Guide to Providing Information to the ECHA Consultation on the Proposed Ban of PFAS substances.

Index

Introduction

In February 2023, ECHA (The European Chemicals Agency) published a draft restriction proposal to ban or severely restrict the use of all Per- and polyfluoroalkyl (PFAS) substances. PFAS substances are a class of about 10000 chemicals, their one common feature being that they contain at least one CF_2 group within their structure. They vary in physical appearance from gases, to liquids and solids. Within this group of chemicals are some that are widely acknowledged to be harmful to the environment. However, it also includes fluoropolymers (such PTFE, PFA, FEP, & PVDF) and fluoroelastomers (including FFKMs (Kalrez, Chemraz, etc.) and FKMs (Viton, etc.), which are not considered to be harmful. In particular, fluoropolymers have been designated as polymers of low concern by the OECD (The Organization for Economic Cooperation and Development).

ECHA is now conducting a public consultation on the proposed ban, and is seeking information from industry, and any other interested parties. This particular consultation continues until September, but it is usual for ECHA to give more weight to responses submitted earlier in such consultations.

From the information that ECHA has published to date it is clear that they have not understood the implications to the EU, both to industry and the public, of implementing this proposed ban. Therefore, all Indutrade companies that use fluoropolymers and fluoroelastomers in their products, or in their production equipment, are being encouraged to submit information to ECHA to provide evidence of the consequences of implementing the proposed ban.

What follows is intended as an aid to help you contribute to the public consultation. ECHA have specifically asked that information be factual, rather than opinion. That said, they are not in a position to challenge information that you provide on the impacts to you and your customers of a ban, so feel free to submit approximate information, although references to published studies that substantiate your claims will add weight to what you say.

The link below is to the restriction proposal:

https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49

Accessing the Public Consultation

ECHA have set up a web portal to allow you to provide information to the consultation (see link below).

Important Notes:

- You have to complete your submission in one session, so it is recommended that you prepare your submission in advance and then copy and paste it into the relevant sections of the portal.
- Each individual field for information has a 9000 character limit. If your submission for any individual field exceeds this, it is possible to add a zipped attachment containing further information, although there is a size limit of 20Mb.

Link to consultation document:

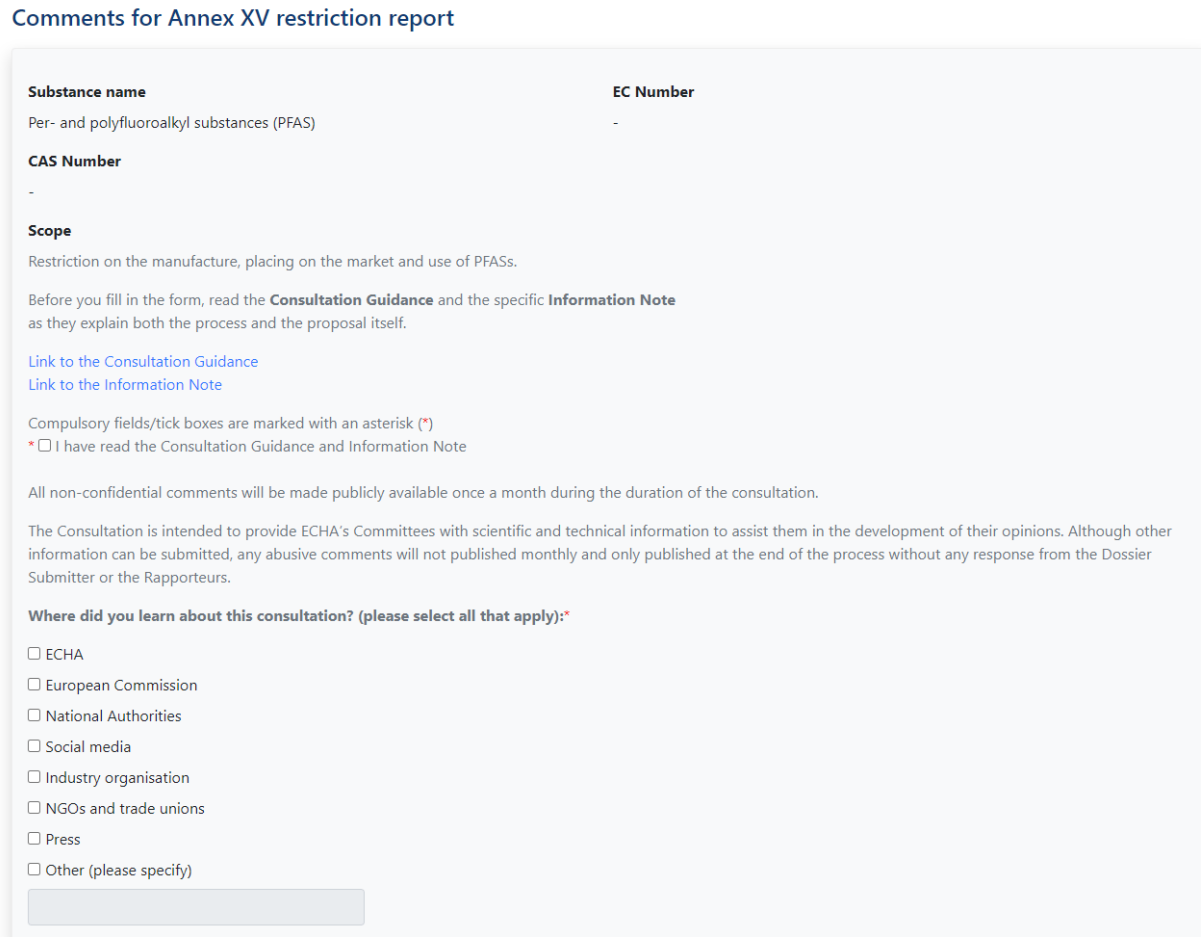
https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjectId=0b0236e1885e69de

Completing the Consultation

The following sections follow the structure of consultation portal, giving comment/advice about completing each section. At the top of each section is an image of the relevant section from the consultation portal. If you have information to add, please tick the relevant box and add information. If you have no information, simply tick the "I don't have information on this topic" box and move to the next section.

Nb. Please do not cut and paste comments from this document. Use your own words and provide information from your own company/industry.

Introductory Section



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.

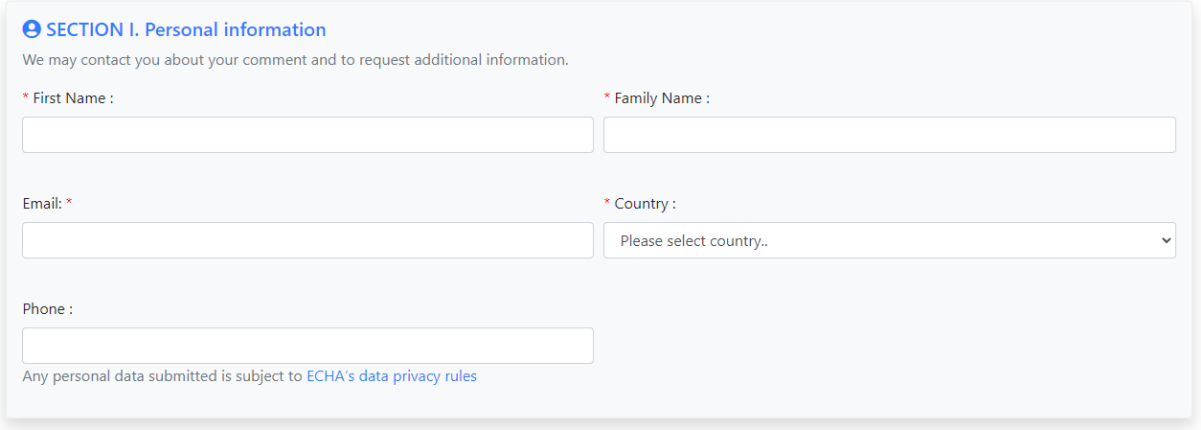
The Consultation is intended to provide ECHA's Committees with scientific and technical information to assist them in the development of their opinions. Although other information can be submitted, any abusive comments will not published monthly and only published at the end of the process without any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

Tick the relevant boxes. The “I have read the Consultation Guidance and Information Note” box is compulsory.

