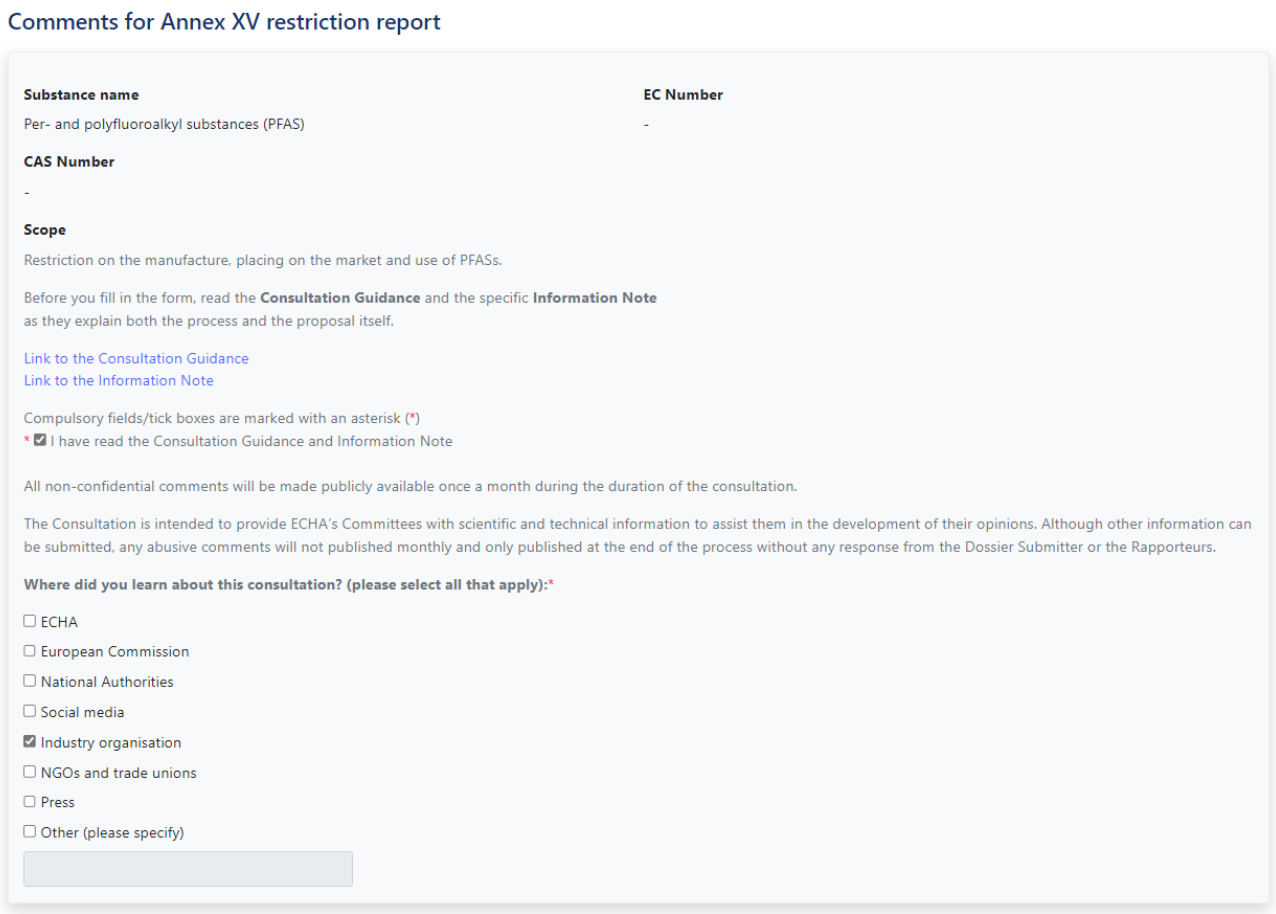
PUBLIC CONSULATION ON PFAS

Teadit Group's Proposed Response to the Annex XV Restrictions Report – ECHA

Available in: ECHA Website (europa.eu)

HEADER



Comments for Annex XV restriction report

Substance name

Per- and polyfluoroalkyl substances (PFAS)

EC Number

-

CAS Number

-

Scope

Restriction on the manufacture, placing on the market and use of PFASs.

Before you fill in the form, read the **Consultation Guidance** and the specific **Information Note** as they explain both the process and the proposal itself.

Link to the Consultation Guidance
Link to the Information Note

Compulsory fields/tick boxes are marked with an asterisk (*)
* ☑ I have read the Consultation Guidance and Information Note

