GUIDE FOR REPLYING TO THE PUBLIC CONSULTATION

— Restriction on the manufacture, placing on the market and use of PFAS —

There is a legislative proposal in the EU to restrict the whole group of PFAS in all, but a few derogated uses. The final regulation will be shaped by the input given by stakeholders in a public consultation with the deadline 25 September 2023.

In this document, you will find the information you need to provide your input to the consultation. This is an important opportunity to influence the details on the restriction. It is especially important to provide input on the availability of alternatives, as this will determine the specificity and timeline of the derogations.

It is also important for the decision makers to understand that there is a support for the regulation amongst companies that have already, or have the ambition to move away from PFAS.

HOW TO PROVIDE INPUT

Important links

- Restriction proposal with annexes
- Q&A on the proposal
- ECHA guidance on how to respond to the consultation
- The public consultation

The different parts of the consultation

1. Personal information.
2. Organisational information.
3. Non-confidential comments on the proposal. Your responses can be entered directly into the form or through section 4 as an attachment. General comments can be on any aspect of the Annex XV restriction report, including issues related to socio-economic analysis.
4. Non-confidential attachments can be added here.
5. Confidential attachments can be added here. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities.

General requirements

- The information must be provided through the web-based form and on time
- Any information needs to be supported by evidence
- Specify the sectors and uses to which your comment applies
- When providing information on the availability of alternatives, also provide information on how long it would take to transition to the alternatives, with clear steps and timelines.
- When providing information on viability of alternatives, for example, alternatives employed within your organization, include information on which uses and functions that the alternatives could replace, and also information on cost, performance and time period that the alternative has been used.

WHAT INFORMATION TO PROVIDE

In order to provide information to the consultation and also to prepare for the upcoming restriction, you will need to find out:

- Have you substituted PFAS already? Can you provide information on alternatives?
- Are any of the proposed derogations relevant to you? Do you have information on alternatives for these?

- Which of your products contain PFAS and will be affected by the restriction?

Examples of information of interest that companies may have

- Process and timeline for substitution of PFAS - what has been done and what is needed to comply with the restriction
- Technical performance and quality management requirements for the use/products
- Availability of alternatives for the use/sector
- Customers' feedback on alternatives
- Cost aspects of switching to alternatives

Uses covered by the restriction

The consultation seeks to bring more information on the less investigated uses but also assuring all information is covered for the more investigated ones. The uses that have been investigated for the proposal and to what level they have been investigated is illustrated in the below table, which can be found in Annex A.

Table A.1. Overview of PFAS applications and the level at which they were researched.

PFAS applications			
PFAS manufacture	Textile, upholstery, leather, apparel and carpets (TULAC)	Food contact materials and packaging	Metal plating and manufacture of metal products
Consumer mixtures	Cosmetics	Ski wax	Applications of fluorinated gases
Medical devices	Transport	Electronics and semiconductors	Energy sector
Construction products	Lubricants	Petroleum and mining	Waste stage PFAS applications
Laboratory equipment & filtration	Plant protection products and biocides	Chemical industry	Firefighting foam
Medicinal products	Plastics (other than packaging) and rubber/elastomer production (including flame retardants)	Pyrotechnics	Personal care products other than cosmetics
Fracking (currently hardly applicable in EEA)	Immersion cooling (currently hardly applicable in EEA)	Defence industry	Printing inks
Cement industry	Professional cleaning and polishing	Other niche applications	Uses (yet) unknown

- Green uses are researched in detail
- Blue uses are researched in general
- Orange uses not researched in detail
- Purple use: Separate restriction proposal

What information is requested

- Further information on alternatives for the researched uses (blue and green in the table)
- For "missing uses"- some uses have not been covered in detail and some might be missing from the report (orange or missing).

For these, information is asked for regarding:

⇒ Functionality of the PFAS
⇒ Availability of alternatives, costs, functionality and time aspects on substituting PFAS
⇒ Tonnages and emissions

Proposed derogations

The derogations are described first in the table from page 4 and forwards in the main restriction report, and also at the end of this document as Annex A.

For these, information is asked for regarding:

- Further information on alternatives
- Used tonnages and emissions of PFAS from this use

Details on questions in the consultation

For a list of the questions included in the consultation, as well as a short description of what information that can be submitted to each question, see Annex B of this document.

Stakeholders guidance to relevant questions and important information to submit

Below is a list of different stakeholders and the questions in the consultation that are most relevant to submit information to.

