VDMA handout

Participation in the public consultation on the regulation of PFAS under the EU REACH Regulation

Consultation period:
22 March to 25 September 2023 (23:59 Helsinki time)

May 2023

Background

German authorities, in cooperation with authorities from the Netherlands, Denmark, Norway and Sweden, have prepared a restriction dossier for per- and polyfluoroalkyl substances (PFAS) under the REACH Regulation and submitted it to the European Chemicals Agency (ECHA) in early 2023. On the February 7th, 2023, ECHA pre-published the restriction proposal. On the March 22nd, 2023, the six-month public consultation according to the REACH Regulation was launched. The consultation ends on the **25th of September 2023 (23:59 Helsinki time)**.
The primary justification for restriction is the very high persistence, high mobility, bioaccumulation and long-range transport potential, global warming potential, ecotoxicity and human health effects of some PFAS substances. It is noted that PFASs may enter the environment during the manufacturing, use and disposal phases.

On the restriction proposal

Chemically: any substance containing at least one fully fluorinated methyl or methylene carbon atom (without H/Cl/Br/I attached). This is estimated to be at least 10,000 different PFAS.
Instead of a comprehensive restriction without exemptions, the submitting authorities currently favour a restriction with application-specific exemptions. The restriction would affect the manufacture, placing on the market and use of PFASs.
The restriction dossier provides for exemptions/derogations for various uses. Some examples are given below:

- Temporally unlimited exemptions: Active substances in biocidal products, in plant protection products and in human and veterinary medicines; refrigerants in HVACR[1] systems in buildings where national safety standards and building regulations prohibit the use of alternatives; PFAS used for the calibration of measuring instruments and as analytical reference materials.
- Time-limited exemptions (examples): Refrigerants in refrigerated centrifuges (13.5 years after entry into force of the restriction); refrigerants in deep-freezing below -50 °C (6.5 years after entry into force of the restriction).
- Exceptions still to be discussed (by way of example): Non-stick coatings in industrial and professional bakeware (6.5 years).

All non-considered applications without exemptions would be affected by the direct PFAS restriction after a transition period of 18 months (approx. 2026 / 2027).

[1] HVACR: Heating, ventilation, and air conditioning

Timetable of the restriction process and opportunities for stakeholder participation

The timetable for the PFAS restriction procedure is shown in Figure 1.

Figure 1: Timetable of the restriction procedure, source: BAuA (Konsultation_Dannenberg.pdf)

During the six-month public consultation period, companies, associations, organisations, private individuals and other authorities can submit their comments and, where appropriate, further information on the proposed restriction. All comments and additional information received during this public consultation will be taken into account by ECHA's two relevant scientific committees (the Committee for Risk Assessment - RAC and the Committee for Socio-Economic Analysis - SEAC) when preparing their opinions on the restriction proposal.

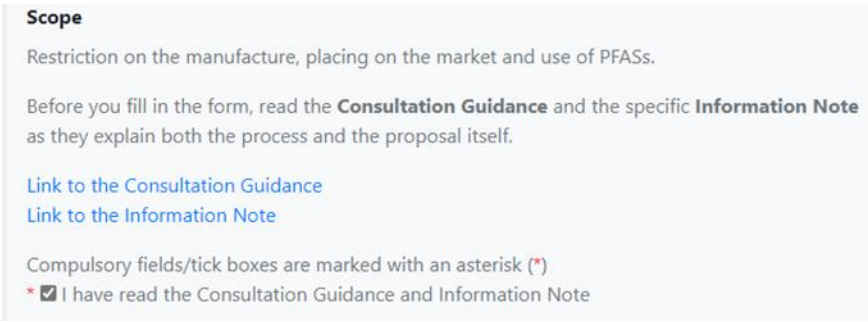
Under the link to the consultation (ECHA Website (europa.eu)) a list of specific questions is published, the answers to which are of particular interest for the further discussions on the restriction proposal.

The involvement of affected companies and supply chains is strongly recommended, especially if no alternatives are available and exemptions from the restriction are needed. Although a number of use-specific exemptions have already been considered in the restriction proposal (see Restrictions submitted for review - ECHA (europa.eu) (please click on "Annex XV report" under "Restriction report"), it can be assumed that many uses have not been considered in the restriction process so far. In this respect, it can be assumed that there are many **"missing uses",** for which application-specific exceptions must be asked.