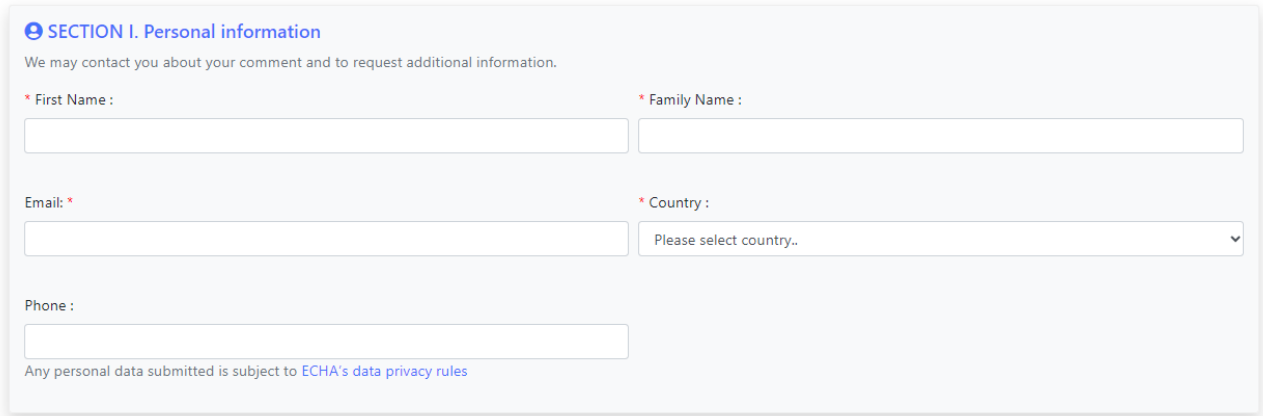
All non-confidential comments will be made publicly available once a month during the duration of the consultation.

The Consultation is intended to provide ECHA's Committees with scientific and technical information to assist them in the development of their opinions. Although other information can be submitted, any abusive comments will not published monthly and only published at the end of the process without any response from the Dossier Submitter or the Rapporteurs.

Where did you learn about this consultation? (please select all that apply):*

- ☐ ECHA
- ☐ European Commission
- ☐ National Authorities
- ☐ Social media
- ☑ Industry organisation
- ☐ NGOs and trade unions
- ☐ Press
- ☐ Other (please specify)

SECTION I. Personal Information



SECTION I. Personal information

We may contact you about your comment and to request additional information.

* First Name :

* Family Name :

Email: *

* Country :

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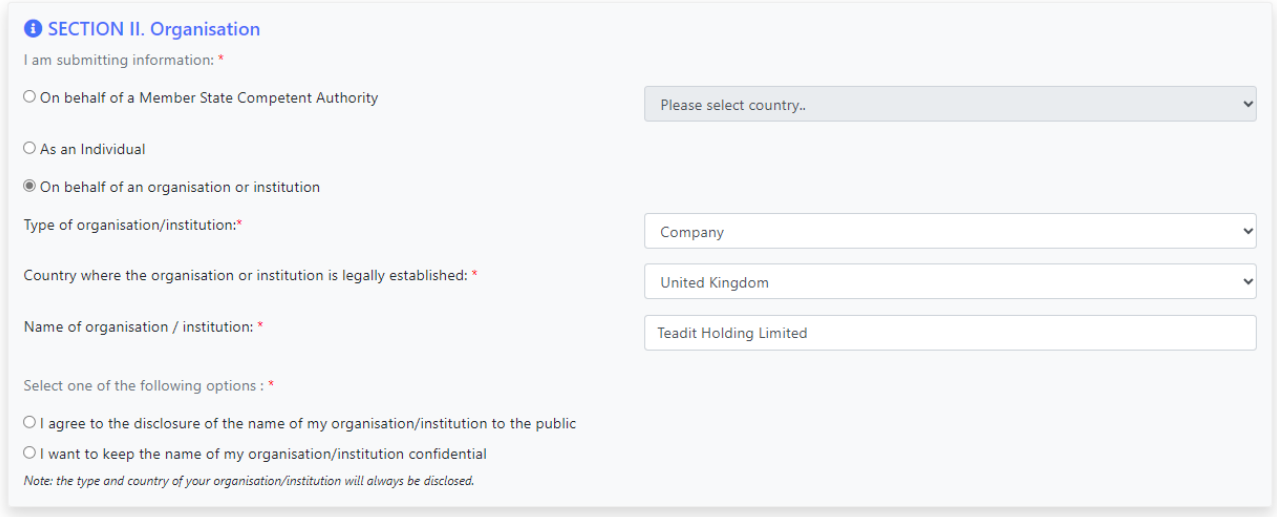
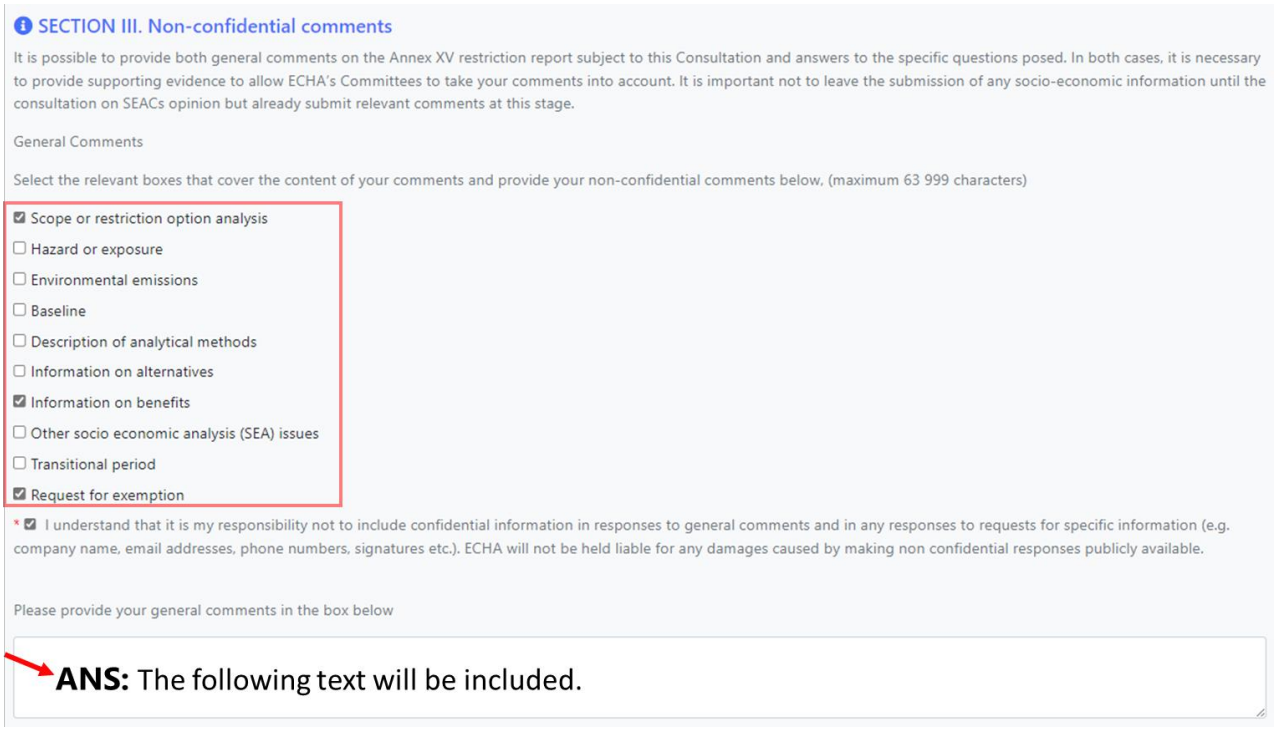
Any personal data submitted is subject to ECHA's data privacy rules

