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Section III – General and specific information

Summary

The family-owned group of company's ADELHELM is a specialist for functional surface coatings. With almost 300 employees 10 locations in DE, CH, CZ, PL, RO, US, and IN, companies from numerous industries worldwide rely on our solutions. With many years of experience and the highest processing standards, we serve basically all technical industries with a broad spectrum of applications/functional coatings.

Industries:

Fittings industry, automotive industry, chemical industry, electrical engineering, energy sector, semiconductor industry, maintenance/repair, plastics processing industry, laboratory technology, painting technology, food industry, aeronautical engineering, mechanical and plant engineering, medical technology (life science), measuring and level technology, furniture industry, off-shore, paper and printing industry, pharmaceutical industry, transportation, watch industry/luxury goods, packaging industry.

Applications/Functional coatings:

Anti-adhesion, anti-slip and traction, chemical protection, electrically dissipative, electrically insulating, noise reduction, glass shatter protection, anti-friction & dry lubrication, hydrophilic, hydrophobic, corrosion protection, screw locking, wear protection, individual surface functionalization.

The great advantage of functional coatings is that only a layer of a few micrometers of a high-performance material on a component surface is sufficient to produce the desired function (non-stick, sliding, resistance, ...). The component body, on the other hand, can be made of less expensive, easier-to-machine and environmentally friendly material. A recoating process by removing the worn coating and reapplying a new coating to the existing base body is also possible. Functional coatings thus significantly optimize material efficiency and make a major contribution to resource conservation!

Materials used:

To meet customer specifications, coatings based on polymers (PE, PA, PUR, PAI, EP, PEEK, PEKK) and fluoropolymers (PTFE, FEP, PFA, ETFE, E-CTFE, PVDF) are processed. Not least because of the increased cost of fluoropolymers, the use of non-fluoropolymers is being specifically tested. Due to the often

very high or combined requirements in terms of electrical, thermal, chemical, mechanical and physiological properties, the material selection inevitably falls on fluoropolymers.

Special features of fluoropolymers:

In the polymeric structure of fluoropolymers, fluorine atoms (F) are bonded to carbon atoms (C). Fluorine has the highest electronegativity of all elements in the periodic table, which means that it has a strong attraction to electrons and creates a polarized C-F bond. The bond of carbon and fluorine (C-F) has the highest electronegativity among the possible covalent bonds. Electronegativity is an important factor affecting the stability and properties of compounds, resulting in the unique characteristics of fluoropolymers:

1. **Stability:** The strong C-F bond gives fluoropolymers exceptional chemical and thermal stability. They are enormously resistant to chemical attack, oxidation and thermal degradation.
2. **Low reactivity:** due to the strong C-F bond, fluoropolymers react only to a very limited extent with other substances, which makes them chemically inert and therefore they are often used as biocompatible materials in medical technology.
3. **Non-wetting effect:** due to the low polarity of the C-F bond, fluoropolymers exhibit a high contact angle with water and other polar liquids, which makes them non-stick and one of the few food-safe materials that can be used in industrial food production.

Alternatives to fluoropolymers:

So far, no adequate alternatives to fluoropolymers are available!

The challenge in developing equivalent alternatives to fluoropolymers is to find or develop materials that offer comparable properties but are made of different elements. Considering the fact that only rarely new elements extend the periodic table and that a new element would have to have a very high electronegativity, the technical implementation seems chemically, physically and mathematically extremely unlikely. At the same time, this alternative or the result of its risk assessment with regard to production, processing, application and disposal would have to significantly improve the risk assessment of fluoropolymers. It is unrealistic to expect that this would be achieved by a material with newly discovered, little researched elements. It is implausible that a material with comparable properties in terms of chemical and thermal resistance would also be more environmentally compatible.

Request for exemption:

As a responsible family business, we are constantly optimizing our ecological footprint and actively managing risks to this end. Sustainability and the associated preservation of a healthy environment for future generations have the highest priority. Resulting risks from necessary economic activity and active value creation must be reviewed and reduced on a recurring basis by means of holistic risk management. A world in which challenges such as climate change, poverty, population growth, scarcity of food and drinking water, shortage of raw materials, etc. have to be overcome, we need solutions that will never be risk-free!

A holistic ban of all PFAS (incl. the fluoropolymers) to avoid risk would have unforeseeable, dramatic consequences not only for the economy of the European Union and the associated jobs, but also for the standard of living of the world's population that is achieved through the use of fluoropolymers in

medical technology supply, necessary green deal technologies, semiconductor production, industrial food production, ...).

A purely European ban on PFAS would increase the risk of possible risk linked of PFAS. The reason for this is that in this case the industry using PFAS would completely migrate to U.S. and mainly Asia. However, the processing standards used there as a basis in comparison to the EU are to be classified as significantly worse and thus riskier for the world, considering the mobility of some PFAS.

GENERAL: We therefore call for a differentiated assessment of these substances and a complete exemption of fluoropolymers within the scope of this possible ban, which are classified as "products of low concern" according to OECD criteria!

SPECIFIED: The exception of fluoropolymers in functional coatings is essential against the background of a necessary conservation of resources!

Scope or restriction option analysis:

Hazard or exposure:

Environmental emissions:

Baseline:

Information on alternatives:

Other socio economic analysis (SEA) issues:

Request for exemption:

General:

Specified:

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1 General information

1.1 Scope on restriction option analysis

PFAS type

General:	Fluoropolymer
Groups:	PTFE, FEP, ETFE, ETCFE, PFA

PFAS definition

Per- and polyfluorinated chemicals (PFCs), or more specifically per- and polyfluoroalkyl substances (PFASs), are a large group of chemicals that have been used since the 1950s as ingredients or intermediates of surfactants and surface protectors for assorted industrial and consumer applications [OECD/UNEP 2013]. The PFAS terminology was proposed by Buck et al. [Buck 2011]. This is a widely accepted and used terminology for PFAS which divides them basically into two sub-groups: non-polymeric and polymeric PFASs. The polymeric PFASs are subdivided into i) fluoropolymers, ii) side-chain fluorinated polymers and iii) perfluoropolyethers. Our contribution focusses on fluoropolymers in general and PTFE in particular. The environmental and toxicological profiles of these polymers are distinctly different to the majority of other PFAS. Fluoropolymers have very high molecular weight (usually > 10,000 Da) and show excellent thermal, chemical, photochemical, oxidative, hydrolytic and biological stability with low flammability, neutral electrical charge and resistance to degradation. Fluoropolymers do not bioaccumulate, are not mobile and no reactive groups are present in the structure of fluoropolymers. They are characterized by a carbon-only polymer backbone with F atoms directly attached to it, a unique feature in the chemical space.