Consultation contribution:

General information:

You should first read the **"Information Note"** and the **"Consultation Guidance"** (see links under ECHA website (europa.eu)) and then confirm the box **"I have read the Consultation Guidance and Information Note"** by clicking on it. This process is mandatory.



Select an option from the list below that best describes how you found out about this public consultation.

Section I. Personal Information.

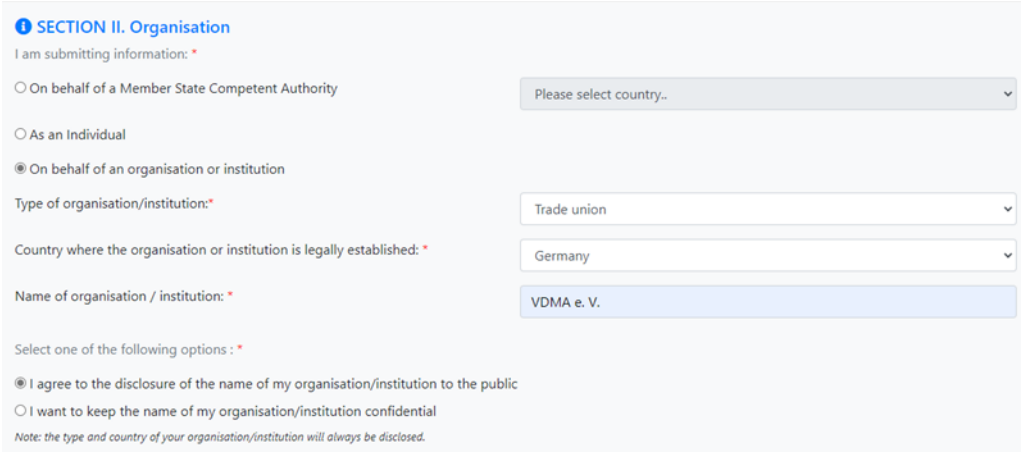
Enter your contact details in this section: **First name, last name, email, country, phone number (optional)**.
Your personal data will not be shared with third parties by ECHA at any stage of the restriction process.

Section II. Details of the organisation.

Click on the option **"On behalf of an organisation or institution".**

In the 'Type of organisation/institution' section, select the 'Company' option (or the option that best describes your organisation).

Select the country where your organisation is legally established. You should indicate the official name of your organisation. Furthermore, you can keep the name of your organisation **confidential by** clicking the appropriate box.

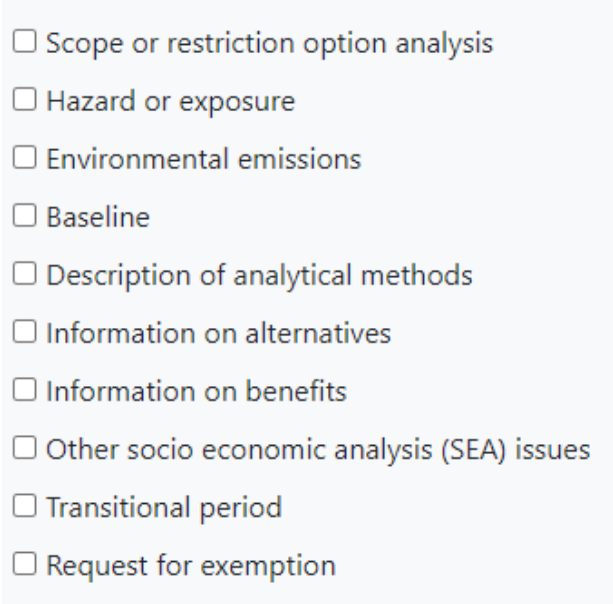


Section III. Non-confidential comments.

It is possible to provide both general comments on the restriction proposal (see Annex XV reporting format 040615 (europa.eu)) and answers to the specific questions raised. In both cases, supporting evidence must be submitted in order for the ECHA Committees to consider your comments. It is **important not to delay the submission of socio-economic information until the SEAC opinion consultation,** but to **submit relevant comments** related to socio-economic information at **an early stage**.