SECTION II. Organisation



SECTION III. Non-confidential comments



ANS.:

Restriction proposal for PFAs should be revised considering the exclusion of fluoropolymers, since polymeric structures generally differ from non-polymeric chemical substances in terms of chemical, physical, thermal and biological properties. The OECD has established precise criteria to distinguish polymers from non-polymers.

In the literature are studies showing that some fluoropolymers, including Polytetrafluoroethylene (PTFE), are non-toxic, not bioavailable, non-water soluble and non-mobile molecules, therefore are considered be of low risk to human health and environment meeting accepted

regulatory assessment criteria to be considered PLCs (Low Concern Criteria). This evidence supports the need to distinguish between fluoropolymers and other PFAS (Annex III and IV) [1-4].

In fluoropolymers family, PTFE represents about 45% of the world market consumption [5], further highlighting its substantial economic and application importance.

PTFE has unique physicochemical properties, including high temperature resistance, unmatched resistance to oxidation and attack from almost all chemicals. It has excellent durability and stability, maintaining their integrity over extended periods. Furthermore, PTFE exhibit one of the lowest coefficients of friction of any material currently available. These characteristics make PTFE an ideal material for applications in extreme conditions that require high temperature, intense abrasion, or aggressive chemical conditions – being crucial for the sealing industry. Additionally, they find utility in scenarios necessitating exceptionally minimal leakage rates or when the flanges are constructed from unconventional chemically resistant materials unsuited for the elevated loads demanded by alternative sealing substances.

In many cases, products containing PTFE are not just the best solution but the only viable one for effectively reducing or eliminating emissions of hydrocarbons and other pollutant fluids, contributing to sustainability and environmental stewardship in the chemical and petrochemical industry. One example is the Low Emission Technology, that utilize packing with PTFE coatings. EPA studies have estimated that valves and connectors account for more than 90% of emissions from leaking equipment with valves being the most significant source [6]. The best available technology for mitigating those emissions is Low-E Packing that contains PTFE being its use mandatory in USA for companies under Consent Decree [7,8].

It is worth mentioning that so far, for the sealing industry, there is no evidence of materials that can replace PTFE achieving the same level of performance. In this way, the development of new materials for each application becomes extremely complex – furthermore technical and economic viability of possible alternatives is still unknown.

Regarding the manufacturing of PTFE itself, and the use fluorinated polymerization aids (FPAs) to produce it, there are already available technologies for the polymerization of PTFE without FPAs (Annex V) [9]. Furthermore, there are also advances in research focused on strategies for destroying PFAS in case it is used (Annex III) [10,11].

Taking into account these considerations, is essential to apply a more rational and scientifically grounded method when regulating these substances. This ensures that those materials deemed safe and non-hazardous are not prohibited due to being grouped solely under the basic definition of PFAS. With the extensive variety of PFAS chemicals in play, it becomes reasonable to

cluster akin PFAS substances together for a comprehensive evaluation of risk within each group. A practical solution could be to clearly define PFAS in the regulations, categorizing polymers separately and conducting a distinct evaluation and detailed analysis for them.

Biocompatibility data

In July 2004, a 100% PTFE Teadit gasket (Teadit 24SH) has been evaluated by a biocompatibility test conducted by BSL BIOSERVICE. This material is manufactured from 100% expanded PTFE, through a specific process capable of generating a uniform and multi-directed fiber structure, a characteristic unique to PTFE. The study followed the procedures indicated according to internationally accepted guidelines and recommendations: United States Pharmacopeia (USP) "Biological Reactivity Tests, in vivo – Classification of plastics" – Plastic Class VI [12].

The tests performed were: Systemic Injection Test, Intracutaneous and Implantation Test. Test results are presented in sequence and the complete study in Annex I.

In the Systemic Injection Test no significant clinical signs were observed.

In the Intracutaneous Reactivity Test the average score was 0.

