EU PFAS Restriction Proposal Guidance on Creating Public Consultations (Public Comments)

April 2023

Conference of Fluoro-Chemical Product Japan (FCJ)

Disclaimer

The content and information contained in this material has been compiled and translated from various sources and is solely the opinion of FCJ, which does not guarantee its contents. Please check the official information on the website of ECHA (European Chemicals Agency), etc. for the latest information, as it is updated as needed according to regulatory content and market trends. Please note that we shall not be liable for any damages of any kind incurred based on such information.

Precautions on submitting opinions

- Scientific and socio-economic data must be presented.
  Comments without supporting data are not considered important.
- Please specify why a derogation is required along with objective data.
- Confidential information must be attached to Section V.
  The input information and attachments for Sections III and IV will be published on the ECHA website.
- It is not possible to save your submission and come back to it. Please have your comments saved in some other format in advance.
- It is not possible for you to retrieve your submission.
  Please take a screenshot or printed copy, etc.

Structure of the public consultation submission form

- ✓ Section I: Personal information
- ✓ Section II: Organizational information
- ✓ Section III: General comments and Questions 1-10 related to specific information (refer to the below)
- ✓ Section IV: Attachment of materials that can be published
- ✓ Section V: Attachment of materials to be kept unpublished (confidential information)

Questions related to specific information in Section III (Questions 1-10)

- ✓ Question 1: (Final) product sectors and (sub-)uses (Reference: Table 9., from page 116 of the restriction proposal)
- ✓ Question 2: Emissions at each stage of manufacturing/use/disposal
- ✓ Question 3: Questions related to incineration
- ✓ Question 4: Impacts on the recycling industry
- ✓ Question 5: Annual tonnage of PFAS and resulting emissions for proposed derogations
- ✓ Question 6: Information on alternatives and socio-economic impact of uses missing from the restriction proposal or that have not been covered in detail.
- ✓ Question 7: Information on alternatives and socio-economic impact of uses with derogation periods marked for reconsideration after the consultation.
- ✓ Question 8: Information on alternatives and socio-economic impact of other identified uses.
- ✓ Question 9: Degradation potential of specific PFAS sub-groups excluded from the restriction proposal (Item 1) (additional information)
- ✓ Question 10: Request for information on analytical methods for PFAS

Explanation of public consultation submission form

The site of a public consultation questionnaire entry form for the European Chemicals Agency's (ECHA) PFAS restriction proposal

https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjectId=0b0236e1885e69de (Click on link)

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

Explanation of public consultation submission form

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)

Compulsory fields/tick boxes are marked with an asterisk (*)

Section I Personal information

SECTION I. Personal information

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

* First Name :

* Family Name :

Email: *

* Country :

Please select country..

Phone :

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

Compulsory fields/tick boxes are marked with an asterisk (*)

Section II Organisation

SECTION II. Organisation

Input information on the organization/individual submitting public consultation (compulsory)

I am submitting information: *

- ○ On behalf of a Member State Competent Authority — Please select country.. — In the case of EU regulatory body /Country ↑
- ◉ As an Individual — In the case of individual
- ○ On behalf of an organisation or institution — In the case organizations/institutions

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 : * Select whether to disclose the name of the organization/institution (compulsory)

- ○ I agree to the disclosure of the name of my organisation/institution to the public — Name of organization/institution may be disclosed
- ○ I want to keep the name of my organisation/institution confidential — Name of organization/institution to be kept confidential

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

Compulsory fields/tick boxes are marked with an asterisk (*)

Section III ~ V Providing non-confidential/confidential information

List non-confidential information not covered under specific information

List non-confidential information on **emissions/final disposal** and **alternatives/socio-economic** impacts, in particular, by **product use/sector**.

* **Including uses/sectors not mentioned in the** restriction proposal

Section III

Non-confidential comments

General Comments

Select the areas you wish to comment on from the 10 areas listed and limit your response to a maximum of 9,000 characters.

Specific Information Requests

Select and respond the relevant parts of Questions 1-10.

Section IV

Non-confidential attachment

(Test data, business data, etc.)

Max 20MB

Section V

Confidential Attachment

(Test data, business data, etc.)

Max 20MB

*Please make sure that each piece of information is not repeated.

