

European Chemicals Agency (ECHA)
Helsinki, Finland
(Submitted to ECHA by webform)

ECHA consultation on a proposed restriction a proposed restriction on per- and polyfluoroalkyl substances (PFAS). (Start of consultation: 22 March 2023, final deadline 25 September 2023) - Finnish CA comments

We thank the dossier submitters for this restriction proposal. We have the following comments on the Annex XV restriction report.

ANNEX XV RESTRICTION REPORT
rest_pfas_axv_report_en.pdf

page 9: "All PFASs subject to this restriction proposal are either persistent themselves or degrade to persistent PFASs, except for a few specific PFAS subgroups with combinations of key structural elements for which it can be expected that they will ultimately mineralize in the environment. As they do not form ultimately persistent PFAS arrowheads, these PFAS subgroups are excluded from the scope definition of this restriction proposal.

Comment: Propose to edit e.g. as: "All PFASs are either very persistent themselves or degrade to very persistent PFASs, with the exception of a few specific PFAS subgroups with combinations of key structural elements. Substances belonging to these specific PFAS subgroups are expected to be less persistent than the other PFASs, to ultimately mineralize in the environment, and to not form ultimately persistent PFAS arrowheads. For these reasons, substances belonging to these PFAS subgroups are excluded from the scope definition of this restriction proposal.

Reason: The first sentence has an inconsistency as it says that not all PFASs subject to this restriction proposal are persistent (or degrade to persistent PFASs).

page 19: "The substance scope of the proposed restriction is additionally a concern-based one as it intends to cover PFASs that are very persistent, with the aim to address the concerns associated with the persistent nature of these substances."

Comment: A fulfilment of P/vP criterion does not exclude a potential for a complete degradation in the environment over time. For the PFASs that are excluded from the scope, no assessment is presented regarding the P/vP property. Therefore, it cannot be excluded that some of the excluded PFASs, or their transformation products, would also be P or vP under REACH. If that is the case, the P/vP property would be expected to be caused by other structural elements than the perfluorinated carbon. An option could be to say that "...intends to cover PFASs that have a very high persistence, exceeding the criterion for very

persistent (vP) according to Annex XIII of the REACH Regulation by far, with the aim to address the concerns associated with the very high persistence of these substances.”, in accordance to text on page 1. The same comment may apply to other parts of the text as well.

page 19: “Generally, PFASs are either very persistent themselves or will ultimately degrade to very persistent degradation products (so-called PFASs arrowheads). There are however a few specific PFAS subgroups with combinations of key structural elements for which it can be expected that they will ultimately mineralize in the environment. Substances belonging to these PFAS subgroups have been shown to fully degrade under environmental conditions³ (see relevant available degradation data summarized in Annex B.4.1.4.) and thus do not form ultimately persistent PFAS arrowheads (perfluoroalkyl acids (PFAAs)).”

Comment: propose to edit e.g. as: “Generally, PFASs are either very persistent themselves or will ultimately degrade to very persistent degradation products (so-called PFASs arrowheads). There are, however, a few specific PFAS subgroups with combinations of key structural elements for which it can be expected that they are less persistent than the other PFASs and that they will ultimately mineralize in the environment. Substances belonging to these PFAS subgroups are expected to fully degrade under environmental conditions (see relevant available degradation data summarized in Annex B.4.1.4.) and not expected to form ultimately persistent PFAS arrowheads (perfluoroalkyl acids (PFAAs)).”

Reason: Please see comment on page 9. In addition, “shown to fully degrade under environmental conditions” is not accurately reflecting the available data (see comments on page 58-63 for the Annex to the restriction report).

page 22: “All PFASs in the scope of this restriction proposal are either very persistent themselves, or degrade into very persistent PFASs in the environment.”

Comment: propose to edit to: “All PFASs in the scope of this restriction proposal either have a very high persistence themselves, or degrade in the environment into PFASs with a very high persistence”. Reason: Please see comments above.

page 22: “All PFASs are considered to be very persistent..”

Comment: Please change to “All PFASs that are in the scope of this restriction proposal...”

page 25: “Degradation of precursor-PFASs in the environment to PFAAs also render the precursors mobile in water at some point of time”

Comment: Propose to modify e.g. to “Degradation of precursor-PFASs in the environment to PFAAs also releases PFASs that are mobile in water..”

page 27: “However, bioconcentration factors below 2 000 L/kg could potentially reach similar levels in biota compared to substances that are known to bioaccumulate due to increasing and irreversible exposure to PFASs (see section 1.1.4.10/ Annex B.4.3.).”