In the Implantation Test no compound-related tissue reactions were found.

According to reported results, the tested product Teadit 24SH meets the requirements of USP Plastics Class VI which certifies that there are no harmful reactions or bodily effects caused by the material.

The results reinforce the need for regulation to differentiate between hazardous and non-hazardous PFAS substances classes.

References:

[1] Henry, B. J.; Carlin, J. P.; Hammerschmidt, J. A.; Buck, R.C.; Buxton, L.W.; Fiedler, H.; Seed, J.; Hernandez, O. 2018. A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. *Integrated Environmental Assessment and Management*. v.14; n.3, 316-334. (Annex III)

[2] Korzeniowski, S. H.; Buck, R. C.; Newkold, R.N., El kassmi, A.; Laganis, E.; Matsuoka, Y.; Dinelli, B.; Beauchet, S.; Adamsky, F.; Weilandt, K.; Soni, V. K.; Kapoor, D.; Gunasekar, P.; Malvasi, M.; Brinati, G.; Musio, S. 2022. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management*. v.00; n.00, 1-30. (Annex III)

[3] Sales, J.; Hernández, F.; Kappor, D.; Van den Noort, M. 2022. Fluoropolymers: The Safe Science That Society Needs. (Annex III)

[4] Memorandum – Gujarat Fluorochemicals GmbH (Annex IV)

[5] S&P Global (2023). Fluoropolymers – Chemical Economics Handbook. Accessed Sep 2023. Available online at: https://www.spglobal.com/commodityinsights/en/ci/products/fluoropolymers-chemical-economics-handbook.html

[6] Leak Detection and Repair - A Best Practices Guide – EPA (2007). Accessed Sep 2023. Available online at: https://www.epa.gov/sites/default/files/2014-02/documents/ldarguide.pdf

[7 Consent Degree – IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MICHIGAN. Accessed Sep 2023. Available online at: https://www.epa.gov/sites/default/files/2013-09/documents/dowchemical-cd.pdf

[8] Consent Degree – IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO. Accessed Sep 2023. Available online at: https://www.epa.gov/system/files/documents/2023-04/thewilliamscompaniesinc-cd.pdf

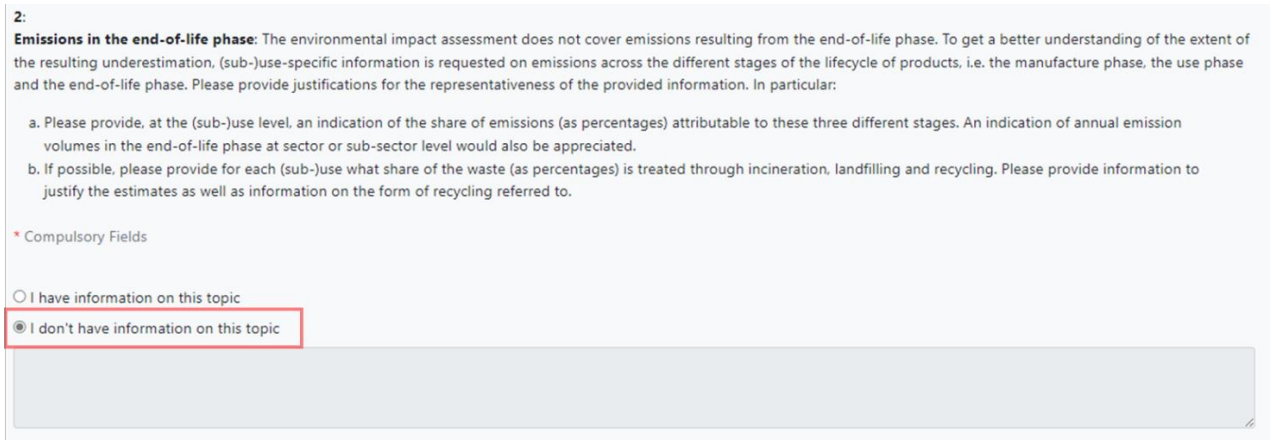
[9] Gujarat Fluorochemicals – Transition from Fluorinated polymerization aid to Non-Fluorinated polymerization aid in the manufacturing of PTFE fine powders. 2023 (Annex V).

[10] Trang, B.; Li. Y.; Xue, X-S., Ateia, M.; Houk, K. N.; Dichtel, W. R. 2022. Low-temperature mineralization of perfluorocarboxylic acids. *Science*. v.377, 839-845. (Annex III)

[11] Scheitlin, C. G.; Dasu, K.; Rosansky, S.; Dejarme, L. E.; Siriwardena, D.; Thorn, J.; Mullins, L.; Zaggerty, I.; Shqau, K.; Stowe, J. 2023. Application of Supercritical Water Oxidation to Effectively Destroy Per- and Polyfluoroalkyl Substances in Aqueous Matrices. *ACS EST Water.* v.3. 2053-2062. (Annex III)

[12] USP Biological Reactivity Tests in vivo. Accessed Sep 2023. Available online at: http://www.pharmacopeia.cn/v29240/usp29nf24s0_c88.html