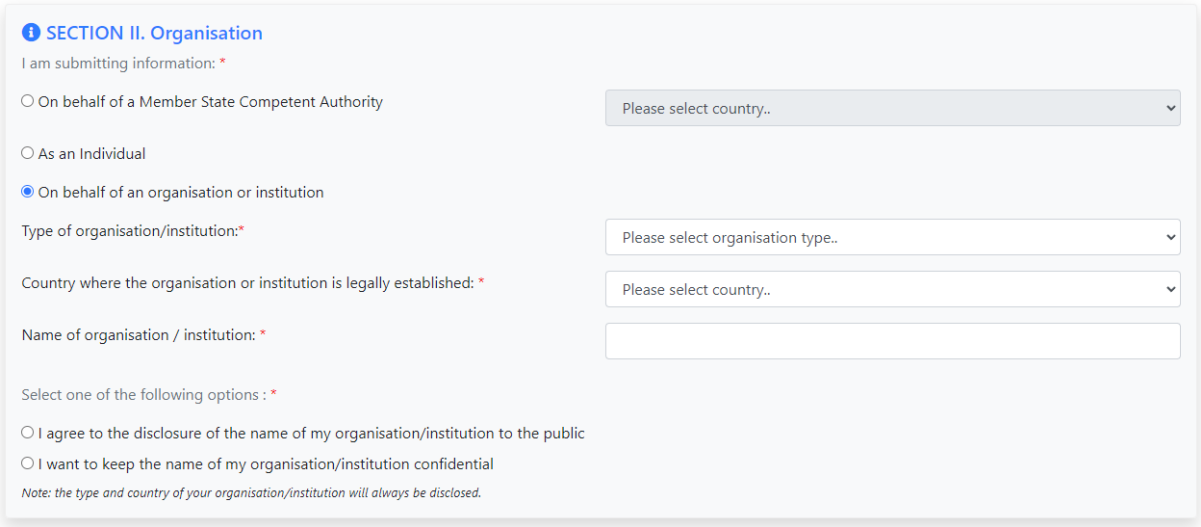
Section I



The consultation is open to everyone. It doesn't matter if you are based in the EU or not. Asterisked fields are compulsory.

Nb. ECHA won't disclose any personal information to third parties.

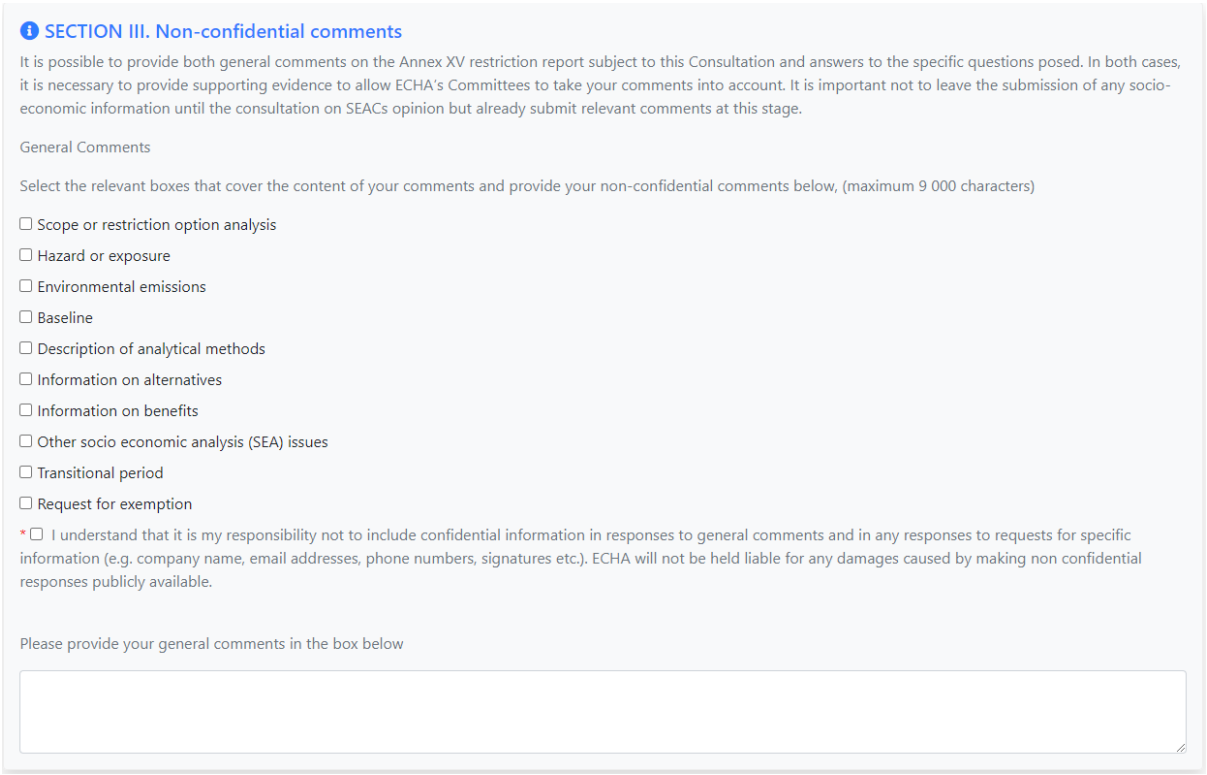
Section II



Once per month ECHA publish non-confidential comments submitted up to that point, and who has submitted them (non-confidential). If you tick the box to keep your organisation confidential then only the ECHA committee members will be able to see your organisation.

Nb. The upper "Please select country" box is only for the use of "Member State Competent Authorities".

Section III



SECTION III. Non-confidential comments

It is possible to provide both general comments on the Annex XV restriction report subject to this Consultation and answers to the specific questions posed. In both cases, it is necessary to provide supporting evidence to allow ECHA's Committees to take your comments into account. It is important not to leave the submission of any socio-economic information until the consultation on SEACs opinion but already submit relevant comments at this stage.

General Comments

Select the relevant boxes that cover the content of your comments and provide your non-confidential comments below, (maximum 9 000 characters)

- ☐ Scope or restriction option analysis
- ☐ Hazard or exposure
- ☐ Environmental emissions
- ☐ Baseline
- ☐ Description of analytical methods
- ☐ Information on alternatives
- ☐ Information on benefits
- ☐ Other socio economic analysis (SEA) issues
- ☐ Transitional period
- ☐ Request for exemption

* ☐ I understand that it is my responsibility not to include confidential information in responses to general comments and in any responses to requests for specific information (e.g. company name, email addresses, phone numbers, signatures etc.). ECHA will not be held liable for any damages caused by making non confidential responses publicly available.

