ECHA Restriction Submission

Assignments and due dates

SECTION I. Personal information

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

* First Name :

* Family Name :

Email: *

* Country :

Please select country..

Phone :

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

SECTION II. Organisation

I am submitting information: *

○ On behalf of a Member State Competent Authority — Please select country..

○ As an Individual

◉ On behalf of an organisation or institution

Type of organisation/institution:* — Please select organisation type..

Country where the organisation or institution is legally established: * — Please select country..

Name of organisation / institution: *

Select one of the following options : *

○ I agree to the disclosure of the name of my organisation/institution to the public

○ I want to keep the name of my organisation/institution confidential

Note: the type and country of your organisation/institution will always be disclosed.

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

Specific Information Requests

1:

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

* Compulsory Fields

★ I have information on this topic

○ I don't have information on this topic

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

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.

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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.

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○ 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

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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.

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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.

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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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9:

Degradation potential of specific PFAS sub-groups: A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.

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10:

Analytical methods: Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

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SECTION IV. Non-confidential attachment

If needed, attach additional non-confidential information (data available in excel format, reports, etc.) below. Do not attach the same information already provided in section III here. If part of the information is confidential, please use section V to share it

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If you would like to submit more than one document, please create a compressed archive where you include all files and upload the compressed file as attachment. Maximum file size is 20 MB.

* ☐ ***I have removed/blanked the information I wish to keep/I have claimed confidential from all the attachments in section IV (e.g.: company name, company logo, personal names, email, signatures, other confidential business data).*** I understand that ECHA will not be held liable for any damages caused by making the attachments publicly available.

SECTION V. Confidential Attachment

If needed, attach confidential information below (for example: studies, laboratory tests, additional contact details, business data, etc.). Do not add the same information already provided in the previous sections here. Confidential information will only be used by ECHA, including its Committees, by the Member State competent authorities and by the European Commission.

If you upload a confidential attachment, please justify the reasons for confidentiality of the information in the field below. This will facilitate ECHA's work if it receives requests for access to documents.

Upload Confidential Attachment:

Add attachment Browse

If you would like to submit more than one document, please create a compressed archive where you include all files and upload the compressed file as attachment. Maximum file size is 20 MB.

* ☐ I have the following reasons enumerated in Article 4(1) or 4(2) of Regulation (EC) No 1049/2001 regarding public access to documents why the information submitted as confidential cannot be disclosed to persons requesting access to documents (please explain below in the commenting field those reasons; a reason could be that the protection of your commercial interests, including intellectual property, would be undermined).

No confidential information of any kind should be included:

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Table 8. RO1 - Summary table of alternatives and cost impacts for PFAS manufacture and major PFAS use sectors resulting from a full ban of PFASs.

Use sector (with sub-uses)	Alternatives	Cost impact
Manufacture (Annex E.2.1.)		
Sector as a whole	The analysis of alternatives for PFASs use is performed at the level of use in the various sectors. • Use of PFASs as polymerisation aids in manufacture of fluoropolymers: Sufficiently strong evidence that technically and economically feasible alternatives exist for non-polymeric PFASs as polymerisation aids in the production of PTFE, PVDF and FKM. • Sufficiently strong evidence that technically and economically feasible alternatives for non-polymeric PFASs as polymerisation aids in the production of polymeric PFASs other than PTFE, PVDF and FKM will become available within 10 years from 2022. Conclusion: High substitution potential at EiF in the production of PTFE, PVDF and FKM and low substitution potential at EiF for other types of polymeric PFASs [sufficiently strong evidence]	• High producer surplus losses (order of magnitude: ~€42 billion NPV over 30 years) as a result of business closures [sufficiently strong evidence] due to (i) a high share of business closures [sufficiently strong evidence], (ii) high producer surplus losses at company level due to high margins [sufficiently strong evidence], (iii) an unknown offsetting potential, i.e. producer surplus losses are balanced out to some extent by producer surplus gains by producers of alternative-based products [no evidence] and (iv) high producer surplus losses in the wider supply chain [sufficiently strong evidence]. • High employment losses (order of magnitude: ~€2.5 billion NPV) as a result of high share of business closures [sufficiently strong evidence]

March'25 will ban use of PFAS
As polymerization aids for PTFE

Table 9. RO2 - Summary table of derogations ('proposed' or 'for reconsideration') for PFAS manufacture and major PFAS use sectors, with substantiation for the derogation period (5 or 12 years) and with cost impacts for the 5 and 12 year derogation periods.

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
Manufacture (Annex E.2.1.)			
Sector as a whole	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for: • Polymerisation aids in the production of polymeric PFASs other than PTFE, PVDF and FKM	Ban with a transition period of 18 months and a **5-year** derogation, because fluorine-free polymerisation aids in the production of polymeric PFASs other than PFFE, PVDF and FKM are expected to become available within 10 years from 2022.	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Lower producer surplus losses compared to RO1 because of business closures [weak evidence] <u>Ban with a transition period of 18 months and a 12-year derogation:</u> Lower costs compared to 5-year derogation.

Use sector (with sub-uses)	Alternatives	Cost impact
Implantable medical devices (not including meshes, wound treatment products, and tubes and catheters)	Sufficiently strong evidence that technically and economically feasible alternatives are not generally available. <u>Conclusion:</u> Low substitution potential at EiF [sufficiently strong evidence]	High socio-economic costs can be expected from the public health effects resulting from increased risk of implant failures and higher frequency of replacements.
Hernia meshes	Weak evidence that technically and economically feasible alternatives are not generally available. <u>Conclusion:</u> Low substitution potential at EiF [weak evidence]	If technically feasible alternatives are indeed not available, a ban of PFASs would lead to increased risk of adverse health impacts (intestinal damage and fistula formation) in patients. These impacts are likely to be associated with high socio-economic costs.
Wound treatment products	Weak evidence that technically and economically feasible alternatives are not generally available. <u>Conclusion:</u> Low substitution potential at EiF [weak evidence]	No information was provided on the cost impacts of a ban, therefore the costs are unknown.
Tubes and catheters	Sufficiently strong evidence that technically and economically feasible alternatives are not generally available. <u>Conclusion:</u> Low substitution potential at EiF [sufficiently strong evidence]	The information obtained indicates that a ban on PFASs in these applications would lead to more procedures that are more invasive and/or more painful for the patient. The socio-economic costs related to these implications can be expected to be high.

		will be identified.	socio-economic costs due to reduced functionality of the devices would be avoided.
Tubes and catheters	Given the sufficiently strong evidence that technically and economically feasible alternatives are not available at EiF, a derogation is **proposed** for: • Tubes and catheters	Ban with a transition period of 18 months and a **12-year** derogation, because identification, development and certification of alternatives would take more than five years to complete [sufficiently strong evidence base].	<u>Ban with a transition period of 18 months and a 5-year derogation:</u> Same as under RO1. <u>Ban with a transition period of 18 months and a 12-year derogation:</u> If feasible alternatives are identified, developed and approved, the public health

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**
		Continued R&D increases the chance that alternatives for the relevant applications will be identified.	concerns (and their related socio-economic costs) due to reduced functionality of the devices would be avoided.
Coatings of Metered	Given the sufficiently strong evidence that	Ban with a transition period of 18 months	Ban with a transition period of 18 months