SECTION III. Specific information request



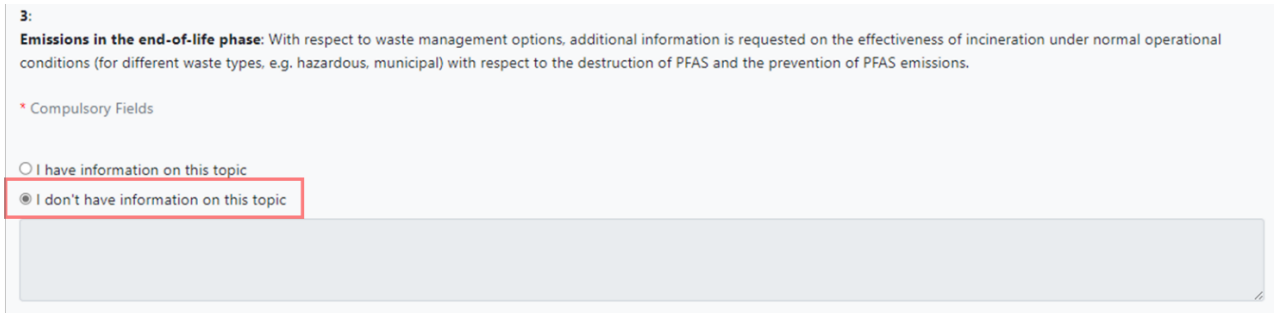


Table 1.

Main applications	Sub uses	Product	Use	Unique attibutes	Industry Sectors
TULAC	Technical textiles	Fabrics	Flange protection to prevent blow out of aggressive media and filters.	Chemically inertness	Chemical and Petrochemical
		Yarns	Used to braid chemically inert packings	Chemically inert, High mechanical strength, Low friction coefficient and able to operate at High temperatures	Pharmaceutical, Food, Mining, Pulp and Paper, Chemical, Power, Petrochemical, Aerospace, Automotive, Steel Mills, Alumina
Food contact materials and packaging	Industrial food and feed production, e.g. in valves and conveyor belts, and for non-stick coatings	FDA Sheets / Gaskets	Creates a seal preventing liquids or gases escaping to atmosphere	Chemically inert, able to operate at high temperatures, low electric conductivity and ability to seal under low stresses	Pharmaceutical, Food
Transport	Sealing applications	Gaskets for Cryo	Tank Lids, Rail Cars, Ships	Chemically inertness, Low Temperature Resistance	Transportations, Chemical, Petrochemical
Energy sector	Proton exchange membrane (PEM) fuel cells / Electrolysis technologies (not PEM)	Threads	Threads for mechanical supporting membranes for Fuel-Cells and Electrolisers	Chemically inertness and High Mechanical Strength	Pharmaceutical, Food, Mining, Pulp and Paper, Chemical, Power, Petrochemical, Aerospace, Automotive, Steel Mills, Alumina
Lubricants		PTFE Packings	Creates a seal preventing liquids or gases escaping to atmosphere	Chemically inert, Low friction coefficient and able to operate at High temperatures	Pharmaceutical, Food, Mining, Pulp and Paper, Chemical, Power, Petrochemical, Aerospace, Automotive, Steel Mills, Alumina
Petroleum and mining	Lining of piping, seals, sensors, cables, etc.	Sheets / Gaskets	Creates a seal preventing liquids or gases escaping to atmosphere	Chemically inert, able to operate at high temperatures, low electric conductivity and ability to seal under low stresses	Pharmaceutical, Food, Mining, Pulp and Paper, Chemical, Power, Petrochemical, Aerospace, Automotive, Steel Mills, Alumina
		Joint Sealing (Tapes)	Creates a seal preventing liquids or gases escaping to atmosphere	Chemically inert, able to operate at high temperatures, low electric conductivity and ability to seal under low stresses	Power (Electrolisers), Pharmaceutical, Food, Mining, Pulp and Paper, Chemical, Petrochemical, Aerospace, Automotive, Steel Mills, Alumina
		Alky IR Protection	Acts as Protective a barrier to prevent crevice corrosion on piping on the alkylation units	Chemically inert, able to operate at high temperatures and ability to seal under low stresses	Petrochemical
		Isolation Gasket	Creates a seal preventing liquids or gases escaping to atmosphere while acting as an insulation for pipeline	Electric Insulation while chemically inert	Power (Transformers), Petrochemical Up, Middle and Downstream
		LE Packings	Lubricating and Blocking agent on graphite Fugitive emission packings to meet Global Low Emission Requirements (ISSO 15848 / API622 / VDI 2440)	Low friction coefficient, Chemical inertness ad high temperature resistance: Reduces friction and act as blocking agents allowing the application of the high stress necessary to met the low emission requirements on hydrocarbon valves that are responsible for more than 60% of the fugitive emissions.	Chemical and Petrochemical

SECTION III. Specific information request

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).
b. The measures that recyclers would need to take to achieve the proposed concentration limits.
c. The costs associated with these measures.

* Compulsory Fields

○ I have information on this topic
◉ I don't have information on this topic

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.

* Compulsory Fields

○ I have information on this topic
◉ I don't have information on this topic

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 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.

* Compulsory Fields

○ I have information on this topic
◉ I don't have information on this topic

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.

* Compulsory Fields

(●) I have information on this topic

( ) I don't have information on this topic

ANS: The following text will be included.

<u>12-year derogation for reconsideration on FDA sheets/gaskets in Food contact materials and packaging (Annex E.2.3)</u>

PTFE has unique properties for this application, so it is important that ECHA consider excluding fluoropolymers from the proposed restriction, as their characteristics are notably different compared to PFAS. Consideration should also be given to the fact that a 5-year derogation is insufficient to cover specific applications like FDA sheets and gaskets in the food process industry being a 12 years derogation the minimum necessary for an actual potential product to be developed, tested and considered safe to replace PTFE on this market.