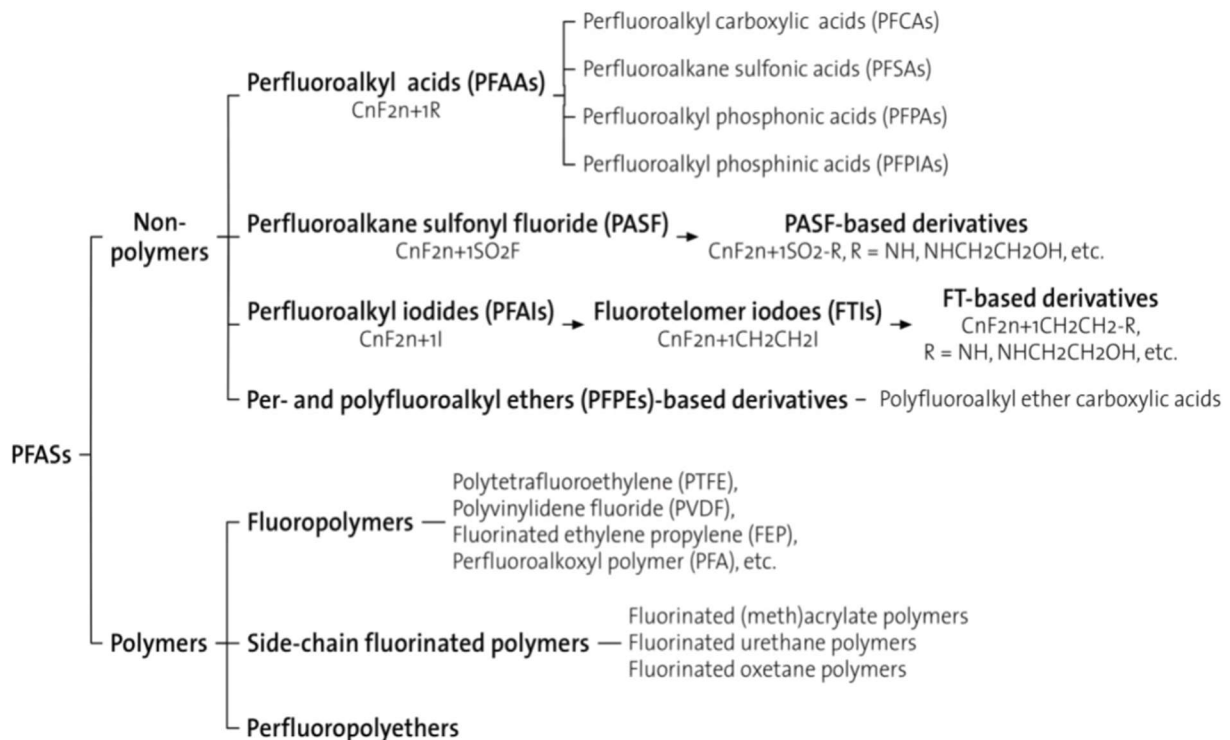


Figure 1: General classification of per- and polyfluoroalkyl substances (PFAS) according to Buck et al. [OECD/UNEP 2013]

Example PTFE - manufactured grades

According to Lohmann et al [Lohmann 2020], there are many different processes for producing fluoropolymer products. For example, some fluoropolymers do not require PFAS-based processing aids during their production by suspension polymerization (e.g., granular PTFE), while other fluoropolymers (e.g., fine powder PTFE and PVDF) are produced using PFAS-based processing aids during emulsion polymerization. Developments in fluoropolymer manufacturing technology with a focus on PFAS removal as a polymerization aid have been evaluated by Ameduri et al [Ameduri 2023]. It is expected that most fluoropolymer production will be developed completely free of PFAS polymerization aids in a relatively short time. Therefore, it seems reasonable to request that fluoropolymers produced without the use of PFAS polymerization aids should be exempted from any regulatory initiatives and that their use should be allowed without unjustified restrictions. A detailed overview of polymerization (with additional consideration of, e.g., supercritical CO₂ polymerization or γ -radiation induced polymerization) up to recycling and disposal of PTFE is given by Guo et al. in their scientific report on porous PTFE membrane technology [Guo 2022].

In suspension polymerization, the TFE is polymerized in water because PTFE is insoluble in water; the polymerized product is precipitated from the water to form primary particles. If the water does not contain a dispersant, the primary particles aggregate into coarse particles or grains, which is commonly known as suspension polymerization. These grains, after being processed into pellets, can be formed. [Chemservice 2021]

PTFE - Polymer of Low Concern (PLC).

PTFE is a "Polymer of Low Concern" (PLC) in the study by Henry et al [Henry 2018] presented data showing that PTFE meets the widely accepted criteria for assessing the hazardousness of polymers and that this polymer should be considered a PLC [OECD 2009].

Overview of the fluoropolymer market

A comparison between the global market and the European market was made in the presentation by M. Schlipf [Schlipf 2023]. It is fluoropolymer consumption data from 2018 (Figure 2). Similar ratios between the different types of fluoropolymers are still valid today.

