# Restriction on the manufacture, placing on the market and use of PFAS

## Fluoropolymers Product Group (FPG) Comments to Annex XV restriction report

Contents

# Executive Summary

The Fluoropolymers Product Group (FPG) welcomes the opportunity to share its views on the Per- and Polyfluoroalkyl substances (PFAS) REACH Restriction Annex XV report and the potential impacts this proposal could have on the fluoropolymer industry.

FPG believes that fluoropolymers and applications containing a fluoropolymer should be not regulated within the REACH restriction. We argue that a total ban on fluoropolymers is not proportionate.

The concerns related to fluoropolymers raised in the restriction proposal can be adequately managed through the implementation of different regulatory frameworks together with Responsible Manufacturing (RM) and End-of-Life (EoL) Risk Management Measures (RMMs). Regulatory frameworks such as the Industrial Emissions Directive (IED), the Waste Framework Directive (WFD), and the Occupational Health Safety Directive (OHS) can address the concerns related to fluoropolymers effectively and more expeditiously compared to the REACH restriction.

- ✓ Segmentation of the PFAS family according to known physico-chemical and (eco)toxicological properties rather than a structure-based classification alone is needed for a risk-based regulatory approach which is scientifically sound. Fluoropolymers should not be grouped together with other PFAS, which may be of concern.

- ✓ Given their benign hazard profile, which has been demonstrated,[1,2] fluoropolymers are intrinsically safe and have been used for decades without safety concerns in industrial, commercial, and consumer applications. Fluoropolymers do not pose a risk to human health or the environment as they are non-toxic, not bioavailable, non-water soluble, non-mobile and do not bio-accumulate.

- ✓ Fluoropolymers are used in critical applications that help deliver strategic EU and UN climate objectives, are an enabler of the European Green Deal, the Net Zero Industry Act, the Critical Raw Materials Act, the EU Chips Act, the Hydrogen Strategy and the Sustainable and Smart Mobility Strategy and are central to the EU's strategic autonomy agenda.

- ✓ The lack of recognized alternatives could open the door for regrettable substitution to alternatives that do not perform to the same specification as fluoropolymers, may be potentially hazardous, less durable and as such would mean applications are unable to meet stringent safety and performance standards.

Therefore, by way of derogation, fluoropolymers and applications containing a fluoropolymer shall not be restricted. We ask for different regulatory measures to be implemented to address potential concerns raised by the regulators in relation to fluoropolymers.



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[1] Henry B. J., Carlin P. J., Hammerschmidt J. A., Buck, R. C., Buxton W., Fiedler H., Seed J., Hernandez O. (2018). A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers, Integr Environ Assess Manag2018:316–334 https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4035

[2] 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., Kapoor D., Gunasekar P., Malvasi M., Brinati G., Musio S. (2022). A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers, Integr Environ Assess Manag2022:1–30 https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4646

The fluoropolymer industry is ready to work with regulators on responsible manufacturing and end-of-life management of fluoropolymers.

## *1. Differentiation should be made between the broad family of PFAS according to their intrinsic and physicochemical properties and (eco)toxicological profiles.*

The REACH restriction dossier proposes a total ban over time on the use of all fluoropolymers in all applications, without distinguishing between fluoropolymers and other PFAS. The proposal makes limited reference to the fact that fluoropolymers have very different hazard profiles to other PFAS substances.

PFAS substances are a large, diverse group with different chemical, physical, thermal, and biological properties. Among the substances defined as PFAS, there are distinct substances with very different properties: polymers and non-polymers, solids, liquids and gases; persistent and nonpersistent substances; highly reactive and inert substances; mobile and insoluble (immobile) substances; and (eco) toxic and nontoxic chemicals. The term PFAS does not inform whether a compound presents risk or not, but only communicates that the compounds under this term share the same structural trait of having a fully fluorinated methyl or methylene carbon moiety.[3]

Fluoropolymers are generally very high molecular weight (typically a number average molecular weight in the range of 60,000 to 120,000 Da) polymers, non-toxic, not bioavailable, non-water soluble and non-mobile molecules, and are deemed as such to have no significant environmental and human health impacts. Fluoropolymers have documented safety profiles and although they fit the PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS.[1,2]

The dossier submitters indicated that persistence is a major criterion for the restriction. Persistence alone does not indicate that there is a present or future risk to human health or the environment and should not be synonymous with hazard. Risk is a function of hazard and exposure and given fluoropolymers benign hazard profile the focus should be on ensuring adequate control across the lifecycle through alternative legislation. Persistent chemicals like fluoropolymers allow materials to be durable and operational under extreme working conditions.[2] Fluoropolymers are used in diverse applications in external harsh environments due to their durability and resistance to degradation.

In conclusion, given the distinct physicochemical and toxicological profiles of fluoropolymers compared to other PFAS, we argue that fluoropolymers shall not be grouped together with other PFAS, which may be of concern, and regulated under the PFAS REACH restriction. Regulatory measures such as the Industrial Emissions Directive (IED) and the Waste Framework Directive (WFD) can control the emissions of fluoropolymers and address the concern of persistence.

## *2. Unmatched fluoropolymer properties are used in critical applications delivering strategic European and industrial objectives and are indispensable drivers of the European Green Deal, E-mobility, and Digital transition.*

[3] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf

Fluoropolymers, as a speciality polymer, have unmatched chemical, thermal, aging and weather resistance and unique electrical performance.[4,5] They are inert to hydrocarbons, solvents, acids, and bases and mixtures of these chemicals. Other highly desirable properties include low dielectric constant, low surface energy (water and oil repellent), low flammability, low refractive index, and low moisture absorption. The high C−F bond strength in these polymers has a critical impact on their great resistance to both hydrolytic and oxidation stability. Their stability in combination with these properties, translates to unique, durable, lasting performance in applications and contributes to extension of product life. Additionally, the durability of fluoropolymers makes them ideal materials that enable the development of innovative technologies. Assessments of alternative materials have shown that, when available, they frequently cannot meet the critical performance characteristics of fluoropolymer-based materials and lack the combinations and ranges of properties required for applications that set fluoropolymer-based materials apart.

Fluoropolymers are safe in products and applications delivering the required combination of functionalities. If alternatives materials would exist, industry pressures and market dynamics would have encouraged downstream users to move away from and replace fluoropolymers in non-critical applications.

Fluoropolymers critically help to deliver strategic EU and UN climate objectives and are an enabler of the European Green Deal, the Net Zero Industry Act, the Critical Raw Materials Act, the Chips Act, Hydrogen Strategy, and Sustainable and Smart Mobility Strategy.

A recently published report from the Joint Research Centre (JRC) on the supply chain analysis and material demand forecast in strategic technologies and sectors in the EU showed that - in order for the European Union (EU) to achieve the ambitious targets it has set for the energy and digital transitions and its defence and space agenda - fluoropolymers are indispensable materials. In particular, fluoropolymers are key materials for the majority of the strategic technologies assessed including Li-ion batteries, fuel cells, wind turbines, solar photovoltaics, data transmission network, robotics and drones, making it apparent that fluoropolymers are needed for delivering the European Green Deal.[6]

The proposed restriction creates general uncertainty that is already undermining investment decisions and innovation in relation to these and other overarching EU ambitions. This could result in a relocation of significant parts of this industry outside the EU with significant impacts for the whole fluoropolymer industry and unpredictable consequences for the critical sectors that rely heavily on these materials. Lack of access to these high-performance materials directly reduces the competitiveness of industry in Europe.

An immediate ban is foreseen for many applications in which fluoropolymers are used and are not included in the time-limited derogations in the restriction proposal. Examples of missing

[4] Study of the thermal degradation of polychlorotrifluoroethylene, poly (vinylidene fluoride) and copolymers of chlorotrifluoroethylene and vinylidene fluoride, S. Zulfiqar et. al., Polymer Degradation and Stability, Vol. 43, Issue 3, 1994, Pages 423-430 https://www.sciencedirect.com/science/article/abs/pii/0141391094900159?via%3Dihub
[5] The Effect of Long-Term Thermal Exposure on Plastics and Elastomer, Laurence W. McKeen, 2014 https://www.elsevier.com/books/the-effect-of-long-term-thermal-exposure-on-plastics-and-elastomers/mckeen/978-0-323-85436-8

[6] Supply chain analysis and material demand forecast in strategic technologies and sectors in the EU – A foresight study, JRC, Publications Office of the European Union, 2023 https://op.europa.eu/en/publication-detail/-/publication/9e17a3c2-c48f-11ed-a05c-01aa75ed71a1/language-en

applications include: the chemical process industry including chlor-alkali processes, batteries for electric vehicles, water and atmosphere purification, water electrolysis, energy/hydrogen storage, applications in pharmaceutical manufacturing equipment, pharmaceutical blister packaging, aerospace, military and defence, transportation and high-end niche applications. Fluoropolymers have many important applications in the construction and automobile industry. Some examples are UV (Ultra Violet) and graffiti resistant paints and coatings, the preservation of stone monuments, the petrochemical industry, aerospace and aeronautics (as seals, O-rings, and gaskets for hydrazine or liquid hydrogen tanks in space shuttle boosters), chemical engineering (high performance membranes and tubing), optics (claddings and cores of optical Fibers), textile treatments, microelectronics, and electrical insulation (cables and wires). As fluoropolymers are an indispensable driver of the European Green Deal an immediate ban of fluoropolymers will hamper key EU strategic sustainability ambitions. At the same time, assessments of alternative materials have shown that, when available, they frequently cannot meet the critical performance characteristics of fluoropolymer-based materials.

The dossier submitters state that a move away from using fluoropolymers to alternative materials in many applications can be made. The industry does not share these views about alternatives and whether they can provide the same combination of functionality and performance as fluoropolymers. The lack of recognized alternatives could open the door for regrettable substitution to alternatives that do not perform to the same specification as fluoropolymers, may be potentially hazardous, less durable and as such would mean applications are unable to meet stringent safety, environmental and sustainability application specific standards.

Regarding the proposed periods for time-limited derogations, these are not substantiated by a strong evidence base, and in many cases will be insufficient. The dossier submitters do not consider that applications may have to be redesigned from the bottom up or that in order to meet stringent standards requirements (e.g., safety standards) testing on potential alternatives, and certification will need to be undertaken to ensure suitability. Furthermore, the utilization of fluoropolymers in the current production process of alternative materials may render them inaccessible if such a restriction would be put forward.

We encourage the ECHA committees to take into consideration stakeholder input to develop an opinion that offers realistic and well substantiated periods of derogations.

In conclusion, a broad PFAS restriction which includes fluoropolymers could result in environmental, health and safety implications such as higher safety risks to employees, medical patients and consumers, and increased emissions from modes of transport due to technical regression. The restriction proposal in its present form could also lead to applications having lower durability and reliability resulting in higher maintenance and replacement frequency and increased waste, negative impacts for emerging and growing technology markets such as energy storage, electrification, renewable energies, and hydrogen and constraints for products required to meet stringent standards requirements (e.g. safety and environmental standards), in addition to the need to re-design products. Together, all these factors will also have significant implications for the global competitiveness of European industry.

3. *A total ban on fluoropolymers is not proportionate. The concerns of persistence raised in the restriction proposal can be adequately managed through the implementation of other regulatory measures such as the Industrial Emissions Directive (IED), the Waste Framework Directive (WFD) and the Occupational*

*Health and Safety Directive (OHS) together with the implementation of responsible manufacturing and EoL risk-management practices.*

The Fluoropolymers Product Group (FPG) recognises the public and political concern about PFAS. FPG acknowledges concerns on losses to the environment during manufacture and on the fate of fluoropolymers at End-of-Life (EoL). However, FPG believes that these concerns can be adequately managed through the implementation of regulatory measures such as the Industrial Emissions Directive (IED), the Waste Framework Directive (WFD) and the Occupational Health and Safety Directive (OHS) together with the implementation of responsible manufacturing and EoL risk-management practices. This would be a proportionate regulatory approach which recognises their benign hazard profile and critical importance to the EU economy and society.

*Responsible Manufacturing*

The fluoropolymer industry is committed to responsible manufacturing. We are constantly improving and/or developing state-of-art technologies in our manufacturing processes and management practices for environmental emissions. Some FPG member companies continue investigating and developing R&D programs for the advancement of technologies allowing for a transition away from using PFAS-based polymerization aids during fluoropolymer production. However, during this transition, it is necessary to continue using fluorinated polymerization aids where needed, until non-PFAS polymerization aids are developed that are proven technically feasible, environmentally sound, meeting the performance and processing requirements, and viable at an industrial and commercial scale. Therefore, time-unlimited derogations (with a periodic review) for all fluoropolymers should be provided.

Regulatory measures such as the IED which can effectively address total emissions during the manufacture of fluoropolymers and at the end-of-life should be considered when regulating fluoropolymers.

*End of Life*

The January 2023 Conversio report "Fluoropolymer waste in Europe 2020" identifies that the 23.5 kt of fluoropolymer waste collected are mainly "*commercial and industrial waste streams, which are usually collected by private waste management or industrial service companies. Only a small proportion of FP waste is collected in residential or private waste streams, such as mixed residential waste, which is often collected on behalf of municipal waste collection services*". According to this report, only 2.2Kt of fluoropolymer waste are potentially in the residential household waste and municipal waste generated by commercial activities which represent < 0.01% of the total municipal waste per weight.[7]

Concerns related to the disposal of PFAS, are not typically related to fluoropolymers as there is evidence that fluoropolymers such as PTFE do not degrade in the environment or release substances of toxicological or environmental concern.[8] Implementation of the WFD and guidance on how fluoropolymers can be mineralized can address the concerns related to the disposal of fluoropolymers. Additionally, multiple industries are already subject to end-of-life regulations including but not limited to electrical, automotive, chemical and medical industries.



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[7] Fluoropolymer waste in Europe 2020 – Conversio-Pro-k EUU Almdel supplerende svar på spørgsmål 49 Report ProK Fluoropolymers 20220719 (ft.dk)
https://www.ft.dk/samling/20222/almdel/euu/spm/49/svar/1951975/2698345.pdf

[8] Fluoropolymers—Environmental Aspects, K. Hintze, W. Schwertfeger, 2014 https://onlinelibrary.wiley.com/doi/10.1002/9781118850220.ch21

Concerning incineration, data is available demonstrating that fluoropolymers are mineralized (all C-F and C-Cl bonds broken, hydrofluoric and hydrochloric acids generated scrubbed to alkali/alkaline earth halides) if their end-of-life occurs in a commercial waste-to-energy incineration facility that operates under normal conditions.[9] [10] [11]

A recent pilot-scale fluoropolymer incineration study conducted under representative European municipal waste combustor conditions for a mixture of fluoropolymers (the four highest volume fluoropolymers (PTFE, PVDF, PFA and FKM) representing more than 80% of commercial fluoropolymer production) clearly demonstrated that fluoropolymers are converted to inorganic fluorides and carbon dioxide.[12] The inorganic fluorides detected were hydrogen fluoride and no short chain PFAS were detected post incineration. These results confirm that fluoropolymers at their end-of-life when incinerated under representative European municipal incinerator conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment.

FPG members continue to proactively work with their downstream users to increase recyclability and reuse of products in line with the objectives of the circular economy. FPG members, together with downstream users, and other research institutions, have multiple ongoing projects and initiatives for recycling of fluoropolymers, end-of-life upcycling and advancing technologies for PFAS destruction through proper incineration.[13,14,15]

In conclusion, the FPG believes that the restriction proposal significantly underestimates the breadth of use and importance of fluoropolymers in key applications, their benefits to society, their instrumental role with regards to the EU ambitions in climate and energy, and economic growth; enabling quality of life for European citizens as well as the lack of viable alternatives to replace them.

We argue that the restriction proposal is not proportional. The intrinsic safety of fluoropolymers together with the industry's commitment to further reduce emissions and the socioeconomic value and benefits of fluoropolymers outweigh the concerns of regulators related to fluoropolymers.

FPG therefore requests that fluoropolymers are not regulated within the REACH restriction and other regulatory frameworks are implemented to address regulators' concerns related to fluoropolymers.



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[9] Bakker et al. 2021. Per- and polyfluorinated substances in waste incinerator flue gases. RIVM Report 2021-0143. https://www.rivm.nl/bibliotheek/rapporten/2021-0143.pdf

[10] Giraud, R.J., Taylor, P. H., Huang, C-p. 2021a. Combustion operating conditions for municipal Waste-to-Energy facilities in the U.S. Waste Management, 132:124-132. https://doi.org/10.1016/j.wasman.2021.07.015 Giraud, R. J. 2021b. Municipal Waste-to-Energy Combustion of Fluorinated Polymers as a Potential Source of PFOA in the Environment. PhD Thesis. University of Delaware.

[11] Aleksandrov et al., 2019. Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Chemosphere, 226:898-906. https://doi.org/10.1016/j.chemosphere.2019.03.191

[12] Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions, H. j. Gehrmann et. al., attached.

[13] https://www.arkema.com/global/en/media/newslist/news/global/corporate/2021/20210525-circular-economy-acquisition-agiplast/

[14] https://www.invertec-ev.de/en/projects/environmental-care/ptfe-recycling/

[15] https://news.engin.umich.edu/2020/08/treating-pfas-water-contamination-with-cold-plasma/

# 1. Introduction

The Fluoropolymers Product Group (FPG) welcomes the opportunity to share its views on the PFAS REACH Annex XV Restriction Report.

FPG represents Europe's leading fluoropolymer producers and experts, and its members are 3M, AGC, Arkema, Chemours, Daikin Chemicals, DuPont, W. L. Gore & Associates, Gujarat, Honeywell, and Solvay.

FPG is a Product Group of Plastics Europe, which counts over 100 member companies, producing over 90% of all polymers across the EU27 plus the UK, Norway, Switzerland and Turkey. Together Plastics Europe members directly employ 1.6 million workers in the EU27.

FPG members are committed to promoting innovation, safe use of our products, sustainable manufacturing and stewardship across the industry for all our products. As the voice of the fluoropolymer industry in Europe, FPG advocates for a balanced regulatory environment based on scientific fact and socio-economic certainty to ensure that European industries remain competitive and sustainable.

The PFAS REACH Annex XV Restriction Report which was submitted by the five Competent Authorities of Germany, Denmark, Netherlands, Norway and Sweden proposes a near-total ban of all PFAS substances, including fluoropolymers.

The dossier submitters do not acknowledge that fluoropolymers are produced and sold worldwide and that they have found application in nearly every field of modern industrial, technological, and scientific endeavor. In applications ranging from chemical industry and power generation to emission controls on vehicles to semiconductor manufacture to aerospace, fluoropolymers provide superior performance in products that contribute to increased safety and sustainability in offices, homes, industries, and communities. Fluoropolymers are indispensable and irreplaceable materials, they used in critical applications that help deliver strategic EU and UN climate objectives and are an enabler of the European Green Deal, the Net Zero Industry Act, the Critical Raw Materials Act, the EU Chips Act, the Hydrogen Strategy, and the Sustainable and Smart Mobility Strategy.