Section III Non-confidential comments:General Comments

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.

You must provide evidentiary information in support of the opinion you are submitting.
It is desirable to provide information on socio-economic issues in this consultation. Specific examples include, "Why is the part needed? / Why can't other materials be substituted? / What will happen if we implement other materials? (increased cost, increased environmental and safety risks, etc.) / What do the users say?" etc.

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

For general comments, please select the check box for the item(s) for which you would like to provide an opinion.

* ☐ 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.

Here you confirm that the general comments do not include confidential information.

Please provide your general comments in the box below

Please write your opinions here with a maximum of 9,000 characters.

Section III Non-confidential comments:General Comments

FCJ believes that the proposal to collectively restrict all of the more than 10,000 organofluorine compounds (PFAS) as substances of concern on the same basis of persistence as PFOS and PFOA, which are already regulated, is an excessive measure.

Therefore, the FCJ would like to propose the following comments in the Scope or Restriction Option Analysis of General Comments of Consultation Section III.

- Nonconformity of restriction proposal
- Exemption from restriction by PFAS subcategory (substance)

If you agree with the FCJ's opinion on the Scope or Restriction Option Analysis of General Comments in Section III, please indicate your endorsement of FCJ's opinion and attach the document linked below to Section IV.

FCJ Comment on PFAS

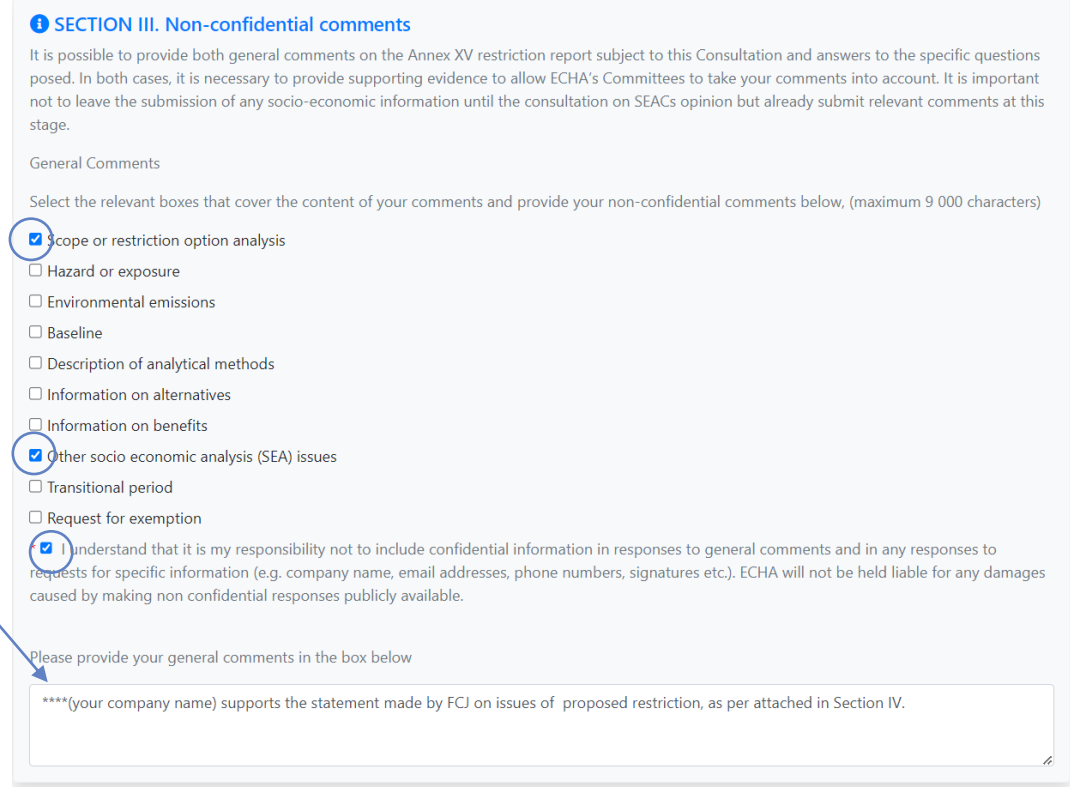
Section III Non-confidential comments:General Comments

Please refer to the following for an example of how to submit the FCJ opinion document.