General comments

Select from the 10 relevant fields that cover the content of your comments (multiple entries are possible) and enter non-confidential comments in the free field (**maximum 9 000 characters**). According to the BAuA, it helps the processor to allocate the information later.



Specific Information Requests:

This part contains **10 specific questions** related to the planned PFAS restriction.

If you would like to contribute to one of these questions, click on the field **"I have information on this topic"** to open the writing field. If you cannot answer all the questions, it is possible to

skip questions. If you do not have a contribution to a questions, please click accordingly on the box **"I do not have information on this topic"** to keep the writing field closed.

You can write your comments in the text box. Alternatively, you can simply indicate that your contribution to this particular question will be included in attachment (see Section IV and Section V).

1: Sectors and (sub-) uses

Please indicate the sectors and (sub-)uses to which your comment refers.

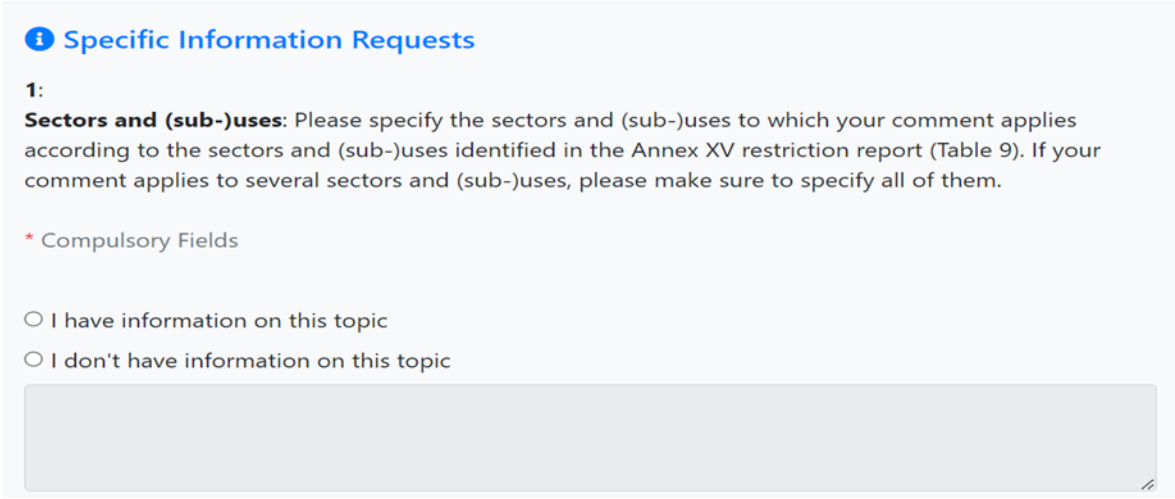


Table 9 of the Restriction Report (pages 116-138 under Annex XV reporting format 040615 (europa.eu)) provides examples in relation to sectors and (sub-)uses.

Example Table 9:

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
vehicles, and affecting the safety of operators, passengers or goods, to the extent not addressed under other parts of this proposed restriction (e.g. under lubricants, electronic equipment and TULAC)	narrow down the scope for a derogation, the following potential derogation is marked **for reconsideration** after the Annex XV report consultation: • [Applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods]	by a 5 year derogation. Substitution requires further research on existing non-PFAS polymers and possible development of new ones, combined with testing of equipment to ensure compatibility or design modifications [sufficiently strong evidence base].	Ban with a transition period of 18 months and a 12-year derogation: Extent of impacts on producers is not estimated and will be dependent on the extent to which drop-in alternatives can be identified without the need for redesign of equipment. A long derogation period provides opportunity to mitigate costs by enabling redesign to be factored into product development cycles [weak evidence]. Given vehicle safety standards and an additional 12 years for development, it is anticipated that safety will not be compromised. Vehicle reliability may however be impacted leading to some consumer surplus loss [weak evidence]. There is no information on the extent to which different parts of the sector are able to pass on added cost to consumers.

If you are missing sectors or (sub-)uses, please **do not** specify them here, but add the relevant information in the comments to **question 6**.