Fluoropolymers are known for their exceptional combination of properties, which make them irreplaceable in industrial and commercial applications. In the next section we highlight some of the main properties of fluoropolymers which help achieve and deliver strategic EU and UN climate objectives and enable the European Green Deal and EU innovation and cannot be found as a combination in other materials, as the dossier submitters propose in the PFAS Annex XV restriction report. A recently published report from the Joint Research Centre (JRC) on the supply chain analysis and material demand forecast in strategic technologies and sectors in the EU showed that in order for the European Union (EU) to achieve the ambitious targets it has set for the energy and digital transitions and its defence and space agenda, fluoropolymers are indispensable materials.[16]

The proposed REACH restriction does not differentiate between fluoropolymers and other PFAS. As noted above, fluoropolymers have unique properties that distinguish them from other PFAS. Additionally, they do not have the toxicological profiles associated with some PFAS that are of concern.[1,2] A balanced restriction proposal should differentiate between the various types of PFAS based on their chemical composition, their hazard profiles, and the production method as all PFAS are not the same.

FPG believes that the restriction proposal significantly underestimates the breadth of use and importance of fluoropolymers use in key applications, their benefits to society, their instrumental role with regards to the EU ambitions in climate and energy, and economic growth, enabling quality of life for European citizens as well as the lack of viable alternatives to replace them. A restriction of all PFAS including fluoropolymers encompasses an inconceivable number of material applications and could have far-reaching consequences to the wider economy and society than are anticipated.

The FPG argues that segmentation of the PFAS family according to their physicochemical and (eco)toxicological properties rather than a structure-based classification alone is needed for a risk-based regulatory approach and requests a general derogation for fluoropolymers under the PFAS REACH restriction. The concerns related to fluoropolymers can be addressed by implementing different regulatory frameworks such as the Industrial Emissions Directive, the Waste Framework Directive and the Occupational Health and Safety Directive. Considering such regulatory frameworks for fluoropolymers rather than a blanket ban will expeditiously address concerns related to fluoropolymers compared to the REACH restriction.

# 2. About Fluoropolymers

Fluoropolymers are crucial to many components, technologies, industrial processes and products used in everyday life as already highlighted in the introduction. They are plastics or elastomers which are chemically inert, non-wetting, non-stick, highly temperature and fire resistant, and highly weather resistant. It is this specific combination of properties that makes them so valuable and broadly irreplaceable.

Recently, a published report from the Joint Research Centre (JRC) on the supply chain analysis and material demand forecast in strategic technologies and sectors in the EU showed that in order for the European Union (EU) to achieve the ambitious targets it has set for the energy and digital transitions and its defence and space agenda, fluoropolymers are indispensable materials. In particular, fluoropolymers are key materials for the majority of the strategic technologies assessed including Li-ion batteries, fuel cells, wind turbines, solar photovoltaics, data transmission network, robotics and drones, making it apparent that fluoropolymers are needed for delivering the European Green Deal.[16]

Fluoropolymers are generally very high molecular weight polymers and possess high thermal, chemical, photochemical, oxidative, hydrolytic, and biological stability. They have low flammability, neutral electrical charge, resistance to degradation, negligible residual monomers and limited low molecular weight leachables, and have no reactive functional groups of concern.[17]

Fluoropolymers are a distinct subset of fluorinated polymers, with fluorine attached to their carbon-only backbone.[18] The carbon–fluorine (C–F) bond is the strongest bond between carbon and another atom. The presence of electronegative and low polarizable fluorine (F) atoms in a material imparts a short C-F bond that possesses a high bond energy dissociation (ca. 485 kJ.mol-1). Thus, fluoropolymers are suitable candidates endowed with outstanding properties such as thermal stability, chemical inertness (to solvents, oils, water, acids and bases), low values of the refractive index, permittivity, dissipation factor and water absorptivity, as well as excellent weatherability, durability and resistance to oxidation. Hence, they have been involved in many High-Tech applications such as protective coatings, fuel cell membranes, fabrics, specific items in the automotive industries (seals, gaskets, or transmission components, as well as cables and hoses, and increasing amounts of items such as fuel cell membranes and components of lithium ions batteries), aerospace and aeronautics (fire retardant-coatings, elastomers as gaskets or O-rings and cables),petrochemical, chemical processing industry (seals, gaskets, coatings) microelectronics, chemical engineering (high performance membranes), textile treatment, protective building coatings (e.g. paints or films resistant to UV and to graffiti or liners in oil tanks of vehicles), and optics (core and cladding of optical fibres).[19]

[16] Supply chain analysis and material demand forecast in strategic technologies and sectors in the EU – A foresight study, JRC, Publications Office of the European Union, 2023 https://op.europa.eu/en/publication-detail/-/publication/9e17a3c2-c48f-11ed-a05c-01aa75ed71a1/language-en
[17] Gangal SV, Brothers PD. 2015. Perfluorinated polymers. In: Kirk-Othmerencyclopedia of chemical technology. New York (NY): Wiley. p 1–68.
[18] Ebnesajjad, S. (2017). Introduction to fluoropolymers. In Applied plastics engineering handbook: Processing, materials, and applications (2nd ed., pp. 55–71). Elsevier
[19] Fluoropolymers: the right material for the right applications, B. Ameduri, 2018, Chemistry - A European Journal https://chemistry-europe.onlinelibrary.wiley.com/doi/abs/10.1002/chem.201802708

Per-and polyfluoroalkyl substances (PFAS), a universe of substances with widely diverse properties that have been used in industrial and consumer applications since the 1950s, include fluoropolymers as a distinct class.[20] Fluoropolymer types include 'fluoroplastics' and 'fluoroelastomers', as discussed in the next sections. Below we list some of the main properties whose unique combination in pure polymer form render fluoropolymers irreplaceable materials.

*Key properties of fluoropolymers*

Heat Resistance: One of the most important properties of fluoropolymers is the outstanding resistance to heat.

Fluoropolymers are highly resistant to heat and can maintain their physical properties even at extremely high temperatures. This makes them suitable for use in applications where high-temperature resistance is required, such as in the production of electronic components, industrial piping systems, and aerospace components. Heat resistance and a combination of resistance to a broad range of fuels, solvents and corrosive chemicals, and excellent dielectric stability means fluoropolymer resins yield an extremely versatile family of engineering materials. These unique properties may provide certain essential performance characteristics needed in the event of fire, in fluid containment or exclusion, electrical overload and similar emergencies.

Chemical Resistance: Fluoropolymers are highly resistant to chemicals, acids, and solvents. This property makes them ideal for use in applications where exposure to harsh chemicals is likely, such as in the production of chemical processing equipment and laboratory apparatus. Fluoropolymers are also used in pharmaceutical industry to provide an effective barrier against organic and inorganic extractables and minimize interactions between drugs and primary packaging components. They are also critical to drug stability, shelf life, and effective medicines.

Environmental Resistance: Fluoropolymers are also highly resistant to environmental degradation, including exposure to ultraviolet (UV) radiation, ozone, and other environmental factors. They are able to maintain their physical properties even when exposed to harsh weather conditions, making them ideal for outdoor applications such as architectural coatings and films.

Durability: Fluoropolymers are highly durable and can withstand harsh conditions without breaking down or losing their physical properties. This makes them suitable for use in applications where long-term durability is required, such as in the production of seals, gaskets, and wire and cable insulation.

Non-Stick Properties: One of the most well-known properties of fluoropolymers is their non-stick property. They are highly resistant to sticking, making them ideal for use in non-stick coatings

[20] Buck, R. C., Franklin, J., Berger, U., Conder, J. M., Cousins, I. T., de Voogt, P., Jensen, A. A., Kannan, K., Mabury, S. A., & van Leeuwen, S. P. J.(2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins. Integrated Environ-mental Assessment and Management,7(4), 513–541. https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.258

where sticking is a concern. Fluoropolymers such as polytetrafluoroethylene (PTFE) and perfluoroalkoxy (PFA) are widely used in the production of non-stick coatings due to their excellent non-stick properties and high chemical resistance.

Mechanical Properties: Fluoropolymers have excellent mechanical properties, including high tensile strength, flexibility, and impact resistance. They are able to maintain their physical properties even when exposed to extreme temperatures and harsh conditions, making them suitable for use in a wide range of industrial and commercial applications.

Inertness: Fluoropolymers are highly inert and non-reactive, making them an ideal choice for use in a range of industrial and commercial applications where exposure to chemicals and other reactive substances is likely. They are also highly stable and do not decompose or degrade over time. Due to the general inertness of the fluoropolymer resins, they fall outside all definitions of hazardous materials within European transport regulations and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Electrical properties: Fluoropolymers have unparalleled cohesive and adhesive properties under high voltage, allowing for closely packed cathode active materials for high density electrodes in batteries. Thanks to PVDF, different battery components can be packed closer and closer together, improving the energy efficiency of a single unit and helping reduce overall size. In addition, fluoropolymers have high dielectric strength with a low dielectric constant. These low loss factors are great for Low Capacitance and Coaxial Cables.

Separation/Barrier Properties: Fluoropolymers have excellent moisture barrier and superior gas separation properties. It is sold in significant commercial quantities as a transparent film for primary and secondary pharmaceutical and medical device packaging, as well as in drug delivery devices. Fluoropolymers such as PCTFE have also been used for the separation of Helium/Hydrogen, Helium/Carbon dioxide and Helium/Methane gas mixtures.

Cryogenic Properties: Fluoropolymers find applications in many high-tech areas such as aeronautics, space, electronics, chemical and medical industries where cryogenic properties are required. Relevant examples include cryogenic and aerospace pump liners, seals, gaskets, valve seats, fittings, gaskets for liquid oxygen and hydrogen, windows for infrared guns or missiles, and blood filters, suture packages, syringe tubes, sterilizable packages and medical implants.

Dielectric Properties: Fluoropolymers have excellent electrical properties, specifically low dielectric constant (Dk) and dissipation factor (Df), at higher frequencies used in modern telecommunications infrastructure. These properties are stable across a wide range of the electromagnetic spectrum earmarked for 5G communications and these properties are relatively unaffected by fluctuations in temperature and humidity, thus making them highly suitable for consumer electronics and telecommunications applications. These properties are also ideally suited for high performance printed circuits used for data centres and advanced data processing.

*Types of fluoropolymers*

*Fluoroplastics* are made by homo- or copolymerization of monomers including, but not limited to: tetrafluoroethylene (TFE), hexafluoropropylene (HFP), vinylidene fluoride (VDF), chlorotrifluoroethylene (CTFE), vinyl fluoride (VF), trifluoroethylene (TrFE) and perfluoroalkyl vinyl ethers (PAVEs) which include trifluoromethyl trifluorovinyl ether (PMVE), pentafluoroethyl trifluorovinyl ether (PEVE) and heptafluoropropyl trifluorovinyl ether (PPVE). In the case of copolymers, monomers that do not contain fluorine attached to the olefinic carbons may be used. These include, but are not limited to, ethylene, propylene and perfluoroalkyl-substituted ethylenes.[21]

Fluoroplastics that are produced by homo- or copolymerization of the monomers listed above include, but are not limited to: polytetrafluoroethylene (PTFE), the TFE-HFP copolymer (FEP), polyvinylidene fluoride (PVDF), polychlorotrifluoroethylene (PCTFE), polyvinyl fluoride (PVF), the ethylene-TFE copolymer (ETFE), the ethylene-CTFE copolymer (ECTFE), the VDF-HFP copolymer (VDF-co-HFP), terpolymers of TFE, HFP and VDF (THV), the VDF-TFE copolymer (VDF-co-TFE), terpolymer of TFE, perfluoroalkyl trifluorovinyl ether and chlorotrifluoroethylene (CPT), terpolymers of TFE, HFP and ethylene (EFEP), polytrifluoroethylene (PTrFE), and perfluorinated polymers with perfluoroalkoxy side-chains resulting from copolymerization of tetrafluoroethylene with either trifluoromethyl trifluorovinyl ether (MFA) or other perfluoroalkyl trifluorovinyl ethers (PFA).[21,22]

*Fluoroelastomers* or 'fluorocarbon elastomers' are rubbery materials based mainly on several of the same monomers as used for producing fluoroplastics, including but not limited to VDF, HFP, TFE, CTFE, PAVEs and propylene, as well as 1-hydropentafluoropropene (HPFP) and 2,3,3,3-Tetrafluoropropene (HFO-1234yf). They are produced as highly viscous materials and then cross-linked (or 'cured', or 'vulcanized') to harden them and impart their elasticity. Cross-linking agents commonly used are multi-nucleophiles (diamines, bisphenols, diisocyanates (e.g., tryallyl isocyanurate), free-radical generators (peroxides), or radiation. Fluoroelastomers can be regarded as a distinct subset of fluoropolymers. While they are based on many of the same monomers as those used for synthesizing fluoroplastics, the main difference between the two families is that fluoroelastomers have unique elastomeric properties resulting from the cross-linking process, with low sub-ambient glass transition temperatures ($T_g$).[21]

FKM (Fluoroelastomers (Fluorine Kautschuk Material)) and FFKM (Perfluoroelastomers), can withstand temperatures greater than 200 °C and are used to manufacture O-rings, seals and gaskets for automotive, aerospace, energy and other industries.

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[21] 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., Kapoor D., Gunasekar P., Malvasi M., Brinati G., Musio S. (2022). A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers, Integr Environ Assess Manag2022:1–30 https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4646

[22] Henry B. J., Carlin P. J., Hammerschmidt J. A., Buck, R. C., Buxton W., Fiedler H., Seed J., Hernandez O. (2018). A Critical Review of the Application of Polymer of Low Concernand Regulatory Criteria to Fluoropolymers, Integr Environ Assess Manag2018:316–334 https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4035

The definitions provided above would include, but not be limited to, the following:

- **ECTFE**: ECTFE is a copolymer of ethylene and chlorotrifluoroethylene having the formula [(CH2-CH2)x-(CFCl-CF2)y]n. ECTFE has a melting point range of 220 - 245ºC and is melt processable. It is available in the form of translucent pellets and as a fine powder.
- **EFEP**: EFEP is a copolymer of ethylene, tetrafluoroethylene, and hexafluoropropylene, with the formula [(CH2-CH2)x(CF2-CF2)y(CF(CF3)-CF2)z]n. EFEP polymers melt at 155 – 200 ºC. It is melt processable and is supplied in pellet form.
- **ETFE**: ETFE is a copolymer of ethylene and tetrafluoroethylene of the formula [(CF2-CF2)x-(CH2-CH2)y]n. Depending on various grades, ETFE melts between 220– 270 ºC. It is melt processable and is supplied in pellet and powder form.
- **F-TPV** (fluoro thermoplastic vulcanizates): "Ready to use" fluoro thermoplastic fluoroelastomers with superior extrusion behaviour and ultra-low permeation, melt processable, offering a unique combination of low permeation, low modulus (high flexibility), and excellent processability with a melting point about 230 °C.
- **FEP**: FEP resin is a copolymer of tetrafluoroethylene and hexafluoropropylene with the formula [(CF(CF3)-CF2)x(CF2-CF2)y]n. It has a melting point range of 245 – 280 ºC and is melt processable. It is supplied in the form of translucent pellets, powder, or as an aqueous dispersion.
- **HTE**: HTE is a copolymer of hexafluoropropylene, tetrafluoroethylene, and ethylene. HTE is melt processible with melting points from 155 to 215 ºC depending on grade. It is available in pellet or agglomerate form.
- **MFA**: MFA is a copolymer of tetrafluoroethylene and perfluoromethylvinylether. It belongs to the generic class of PFA polymers. MFA melts at 280- 290 ºC. It is available in the form of translucent pellets and aqueous dispersions.
- **PCTFE**: PCTFE is a polymer of chlorotrifluoroethylene with the formula [CF2-CFCl]n. It has a melting point range of 210-220 ºC and is melt processable. It is available in pellet, granular, powder and film forms.
- **P(CTFE-VDF)** is a copolymer of chlorotrifluoroethylene and vinylidene fluoride with the formula [(CF2-CFCl)x- (CF2-CH2)y]x. It has a melting point range of 188 – 204 ºC and is melt processable. It is available in pellet, granular, powder and film form.
- **PFA**: PFA resins are copolymers of TFE fluorocarbon monomers containing perfluoroalkoxy side chains. PFA melts at 280 ºC minimum and is melt processable. It is available in the form of pellets, powder, and as an aqueous dispersion.
- **CPT**: CPT is a terpolymer of TFE, perfluoroalkyl trifluorovinyl ether and chlorotrifluoroethylene. CPT has the melting point at 235 – 255 ºC . CPT is available in the form of pellets and powder.
- **PTFE**: PTFE is a polymer consisting of recurring tetrafluoroethylene monomer units, whose formula is [CF2-CF2]n. PTFE does not melt to form a liquid and cannot be melt-extruded. On heating the virgin resin, it forms a clear gel at 330 ºC ±15. Once processed, the gel point (often referred to as the melting point) is 10 ºC, lower than that of the virgin resin. It is sold as a granular powder, a fine powder, or an aqueous dispersion. Each is processed in a different manner.

- **PVDF**: PVDF is a homopolymer of vinylidene fluoride having the formula [CH2-CF2]n or a copolymer of vinylidene fluoride and hexafluoropropylene having the formula [CF(CF3)-CF2)x(CH2-CF2)y]n. Copolymers of vinylidene fluoride are also produced with (1) chlorotrifluoroethylene, (2) tetrafluoroethylene, and (3) tetrafluoroethylene and hexafluoropropylene. These are all sold as PVDF copolymers. PVDF polymers/copolymers melt at 90 -178 ºC), are melt processable, and are supplied in the form of powder, pellets, and dispersions.
- **THV**: THV is a copolymer containing tetrafluoroethylene, hexafluoropropylene and vinylidenefluoride. THV is melt-processable with melting points from 115 to 235 ºC depending on grade. It is available in pellet, agglomerate or aqueous dispersions.
- **FKM**: FKM fluoroelastomers contain vinylidene fluoride (VDF) as a monomer combined with a variety of other fluoromonomers to create a palette of polymers with properties tailored for specific uses. Cross-linked FKM fluoroelastomers are amorphous polymers designed for demanding service applications in hostile environments characterized by broad operating temperature ranges in contact with industrial chemicals, oils, or fuels. Uncured FKM fluoroelastomers are used as a polymer processing additive (PPA) or polymer extrusion aids in small amounts (50–2000 ppm) dispersed in polyolefins such as high-density polyethylene (HDPE) and linear low-density polyethylene (LLDPE), significantly improving their film extrusion characteristics, reducing melt fracture and die build-up.
- **FFKM**: Perfluoroelastomers (FFKM), are a fully fluorinated class of elastomers that are typically made up of tetrafluoroethylene (TFE), a perfluoro (alkyl vinyl ether; PAVE), and a cure site monomer(s). FFKM elastomers offer superior chemical and temperature resistance, excellent resistance to gas and liquid permeation, and resistance to weather and ozone with operating temperatures ranging from −40 to 325 °C.



# 3. Fluoropolymer safety

*Fluoropolymers are polymers with properties predictive of low hazard.*

There is sufficient data proving the safety of fluoropolymers, which the dossier submitters did not acknowledge in the restriction proposal.