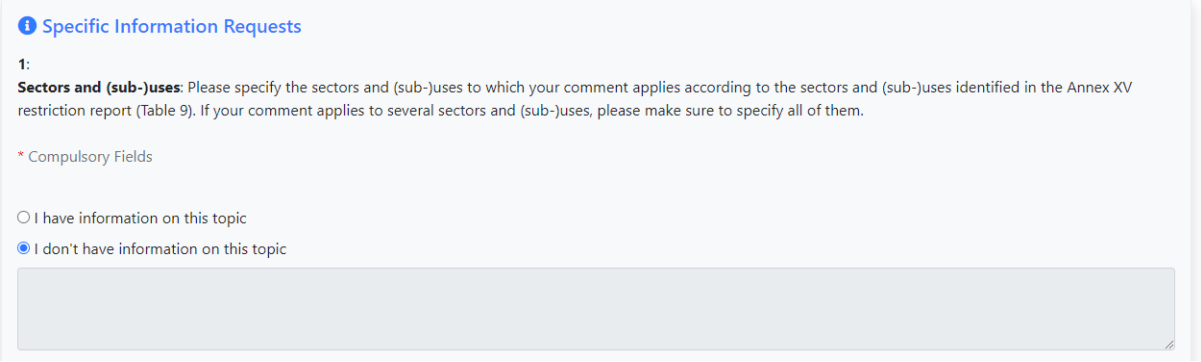
Please provide your general comments in the box below

Tick all of the boxes where you have information that you want to submit, and include the last one. Add your information into the box below. It is quite likely that you will exceed the 9000 character limit. Therefore, it may be more appropriate to attach a separate document.

Of particular importance, please ensure that you explicitly request that fluoropolymers and fluoroelastomers are exempted from the current restriction proposal.

Specific Information Requests

1. Sectors and (sub-) uses



The restriction proposal (see link at start of document if you want to access it) considers quite a few uses of PFAS chemicals. For each identified use, the consequences of a ban, and possible alternatives have been considered. However, the majority of uses of fluoropolymers and fluoroelastomers by industry have not been included in this assessment, but as drafted, the ban will cover all uses.

This section of the public consultation is seeking additional information about the uses that were identified in the restriction proposal. Table 9 refers to the table in the restriction proposal (pages 116 – 138) that summarises all of the identified uses of PFAS chemicals. It is recommended that you look at this table to see if any of your uses of fluoropolymers or fluoroelastomers are covered. Nb. Some of the areas considered are: medical devices; transport; electronics & semiconductor; construction products; petroleum and mining.

As an example, the images below show the information for semiconductors and mining uses.

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
Semiconductors	Given the weak evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [The semiconductor manufacturing process]	Ban with a transition period of 18 months and a **12-year** derogation, because the information provided suggests considerable transition times (3-10+ years) when alternatives become available.	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1. Ban with a transition period of 18 months and a 12-year derogation: Added time for the derogation provides manufacturers with more opportunity to identify and develop cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses.

Use sector (with sub-uses)	Proposed derogation or derogation for reconsideration	Duration of derogation period, including substantiation	Cost impact of 5 and 12 year derogation periods
Petroleum and mining (Annex E.2.15.)			
Non-polymeric PFAS applications (tracers and anti-foaming agents)	Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.	Not applicable	Same as under RO1.
Fluoropolymer applications	In light of the sufficiently strong evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, a derogation is **proposed** for: • Fluoropolymer applications	Ban with a transition period of 18 months and a **12-year** derogation, because manufacturers and suppliers have indicated that it could take a relatively long time (several years to several decades) to transition towards using alternatives that can achieve the same level of performance. Furthermore, given the relatively large (up to hundreds or thousands) number of individual products supplied in this sector, all with different specific formulations, this would be a complex undertaking needing sufficient time [sufficiently strong evidence base]. Continued R&D increases the chance that alternatives for the relevant applications will be identified.	Ban with a transition period of 18 months and a 5-year derogation: Same as under RO1. Ban with a transition period of 18 months and a 12-year derogation: If technically and economically feasible alternatives are identified: • The costs related to loss of functionality would be avoided. • The costs related to product reformulation and quality assurance would (at least partly) remain but would be postponed or spread out over a longer period of time.

For each identified use, ECHA is recommending either: a ban as soon as the restriction comes into force; a 5 year derogation; or a 12 year derogation. These derogations are simply a postponement of bans to provide a little more time for alternatives to be found. As drafted, there is no possibility to extend these periods if no alternative materials have been identified.

2. Emissions in the end of life phase

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.

* Compulsory Fields

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

Add any relevant information that you have, or leave blank.

3. Emissions in the end of life phase

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.

* Compulsory Fields

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

Add any relevant information that you have, or leave blank.

4. Impacts on the recycling industry

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

Add any relevant information that you have, or leave blank.

5. Proposed derogations – Tonnage and emissions

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.

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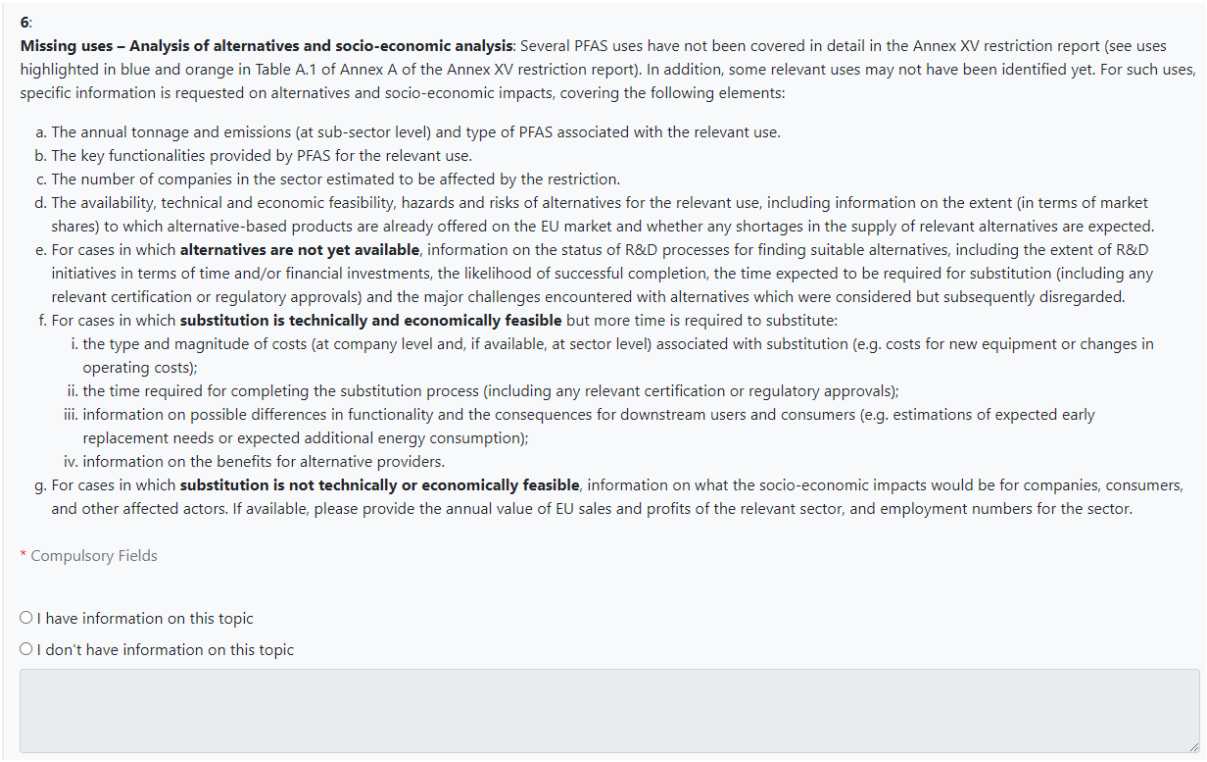
Add any relevant information that you have, or leave blank.