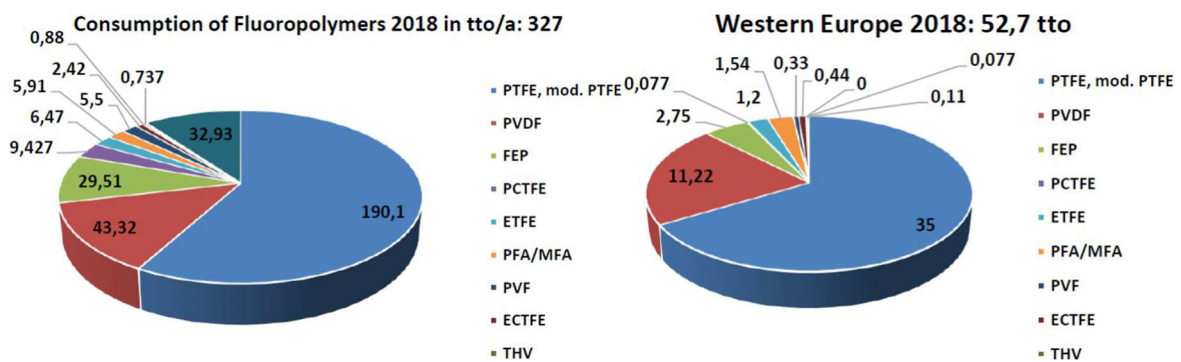


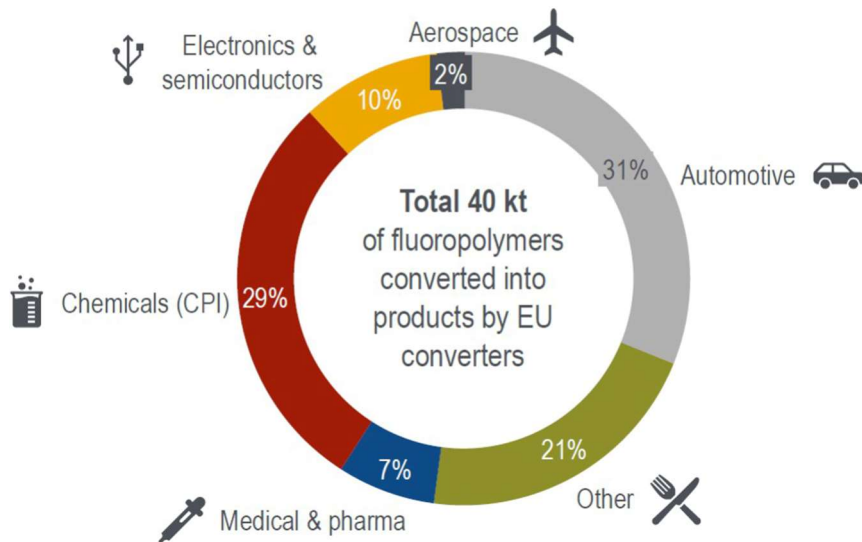
Figure 2: Consumption of fluoropolymers: left: worldwide figures from 2018; right: figures for Western Europe from 2018 (unit tto = million kg).

Conversio has mapped the fluoropolymer market by industry segment, as shown in the following figure [Conversio 2023]. It is very clear that fluoropolymers, of which PTFE accounts for 56% (in 2020), are used in industries with very high requirements and standards, i.e. electronics and semiconductors, chemical industry, automotive, medical and pharmaceutical. It is therefore incomprehensible why these extremely important industries seemed to be disadvantaged compared to the industries

addressed in the restriction proposal, such as TULAC, food contact materials and packaging, consumer blends, cosmetics, ski wax, etc. Sophisticated and demanding high-tech products and industrial applications were therefore undervalued and overshadowed by consumer products.

Fluoropolymer market by industry segments 2020

Shares based on quantity in kt



A Figure 3: Fluoropolymer market by industry segments 2020 [Conversio 2023]

sPTFE market overview [IndustryARC 2023].

Suspension PTFE market size is estimated to reach US\$ 1,500 Mn by 2027, having grown at a CAGR of 7.2% from 2022 to 2027. General market overview data of sPTFE can be given as follows.

Molding Process

- PTFE Extrusion Process
- PTFE isostatic process
- PTFE compression molding process

Applications:

- Coatings
- Seals
- Valves
- expansion joints
- Pipes
- protective linings
- electrical insulators
- electrical tapes

End-use industry

- automotive and transport
- oil and gas

- chemical processing
- electrical engineering and electronics
- medicine (implants, surgical instruments and others)
- Cookware (pans, baking sheets and others),

Construction (residential, commercial and industrial), consumer goods, paints and coatings and others.

PTFE-Eigenschaften

PTFE ist ein Hochleistungspolymer mit einer Reihe einzigartiger Eigenschaften:

- Hochmolekulares Gewicht und hoher Schmelzpunkt
- Temperaturbereich von -250 bis +260°C
- Universelle chemische Beständigkeit
- Antiadhäsive Oberfläche, extrem niedriger Reibungskoeffizient
- Hydrophobe Eigenschaften
- Poröse Eigenschaften durch spezielle Behandlung verfügbar
- Ausgezeichnete dielektrische Eigenschaften
- Hohe UV-Beständigkeit und Witterungsbeständigkeit
- Hohe Reinheit
- Hohe Flammfestigkeit nach UL94 V-0
- Physiologisch unbedenklich

Es gibt keine Materialien, die diese Eigenschaften aufweisen. Die Suche nach alternativen Materialien endet immer in einem Kompromiss, der für bestimmte Produkte und Anwendungen ausreichend sein könnte. Die meisten High-End-Produkte erfordern eine bestimmte kompromisslose Kombination von Eigenschaften, um Effizienz, Stabilität, Haltbarkeit, Gesundheit und Sicherheit zu gewährleisten! Das ist es, was PTFE und auch die meisten anderen Fluorpolymere unersetzlich macht!

PTFE Properties

PTFE is a high performance polymer with a number of unique properties:

- High molecular weight and high melting point.
- Temperature range from -250 to +260°C
- Universal chemical resistance
- Anti-adhesive surface, extremely low coefficient of friction
- Hydrophobic properties
- Porous properties available through special treatment
- Excellent dielectric properties
- High UV and weathering resistance
- High purity
- High flame resistance according to UL94 V-0
- Physiologically harmless

There are no materials that have these properties. The search for alternative materials always ends in a compromise that may be sufficient for certain products and applications. Most high-end products require a certain uncompromising combination of properties to ensure efficiency, stability, durability, health and safety! This is what makes PTFE and also most other fluoropolymers irreplaceable!

Fluoropolymers at Adelhelm LubriCoat GmbH and Adelhelm Kunststoffbeschichtungen GmbH

Supply chain for fluoropolymer products

According to declarations of our suppliers, the formulations produced for the Adelhelm Group do not contain fluoropolymers manufactured with PFAS* of concern. In particular, PFOA and PFOS (according to EU VO 2017/1000 and EU VO 2022/2388, respectively) are addressed in the respective confirmations. In addition, most of our functional coating systems are suitable for the application in contact with food and/or corresponding requirements for medical devices.

Industries	Product / Applications
Aerospace	Bushings, guide rails, toilet bowls (huge savings in flushing water!), seals, die-casting molds, fasteners, etc.
Automotive industry	armatures for valves, body components such as pawls, seals, production racks, etc.
Chemical and Industrial Processing	Reactors, vessels, tanks, chemical fittings, piping, fasteners, etc.
Electronics and electrical engineering	Guide elements, elastomers, busbars, etc.
Food Industry	Pump housings, process tanks, circular and sickle blades, pump impellers, cutting machine components, conveyor belts, pizza trays, box bracing, etc.
Laboratory equipment/technology	Fittings (here: glass splinter protection)
Medical equipment and components	Forceps, clamps (monopolar and bipolar), shaft tubes for endoscopy, monopolar slings, resection instruments, guide wires, catheters, etc.
Semiconductor technology and microelectronics	Duct work for aeration and deaeration systems, system components for plasma treatment and coating systemslications

*** Definition of PFAS-of-Concern**

a subset of per- and polyfluoroalkyl substances (PFAS) that are considered to be particularly problematic due to their potential adverse effects on human health and the environment (in terms of persistence, bioaccumulation, and toxicity), like short-chain non-polymeric PFAS or fluorosurfactants (e.g. fluorinated production aids).

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1.2 Hazard or exposure

Fluoropolymers such as PTFE (polytetrafluoroethylene), PFA (perfluoroalkoxy) or ECTFE (ethylene-chloro-trifluoroethylene), PVDF (polyvinylidene fluoride) for example, have been used successfully for

decades in various formulations as coatings or also as functional fillers in both the food industry and medical technology.