Fluoropolymers are known for their high chemical stability and inertness and low reactivity. These compounds are of low toxicity, demonstrating little if any toxicological activity. Where toxicological studies have been conducted on fluoropolymers, no findings of significance for human health hazard assessment have been reported. None of the fluoropolymers is known to be a skin irritant or sensitiser in humans. Following grossly excessive exposure to fluoropolymer resin dust by inhalation, increases in urinary fluoride were produced, however, no toxic effects were observed.[23]

A recently submitted study report to ECHA based on the provisions of ISO/IEC 17025-2005 showed that a PTFE test article (non-absorbable surgical suture) did not cause acute systemic toxicity following injection to mice. Under the conditions of the study, there was no mortality or evidence of acute systemic toxicity from the extract of the test article, proving again that fluoropolymers like PTFE are non-toxic substances.

PCTFE has negligible leaching and almost no toxicological activity under normal conditions. It is physiologically inert and has been approved by the US Food & Drug Administration and European Medicines Agency for use in contact with food or for human implants. PCTFE is made from the non-PFAS monomer chlorotrifluoroethylene (CTFE). The preferred methods for disposing PCTFE-based materials are recycling and reusing them. The clean, unfilled, and unpigmented scrap materials from the manufacturing and processing of PCTFE can be recycled back into raw materials to be reused in applications where the quality requirements are much lower.[24]

PVDF is considered not to pose risks to human health, have a favourable (eco)toxicological profile, and is not bioavailable. It is an inert material approved by many stringent standards: Food Contact US &EU, ISAO10993 biocompatibility, NFS61 for potable water systems for example. Some references toxicology tests are available in the IUCLID database.

The dossier submitters do not acknowledge that during the use-phase, fluoropolymers have documented safety profiles and aside from being fluorinated polymers 96% of the available commercial fluoropolymers meet the OECD Polymer of Low Concern (PLC) criteria, demonstrating the insignificant risk they have on human health or the environment. PLC criteria were developed overtime within regulatory frameworks around the world as an outcome of chemical hazard assessment processes, which identified physical–chemical properties of polymers that determine polymer bioavailability and thereby report a polymer's potential hazard.[1]

There is strong scientific basis to separate and subsequently remove fluoropolymers from the PFAS discussions of other PFAS as a class or in terms of their impacts on human or environmental health as 18 groups of fluoropolymers are proved to meet the PLC OECD criteria based on scientific tests/data and therefore are expected to be negligibly soluble, non-mobile, non-bioavailable, non-bio accumulative, and non-toxic.[1] [2]

The environmental impacts of fluoropolymers are also negligible, as fluoropolymers are chemically and thermally stable and do not degrade at relevant environmental conditions. As an example, independent laboratory studies have shown that fine powder PTFE meeting the ASTM D4895 is non-soluble in water and not biodegradable. Also, PVDF has been demonstrated to be non-biodegradable according to ASTMD5511 and OECD Guideline 301F.



[23] Guide for the safe handling of fluoropolymer resins, 2021, https://fluoropolymers.plasticseurope.org/application/files/6216/3178/0517/Fluoropolymers_Safe_Hand_EN__June_2021.pdf
[24] Structure, Properties, and Modification of Polytrifluorochloroethylene: A Review, 2020, J. Zou et. al., Volume 9 - 2022 https://doi.org/10.3389/fmats.2022.824155

The studies[25] which met the OECD guidelines were performed to investigate if persistence implies future degradation, release, or transformation into a continuous source of substances of concern. Among the different tests performed, OECD 105 Water Solubility, Ready Biodegradation OECD 301B and Inherent Biodegradation OECD 302C tests applied to investigate potential partitioning of PTFE to water and the potential of biodegradability. The results showed that the tested PTFE was insoluble in water and not biodegradable confirming the low probability of water exposure to PTFE degradants or leachables.[26]

Additional studies to investigate the potential partitioning to soil included testing using the Molecular Weight OECD 118. PTFE was determined not to be sufficiently soluble for gel permeation chromatography even after sonication and stirring for 19 hours in tetrahydrofuran, dichloromethane, dimethylformamide, or dimethyacetamide. Using alternative methods of standard specific gravity and melt flow rheology, the molecular weight was determined to be above 500,000 Da.[26]

The potential of PTFE partitioning to air was determined via the Molecular Weight OECD 118, Vapor Pressure OECD 104, Melting Temperature OECD 102, Thermal Stability OECD 113 and Thermal Gravimetric Analysis tests. The results showed lack of inhalation exposure potential at environmentally relevant temperatures.[26]

Generated data for eighteen types of fluoropolymers including PTFE, ETFE, FEP, PFA, PVDF, ECTFE, FKM and FFKM among other, meet the OECD PLC criteria and account for 96% of the fluoropolymers market showed that the tested materials will not partition to air, water, or soil. Additionally, potential inhalation, oral or dermal exposure to fluoropolymers evaluated for biota or the environment is unlikely based on this data. [1,2]

The above results show that grouping all PFAS together for regulatory purposes is not scientifically sound as they do not share common properties and they do not have identical toxicological profiles. A segmentation of the PFAS family according to known properties rather than a structure-based classification alone is needed for a risk-based regulatory approach and a general derogation for fluoropolymers under the PFAS REACH restriction should be provided.

## *Temperature resistance and Decomposition*

The restriction proposal does not acknowledge that fluoropolymers are amongst the most thermally stable polymers known and decomposition occurs only above the recommended continuous service temperature for the polymer in question.[23] The quantity of effluent evolved remains small until temperatures above the normal processing temperature for the polymer are reached. Rates of thermal decomposition for various fluoropolymers have been determined using a thermogravimetric analyser. Samples were heated in dry air flowing at a rate of 30 ml/minute. The temperature was increased at 20°C/minute from room temperature to the test temperature. The samples were then held at constant temperature for one hour and the weight loss during the

[25] https://www.gore.com/system/files/2023-03/Summary-of-CRL-and-ALS-Studies-on-PTFE.pdf

[26] https://www.gore.com/system/files/2023-03/Summary-of-CRL-and-ALS-Studies-on-PTFE.pdf

hour was measured (isothermal weight loss). The rate of weight loss was determined for each polymer at a series of three constant temperatures (four for PVDF). The test temperatures used were different for each fluoropolymer and were chosen according to the increasing thermal stability of the polymer. The results are shown in Figure 1.[27]

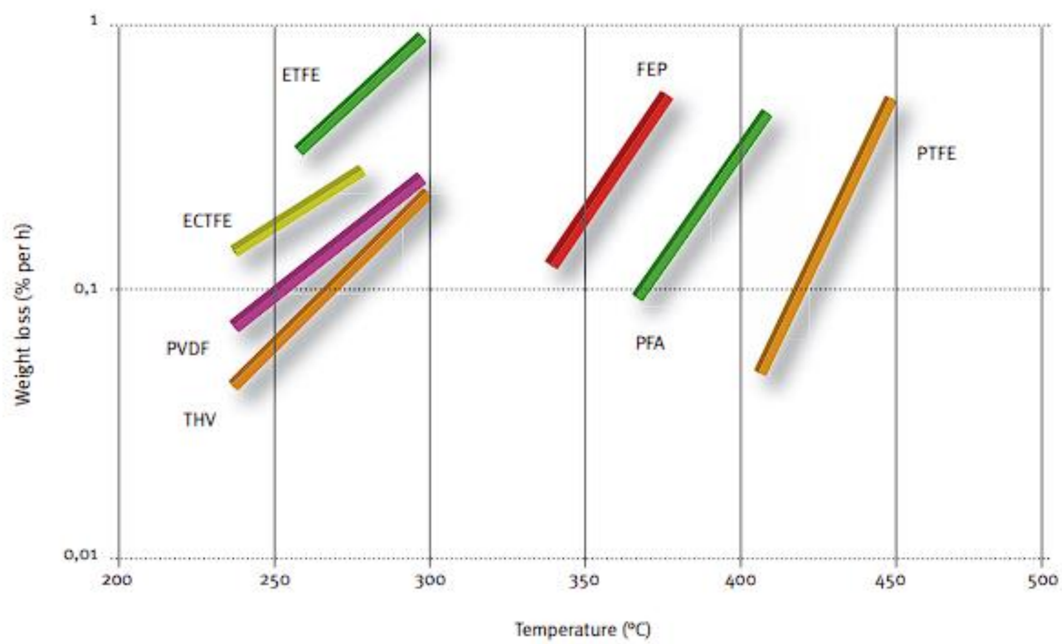


Figure 1. Typical weight loss of fluoropolymers heated in air.[27]

It should be remembered that within any polymer type, different grades will have different thermal stabilities according to properties such as molecular weight. The data presented in Figure 1 give a general indication of the relative thermal stabilities of each polymer.

Typical melting points, continuous service temperatures and processing temperatures for the different fluoropolymers are given in

Table 1.

Table 1. Typical melting points, continuous use and processing temperatures of fluoropolymers. The information above is taken from the Guide to Safe Handling of Fluoropolymer Resins.**Error! Bookmark not defined.** The most recent version is available here.

| Polymer | Typical melting point (°C) | Typical maximum continuous service temperature (°C) | Typical processing temperature (°C) |
|---|---|---|---|
| PTFE | 340 | 260 | 380 |

[27] https://fluoropolymers.plasticseurope.org/application/files/5116/3671/1909/Fluoropolymers_Safe_Hand_EN_2021.pdf

| | | | |
|---|---|---|---|
| PFA | 265-310 | 225-260 | 260-380 |
| FEP | 250-270 | 205 | 360 |
| ETFE | 210-270 | 150 | 310 |
| ECTFE | 190-240 | 150 | 280 |
| PVDF | 160 | 140 | 230 |
| THV | 110-230 | 70-130 | 200-270 |
| PCTFE | 212-216 | (-)200-193 | 260-320 |

A recent study by RIMV[28] also discussed the decomposition temperatures of fluoropolymers, indicating that PTFE is the most thermally stable of all fluoropolymers, including fluorine-containing polymers that are only partially fluorinated such as polyvinylidene fluoride (PVDF) and ethylene-tetrafluorethylene (ETFE). The study noted that PTFE can be used for a long time at 260 °C and for a short time up to a temperature of 450 °C without loss of mass due to the formation of fluorine-containing gases and that significant mass loss does only occur at temperatures of >550 °C. For the other polymers like ETFE degradation occurred at temperatures of around 470 °C.

As far as weight loss was concerned, it was noted that the order of relative thermal resistance for the different polymers is: PTFE > PFA> MFA> FEP> ETFE > PVDF ≈ PE > ECTFE > PCTFE. For PFA, MFA and FEP significant weight loss occurred at temperatures between 550 and 520 °C.

Fluoropolymers' high resistance to heat makes them ideal for use in extreme conditions and suitable for use in applications where high-temperature resistance is required, such as in the production of electronic components, industrial piping systems, and aerospace components.

The dossier submitters seem not to recognize that replacing fluoropolymers in these applications would lead to materials and/or applications of lower performance and shorter durability as well as putting safety at risk.

## *Durability*

Fluoropolymers are highly durable materials that can withstand harsh chemical environments, and extreme temperatures in demanding applications. Their exceptional resistance to degradation and long-term stability makes them valuable in a wide range of industries, including chemical processing, automotive, electronics, aerospace, and many more, as already discussed in the previous section.

The durability of fluoropolymers is a factor that helps enable EU sustainability goals:

28 https://www.rivm.nl/bibliotheek/rapporten/2021-0143.pdf

- Reduced Material Consumption: Fluoropolymers have a long lifespan meaning they do not need to be replaced as often compared to less durable materials. Such a benefit results in reduced material consumption and lower resource depletion. By using longer-lasting fluoropolymer components, industries can minimize waste generation and contribute to resource conservation.
- Lower Environmental Impact: As a durable and long-lasting material, fluoropolymers reduce the need for frequent manufacturing, transportation, and disposal associated with shorter-lived alternatives. This can result in lower energy consumption, reduced greenhouse gas emissions, and a smaller environmental footprint. By using durable fluoropolymers, industries can achieve a lower overall impact on the environment.

- Moreover, without the durability afforded by fluoropolymers EU strategic objectives e.g. the Net Zero Industry Act and Critical Raw Materials Act would be undermined. The extension of product life brought about fluoropolymers enables strategic technologies and reduces demand for critical raw materials.[29]

Fluoropolymers are durable in applications; they resist wear and tear and this means that applications made with fluoropolymers will last longer and require less maintenance over time. In transport applications for example, fluoropolymers are used to improve safety: they are used to in brake pads for their longevity, in tyres they enable resistance to degradation and enhance grip on different surfaces such as in slippery or icy conditions. Finally, they can be used to strengthen the frame of vehicles to reduce structural damage in the case of an accident. Fluoropolymers have been used for decades to provide durable and effective protection against heat, aggressive fluids and fuels, humidity, vibrations and compressions, they prolong the useful life of various components critical for performance, emission control, and safety to the aerospace industry.

Durability can be translated as persistence. Fluoropolymers, as all the PFAS substances, are among the most stable organic compounds due to the presence of the C-F bond. Fluoropolymers do not biodegrade and therefore can be considered persistent. Though the dossier submitters raise concerns on persistence, we interpret this being related to potential losses to the environment. FPG believes these can be adequately managed through the implementation of further responsible manufacturing and End of Life risk-management practices. This would be a proportionate regulatory approach which recognises their benign hazard profile and importance to the EU economy and society.

The definition for PFAS as described in the proposal includes thousands of different substances with very different properties and environmental and safety profiles. While persistence in the environment warrants close attention, persistence alone does not imply that there is a present or future risk to human health or the environment. As already discussed, fluoropolymers present insignificant risk for human health and the environment.



[29] https://publications.jrc.ec.europa.eu/repository/handle/JRC132889

Up to today, REACH has regulated persistence in the context of PBTs and vPvBs, where Persistence (P) must be associated with Bioaccumulation (B) and Toxicity (T) (or very Persistence (vP) must be associated with very Bioaccumulation (vB)) to justify qualification as a substance of very high concern (SVHC). Fluoropolymers are neither bio-accumulative nor toxic and therefore are not PBT substances. Likewise, fluoropolymers are non-mobile (M or vM) in the environment given their negligible solubility and have been demonstrated to have no systemic toxicity. The inertness and stability of fluoropolymers is precisely why they are used in many diverse applications of high societal value necessary for modern life (e.g., medical devices, renewable energy, and automotive and semiconductor applications).

To summarise:

- Fluoropolymers do not meet the REACH criteria for restriction: Fluoropolymers are durable, chemically stable, biologically inert, insoluble in water, and non-mobile. and as polymers of low concern, they pose no significant risk. Therefore, they do not meet the REACH criteria for restriction. Different regulatory measures as the IED, the WFD and the OHS could be implemented to address concerns related to fluoropolymers.

- Fluoropolymers pose no significant risk: The stability of fluoropolymers gives it unique, durable, lasting performance in critical uses and applications. A substantial body of scientific data demonstrates that fluoropolymers do not pose a significant risk to human health or the environment, because of their unique characteristics. Fluoropolymers have negligible solubility in water and cannot enter or accumulate in a person's bloodstream. Aside from being fluorinated polymers fluoropolymers do not meet any of the other criteria that are being suggested for polymers requiring registration.



## 4. Differentiation between fluoropolymers and other PFAS

A segmentation of the PFAS family according to known properties rather than a structure-based classification alone is needed for a risk-based regulatory approach and requests a general derogation for fluoropolymers under the PFAS REACH restriction.

PFAS substances are a large, diverse group with different chemical, physical, thermal, and biological properties. Among the substances defined as PFAS, there are distinct substances with very different properties: polymers and non-polymers, solids, liquids and gases; persistent and non-persistent substances; highly reactive and inert substances; mobile and insoluble (non-mobile) substances; and (eco) toxic and nontoxic chemicals. The term PFAS does not inform whether a compound presents a risk or not, but only communicates that the compounds under this term share the same structural trait of having a fully fluorinated methyl or methylene carbon moiety.[21]

PFAS are divided into 2 primary categories as shown in Figure 2 (below): the non-polymeric PFAS, which include perfluoroalkyl and polyfluoroalkyl substances, and the polymeric PFAS which include fluoropolymers, perfluoropolyethers, and side-chain fluorinated polymers.

Polymers generally have very different physical, chemical, and biological properties than do non-polymer chemical substances of low molecular weight.[22]

Fluoropolymers are high molecular weight plastics with unique properties attributable to the strong C–F bonds, the strongest bond between C and another atom, making them highly stable. Carbon atoms alone form the fluoropolymer backbone, each surrounded by a sheath of F atoms. An example is given in **Error! Reference source not found.Error! Reference source not found.**.

Fluoropolymers are of very high molecular weight have high thermal, chemical, photochemical, oxidative, hydrolytic, and biological stability. Fluoropolymers have low flammability, neutral electrical charge, and resistance to degradation and have negligible residual monomers and low molecular weight oligomer content. Fluoropolymers are negligibly soluble in water, non-mobile, non-bioavailable, non-bioaccumulative, and non-toxic.[22] Fluoropolymers have documented safety profiles and although they fit the PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS.[21]

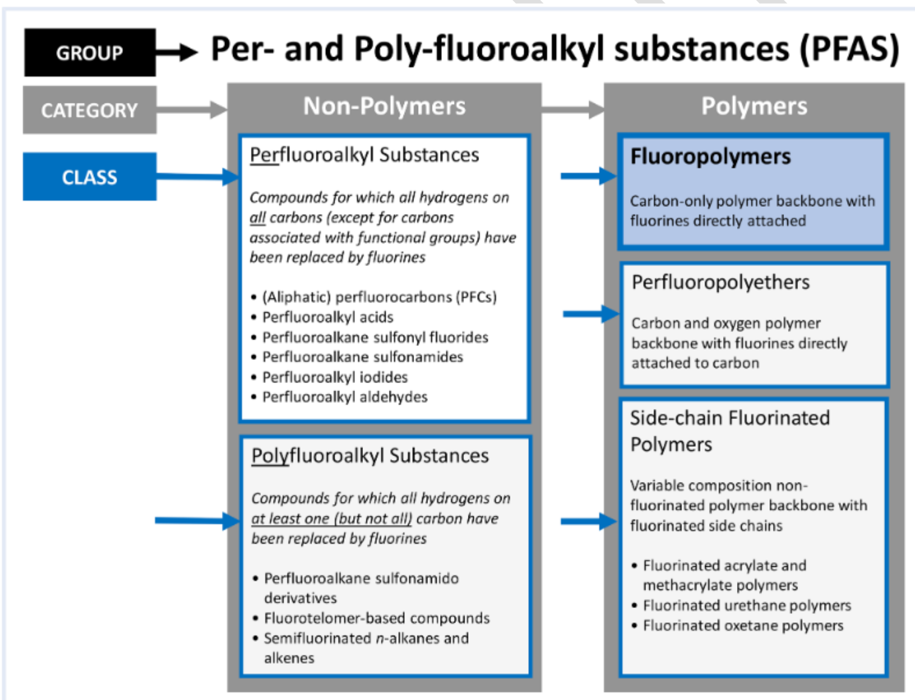


Figure 2. Per- and polyfluoroalkyl substances (PFAS).