2: Emissions in the end-of-life phase (during the life cycle)

Table 1.: Distribution of emissions over the life cycle of the product

Compo-nent	Weight	Number in the end-product	Number of products sold (year)	Total weight per year	Emissions (%) disposal/recycling	Weight of emissions disposal/recycling

The information in Table 1 could be submitted.

If possible, please indicate at the (sub-)use level the share of emissions (in percent) attributable to these three different stages, i.e. the **production**, **use** and **end-of-life phases**. An indication of the annual emission quantities in the end-of-life phase at sector or sub-sector level would also be desirable, if these data are known.

If possible, please indicate for each (sub-)use what proportion of the waste (in percent) is treated by incineration, landfilling and recycling. Please provide information on the justification of the estimates as well as information on the mentioned form of treatment.

3: Emissions in the end-of-life phase

If you have appropriate information on the **entire life cycle** and in particular on the **end-of-life phase of** e.g. fluoropolymers, please submit this data as requested.

If you have suitable information on the **combustion process** in the **end-of-life phase of e.g.** fluoropolymers, submit this data.

4: Impact on the recycling industry

In order to understand the impact of the proposed restriction on the recycling industry, information is requested on the following aspects:

- The impacts due to concentration limits. The impact that the concentration limits proposed in section 2 of the restriction proposal (see table starting on page 4 of the summary of the restriction report under Annex XV reporting format 040615 (europa.eu)) has on the technical and economic feasibility of recycling processes (together with a clear indication of the waste streams to which the described impacts relate).
- The measures that recyclers would have to take to achieve the proposed concentration limits.
- The costs associated with these measures.

5: Tonnage and emissions of the proposed derogations

A number of derogations/exemptions are proposed in **sections 5 and 6 of** the restriction proposal (see Annex XV reporting format 040615 (europa.eu)). **For these proposed exemptions,** information is required on the amount of PFAS used per year and the resulting **emissions to the environment** for each use. **Important: the representativeness of the information submitted must be justified**.

Example

5. By way of derogation, paragraphs 1 and 2 shall not apply to:
    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.

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;

6: Missing uses

Many PFAS uses were not addressed or not addressed in detail in the submitted restriction proposal (see blue and orange highlighted sectors and uses in Table A.1 in Annex A of the Restriction Report at f71f3bed-e48d-5004-d195-e293c38d0602 (europa.eu).

Example Table A.1. (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

Accordingly, it can be assumed that many relevant uses have not yet been identified. For such uses, specific information on alternatives and socio-economic impacts is requested, which includes the following information:

a. **Annual tonnage and emissions** (at sub-sector level) and **type of PFASs** associated with each use.
b. **The most important functions of PFAS** for the relevant use.
c. The **number of companies in the sector** that are likely to be affected by the restriction.
d. **Availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use**, including information on the extent (in terms of market share) to which **alternative products** are already available on the **EU market** and whether **shortages in the supply of** relevant alternatives are expected.
e. In cases where **alternatives are not yet available,** information on the status of R&D processes to find suitable alternatives, including the extent of **R&D initiatives in terms of time and/or financial investment, the likelihood of successful completion**, the **time** expected to be needed for **substitution** (including any relevant **certification** or **regulatory approvals**), and the main challenges encountered with alternatives that were considered but then rejected.
f. For cases where **substitution is technically and economically feasible,** but more time is needed for substitution:

    1) the type and magnitude of **costs** associated with substitution (at company level and, if available, at sector level) (e.g. costs of new equipment or changes in operating costs);
    2) the **time** required to complete the substitution process (including any relevant certification or regulatory approvals);
    3) Information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimates of expected early replacement needs or expected additional energy consumption);
    4) Information on the benefits for alternative providers.

g. For cases where **substitution is not technically or economically feasible,** information on the socio-economic impacts for companies, consumers and other stakeholders is required. If available, please provide the annual value of EU sales and profits of the sector concerned, as well as employment numbers for the sector.