Due to their inertness, fluoropolymers are polymers of low concern (PLC) in terms of their potential impact on the environment and human health. To confirm this, two other sources of information are provided that relate to hazard or exposure, i.e. i) Material Safety Data Sheets and ii) Declarations of Conformity (e.g. food contact material, USP Class VI).

Toxicological studies on PTFE show no acute or subchronic systemic toxicity, irritation, sensitization, local toxicity at implantation, in vitro and in vivo genotoxicity, hemolysis, complement activation, or thrombogenicity [Henry 2018]. In addition, fluoropolymers have generally been found to be classified as low concern polymers (PLCs), including their low potential impact on the environment and human health. They are not classified as carcinogenic, mutagenic, or toxic to reproduction.

Two other sources of information can be provided in relation to hazard or exposure using PTFE as an example, namely:

- Material Safety Data Sheet: the Material Safety Data Sheet of PTFE does not contain any hazard statements or precautionary statements. Material Safety Data Sheets from two PTFE suppliers are listed as examples in the "Confidential Documents" in Section V.

- Statement of Conformity: PTFE has all relevant approvals related to human health (i.e., hazards and exposure) as evidenced by the following, e.g., based on migration tests. Conformity documents from various suppliers are listed in the "Confidential Documents" in Section V. The following standards are generally met:

- FDA-conformity (21 CFR 177:1550)
- TSCA
- drinking water approval
- USP class VI (biocompatibility)
- Hygiene standards

It should be noted that the fluoropolymers used at Adelhelm are produced without fluorinated production aids, such as fluorosurfactants. This is already confirmed in section 1.1. **The argument of environmental emissions in connection with production aids therefore does not apply here!**

Finally, we would like to emphasize that Article 68 (1) of REACH (Introduction of new and modification of existing restrictions) formulates that there must be an unacceptable risk to human health or the environment resulting from the manufacture, use or placing on the market of substances [REACH 2023].

In this section it is shown that this is not the case!

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[REACH 2023] REACH online, <https://reachonline.eu/reach/en/title-viii-chapter-2-article-68.html>, besucht am 05.05.2023

1.3 Environmental emissions

The processing of fluoropolymers does not result in emissions of PFAS of concern due to heating in the sintering process.

In order to further optimize the use of resources and to meet the criteria of "Operation Clean Sweep", the Adelhelm group currently has various projects in planning or already underway.

Specifically, talks have already been held in this regard with the University of Bayreuth and with the resulting InVerTec - Institut für Innovative Verfahrenstechnik e.V. (Institute for Innovative Process Engineering). A joint project on the subject of fluoropolymer recycling is currently being drawn up.

Scientific studies have shown that municipal incineration of fluoropolymers using the best available technologies is not a significant source of PFAS and should be considered an acceptable form of waste treatment.

Emissions

Ground fluoropolymers are processed either as functional fillers in paint formulations (different polymers such as polyurethanes or epoxies) or as pure substances. Usually, one of the process steps is thermal treatment (chemical curing or sintering of the polymer films). For this purpose, the previously coated workpieces are heated to a specific temperature in an oven with circulating air for a specific time.

The raw materials used are free of PFAS-of-concern*. This is proven by corresponding manufacturer declarations (no use of fluorinated production aids, such as fluorosurfactants), see section 1.1.

The New York State Department of Environmental Conservation (DEC) requested a qualitative characterization of emissions from polytetrafluoroethylene (PTFE) sintering furnaces from the U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) [Gentile 2019]. The overall results indicate extremely low emissions from PTFE sintering furnaces at their facility. Substitutes for shorter-chain fluoropolymers, perfluoroethanoic acid (C2), perfluoropropanoic acid (C3), and perfluorobutanoic acid (C4), were identified and gradually introduced. Since we can confirm that the manufacturing companies of the Adelhelm group of companies do not use such auxiliary substances in their raw material or as production aids during manufacturing, it is unlikely that short-chain PFAS are emitted during the sintering process.

Production waste, reuse and recycling

Production waste does not fall under the concept of emission as defined by BImSchG 2022. As waste management is a very important part of the overall production process, production and waste figures (related to reuse and recycling, upcycling and incineration) are provided in the "confidential document" in section V. The Adelhelm Group of Companies has taken measures to further optimize the use of resources in order to meet the criteria of "Operation Clean Sweep" [OCSweep 2023]. It is undisputed that the fluorine cycle should be closed.

Paint waste containing fluoropolymers is collected in ASP or ASF containers and disposed of externally. The thermal recycling process of our waste management company is certified. Please refer to the confidential section V for details.

Conversio performed a detailed analysis of fluoropolymer waste in Europe in 2020. The main industry segments were chemicals (~29% including energy), automotive (~31%), and other (~21% including coated metals, cookware, lubricants, textiles, food and beverage, etc.), which are also shown in Section

1.1. The schematic in Figure 5 shows the treatment pathway of post-consumer fluoropolymer waste and indicates that about 84% of fluoropolymers are mainly recycled for energy or thermally separated from other materials [Conversio 2023]. Therefore, it is very likely that the fraction of landfilled fluoropolymers attributable to industrially used PTFE is very small.

Thermal degradation of PTFE by combustion has been thoroughly studied and summarized by Sales [Sales 2022]. For PTFE, it was found that complete thermal decomposition is achieved at a temperature of about 800 °C.

Combustion was studied in more detail by Aleksandrov et al [Aleksandrov 2019]. The conclusion was that no significant evidence of PFAS formation (out of the 31 PFAS species studied) was concluded during the combustion of PTFE. Therefore, it can be concluded that municipal incineration of PTFE using best available technologies (BAT) is not a significant source of the investigated PFASs and should be considered an acceptable form of waste treatment. This study was further elaborated by the Karlsruhe Institute of Technology (KIT) in collaboration with Société Générale de Surveillance (SGS), initiated by Gujarat Fluorochemicals Limited (GFL) [GFL 2023]. 27.06.2023.

They confirmed the complete thermal destruction of fluoropolymers during incineration, and no organic fluorides and especially no PFAS substances were present in the flue gas of the incineration.