PTFE is widely recognized for its chemical inertness and proven safety for application in contact with food, meaning it does not release toxic or undesirable substances and does not affect the taste or quality of food products. Additionally, this fluoropolymer is known for its exceptionally low surface tension, resulting in a liquid-repellent characteristic. This property makes PTFE highly resistant to liquid penetration, including oils, water, and chemicals, thus preventing the creation of surfaces conducive to the proliferation of bacteria and microorganisms. This is particularly critical in the food industry, where hygiene and bacterial contamination prevention are paramount for product safety.

In this way, PTFE is widely recognized and accepted by the United States Food and Drug Administration (FDA) as a safe material for food contact. Its chemical inertness, low surface tension, and resistance to contamination ensure compliance with rigorous food safety standards.

Currently, there are no alternative materials available that meet these requirements to replace the use of PTFE in sealing articles. Recognizing the importance of food safety and the need for stringent regulation, a derogation of 12 years for PTFE is fundamental to ensure the integrity of food products and the reliability of industrial processes.

12-year derogation for reconsideration on Gaskets for cryogenic temperature in Transport (Annex E.2.10)

The use of PTFE in sealing applications for the transport vehicle industry deserves special attention when it comes to cryogenic temperatures. Cryogenic temperatures typically refer to extremely low temperatures, near or below the freezing point of liquid nitrogen (-196°C). Developing materials that withstand these temperature conditions is a significant challenge, and PTFE stands out once again in this regard. PTFE exhibit high strength, toughness, and self-lubrification at low temperature, and operates at temperature ranging from -268°C to 260°C, as showed in "Teflon PTFE – Properties Handbook" in Annex VI).

Even at extremely low temperatures, PTFE maintains its flexibility, which is essential to ensure that seals remain effective in cryogenic conditions, where stiffer materials could break or lose their seal.

In addition to this characteristic, PTFE's resistance to a wide range of chemicals is reinforced, maintaining its integrity even under prolonged exposure to these substances. This is critical to ensure the durability of seals in vehicles that may be exposed to cryogenic liquids and chemicals.

Applications at cryogenic temperatures involve a unique combination of low temperatures, chemical resistance, and effective sealing properties. Finding a material that meets all these requirements is a complex task. Furthermore, extensive testing for strength, durability, and compliance with regulations is required to ensure safety and effectiveness, thus extending the development time for these future products.

To date, there are no widely available and proven materials that can fully replace PTFE in cryogenic temperature applications, and searches for viable alternatives even more challenging. It is important to emphasize the need to exclude fluoropolymers from the restriction imposed by ECHA, given that their characteristics are notably different compared to PFAS and a derogation lasting at least 12 years is the minimum necessary to try finding a feasible solution to address this market.

12-year derogation for reconsideration on electrolyzers thread reinforcement and gaskets in Energy sector (Annex E.2.12)

There is a granted 5-year derogation for fuel cells, but there is no information regarding the application of fluoropolymers in electrolyzers. It is important to emphasize the need to either exclude fluoropolymers from the restriction imposed by ECHA, given that their characteristics are notably different compared to PFAS.

It is worth emphasizing that hydrogen production through electrolyzers plays a crucial role in clean energy storage and transportation. Therefore, the derogations for electrolyzers becomes essential to accelerate the adoption of renewable energy and decarbonization.

The application of fluoropolymer, more precisely PTFE, in specific components of electrolyzers can enhance the overall process efficiency. PTFE can reduce energy losses due to its low friction coefficient, resulting in more efficient energy consumption in hydrogen production. Furthermore, its low gas permeability helps minimize hydrogen losses during the electrolysis process.

Currently, there are limited alternatives to replace PTFE for applications in electrolyzers. Developing safe and effective alternative materials is a complex and time-consuming process, as these materials must withstand corrosive environments, maintain energy efficiency, and be safe for large-scale use.

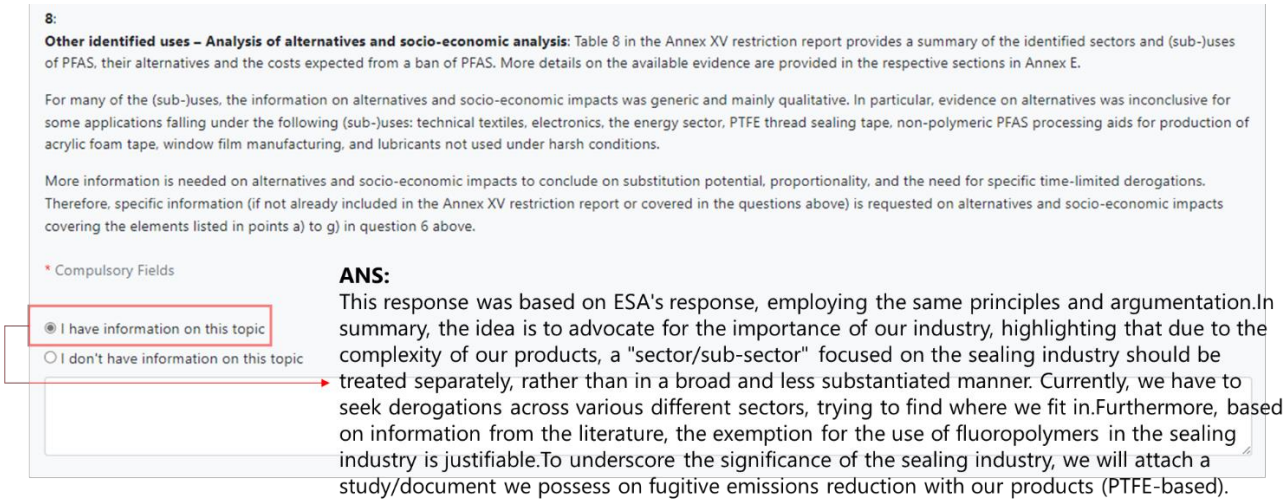
Considering these factors, a derogation of at least 12 years becomes extremely important to facilitate the development of alternatives to PTFE, allowing for a more gradual and secure transition to more sustainable electrolysis technologies.