6. Missing uses – Analysis of alternatives and socio-economic analysis



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

This is the section where you can add information about uses of fluoropolymers and fluoroelastomers that have not been considered in the original restriction proposal. Once again, it is likely that you will exceed the 9000 character count, so a separate attachment for your response is the best option.

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

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

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○ I don't have information on this topic

Add any relevant information that you have, or leave blank.

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

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.

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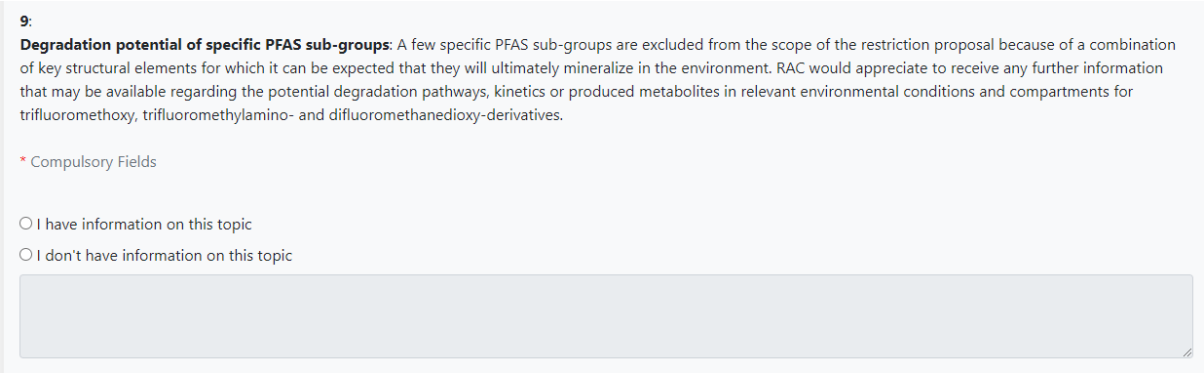
Add any relevant information that you have, or leave blank.

9. **Degradation of specific PFAS sub-groups**



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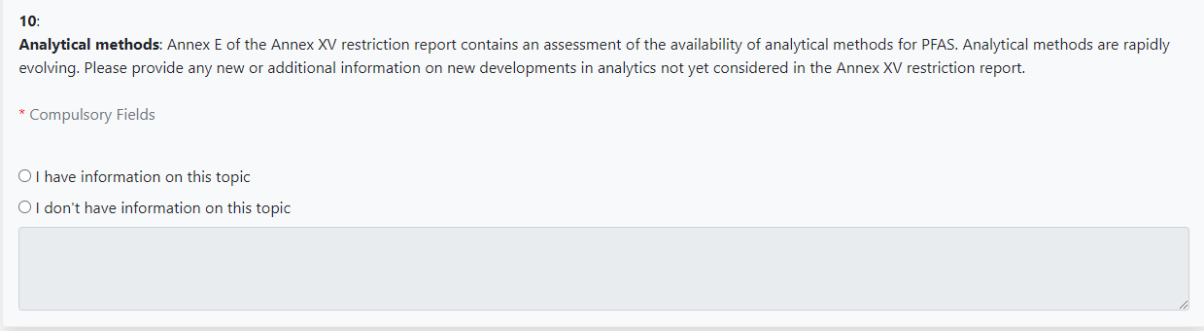
10. **Analytical methods**



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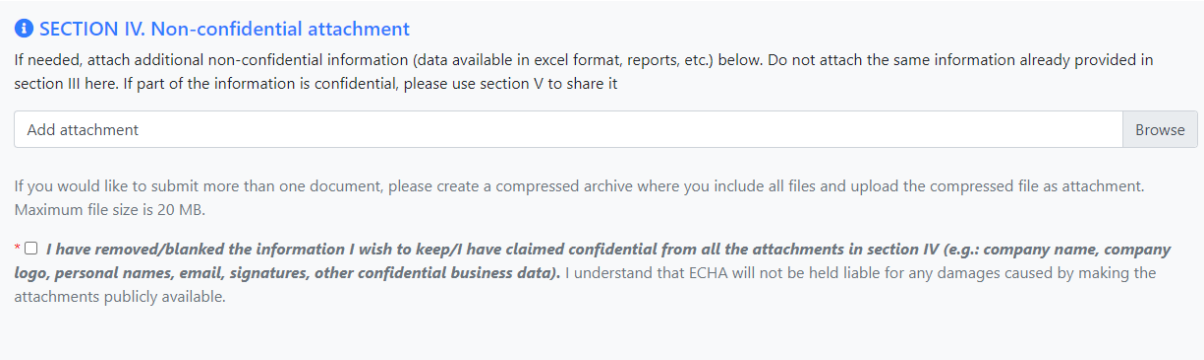
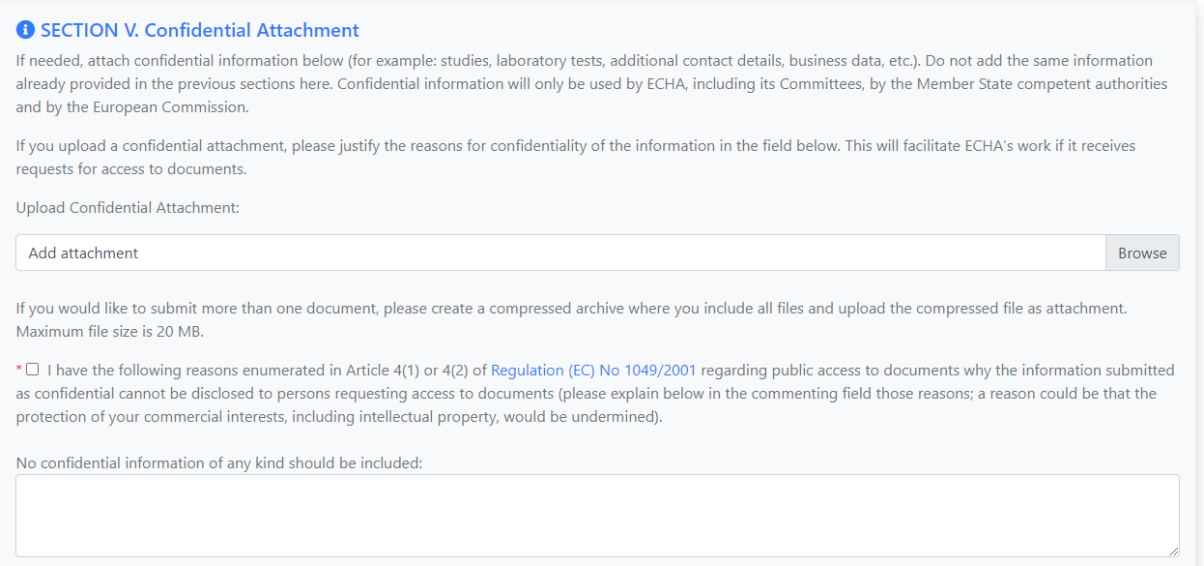
Section IV. Non-confidential attachment