7: Potential derogations/exceptions marked for reconsideration

In paragraphs 5 and 6 of the restriction proposal (see Annex XV reporting format 040615 (europa.eu)), a number of possible exemptions (marked with square brackets [...]) are proposed for reconsideration after consultation. These are uses of PFASs where the evidence underlying the substitution potential assessment was weak. The substitution potential is determined on the basis of the following criteria:

i. whether technically and economically feasible alternatives have already been identified or products based on alternatives are available on the market at the assumed date of entry into force of the proposed restriction,
ii. whether known alternatives can be introduced before the end of the transition period (taking into account the time requirements for substitution and certification or regulatory approval), and
iii. whether known alternatives are available on the market at the assumed date of entry into force in sufficient quantities to allow the affected companies to substitute.

Table 8 of the Restriction Report (see page 81 ff. under Annex XV reporting format 040615 (europa.eu)) provides a summary of the available evidence as well as the main aspects that could justify a derogation. **Further details** are provided in the relevant sections of **Annex E** 57812f19-8c98-ee67-b70f-6e8a51fe77e5 (europa.eu).

Example Table 8:

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
Lubricants (Annex E.2.14.)		
Sector as a whole	Sufficiently strong evidence that technically and economically feasible alternatives do not exist for the uses where lubricants containing PFASs are applied under harsh conditions or for safe functioning or safety of equipment. There is inconclusive evidence on the existence of alternatives for PFAS-based lubricants not applied under conditions considered harsh or safety-related: for some they are available, but probably not for all. Conclusion: Low substitution potential at EiF for lubricants applied under harsh conditions or for safe functioning or safety of equipment [sufficiently strong evidence]. Unclear substitution potential at EiF for lubricants not applied under harsh conditions or for safe functioning or safety of equipment [inconclusive evidence].	High socio-economic costs are to be expected due to the non-existence of alternatives. Functionality loss, e.g. related to performance level and lifetime, is likely to affect an unknown number of industries and end-users. Product reformulation costs are estimated to range between tens of thousands and several million euros, but reformulation is unlikely to be possible within the given timeframe.

In order to support the justification for a derogation for these uses, **additional specific information is** requested on **alternatives** and **socio-economic impacts** covering **the** elements described in **question 6** under **points a) to g).**

8: Other uses

Table 8 of the Restriction Report (see Annex XV reporting format 040615 (europa.eu)) provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the costs expected from restricting PFAS. Further details on the available evidence are provided in the relevant sections of Annex E 57812f19-8c98-ee67-b70f-6e8a51fe77e5 (europa.eu).

For many of the (sub)uses, the information on alternatives and socio-economic impacts was general and mainly qualitative. In particular, for some applications falling under the following (sub-)uses, the evidence on alternatives was inconclusive: **technical textiles, electronics, energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for acrylic foam tape production, window film production and lubricants not** used in **"harsh"conditions.**

More information on alternatives and socio-economic impacts is needed in order to make statements on substitution potential, proportionality and the need for specific time-limited derogations. Therefore, specific information on alternatives and socio-economic impacts is requested (if not already included in the restriction report or addressed in the questions above) covering the elements listed in question 6 under points a) to g).

9: Degradation potential of specific PFAS subgroups

Some specific PFAS subgroups are excluded from the scope of the restriction proposal because they have a combination of key structural elements that can be expected to be eventually mineralised in the environment. RAC would welcome further information on the potential degradation pathways, kinetics or metabolites produced in the relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino and difluoromethanedioxy derivatives.

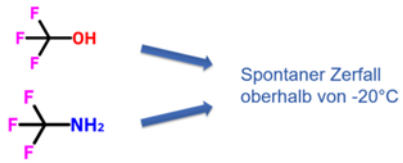


Figure 1: Naturally unstable major fluorinated compounds (trifluoromethanol and trifluoromethylamine).

10: Analytical methods

Annex E of the restriction proposal (see 57812f19-8c98-ee67-b70f-6e8a51fe77e5 (europa.eu)) contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide new or additional information on new developments in analytical methods that have not yet been considered in the restriction report.