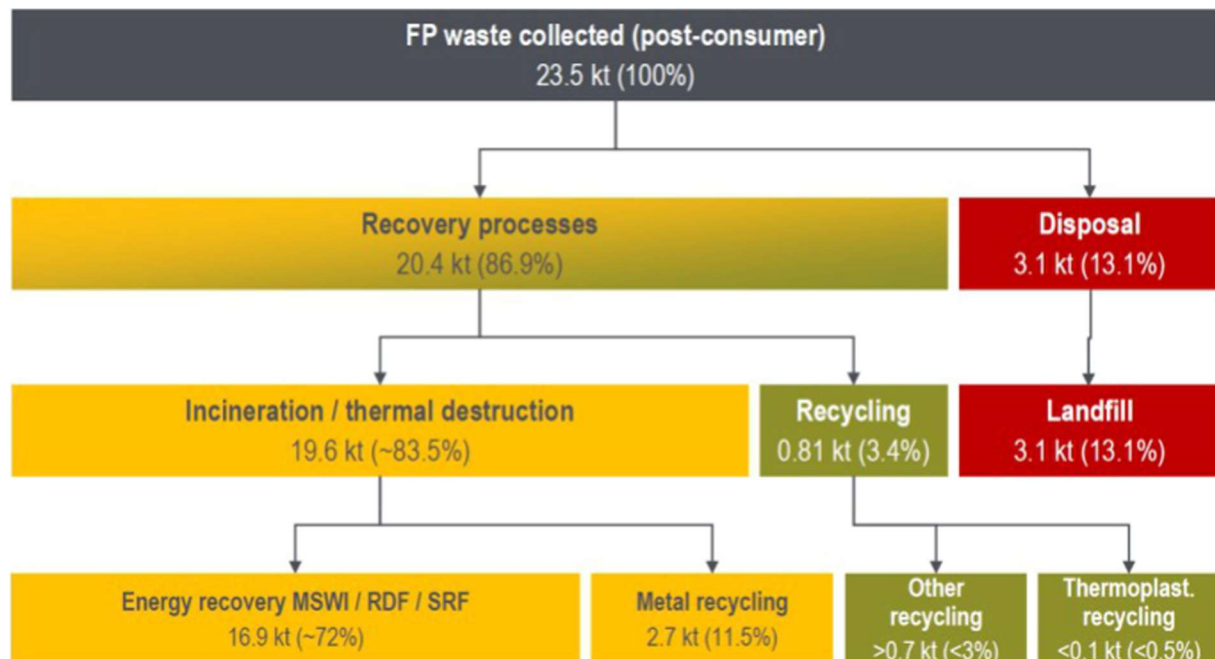


Figure 5: (Co-)treatment route of post-consumer fluoropolymer waste in the EU in 2020 [Conversio 2023].

Decomposition to microplastics

The relationship between PTFE and its global impact as microplastics (MP) in the marine environment was investigated using the risk screening method [Yuan 2022]. 36 different polymers were evaluated on a global scale using five different risk factors covering the likelihood of human exposure to MP and the potential impacts. PTFE was ranked 17/36 with a risk score of 22! This compares to, for example, polyurethane (PUR), which is ranked 1/36 with a risk score of 150, or polyvinyl chloride (PVC), which is ranked 2/36 with a risk score of 135. The annual production of the latter polymers is noteworthy: 27 and 38 million tons, respectively, compared to 0.1 million tons in the case of PTFE. The recycling rates of PUR and PVC were 40% and 60%, respectively. It was assumed that PTFE could

not be recycled (recovery rate of 0%!), which contradicts what is stated in this section. Under the correct assumptions, PTFE should have been ranked lower! Persistence, density and particle size were the main factors contributing to the PTFE rating.

The fluoropolymers used at Adelhelm are not used on consumer products, so the contribution to microplastic formation is considered low.

Degradation to PFAS-of-Concern*

Finally, fluoropolymers are substantially different from the other polymeric PFAS in terms of potential emissions due to degradation into small PFAS molecules during intended use or under environmental conditions and, for this reason, they have no environmental impact. Fluoropolymers have a high molecular weight, no water solubility and volatility, therefore they are not expected to degrade to lower molecular weight PFAS. Also, they are not expected to lead to the formation of long-chain PFAS as a result of degradation. [Sales 2022]

Fluorosurfactant-free manufacturing

It should be noted, that the used suspension PTFE is manufactured without using fluorinated production aids, like fluorosurfactants. This is already confirmed in section 1.1. So, the argument of environmental emissions related to manufacturing aids **does not apply** here!

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1.4 Baseline

Adelhelm Kunststoffbeschichtungen as well as Adelhelm LubriCoat GmbH design and produce functional coatings for various industries: Semiconductor industry, laboratory equipment/technology, automotive, aerospace, chemical industry, industrial processing, electronics and electrical equipment, food and beverage, medical technology, etc.

In most cases, the functionalities sought in these applications can be realized exclusively by coating structures, either consisting of or containing fluoropolymers. Functionalities are for example

- electrical insulation
- dry lubrication effects or tribological solution of critical sliding pairings
- anti-adhesion effects
- heavy chemical and corrosion protection
- etc.

1.5 Description of analytical methods

1.6 Information on alternatives

As mentioned above, the enormously advantageous and chemically non-substitutable properties are unmatched, especially when combined, making fluoropolymers high-performance materials.

This property portfolio, combined with the comparatively low polymer film thickness, makes the difference compared to supposedly alternative materials.

Processing fluoropolymers as high-performance plastics enables exceptional end-use applications. However, this goes hand in hand with comparatively high manufacturing costs, which means that these highly specialized products are generally only used when there really is no material-related alternative.

If more cost-effective alternatives exist in terms of properties, these are definitely used in the market.

Fluoropolymers are generally only used if the respective requirement profile is correspondingly demanding and the combination of different material properties is essential. Explained using the example of PTFE: This high-performance material has many advantageous properties, and it is the combination of these properties in particular that makes the difference compared to alternative materials. Compared to standard plastics such as polyolefins (e.g. LDPE, HDPE or PP) or PVC, PTFE is relatively expensive but thermally stable (Relative Temperature Index (RTI) > 150 °C [Haghani 2021]). Engineering plastics such as polyamides, POM, or PMMA are less expensive than PTFE but thermally inferior. High performance plastics enable exceptional end-use applications and specialty products at high cost. Generally speaking, PTFE is only used when it is truly required for the application, otherwise a lower cost material is chosen. PTFE is not used for convenience, but for high-end products where a certain combination of properties is really necessary (essential use!). This is also expressed in the annual production of fluoropolymers, i.e. 0.1% of the total plastic production worldwide (380 million tons in 2022). [Schlipf 2023]

Alternative materials can also be glass, ceramics or other inorganic materials. However, the combination of certain properties generally makes fluoropolymers irreplaceable.