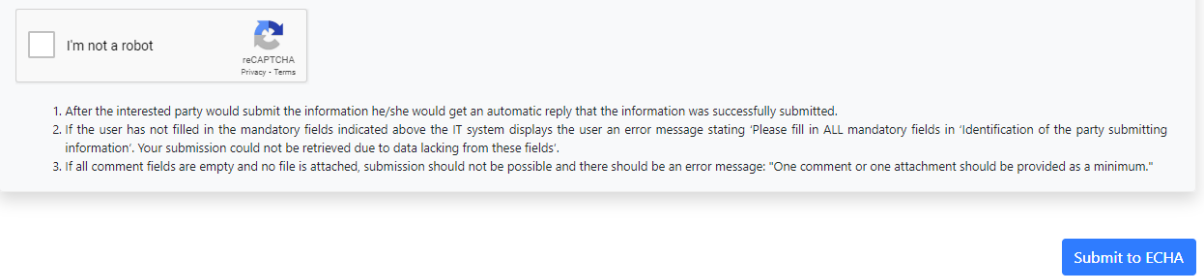
This is where you can add any additional information that didn't fit into the 9000 character limits of the answer boxes of earlier questions. Also, if there is additional information that you want to provide, such as additional documents that have more detailed information, here is where to add it. Nb. If you are referencing published documents (books, research papers, etc.) you only need to supply the reference, and not the entire document.

Please also create a single zip file for all of your non-confidential attachments to upload.

Section V. Confidential attachment



This is where to upload any confidential information that you want to submit. As above, please create a single zip file for all of your attachments to upload in this section.



Here you only need to tick the "I'm not a robot" box and click the "Submit to ECHA" button.

Nb. The "not a robot" button is time limited (it unticks itself after a short period of time). However, if it does, you can simply retick it.

Appendix 1 Corrosion Resistant Products Ltd Submissions for Various Sections

Section III

As drafted, the scope of the Annex XV restriction proposal concerning polyfluoroalkyl substances (PFASs) covers a wide range of chemicals including gases, liquids and solids.

Scope of restriction option analysis

As drafted, the scope of the Annex XV restriction proposal concerning polyfluoroalkyl substances (PFASs) covers a wide range of chemicals including gases, liquids and solids.

These PFAS's have significantly different properties and are utilised in a very wide range of industries and applications.

This submission is particularly concerned with the inclusion of fluoropolymers (such as PTFE and PFA) in the restriction proposal, specifically used in the lining of process pipework and associated equipment in the pharmaceutical, semiconductor, fine chemicals manufacture[1], bulk chemicals manufacture, water treatment and the oil and gas industries.

PTFE / PFA fluoropolymer lined pipework and valves are used in the production of semi-conductors, medicines, drugs, food stuffs, petrochemicals, and fresh water. In general, they convey highly corrosive media such as hydrochloric, sulfuric, nitric acids etc, prevent spillage and leakage of these substances whilst maintaining their purity by preventing contamination from the steel pipework structure.

At present, PTFE / PFA fluoropolymers are the only pipe / valve lining that can withstand the nature of the corrosive media, maintain the required purity levels, and tolerate wide-temperature variations necessary in many of the processes. These fluoropolymers are the only sustainable material of choice for almost every process industry, where they serve as linings for vessels, piping, pumps, valves, columns, column internals, hoses, expansion joints, seals and gaskets. They provide durable low cost, low maintenance, reliable alternatives to more expensive and unsustainable exotic metal alloys.

The current scope of the restriction fails to consider these very significant uses of fluoropolymers, and the significant consequences of the proposed ban. Therefore, it is necessary that such PTFE / PFA fluoropolymers should be removed from the current restriction proposal.

Hazard or exposure

The production of PTFE is now possible without the use of any surfactants such as perfluorooctanoic acid (PFOA), which has been associated with environmental and health concerns. So, when carried out in a suitable environment PTFE and PFA manufacture is a considered to be a safe process. In addition, use as pipe and associated equipment linings, PTFE / PFA fluoropolymers are electrochemically, biochemically, enzymatically and chemically virtually inert. Unlike some other PFAS molecules, fluoropolymers are considered to be non-bio-accumulative, non-bio-available, non-

[1] Fine chemicals are typically high purity, complex molecules that are used as active ingredients, intermediates, or raw materials in the manufacture of pharmaceuticals, agrochemicals, flavours, fragrances, and other specialty chemicals. They are often produced through multi-step chemical synthesis and require specialized expertise and equipment for their production.

hazardous, insoluble (and therefore not mobile in water), non-toxic (locally or systemically), and are classed as polymers of low concern by the OECD[2].

CRP has been processing fluoropolymers for over 40 years with annual staff health checks with no related ill health incidents. Many of the staff have worked for the company for more than 20 years.

Information on alternatives

At present there are no known pipe/valve lining materials in development that will provide equivalent, or similar, properties, able to withstand such harsh environments and high temperatures to fluoropolymers irrespective of cost/price.

More expensive options include glass lined steel, or exotic metal pipes/coatings and in some circumstances, these materials may be suitable alternatives for handling particular individual chemicals (see attached Flowserve documents, "Selecting Corrosion Resisting Alloys" and "Guide to the Selection of Corrosion Resisting Non-Metallics"). However, even these alternatives are more limited in the type of media and temperatures they can withstand.

Turning to consider the alternative materials in a little more detail:

> **Glass lined piping.** Over the last 2 – 3 decades industry has largely moved away from this product range, simply because the glass linings are brittle and can be easily damaged. Damaged linings lead to product failure, varying from minor leaks, product contamination through to catastrophic failures. Such events result in environmental damage and potentially loss of human life.
>
> **Exotic metallic pipework** (such as hastelloy, inconel, incoloy, titanium, and tantalum). This pipework is in the order of 2 to 10 times more expensive than fluoropolymer lined pipework, making it economically unviable compared to PTFE / PFA fluoropolymer lined in almost all circumstances. In addition, while each individual material may be suitable for a specific duty, often it is not suitable for the range of duties that individual manufacturers require. Also, due to its lack of universal corrosion resistance there is a danger that an unsuitable chemical will be put through such pipework, leading to failure, with all of the associated costs and hazards to personnel and the environment. Finally, the extraction and processing of these rare metals brings additional environmental considerations, particularly when this is done in countries with less stringent environmental protection legislation, such as: Khazakstan, India, Albania (chromium); Indonesia, Russia (nickel); Sierra Leone, Russia (titanium); Democratic Republic of Congo, Rwanda, Brazil (tantalum).

The attached tables highlight the different performance characteristics of PTFE / PFA fluoropolymers compared to the various alternatives available today. This shows how every other alternative has inferior performance characteristics to that of PTFE / PFA fluoropolymers. Add in the implications in terms of cost and physical performance then it is clear that there isn't a viable alternative for many production processes at this time.

[2] A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. *Barbara J Henry, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, Heidelore Fiedler, Jennifer Seed, and Oscar Hernandez*

Subsequently, if PTFE / PFA fluoropolymers were to be banned, leaving only glass or exotic metal lining options there are a number of consequences:

(i) Many pharmaceutical plants run a batch manufacturing process, making a batch of one drug, followed by a batch of a different type with a different set of parameters. Piping lined with PTFE / PFA fluoropolymer can easily accommodate this due to its broad suitability to cope with a wide range of circumstance. If fluoropolymers were to be banned, such multipurpose plant would cease to be possible, again making such manufacturing less competitive in the EU.

(ii) To cope with a particular set of process chemistry, it would be necessary to double up on piping, pumps, valves etc., to allow each chemical to be handled through an individual set of pipework, with the additional costs associated with such a set-up, thus increasing manufacturing costs and reducing efficiency. This would make EU production uneconomic and could result in production being moved to non-EU based factories.