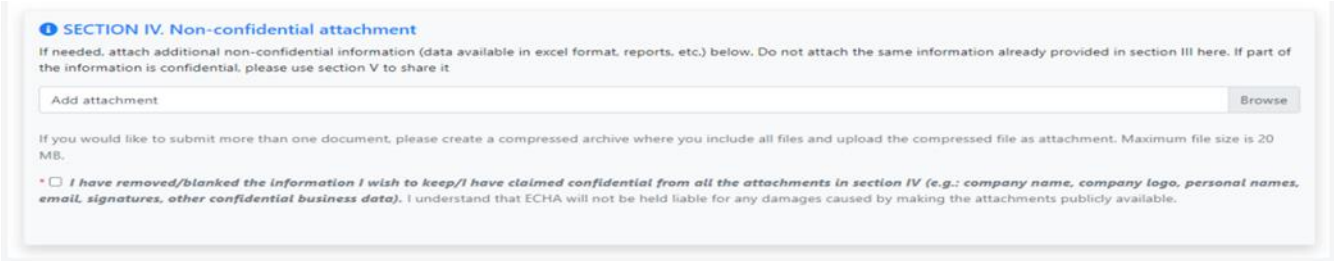
Section IV. Non-confidential Annexes.

If you would like to contribute your input (general comments and answers to the specific questions) to the consultation in separate attachments, you can upload them in this section.

If more than one document is to be sent, a compressed archive (e.g. Zip) must be created. The maximum file/archive size is **20 MB**.

Then click on the obligatory box:

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.

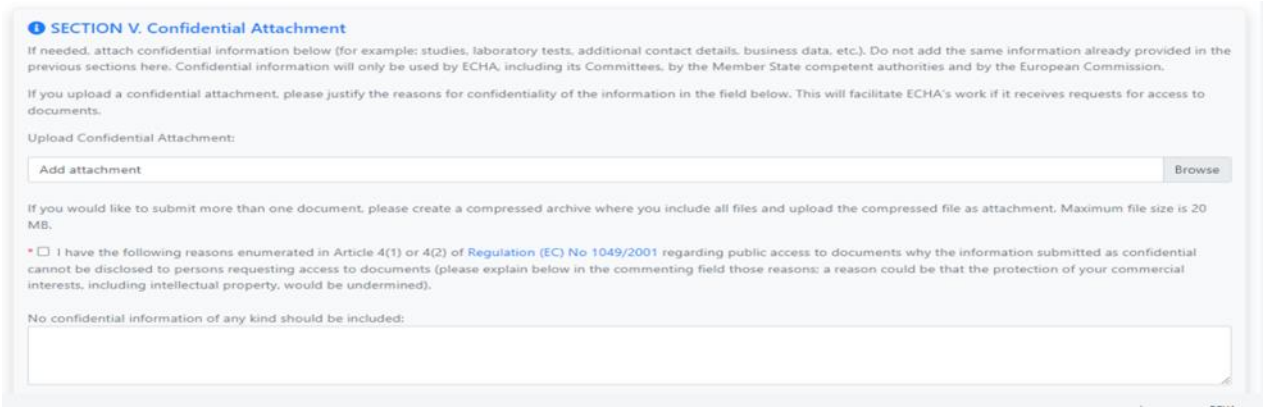


Section V. Confidential Annexes

In this section you can attach your **confidential data** as a separate document. Attach confidential information if needed (e.g. studies, lab tests, additional contact details, business data, etc.). Do not include the same information here that you have already provided in the previous sections. Confidential information will only be used by ECHA, including its Committees, EU Member State Competent Authorities and the European Commission.
If you upload a confidential attachment, please justify the confidentiality of the information in the box below. This will facilitate ECHA's work.
If more than one document is to be sent, a compressed archive (e.g. Zip) must be created.

The maximum file/archive size is also **20 MB** here.