1. For all stakeholders – necessary information to provide
    a. Section I and II – general information, personal and organizational

2. Alternative providers
    a. Most relevant questions
        i. Section III part I – for providing general comment – indicate in the check boxes which sectors/uses are covered in the submitted comment
        ii. Section III – Questions 1, 6, 7, and 8
    b. Most important pieces of information to submit
        i. Information on alternatives including functionality, performance, cost, and viability (examples of use cases etc)

3. Users of alternatives – such as brands and retailers
    a. Most relevant questions
        i. 1
        ii. 2
    b. Most important pieces of information to submit
        i. Information on viability of alternatives

4. Supporters of a strict regulation
    a. Most relevant questions
        i. Section III part I – for providing general comment – indicate in the check boxes which sectors/uses are covered in the submitted comment

5. Test/analysis professionals
    a. Most relevant questions
        i. Section III – Question 10
    b. Most important pieces of information to submit
        i. Information on methods of analysis of PFAS

6. Recyclers
    a. Most relevant questions
        i. Section III – Question 4
    b. Most important pieces of information to submit
        i. Information on impacts on recycling industry and recycling possibilities concerning the proposed concentration limits

Other information of interest

- Information related to end-of-life: emissions, waste management options, impacts from the ban on the recycling industry
- Additional information on analytical methods

CHEMSEC RESOURCES THAT MAY BE USEFUL IN THE PROCESS

- The PFAS guide assists in understanding where PFAS is used and is a good starting point
- The Marketplace is a database of potential alternatives
- On the ChemSec website there are a number of articles and recorded webinars related to PFAS

ANNEX A

Proposed derogations in detail

a. polymerisation aids in the production of polymeric PFASs until 6.5 years after EIF. This derogation does not apply to the production of PTFE, PVDF and FKM.
b. Textiles used in personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c), until 13.5 years after EiF;
c. textiles used in personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m), until 13.5 years after EiF;
d. impregnation agents for re-impregnation of articles referred to in paragraph 5b and 5c until 13.5 years after EiF;
e. textiles for the use of infiltration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence until 6.5 years after EiF;
f. refrigerants in low-temperature refrigeration below -50 °C until 6.5 years after EiF;
g. refrigerants in laboratory test and measurement equipment until 13.5 years after EiF;
h. refrigerants in refrigerated centrifuges until 13.5 years after EiF;
i. maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternative exist until 13.5 years after EiF;
j. refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives;
k. industrial precision cleaning fluids until 13.5 years after EiF;
l. cleaning fluids for use in oxygen-enriched environments until 13.5 years after EiF;
m. clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health until 13.5 years after EiF;
n. diagnostic laboratory testing until 13.5 years after EiF;
o. additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry until 13.5 years after EiF;
p. refrigerants in mobile airconditioning-systems in combustion engine vehicles with mechanical compressors until 6.5 years after EiF;
q. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF;
r. insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EIF
s. lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment until 13.5 years after EIF;
t. calibration of measurement instruments and as analytical reference materials.

The following potential derogations are marked for reconsideration after the Annex XV report consultation

u. [textiles for the use in engine bays for noise and vibration insulation used in the automotive industry until 13.5 years after EiF]; v.[hardchromeplatinguntil6.5yearsafterEiF];
w. [foam blowing agents in expanded foam sprayed on site for building insulation until 6.5 years after EiF];
x. [industrial and professional use of solvent-based debinding systems in 3D printing until 13.5 years after EiF];
y. [industrial and professional use of smoothing agents for polymer 3D printing applications until 13.5 years after EiF];
z. [propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiF];
aa. [preservation of cultural paper-based materials until 13.5 years after EiF];
bb. [cleaning and heat transfer: engineered fluids for medical devices until 13.5 years after EiF]; cc. [membranes used for venting of medical devices until 13.5 years after EiF];
dd. [use as refrigerants and for mobile air conditioning in vehicles in military applications until 13.5 years after EiF];
ee. [the semiconductor manufacturing process until 13.5 years after EiF].

6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in:

a. food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF;
b. implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF;
c. tubes and catheters in medical devices until 13.5 years after EiF;
d. coatings of Metered Dose Inhalers (MDIs)until 13.5 years after EiF;
e. proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF;
f. fluoropolymer applications in the petroleum and mining industry until 13.5 years after EiF.