Fluoropolymers are also very different in composition and structure as well as physical, chemical and biological properties to Side-Chain Fluorinated Polymers (SCFPs). Fluoropolymers such as polytetrafluoroethylene (PTFE) and polychlorotrifluoroethylene (PCTFE) are presented in

Figure 3, have a carbon atom backbone with fluorine atoms (F) and a chlorine atom bound to the polymer backbone carbon atoms. Fluoropolymers have molecular weights up to millions, meaning thousands of connected carbon atoms to which fluorine is bound.

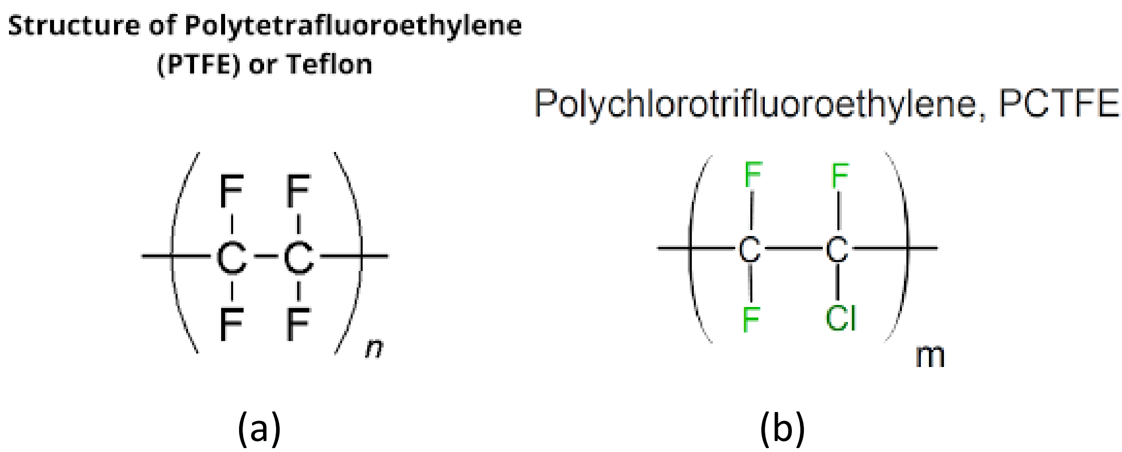


Figure 3. (a) Polytetrafluoroethylene (PTFE) and (b) polychlorotrifluoroethylene (PCTFE).

Side-Chain Fluorinated Polymers are a hydrocarbon polymer backbone with a polyfluoroalkyl side-chain connected to the backbone via functional group. The side-chain frequently contains a six-carbon perfluoroalkyl moiety as well as side-chains that have no fluorinated carbons. The structural representation is presented in Figure 4.

The polymer has a comb structure where some of the tines (aka teeth) are a side-chain with the perfluoroalkyl moiety (imagine six pearls, using the analogy above) while other side chains contain hydrocarbon functionality, no fluorine. The perfluoroalkyl moiety in SCFPs "can potentially lead to the formation of non-polymer PFAS as a result of degradation", something that is not possible with fluoropolymers.

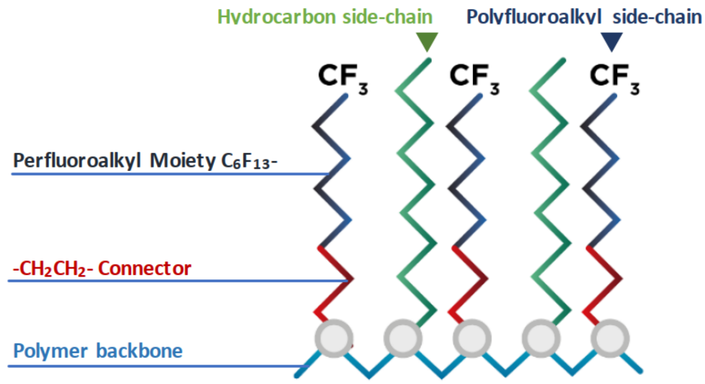


Figure 4. Side-chain fluorinated polymer structure.

In a recent peer-review scientific article, a panel of leading PFAS scientific experts agreed that the lack of knowledge about exposure, dose/body-burden-response relationships, relevant health effects, mode(s) of action, and potential interactions, does not allow for a science-based grouping of PFAS for the purposes of human health risk assessment.[30] Grouping fluoropolymers with all classes of PFAS for "read across" or structure–activity relationship assessment had been previously described as not scientifically appropriate.[22]

Although the grouping approach in chemicals is used by the authorities (such as ECHA) to speed up the identification of chemicals that need regulatory action and avoid regrettable substitution, different challenges that could lead to over-regulation have been identified when grouping the substances in the PFAS family.



[30] Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts, J.K. Anderson, Regulatory Toxicology and Pharmacology 134 (2022) 105226.
https://reader.elsevier.com/reader/sd/pii/S0273230022001131?token=491C969E3DFF3A8BAA1ED1DB5DE857A099CA9A77E6C66360F6950358F6A8860DA9D1EA68B3FEFCFDD5C713D1BBF2CD9A&originRegion=eu-west-1&originCreation=20230201115508

## 5. Life-Cycle analysis of fluoropolymers

*Responsible Manufacturing*

FPG Members have committed voluntarily to responsible manufacturing principles in terms of continuously improving and/or developing best available techniques in the manufacturing process, management of environmental emissions, development of R&D programs for the advancement of technologies allowing for the replacement of PFAS-based polymerization aids. However, during this transition, it is necessary to continue using fluorinated polymerization aids where needed, until non-PFAS polymerization aids are developed that are proven technically feasible, environmentally sound, meeting the performance and processing requirements and viable at an industrial and commercial scale.

The FPG members also work to increase in recyclability and reuse of its products in line with the objectives of circular economy.

The implementation of a Voluntary Industry Initiative to address concerns related to fluoropolymers strengthen the already on-going efforts performed by the fluoropolymer industry in ensuring responsible manufacturing practices. FPG members are committed to working with EU authorities to establish and implement the technical actions that may be required to guarantee adequate control of the risks derived from the manufacture and use of fluoropolymers, and remove such risks wherever possible, with a strong emphasis on R&D for the continued improvement of the manufacturing process. FPG members agree that concerns around emissions related to fluoropolymers at different phases of their lifecycle should be addressed, yet firmly believe a REACH restriction is not proportionate. Different regulatory measures such as the IED, as already discussed above, could be implemented to effectively control the emissions during manufacturing.

Emissions of concern may include non-polymeric PFAS such as fluorinated processing aids, unreacted PFAS monomers, PFAS oligomers, or other unintended by-products formed during manufacturing.

FPG members are committed to further reducing emissions. Whilst our manufacturing sites adhere to local and EU environmental regulations, we consider the need for constant improvement via evaluation of additional measures that can further enhance responsible stewardship.

Important emission reduction has been demonstrated by fluoropolymer manufacturers including fluorinated processing aid recovery for reuse, 99% removal of fluorinated processing aid in wastewater treatment, and 99.99% capture and destruction efficiency of gaseous emissions routed to a thermal oxidizer,[31] as well as 99–99.9 plant emission reductions.[32,33] Four companies have reported replacement of fluorinated processing aids with nonfluorinated processing aids for certain products, when performance is not sacrificed, and some companies use non-PFAS raw materials.[34,35,36,37,38]

The FPG members are collaborating, as an industry association, to share its best practices and continue to develop new technologies for emissions control to water and air and associated analytical techniques.

*Use Phase: Fluoropolymers are Polymers of Low Concern (PLC)*

The dossier submitters do not recognise the scientific evidence around the safety of fluoropolymers.

During the intended use-phase, fluoropolymers have documented safety profiles and 96% of the available commercial fluoropolymers are deemed to fulfil the OECD PLC criteria and, aside from being fluorinated polymers, do not meet any of the other EU criteria suggested for polymers requiring registration, demonstrating the insignificant risk they have on human health or the environment.

PLC criteria have been discussed and elaborated globally for decades to ensure international consistency. The criteria were created to facilitate polymer hazard assessment that identifies low risk polymers that in turn assists in prioritizing regulatory activity on high-risk substances.[21]

- In 1993, the Organisation for Economic Co-operation and Development (OECD) Expert Group on Polymers found that sufficient data existed to create a consensus document identifying the essential data elements to qualify a polymer as a PLC to human health and the environment.**Error! Bookmark not defined.**

- By 2007, the OECD Expert Group on Polymers agreed that, "Polymers of low concern are those deemed to have insignificant environmental and human health impacts"**Error! Bookmark not defined.** and in 2015 several countries agreed on the polymer properties

[31] Chemours. (2021c). Thermal oxidizer destroying PFAS at greater than 99.99% efficiency. https://www.chemours.com/en/-/media/files/corporate/ fayetteville-works/2020-0320-thermal-oxidizer-efficiency-resultsannounced.pdf?rev=87dbfd0ebb9c45aeaa475fddd2a899b4&hash= 05916EC2AC2B5A3C41135773A3FCDED0
[32] Daikin. (2021c). Daikin–A responsible steward for PFAS emission reductions and safe alternatives. https://www.daikinchem.de/sites/default/files/pdf/ News/Daikin_Responsible_Steward_PFAS_Emission_Reduction_ 210601.pdf
[33] Daikin. (2022). Measures concerning environment emission of PFAS. https://gfl.co.in/ upload/pages/ebce5fed9030753d0ee651bf1f48d0a0.pdf
[34] Arkema. (2008). Arkema eliminates fluorosurfactants from Kynar 500PVDF®. https://www.pcimag.com/articles/88876-arkema-eliminatesfluorosurfactants-from-kynar-500-pvdf
[35] Arkema. (2021b). Fluorosurfactant free KynarPVDF resin®. https://kynar500.arkema.com/en/product-information/fluorosurfactant-free/
[36] Chemours. (2022). Chemours announces process innovation with New Viton™ fluoroelastomers advanced polymer architecture (APA) offering. https://gfl.co.in/ upload/pages/ebce5fed9030753d0ee651bf1f48d0a0.pdf
[37] Gujarat Fluorochemicals Limited. (2022). Company announcement on the development of a non-fluorinated polymerization aid. https://gfl.co.in/ upload/pages/ebce5fed9030753d0ee651bf1f48d0a0.pdf
[38] Solvay. (2022). Innovating with non-fluorosurfactant technologies. https:// www.solvay.com/en/innovation/science-solutions/pfas

predictive of adverse human health and environmental hazard. The report outlined eligibility criteria for a polymer to be considered a PLC.**Error! Bookmark not defined.**

PLC criteria were developed over time within regulatory frameworks around the world as an outcome of chemical hazard assessment processes, which identified physical–chemical properties of polymers that determine polymer bioavailability and thereby report a polymer's potential hazard. For example, many of the physicochemical properties, such as molecular weight (MW), limit the ability of a polymer to cross the cell membrane and therefore limit its bioavailability.[21]

Thirteen PLC criteria that relate to the polymer structure and properties, including three to physicochemical properties and five to stability, set forth in BIO by Deloitte in 2015.**Error! Bookmark not defined.** A detailed description of the PLC criteria is provided in Annex I.

The extensive review conducted by Henry et al.[22] in 2018 concluded that 4 types of fluoropolymers including polytetrafluoro-ethylene (PTFE), fluorinated ethylene propylene (FEP), ethylene tetrafluoroethylene (ETFE), and tetrafluoroethylene copolymers with perfluoroalkyl vinyl ethers (e.g., perfluor-oalkoxy polymer, PFA), accounting for approximately 70% to 75% of the world fluoropolymer consumption in 2015, fulfil the PLC criteria. This study was supplemented by the review of Korzeniowski et al.[21] who additionally studied 14 types of fluoropolymers, including fluoroplastics and fluoroelastomers, and presented data to demonstrate that these fluoropolymers also satisfy the widely accepted polymer hazard assessment criteria to be considered as PLC. The full list of the studied fluoropolymers can be found in Annex II and the analysis and results of the PLC criteria for each of the eighteen fluoropolymers can be found in Supplementary Data.

The two scientific reviews of Henry et. al. and Korzeniowski et. al. proved that eighteen types of fluoropolymers which represent 96 % of the global commercial fluoropolymer market are polymers of low concern and are deemed to have low health and environmental hazards.

The properties and characteristics of fluoropolymers are anchored in the strength of the carbon–fluorine bond, rendering them highly stable (thermally, chemically, and biologically), inert, and durable, long lasting in use under exacting and high-performance conditions. Physical, chemical, thermal, and biological stability are important criteria for a polymer to be considered a PLC.[21]

The results of the latter studies add further evidence to demonstrate that fluoropolymers are demonstrably different when compared to other PFAS. In particular,

- Fluoropolymers are not mobile in the environment and are not bioaccumulative and not able to bioconcentrate.
- Fluoropolymers possess great stability in terms of light, hydrolysis, heat, oxidation, and biodegradation. When coupled with the lack of solubility, these fluoropolymers are most often characterized as relatively inert materials in the environment.
- Fluoropolymers are large molecules with no water solubility and are biologically inert without the practical ability to cross cell membranes.
- Fluoropolymers have negligible monomer, oligomer, and leachable content and no reactive functional groups with high toxicity. Therefore, their contribution to landfill

leachate is expected to be negligible.

Considering the above-mentioned studies and the fact that 96% of fluoropolymers meet the PLC criteria demonstrating the insignificant risk fluoropolymers have on human health or the environment during the intended use phase (and aside from being fluorinated polymers do not meet the other criteria for polymers requiring registration), the Fluoropolymers Product Group advocates for the segmentation of the PFAS family before performing any grouping-based hazard assessment for regulatory purposes. Environmentally stable compounds such as the fluoropolymers should be placed into a separate category as they are distinctly different from other polymeric and nonpolymeric PFAS. Grouping fluoropolymers with all classes of PFAS for 'read across' or structure–activity relationship assessment is not supported by the scientific data and does not take into account that there is no inherent risk from the materials itself and that risks related to manufacturing and end-of-life can be addresses by emission control laws.



## *End-of-life*

The dossier submitters consider that the end-of-life of all PFAS is a concern and that emissions are not adequately controlled.

At end-of-life when a fluoropolymer has fulfilled its intended use it may be disposed via the following routes: landfill, incineration (e.g., waste-to-energy [WTE] facilities), or reuse/recycling.

The January 2023 Conversio report "Fluoropolymer waste in Europe 2020" identifies that the 23.5 kt of fluoropolymer waste collected are mainly "*commercial and industrial waste streams, which are usually collected by private waste management or industrial service companies. Only a small proportion of FP waste is collected in residential or private waste streams, such as mixed residential waste, which is often collected on behalf of municipal waste collection services*".[7]

In 2020, around 23.5 kt of FP waste were collected. The investigation shows that the largest share of fluoropolymer waste is thermally treated (over 84%). 72% go into energy recovery or thermal destruction (metal recycling ~12%) processes. A small proportion of fluoropolymer waste of around 3% is recycled and the rest of fluoropolymers waste (around ~13%) is landfilled.

According to the above mentioned report, only 2.2Kt of fluoropolymer waste are potentially in the residential household waste and municipal waste generated by commercial activities which represent < 0.01% of the total municipal waste by weight.[7]

**Incineration**

Incineration of fluoropolymers is considered safe and effective. The Industrial Emissions Directive 2010/75/EU foresees that for municipal incinerators a minimum combustion temperature of 850 °C is required.

A recent literature study contracted by RIVM,[39] discussed the decomposition temperatures of fluoropolymers. RIVM's repost indicated that PTFE is the most thermally stable of all fluoropolymers, including fluorine-containing polymers that are only partially fluorinated such as polyvinylidene fluoride (PVDF) and ethylene-tetrafluorethylene (ETFE).

The study noted that PTFE can be used for a long time at 260 °C and for a short time up to a temperature of 450 °C without loss of mass due to the formation of fluorine-containing gases and that significant mass loss does only occur at temperatures of >550 °C. For the other polymers like EFTE degradation occurred at temperatures of around 470 °C.

As far as weight loss was concerned, it was noted that the order of relative thermal resistance for the different polymers is PTFE > PFA> MFA> FEP> ETFE > PVDF ≈ PE > ECTFE > PCTFE. For PFA, MFA and FEP significant weight loss occurred at temperatures between 550 and 520 °C.

The study concluded that PTFE's thermal decomposition is achieved at a temperature of about 800 °C and it can therefore be assumed that other fluorine-containing polymers also thermally decompose completely at a temperature of 800 °C (as PTFE is the most thermally stable of all). As a minimum combustion temperature of 850 °C is required for municipal incinerators it can be concluded that PTFE and other fluoropolymers are effectively degraded during incineration.

Regarding by-products generation, as almost 84% of fluoropolymers are incinerated at end-of-life, it is crucial to ensure emissions are well controlled and there is no release of by-products.

In recent pilot scale studies representative of full-scale WTE facilities, the most common form of end-of-life destruction conducted on PTFE found that combustion converted the fluorine into controllable hydrogen fluoride gas and that, of the 31 PFAS studied, no fluorine-containing products of incomplete combustion were produced above background levels.[40]

Further, a recent study investigating the presence of PFAS in waste incinerator flue gas stated: "based on a literature review, RIVM expects that most of the PFASs will largely degrade during the incineration process and then be removed when the flue gases are cleaned. The remaining PFASs are expected to be removed during the recovery of the carbon dioxide".[41]

Studies for additional fluoropolymers and those with additional pilot and/or full-scale fluoropolymer studies would contribute to this body of data and further affirm their results. In line with this, FPG members are currently carrying out incineration studies to identify potential emissions or generation of by-products during incineration of fluoropolymers.

A pilot-scale fluoropolymer incineration study recently conducted by FPG members under representative European municipal waste combustor conditions demonstrated that when fluoropolymers are incinerated, they are converted to inorganic fluorides and carbon dioxide. Four

[39] https://www.rivm.nl/bibliotheek/rapporten/2021-0143.pdf

[40] Aleksandrov, K., Gehrmann, H. J., Hauser, M., Matzing, H., Pigeon, D., Stapf, D., & Wexler, M. (2019). Waste incineration of polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and poly-fluorinated alkyl substances (PFAS) in flue gas. Chemosphere, 226, 898–906. https://doi. org/10.1016/j.chemosphere.2019.03.191

[41] Bakker, J., Bokkers, B., & Broekman, M. (2021). Per- and polyfluorinated substances in waste incinerator flue gases (RIVM Report 2021-0143). https://www.rivm.nl/bibliotheek/rapporten/2021-0143.pdf

fluoropolymers (PTFE, PVDF, PFA and FKM) representing more than 80% of the commercial fluoropolymer production incinerated as a mixture under standard operating conditions for municipal and industrial waste incineration. Experiments were conducted under two sets of conditions (860 °C and 1100 °C) over a period of 9 days.[12]

The study clearly demonstrated that fluoropolymers are converted to inorganic fluorides and carbon dioxide. The inorganic fluorides detected were hydrogen fluoride. A large majority of samples indicated that long chain PFAS were below levels of 1 ng/$m^3$. Additionally, no short chain PFAS detected post incineration, and TFA was non detectable in all samples with a reporting limit of 14 µg/$m^3$. These results confirmed that fluoropolymers at their end-of-life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment.