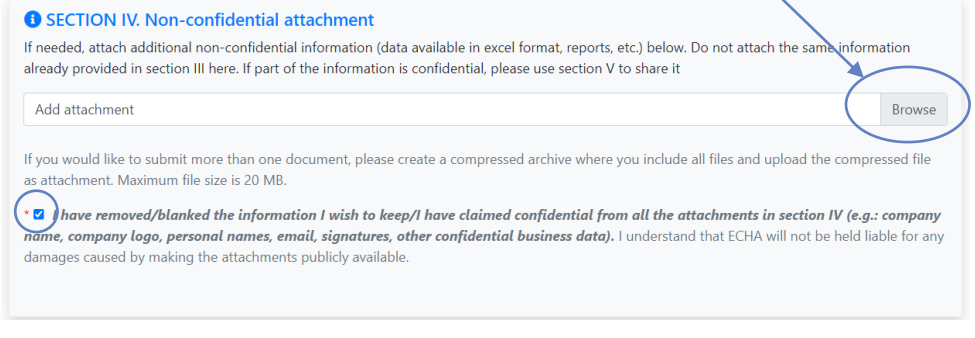
https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjectId=0b0236e1885e69de (Click on link)

Step (1) List comments in Section III.

[Sample wording]
****** (your company name) supports the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV.**



Step (2) Attach a Word document in Section IV.



Overview of information to be provided in Section III

Lifecycle

Section III: General comments
Specific information (Questions 1-10)

Manufacturing/processing

Raw materials/ components

What PFAS-containing raw materials/components are you using?
List the sectors and (sub-) uses of final products in Question 1.

Equipment/ facilities

Are PFAS used in equipment and facilities? (e.g., lubricants) List sectors and (sub-) uses in Question 1.

Some things to think about...
- What emissions are there at the manufacturing stage?
  (e.g., release to the atmosphere (outside factories), volatilization/exposure to employees (inside factories), discharge into water, residue in products, etc.)
  List in Question 2 or Question 5
- Are these well-controlled?
  Question 2
- What risks or hazards are there from working with PFAS? (e.g. worker safety/health)
  List in general comments (Hazard or exposure)

Products

Functions/ benefits

What are the functions and benefits of PFAS in the product? Why is it important? (Importance of PFAS in achieving the required standard)
List in Question 6-8
What is the lifetime of your product?
List in Question 6-8

Alternatives

Why are there no PFAS alternatives? (e.g., availability of alternatives, performance trade-off information, etc.)
List in Question 6-8

Some things to think about...
- What emissions are there during the use stage?
  List in Question 2 or Question 5
- Results of product degradation tests (e.g., under high temperatures/in contact with strong chemicals/in contact with water, etc.)
  List in Question 6-8
- For products that need to meet any EU international standard, name of the standard and information on the testing process required to meet the standard.
  List in Question 6-8

Disposal

Disposal method

What are the options for disposal method? (e.g., landfill, incineration).
Question 3
Do you have data on emissions that are generated if e.g. landfilled or incinerated? List in Question 2 or Question 5

Some things to think about...
- Do you know the disposal method for your products?
  List in Question 3
- Do you receive from your supplier, or do you provide guidance to your customers on correct disposal method? List in Question 3
- Do you know if your product can be recycled?
  List in Question 3

If the content differs from the purpose of each question, please attach materials to Section IV (non-confidential information) or Section V (confidential information).

*Prepared by FCJ from information contained in “Guidance on how to respond to the PFAS REACH restriction public consultation” compiled by the Fluoropolymers Product Group of Plastics Europe.

Regarding each question in Section III - 1: Sectors and (sub-)uses

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.

List the sectors and (sub-)uses of (final) products containing PFAS. (e.g., aviation, electronics, food contact, etc.).
List with reference to Table 9., from page 116 of the restriction proposal.
If there are several sectors and (sub-)uses, list all of them
If there is no applicable sector or (sub-)use in Table 9, list the relevant sectors or (sub-)uses by specifying that it is omitted from the restriction proposal.

Link to Table 9 in the restriction proposal

https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49#page=136 **(Click on link)**

Question 2: Emissions at each stage of manufacturing/use/disposal

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.