12-year derogation for reconsideration on PTFE Packings in Lubricants (Annex E.2.14)

A 12-year derogation period for PTFE is justified considering that similar derogations of 12 years were granted for other fluoropolymers, such as PFPE and PCTFE, for the lubricants sector (chemical industry).

It is worth noting that PTFE has unique advantages and properties compared to other fluoropolymers, such as: high chemical inertness, a broader temperature operating range compared to PFPE and PCTFE, exceptionally low friction coefficient among others.

These unique characteristics conferred to PTFE reinforce the importance of including this fluoropolymer in the proposal. In addition, it is important to emphasize the need to either exclude fluoropolymers from the restriction imposed by ECHA, given that their characteristics are notably different compared to PFAS.



ANS.:

Proposal for the inclusion of Protective Fabrics as Technical Textiles (Flange Protectors) – TULAC (Annex E.2.2.)

One significant application within the TULAC subsector, which was not covered in the proposal, relates to the use of fluoropolymers in flange protectors.

Flange protectors serve as a valuable alternative in preventing industrial accidents. They act as a physical barrier, providing protection against potential splashes resulting from leaks in the flanges of pipelines carrying chemically aggressive fluids. Additionally, they ensure the safety of workers by preventing direct contact with hot, pressurized, or hazardous flanges.

In addition to these benefits, flange protectors play a crucial role in mitigating the risks of chemical or toxic substance leaks, significantly contributing to environmental preservation and the prevention of soil, water, and air contamination.

The choice of materials for manufacturing flange protectors varies and depends on the products transported through the pipelines. For instance, when crafted from PTFE fabrics and cords, these protectors can be reused for extended periods. PTFE is resistant to chemical attacks, and its low coefficient of friction reduces wear and friction between contacting surfaces, thus extending the protector's lifespan. Another relevant feature is its low permeability to gases and liquids, which helps prevent leaks and maintain the integrity of the flanges.

Based on the arguments presented, the importance of including protective fabrics as technical textile in the proposal is underscored.

Proposal for the inclusion of PTFE yarns as Technical Textiles – TULAC (Annex E.2.2.)

The use of PTFE yarns for braiding packings is well-established in the industrial sector. Due to its exceptional properties, which have been previously elucidated, including excellent chemical resistance, a low coefficient of friction, and high resistance to extreme temperatures, PTFE is an ideal material for sealing and insulating systems under adverse conditions and within a wide temperature range, from cryogenic temperatures to high temperatures.

Another advantage of using PTFE yarns to create packings is their high flexibility, a crucial characteristic for applications that involves repetitive movements or compression.

There are numerous possibilities for combining PTFE yarns with other materials, such as expanded graphite, aramid fiber, or glass fiber. This combination of materials allows gaskets to offer specific properties tailored for each type of application.

Based on these application considerations, the utilization of PTFE yarns for braiding packings is a significant market and should not be disregarded. Therefore, is relevant to include the use of PTFE threads for applications within the sector of Technical Textiles.

Proposal for the inclusion of Sealing devices as a separate sector

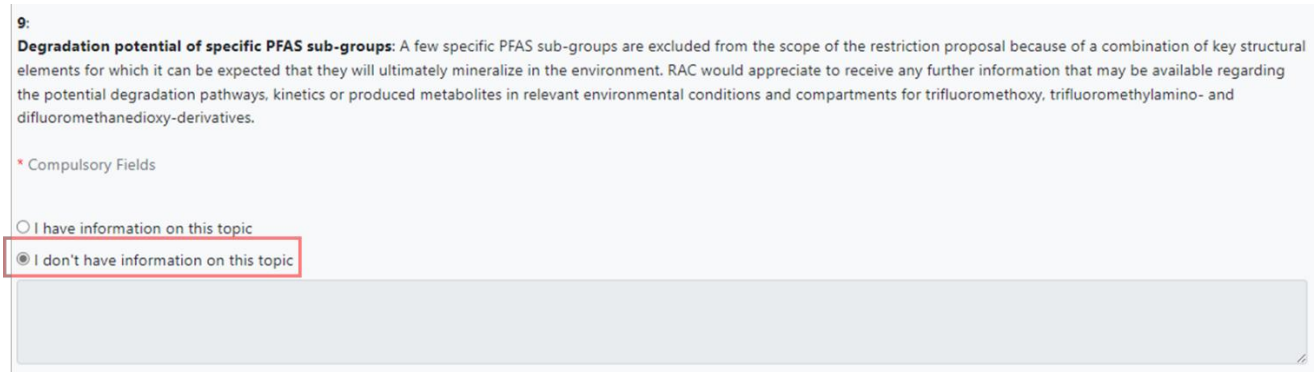
In accordance with European Sealing Association (ESA) position and Fluid Sealing Association (FSA), AK-Dichtungen (Association of Sealing Manufacturers in Germany) as well as other trade organizations, sealing devices have vital role in mission-critical applications in many important industries. ECHA should consider treating this segment as a separate sector within the framework of restrictions due to this vital role and potential impact on the safety of industrial operations. Industries of the most varied segments utilizes sealing devices, such as, power generation, water & wastewater treatment, oil & gas production, mining and ore processing, pulp and paper, pharmaceutical, aerospace, and semiconductor production, and many others. Relying solely on exemptions granted to specific industries does not reflect the importance of our business and the use of fluoropolymers for these applications.