What has been said thus far is generic and covers a wide range of uses for fluoropolymer lined piping. What follows are a couple of specific examples of uses where there are no suitable alternative materials:

Production of electronic chips – requiring High Purity Acid:

The etching of microchips in the electronic industry requires high purity (sulfuric and hydrofluoric) acids with less than 36ppt (parts per trillion) contamination. As the circuits on the chips get smaller, so the purity of acid required gets higher. The only pipework suitable to handle these acids and maintain the purity required are fluoropolymer lined pipework. If fluoropolymers were to be banned, then electronic chip & computer manufacture is unlikely to be sustainable within the EU compared to manufacturing in other countries.

Process:
The normal “dirty” acid which is available after the standard acid production process needs to be refined by evaporation followed by absorption/condensing. This process runs at around 150°C and requires corrosion resistant material of construction. Glass or glass lined steel cannot be used, because the acids leach out chemical elements from the glass (glass lining) which are harmful to the electronic circuits on the electronic chips. Exotic metal lining (including tantalum) cannot be used either, because metal ions they release would generate short circuits in the electronic chips after etching. Other plastics are clearly not temperature or chemical resistant enough for this application.

Production of Toluene Diisocyanate (TDI) and Methylene diphenyl diisocyanate (MDI) for Polyurethane production:

Polyurethane is a common base material for many things including advanced glues used in products such as light weight high tech designs like cars, airplanes and buildings, as well as in the manufacture of high-performance insulation.

Process:
Manufacturing polyurethane is a highly corrosive process running at temperatures between 100° and 150°C. Here glass lined steel pipework is used for the chemical reaction and transportation for these highly corrosive chemicals. However, this ‘stress sensitive’ material needs expansion joints and bellows made from a material able to withstand the chemicals and temperatures used to prevent cracks in the pipework and vessels. PTFE is used to

manufacture such bellows and maintain the cleanliness criteria needed. Any materials other than PTFE, such as rubber, would not survive more than a few months in this application, while PTFE bellows have a lifetime of around ten years.

Information on benefits

Due to the properties, uses and importance of PTFE / PFA fluoropolymers we can see no benefit to the inclusion of such fluoropolymers in the scope of Annex XV.

Other socio-economic analysis (SEA) issues

If PTFE / PFA fluoropolymers were to be included in the scope of Annex XV as proposed, there are several foreseeable consequences:

Our business would not be able to continue selling PTFE / PFA fluoropolymer lined pipework and valves and as this constitutes 95% of our sales then the business would not be able to continue resulting in the loss of 70+ direct jobs plus as at least that many again in the local economy as sub-suppliers.

In the UK there are over 700 businesses that manufacture pharmaceutical and chemical products. Their combined turnover is almost £10 billion, employing over 136,000 people[3]. In Europe, there are over 2,100 businesses that manufacture pharmaceutical products. Their combined turnover is almost £300 billion, employing approximately 840,000 people[4], almost all of which use PTFE / PFA fluoropolymer lined pipework and fittings in one form or another. If the cost of production of such products increases significantly then the 'attractiveness' of Europe (and the UK) as a pharmaceutical and chemical manufacturing centre will reduce resulting in plant closures as they migrate to cheaper locations. The size of any socio-economic impact of such a ban is difficult to estimate but given intense commercial pressure under which these companies operate, the impact will be significant and detrimental.

Having to replace PTFE / PFA fluoropolymer lined pipework with less effective alternatives, where this is even possible, will result in less reliable process plant. This in turn will lead to more failures/leaks, leading to more damage to the surrounding equipment, more potential for leaks of hazardous chemicals into the environment, more potential injuries to personnel, more repair/rectification costs. Also, the replacement process pipework will have shorter lifetimes, leading to higher costs due to increased maintenance costs, more frequent replacement of equipment, the increased use of scarce resources to produce replacement parts, and additional disposal costs of the scrap products.

Transitional period

Given the current lack of suitable alternatives to PTFE / PFA fluoropolymers it is not appropriate to implement a ban in any form on these substances as used in lined pipework and associated equipment. The restrictions it would place on critical industries and the impact of their movement of production centres to non-European locations would be catastrophic both in economic and social

[3] Reference: Statistica - Pharmaceutical industry in the United Kingdom (UK) - Statistics & Facts https://www.statista.com/topics/5056/pharmaceutical-industry-in-the-uk/
[4] Reference: Statistica - Pharmaceutical industry in Europe - Statistics & Facts, https://www.statista.com/topics/8631/pharmaceutical-industry-in-europe/#topicOverview

terms. The industries that would be affected by such a ban (even over an extended period) are key to the success of any Western economy and critical to the wellbeing and standard of living for its citizens.

On that basis it is suggested that a transitional period would not be appropriate for PTFE / PFA fluoropolymer pipe lined products at least until a commercially viable alternative has been identified.

Request for exemption

In conclusion to the information provided above, PTFE / PFA fluoropolymers are polymers of low concern. Their properties are completely different from many of the other PFAS molecules that the current restriction proposal is designed to ban. It is therefore requested that they be excluded from the current restriction proposal, since to include them would create massive unintended consequences for both industry and wider society within the EU.

Specific Information Requests

1. **Sectors and (sub-) uses**

Specifically, we are commenting on the semiconductors, petroleum and mining sectors.

In considering the possible replacement of PFAS by substitutes or alternatives as a response to any risk management action, it is necessary to consider their technical suitability, cost (economic feasibility), environmental and human health effects, as well as their capability to meet relevant required performance standards.

For fluoropolymers and fluoroelastomers, the industry view appears to be that for many or most uses there are no alternatives with the requisite performance characteristics.

PTFE / PFA fluoropolymer lined pipework and associated equipment are deployed on a global basis, safely transporting various liquids and liquified gases in bulk around a huge variety of manufacturing and processing sites, most of which are classified as dangerous goods or are otherwise potentially hazardous.

These highly regulated industries, rely upon the PTFE / PFA fluoropolymer lined pipework and associated equipment to withstand extreme conditions in terms of corrosion and temperature as well as being versatile enough to be capable of handling many different types of media as processes change.

PTFE / PFA fluoropolymer lined pipework and associated equipment must provide a range of technical properties that ensure the materials function as reliable and safe containment the respective chemicals. Fluoropolymer, materials such as PFA and PTFE, are widely used because of the proven properties of chemical resistance, temperature range, durability and vibration resistance.

The exceptional properties of these lined pipe and associated equipment significantly impact on the operational safety and leak tightness record of the chemical process industry.

Alternative lining element materials have been researched and in some controlled applications have been trialled but there is an overwhelming technical need to continue the use of fluoropolymers. There is a risk to the environment and the public should access to the totally reliable existing pipe lining element material be restricted.

The material in this form does not shred or degrade into particles. Sealing elements have a long-life expectancy and are eventually safely disposed of as licensed industrial waste. Several trade bodies and associations have initiated a variety of programs to consolidate used materials and to seek recycling options.

The safe containment and minimised contamination of chemicals is the prime consideration of the user of PTFE / PFA fluoropolymer lined pipework and associated equipment. This requires the use of lining and sealing elements with a critical range of properties and attributes.

Essential operational properties of these materials include:

- Chemical resistance and compatibility
- Thermal stability
- Durability

Chemical resistance and compatibility

Process and manufacturing industries use a wide range of chemicals which require the lining and sealing elements to be compatible over the range. This is achieved by currently the use of PTFE / PFA fluoropolymer lined pipework and associated equipment.