The following potential derogations are marked for reconsideration after the Annex XV report consultation:

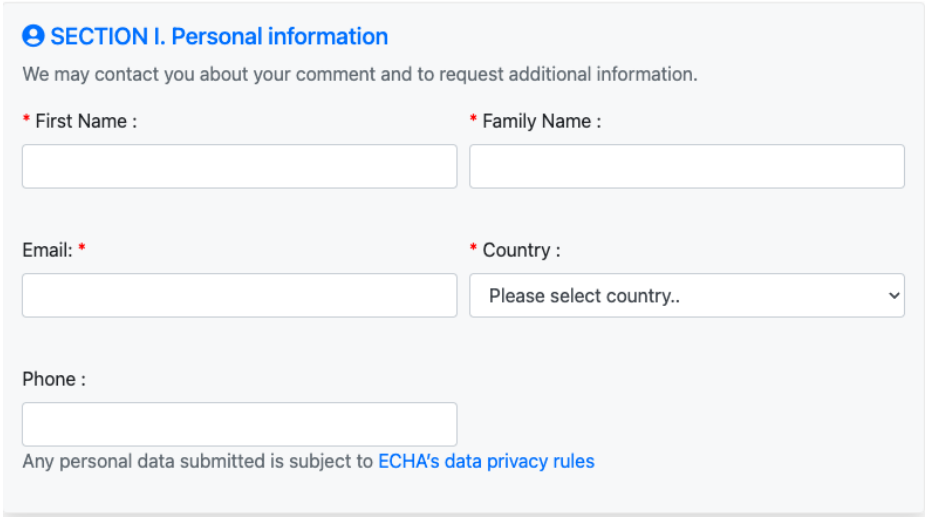
g. [non-stick coatings in industrial and professional bakeware until 6.5 years after EiF];
h. [hernia meshes until 13.5 years after EiF];
i. [wound treatment products until 13.5 years

after EiF];
j. [coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF];
k. [Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF];
l. [PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 13.5 years after EIF];
m. [PTFE in ophthalmic solutions packaging until 13.5 years after EIF];
n. [packaging of terminally sterilised medical devices until 13.5 years after EIF];
o. [applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods until 13.5 years after EiF].

ANNEX B

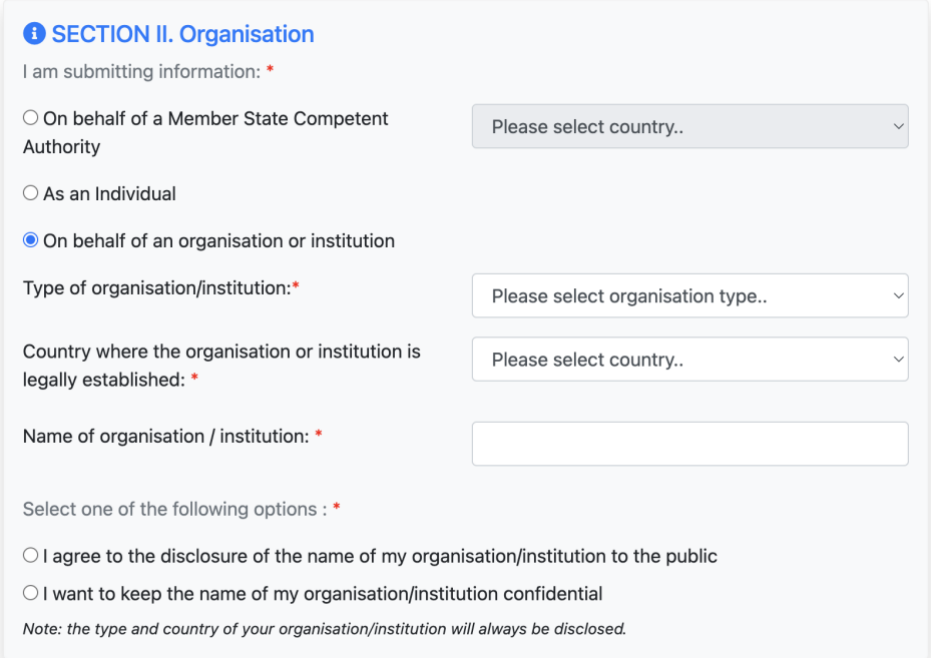
Details on the questions in the consultation.