For each (sub-)use, we recommend that you submit the following information along with supporting data:
(Excluding confidential information)

- Annual emissions at each stage of the life cycle (manufacturing, use and disposal)*
  (e.g., release to the atmosphere (outside factories), volatilization/exposure to employees (inside factories), discharge into water, residue in products, etc.)

- Information on the ratio of disposal through incineration, landfilling and recycling (as well as information on the form of recycling referred to).

*Please note that you are being asked for information on manufacturing, use, and disposal in the EU region.

Question 3: Questions related to incineration

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.

It is recommended that any additional information on the incineration of hazardous and general waste under ordinary operating conditions that is useful for PFAS destruction and emissions prevention be submitted with supporting data. (Excluding confidential information)

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.

Impacts on the recycling industry in the EU region*.
It is recommended that the following information be submitted along with supporting data. (Excluding confidential information)

a. The impacts that the concentration limits (25ppb, 250ppb, 50ppm) in paragraph 2 of the restriction proposal have on the technical and economic feasibility of recycling processes.
b. Measures needed to achieve the proposed concentration limits.
c. The costs associated with these measures.

*Recycling companies in the EU region are in scope for this question.

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.

Indicate the annual quantity of PFAS used and released to the environment in applications that fall under the derogation in Sections 5 and 6 of the restriction proposal. (Excluding confidential information)
(e.g., release to the atmosphere (outside factories), volatilization/exposure to employees (inside factories), discharge into water, residue in products, etc.)

In such cases, it is necessary to demonstrate the relevance of the data as representative data for the relevant use.

Questions 6-8: Listing of information on socio-economics and alternatives by use

- The sector of use for which information is provided will be answered in one of the Questions 6-8, depending on the status of the wording in the restriction proposal.
- In Questions 6-8, you are requested to provide information for the following seven items a-g.
- Please check the following pages for further details.

Item	Question 6 Uses not covered in the restriction proposal (e.g., listed in Table A.1 in Annex A)	Question 7 Uses for which derogation periods were mentioned in square brackets in the restriction proposal	Question 8 Other uses mentioned in the restriction proposal
a	Type of PFAS and annual tonnage and emissions 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.		
e	For cases in which alternatives are not yet available, the status of R&D, time/financial planning and the time required for substitution, etc.		
f	For cases in which substitution is technically and economically feasible but more time is required to substitute, the impacts on costs and products, etc.		
g	For cases in which substitution is not technically or economically feasible, the socio-economic impacts on companies and consumers, etc. Sales, etc. in the EU for the related sector		

For alternatives, please first list availability, etc. in d, and then add details including socio-economics in e-g as applicable.

* In addition, please provide supporting scientific/socio-economic data/information.

Question 6: Alternatives for uses not covered in detail or missing uses (a-c)

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.

We recommend submitting information a-g below, along with supporting data for those uses not covered in detail in the restriction proposal (uses highlighted in blue and orange in Table A.1 of Annex A) and for alternatives to the missing uses. (Excluding confidential information)

a. Type of PFAS and annual tonnage and emissions 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.

Question 6: Alternatives for uses not covered in detail or missing uses (d-e)

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.

d. The availability, technical and economic feasibility, hazards and risks of alternatives. This includes 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 (including likelihood of successful completion, term/financial planning, and the time required for substitution (including certification or regulatory approvals) and the major challenges encountered with alternative candidates studied in the past).

Question 6: Alternatives for uses not covered in detail or missing uses (f-g)

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.

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)
   ii) Time required for completing the substitution process (including any relevant certification or regulatory approvals)
   iii) Possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs)
   iv) 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, provide the value of EU sales and profits and employment numbers for the sector.

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.

The uses indicated with [square brackets] in paragraphs 5 and 6 of the restriction proposal are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak* as a basis for substitution and socio-economic impact analysis, and a derogation period will be reconsidered after the consultation. It is recommended that specific information (clearly stating the reasons for non-substitutability (e.g., functionality/longevity/cost) and supporting comparative evidence be submitted, including the elements listed under a-g in Question 6 to strengthen the rationale for the derogation period. (Excluding confidential information)

*Please refer to Table 8 of the restriction proposal. Further details can be found in the sections of Annex E.

https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49#page=101 (Click on link)

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.