## Landfill

Around 13% of fluoropolymers are landfilled across Europe at the end-of-life. Fluoropolymers are chemically, thermally, and biologically stable[21,22] and therefore are not expected to transform to dispersive non-polymeric PFAS when disposed of in a landfill.

A recent study presented results from OECD guideline biodegradation studies demonstrating that PTFE is stable and does not degrade under environmentally relevant conditions (see further information below).[42] Further, fluoropolymers that meet the criteria to be considered PLC, have negligible leachables, unreacted monomers, and oligomers most likely destroyed in fluoropolymer use processing. Therefore, their contribution to landfill leachate is expected to be negligible.[42]

Independent laboratory studies have shown that fine powder PTFE meeting the ASTM D4895 is non-soluble in water and not biodegradable.

Degradation studies[43] which met the OECD guidelines were performed to investigate if PTFE could degrade in relevant environmental conditions. Among the different tests performed, OECD 105 Water Solubility, Ready Biodegradation OECD 301B and Inherent Biodegradation OECD 302C tests applied to investigate potential partitioning of PTFE to water and the potential of biodegradability. The results showed that the tested PTFE was insoluble in water and not biodegradable confirming the low probability of water exposure to PTFE degradants or leachables.

Additional studies to investigate the potential partitioning to soil included testing using the Molecular Weight OECD 118. PTFE was determined not to be sufficiently soluble for gel permeation chromatography even after sonication and stirring for 19 hours in tetrahydrofuran, dichloromethane, dimethylformamide, or dimethyacetamide. Using alternative methods of standard specific gravity and melt flow rheology, the molecular weight was determined to be above 500,000 Da. [43]

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[42] Ruwona and Henry. (2021). PTFE: Persistence without hazard at environmentally relevant temperatures and durable by design. Fluoros 2021, Providence, RI. https://www.ideals.illinois.edu/items/117612

[43] https://www.gore.com/system/files/2023-03/Summary-of-CRL-and-ALS-Studies-on-PTFE.pdf

The potential of PTFE partitioning to air was determined via the Molecular Weight OECD 118, Vapor Pressure OECD 104, Melting Temperature OECD 102, Thermal Stability OECD 113 and Thermal Gravimetric Analysis tests. The results showed lack of inhalation exposure potential at environmentally relevant temperatures.

PVDF has been tested according to OECD 301F – Aerobic biodegradability for 28 days showing. no biodegradation. PVDF has also been tested according to ASTM D5511 – Anaerobic biodegradability demonstrating no biodegradation after 90 days representing 6.25 years of landfill. Those two test methods are state of the art in environmental studies. In addition, in each test no presence of by-products in the environment has been detected.

These results show once again that fluoropolymers do not contribute to the environmental leachate and do not degrade.



**Recycling**

Many fluoropolymers (as they are thermoplastic materials) are theoretically mechanically recyclable. But as fluoropolymers are used predominantly in small components of larger finished articles involving a wide variety of materials, recycling is difficult for article complexity reasons.[21] The Conversio study showed that only around 3% of fluoropolymers are recycled across Europe.[7] The recycling of fluoropolymer materials today is often limited to 'clean' pre-consumer materials from fluoropolymers manufacturers. Only small volumes of post-consumer fluoropolymer materials are recovered for recycling.

The recycling of post-consumer fluoropolymers waste is limited to the recovery and separation of 'clean' fractions, e.g., from commercial and industrial production and processing equipment. The accessible quantity of post-consumer fluoropolymers waste suitable for recycling is significantly smaller. However, it should be noted that upcycling treatment is applicable to some articles containing fluoropolymers, such as pipe liners in chemical plants, as well as other plant components such as pumps, tank liners, seals, hoses, compensators, and many other fluoropolymer components and systems. These are the products for which the high quantities of fluoropolymers are used offering significant recycling potential.[21] The recycling might be encouraged through an adapted regulation.

The above data show that at the end-of-life stage, most of fluoropolymers are safely incinerated. Moreover, landfilling of fluoropolymers does not lead to contamination of leachates with PFAS as fluoropolymers do not degrade under relevant environmental conditions.

## 6. About the fluoropolymer manufacturing industry

Since the discovery of polytetrafluoroethylene (PTFE) in 1938, the use of fluoropolymers has grown considerably to take advantage of their unique physical–chemical, thermal, and biological properties.[22] Fluoropolymers have become critical components in numerous technologies, industrial processes and everyday applications ranging from the aviation industry to medical devices and energy production to technical apparel. Their use is so widespread that it is a challenge to identify and evaluate the full extent of the socio-economic benefits that they create.

They are durable, chemically inert and mechanically strong in harsh conditions, making them a critical chemical in many sectors, with few if any viable alternatives. Fluoropolymers' unique physicochemical properties are distinctly different when compared to other PFAS substances.

Several downstream industries depend on fluoropolymers, including automotive (including batteries), hydrogen production, semiconductor, 5G, medical applications, defense & aerospace as well as various industrial applications.

Fluoropolymers are helping to drive the competitiveness of EU industry as well as enabling major innovations across a wide range of critical industries. In addition, fluoropolymers are a key enabler of the European Green Deal and critical for long-term sustainability. They are used, for example, across smart mobility, clean energy and sustainable industry - and are used within various vital components of renewable energy installations, such as hydrogen and PV panels. In addition, they facilitate advanced energy storage and conversion technologies such as lithium-ion batteries.[44]

A recently published report from the Joint Research Centre (JRC) on the supply chain analysis and material demand forecast in strategic technologies and sectors in the EU showed that in order for the European Union (EU) to achieve the ambitious targets it has set for the energy and digital transitions and its defence and space agenda fluoropolymers are indispensable materials. In particular, fluoropolymers are key materials for the majority of the strategic technologies assessed including Li-ion batteries, fuel cells, wind turbines, solar photovoltaics, data transmission network, robotics and drones, making it apparent that fluoropolymers are needed for delivering the European Green Deal.[45]

A ban of fluoropolymers will likely lead to supply chain vulnerabilities with a potential reliance on third countries impacting the EU's ability to access the fluoropolymers it needs to develop strategic technologies.

As discussed in the JRC report and other literature studies,[46,47] for Li-ion batteries, Polyvinylidene fluoride (PVDF) and polytetrafluoroethylene (PTFE) are precursor materials for battery components. Regarding fuel cells, the graphene nanosheets in the proton exchange membranes are treated with PTFE. In the field of wind turbines, fluoropolymers are used as coatings on the towers and blades of wind power generators. Fluoropolymers are also used in solar photovoltaics as they are important for the protection of photovoltaic systems from harsh weather and stains. PTFE is also used in robotics and drones among the processed materials.[6]

[44] Regulatory management option analysis for fluoropolymers, Final report prepared for Fluoropolymers Group (FPG) of PlasticsEurope, ChemService, 2021

[45] Supply chain analysis and material demand forecast in strategic technologies and sectors in the EU – A foresight study, JRC, Publications Office of the European Union, 2023 https://op.europa.eu/en/publication-detail/-/publication/9e17a3c2-c48f-11ed-a05c-01aa75ed71a1/language-en

[46] Chemours, Renewable Energy Factsheet, Microsoft Word - Fluoropolymer Industry Fact Sheets.docx (chemours.com); Plastics Europe, RENEWABLE ENERGY Helping to innovate across smart mobility, clean energy and sustainable industry to achieve Green Deal objectives

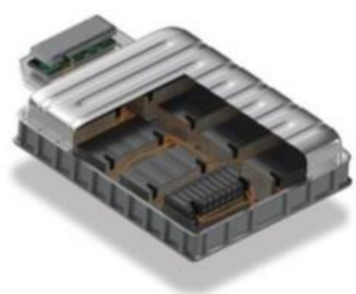
[47] Fluorostore, Fluoropolymer Applications in the Renewable Energy industry, 2022, Fluoropolymer Applications in the Renewable Energy industry — Fluorostore.

Other key applications of fluoropolymers include, but are not limited to, the following:[48]

- Automotive

Fluoropolymers have multiple applications in the automotive sector. Fluoropolymers are a key driver of vehicle durability and efficiency, including enhanced resistance to heat, cold, fire, aggressive fluids and fuels, moisture and compression in addition to improved fuel efficiency. The applications include HVAC, wire & cables insulation, parts in any fluid's pumps. Their use in the automotive sector can lead to a reduction in $CO_2$ emissions as well as reductions in fuel consumption. The growth of fluoropolymers in the automotive industry has been recognized as contributing to the projected global growth of the fluoropolymers market to EUR 9281.87 million by 2027. The CAGR is expected to be 5.2% over the 2021-2028 period.

- E-mobility



Fluoropolymers are an important component in fuel cells to allow the electrochemical reaction turning hydrogen and oxygen into electricity. Fuel cell applications (and electrolysers) are the hydrogen industry's fundamental technologies and alongside industrial processes (compression, purification, liquefaction storage components) are heavily reliant on fluoropolymers. The European Hydrogen Strategy aims to support an increase in renewable hydrogen from 1 million tonnes in 2024 to 10 million tonnes in 2030. As a result, growth in demand for fluoropolymers is expected, to help achieve these ambitious European targets.

Fluoropolymers are also key elements of safe and efficient Lithium-ion batteries. Fluoropolymers are used in a wide variety of battery components. A commonly used one is polyvinylidene fluoride (PVDF), serving as electrode binders and separator coatings in lithium-ion batteries, providing interconnectivity within each electrode, facilitating electronic and ionic conductivity, increasing the cell manufacturing productivity and the cell safety. Fluoropolymers have 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 closer and closer together, improving the energy efficiency of a single unit and helping reduce overall size. Fluoropolymers such as PVDF also offer high durability, flexibility and other exceptional mechanical properties when used in separators and gaskets, helping resist the harsh conditions faced within a lithium-ion battery. This dramatically improves



[48] Data taken from the Fluoropolymer Product Group of PlasticsEurope: Update of market data for the socio- economic analysis (SEA) of the European fluoropolymer industry, Final report. Wood Group UK Limited – May 2022.

performance, as well as the lifespan of batteries, which are increasingly used in applications that require a guaranteed and dependable level of output.

The sale of electric vehicles in Europe has increased from 0.2 million registrations in 2015 to 2.3 million registrations in 2021. This trend is expected to continue. PVDF is used in lithium-ion batteries which are used in electric vehicles. In 2021, ACEA reported a 10-fold increase in the sales of electric vehicles between 2017 and 2021 and it is anticipated that this growth will continue in the longer-term. The growth of fluoropolymers in the E-mobility sector is likely to follow a similar trend.

- Semiconductors

Fluoropolymers are a key component in semiconductor production infrastructure and the wider electronics industry due to their chemical resistance, high dielectric strength, resistance to high temperatures and high purity. Because of the chemical and thermal stability of fluoropolymers, they generally do not require the use of antioxidants, or other stabilizers, making them ideal for high-purity water applications. Among all fluoropolymers, the alternated CH2/CF2 structure of polyvinylidene fluoride (PVDF) allows for a particularly attractive combination of chemical and environmental resistance with excellent mechanical properties and mild processing conditions, thanks to their low melting point. All this, in combination with high-purity production technologies, constitutes the core of the value that PVDF, as well as other fluoropolymers, provide to the semiconductor industry, and other industries requiring the use of high-purity water.[49] As a result, demand for fluoropolymers in this sector is expected to rise reflecting the increase in demand for semiconductors themselves. The EU Chips Act is anticipated to aim for a doubling of the EU's current market share of semiconductor technology to 20% in 2030.

The global semiconductor market is projected to grow from €411.68 billion in 2021 to €731.11 billion in 20281 and is predicted to have a CAGR of 8.6% between 2021 and 2028.[48]

- Construction

One of the most common uses of fluoropolymers in the construction sector is for coating applications which ensure long lasting and weather-proof buildings. Fluoropolymer-based metal roofing coatings also enhance performance and save energy through solar reflection and reduced heat transfer to buildings. Due to an increased focus on energy and material efficiency of

[49] Fluoropolymer Applications in High-Purity Water Distribution Systems. Giovanni Biressi, Ph.D., Kris Haggard, Ph.D., and Brigitte Neubauer, Ph.D. December 2013. https://www.ultrapurewater.com/articles/misc/fluoropolymer-applications-in-high-purity-water-distribution-systems

buildings, it is therefore expected that fluoropolymers will continue to play an important role in construction. The global fluoropolymers market is projected to reach €9,281.87 million by 2027 and increasing spending on construction activities is seen as one of the biggest contributors to this.[48]

- Renewable energy

The growing concern of climate change has prompted the expansion of renewable energy use across Europe. 22.1% of the EU's energy consumption in 2020 came from renewable energy and the current target for 2030 has been set at 32% (a more ambitious target of 40% is being sought after). In 2020, the renewable energy sector was valued at EUR 802.61 billion and this is expected to reach €1,800.21 billion by 2030.48[48] The CAGR over the 2021-2030 period is projected to be 8.4%.[48]

As fluoropolymers, especially fluoropolymer films are widely used in this sector (e.g., photovoltaic front sheets, wind turbines and hydrogen fuel cells), the growth of fluoropolymers in this sector could be seen to follow a similar pattern to the growth of the sector itself.

- Advanced medical applications

In the medical field, fluoropolymers are used as a coating or insulation in surgically implantable medical devices such as vascular grafts and heart patches, diaphragm pumps, medical meshes, membranes for filtering and venting purposes, catheters, and MRI machines. Allied Market Research reports that "Due to strong biological applications such as artificial corneas and heart valves, the global fluoropolymer market is likely to report robust growth in the near future. Fluoropolymer is experiencing large-scale demand in the market".

- Chemical and process industry in general

Fluoropolymers are the material of choice for the chemical industry thanks to their unmet chemical and temperature resistance compared to other plastics and elastomers allowing to handle the chemicals and the reacted chemicals throughout the production process. They are also critical for system controls and safety devices such as sensors and control valves.

As an example, Ethylene Oxide requires fluoropolymers and is one of the most important raw materials used in large-scale chemical production: perfumes, cosmetics, pharmaceuticals, lubricants, paint thinners, plasticizers, brake fluids, detergents, solvents, lacquers, paints soap, detergents, natural gas purification, detergents, surfactants, emulsifiers and dispersants.

Ethylene oxide is a commonly used sterilization methods in the healthcare industry. The industrial applications include reactors, scrubbers, electrolytic cell liners, transport and storage tanks, tower packing, pipe, and fittings, all exposed to very aggressive chemicals.[50]

PVDF thanks to its inertness and corrosive materials high resistance is also a material of choice for chemical process industry. A chemical, food or nuclear plant is using fluoropolymers in many applications: fluids transportation, pumps, gaskets and other. Many of those applications being related to the safety and integrity of the process.

- Food and Pharmaceutical manufacturing

Fluoropolymers enable durable processing equipment, ensuring food freshness and pharmaceuticals purity as well as a high level of efficiency by preventing corrosion and facilitating cleaning. As they are durable, fluoropolymers play an important role in extending the lifespan of a range of products, such as flexible plastic-based food packaging. Fluoropolymer coatings on flexible plastic-based food packaging can help keep food fresh, thereby reducing food waste and helping the EU achieve its sustainability goals by reducing packaging sizes while delivering required moisture and barrier properties.

In the European biopharmaceutical manufacturing sector alone, €270 million was saved in 2012 compared to 2008 from contamination and material failure reductions. Such improvements can be attributed to a range of factors, but fluoropolymers play an important role in these efficiency gains.



Volumes of fluoropolymers[48]

In 2020, around 40,000 tonnes of fluoropolymers are estimated to be sold in both the EU28 and the EEA. Europe is currently a net exporter of fluoropolymers, with 49,000 tonnes estimated to be produced annually in the EU28/EEA, 24,000 tonnes exported outside of the EU28/EEA, and around 15,000 tonnes imported. The fluoropolymer producers in Europe anticipate sustained growth in the fluoropolymer market in the medium term (e.g., by 2025). Growth is expected to continue in the long term (e.g., until 2050), partly driven by increasing demand in several key sectors impacted by global mega-trends such as the energy transition and digitalisation. The Allied Market Research “fluoropolymers market” report [REF] indicated that the global fluoropolymers market is expected to grow at a compound annual growth rate (CAGR) of 6.5%

[50] Fluoropolymers for the Chemical Processing Industry Applications, May 2010. Conference paper by Alex Sant'Anna, J.K.Argazinski, Marcos R. Tristante https://www.researchgate.net/publication/327212578_Fluoropolymers_for_the_Chemical_Processing_Industry_Applications

from 2020 to 2027 due to various growth opportunities, including an increase in demand for high insulation materials in electrical and electronics applications; lightweight materials such as carbon fibre-reinforced polymers in automobiles and manufacturing components of aircraft, and also the use of fluoropolymers in various new and innovative applications in the construction, renewable, E-mobility, medical and chemical processing sectors. Whilst the EU is a net exporter of fluoropolymers today, that situation could change due to any number of factors, including uncertainty created by regulatory challenges to PFAS. In its foresight report 2023, the JRC underlines that dependencies and vulnerabilities are present in various steps of the value chain. The supply of raw materials is not the only challenge, but also their processing, refining and manufacturing. Sometimes, as in the case of solar PV and digital technologies, dependencies extend throughout the complete value chains. In identifying and managing vulnerabilities and bottlenecks, attention should be given to the fact that the development of capacity at one stage of the value chain cannot happen without ensuring sufficiency in the previous steps.[51]

# 7. Socio-Economic Analysis (SEA) of fluoropolymers[48]

Quantities of fluoropolymers

As can be observed in Table 2, and mentioned previously in this consultation response, the results in terms of tonnages of fluoropolymers on the European market are approximately the same for the EU28 and the EEA (after rounding). Around 40,000 tonnes of fluoropolymers are estimated to be sold in both the EU28 and the EEA. Europe is a net exporter of fluoropolymers, with 49,000 tonnes estimated to be produced annually in the EU28/EEA, 24,000 tonnes exported outside of the EU28/EEA, and around 15,000 tonnes imported.

This reflects a drop of about 23% in sales of fluoropolymers in Europe in 2020 compared to 2015 (the 2016-2017 fluoropolymer SEA study), which has resulted mostly in a drop of fluoropolymer imports (-30%) and only a small drop in fluoropolymer production (-4%) in Europe, while exports have even increased (+17%) over the same period.

A key caveat of the market data presented here and the comparison to the 2015 data, is that in the 2016-2017 Fluoropolymer SEA study, original survey results were extrapolated using an external reference[52] on the size of the whole EU market, because the Fluoropolymers Product Group members that participated in the survey did not cover the whole European market. Such an extrapolation has not been undertaken for the present report, because (1) more companies have participated in the new survey for the present study, representing the European market more completely than the previous survey for the 2016-2017 Fluoropolymer SEA study, and (2)

[51] Supply chain analysis and material demand forecast in strategic technologies and sectors in the EU – A foresight study Carrara, S., Bobba, S., Blagoeva, D., Alves Dias, P., Cavalli, A., Georgitzikis, K., Grohol, M., Itul, A., Kuzov, T., Latunussa, C., Lyons, L., Malano, G., Maury, T., Prior Arce, A., Somers, J., Telsnig, T., Veeh, C., Wittmer, D., Black, C., Pennington, D. and Christou, M., https://publications.jrc.ec.europa.eu/repository/handle/JRC132889

[52] ECHA, 2014. ANNEX XV PROPOSAL FOR A RESTRICTION – Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances. https://echa.europa.eu/documents/10162/e9cddee6-3164-473d-b590-8fcf9caa50e7

because of a lack of an up-to-date external reference on the size of the whole EU market that is similarly reliable as the one used for the 2016-2017 Fluoropolymer SEA study. This could mean that the new numbers presented in this report are a slight underestimate of the whole EU market, and the comparison to the 2015 numbers is slightly skewed towards a decline (or smaller growth). However, it is expected that the market coverage of the data presented here is high, considering that the main companies supplying fluoropolymers to the European market have participated in the survey for this report.

Table 2. Quantities of fluoropolymers sold in Europe per year.[48]

| Quantities (tonnes) | EEA in 2020 | EU28 in 2020 | EU28 in 2015 | % change in EU28 2015-2020 |
|---|---|---|---|---|
| Tonnes produced in the EU28 / EEA | 49,000 | 49,000 | 51,000 | -4% |
| Tonnes imported into the EU28 / EEA | 15,000 | 15,000 | 21,500 | -30% |
| Tonnes exported from the EU28 / EEA | 24,000 | 24,000 | 20,500 | +17% |
| **Tonnes sold in the whole EU28 / EEA** | **40,000** | **40,000** | **52,000** | **-23%** |

Source: Wood / Amec Foster Wheeler Surveys with Members of the FPG, 2016 and 2021. Tonnages are rounded to the closest 500 tonnes. Note the following important caveat when comparing 2015 and 2020 data: 2015 data had been extrapolated from original survey data, whereas 2020 data has not been extrapolated as the underlying survey covered a larger number of companies than in 2015 (see also further explanation of this caveat in the text above this table).

The fluoropolymer producers anticipate strong growth in the fluoropolymer market in the medium term (e.g., by 2025) due to the recovery from the COVID-19 pandemic which compressed the market in 2020, the year of the baseline data shown above.

Growth is expected to continue in the long term (e.g., until 2050), partly driven by increasing demand in several key sectors impacted by global mega-trends such as the energy transition and digitalisation. The Allied Market Research5 "fluoropolymers market" report indicated that the global fluoropolymers market is expected to grow at a compound annual growth rate (CAGR) of 6.5% from 2020 to 2027 due to various growth opportunities, including an increase in demand for high insulation materials in electrical and electronics applications; lightweight materials such as carbon- fibre-reinforced polymers in automobiles and manufacturing components of aircraft;, and also the use of fluoropolymers in various new and innovative applications in the construction, renewable, E- mobility, medical and chemical processing sectors.

Revenues

According to FPG members, sales of fluoropolymers onto the EEA market generate a revenue of around €750 million per year, and sales onto the EU28 market generate €740 million per year, as seen in Table 3. Just over a billion Euros worth of fluoropolymers are produced in the EU28/EEA, with the value of exports (€550 million) more than twice the sales value of imports (€270 million).

It is important to note that this is the value of sales of fluoropolymers in basic form; this is just the first stage of the value chain. The value of the final products made using fluoropolymers would be substantially greater.

Compared to 2015, the total value of fluoropolymers sold in the EU28 has slightly decreased (-5%), as has the value of imports (-13%), while the values of production (+23%) and especially exports (+45%) have experienced strong growth. The average sales value per tonne has increased for production (+28%), import (+25%), export (+24%) and sales (+23%). It can also be observed that the average values per tonne of fluoropolymers produced in Europe (€21,000) and exported from Europe (€23,000) are significantly higher than the average values per tonne of fluoropolymers imported into (€18,000) and sold (€19,000) in Europe. This could indicate the European producers are increasingly focusing on the higher value market.

The data presented here and the comparison to the 2015 data is subject to the same caveat as the tonnages presented above, namely that in the 2016-2017 Fluoropolymer SEA study, original survey results were extrapolated to the whole EU market, while the survey presented in the present report is expected to already cover a high share of the market and has not been extrapolated.

Table 4. Sales of fluoropolymers onto the EEA market.

| Quantities (€m) | EEA in 2020 | EU28 in 2020 | EU28 in 2015 | % Change in EU28 2015-2020 |
|---|---|---|---|---|
| Sales value of product produced in the EU28 / EEA | 1,030 | 1,030 | 840 | +23% |
| Sales value of imports into the EU28 / EEA | 270 | 270 | 310 | -13% |
| Sales value of exports from the EU28 / EEA | 550 | 550 | 380 | +45% |
| **Total value sold in the whole EU28 / EEA** | **750** | **740** | **780** | **-5%** |

Source: Wood / Amec Foster Wheeler Surveys with Members of the FPG, 2016 and 2021. Notes: Rounded to the closest €10m. Due to rounding, the sum of production and imports minus exports does not match the total sales. Note the following important caveat when comparing 2015 and 2020 data: 2015 data had been extrapolated from original survey data, whereas 2020 data has not been extrapolated as the underlying survey covered a larger number of companies than in 2015 (see also further explanation of this caveat in the text above this table).

<u>Employment</u>

- Direct employment (manufacturing of fluoropolymers in basic form)

In terms of employment, in total, 43,800 people are employed in the FPG companies in the EU28, and roughly the same number in the EEA. This is an increase of about 38% compared to 2015, as presented in Table 5. In their survey responses, FPG companies also estimated the number of their employees directly related to the production of fluoropolymers in their basic form. This indicates that some 4,500 employees are involved across the EU28, and roughly the same number in the EEA. This is about twice the figure from 2015.

Considering that a reduction in production volumes was observed over the same period, it stands to reason that the increase in employment directly associated with fluoropolymer manufacture reflects at least to some extent either (1) a difference in interpretation in which employees are counted as “directly associated with fluoropolymer manufacture” in the new survey responses compared to those undertaken for the previous study, or (2) an underestimate in the 2016-2017 Fluoropolymer SEA study due to the extrapolation of original survey results to the whole EU market (see also more detailed discussion on extrapolation in the 2016-2017 Fluoropolymer SEA study in Section 3.1), or (3) that the Covid-19 pandemic has led to a temporary contraction of production and sales for 2020 but not to a reduction in employees.

Table 5. Total employment in surveyed companies and direct employment associated with European fluoropolymer production.

| Number of employees | EEA in 2020 | EU28 in 2020 | EU28 in 2015 | % change in EU28 2015-2020 |
|---|---|---|---|---|
| Total number of employees in the FPG Member Companies | 43,800 | 43,800 | 31,700 | +38% |
| Employment directly associated with fluoropolymer manufacture in the FPG Member Companies (first stage in value chain only) | 4,500 | 4,500 | 2,200 | + 103% |

Source: Wood / Amec Foster Wheeler Surveys with Members of the FPG, 2016 and 2021. Note the following important caveat when comparing 2015 and 2020 data: 2015 data had been extrapolated from original survey data, whereas 2020 data has not been extrapolated as the underlying survey covered a larger number of companies than in 2015 (see also further explanation of this caveat in the text above this table).



Indirect Employment

In any industry, the effect of economic activity extends beyond the direct sales of the product. Economic multipliers are used to quantify these further indirect effects, as they are ‘multiplied’ through the economy via several spending rounds. These multipliers enable an estimate of the economic effects of the industry via three channels of effect:

- Direct impact: This relates to the activities of the industry itself, such as production of fluoropolymers, the sales/value added, and the number of people directly employed from it. These were discussed in the previous sections of this report.
- Indirect impact: Also called a supply linkage multiplier, this reflects additional purchases made by the fluoropolymer industry itself (on raw materials, energy etc.) and further purchases with other linked firms along the supply chain (i.e. the purchases made by the companies providing fluoropolymer manufacturers with raw material, for example), as well as the employment resulting from that.
- Induced impact: Also called a consumption or income multiplier, this reflects expenditure – often local – of those who earn income from the direct and indirect effects described

above. For example, this would include the purchase of a new car, house or holiday, by one of the employees of the fluoropolymer manufacturers.

Direct, indirect and induced gross value added (GVA) and the associated employment are estimated based on the methodology described in the Wood Group UK Limited final report (Update of market data for the socio- economic analysis (SEA) of the European fluoropolymer industry), which can be found in Supplementary Data.

Table 6 summarises the results. Note that these results should be considered indicative only, given that they are based on a range of assumptions as outlined in the methodology.

Overall, while around 4,500 employees are directly employed in the manufacture of fluoropolymers, we estimate that employment associated with indirect and induced value added could be in the order of 4,400 people. This suggests some 8,900 people in total are sustained directly and through indirect and induced effects by the production of fluoropolymers. The results are approximately the same for the EU28 and the EEA (after rounding).

Table 6. Summary of results from the multiplier analysis for indirect and induced employment supported by the fluoropolymer industry in the EU (number of employees).

| | EEA | EU28 |
|---|---|---|
| **Employment (direct)** | 4,500 | 4,500 |
| **Estimated employment associated with indirect and induced GVA** | 4,400 | 4,400 |
| **Total employment (direct, indirect and induced)** | 8,900 | 8,900 |

Sources: Wood, based on result of survey with FPG members, Eurostat annual detailed enterprise statistics for industry (value added at factor cost in percentage of production value and gross value added per employee, EU28 in 2018), Eurostat basic breakdowns of main GDP aggregates and employment (gross value added and employment, EU28 in 2019), and multipliers derived from Eurostat output multipliers for 2019.
Key assumptions: Value added is 20.9% of fluoropolymer production value, indirect and induced GVA multiplier is 2.5, average GVA per employee in relevant industries is €100,000 (see Appendix A for more details).
Note numbers have been rounded to the closest 100 employees.

Beyond the economic impacts of the fluoropolymer industry itself, fluoropolymers are further processed into products and used as components in more complex objects (products that consist of multiple components from different materials such as cars, electronic devices, buildings, etc.). The production of these products, which fluoropolymers are a part of, generate further economic activity and associated employment. These are not covered within the estimates provided above.

Sales of fluoropolymers to downstream users

Sector breakdowns are only shown for the EEA here. As shown under Revenues and Volume of use sections, the overall size of the market is nearly identical for the EU28 and the EEA (after rounding), and so no differences in the sector breakdown can be observed after rounding between these two geographies.

The FPG survey obtained data on the volume and value of fluoropolymer sales disaggregated into the various downstream sectors where they are further processed into final products. Data has been collected according to two different sector breakdowns, in order to ensure both comparability with the previous data collected for the 2016-2017 Fluoropolymer SEA study, and compatibility with the new data needs for the current PFAS restriction proposal.

The first sector breakdown is shown in Table 7, and visualised in Figure 5 also below. According to this breakdown, transport (15,500 tonnes worth €280 million) and chemical and power (11,000 tonnes worth €200 million) were by far the largest sectors in 2020. Compared to 2015, in terms of tonnages, most sectors remained stable (electronics, renewable energy) or experienced a decrease in volumes which was most pronounced for medical applications (-67%) and textiles and architecture (-50%). The only exception was “other sectors” (not elsewhere classified) which grew by about 50%. However, in terms of sales values, several sectors experienced significant growth, namely renewable energy (+300%), electronics (+40%) and “other sectors” (+100%).

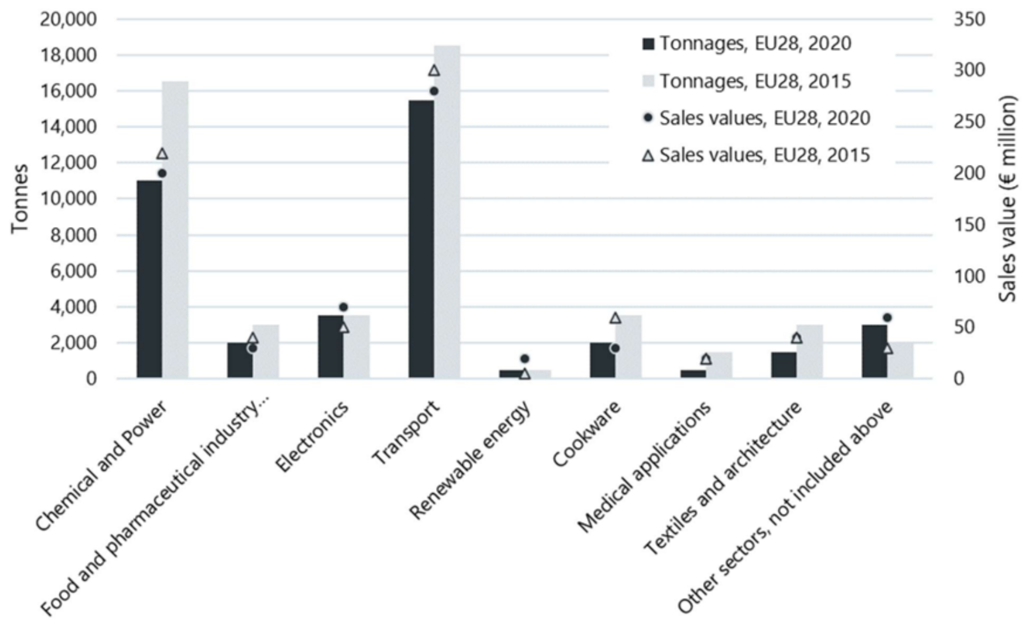
It should be noted that the attribution of sales of fluoropolymers in basic forms to downstream sectors is complicated and can be uncertain, among other reasons because certain products that fluoropolymers are used in can be applied in many different sectors (e.g., cables in electronics and transportation). This means that the comparison between 2015 and 2020 data could be distorted if companies (on average) have reported the downstream user sectors of their products differently, especially since additional companies have participated in the current survey that did not participate in the previous one.

The data presented here and the comparison to the 2015 data is also subject to the same caveat as the tonnages and revenues presented in previous sections, namely that in the 2016-2017 Fluoropolymer SEA study, original survey results were extrapolated to the whole EU market, while the survey presented in the present report is expected to already cover a high share of the market and has not been extrapolated.

Table 7. Downstream applications of fluoropolymers in Europe (tonnes and value) - First sector breakdown (as in 2016-2017 Fluoropolymer SEA study).

| Sector | Total quantity sold (tonnes) | | | Total value (€ million) | | |
|---|---|---|---|---|---|---|
| | In 2020 | In 2015 | % change 2015-2020 | In 2020 | In 2015 | % change 2015-2020 |
| Chemical and Power | 11,000 | 16,500 | -33% | 200 | 220 | -9% |
| Food and pharmaceutical industry (F&P) | 2,000 | 3,000 | -33% | 30 | 40 | -25% |
| Electronics | 3,500 | 3,500 | +/- 0% | 70 | 50 | +40% |
| Transport | 15,500 | 18,500 | -16% | 280 | 300 | -7% |
| Renewable energy | 500 | 500 | +/- 0% | 20 | <5 | +300% |
| Cookware | 2,000 | 3,500 | -43% | 30 | 60 | -50% |
| Medical applications | 500 | 1,500 | -67% | 20 | 20 | +/- 0% |
| Textiles and architecture | 1,500 | 3,000 | -50% | 40 | 40 | +/- 0% |
| Other sectors, not included above | 3,000 | 2,000 | +50% | 60 | 30 | +100% |
| **Total** | **40,000** | **52,000** | **-23%** | **740** | **780** | **-5%** |

Source: Wood / Amec Foster Wheeler Surveys with Members of the FPG, 2016 and 2021. Note all sales values are rounded to the nearest €10m all tonnage data are rounded to the nearest 500 tonnes. Note the following important caveat when comparing 2015 and 2020 data: 2015 data had been extrapolated from original survey data, whereas 2020 data has not been extrapolated as the underlying survey covered a larger number of companies than in 2015 (see also further explanation of this caveat in the text above this table).




Source: Wood / Amec Foster Wheeler Surveys with Members of the FPG, 2016 and 2021. Note all sales values are rounded to the nearest €10m all tonnage data are rounded to the nearest 500 tonnes. Note the following important caveat when comparing 2015 and 2020 data: 2015 data had been extrapolated from original survey data, whereas 2020 data has not been extrapolated as the underlying survey covered a larger number of companies than in 2015 (see also further explanation of this caveat in the text above this table).

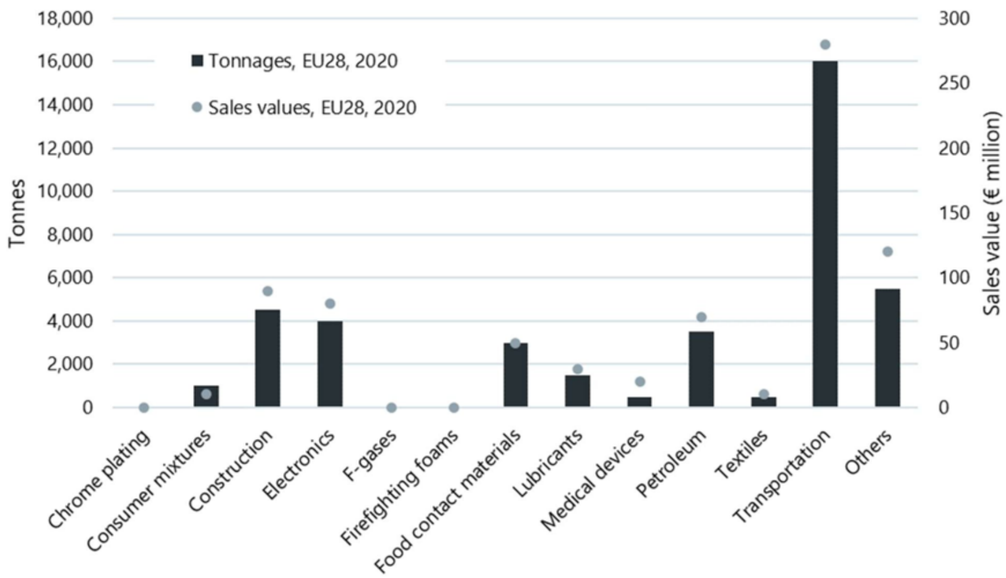
Figure 5. Downstream applications of fluoropolymers in Europe (tonnes and value) - First sector breakdown (as in 2016-2017 Fluoropolymer SEA study).

The second sector breakdown is shown in Table 8 and visualised in Figure 6. According to this breakdown, transportation is the largest sector by far (16,000 tonnes worth €280 million). Other large sectors include construction (4,500 tonnes worth €90 million), electronics (4,500 tonnes worth €80 million), petroleum (3,500 tonnes worth €70 million), food contact materials (3,000 tonnes worth €50 million) and “others” (not elsewhere classified; 5,500 tonnes worth €120 million). According to the FPG survey, fluoropolymers are not sold into the sectors chrome plating, F-gases or fire-fighting foam. For sectors where fewer than three FPG Members have indicated sales tonnages and values, the data cannot be disclosed (marked “confidential” in the table below).

Table 8. Downstream applications of fluoropolymers in Europe (tonnes and value) – Second sector breakdown (as in studies supporting PFAS restriction proposal)

| Sector | Total quantity sold (tonnes) in 2020 | Total value (€ million) in 2020 |
|---|---|---|
| Chrome plating | 0 | 0 |
| Consumer mixtures | 1,000 | 10 |
| Cosmetics | Confidential | Confidential |
| Construction | 4,500 | 90 |
| Electronics | 4,000 | 80 |
| F-gases | 0 | 0 |
| Firefighting foams | 0 | 0 |
| Food contact materials | 3,000 | 50 |
| Lubricants | 1,500 | 30 |
| Medical devices | 500 | 20 |
| Petroleum | 3,500 | 70 |
| Mining | Confidential | Confidential |
| Ski wax | Confidential | Confidential |
| Textiles | 500 | 10 |
| Transportation | 16,000 | 280 |
| Others | 5,500 | 120 |
| Total | 40,000 | 740 |

Source: Wood Survey with Members of the FPG, 2021. Note all sales values are rounded to the nearest €10m all tonnage data are rounded to the nearest 500 tonnes. Due to rounding, the sum of the values for individual sectors does not match the total. "Confidential" indicates sectors where fewer than three FPG Members have indicated sales.




Source: Wood Survey with Members of the FPG, 2021. Sectors with confidential data not shown (Cosmetics, Mining, Ski Wax). Note all sales values are rounded to the nearest €10m all tonnage data are rounded to the nearest 500 tonnes.

Figure 6. Downstream applications of fluoropolymers in Europe (tonnes and value) - Second sector breakdown (as in studies supporting PFAS restriction proposal), excluding confidential sectors.

“Energy” has not been classified as its own sector, and it is inherently difficult to distinguish from other sectors using the same types of products that contain fluoropolymers. Examples of applications that overlap between energy and other sectors include:

- Fluoropolymer cable coatings can be used in the energy sector as well as in electronics, transportation, and other sectors.
- Fluoropolymer pipe linings, vessels, valves, pumps etc. can be used in the energy sector as well as in the petroleum, construction, food processing, and other industries.

Based on a combination of the data from relevant sectors in the first sector breakdown and input from Members of the FPG, it is estimated that, if “energy” (excluding petroleum) were classified as its own sector, it would likely account for around 1,000 tonnes to several thousand tonnes of sales of fluoropolymers. This would be equivalent to about €20 million up to the low hundreds of millions in terms of sales value.

# 8. Fluoropolymers and the proposed PFAS REACH restriction

The FPG argues that a segmentation of the PFAS family according to known properties rather than a structure-based classification alone is needed for a risk-based regulatory approach and requests that fluoropolymers are not regulated under the PFAS REACH restriction. Instead, different regulatory measures can be implemented to address concerns related to fluoropolymers such as the IED, the WFD and the OHS.

The PFAS REACH restriction proposal looks at addressing the concerns around these materials by grouping more than 10,000 substances. The grouping approach is based on structural considerations, rather than on their physicochemical or biological properties: PFAS are taken to be organic fluorine compounds that contain at least one perfluoroalkyl (CnF2n+1–) group, with n ≥ 1.[20] This definition was later broadened to also include perfluoroalkylene groups (–CnF2n–, n ≥ 3) and perfluoroalkylene ether groups (–CnF2nOCmF2m–, with both n and m ≥ 1) (OECD, 2018). In a further expansion of the structural definition, the scope of the Call for Evidence launched by five EEA Member States in 2020, to assess PFAS in scope of the drafting of a proposal for a REACH restriction, included substances that contain at least one aliphatic -CF2- or -CF3 element.[53] The dossier submitters consider as PFAS any substance which contains at least one aliphatic -CF2- or -CF3 element (without any H/Cl/Br/I attached to it).

Contrary, the UK Health and Safety Executive (HSE) who recently published the analysis of the most appropriate regulatory management options (RMOA) for PFAS in the UK has narrowed the definition of PFAS.[54] The UK HSE in the RMOA removed the criterion that a single isolated methylene group (–CF2–) is sufficient for classification as a PFAS and considered that PFAS are defined as fluorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), or two or more contiguous perfluorinated methylene groups (–CF2–) limiting the number of PFAS in scope to hundreds of substances.

In UK's RMOA, the HSE did not prioritise fluoropolymers for regulatory measures and considered that a restriction would not apply to low hazard groups as for example fluoroplastics or fluoroelastomers.

As noted in the Annex XV report, the main concern of the PFAS substances is the property of persistence, which for some types of PFAS, is also associated with bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects.

Fluoropolymers are durable materials and therefore persistent. However, as already discussed they do not bioaccumulate, they are non-mobile and non-toxic, therefore rendering their restriction under the PFAS proposal unjustified. Regulating all PFAS as one homogenous group may result in non-replaceable fluoropolymers being unjustly banned from critical applications with high societal value.

[53] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b
[54] https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf

The restriction proposal also mentions that most PFAS are either mobile in water or accumulate in biota, and both lead to unavoidable exposure of humans and the environment, and refers to groundwater, surface water contamination. This assumption however is not supported by scientific data for fluoropolymers. Fluoropolymers are high molecular weight substances which are not mobile and do not accumulate. The grouping approach in this case is not scientific sound and a total ban of all PFAS including fluoropolymers is not the most appropriate and effective option to adequately control such a large and complex group of substances which are used in numerous applications as the different groups have different physicochemical properties, and toxicological profiles.

In a recent peer-review scientific article, a panel of leading PFAS scientific experts agreed that the lack of knowledge about exposure, dose/body-burden-response relationships, relevant health effects, mode(s) of action, and potential interactions, does not allow for a science-based grouping of PFAS for the purposes of human health risk assessment.[55] Grouping fluoropolymers with all classes of PFAS for "read across" or structure–activity relationship assessment had been previously described as not scientifically appropriate.[22]

Although the grouping approach in chemicals is used by the authorities (such as ECHA) to speed up the identification of chemicals that need regulatory action and avoid regrettable substitution, different challenges that could lead to over-regulation have been identified when grouping the substances in the PFAS family.

In particular,

- When assessing human health risk, properties such as toxicity, bioaccumulation, toxicokinetics, and exposure profiles should be considered. These characteristics could vary among different PFAS.
- Similarly, grouping all PFAS together as "persistent" is not supported as practical nor appropriate for assessing human health.
- There is not a global harmonized definition of PFAS. The term "PFAS" is broad, general, and nonspecific, which does not inform whether a compound presents risk or not, but only communicates that the compounds under this term share the same structural trait of having a fully fluorinated methyl or methylene carbon moiety.
- Most PFAS risk assessments will need to employ substantial assumptions and defaults. These assumptions are often multiplicative and can lead to overestimates of both potency and exposure, and therefore, over-regulation.[55]

[55] Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts, J.K. Anderson, Regulatory Toxicology and Pharmacology 134 (2022) 105226.
https://reader.elsevier.com/reader/sd/pii/S0273230022001131?token=491C969E3DFF3A8BAA1ED1DB5DE857A099CA9A77E6C66360F6950358F6A8860DA9D1EA68B3FEFCFDD5C713D1BBF2CD9A&originRegion=eu-west-1&originCreation=20230201115508

FPG commissioned the consulting firm ChemService to perform an independent Regulatory Management Option Analysis (RMOA) for fluoropolymers (FPs) to ensure decisions are taken based on scientific facts and evidence (the RMOA can be found in attachment with this submission).

Chemservice performed a screening of Risk Management Options (RMOs) which led to the following RMOs:

- RMO 1: full restriction leading to a practical ban or elimination of FP manufacture and use from the EU.
- RMO 2: partial restriction including a derogation of FP manufacture and uses but a ban on the use of PFAS polymerization aids for the manufacture of FPs.
- RMO 3: restriction including a broad derogation to allow continued manufacture and use of FPs in the EU, linked to a Voluntary Industry Initiative which guarantees that industry will address the situations of concern related to manufacture and use of FPs.
- RMO 4: update of existing EU regulations on waste that would impact the end-of-life treatment of FP products and articles.

The outcome of the RMOA, which intended to identify the most appropriate instrument to address potential concerns related to fluoropolymers and to provide the best possible balance between risk control and enhancement of the competitiveness of the European industry, showed that <u>the inclusion of fluoropolymers in the REACH restriction of PFAS would not be an adequate regulatory option</u>.

Chemservice's RMOA concluded that full restriction is not the most effective tool to meet these objectives set by the five competent authorities. Instead, a combination of

- restriction including a broad exemption for fluoropolymers and relevant monomers from the PFAS REACH restriction supplemented by a Voluntary Industry Initiative which guarantees that industry will address the situations of concern related to manufacture and use of FPs (RMO3) and,
- an update of existing EU regulations on waste that would impact the end-of-life treatment of FP products and articles (RMO 4) is the most appropriate approach to ensure adequate control of risks, while maintaining a proportionate balance in terms of use of necessary fluoropolymers on the European market.

The FPG believes that the restriction proposal significantly underestimates the breadth of use and importance of fluoropolymers use in key applications, their benefits to society, their instrumental role with regards to the EU ambitions in climate and energy, and economic growth, enabling quality of life for European citizens as well as the lack of viable alternatives to replace them. The difficulty to replace them as well as potential time of alternative solution development and implantation is also underestimated.

FPG believes that the concerns of persistence raised by the dossier submitters can be appropriately managed through the implementation of different regulatory measures and responsible manufacturing and end-of-life risk-management practices and therefore requests that fluoropolymers are not regulated under the PFAS REACH restriction.

The suggested concerns by the dossier submitters related to fluoropolymers can be appropriately managed through the implementation of different regulatory frameworks together with responsible manufacturing and End-of-Life risk-management practices. Regulatory frameworks such as the Industrial Emissions Directive, the Waste Framework Directive, and the Occupational Health and Safety Directive can address the concerns related to fluoropolymers effectively and quickly.

# 9. Alternatives

Fluoropolymers are a distinct type of fluorinated polymers that can be clearly distinguished from other Per- and polyfluoroalkyl substances (PFAS) as they have different physicochemical properties and toxicological profiles.

Their combination of properties such as unmatched chemical and temperature resistance and unique electrical performance and durability, render them ideal materials for a wide range of applications and ideal materials that enable the development of innovative technologies.

The dossier submitters state that a move away from using fluoropolymers to alternative materials in many applications can be made. The fluoropolymers industry does not share these views about alternatives and whether they can provide the same combination of functionality and performance as fluoropolymers. The lack of recognized alternatives could open the door for regrettable substitution to alternatives that do not perform at the same specification as fluoropolymers, may be potentially hazardous, less durable and as such would mean applications are unable to meet stringent safety standards. Additionally, several alternative materials are using fluoropolymers for their manufacturing process since the production of plastic or elastomers is a chemical process. This therefore questions the availability of these alternatives should a fluoropolymers restriction would be put forward.

The FPG members commissioned a study on the socio-economic impact assessment for fluoropolymers where the possibility to substitute fluoropolymers by alternatives is analysed. The full report is submitted together with our response to the public consultation.

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

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

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

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

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

Although some alternatives materials are given for the sectors covered in the proposal, no further information is presented on their performance, suitability or applicability in the different uses and not all uses of fluoropolymers are covered.

In some cases, the dossier submitters propose alternatives to fluoropolymers that are currently under investigation as they seem to present a risk to human health and the environment.

The weight given to the different submission on alternatives seems unclear.

Overall, while some alternatives might have a similar performance to fluoropolymers for a parameter or property, it is the combination of properties required for the applications that sets fluoropolymers apart. Implications of a transition could include lower performance, lower durability and reliability, and increased weight (with associated effects on fuel consumption and fuel efficiency).

Economic implications include regression of advanced technologies and the reduced ability of Europe to attract high and medium technology manufacturing investment. This could result in efficiency losses, as well as higher capital and maintenance costs. The diversity of fluoropolymer applications would pose major product qualification issues in addition to design implications. Environmental / health and safety implications include potential higher safety risks to medical patients and consumers, alongside increasing emissions from technical regression.

Even when used in small amounts, fluoropolymers offer key attributes: non-wetting, high dielectric, non-stick, fire resistant, temperature resistant, weather resistant, and with near universal resistance to chemicals. It is their specific combinations of properties that are not matched by any other alternative and which thus make them so valuable (see the attached socio-economic report, p.3). For each of the key sectors and applications in the previous chapters, we considered the possible alternatives to fluoropolymers, whether these were used historically, before the transition to fluoropolymers, or are used in other similar applications today. This is a high-level assessment based on a consultation which industry conducted in 2016, alongside desktop research. The consultation was conducted amongst five manufacturers of fluoropolymers and 17 downstream users which operate in all the sectors covered by this study (see SE, Appendix C). It is recognised that R&D activities within the companies consulted, and amongst the large number of downstream users are confidential.

Where fluoropolymers are used in specific components for each, they serve a slightly different purpose and hence each of the valuable characteristics of fluoropolymers is needed. Whilst some alternatives might have a similar performance to fluoropolymers for a particular parameter or property, it is the combination or range of properties required for the applications where fluoropolymers are used that is the key characteristic. In sectors such as chemical & power, pharmaceuticals or transport, fluoropolymers provide resistance to a wide range of low and high temperatures and universal chemical resistance. This “universal” resistance to chemicals is a crucial characteristic of fluoropolymers that is not present in any of the alternatives, according to consultation feedback. There are alternatives that are more or less resistant to specific chemicals, but there is not one that is universally suitable. Further information is provided in the Socioeconomic Impact Assessment for fluoropolymers (attached). In considering the implications of alternatives, the criteria considered are as follows:

- What are the key criteria of selection for an application? Which property cannot be compromised?
- Technical feasibility: Could the alternative provide an equivalent technical function to fluoropolymers in the application concerned? Would the alternative provide the final products with the same/similar technical functionality?
- Economic feasibility: Would adoption of the alternative incur additional costs to manufacturers, downstream users or consumers? This may arise from higher unit costs, process or production changes requiring new or altered machinery or loss of functionality to the end user, which might impose additional costs.
- Availability: Is the alternative likely to be available? Are they likely to be available in the required quantities and without undue delay?
- Hazards and risks of the alternative: Would the overall risks to human health and the environment from the use of the alternative increase or decrease? The information on alternatives contained in Appendix C is based on general feedback on alternatives and on specific examples. As a result, it does not necessarily cover all applications and/or all products. The alternatives mentioned as part of the consultation include steel and other metals; high nickel alloys, polypropylene, PVC, glass, ceramics, mica, polyether sulfone, polyimide, ethylene propylene diene monomer (M-class) rubber (known as EPDM rubber), nitrile rubber (NBR), hydrogenated nitrile rubber (HNBR), acrylic rubber (ACM), Ethylene-acrylic rubber (AEM rubber), graphite, aramid, slip agents. Each would only be a possible alternative for some of the applications of fluoropolymers.

In summary, whilst the implications differ across specific applications, they include:

- Technical implications: Various implications which include lower performance, increased weight (with associated effects on fuel consumption and fuel efficiency), and reduced durability, less compatibility and versatility, hence increased challenges associated with component redesign and operating condition requirements.
- Economic implications: Various which would include efficiency losses, higher initial (investment) costs and higher maintenance costs. The diversity of specific applications would post major product qualification issues alongside design implications.
- Environmental / health implications: Potential for higher risk of exposure of staff to

hazardous substances, higher safety risks (vehicle or aircraft failure), higher emissions arising from weight increases, e.g., in transport.

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

As a conclusion, 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 for many sectors/applications.

# 10. Conclusions and FPG key messages

The Fluoropolymers Product Group believes that fluoropolymers and applications containing a fluoropolymer should be not regulated within the REACH restriction. A total ban on fluoropolymers is not proportionate.

The suggested concerns related to fluoropolymers raised in the restriction proposal can be appropriately managed through the implementation of different regulatory frameworks together with Responsible Manufacturing and End-of-Life risk-management practices. Regulatory frameworks such as the Industrial Emissions Directive, the Waste Framework Directive, and the Occupational Health and Safety Directive can address the concerns related to fluoropolymers effectively and quickly.

- A segmentation of the PFAS family according to known physico-chemical and (eco)toxicological properties rather than a structure-based classification alone is needed for a risk-based regulatory approach which is scientifically sound. Fluoropolymers should not be grouped together with other PFAS.
- Given their benign hazard profile, which has been demonstrated,[56,57] fluoropolymers are intrinsically safe and have been used for decades without safety concerns in industrial, commercial, and consumer applications. Fluoropolymers do not pose a risk to human health or the environment as they are non-toxic, not bioavailable, non-water soluble, non-mobile and do not bio-accumulate.
- Fluoropolymers are critical materials and are enablers of the European Green Deal, the Net Zero Industry Act, the Critical Raw Materials Act, the EU Chips Act, the Hydrogen Strategy, the Sustainable and Smart Mobility Strategy, and are central to the EU's strategic autonomy agenda.
- The lack of recognized alternatives could open the door for regrettable substitution to alternatives that do not sufficiently perform compared to fluoropolymers, may be potentially hazardous, less durable and as such would mean applications are unable to meet stringent safety standards.
- The proposed restriction creates general uncertainty already undermining investment decisions and innovation undermining important EU ambitions and strategic goals. This could result in the complete relocation of the fluoropolymer industry outside the EU with significant impacts and unpredictable consequences for critical European sectors that rely heavily on these materials.

Therefore, by way of derogation, fluoropolymers and applications containing a fluoropolymer shall not be restricted. We ask for different regulatory measures to be implemented to address potential concerns raised by the regulators in relation to fluoropolymers.



[56] Henry B. J., Carlin P. J., Hammerschmidt J. A., Buck, R. C., Buxton W., Fiedler H., Seed J., Hernandez O. (2018). A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers, Integr Environ Assess Manag2018:316–334 https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4035

[57] 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., Kapoor D., Gunasekar P., Malvasi M., Brinati G., Musio S. (2022). A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers, Integr Environ Assess Manag2022:1–30 https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4646

**Glossary**

ACM Acrylic rubber

ACS (France) Certificate of Sanitary Compliance

AEM Ethylene-acrylic rubber

BAT Best available techniques

CBI Confidential business information

CHP Combined Heat and Power plant

CLH Harmonised classification and labelling

CLP EU Regulation 1272/2008 on classification, labelling and packaging of substances.

and mixtures

CMR Carcinogenic, mutagenic, or toxic to reproduction

COM European Commission

CSR Chemical safety report

CT Computerised tomography

C&L Classification & Labelling Inventory

Dow Octanol-water distribution coefficient

DU(s) Downstream user(s)

ECHA European Chemicals Agency

EFSA European Food Safety Agency

EMAS EU Regulation 1221/2009 on the voluntary participation by organisations in a

Community eco-management and audit scheme

EPA (United States) Environmental Protection Agency

ES Exposure scenario

eSDS(s) extended Safety Data Sheet(s)

EU European Union

FCM(s) Food contact material(s)

FDA (United States) Food and Drug Administration

FP(s) Fluoropolymer(s)

FPG Fluoropolymer Group of PlasticsEurope

GAC Granular activated carbon

HEPA High efficiency particulate air

HNBR Hydrogenated nitrile rubber

HPLC High performance liquid chromatography

IE Ion exchange

IEM(s) Ion exchange membrane(s)

ISO International Organization for Standardization

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Koc Organic carbon-water partition coefficient

LED Light emitting diode.