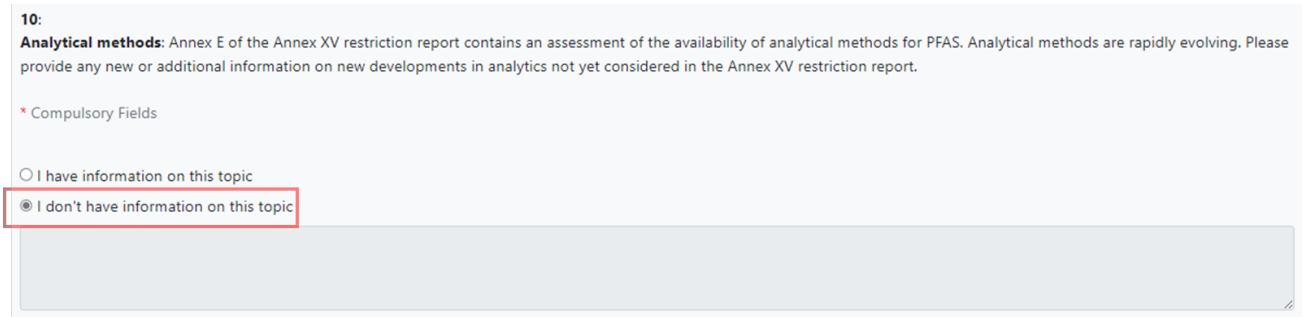
Stands out here again that for the sealing industry the use of fluoropolymers (PTFE) is indispensable. These materials have unique characteristics that make them irreplaceable in applications that require extreme operating conditions, such as heat, corrosion, pressure, among others, contributing to the safety and reliability of processes involving gases, liquids and powders. In the current scenario, there are no materials available on the market that can replace the use of fluoropolymers in sealing applications.

In this way, one must consider that for these applications it is estimated an extensive period for research and development of alternative materials capable of replacing fluoropolymers, considering that the studies are in the early stages. In addition, one must take into account the period

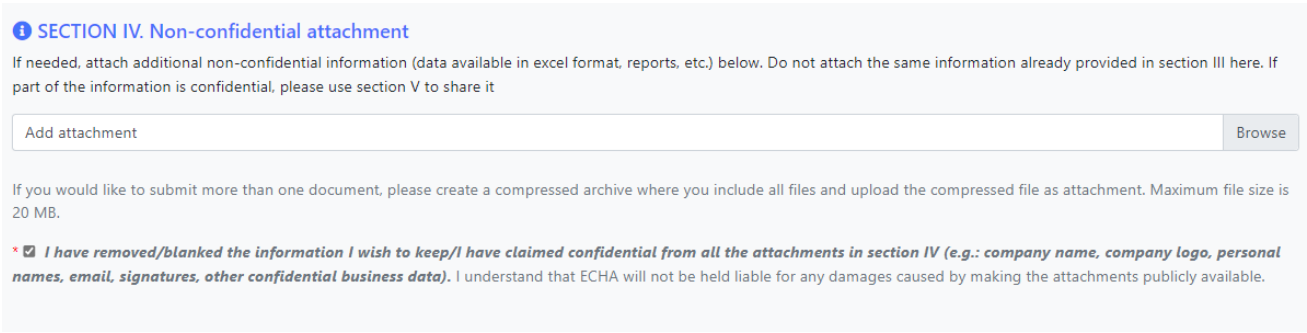
of regulation of these “new materials”, that in many sectors (e.g., aerospace, nuclear power plants, pharmaceutical industry) the testing and approval process can take years. Another relevant factor that must be highlighted is that sealing devices, such as gaskets and packings, are critical components to meet Greenhouse Gas (GHG) emissions reduction objectives. The sealing industry plays a fundamental role in reducing fugitive emissions, contributing to customers and end-users achieving their own ESG goals like carbon neutrality and keeping global warming below 1.5°C (in accordance with the Paris Agreement).

Based on these considerations, an exemption for the use of fluoropolymers in the sealing industry is justifiable, due its importance on the economy and the lack of viable alternatives.





SECTION IV. Non-confidential attachment



Documents to be attached

1. Biocompatibility Test – Teadit 24SH
2. N/A

3. Paper: Henry et al, 2018; Korzeniowski et al., 2022; Sales et al, 2022; Trang et al, 2022 and Scheitlin, et al. 2023.
4. Memorandum – Legal Observations Gujarat.
5. Gujarat Fluorochemicals - Transition from Fluorinated polymerization aid to Non-Fluorinated polymerization aid in the manufacturing of PTFE fine powders.
6. Teflon PTFE – Properties Handbook - Dupont

SECTION V. Confidential attachment