For many of applications, the evidence/information on alternatives is only in general terms, and much of it is qualitative* (especially some yellow-highlighted areas are inconclusive). Therefore, we recommend that you clearly state specific information (reasons for non-substitutability (functionality/longevity/cost, etc.)) that includes the elements listed in a-g of Question 6 and provide supporting evidence. (Excluding confidential information)

*Please refer to Table 8 of the restriction proposal. Further details can be found in the sections of Annex E.

https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49#page=101 (Click on link)

9: Degradation potential of specific PFAS sub-groups

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.

Please consider submitting any additional information you may have regarding the degradation potential of certain sub-groups excluded from the restriction in **Column 1** of the restriction proposal. (Information on potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.)

10: 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.

Annex E of the restriction proposal contains an assessment of the availability of analytical methods for PFAS. Those who have new or additional information on new developments in analytics not considered in the restriction proposal, please consider submitting them.

Section IV Non-confidential attachment

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.

If needed, attach additional non-confidential information (excel data, test reports, etc.).
Do not attach the same information already provided in Section III here.
If you would like to submit more than one document, please create a compressed archive and upload it (maximum file size is 20MB).
If part of the information is confidential, please attach in Section V, not Section IV.

Section V Confidential Attachment

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:

If needed, attach confidential information (studies and test data, business information, etc.).
Write reasons for confidentiality in the yellow highlighted field.
(However, please do not include any confidential information in the comment field.)
Do not attach the same information already provided in the Section III and IV here.
If you would like to submit more than one document, please create a compressed archive and upload it (maximum file size is 20MB).

Specific case example (1) Semiconductor manufacturing process uses for which the derogation is reconsidered

Item	Number	Classification	Applications and products	Duration of derogation
5	ee	Semiconductors	Semiconductor manufacturing process	12 years

[Concept]
Semiconductor manufacturing process uses are uses for which the derogation period will be reconsidered after the consultation period, so enter your comments in Question 7.
Due to the broad scope of the subject, specific uses are identified as much as possible, and information on material comparisons for each performance requirement is provided.
Indicate that there is no alternative, request an exemption, or indicate specifically that a minimum of 12 years is required as a substitution period including certification and approval. (Input the information according to the sub-items a. through g. specified in Questions 6-8)

[Examples of Public Consultations]

a. △△(compound name) is used for the ○○ application in the ○○ process of the semiconductor manufacturing process. Annual tonnage and emissions are ○ tons each.

b. △△ is adopted as the only component that simultaneously satisfies the required performance properties of ○○, XX, and □□ in the relevant process.
The above required performance is directly related to the yield of semiconductor manufacturing and the ○○ and XX performance of products, and is an extremely important component for the semiconductor industry.

c. It is estimated that approximately ○○ companies in the semiconductor manufacturing sector will be affected by the unavailability of △△.

d. ○○ is an alternative-based product already offered on the EU market with a market share of XX%. However, this is an incomplete alternative that can only be applied for some processes in this use due to its inferior alkali resistance under high-temperature conditions compared to △△. Comparative evaluation data of ○○ and △△ for this use is shown (detailed data is attached in Section IV (or Section V)). As conditions for a complete alternative for △△, it is essential that the strength at xx°C be at least ○○N/mm^2 and the weight reduction to 40% NaOH be less than ○○%, but there is no alternative available on the market with such performance other than the PFAS △△ currently in use.

e. As for alternatives, several candidate substances such as ○○ and XX are under consideration. Development of an alternative candidate (Year ○○, budget ○○ million yen), commercialization study (Year ○○, budget: ○○ million yen), and application for certification and approval (Year ○○, budget ○○ million yen) are expected to take a total of XX years, or over 12 years. No technically or economically feasible alternative candidate substance has been found among the ○○type under consideration, and the likelihood of successful development is expected to be quite low. The results of a current study indicate that Substance A costs 10 times more and does not have the required ○○ performance, while Substance B has the same cost but does not have the required XX performance. No substance has been found that simultaneously satisfies all three required properties and cost requirements. (Attach detailed data in Section IV (or Section V)). Another issue is that the replacement frequency will be ○ to X times more frequent because the alternative candidate will have a product life that is ○ to XX% of the existing substance. In addition, the restriction should not be applied from the perspective of waste reduction because the waste volume will increase ○○ times from the current ○○ tons.

f. At this point, there is no prospect of technological or economic alternatives.

g. Socio-economic impacts on companies, consumers, and other actors are expected to be ○○, xx, etc. In addition, sales, profits and employment in the EU in the semiconductor-related sector were ○○ million yen, ○○ million yen and ○○people (For confidential information, attach materials in Section V).