Whereas some processes are dedicated to a specific chemical at a specific temperature, most are designed to be 'flexible' in their design to handle different substances according to production demand.

The cost of labour, materials, and downtime to change pipework and associated equipment before each process change, should the current universally compatible lining and sealing elements not be available due to regulatory restriction, would be prohibitive. Furthermore, the need to change contaminated lining and sealing elements would result in an added safety risk to maintenance personnel and increased waste disposal.

Thermal stability

PTFE / PFA fluoropolymer lined pipework and associated equipment are manufactured to meet the general industrial required temperature range of -40°C to +200°C. These lining and sealing elements must therefore equally perform at these temperatures.

Even if operating at ambient temperatures, certain corrosive chemicals are incompatible with alternatives fluoropolymer lined pipework and associated equipment. Furthermore, it is possible that such installations must be able to withstand high pressure water and cleaning fluid temperatures of up to 95°C and steam of about 160°C during the decontamination process.

Some process and manufacturing industries require these chemicals to circulate at a variety of concentrations, temperatures and pressures depending on the role they are fulfilling which again calls for a versatile solution that currently only PTFE / PFA fluoropolymer lined pipework and associated equipment can provide.

Durability

Lining and sealing elements must be hard-wearing and be capable of withstanding a degree of handling damage as well as movement between different components.

In addition, lining and sealing materials should not absorb the substances they transport. During maintenance programmes, absorbed substances which are often dangerous goods, are a safety risk to personnel undertaking works.

In the manufacturing and process industries, chemicals are transported over relatively long distances, at height, often in difficult to reach areas of a factory and as such have limited access for frequent inspection. Lining and sealing elements once installed and tightened to the specified torque, must remain reliably leak tight. This means that the material properties are required to resist any compressive set which would allow vibratory forces to act on the fixings and consequently risk leakage.

Semiconductor Sectors.

As semiconductors become more complex, they require increasingly higher purity of etching acids ($36x10^{-12}$ or 36 parts per trillion) in the manufacturing process. Consequently, metallic equipment cannot be used as wetted materials in this process hence lined pipe and equipment is necessary. At present **ONLY** PTFE or PFA lined products can provide the

necessary characteristics required in terms of temperature (150°C) and corrosion resisting performance for these duties.

Given the importance of this industry and the rate of its development, a ban or even a 12-year derogation would jeopardise the semiconductor manufacturing industry substantially.

Petroleum and Mining Sectors.

Again, the refining and transportation of petro-chemicals and mining solutions require the use of chemicals that are incompatible with the majority of lined and unlined pipework. As in the semiconductor sector, currently there are no alternatives to PTFE/PFA lined pipework that can tolerate the varieties of substances, their varied concentrations and operating temperatures. At present it is unclear whether technically and economically feasible alternatives to PTFE / PFA fluoropolymers can be developed within a 12-year timescale.

2. **Emissions in the end of life phase**

It follows that the benefit of existing PTFE / PFA fluoropolymer lined pipework and associated equipment, which have a long-life expectancy and wide chemical compatibility, is that it reduces the frequency of pipe and valve element maintenance and replacement and therefore the quantity of items manufactured per annum and the quantity disposed.

New material from manufacturing off-cuts and machining and drillings can be recycled.

Used material recycling is currently problematic. However, some companies have developed methods for recycling PTFE. PTFE and PFA can be broken down into its constituent monomers, which can then be used to create new PTFE, PFA or other fluoropolymer materials. Another approach involves grinding PFA into a fine powder, which can be used as a filler in other materials.

While these recycling methods are still in their early stages, they show promise for reducing the environmental impact of PTFE production and waste.

3. **Emissions in the end of life phase**

Incineration involves burning the PTFE / PFA fluoropolymers at high temperatures in the presence of oxygen, which breaks down the polymer into its constituent elements. However, it's important to note that incineration of PTFE can release toxic gases such as hydrofluoric acid and other hazardous air pollutants.

Therefore, it's essential that PTFE / PFA fluoropolymers are incinerated in specialized facilities that are designed to safely handle hazardous waste. These facilities are equipped with advanced air pollution control technologies, such as scrubbers and filters, to capture and treat the toxic gases released during the incineration process.

Overall, incineration of PTFE / PFA fluoropolymers can be a safe and effective way to dispose of the material when done in a controlled manner in specialized facilities that are equipped to handle hazardous waste with the heat created used to generate electrical energy.

4. **Impacts on the recycling industry**

Nothing to add.

5. **Proposed derogations – Tonnage and emissions**

Nothing to add.

6. **Missing uses – Analysis of alternatives and socio-economic analysis**

Annual tonnage (and emissions).

The EFCTC estimates that the total European market for all fluoropolymers, including PTFE and PFA, was around 14,500 metric tons in 2020. Our estimated breakdown by industry sector of PTFE and PFA use in terms of PTFE / PFA fluoropolymer lined pipework and associated equipment is as follows;

Semiconductor:	44%
Pharmaceutical manufacture:	24%
Fine chemicals manufacture:	22%
Bulk chemicals manufacture:	6%
Water treatment:	2%
Oil and gas – downstream product manufacture:	2%

Key functionalities provided by Fluoropolymers.

The principal reason for using PTFE / PFA fluoropolymer lined pipework and associated equipment is the corrosion resistance of the fluoropolymer linings. This near universal corrosion resistance of the linings, allows customers to handle individual chemicals, mixtures of chemicals and different chemicals in series, without the need to change pipework when switching chemicals to be handled. This allows multi-use manufacturing and processing plants to be built and avoids the necessity for duplicate production lines to handle different chemistries which would be the case for all of the possible alternative lining materials (i.e. glass lined steel, or exotic metallic pipework such as titanium, Hastelloy, Incoloy, Inconel, and tantalum).

PTFE / PFA fluoropolymer lined pipework and associated equipment is:

- Much more cost competitive than exotic metallic alternatives which can be 5-10 times more expensive than PTFE / PFA fluoropolymer lined products.
- Exotic metallic alternatives are also not as resistant to the variety of chemicals, temperatures and concentrations as fluoropolymers.
- PTFE / PFA fluoropolymer lined products are much easier to clean (very important for batch manufacturing plants) and so allow quick, efficient change-over of product processes.
- PTFE / PFA fluoropolymer lined products are mechanically more robust than glass lined pipework (very important if pipework has to be disassembled for cleaning).

Number of companies in the sector estimated to be affected by the restriction.

Within Europe, we have estimated that over 3,000 companies use PTFE / PFA fluoropolymer lined products in various industries, including chemical processing, pharmaceuticals, and food and beverage production, among others.

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.

At present there are no alternative materials that provide the crucial performance range achieved by existing PTFE / PFA fluoropolymer lined pipework and associated equipment.

Some of the non- fluoropolymer alternatives researched could be economically beneficial except that the operational cost resulting from leakage, replacement and increased maintenance requirements from an inferior material would by far exceed any saving. Furthermore, alternative materials are technically unsuitable in many required applications.

The alternatives listed below as replacement for PTFE / PFA fluoropolymer lined pipework and associated equipment do not possess the universal range of properties to be a suitable direct replacement, especially when their mechanical properties and their function differ depending upon their location and purpose within the process in which they are being used.

Increased Waste:

The loss of fluoropolymers for manufacturing lining and sealing materials would require a significant increase in the number of pipes, valves, seals and gaskets manufactured for maintenance replacement parts due to the fact that the listed alternative materials do not achieve the same range of substance compatibility and durable life expectancy.

