

Comments for Annex XV restriction report on Per- and polyfluoroalkyl substances (PFAS)

Preliminary comments

UNIGASKET GROUP 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).

We represent an international player in the production of fluoropolymer hoses, thermoplastic tubing, and gaskets with high added value for automotive and high-end professional appliances. Over the years, the Group has expanded its presence in European and foreign markets thanks to the opening of its branches in Spain, Romania, Poland, USA, Hong Kong, and India and the acquisitions of different companies. Thanks to this growth path, the Group has become vertically integrated, expanding its range, and developing high-tech products for hydraulic and pneumatic braking systems, for industrial, pharmaceutical, and high-tech industry applications. **UNIGASKET GROUP** is therefore an integrated and international group capable of offering innovative solutions to create products of tomorrow.

The Group currently comprises the following European Companies:

- UNIGASKET S.R.L (Italy)
- ALLEGRI CESARE SpA (Italy)
- POLIPLASTIC S.R.L. (Italy)
- UNIGOMMA S.R.L (Italy)
- UNITAPE S.R.L. (Romania)
- UNIGASKET S.L. (Spain)
- POLYFLUOR BV (Netherlands)

UNIGASKET 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.

1. Request for exemption of fluoropolymers

The proposed restriction does not differentiate between fluoropolymers (covering fluoroplastics such as PVDF, ECTFE, FEP, PFA, PTFE, etc., as well as fluoroelastomers such as FKM, FFKM, etc.) and other families 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, as well as in technical apparel. 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 alternatives (when available) that do not provide the same advanced performance and safety as fluoropolymers. Furthermore, any alternative 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) with no further conclusion. These uses are as follows:

- Industrial sector:
 - Hoses for hydraulic applications used to transmit forces using hydraulic fluid;
 - Pipes used on robots equipped with grippers to transport aggressive fluids at high pressures and temperatures (-70 °C to 260 °C) thanks to the lack of absorption of humidity;
 - Tubes with an internal non-stick core that do not contaminate the painting equipment and allow an excellent flow of air and pigment and in addition are able to withstand the vibrations and high operating temperatures typical of painting lines.
 - Tubing used for the transport of compressed air, fluids, and gases at low pressure in the industrial field in contact with high temperature.
 - Tubing used to transfer particularly aggressive media with low pressure.
- Pharmaceutical sector:
 - Tubes produced in a specific clean room, using special materials based on fluoropolymers, that are fully validated and tested in accordance with international Pharmacopeia (European, US Class VI, ISO 10993, NSF, FDA, etc.).
- Chemical sector:
 - Range of products capable of conveying many fluids typical of the chemical industry (solvents, vapours, aggressive liquids), combining excellent resistance to pressure and flexibility.
- Sanitary sector:
 - Hoses are used to transfer media without any contaminations because they are no toxic and they are not losing any external additive during their work life.
- Heating sector:
 - Tubes are used to transfer media in extreme conditions without any possibility to reduce performance in their useful life.

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:

- Food sector (consumer use):
 - Food contact materials (e.g., pipes and gaskets for coffee machines) for the purpose of consumer food preparation. The pipes are tasteless and odourless, free of phthalates, resistant to the liquids transported and to the products intended for cleaning, and able to comply with the hygiene standards.
 - Special gaskets, used in the production of big and little household appliances, are non-toxic, conductive, food compliant, and have a good performance at very high and very low temperatures.

- Medical sector (products other than tubes and catheters):
 - Products (e.g., foils, pipettes, etc.) that are clean, smooth, non-toxic, and non-allergenic, utilized for use in short-term applications with human tissues and fluids.
- Electronics sector:
 - Products (e.g., tubes, films, foils, etc.) with high chemical, mechanical, and electrical resistance, that are designed for the insulation of electrical circuits and protective systems against humidity.

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 specific 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 express our appreciation for the consideration of the following potential derogations:

- Applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers, or goods. Point 6o.
- The semiconductor manufacturing process. Point 5ee.

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:

- Food contact materials for the purpose of industrial and professional food and feed production. Point 6a.
- Tubes and catheters. Point 6c.
- Fluoropolymer applications in petroleum and mining industry. Point 6f.

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

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.