Comment: For clarity of the sentence please edit e.g. to: “However, PFAS with bioconcentration factors below 2 000 L/kg could potentially reach similar levels in biota compared to non-PFAS substances that have higher bioconcentration factors, due to increasing and irreversible exposure to PFASs (see section 1.1.4.10/ Annex B.4.3.).”

page 34: Please indicate the emission pattern used as model setting for the scenarios based on the Crookes and Fisk model. Is it based on continuous emission at a constant rate?

page 34: "The report by Crookes and Fisk (2018) indicates that also substances which have bioconcentration factors below 2 000 L/kg could potentially reach similar levels in biota compared to substances that are known to bioaccumulate, provided that they are sufficiently persistent and mobile in the environment."

Comment: Please change "substances that are known to bioaccumulate" to "substances fulfilling the B or the vB criterion". We note that under the CLP, a BCF in fish of ≥ 500 is indicative of the potential to bioconcentrate for classification purposes under the hazard class "Hazardous to the aquatic environment".

page 35: "For the substance B combination of BCF of 1 and half-life of 30 years the high steady state would be reached very slowly far beyond the time-scale of the simulation. When the model from the Crookes and Fisk (2018) report is used for PFASs, concentrations of very persistent and mobile subgroups in biota may be expected to exceed the biota concentrations for a persistent and bioaccumulative substance over time."

Comment: Propose to modify as: "...concentrations of a very persistent and mobile PFAS substance in biota may be expected to exceed the biota concentrations for a persistent and bioaccumulative substance over time."

Reason: To our understanding this is a comparison between individual modelled substances with certain assumed properties. Therefore "concentrations of PFAS subgroups" is somewhat confusing in this sentence. As an additional remark, to our understanding, in this model, with a substance of BCF of 1 the estimated concentration in biota at steady state is equal to the concentration in environment. For such substances, concentration in biota would not exceed the concentration in the environment. In other words, concentration in biota can only increase if concentration in the environment increases.

page 36: "Accumulation of many PFASs in edible plants, the bioaccumulation potential observed some PFASs in fishery products (and other products) and the very high persistence and mobility as discussed above human exposure via food."

Comment: Please check the sentence for missing words or other editorial corrections needed to make the sentence complete and clear.

page 37: "Current exposure of the general population can be observed for the available biomonitoring data (see Annexes B.9.21. and B.9.22.)."

Comment: "for" should be "from"?

Annex to the ANNEX XV RESTRICTION REPORT **rest_pfas_annex_b_en.pdf**

page 18: "For additional details on the training sets for the QSAR models and their reliability, see Appendix B.4.1.2."

Comment: We were not able to find this Appendix on the ECHA web page.

page 19: Comment: Under B.4.1.2.3. we propose to include the OECD TG 308 study for 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6-dodecafluoro-2-(trifluoromethyl)-hexane (EC 435-790-1). Currently the restriction proposal does not include any OECD TG 307, 308, or 309 studies for a perfluorinated compound with natural surface water/soil/sediment. Therefore, we consider that this study provides valuable information for the restriction proposal. Information is available in the Registered substance factsheet

(<https://echa.europa.eu/fi/registration-dossier/-/registered-dossier/21902/5/3/3/?documentUUID=1cc737ac-b772-4f55-acb5-1dab5513b148>).

Kentän koodi muuttunut

page 25: "PFBS and its salts have been included in the REACH Candidate List meeting the criteria under REACH Article 57(f), due to its very high persistence (ECHA, 2019e).

PFHxS fulfils the criteria for being "very persistent" and has been adopted as SVHC by the Member State Committee in 2017 (ECHA, 2017c)."

Comment: Propose to modify to: "PFBS and its salts have been included in the REACH Candidate List meeting the criteria under REACH Article 57(f), due to its combined intrinsic properties (e.g., very high persistence) and observed probable serious effects (ECHA, 2019e)."

PFBS and its salts and PFHxS (ECHA, 2017c) have been included in the REACH Candidate List meeting the criteria under REACH Article 57(e) (very persistent and very bioaccumulative (vPvB)) (ECHA, 2017c)."

Reason: 1) The SVHC identification of PFBS was not based only on persistence. 2) We do not think there is a particular reason to mention MSC in the text for either of the substances. Both PFHxS and PFBS underwent an MSC process (this is clear also from the references cited) but currently MSC is mentioned only for PFBS.

page 26: Comment: After "...according to OECD Test Guideline (TG) 309" please add e.g. "; however, with the significant exception that the study was conducted with a wastewater effluent instead of natural surface water."

Reason: It is incorrect to state the study was made in according to OECD TG 309. This comment applies also to other parts where this test is discussed.

page 27: "exceeds too much" is unclear, please delete "too much" if not necessary, or specify what it means

page 30: "SFPs are similar to from non-polymeric PFAS precursors and are expected to follow the same reactivity pattern."

Comment: "from" seems to be redundant. Also, the sentence would need some other modification (explain in which way they are similar) as SFPs do differ from non-polymeric precursors (by being polymers).

page 58: "As the above three key perfluorinated compounds are chemically unstable, all compounds that lead to these substances during degradation, and no other perfluorinated degradation products, will degrade under any relevant environmental conditions."

Comment: It is unclear how the instability of the perfluorinated fragment would cause the whole molecule to quickly mineralize. Would that not be affected by the molecular structure of the transformation product(s) remaining after the perfluorinated part has degraded/detached? We propose to modify and to not exclude the formation of P or vP transformation products.

page 58: "A larger molecule containing a trifluoromethoxy-group attached to a degradable moiety (CF₃-X, where X = -OR and where R = methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-

C(O)-)) is expected to degrade with formation of trifluoromethanol. As this substance is inherently unstable, it will quickly mineralize under environmental conditions as described above. Hence, it cannot be persistent in itself nor degrade to a persistent PFAS"

Comment: If the R group is a methylene or a carbonyl group, there are more carbons attached to it. Thus a high number of different molecular structures can fulfil this definition and these will most likely differ in their degradability. Therefore, the possibility of P or vP transformation products in this group of compounds cannot be excluded. Also the degradability of an aromatic group could depend on the substitution. In addition, is there any information to which extent the instability of the perfluorinated part is dependent of the complexity and structure of the rest of the molecule? We propose to modify the text so that these factors are considered. The same comment is applicable to other similar parts of the document, at least on page 59.

page 60: "These results represent a water test that indicate biotic degradation of the substance in the environment."

Comment: Please note that this was a fixed-bed bioreactor study. Therefore please modify to : " The results indicate the potential of the microorganisms originating from a natural surface water to degrade the substance in a laboratory-scale bioreactor study". In addition, we propose to add some details of the type of experimental system as with the current information it is difficult to estimate to which extent this study corresponds e.g. to OECD TG 309 or 308, how optimized the test conditions were (e.g. use of carrier materials or nutrients), was it a batch study or a continuous system, etc.

page 62: "The results indicate biotic degradation of the substance in the environment."

Comment: Please reconsider this sentence because the study was conducted with effluent water from a municipal wastewater treatment plant. It could be stated that "These results indicate biotic degradation of the substance by organisms in municipal wastewater treatment plant effluent in a laboratory study".

page 63: "The above assessment explains that substances that degrade via trifluoromethanol (and no other perfluoroalkyl fragments) are not to be considered as persistent PFASs, as there are no possible stable PFAS that may be formed from the indicated substances. Furthermore, examples of degradation of specific substances have been included to show that there is experimental data to support this consideration."

Comment: "persistent PFASs" would need to be specified to clarify that it refers to the very high persistence which is the main reason for the current restriction proposal and that these compounds might still fulfill the P or vP criteria of REACH (unless there is sufficient data for these compounds to conclude that REACH P criterion would not be fulfilled). For example, consider modifying as: "The above assessment explains that substances that degrade via difluoromethanediol (and no other perfluoroalkyl fragments) are not to be considered as PFAS with a very high persistence, as there are no possible stable PFAS that may be formed from the indicated substances. Furthermore, examples of degradation of specific substances have been included to show that there is experimental data to support this consideration. However, in the present document, it is not assessed whether these compounds fulfill the P and/or vP criteria of REACH or whether the available data would allow a conclusion on P/vP."

The comment may be applicable also to other parts with similar wording (page 64, 65).

page 63: Comment: Regarding the study by Peschka et al. (2008), please note that they also report results of a Zahn-Wellens test 10-(trifluoromethoxy)decane-1-sulfonate. We propose to mention these results in the report, as this is one of the standard inherent biodegradation tests.

page 67: "A half-life of 2 000 days or 5.5 years is long, but not excessively high. PFASs, for example most PFAAs, can have much longer half-lives."

Comment: Propose to modify, e.g., as: "A half-life of 2 000 days or 5.5 years is long, but not excessively high for PFASs, considering the available information on degradation (see Sections B.4.1.1 and B 4.1.2.)."

Reason: 5.5. years actually is an excessively high half-life, at least for any substance that is considered to be a concern for the human health or environment. But what is probably meant here is that it is not excessively high considering the data available for PFASs.

page 67: "Similarly, the increase in the total inventory of chemical in the model system is only around a factor of 550 to 600 because of the increasing effect of the non-degradation losses."

Comment: We propose to clarify the sentence. Particularly "increasing effect of the non-degradation losses" is difficult to understand.

<http://echa.europa.eu/restrictions-under-consideration>

<https://echa.europa.eu/fi/restrictions-under-consideration/-/substance-rev/69104/term>

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