This would inherently raise the risk of leakages caused by inadvertently fitting incompatible products to different processes as well as significantly increase the waste streams produced by frequent repurposing of the production plant.

Fundamentally, many industries would not be able to cope with this dramatic change. It might cause a reduction in production capacity and an increase in costs and the relocation of manufacturing and processing business to outside of the impacted countries (the EU).

PTFE, ETFE, PVDF, PFA, FEP, FKM, FFKM

Although there are alternative non-PFAS materials each with capabilities of temperature and chemical compatibility, none has the unique combination of temperature range and chemical compatibility of PTFE and similar fluoropolymer materials.

To restrict the entire range of fluoropolymer materials irrespective of its solid form and use, would severely disrupt the pharmaceutical, chemical, food and water industries and in some instances would curtail some operations.

The alterative materials are incompatible with some applications such as the transport of cryogenic liquified gases, chlorine, anhydrous hydrogen fluoride, hydrofluoric acid solutions, hydrochloric acid and sulfuric acid, to name a few.

At a practical level, lined pipework and associated products tend to look very similar in appearance. The traditional ‘milky white’ colouring associated with PTFE and PFA lined equipment is the almost identical to that of the less resilient lined products which could lead to confusion and errors in installation/replacement leading to product contamination, system failure and leakage of chemicals due to incorrect usage.

Ultra-High-Molecular-Weight Polyethylene “UHMWPE”

Ultra-High-Molecular-Weight Polyethylene “UHMWPE” has been researched as a possible alternative to a PTFE / PFA fluoropolymer lined pipework and associated equipment. However, it is only able to reduce corrosion resistance at lower temperatures.

The temperature, chemical resistance range and rigidity UHMWPE (particularly at elevated temperature) is insufficient as direct replacement PTFE / PFA fluoropolymer lined pipework.

‘Exotic metal’ lining materials:

An alternative to products being lined with PTFE / PFA fluoropolymers is the use of so called ‘exotic metal’ linings. However, there are both practical and economic issues associated with this ‘alternative'.

- Cost: 5 – 10 time more expensive – which can make some industries not cost competitive.
- Longevity: For a single use/individual chemical exotic metals can be used, but if handling combinations of product at varying temperatures they may not be suitable. This means that there is always a possibility that the wrong chemical can be transported in a particular pipe which may give rise to contamination of product, the environment and potential risk to health and life.
- Availability: Many exotic metallics are in short supply and often mined in inhospitable and/or politically unstable countries with little or no Health and safety legislation.
- Environmental damage: Exotic metals must be mined, transported, refined and, processed which can have a significant environmental impact. This is particularly true when the raw materials are mined in less developed nations where environmental protection legislation is less well developed than in the EU.
- Persistence: For these materials to handle the operating conditions, they are inherently persistent in the environment.
- Risks: In most cases, exotic metallic options do not provide the almost universal chemical resistance provided by fluoropolymer lined products. This can lead to:
    - shorter lifespans of products (increased replacement costs)
    - increased maintenance costs (additional monitoring of products to ensure that they are still fit for purpose),
    - an increased risk of catastrophic failure, particularly if an unsuitable chemical is put through the pipework, (potentially leading to release of hazardous chemicals into the environment, damage to surrounding process plant, injury to plant personnel, and possibly the wider public, depending upon the nature of the failure).

In addition to technical risks, there are market risks. At present many of the exotic metallic alloys considered are difficult to purchase (lack of availability, fluctuating prices, long lead times), making the construction of a process plant using them problematic as well as cost uncompetitive.

Glass lined steel piping:

Glass lined piping is also considered as an alternative to the use of PTFE / PFA fluoropolymers. However, again there are similar practical and economic issues associated with this ‘alternative'.

- Longevity: For a single use/individual glass lined pipework can be used, but if handling combinations of product at varying temperatures they may not be suitable. This means that there is always a possibility that the wrong chemical can be transported in a particular pipe which may give rise to contamination of product, the environment and potential risk to health and life.
- Persistence: For these materials to handle the operating conditions, they are inherently persistent in the environment.
- Risks: In most cases, glass lined piping options do not provide the almost universal chemical resistance provided by fluoropolymer lined products. This can lead to:
    - shorter lifespans of products (increased replacement costs)
    - increased maintenance costs (additional monitoring of products to ensure that they are still fit for purpose), an increased risk of catastrophic failure,

particularly if an unsuitable chemical is put through the pipework, (potentially leading to release of hazardous chemicals into the environment, damage to surrounding process plant, injury to plant personnel, and possibly the wider public, depending upon the nature of the failure).

- Robustness: Glass lined pipework is less mechanically robust than PTFE / PFA fluoropolymer lined pipework, making damage during initial installation or disassembly and reassembly for cleaning more likely

Polypropylene, Silicone, PVC (tank lining suggested alternatives)

PVC-U has a temperature range of 0°C to +60°C which is too low for most process industries. PVC-U is also not resistant to many chemicals including aromatic and chlorinated hydrocarbons or chlorine. Additionally, PVC-U may not be suitable due to the potential to emit corrosive/poisonous chlorine gas which can cause chloride stress corrosion cracking in austenitic stainless steels, which is the material used for many pipes and valves. PVC also contains SVHC which is likely to be restricted by other environmental regulations.

Polypropylene

Polypropylene has a slightly wider temperature range of -10°C to +80°C but still not sufficient to satisfy most of the associated industry applications. Polypropylene has a wide chemical resistance at ambient temperature, but its chemical resistance significantly reduces with increased temperature particularly with strong inorganic acids.

Elastomeric compounds

Some Silicone grades have a temperature range of -55°C to +300°C and can be used within sealing elements in certain applications but are not resistant to many of the chemicals used in production including most solvents and hydrochloric or hydrofluoric acids. The lack of hardness also restricts the use of these material for some sealing elements. Elastomeric compounds such as silicone, nitrile, and neoprene, can also be regarded as bio- accumulative and toxic to the environment.

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.

At present we are unaware of any potential alternatives currently under development, but not yet available.

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

At present we are unaware of any potential alternatives currently under development, but not yet available.

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.

Pharmaceutical manufacture:

Whilst pharmaceuticals as a product do not contain PTFE / PFA fluoropolymers as discussed in this response, PTFE / PFA fluoropolymer lined products are necessary for their production.

Pharmaceutical companies tend to be large multinational organisations, producing high value products in facilities that are expensive to build and maintain. A ban on the use of PTFE / PFA fluoropolymers in such plants will make their operation significantly more costly. Consequentially, if fluoropolymers are banned in the EU, it is likely that these companies will simply move their production to alternative geographical locations, leading to a significant loss of manufacturing capacity, skilled employment, and intellectual property from the EU, also significantly damaging the EU's preparedness for future pandemics.

Non-European pharmaceutical companies are already well established but will be even more dominant if PTFE & PFA are banned. It is eminently possible that due to the likely transition of manufacturing from the EU, existing shortages on medicine across Europe will get even worse.

7. **Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis**

Nothing to add

8. **Other identified uses – Analysis of alternatives and socio-economic analysis**

Nothing to add

9. **Degradation of specific PFAS sub-groups**

Nothing to add

10. **Analytical methods**

Nothing to add.

Section IV. Non-confidential attachment

In addition to the long answers above, CRP also uploaded two Flowserve documents about the selection of corrosion resisting alloys and non-metallics that demonstrate the superior corrosion performance of PTFE and PFA. We also created a spreadsheet summary of the two documents to make is simpler for the reviewer of our submission to understand the information being submitted.

Section V. Confidential attachment

Nothing to add.