fluoropolymers offer for the application, as well as in relation to the potential alternatives. While this can be clearly seen in some of the cases described in this report, in other situations only one specific example has been provided, however this does not preclude that the application may be relevant for other industrial sectors. For example, the use of fluoropolymers in seals and gaskets has only been described for the chemical process industries, however fluoropolymer-based seals and gaskets are also critical for sectors such as transport of dangerous goods, automotive or aerospace industry (e.g., in safety components such as wing flaps in aircrafts). In any case, the specific cases described should be taken as a small representation of the vast spectrum of applications in which fluoropolymers can be used in the modern society.

5. References

- ACEA, 2022. The Automobile Industry. Pocket Guide 2021/2022. *European Automobile Manufacturers' Association*. Available at: https://www.acea.auto/files/ACEA_Pocket_Guide_2021-2022.pdf#page=6. Last access: June **2022**.
- BfR, 2019. Available at: <https://www.bfr.bund.de/cm/343/neue-gesundheitsbezogene-richtwerte-fuer-die-industriechemikalien-pfos-und-pfoa.pdf>. Last access: July **2022**.
- Bloomberg NEF, 2021. Electric Vehicle Outlook. Available at: <https://about.bnef.com/electric-vehicle-outlook/>. Last access: June **2022**.
- Danish Consumer Council (2017). Available at: <https://kemi.taenk.dk/test/test-kemi-i-stegepander>. Last access: July **2022**.
- Eckardt, M., Greb, A. and Simat, T.J. Polyphenyl sulfone (PPSU) for baby bottles: a comprehensive assessment on polymer-related non-intentionally added substances (NIAS). Food Additives & Contaminants: Part A. Volume 35, **2018** - Issue 7.
- EFPIA, 2022. Data Centre of the Pharmaceutical Industry. *European Federation of the Pharmaceutical Industries and Associations*. Available at: <https://www.efpia.eu/publications/data-center>. Last access: June **2022**.
- ESIA, 2022. European semiconductor market in December 2021. *European Semiconductor Industry Association*. Available at: https://www.eusemiconductors.eu/sites/default/files/uploads/ESIA_WSTS_PR_2112.pdf. Last access: June **2022**.
- ESIA, 2021. European semiconductor market in December 2021. *European Semiconductor Industry Association*. Available at: https://www.eusemiconductors.eu/sites/default/files/uploads/ESIA_WSTS_PR_2012.pdf. Last access: June **2022**.
- Eurochlor, 2022. Mercury Cell Process. Available at: <https://www.eurochlor.org/about-chlor-alkali/how-are-chlorine-and-caustic-soda-made/mercury-cell-process/>. Last access: June **2022**.
- European Commission, 2022. A Water Blueprint – taking stock, moving forward. Available at: https://ec.europa.eu/environment/water/blueprint/index_en.htm. Last access: June **2022**.
- European Commission, 2021. Inside the future: Europe's plan to thrive in the global microchip race. Available at: https://ec.europa.eu/commission/commissioners/2019-2024/breton/announcements/inside-future-europes-plan-thrive-global-microchip-race_en. Last access: June **2022**.
- Findaboutplastics, 2020. Available at: <https://www.findoutaboutplastics.com/2020/05/design-properties-for-engineers.html>. Last access June **2022**.

FoodDrinkEurope, 2022. Data and trends of the European Food and Drink Industry in 2021. Available at: <https://www.fooddrink europe.eu/resource/data-trends-of-the-european-food-and-drink-industry-2021/>. Last access: June **2022**.

FPG, 2022a. Fluoropolymers vs. Side chain fluorinated polymers. *Fluoropolymers Product Group. Plastics Europe*. Available at: https://fluoropolymers.plasticseurope.org/application/files/3516/3913/1778/Fluoropolymers_vs_side_chain_fluorinated_polymers_final.pdf. Last access: June **2022**.

FPG, 2022b. Update of market data for the socioeconomic analysis (SEA) of the European fluoropolymer industry. *Fluoropolymers Product Group. Plastics Europe*. Available at: https://fluoropolymers.plasticseurope.org/application/files/1216/5485/3500/Fluoropolymers_Market_Data_Update_-_Final_report_-_May_2022.pdf. Last access: June **2022**.

FPG, 2021. Regulatory Management Option Analysis on Fluoropolymers. *Fluoropolymers Product Group. Plastics Europe*. Available at: https://fluoropolymers.plasticseurope.org/application/files/5416/5104/8333/20211104_FP_RMOA_Final_3.pdf. Last access: June **2022**.

FPG, 2017. Socio-economic Analysis of the European Fluoropolymer Industry – Executive Summary. *Fluoropolymers Product Group. Plastics Europe*. Available at: https://fluoropolymers.plasticseurope.org/application/files/7816/1167/4026/Final_SEA_Fluoropolymers_summary2017_3.pdf. Last access: June **2022**.

Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. *Integr Environ Assess Manag*. **2018**: 316-334.

Hydrogen Council, 2021. Hydrogen Insights: A perspective on hydrogen investment, market development and cost competitiveness. Available at: <https://hydrogencouncil.com/wp-content/uploads/2021/02/Hydrogen-Insights-2021.pdf>. Last access: June **2022**.

Hydrogen Europe, 2022. Direct communication.

Hydrogen Roadmap Europe, 2019. A Sustainable Pathway for the European Energy Transition. Available at: https://www.fch.europa.eu/sites/default/files/Hydrogen%20Roadmap%20Europe_Report.pdf. Last access June **2022**.

JRC, 2014. Best Available Techniques (BAT) Reference Document for the Production of Chlor-alkali. *Joint Research Centre Science and Policy Reports*. **2014**. Available for download at: <https://publications.jrc.ec.europa.eu/repository/handle/JRC91156>

Kang, J.S., Choi, J.S., Kim, W.K., Lee, Y.L., and Park, J.W. Estrogenic potency of bisphenol S, polyethersulfone and their metabolites generated by the rat liver S9 fractions on a MVLN cell using a luciferase reporter gene assay. *Reprod. Biol. Endocrinol*. **2014**; 12: 102.

Korzeniowski S.H., Buck R.C., Newkold R.M., El kassmi A., Laganis E., Matsuoka Y., Dinelli B., Beauchet S., Adamsky F., Weilandt K., Soni V.K., Kapoor D., Gunasekar P., Malvasi M., Brinati G., and Musio S. A. Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers. *Integr Environ Assess Manag.* **2022** (in-press).

Li, Y., Liu, Y., Liu, S., Zhang, L., Shao, H., Wang, X., and Zhang, W. Photoaging of Baby Bottle-Derived Polyethersulfone and Polyphenylsulfone Microplastics and the Resulting Bisphenol S Release. *Environ. Sci. Technol.* **2022**, 56, 5, 3033–3044.

Mesothelioma, 2017. How asbestos invaded the chlorine industry. Available at: <https://www.mesothelioma.com/blog/how-asbestos-invaded-the-chlorine-industry/>. Last access: June **2022**.

OECD, 2009. Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern. *Organisation for Economic Co-operation and Development*. Available at: <http://www.oecd.org/chemicalsafety/risk-assessment/42081261.pdf>. Last access: June **2022**.

Ruf, Y., Baum, M., Zorn, T., Menzel, A., and Rehberger, J. Fuel Cells Hydrogen Trucks – Heavy duty's High Performance Green Solution. Available at: https://www.fch.europa.eu/sites/default/files/file_attach/FCH%20HDT%20-%20Study%20Report_final_vs.pdf. Last access: June **2022**.

The MBR Site, 2017. The material question - choosing MBR membrane materials. Available at: <https://www.thembrsite.com/blog/choosing-mbr-membrane-materials/>. Last access: June **2022**.

Annex I: Questionnaire for downstream users of fluoropolymers

1. Please provide identification information of your company in the EEA¹ and the relevant contact person.

Company Name	
Country	
Contact person name	
Role	
Telephone number	
e-mail address	

2. Please indicate at least 3 examples of major applications using fluoropolymers that are relevant to your business, and the industries in which they are used.

For an overview of possible industry & sector of use, please refer to Annex I. If the application of interest is not found in the Annex, please describe it.

Case #	Description of application	Fluoropolymers used (see list below)	Industries involved
Case 1			
Case 2			
Case 3			

List of (major) fluoropolymers that will be covered in this questionnaire.

Abbreviation	Name	CAS #
PTFE	Polytetrafluoroethylene	9002-84-0
PFA	Perfluoroalkoxy polymer	26655-00-5 / 31784-04-0
FEP	Fluorinated ethylene propylene	25067-11-2
FKM	Vinylidene fluoride-hexafluoropropylene copolymer	9011-17-0
ETFE	Ethylene tetrafluoroethylene	25038-71-5 / 68258-85-5
PVDF	Polyvinilidene fluoride	24937-79-9

¹ EEA: European Economic Area = EU + Iceland, Liechtenstein, and Norway. It is expected that all the replies to the following questions refer to this economic area.

3. Please indicate which of the following technical properties are relevant for the applications listed in question 2 (more than one selection is possible).

If possible, please indicate any technical requirements that may be relevant to justify the importance of the use of fluoropolymers, including units of properties. For example, “a minimum value of xx Pa for mechanical strength is required for the product to perform in Case 1”.

Case 1

Category	Technical property	Relevant to application	Specification & Measurement standard
Durability	Mechanical strength		
	Wear resistance		
	Mechanical properties (e.g., flexibility)		
	Low coefficient of friction		
Inertness – stability	Resistance to harsh chemicals		
	Resistance to high temperatures		
	Resistance to low temperatures (e.g., cryogenic properties < 50°C)		
	Wide temperature range of operation		
	Weather resistance		
	Biocompatibility		
	High limiting oxygen index		
Functionality	Electrical insulator (high data transmission range)		
	Ionic conductivity		
	Piezoelectric properties		
	Dielectric strength		
	Barrier properties		
	Non-stick properties		
	Optical clarity		
	Fire retardancy / smoke suppression		
	Low bacterial / algae growth		
	Low refractive index for optical effects		
	Other (please specify):		

Case 2

Category	Technical property	Relevant to application	Specification & Measurement standard
Durability	Mechanical strength		
	Wear resistance		
	Mechanical properties (e.g., flexibility)		
	Low coefficient of friction		
Inertness – stability	Resistance to harsh chemicals		
	Resistance to high temperatures		
	Resistance to low temperatures (e.g., cryogenic properties < 50°C)		
	Wide temperature range of operation		
	Weather resistance		
	Biocompatibility		
	High limiting oxygen index		
Functionality	Electrical insulator (high data transmission range)		
	Ionic conductivity		
	Piezoelectric properties		
	Dielectric strength		
	Barrier properties		
	Non-stick properties		
	Optical clarity		
	Fire retardancy / smoke suppression		
	Low bacterial / algae growth		
	Low refractive index for optical effects		
	Other (please specify):		

Case 3

Category	Technical property	Relevant to application	Specification & Measurement standard
Durability	Mechanical strength		
	Wear resistance		
	Mechanical properties (e.g., flexibility)		
	Low coefficient of friction		
Inertness – stability	Resistance to harsh chemicals		
	Resistance to high temperatures		
	Resistance to low temperatures (e.g., cryogenic properties < 50°C)		
	Wide temperature range of operation		
	Weather resistance		
	Biocompatibility		
	High limiting oxygen index		
Functionality	Electrical insulator (high data transmission range)		
	Ionic conductivity		
	Piezoelectric properties		
	Dielectric strength		
	Barrier properties		
	Non-stick properties		
	Optical clarity		
	Fire retardancy / smoke suppression		
	Low bacterial / algae growth		
	Low refractive index for optical effects		
	Other (please specify):		

4. Please indicate a list of potential non-fluoropolymer alternatives ² (second best alternatives) for the applications listed in question 2.

Case #	Potential alternatives to fluoropolymers that could be considered as alternatives
Case 1	
Case 2	
Case 3	

5. Please explain possible trade-offs that could be expected when alternatives to fluoropolymers are used in these applications. Use the following guidance for completion.

- Amount of product used: how much fluoropolymer is used per year, and how much alternative would be required? If total volumes cannot be reported, please state ratio (e.g., if double amount of alternative would be required, please state 1/2 in the non-fluorinated alternative column.
- Property comparison: how will the main technical function of the manufactured products be impacted if alternatives are used instead of fluoropolymers?
- Combination of functionalities: how will the use of an alternative compare in relation to the combination of technical functions that fluoropolymers bring to manufactured products?
- Overall performance: what will be the ultimate impact on the manufactured products if fluoropolymers were to be replaced with the alternatives?
- Safety & reliability: will there be any impact to the overall safety of the manufactured products (and those further down in the value chain)? If yes, please describe.
- Application life: will the service life of the manufactured products be different if alternatives are to be used in the relevant application? If yes, please describe.
- Circularity: would there be any impact in the contributions of the sector to the circular economy if alternatives to fluoropolymers were used? If yes, please describe.
- Decarbonisation: would there be any impact in the contributions of the sector to a green energy transition? If yes, please describe.
- (Eco)toxicity comparison: how would the alternatives compare to fluoropolymers from a hazard perspective?
- Other: if you can identify additional relevant criteria, please specify, and describe expected impact.

² The principle to follow is that there is always a possibility to substitute, therefore indicating that there are no alternatives for a specific application is not a valid reply; there will be opportunities in following questions to describe why an alternative is not considered to be ideal. Alternatives cannot be other fluoropolymers or fluorinated products (e.g., PFAS).

Case 1		
Criteria	With Fluoropolymer	With non-fluorinated alternatives
Amount of product used:		
Property comparison:		
Combination of functionalities		
Overall performance		
Safety & Reliability		
Application life		
Circularity		
Decarbonisation		
(Eco)toxicity comparison		
Other (please describe):		

Case 2		
Criteria	With Fluoropolymer	With non-fluorinated alternatives
Amount of product used:		
Property comparison:		
Combination of functionalities		
Overall performance		
Safety & Reliability		
Application life		
Circularity		
Decarbonisation		
(Eco)toxicity comparison		
Other (please describe):		

Case 3		
Criteria	With Fluoropolymer	With non-fluorinated alternatives
Amount of product used:		
Property comparison:		
Combination of functionalities		
Overall performance		
Safety & Reliability		
Application life		
Circularity		
Decarbonisation		
(Eco)toxicity comparison		
Other (please describe):		

6. In a hypothetical case that fluoropolymers were not available for use in the EEA, and you were forced to use alternative products, do you think that the application would continue? Or could it be expected that technology would be transferred outside the EEA? Please justify your answer, including potential impacts down in the value chain.

Case 1	
Case 2	
Case 3	

7. Please indicate the expected socio-economic impact that should be expected if fluoropolymers were no longer available for these applications, and industry was forced to use alternative products.

When providing your replies, please consider the impact (if relevant for each case) of potential technological downgrades resulting from the use of alternatives, particularly since the EEA's economic strength is based on developing and supplying high technology across the globe.

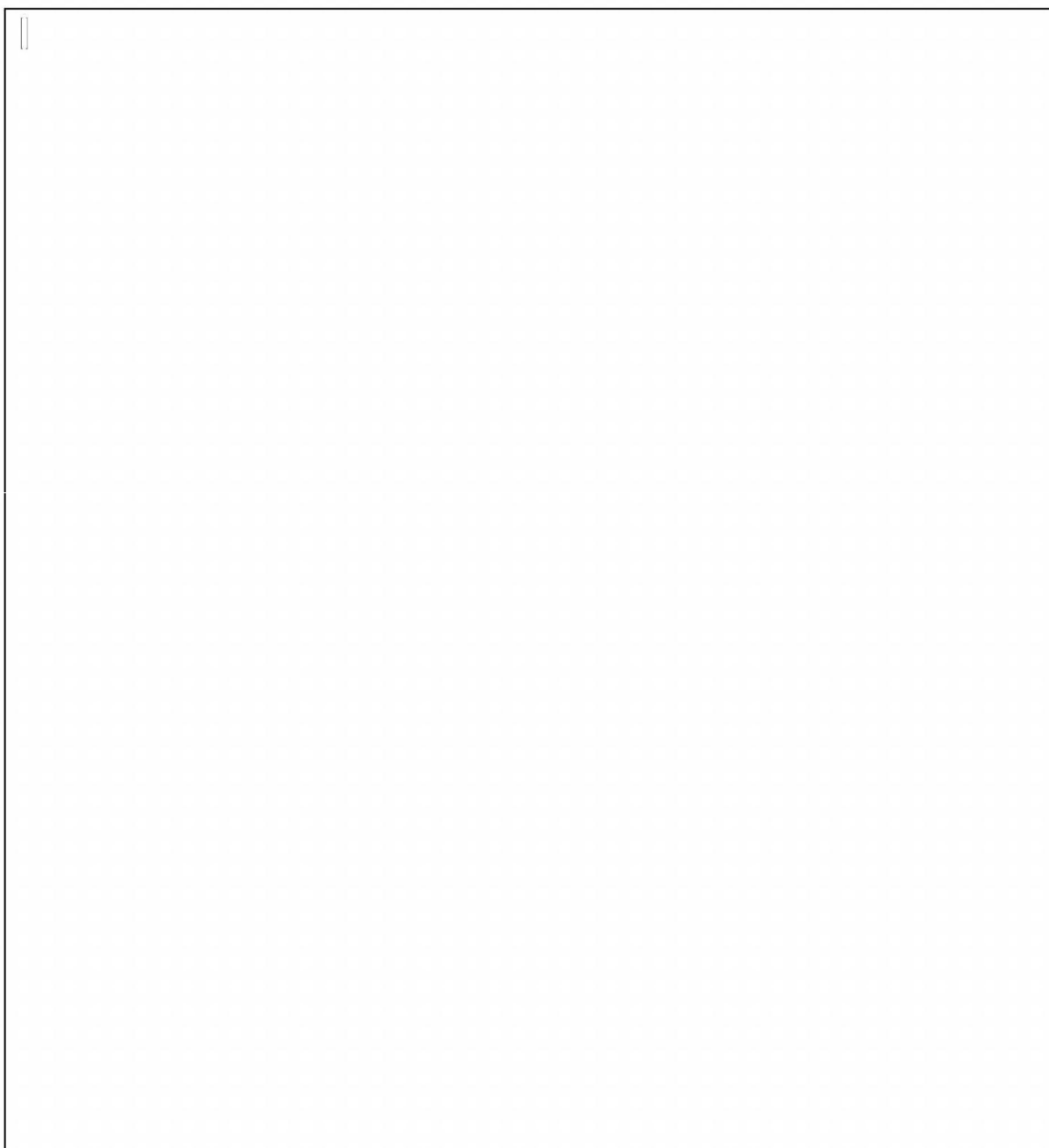
- Economic impacts: based on your knowledge of the value chain, what could be the consequences to be expected for end-use applications in the EEA if fluoropolymers were to be replaced by non-fluorinated alternatives? If available, quantitative data (real or estimated) would be highly valuable, particularly related to impacts on revenue, GDP and/or jobs that could be lost (direct and indirect); if this is not available, a qualitative estimate based on your experience could also be valuable.
- Societal impacts: in which way would society be affected, e.g., which products or services would be impacted, and how, if fluoropolymers were no longer available for the specific application under discussion? What would be the consequences for the EEA's position in terms of technological competitiveness compared to other regions globally?

Case 1	
Economic impacts:	
Societal impacts:	

Case 2	
Economic impacts:	
Societal impacts:	

Case 3	
Economic impacts:	
Societal impacts:	

8. Please provide any additional information that you believe could be relevant to defend the continued use of fluoropolymers in the EEA.

A large, empty rectangular box with a thin black border, intended for providing additional information to defend the continued use of fluoropolymers in the EEA. There is a small vertical line or artifact on the left side near the top corner.

Annex II: Main fluoropolymers covered in this report

Abbreviation	Name	CAS #
PTFE	Polytetrafluoroethylene	9002-84-0
PFA	Perfluoroalkoxy polymer	26655-00-5 / 31784-04-0
FEP	Fluorinated ethylene propylene	25067-11-2
FKM	Vinylidene fluoride-hexafluoropropylene copolymer	9011-17-0
ETFE	Ethylene tetrafluoroethylene	25038-71-5 / 68258-85-5
PSEPVE	Sulfonated tetrafluoroethylene	31175-20-9
PVDF	Polyvinilidene fluoride	24937-79-9

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