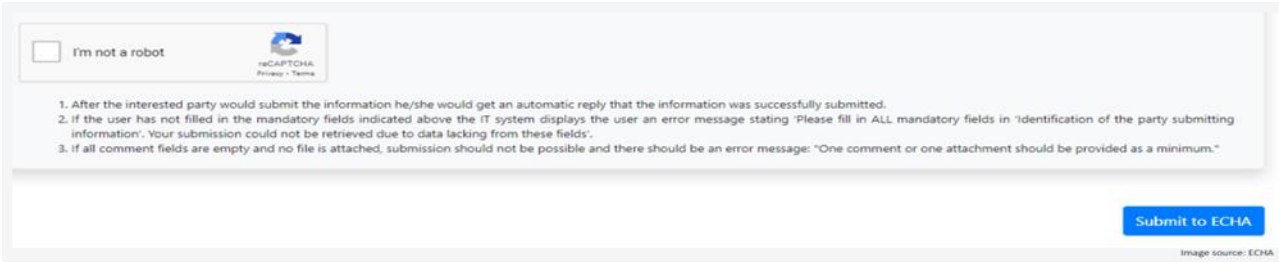
Click on the obligatory box " I have the following reasons enumerated in Article 4(1) or 4(2) of Regulation (EC) No 1049/2001…". Add an explanation of the reasons why this information is considered confidential.



Submission of comments

To submit your comments, you need to follow these two steps:

- » - Click on the box **"I'm not a robot"**.
- » - Click on the "**Submit to ECHA"** button.



Further hints/tips to keep in mind when preparing your contribution to the public consultation

- After an exchange (information event on effective participation in the consultation) with the BAuA (Federal Institute for Occupational Safety and Health), the following aspects are necessary with regard to efficient participation in the consultation. The core message we have taken away is that emotional statements such as **"this is the death of industry"** or similar should be avoided. On the other hand, **the impact of your applications should be presented as specifically as possible**.
- Be **as specific as possible** about how your applications are affected. **Important: Scientific studies are not absolutely necessary, but you should provide well-founded justifications. It is important to ensure that the statements are plausible.**
- Be sure to consider the socio-economic impacts of the restriction. Here, all provable and plausible information is relevant that can provide information on what impacts (also in the value chain) are to be expected. Draw up a provable and plausible worst-case scenario. Information could be, for example: sales volume, jobs, market share of the company, representativeness in the EU, costs of switching to alternative(s), of the impact on functionality, of the re-qualification, etc.
- The following argumentation example can be provided:
  - **1. Substances and tonnage/quantities**
  - Information on which specific PFAS (including quantities/tonnage) you use in your product.
  - **2. Function/substitution possibilities**
  - Why are PFASs used? What **specific properties** are needed?
  - What alternatives have already been tried out? It is important to look back at the history of the company. Why was the switch to PFAS made at that time? New safety requirements/regulations?
  - What would this mean for my product if I had to switch to a PFAS-free alternative? Effects would include re-qualification of my product, possibly resulting in inferior/worse functionality, loss of customers, job losses, etc.
  - **3. Socio-economic effects**
  - All possible variants are desired, but preferably concrete examples, or with causal justification. E.g. a company XY buys products/seals containing PTFE, but cannot find an alternative to PTFE. **Consequence:** loss of jobs, machines do not work properly. But here, too, no end-time arguments, but rather justify the effects/consequences as specifically/objectively as possible.
  - **4. Exception/derogation request**
  - Formulate exception as specifically as possible. Generic exceptions need to be better justified.

IMPORTANT:

Participation in the ongoing public consultation is crucial to ensure the continued safe use of PFAS-containing applications/products including fluoropolymers in the EU. This is the official way to make your **voice** heard. VDMA would therefore very much appreciate if you could take the time to send your comments to ECHA.

Furthermore, we recommend our members to submit the information in the consultation as early as possible. The deadline is **25 September 2023 (23:59 Helsinki time)**. It is also possible to participate in the consultation more than once. It is recommended to reference the previous participation when participating again.

The **main objective** should be to achieve a comprehensive **exemption** for **mechanical and plant engineering industry** within the PFAS restriction.

If you have any further questions in this regard, please do not hesitate to contact us.

Further information:

- ECHA Webinar "Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH" on 5 April 2023: All Webinars - ECHA (europa.eu)
- Webinar of the German REACH-CLP Biocide Helpdesk "PFAS - Quo vadis ? The restriction proposal and how you can get involved": Helpdesk - Homepage - PFAS - Quo vadis ? The restriction proposal and how you can get involved - Federal Institute for Occupational Safety and Health (reach-clp-biocide-helpdesk.de)

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