Based on the above, PFAS alternatives should be exempted from this restriction proposal, rather than a 12-year derogation period, because it is extremely likely that they will not be a complete substitute and are, for all practical purposes, irreplaceable.

Specific case example (2) Lubricant uses for which a 12-year derogation is proposed

Item	Number	Classification	Applications and products	Duration of derogation
5	s	Lubricants	Lubricants used under extreme conditions or required for safe functioning and equipment safety	12 years

[Concept]
With respect to the uses covered under derogation, Question 5 asks only for annual tonnage and emissions, which is inappropriate as an input point for discussing the availability of alternatives. In this example, the appeal is for an exemption, not a 12-year derogation, so select “Exemption” in Section III, General Comments, and enter your comments, or enter your comments in Question 8 (Other identified uses). (Input the information according to the sub-items a. through g. specified in Questions 6-8)

[Examples of Public Consultations]

a. Lubricant OO (compound name) is used for ○○ application of ○○ products. Annual tonnage and emissions are ○ tons each.
b. △△ is adopted as the only component that simultaneously satisfies the required performance properties of ○○, XX, and □□ in the relevant use. △△ is an essential component for the ○○ performance of the ○○ product.
c. It is estimated that approximately ○○ companies in the ○○ sector will be affected by the unavailability of △△.
d. Annex E.2.14.2.3 lists PCTFE although there is no conclusive evidence for the existence of alternatives. PCTFE still cannot be an alternative for PFPE because it falls under PFAS and is inconsistent with the restriction proposal itself.
Similarly, fluorosilicones were mentioned as an alternative. Fluorosilicones need to be specified, but what can be defined as non-PFAS is limited. Inconsistent with the proposed limit itself?
e. Present comparative evaluation data for specific PFPEs in actual use and non-PFAS fluorosilicone oils studied in the past for different uses. • • • (See Annex A.3.15.1 for thermal stability, nonflammability, radiation resistance, etc. in the operating temperature range, and attach detailed data, if available, in Section IV (or Section V)).
f. At this point, there is no prospect of technological or economic alternatives.
g. Socio-economic impacts on companies, consumers, and other actors are expected to be ○○, xx, etc. In addition, sales, profits and employment in the EU in the related sector were ○○ million yen, ○○ million yen and ○○ people (For confidential information, attach materials in Section V).

Based on the above, the candidate alternative technologies/substances listed in Annex E.2.14.2.3 are not substituted due to being PFAS. In addition, non-PFAS fluorosilicones, which have been compared in the past, are not substitutable for practical purposes. Therefore, the proposed 12-year period is also not appropriate, and lubricants should be exempted from the restriction proposal.

Reference: Location of consultations already submitted

As explained previously, submitted consultations will be published by ECHA on a regular basis (non-confidential information only) at the following link.

Please refer to the submissions to date, which have already been published.

https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term

Restriction report	Annex XV report
Restriction report annexes	Annex A Annex B Annex C Annex D Annex E Annex F Annex G Appendix E4 Appendix G1 Appendix G2 Appendix E2
Consultation on restriction report	**Give Comments**
Start of consultation on Annex XV report	22/03/2023
1st deadline for comments on Annex XV report	
End of consultation on Annex XV report	25/09/2023
Comments submitted to date on restriction report	
Response to comments on the restriction report	

A file summarizing the submitted consultations is uploaded here.

Reference: Link to the above comments submitted to date (Word file): Number 3834-3871 (some numbers are missing)

https://echa.europa.eu/documents/10162/23bc6cb4-4d81-cb8e-d3b9-c3d458c25f81

About the FCJ

Name of organization:

Conference of Fluoro-Chemical Product Japan(**FCJ**)

Established: March 6, 2021

Established to provide appropriate information dissemination, advocacy activities, etc. as fluorochemical manufacturers.

Business Profile (Excerpt)

- Research on environmental regulation trends, etc. for fluorochemicals
- Collaboration and coordination with domestic and international organizations
- Making recommendations to the government or related organizations

Activities to date (excerpted)

- Information-sharing and exchange on PFAS to related industry associations
- Providing input on proposed chemical evaluation methods (essential use and PMT/ED definitions) (In collaboration with JCIA)
- Recommendations on PFAS to the EU-Japan Business Round Table (EU-Japan recommendations)
- Collaboration with overseas chemical industry organizations

Participating companies (as of March 2023)

AGC Inc., Kitamura Limited, Kureha Corporation, Chemours Kabushiki Kaisha, Central Glass Co., Ltd., Daikin Industries, Ltd., DIC Corporation, Tosoh Finechem Corporation, Chemours-Mitsui Fluoroproducts Co., Ltd.

Reference: “FCJ” Conference of Fluoro-Chemical Product Japan (cfcpj.jp); https://cfcpj.jp/

Reference materials: From the 3rd FCJ webinar

What are public consultations in the REACH restriction process?

A public consultation (public comments) can be submitted by any individual, company, or organization.
The public comments and opinions of the European Chemicals Agency (ECHA)'s two committees will be compiled to form the restriction proposal.

Phase 1: Preparation and submission of the restriction proposal
Restriction proposals are prepared by the proposing countries and submitted to the European Chemicals Agency (ECHA)
ECHA confirms the contents.

Phase 2: Consultation and deliberations
Deliberations at ECHA will be carried out in parallel with the consultations.

Phase 3 Legal decision and preparation of restriction
A period of preparation before the content of the legislation is decided and restriction begins.

Starting the REACH restriction process

Registration of intention to submit a restriction proposal
July 15, 2021
Preparation of restriction proposal
Submission of restriction proposal
January 13, 2023 (Submitted)
February 7, 2023 (Pre-publication)
After conformity check
March 22, 2023 (Official publication expected)

ECHA EUROPEAN CHEMICALS AGENCY

2A) Gathering of opinions (consultation)

Consultations regarding the restriction proposal
March 22 - September 22, 2023
(April 5: Briefing on consultations)

Consultations regarding the SEAC proposal

Opinion development by RAC (Committee of Risk Assessment)

Opinion development by SEAC (Committee of Socio-Economic Analysis)

B) Deliberations by experts

EC decision on restriction proposal

The time for industries to comply with the restriction

Start of restriction

Progress in PFAS restriction

Reference : https://echa.europa.eu/restriction-process

*Please access the link below if you would like to view the 3rd FCJ webinar materials.

https://cfcpj.jp/pdf/No3_webiner_Document-20230407.pdf

Reference materials: From the 3rd FCJ webinar

What are public consultations in the REACH restriction process?

We recommend that the first round of consultations be submitted by June, when both committees begin their discussions.

Regarding the timing of the submission, this information had not been released to the public and is corrected as follows.

- No primary deadline has been set this time.

Reference :https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term

- As mentioned in the April 5 ECHA briefing, comments submitted by the deadline will be treated equally.

Reference :https://www.youtube.com/watch?v=JzZRtmaJeoQ

- At this briefing, there were repeated comments that evidence is important.
- Some comments requested an earlier submission in general.

Therefore, we recommend that you submit your consultation as soon as possible after the evidence is available.

Not applicable	Discussion of the issues presented in the consultations on the SEAC draft proposal and adoption of final opinion	Start of consultations regarding the SEAC draft proposal (Second consultation)

https://echa.europa.eu/documents/10162/9cb3c4f8-c2d9-c1dd-9a91-65dbb020f95a

Reference: Meetings of the RAC - ECHA (europa.eu); https://echa.europa.eu/meetings-of-the-rac/2023

Meetings of the SEAC - ECHA (europa.eu); https://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis/meetings-of-the-seac/2023

Reference materials: From the 3rd FCJ webinar

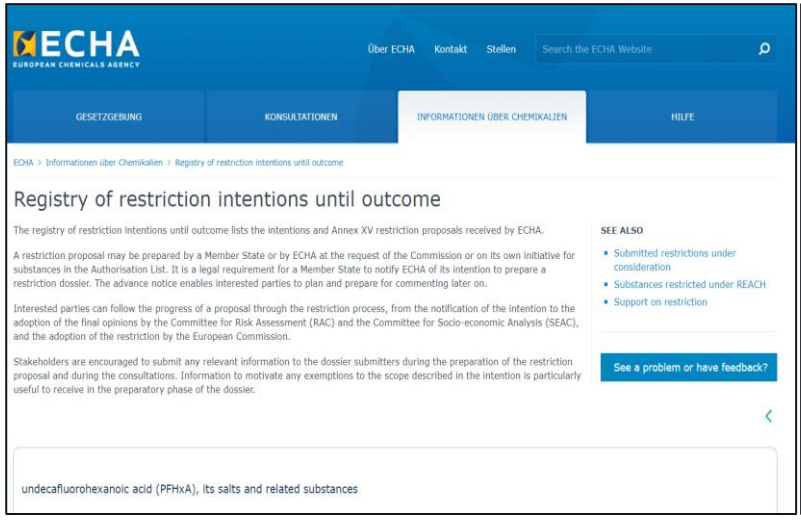
What are public consultations in the REACH restriction process?

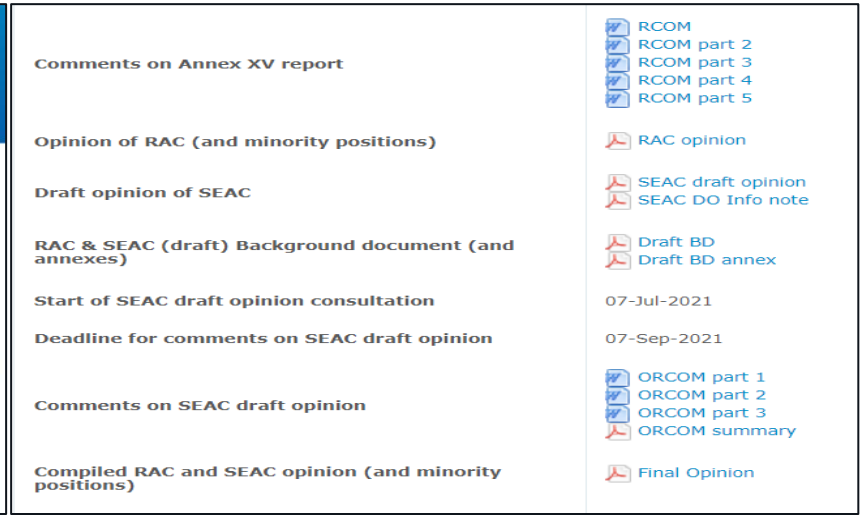
■ Submitted consultations will be:

used in the deliberations of the Committee of Risk Assessment (RAC) and the Committee of Socio-Economic Analysis (SEAC), which are expert committees of ECHA (European Chemicals Agency). **Both committees will develop their opinions as ECHA based on the restriction proposal and the consultations received.**

Committee of Risk Assessment (RAC): Consolidates opinions on whether the restriction proposal is appropriate to reduce risks to human health and the environment

Committee of Socio-Economic Analysis (SEAC): Consolidates opinions on the socio-economic impacts associated with the proposal, i.e., benefits and costs to society





Consultations and committees' responses to consultations

Risk Assessment Committee opinions

Committee for Socio-Economic Analysis opinions

Consultations on the Committee for Socio-Economic Analysis proposal

PFHxA case example Reference: Registry of restriction intentions until outcome - ECHA (europa.eu) ; **https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d**

Reference materials: From the 3rd FCJ webinar

What are public consultations in the REACH restriction process?

■ Risks of not submitting consultations

Generally, **it is said that not providing an opinion is an admission by the individual company/organization that they accept the restriction proposal**. (Alternatives, rebuttal to derogation periods, and description of uses not listed are required)

In some cases, they may also ask for individual opinions from those who submit consultations, which means that they will not be on the negotiating table. Therefore, **it is important to have written arguments from both the individual companies and the industry organizations.**

■ Examples of successful consultations so far

As for the restrictions on PFOA and C9-14**, the opinions of industry have been adopted and exemptions have been obtained for each.**

*Detailed information is provided as a basis for submitting a written opinion.