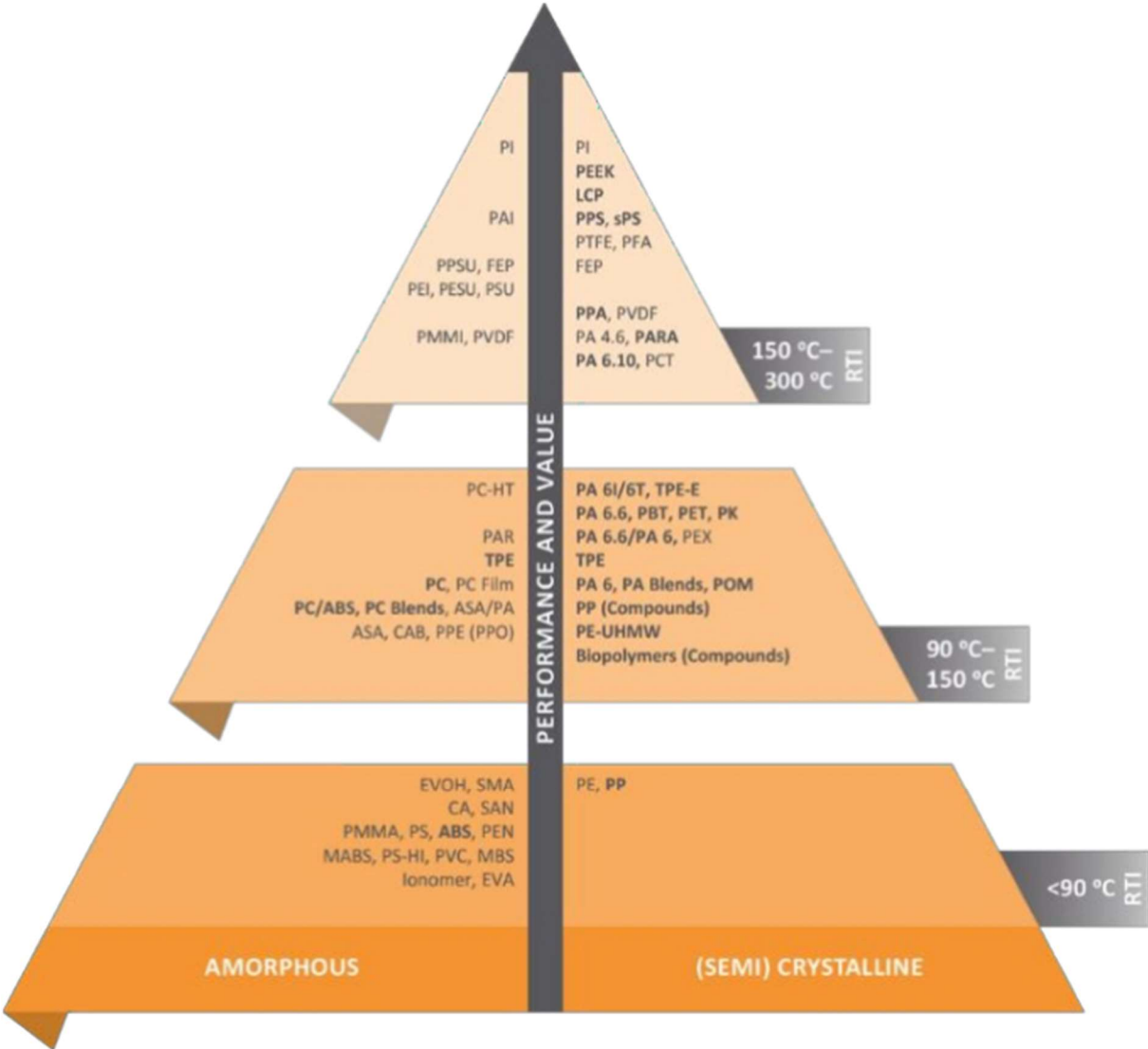


figure 6: Thermoplastics classification [Haghani 2021]

Currently, many different PFAS (on the order of several thousands) are used in a wide range of applications, and there is no comprehensive source of information on the many individual substances and their functions in different applications.

A broad overview of many use categories where PFAS have been employed and for which function was given by Glüge et al. [Glüge 2020]. They also specified which PFAS have been used and discuss the magnitude of the uses. Despite being non-exhaustive, this study clearly demonstrates that PFAS are used in almost all industry branches and many consumer products. In total, more than 200 use categories and subcategories are identified for more than 1400 individual PFAS. The search for alternatives is therefore a challenging and extensive task and is important in all use categories.

Chemservice provided an analysis of alternatives to fluoropolymer and evaluated many case studies in many different sectors [Chemservice 2022]. The case studies that are described in that report are based on specific applications as reported by a selection of downstream users of fluoropolymers. The applications should be considered as a reduced sample of the broad industrial sectors that rely on fluoropolymers today. The conclusion was that 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.

The possibility to apply alternative materials depends strongly on the application and the technical and safety requirements. There is no general alternative material for fluoropolymers and in many cases there is simply no alternative for PTFE. In section 2.6, possible alternatives accompanied with the compromises and drawbacks are described for the missing uses not addressed in the restriction proposal.

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[Schlipf 2023] M. Schlipf, Title: Fluoropolymers Global Market Overview; Conference: Innovations using Fluoropolymers, SKV, 3-4 Mai 2023 in Würzburg (see section 1.1)

[Glüge 2020] Glüge et al., An overview of the uses of per- and polyfluoroalkyl substances (PFAS), Environ. Sci.: Processes Impacts, 2020, 22, 2345-2373 (<https://doi.org/10.1039/d0em00291g>)

[Chemservice 2022] Chemservice, technical report - analysis of alternatives to fluoropolymers and potential impacts related to substitution in different sectors of use, Version 1, 19.7.2022, Information on benefits

There is nothing to be said against using fluoropolymers in industrial applications or in high-tech products if the required combination of properties - especially with the comparatively very low film thicknesses - can only be achieved by fluoropolymers!

1.7 Other socio economic analysis (SEA) issues

In more than 50 years, considerable expertise has been developed within the Adelhelm group of companies with regard to the processing and the correct applications of fluoropolymers. Particularly noteworthy here are safety-relevant areas in the automotive industry (brakes, belt systems, etc.), the chemical industry and, last but not least, medical technology.

The products of the Adelhelm group of companies can be found at various points in practically all value chains.

The Adelhelm group of companies a technology and family business with XX employees and XX million EUR turnover (both figures from 2022) and operates subsidiaries in the following locations:

- Germany 4x
- Switzerland 1x
- Czech Republic
- Poland
- Romania
- India
- United States

If the EU-wide restriction comes into force, it is to be expected that the Adelhelm group of companies will lose a considerable (!) share of its total sales.

In addition, niche products and applications are often served which, due to their essential effect or functionality, are indispensable in the most diverse areas of industrial production. From the point of view of the Adelhelm Group, the intended ban would thus bring numerous value chains to a standstill, since fluoropolymers are used practically everywhere where other plastics fail.

The logical consequence of this is that, in order to remain competitive, the Adelhelm Group must relocate its entire production to non-European countries, as this is the only way for the company to continue as a going concern.

It does not need to be mentioned that this will lead to the loss of jobs, taxes and technical as well as productive know-how in Europe!

Due to the now threatening and from our point of view wrong and therefore nonsensical complete ban of fluoropolymers, we see the continued existence of the Adelhelm group of companies in highest danger; that it would have devastating effects on numerous branches of industry as well as end consumers, for example medical patients, is however beyond doubt!