SECTION I. Personal information



SECTION II. Organizational information

- *Note that there is an option to make this information publicly disclosed or not.*



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

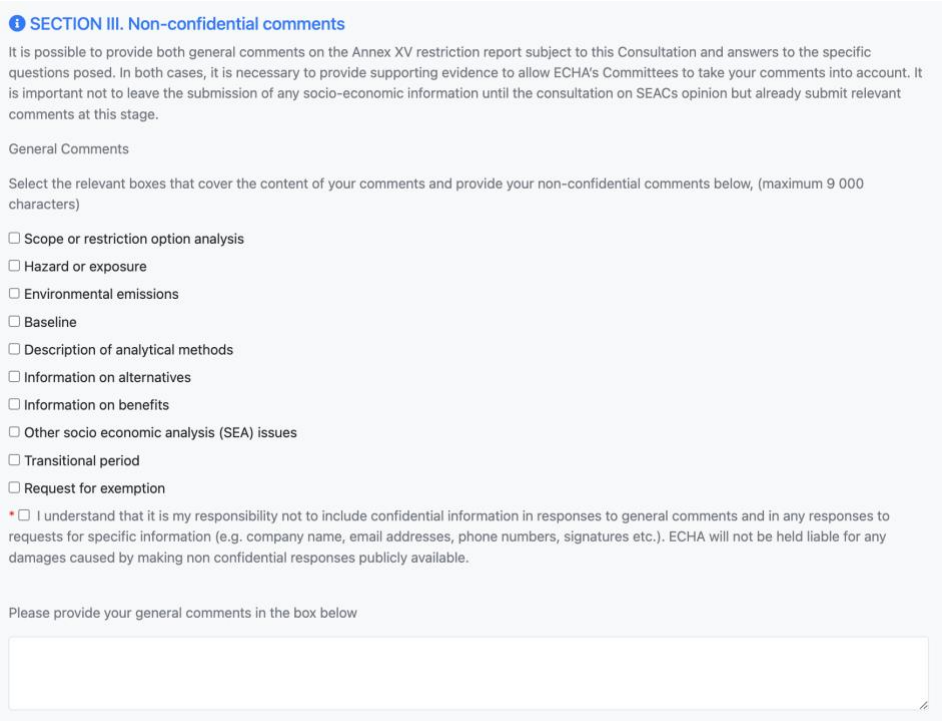
Note: the type and country of your organisation/institution will always be disclosed.

SECTION III. Non-confidential information

- *Important to indicate (by ticking the boxes) all the content that the reply covers.*
- *Contains two different ways of submitting information*

1. *A free text comment*
- *Submitted in the form of a free text comment in the box.*
- *9 000 characters available for comment.*
- *Can cover several areas and include topics not included in the specific requests*

2. *A set of specific information requests – individually commented below*



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)

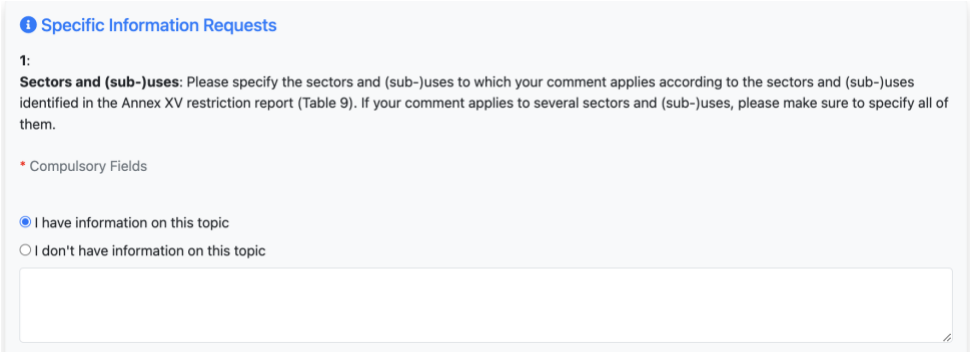
☐ Scope or restriction option analysis
☐ Hazard or exposure
☐ Environmental emissions
☐ Baseline
☐ Description of analytical methods
☐ Information on alternatives
☐ Information on benefits
☐ Other socio economic analysis (SEA) issues
☐ Transitional period
☐ Request for exemption

* ☐ 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

SECTION III. Specific information request 1 – Sectors and (sub-)uses

- *List the sectors and (sub-)uses that the information submitted covers. An overview of the identified sectors and (sub-)uses can be found in the restriction report*



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.

