

Comments for Annex XV Restriction Report on Per- and Polyfluoroalkyl Substances (PFAS)

Preliminary Comments

Textiles Coated International (TCI) welcomes the opportunity to contribute to the public consultation issued by the European Chemicals Agency (ECHA) regarding the restriction proposal of Per- and polyfluoroalkyl substances (PFAS) under Regulation (EC) No. 1907/2006 (REACH).

TCI has been a leading global manufacturer of high-performance fluoropolymer films, laminates, and composites globally, since 1985. TCI's products are designed to work in the most demanding environments and are especially suited for harsh chemical and thermal conditions in numerous industries.

TCI appreciates the work performed by the five submitters of the restriction proposal and the efforts of the European authorities on the protection of human health and the environment in front of the effects of the PFAS substances that are of concern. TCI submits the below information to contribute to the understanding of fluoropolymers and the rationale for and importance of exempting them from the restriction.

TCI is part of an informal group of six companies¹ that have in common a number of fluoropolymer use applications. However there is diversity across the companies according to the type of industries each serves, and as such we do not have an industry association to represent us for regulatory matters. Relating to the proposed ECHA (universal) PFAS Restriction, the group shares the view that fluoropolymers should be exempted. The next section of this statement provides the justification for our position. For the purpose of working together on this matter, the group of six companies has engaged an independent third party trustee for handling and aggregating confidential business information for each company.

The following table provides an aggregated overview of the volumes in metric tonnes of fluoropolymers used within the EEA by the six companies over the last five years. The majority of the fluoropolymer volume relates to the use of PTFE, with additional fluoropolymers such as FEP, PFA, ETFE, FKM and others contributing to the total volume used.

2018	2019	2020	2021	2022
Vol. used in EEA	Vol. used in EEA	Vol. used in EEA	Vol. used in EEA	Vol. used in EEA
1564	1433	1224	1508	1525

¹ The six companies are: Fothergill Group, Fiberflon, Taconic International, Textiles Coated International, Verseidag-Indutex GmbH and AFC Materials, located in multiple jurisdictions globally, notably the European Union, U.K., U.S.A., Turkey and Australia, with each company serving EU/EEA markets.

Across the six companies, the number of workers potentially impacted by the proposed restriction is as follows:

Location of sites	Number of workers
EEA	261
Rest of the World	661
Total	922

This submission is made on an individual company basis to allow provision of confidential data in greater detail.

1. Request for exemption of fluoropolymers

The proposed restriction does not differentiate between fluoropolymers (covering fluoroplastics such as PVDF, ECTFE, ETFE, FEP, PFA, PTFE, etc., as well as fluoroelastomers such as FKM, FFKM, etc.) and other categories of PFAS. Fluoropolymers have unique properties that distinguish them from other PFAS and they do not have the environmental and toxicological profiles associated with some substances in this class of chemicals that are of concern. For this reason, we strongly believe that the restriction proposal should differentiate between the different families of PFAS based on their chemical composition, their toxicological profile, and the production method (e.g., the production of fluoropolymers without fluorinated polymerisation aids).

Fluoropolymers are durable, stable, and mechanically strong in harsh conditions in a variety of sectors including but not limited to automotive, aerospace, environmental controls, energy production and storage, and electronics. They are also stable in air, water, sunlight, chemicals, and microbes, and chemically inert, meeting the requirements for low levels of contaminants and particulates in manufacturing environments critical for the food and beverage, pharmaceutical, medical, and semiconductor industries. Finally, fluoropolymers are biocompatible; non-wetting, non-stick, and highly resistant to temperature, fire, and weather. These unique characteristics make them a critical material for a broad range of industries and sectors, playing a diverse and crucial role for society, with few, if any, viable alternatives, and making them essential in numerous technologies, industrial processes, and everyday products. Furthermore, the restriction of fluoropolymers will make it impossible to achieve key goals set by the European Union, such as the Green Deal, the transition to a circular economy, and the autonomy of Europe in critical technological sectors.

Beyond their socio-economic value for European industry, their unique stability means that they are low-risk polymers for human health and their environment. Trying to replace them in their many applications would lead to substitution with materials that cannot provide the same advanced performance and safety as fluoropolymers. Furthermore, any substitute that may be suggested to replace fluoropolymers will

need to perform at least at some degree (even if at lower levels) of chemical and temperature resistance, which means that such alternatives will likely be persistent materials like fluoropolymers.

Since fluoropolymers are different from the other families of PFAS, there is no scientific, economic, or social basis to justify regulating them in the same way as all of the PFAS. For this reason, we request that fluoropolymers should be fully exempted from this restriction proposal under the REACH regulation.