MEA(s) Membrane electrode assembly(ies)

MEMS(s) Micro-electro-mechanical system(s)

Mn Number-average molecular weight

MRI Magnetic resonance imaging

MSCA(s) Member State Competent Authority(ies)

MW Molecular weight

NBR Nitrile rubber

OC(s) Operating condition(s)

OML Overall migration limit

OHSAS Occupational Health and Safety Assessment Series

PBT(s) Persistent, bioaccumulative, and toxic

PEM Proton exchange membrane

PFAS Per-and polyfluoroalkyl substances

PFAAs Perfluoroalkyl acids (and its salts)

PFHxA Perfluorohexanoic acid (and its salts)

PFNA Perfluorononanoic acid (and it salts)

PFOA Perfluorooctanoic acid (and its salts)

PFOS Perfluorooctane sulfonic acid (and it salts)

PFPE(s) Perfluoropolyether(s)

PLC(s) Polymer(s) of low concern

POP Persistent Organic Pollutant

PMT Persistent, mobile, and toxic

PRR Polymers requiring registration.

PV Photovoltaic

RAC Risk Assessment Committee

RC Responsible care

REACH EU Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

RFG(s) Reactive functional group(s)

RMO(s) Regulatory management option(s)

RMOA(s) Regulatory management option analysis

RMM(s) Risk management measure(s)

RoI Registry of intentions

RTO Regenerative thermal oxidation

R&D Research and development

SEA Socio-Economic Analysis

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SEAC Socio-Economic Analysis Committee

SME Small and medium enterprises

SML(s) Specific migration limit(s)

SVHC Substance of very high concern

TWA Time-weighted average

UBA German Environment Agency

UPLC Ultra-performance liquid chromatography

USA United States of America

US EPA United States Environmental Protection Agency

UV Ultraviolet radiation

VII Voluntary Industry Initiative

VOC(s) Volatile organic compound(s)

vPvB Very persistent and very bioaccumulative

vPvM Very persistent and very mobile

WRAS (United Kingdom) Water Regulations Advisory Scheme

Annex I

Polymer of low concern (PLC) criteria descriptions as reported in S. Korzeniowski et. al.[21] review.

| PLC Criteria | Description |
|---|---|
| Polymer composition | The polymer composition criterion requires structure and elemental composition of the polymer be described and identified (e.g., by chemical Abstracts Service [CAS] number). |
| Molecular weight, number average molecular weight, MW distribution, and % oligomer <1000 Da | The number average molecular weight (Mn) and oligomer content are the most commonly used criteria for PLC assessment. The EU assessment report (BIO by Deloitte, 2015)**Error! Bookmark not defined.** states that the "most potential health concern polymers have a number average molecular weight, Mn, <1000 Da and oligomer content >1%."<br>Molecular weight (MW) is an important predictor of biological effect because large molecules (>1000–10 000 Da) are too large to penetrate cell membranes. Because large molecular weight polymers cannot enter the cell, they cannot react with "target organs," such as the reproductive system, and are not bioavailable. "Therefore, as the Mn of a polymer increases, a reduced incidence of potential health concern effects might be expected."**Error! Bookmark not defined.**<br>An additional PLC consideration is the weight percentage of oligomers that are <1000 Da. Oligomers may be composed of, for example, dimers, trimers, and tetramers, meaning they have 2- monomer, 3- monomer, and 4-monomer units, respectively. The EU report (BIO by Deloitte, 2015) concluded that most potential health concern polymers have Mn of <1000 Da and oligomer content of >1%: "…the distribution of potential health concern polymers exhibited an increased incidence of higher oligomer content that began at 5% for <1000 Da and 2% for <500 Da oligomeric content."**Error! Bookmark not defined.** Molecular weight distribution (MWD), also known as "polydispersity index," measures the heterogeneity of size of polymer molecules in a polymer. The MWD is an important parameter for predicting potential biological effects of polymers because, although Mn may be a large value, low MW oligomers <1000 Da may be present, which could penetrate the cell. |
| Ionic character | Electrical charge or ionic character can be anionic, cationic, amphoteric, or nonionic. Specifically, cationic polymers have been associated with aquatic toxicity. |
| Reactive functional groups and | A "reactive functional group" (RFG) is defined as an atom or associated group of atoms in a chemical substance that is intended or can be reasonably expected to undergo facile chemical reaction. Some highly |

| | |
|---|---|
| RFG ratio to MW | reactive functional groups (or a high ratio of RFGs per mole) have been associated with adverse human health and ecotoxicology. The functional group equivalent weight (FGEW) is used to determine if the RFGs in a polymer are substantially diluted by polymeric material to allow the polymer to be a PLC.[58] The FGEW of a polymer is defined as the ratio of the Mn to the number of functional groups in the polymer. The FGEW is used as an indication of the degree of reactivity of the polymer; the lower the FGEW, the more reactive the polymer and the greater the potential for health and environmental impact.**Error! Bookmark not defined.** |
| Low MW leachables | Low MW leachables are chemical molecules, either inorganic or organic, that migrate (i.e., leach) out of the polymer. These could be residual monomers or oligomers resulting from incomplete polymerization processes, surface residues, or other chemicals used in the manufacturing processes (e.g., initiators, catalysts, chain transfer agents, surfactants).<br><br>Low MW leachables are critically important to the potential for a polymer to affect health and the environment, given that they may be able to migrate out of the polymer and cross cell membranes to potentially react with biomolecules. A report to the EU (BIO by Deloitte, 2015) concluded that "Polymers with <1% MW < 1000 Da and low water extractability are not able to cause systemic effects which are toxicologically or ecotoxicologically relevant."<br><br>Monomers, by nature, are reactive. Unreacted monomers left in a polymer may migrate out of the polymer to react with biomolecules to cause potential adverse effects. |
| Particle size | Particle size is also a PLC criterion. Particles that are small enough to reach the deep lung upon inhalation are often associated with adverse health effects. Therefore, to qualify as a PLC, median mass aerodynamic diameter (MMAD) of the polymer particle size should be >5 µm. |
| Structural and elemental composition | In the US, Chemical Categories of Concern are the result of the review of new chemicals by the USEPA under the TSCA (see https://www.epa.gov/reviewing-new-chemicals-undertoxic-substances-control-act-tsca/chemical-categories-used-review-new). The categories describe the molecular structure, boundary conditions such as MW, equivalent weight, the log of the octanol–water partition coefficient, log P, or water solubility, and standard hazard (mammalian and ecological) and (environmental) fate tests to address concerns. |



[58] USEPA. (1997). Polymer exemption guidance manual (EPA-744-B-97-001). June

**Elemental composition**

The elemental composition is a factor in the assessment of the eligibility of polymers for reduced notification requirements. The exclusion of polymers under this step is not a conclusion of hazard but a determination that the elemental composition does not fall within the parameters of the polymer set under which this rule was formulated, and consequently, these polymers would have to follow the standard notification and review process. These elemental requirements differ across jurisdictions as covered in the report to the EU on global regulatory approaches to polymer assessment.**Error! Bookmark not defined.**

For example, in the EU under REACH it is proposed that polymers composed from among these elements, covalently bound to C, have reduced hazard: H, N, O, Si, S, F, Cl, Br, or I.**Error! Bookmark not defined.** In contrast, the USEPA Polymer Exemption Rule states that a polymer is eligible for reduced agency review when it has at least two of the following elements: C, H, O, N, S, or Si.[59]

**Water and lipid solubility and the octanol–water partition coefficient**

Water solubility is the extent to which a compound will dissolve in water. According to the OECD (2009) meeting of the Expert Group on Polymers, polymers with "negligible" water solubility, or those described as "hydrophobic" have been represented with a water solubility of 0.000001 mg/L (1 × 10–6 mg/L; assigned arbitrarily).**Error! Bookmark not defined.** That is equivalent to 1 ppt, a very conservative definition.

Polymers with water solubility <10 mg/L showed generally low health concerns. The octanol–water partition coefficient (Kow) is another criterion to assess chemicals and their environmental and health impact. The Kow is a physical–chemical property at equilibrium to represent the lipophilic or hydrophilic nature of a chemical, the distribution of a compound in octanol, representing the lipophilic nature, to its solubility in water, representing the aqueous nature. The higher the Kow, the more lipophilic the compound.

Typically, a Kow >5000 or a log Kow >5 means high lipophilicity and, thus, a high potential to bioaccumulate or bioconcentrate. According to the Stockholm Convention, a bioconcentration factor of >5000 and a log Kow >5 is used as a criterion for bioaccumulation.

**Stability**

Stability is resistance to physical, chemical, or biological transformation. Loss of stability in the polymer breaks it down into smaller pieces, producing low MW species. As was previously described in the Polymer of Low Concern section under the molecular weight, number average molecular weight, MW distribution, and % oligomer <1000 Da heading, molecules with Mn <1000 Da are capable of crossing cell membranes,

[59] United States Federal Register (USFR). (1995). Premanufacture notification exemptions; Revisions of exemptions for polymers (Final rule 60 FR 16316. 1995 Mar 29. FRL-4929-8). Fed Regist 60(60), 16316–16336. Environmental Protection Agency

| | |
|---|---|
| | making unstable polymers potentially hazardous to health and the environment. |
| Abiotic stability | Polymers are stable; monomers are not. Abiotic degradation may involve sunlight, water, or oxygen. Photochemical transformation is a reaction involving the radiation energy of sunlight (ultraviolet radiation) that may break a bond in a molecule to change it to another chemical entity. Hydrolytic degradation of polymers is another potential way to break the polymer bonds, creating smaller oligomers that may be bioavailable. Chemical oxidation is a reaction involving the loss of electrons from one atom to another. |
| Biotic stability: aerobic, anaerobic, and in vivo | Biotic stability is assessed by whether the polymer is degraded by microorganisms under oxygenated (aerobic) or anoxic (anaerobic) conditions; in vitro and in vivo stability studies demonstrate this. In vivo biodegradation involves the breaking of the polymer bonds by the action of bacteria, enzymes, and oxidants within the organism. |
| Thermal stability | Thermal stability of a polymer can be assessed when used as intended under normal, foreseeable use conditions or in extreme temperatures during disposal, such as by incineration. Thermal stability testing may involve Thermogravimetric Analysis (TGA), which determines mass loss over time and temperature of a test substance. |

Annex II

Studied fluoropolymers, including fluoroplastics and fluoroelastomers, against the Polymer of Low Concern (PLC) criteria by S. Korzeniowski et. al.[21] and B. Henry et. al.[22]

All investigated fluoropolymers listed hereinafter fulfil the internationally recognized PLC criteria.

| **Fluoroplastics**[22] | **CAS number** | **Fluoroplastics**[21] | **CAS number** |
|---|---|---|---|
| PTFE (polytetrafluoroethylene) | 9002-84-0 | EFEP (ethylene-tetrafluoroethylene-hexafluoropropylene) | 35560-16-8 |
| ETFE (ethylene tetrafluoroethylene) | 25038-71-5, 68258-85-5 | CPT (terpolymer, chlorotrifluoroethylene-tetrafluoroethylene (CPT) terpolymer) | 116018-07-6 |
| FEP (fluorinated ethylene propylene) | 25067-11-2 | THV (d tetrafluoroethylene, hexafluoropropylene, vinylidene fluoride (TFE-HFP-VF2 [THV]) | 25190-89-0 |
| PFA (perfluoroalkoxy polymer) | 26655-00-5, 31784-04-0 | | |
| **Fluoroplastics**[21] | **CAS number** | **Fluoroelastomers**[21] | **CAS number** |
| PVDF (Polyvinylidene fluoride) | 24937-79-9 | FEPM (Tetrafluoroethylene-propylene copolymer) | 27029-05-6 |
| PVDF-HFP copolymer (Vinylidene fluoride, hexafluoropropene copolymer) | 9011-17-0 | FKM (1-Propene,1,1,2,3,3,3-hexafluoro-polymer with 1,1-difluoroethylene copolymer and terpolymers) | 9011-17-0, 26425-79-6, 25190-<br>89-0 |
| ECTFE (Ethylene, chlorotrifluoroethylene copolymer) | 25101-45-5 | FFKM (Tetrafluoroethylene-trifluoromethyl trifluorovinyl ether copolymer) | 26425-79-6 |
| ECTFE (Ethylene, chlorotrifluorethylene, hexafluoroisobutylene terpolymer) | 54302-04-04 | **Specialty fluoroplastics**[21] | **CAS number** |
| PCTFE (Polychlorotrifluoroethylene) | 9002-83-9 | Amorphous Perfluoro (alkenyl vinyl)<br>ether polymer | 37626-13-4 |

| | | | |
|---|---|---|---|
| FEVE (fluoroethylene-vinyl ether) | cbi | Ionomer (Sodium or potassium salts of perfluorosulfonic acid/TFE copolymer or perfluorocarboxylic acid/TFE copolymer) | 9002-84-0, 1314-23-4, 409-21-2, 111173- 25-2 |

**Supplementary materials**

Please find attached the following documents as supplementary material to FPG's consultation response.

1. Guide for the safe handling of fluoropolymer resins, Plastics Europe,2021. https://fluoropolymers.plasticseurope.org/application/files/6216/3178/0517/Fluoropolymers_Safe_Hand_EN__June_2021.pdf
2. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Henry et.al, https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4035
3. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and Fluoroelastomers. Stephen H Korzeniowski et al, 2022 https://pubmed.ncbi.nlm.nih.gov/35678199/
4. FPG RMOA, 2020
5. FPG SEA 2017/18, 2022 and 2023
6. Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions
7. Socioeconomic Impact Assessment for fluoropolymers FPG response to the PFAS draft restriction proposal (first draft ERM report)

## Specific Information Requests

ECHA has requested additional information on PFAS and asked stakeholders to input data on specific topics. Below are listed ECHA's ten questions stakeholders will need to provide information on (if they do have).

**1: Sectors and (sub-)uses:** Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.

Fluoropolymers (which includes fluoroplastics and fluoroelastomers) manufacturing, currently grouped under PFAS within the current ECHA draft restriction proposal.

**2: Emissions in the end-of-life phase:** The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e., the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:

a. Please provide, at the (sub-)use level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or sub-sector level would also be appreciated.

b., If possible, please provide for each (sub-)use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.

a. No data on emissions

b. The January 2023 Conversio report "Fluoropolymer waste in Europe 2020" identifies that the 23.5 kt of fluoropolymer waste collected are mainly "*commercial and industrial waste streams, which are usually collected by private waste management or industrial service companies. Only a small proportion of FP waste is collected in residential or private waste streams, such as mixed residential waste, which is often collected on behalf of municipal waste collection services*".[7]

In 2020, around 23.5 kt of FP waste were collected. The investigation shows that the largest share of fluoropolymer waste is thermally treated (over 84%). 72% go in energy recovery or thermal destruction (metal recycling ~12%) processes. A small proportion of fluoropolymer waste of around 3% is recycled and the rest of fluoropolymers waste (around ~13%) is landfilled.

According to the above mentioned report, only 2.2Kt of fluoropolymer waste are potentially in the residential household waste and municipal waste generated by commercial activities which represent < 0.01% of the total municipal waste by weight.[7]

In primary and secondary recycling, solid fluoropolymer waste is ground and later fed back into the manufacturing cycle of some fluoropolymer products. In secondary recycling, waste is ground, followed by degradation to approximately 1% of the original degree of polymerization by using electron beams, gamma rays or thermo-mechanical degradation.

In tertiary recycling, solid fluoropolymer is ground, then decomposed into the starting monomers at temperatures above 600 °C to obtain the same chemical components from which the fluoropolymer was manufactured. In that way high quantities of fluoropolymers can be recovered contributing to circular economy.

**3: Emissions in the end-of-life phase:** With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g., hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.

Polytetrafluoroethylene (PTFE) is the most stable fluorine containing polymer. For PTFE it can be concluded that complete thermal decomposition is achieved at a temperature of about 800 °C. It can therefore be assumed that other fluorine-containing polymers also thermally decomposed completely at a temperature of 850 °C.

According to Aleksandrov et al. (2019)[1] thermal degradation of PTFE starts at about 500–550 °C and is complete at a temperature of about 650 °C. Alexandrov et al. (2019) reported no statistical difference between baseline PFAS emission levels and PFAS emission levels associated with incineration of polytetrafluoroethylene (PTFE) in a large pilot-scale facility representative of a municipal energy from waste (EfW) plant. Accordingly, they concluded that municipal EfW combustion of PTFE is not a significant PFAS emission source. When feeding elevated levels of fluorine in the form of PTFE for this testing, the authors noted “The fluorine content in the fly ash could be neglected compared to the HF [in the flue gas prior to control].”

[1] https://www.sciencedirect.com/science/article/pii/S0045653519306435

4: **Impacts on the recycling industry**: To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:

a. The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate). No data

b. The measures that recyclers would need to take to achieve the proposed concentration limits. No data

c. The costs associated with these measures. No data

**5: Proposed derogations – Tonnage and emissions:** 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 proposed derogations. For these proposed derogations, information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.

Polymerisation aids in the production of polymeric PFAS are given 6.5 years after EIF. This derogation does not apply to the production of PTFE, PVDF and FKM.

FPG member companies continue investigating and developing R&D programs for the advancement of technologies allowing for a transition away from using PFAS-based polymerization aids during fluoropolymer production. However, during this transition, it may be necessary to continue using fluorinated polymerization aids until non-PFAS polymerization aids are developed that can produce polymers that meets all performance requirements. Therefore, time-unlimited derogations (with a periodic review) for all fluoropolymers should be provided.

**6**: **Missing uses – Analysis of alternatives and socio-economic analysis**: Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:

a. The annual tonnage and emissions (at sub-sector level) and type of PFAS are associated with the relevant use.

b. The key functionalities provided by PFAS for the relevant use.

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

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.

e. For cases in which **alternatives are not yet available**, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.

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);

   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);

   iv. information on the benefits for alternative providers.

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.

Identified missing uses.

- Use of monomers for fluoropolymers production
- Industrial equipment (uses in chemical industry)
- Examples of missing applications include, the chemical process industry including chloro-alkali processes, batteries for EV, water and atmosphere purification, water electrolysis, energy/hydrogen storage, applications in pharmaceutical manufacturing equipment, electronics, aerospace, military & defence, transportation, semiconductor manufacturing and high-end niche applications.

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

**8**: **Other identified uses – Analysis of alternatives and socio-economic analysis**: Table 8 in the Annex XV restriction report 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.

**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.

No data

**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.

No data