The European part of the company would probably not continue to exist.

Investments and recruitment

It must be mentioned that the consequence of this proposal is the uncertainty it brings. This uncertainty causes investments to be halted (or at least postponed) and staff recruitment activities to be delayed. Instead of moving forward, we are stalled. More regulatory obligations for fluoropolymer producers and processors will lead to a decline in production and processing in Europe during the transition period and a complete halt in production after a possible ban. Materials will be in short supply, the supply chain will be at risk, reliable delivery times will be at stake, leading to higher costs and customer dissatisfaction.

Conclusion

Once the restriction comes into effect, it is expected that the Adelhelm Group of Companies will lose a large portion of the total revenue that is attributed to the European business. Customer needs can no longer be met and competitive products can no longer be offered.

Key technologies can therefore no longer be served, such as renewable energy, batteries, electrification of vehicles, semiconductors, medical technology, drinking water supply, industrial food and feed production, which rely on the use of fluoropolymers within the entire value chain.

The ban carries the immanent risk that the energy turnaround or the European Green Deal cannot be realized at all, that European industry will fall back to the level of the 1950s, and that dependencies on Asia and the USA will be created that are currently being tried to be eliminated. The costs of the European health care system will explode. Due to a lack of treatment options, treatment risks and times will increase massively, which will have a noticeable effect on the annual European mortality rate in a negative sense!

In 2021, according to the German Federal Statistical Office⁸, about 60 million operations and treatment procedures were performed in German hospitals, not including cases in doctors' offices. It can be roughly assumed that one third to one half of these involve the use of PFAS-relevant products. Minimally invasive procedures in particular avoid large (abdominal) incisions and have significantly shortened postoperative hospitalization times. A growing proportion of procedures can be performed on an outpatient or day-case basis. Without PFAS this is not possible.

[Spectaris, https://www.spectaris.de/fileadmin/Content/Verband/Positionen/SPECTARIS-PFAS-Positionspapier_230525_final.pdf]

It is no longer possible to imagine a wide variety of areas of industrial production without PFAS. From the point of view of the Adelhelm Group, the intended ban would thus bring numerous value chains to a standstill, since fluoropolymers are used practically everywhere where other plastics fail.

The logical consequence of this is that, in order to remain competitive, the Adelhelm Group must relocate its entire production to non-European countries, as this is the only way for the company to continue as a going concern. It does not need to be mentioned that this will lead to the loss of jobs, taxes and technical as well as productive know-how in Europe! Due to the now threatening and from our point of view wrong and therefore nonsensical complete ban of fluoropolymers, we see the continued existence of the Adelhelm group of companies in highest danger; that it would have devastating effects on numerous branches of industry as well as end consumers, for example medical patients, is however beyond doubt!

The European part of the company would probably not continue to exist.

1.8 Transitional period

1.9 No transition period is requested. An exemption for fluoropolymers in general and for PTFE, ECTFE, ETFE, PVDF, FEP and PFA in particular is required!

1.10 Request for exemption

The Adelhelm Group of Companies cannot understand the possible ban of fluoropolymers in general, of PTFE, ECTFE, FEP and PFA in particular. As already mentioned, these are harmless polymers. In the production of the majority of fluoropolymers, the use of fluorine-containing production aids, such as fluorosurfactants, can now be dispensed with entirely, as has already been confirmed by suppliers. Particular mention should be made here of the two substances of concern, PFOA (perfluorooctanoic acid) and PFOS (perfluorooctanesulfonic acid), whose maximum levels in foodstuffs are strictly regulated by COMMISSION REGULATION (EU) 2022/2388, which was adopted on December 7, 2022.

As a matter of principle, we generally switch to more environmentally friendly formulations and production aids wherever possible, and this is a self-evident continuous optimization process (PDCA) in our DIN EN ISO 14001 certified company.

Adelhelm supports the approach to restrict/limit hazardous mobile PFAS. However, a clear differentiation should indeed be made here between high and low risk substances on the basis of a scientifically conducted risk assessment.

As already stated above, the use of fluoropolymers is limited to the minimum necessary, if only for reasons of production costs.

The uncertainty of various interest groups, which is already evident in the initial reluctance to invest after the publication of the restriction dossier, already gives an idea of how dramatically and quickly the Adelhelm Group of Companies would be affected by a possible fluoropolymer ban.

General: Fluoropolymers should be exempted from all regulatory measures under the REACH restriction!!!

Specified: Exemption for PTFE, ECTFE, ETFE, FEP and PFA, materials that are essential in high-tech products and products and production aids for industrial applications in a wide range of industries and cannot be substituted!

2 Specific information

2.1 Sectors and (sub-)uses

Sector	Annex	Sub-sector
Manufacture	E.2.1	Sector as a whole
Food contact materials and packaging	E.2.3	Industrial food production
Metal plating and manufacture of metal products	E.2.4	Sector as a whole
Metal plating and manufacture of metal products	E.2.4	Tribological applications for valves, etc
Metal plating and manufacture of metal products	E.2.4	Heavy chemical and corrosion protection
Metal plating and manufacture of metal products	E.2.4	Electrical
Medical devices	E.2.9	Surgical instruments such as shaft tubes, forceps, HF surgery, monopolar and bipolar clamps, sealings, etc.

2.2 Emissions in the end-of-life phase

This information is already provided in section 1.3.

2.3 Emissions in the end-of-life phase

This information is already provided in section 1.3.

2.4 Impacts on the recycling industry

This information is already provided in section 1.3.

2.5 Proposed derogations – Tonnage and emissions

This information is already provided in section 1.3.

2.6 Missing uses – Analysis of alternatives and socio-economic analysis

2.6.1 ECTFE for heavy corrosion and chemical protection and for electrical insulation under extreme conditions

One remark in advance: a comprehensive review of the elementary applications that can be realized **exclusively with functional fluoropolymer coatings** and cannot be substituted is not possible for reasons of time and would also go beyond the scope of this document, which is why we will limit ourselves here to a few examples.

Industry: medical technology, chemical industry, semiconductor industry, food and beverage industry.

Application: Industrial process equipment, e.g.

- Tanks and vessels, e.g. etch tanks, process tanks, storage tanks

- Pump components, i.e. pump housings, containment cans, pump impellers, containment can inserts for pumps,
- seals and gaskets
- Endoscopes for minimally invasive surgery and other surgical instruments
- Flanges and couplings
- agitators
- Heaters for galvanic plants
- KTL racks for automobile bodies
- Piping for aeration and deaeration systems (duct work, semiconductor industry)
- Etc.

