Consultation on a proposed restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS)[1]

NB: This restriction proposal **does not cover use in firefighting foams**; therefore, further information relating to that specific use is not required in this consultation. The use of PFAS in firefighting foams has already been addressed in another restriction proposal that can be found here.

SUMMARY

The proposed restriction aims to address the risks to human health and the environment posed by the use of per- and polyfluoroalkyl substances (PFAS).

All PFAS in scope of the proposed restriction (or their degradation products) have very high persistence and may remain in the environment from decades to centuries, longer than any other man-made chemical. In addition, many have varying (eco)toxicological effects, are bioaccumulative, mobile and can even reach remote and pristine areas of the world. PFAS are ubiquitously present in a wide range of products intended for industrial, professional and consumer uses and are continuously emitted into the environment. Due to the high persistence, ongoing emissions, and lack of appropriate remediation measures, concentrations of PFAS are constantly and irreversibly increasing in the environment and will inevitably lead to negative effects for human health and the environment.

The substances in the scope of the proposed restriction are aligned with the OECD definition[2] of PFAS which encompasses more than 10 000 substances. Included in the OECD definition but excluded from the scope of the proposed restriction are a few fully degradable PFAS subgroups that are described in the proposal by their key structural elements.

The Dossier Submitters assessed the strengths and weaknesses of two different restriction options:

(i) a full ban with an 18-month transition period (referred to as RO1); and

(ii) a ban with use-specific (mainly) time-limited derogations (referred to as RO2).

The proposed restriction option corresponds to RO2 and would ban the manufacture, placing on the market and use of PFAS as such, as constituent in other substances, in mixtures, and in articles above a set concentration limit. The proposed restriction option would allow for an 18-month transition period (after entry into force) and use-specific time-limited derogations for several sectors. The time-limited derogations and their

[1] The information note has been prepared based on the Annex XV restriction report prepared by the national authorities of Germany, the Netherlands, Denmark, Norway, and Sweden (the 'Dossier Submitters').

[2] Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).

duration (either 5 or 12 years from the end of the general transition period of 18 months) are based on socio-economic considerations and the availability of alternatives. In addition, some time-unlimited derogations are proposed, such as for PFAS used as active substances in plant protection products, biocidal products, and human and veterinary medicinal products, as these are addressed under their respective regulations.

Furthermore, the proposed restriction option lists potential derogations for reconsideration after the consultation. For the PFAS uses in question, the Dossiers Submitters have some indications that a derogation could potentially be warranted, the available evidence is however considered insufficient to allow a firm conclusion. Therefore, further information may be submitted in the consultation on the Annex XV restriction report to enable ECHA's Committees to evaluate the justifications for any potential derogations.

ANNEX XV RESTRICTION REPORT CONSULTATION

The consultation on this proposed restriction will start on **22 March 2023** and end on **25 September 2023** at 23h59 (local time in Helsinki).

Interested parties can comment on the Annex XV restriction report using the relevant web form on the ECHA website. When submitting information, please keep the following in mind:

- Please ensure you are referring to the most recent version of the Annex XV restriction report and any annexes (i.e. those published alongside the consultation).
- Information arriving after the closing date or via other channels than the web form will not be considered by ECHA's Committees.
- It is your responsibility to remove confidential information from the comments and attachments submitted with non-confidential status.
- It is necessary to provide supporting evidence to justify the information submitted in the consultation, otherwise ECHA's Committees may not be able to independently evaluate the information submitted.
- Please specify the sectors and (sub-)uses to which your comment applies (see specific information request #1).
- When providing information on the availability of alternatives, please also provide information on how long it would take to transition to the alternatives, presenting clear steps and timelines.
- When providing information on socio-economic impacts, please focus on the incremental costs and benefits, i.e. strictly those related to implementing the proposed restriction as compared with not implementing it. Also, please make sure to provide relevant contextual information (e.g. what sources the estimates are based on) as well as the calculations underpinning any estimates provided. Finally,

please make sure to specify whether the impacts are one-off (e.g. investment costs) or recurring (e.g. operating costs).

Further information can be found in the consultation guidance available at: https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c

HOW TO SUBMIT A COMMENT IN THE CONSULTATION

When you are ready to make your comments, click on the appropriate link on the ECHA website. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance. The web form contains five main parts:

- Introduction: Containing some general information on the restriction and a link to this note and the consultation guidance.
- Section 1: Personal information.
- Section 2: Organisational information.
- Section 3: Non-confidential comments on the proposal – both general comments and information on specific information requests (see below). Your responses can be entered directly into the form or through section 4 as an attachment. However, please do not submit the same comments via both means. General comments can be on any aspect of the Annex XV restriction report, including on issues related to socio-economic analysis.
- Section 4: Non-confidential attachments can be added here.
- Section 5: Confidential attachments can be added here. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities. However, if ECHA receives an Access to Documents request, we may come back to you for justifications why the information is confidential. You can also add this information already in the relevant part of the webform.

Once you have finished your submission press the submit button and your comments will be submitted. You will receive a submission number via e-mail, and you should refer to this in any communication with ECHA on this issue.

It is not possible for you to retrieve your submission so you may want to take a screenshot, or printed copy, for your future reference.

The Dossier Submitters and the RAC and SEAC rapporteurs will respond to the issues raised in the consultation. A response to comments will be published after the adoption of the RAC opinion and the agreement of the SEAC draft opinion.

SPECIFIC INFORMATION REQUESTS

In addition to an opportunity to provide general comments, as outlined above, the consultation includes the following specific questions to gather information that is considered to be particularly relevant to the evaluation of the proposal:

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.