2. Missing uses

Following the review of the current version of the Annex XV restriction report, we have identified the absence of specific uses of fluoropolymers that have not been evaluated, either because they have not been researched, or that have been searched in general by the dossier submitters (according to Table A.1 of Annex A of the Annex XV restriction report). These uses are as follows:

- **Photovoltaic and solar films/foils (ETFE, ECTFE and PVDF)**
Films applied to solar or photovoltaic (PV) panels, cells and other solar collectors provide necessary protection from the outdoors and fire while also providing excellent solar light transmission and UV resistance. These applications are relevant to the clean energy and solar heat sectors.
- **Foils/films for medical and pharmaceutical containment (PTFE, ETFE, FEP)**
Films are used as vial cap liners, septa and stopper applications, sampling bags, culture bags, blood storage bags, and storage/containment for drugs or vaccines because they are chemically inert, have an unlimited shelf life, withstand extreme temperatures, have high purity and low friction, and are biocompatible.
- **Floating roof seals (PTFE)**
Protects against release of dangerous gases from above-ground storage tanks. Creates a seal between the floating roof of the tank and the wall of the tank, and guards against gases escaping based on its resistance to chemical attack, resistance to tearing, extreme temperature, UV, moisture, and its non-porosity.
- **Flexible ducting (PTFE)**
PTFE flexible ducting has a non-stick surface, resists most chemicals, operates at extreme temperatures, resists tearing and is suited to wet and dry applications, and so is used in a wide range of specific applications, including flexible hose ducting, clean room ducting, semiconductor ducting, food grade ducting, and industrial ducting, and as flexible ventilation ducts.
- **Fabric expansion joints (PTFE)**
Fabric expansion joints are used in industrial piping and ducting systems in power plants, sewage treatment facilities, and many other industrial plants, to transport gases by holding piping, ducting and other parts together and allowing for movement or pipe expansion in multiple directions. Non-metallic, fluoropolymer fabric expansion joints provide resistance to extreme temperatures, corrosion and chemical attack, and typical wear and tear, but remain flexible enough to reduce stress at junctions. Fabric expansion joints made with PTFE can last several years longer than expansion joints made from less durable and resistant materials. Use of *non*-fluoropolymer expansion joints increases operational and energy costs due to the increased frequency of replacement of non-fluoropolymer parts and plant

shut-downs to replace those parts, and increases the risk of leakage of noxious gases or chemicals that fluoropolymer fabric expansion joints resist.

- **Spray shields (PTFE)**

Spray shields are used to prevent injury or damage in the event of a leak or spray-out of dangerous liquids at piping connections in nearly all industries. The all-PTFE film spray shields protect against corrosion, spray-out and are more durable than any other material and so require less monitoring and create less potential for a spontaneous spray-out of harmful chemicals.

- **Flexible connectors (PTFE)**

Provide piping systems with the flexibility needed to absorb noise and vibration. Removing vibration from piping systems in countless industrial processes is necessary for the longevity and efficiency of the equipment, and removing noise is needed to improve working conditions in facilities and offices. PTFE flexible connectors meet these needs in power plants, marine systems, and numerous industrial processes because they resist corrosion and high temperature, have zero porosity and are non-stick, and so provide the longest-lasting and effective flexible connectors to avoid chemical releases.

- **Insulation jacketing (PTFE)**

Also called removable insulation covers or blankets, these materials protect industrial process equipment from fluctuating heat loss or gain, moisture, and weather, and are flame and chemical resistant. Without these coverings in the energy, chemical, steel, oil/refining and other industries, tubing and piping fail and disrupt productivity, efficiency and safety of industrial and manufacturing processes. Much of industry uses rigid, immovable coverings that degrade easily and do not allow for inspection of the piping for corrosion. This inspection for corrosion under insulation (CUI) on a regular basis is critical to the function of steel piping, for instance, that can crack if water and oxygen get between the insulation and pipe.

Furthermore, we have identified some uses that have been evaluated in detail by the dossier submitters (according to Table A.1 of Annex A of the Annex XV restriction report) but for which no derogation has been defined. These uses are the following:

- **Construction sector: Architectural membranes (ETFE) in construction products**

Provides a membrane or cover with exceptional transparency, elasticity and durability. Used as covers or enclosures in stadiums and other public spaces and greenhouses.

- **Tank and drum liners (PTFE)**

These PTFE liners of industrial drums and tanks protect against the release of harsh chemicals because of their corrosion and temperature resistant properties. The current derogation relating to this quite generic use is given under the petroleum and mining industry, rather than being industry-wide, therefore it is considered to be a missing use.

- **Radome covers (ETFE, PTFE)**

Weatherproof structures that protect radar and microwave communication antennas and planar radomes from weather and debris with low interference with signal transmission. The fluoropolymer films on the exterior of the radome cover provide a level of protection and signal transmission that cannot be provided by any other material. Radome covers protect antennas in the commercial and military aircraft and marine vessel, automobile and telecommunications industries, among others.

We are aware that fluoropolymers play a key role in the uses detailed above. Therefore, we can provide enough scientific, technical, and economic information about them to be evaluated by RAC and SEAC and included in the review of the restriction proposal. We will provide this information through different statements that will be submitted separately during the public consultation period (see section 5 of this document).

In all cases, and in our opinion, these uses could be included in the general exemption of fluoropolymers requested in section 1 of this document. Alternatively, we are confident that they could merit derogations.

3. Potential derogations marked for reconsideration

Although we believe that fluoropolymers should be fully exempted from this regulatory action, alternatively, we want to support some of the derogations marked for reconsideration that are defined in the current version of the Annex XV restriction report.

For this reason, we would like to request consideration of the following potential derogations:

- **Electronics and semiconductors sector: Films for electrical applications (FEP, PFA, ETFE, PTFE)**
Fluoropolymer films are used in a wide range of electrical applications, such as circuit board laminates and high-temperature insulation tapes for wire wrapping, because of their superior dielectric properties, chemical and temperature resistance, and weldability. ETFE films are also broadly used as cushioning/release media in Film Assisted Molding (FAM) processes of semiconductors and integrated circuits. TCI's fluoropolymer films reduce release force when the integrated circuit is removed from the mold and increases productivity by alleviating the need to clean the mold between each use.
- **Food contact materials: Belting and conveyor (PTFE)**
Belts, grill sheets and conveyors used to transport food or material in food production and packaging. The PTFE material is corrosion resistant, quick to install easy to clean and unaffected by cleaning chemicals, making these belts and conveyors the most durable and effective movers of food and packaging material.
- **Applications in the energy and petroleum and mining industries**
Fluoropolymer fabric expansion joints, insulation jacketing, flexible connectors, floating roofs and spray shields are important, current uses in power plants, refineries and other petroleum or gas facilities.
- **Non-stick coatings in industrial and professional bakeware**
PTFE-coated commercial food trays and baskets used for food production and rapid oven cooking. The fluoropolymer cooking containers are longer lasting and easier to clean than other, non-fluoropolymer based materials and are the only option for certain rapid cook speed ovens.

We are aware that fluoropolymers play a key role in the uses related to these potential derogations. Therefore, we can provide enough scientific, technical, and economic information about them to be evaluated by RAC and SEAC in order to move these derogations marked for reconsideration into proposed

derogations. We will provide this information through different statements that will be submitted separately during the public consultation period (see section 5 of this document).

4. Proposed derogations

Although we believe that fluoropolymers should be fully exempted from this regulatory action, alternatively, we want to support some of the proposed derogations that are defined in the current version of the Annex XV restriction report.

For this reason, we would like to express our appreciation for the consideration of the following proposed derogations:

- **Medical devices and containment**
Fluoropolymers are a necessary component in many implanted or used medical devices, and fluoropolymers films are an essential material to the storage and containment of certain drugs and vaccines for humans. We support ETFE-based packaging of medicinal preparations and vaccines.

We are aware that fluoropolymers play a key role in the uses related to these proposed derogations. Therefore, we can provide additional scientific, technical, and economic information about them to be evaluated by RAC and SEAC in order to support these proposed derogations. We will provide this information through different statements that will be submitted separately during the public consultation period (see section 5 of this document).

5. Further submissions

Although we appreciate the proposed derogations and those marked for reconsideration in the current restriction proposal, we believe they are neither clear enough nor broad enough to cover all the applications where fluoropolymers are essential. Additionally, due to the vast amount of socially important uses of fluoropolymers and their distinct safety profiles compared to other PFAS, we believe that a broad exemption of fluoropolymers from the proposed PFAS restriction is appropriate.

The above statements and observations will be further substantiated in the course of the consultation process. In particular, we will provide further comments on the proposal and the effects of the contemplated restriction as well as the requested exemptions and/or derogations. We will also provide further justifications as regards the details to be considered for exemptions and/or derogations. For the time being, we kindly request ECHA, including RAC and SEAC, as well as Member States to consider this initial submission as a preliminary statement.