Background information:

Coatings made of ethylene-chlorine-trifluoro-ethylene are used to protect metallic workpieces against chemical attack. Several properties are achieved with this functional coating:

- Chemical protection or heavy corrosion protection
- Non-stick properties or lotus effect
- Special coloring if required
- Electrical insulation

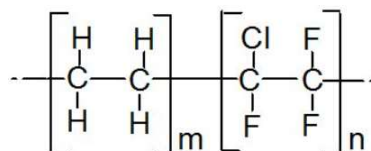


Figure 7: constitutive structural element of ethylene-chloro-trifluoroethylene

Example: Surgical instruments and electrosurgical devices:

The combination of different functionalities on surfaces of, for example, HF surgical instruments, which is required by the fundamentally highly demanding requirement profiles, can be realized overall exclusively by coating with fluoropolymers. It should also be noted that, due to the fluoropolymer coating, these instruments can be reused several times and thus make a positive contribution to the waste balance of single-use surgery.

Recent tests with e.g. polyamide, polyethersulfone or polyaryletheretherketone have shown that there is definitely NO alternative to fluoropolymers in terms of materials! A general ban of (simply non-substitutable) fluoropolymers would therefore have devastating effects on the health care system!



Figure 8: ECTFE-coated surgical instruments

Further examples: tanks and vessels, e.g. etch tanks, process tanks, storage tanks, ultrapure water tanks:

For decades, the coating of reactors, storage tanks, etc. with ECTFE has already been good common practice and is also used in a wide range of food technology applications as well as in the semiconductor industry. Here, too, the unrivaled material properties come into play.

Countless chemical manufacturing processes are only made possible by fluoropolymer protective coatings.

It cannot be emphasized often enough that the use of fluoropolymers is essential and cannot be replaced by any other material! For details, please refer to the confidential section V.

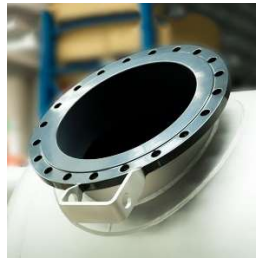


Figure 9: process tank coated with ECTFE

The applications mentioned under 2.6.1 show only a very manageable section of reality. The need for fluoropolymer coatings is well known and indisputable. We consider it deficient that fluoropolymer coatings for industrial applications are practically not or only very briefly dealt with in Annex XV reporting format 040615 (europa.eu) (page 99, "other coatings").

a. Annual tonnage and emissions (at subsector level) and type of PFAS associated with each use.

The following data are included in the "confidential document" in Section V.

Annual tonnage of this ECTFE: 2022 XX tons.

Emissions during production: none

Scrap rate of production: 2022

Of which reuse/recycling: XX tons

Incineration: XX tons

The annual tonnage is indicative and may vary from year to year. These figures can be related to the manufacturing totals given in Section 1.3.

Reuse/recycling/upcycling/incineration can be calculated proportionally to the data presented.

b. The major functions of PFAS for each application.

Fluoropolymers are referred to (PLC).

- High molecular weight and high melting point
- Very wide temperature application range
- Universal chemical resistance
- Anti-adhesive surface, very low coefficient of friction

- Hydrophobic properties
- Electrical insulation
- Autoclave resistance
- High UV resistance and resistance to weathering and radiation
- High purity
- High flame resistance according to UL94 V-0
- Good processability

c. *The number of companies in the sector estimated to be affected by the restriction.*

All manufacturing companies of the Adelhelm group of companies

d. *The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.*

Apart from other fluoropolymers (according to the latest definition also PFAS) such as PFA and ETFE, there are de facto no adequate material alternatives. Therefore, it is not necessary to provide information on market share and potential risks etc. regarding products based on alternatives to fluoropolymers.

Overview of fluoropolymers compared to other plastics:

	Fluoropolymers	PE and PP	PI	PEEK	Elastomers
Molecular weight	Green	Green	Green	Green	Red
Slip properties	Green	Red	Red	Red	Red
Non-stick properties	Green	Red	Red	Red	Red
Temperature range	Green	Red	Red	Red	Red
Porosity	Green	Red	Red	Red	Red
UV resistance	Green	Red	Red	Red	Red
Weather resistance	Green	Red	Red	Red	Red
High flame resistance	Green	Red	Green	Green	Red
Electrical insulation	Green	Red	Green	Red	Red
Physiological properties	Green	Green	Green	Green	Yellow
Lifetime	Green	Red	Red	Red	Green

In practically all applications, the requirement profiles demand a combination of different functionalities or properties of the coating and can therefore only be realized by fluoropolymer coatings.

In principle, it must be recognized that - whether considered in general or in particular - for the reasons already mentioned several times, unfortunately no alternatives exist at present or in the future.

The search for alternative materials to fluoropolymers or coatings with even approximately similar properties and total coating thickness is sobering after only a short time, since there are simply no adequate substitutes!

e. *For cases where alternatives are not yet available, information on the status of R&D processes to find suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial*

investment, the likelihood of successful implementation, the time expected to be required for substitution (including any relevant certifications or regulatory approvals), and the major challenges encountered with alternatives that were considered but then rejected. After it had to be recognized that in the areas of

- Heavy corrosion and chemical protection
- anti-adhesive coatings
- electrical insulation in special applications

or their combination, we are currently focusing our activities on the area of fluoropolymer-containing bonded coatings (PTFE-functionalized) and are conducting extensive series of tests with alternative dry lubricants. And even though some trials can be concluded with promising results, there are still major differences overall (service life, wear rate, coefficient of friction).

f. For cases in which substitution is technically and economically feasible but more time is required to substitute:

i. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g.

costs for new equipment or changes in operating costs); Not applicable. We manufacture high performance coatings. An alternative will only ever be a compromise!

ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals);

iii. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);

Functionality cannot be assured (reliability, safety and efficiency). Inferior mechanical properties, no-stick properties, temperature application range with required chemical stability will result in decreased lifetime, leading to more often exchange (CO₂ footprint ↑, material use ↑, maintenance costs ↑)

iv. information on the benefits for alternative providers. Not applicable.

g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

The impact on downstream users, companies, consumers and medical patients will be significant if no alternative materials (with similar or better safety, health and technical properties) can be found.

The socio-economic impacts are described in detail in section 1.8 and will be devastating for the Adelhelm Group of Companies!!!

2.7 Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis

Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the

assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.

A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.

To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic im-

pacts covering the elements described in points a) to g) in question 6 above.

Answer: No comment.

2.8 Other identified uses – Analysis of alternatives and socio-economic analysis

Table 8 in the Annex XV restriction report (starts on page 80) provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E.

For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions.

More information is needed on alternatives and socio-economic impacts to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.

Answer:

No comments.

2.9 Degradation potential of specific PFAS sub-groups

A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives. The fluoropolymers we use have no degradation potential.

2.10 Analytical methods

Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

As a downstream user (coater), we do not analyze our materials ourselves, but refer to the documentation provided by the supplier in the form of MSDS and supplier declarations.

25.09.2023

Literaturverzeichnis

The source references associated with the contributions are appended to the individual sections in each case.