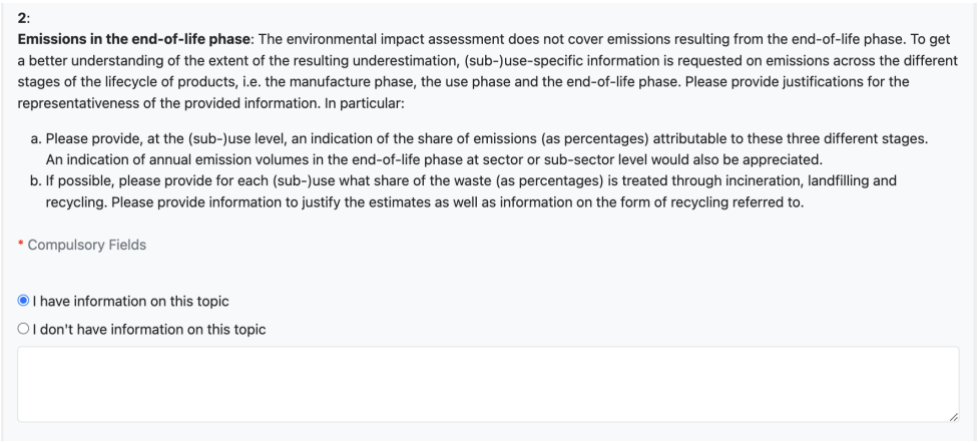
* Compulsory Fields

(•) I have information on this topic

( ) I don't have information on this topic

SECTION III. Specific information request 2 – Emissions in the end-of-life phase

- *Information regarding emissions, on a (sub-)use level*
- *Data on incineration, landfilling and recycling, shares of the different end-of-life pathways*



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.

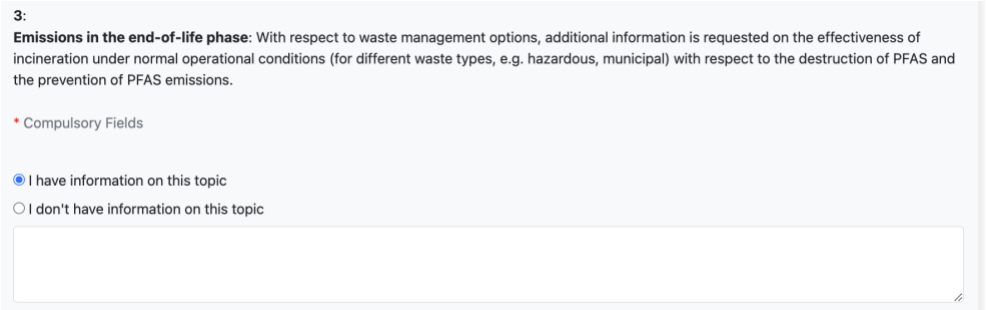
* Compulsory Fields

(•) I have information on this topic

( ) I don't have information on this topic

SECTION III. Specific information request 3 – Emissions in the end-of-life phase

- *Specific information on incineration effectiveness with respect to the destruction of PFAS*



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

SECTION III. Specific information request 4 – Impacts on the recycling industry

- *Impacts on the recycling industry with respect to:*
    a. *Concentration limits impact on technical and economic feasibility*
    b. *How to reach the concentrations limits*
    c. *Costs*

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

SECTION III. Specific information request 5 – Proposed derogations – Tonnage and emissions

- *Information on the proposed derogations concerning tonnage and emissions per use*

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

SECTION III. Specific information request 6 – Missing uses – Analysis of alternatives and socio-economic analysis

- *Detailed information on alternatives for uses not covered in the dossier*
- *All details on such alternatives are interesting, see picture for complete list*

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

SECTION III. Specific information request 7 – Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis

- *Detailed information on the [proposed derogations] in the proposal*
- *Information that warrants or justifies the proposed derogations*
- *Information regarding available information especially interesting*

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

SECTION III. Specific information request 8 – Other identified uses – Analysis of alternatives and socio-economic analysis

- *Detailed information on alternatives and socio-economic impacts for other uses*

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.

* Compulsory Fields

(•) I have information on this topic
( ) I don't have information on this topic

SECTION III. Specific information request 9 – Degradation potential of specific PFAS sub-groups

- *Detailed information on the degradation potential of PFAS*

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.

* Compulsory Fields

(•) I have information on this topic
( ) I don't have information on this topic

SECTION III. Specific information request 10 – Analytical methods

- *Detailed information on analytical methods*

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.

* Compulsory Fields

(•) I have information on this topic
( ) I don't have information on this topic

SECTION IV. Non-confidential attachment

- *Possibility to add additional information and data as attached documents*

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

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 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

- *Possibility to add additional information and data as attached documents*

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: