CONSULTATION

***Note 16.07.2020**: this is an updated version (version 3) of the information note version 2 published on 22.04.2020. The updates of version 3 are highlighted in green in the text, while updates made in version 2 are highlighted in yellow.*

Proposed restriction on undecafluorohexanoic acid (PFHxA), its salts and related substances[1]

Summary

The Annex XV report details a proposal to restrict the placing on the market of undecafluorohexanoic acid (PFHxA), its salts and related substances. Due to their unique properties (including providing oil, dirt and water repellency and film forming), PFHxA, its salts and related substances are used in a variety of sectors in large quantities in the EU. The uses include fire-fighting foams, textiles, food contact materials, cosmetics, semiconductors, intermediate uses, etc. ~~Forty-six substances registered under REACH (in 75 registrations)~~ 110 CLP or registered substances are within the scope of the proposal. ECHA has also compiled a further indicative list of substances covered by the scope of this restriction proposal. The indicative list is provided in a separate Annex to this information note.

The Dossier Submitter concluded that the use of (PFHxA), its salts and related substances cause a risk to environment and human health and that the emissions need to be minimised. PFHxA salts and related substances transform/degrade into PFHxA and would hence also need to be restricted. The Dossier Submitter proposes that PFHxA has a combination of hazardous properties: PFHxA has a very high persistence which leads to an increasing pollution stock in the environment if the releases are not controlled. The substance is also mobile and has surface active properties such that the use of the substance causes contamination of ground water, surface waters and the marine environment on a wide geographical scale. Furthermore, its removal, e.g., from contaminated drinking water and soil is currently not economically feasible. Exposure of humans takes place mainly via drinking water and food, including infants via breast milk. Due to the very long-term and increasing exposure, long-term risks to human health and environment cannot be quantified with sufficient certainty.

The consultation on this proposed restriction will start on 25/03/2020 and ends on 25/09/2020.

When responding to the consultation, stakeholders should ensure that they are referring to the most recent version of the Annex XV report and any annexes (i.e. those published alongside the consultation).

Respondents are also encouraged to take into account when certain aspects of the proposal are planned to be discussed in the committee's plenary meetings (see table below) and time their submissions accordingly (multiple submissions are possible throughout the consultation).

[1] The information note has been prepared based on the Annex XV report prepared by Germany.

	Committee	
Plenary meeting of the Committee (timing)	**Risk Assessment Committee (RAC)**	**Socio-Economic Assessment Committee (SEAC)**
1 (2.5 months after PC starts)	Verify the proposed scope. Conclude on hazard and hold preliminary discussion on exposure/risk.	Verify the proposed scope. Conclude on costs of the proposed restriction and hold preliminary discussions on its benefits.
2 (5.5 months after PC starts)	Conclude on exposure/risk and hold preliminary discussion on derogations.	Conclude on benefits and hold preliminary discussions on proportionality and derogations.
3 (8.5 months after PC starts)	Finalise the derogations. Finalise the opinion plus justification text and adopt the final opinion.	Conclude on proportionality and derogations. Finalise the opinion plus justification text and agree the draft opinion.
4	Not relevant.	Conclude on issues raised during the SEAC draft opinion consultation. Adopt the final opinion.

Information on the hazards of the substance(s) and the costs of the proposal would make the most impact if submitted by month two and exposure/risk, benefits and derogations by month four of the consultation. This early submission would allow the information to be considered at the appropriate time during opinion making. This timing takes into account that stakeholders have access to the dossier much earlier than in the past, as it is published two weeks after submission or more than six weeks in advance of the start of the consultation.

It is possible to submit more than one consultation response during the six month period so please take this into account when deciding when to submit information.

How to submit a comment in the consultation on the proposed restriction

Firstly please read the consultation guidance that describes the relevant information that should be submitted. Comments should always be substantiated with supporting information. The Guidance can be downloaded here.

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 PC guidance.
- Section 1: Personal information
- Section 2: Organisational information
- Section 3: Non-confidential comments on the proposal - both general comments and information on specific issues (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 proposal, 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 screen shot, or printed copy for your future reference.

Specific information requests

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

General:

1) Additional uses:

- In addition to the uses described in the Annex XV dossier, are you aware of any other present or future intentional uses, or uses where impurities are above the concentration limit proposed? The question concerns both uses in the EU and outside the EU involving imports to the EU. If such uses exist, please provide the following:
    a. Description of the use,
    b. Quantities used and information regarding the potential risks to the environment (e.g. quantified release estimates)

CONSULTATION

Specific sectors / uses:

2) Emissions of PFHxA from polymers:

- PFHxA, its salts and its related substances are emitted from side chain fluorinated polymers. Such emission may also take place from fluoropolymers. The available data describing these emissions is, however, limited. Please provide any additional data you may have on the extent of these emissions.

3) Textile sector:

Note to the version 2 of this information note: this part has been further clarified, see changes tracked.

- The majority of clothing used in the EU is imported from outside the EU. Please, provide any additional data you may have on:
  - the share of imported clothing (outdoor and occupational clothing) that is treated with side-chain fluorinated polymers ~~fluoropolymers~~; ~~Please, provide, if available,~~
  - the share of imported clothing treated with fluoropolymers (C6-chemistry integrated in the polymer backbone);
  - the share of imported clothing treated with PFHxA, its salts and/or related substances;
  - the content of extractable perfluorinated substances and applied fluoropolymers in treated textiles. ~~Please, provide, if available, the share of imported clothing treated with PFHxA, its salts and/or related substances.~~

4) Coatings:

- Please provide any data you may have on tonnages used in coatings and for the release of PFHxA, its salts and/or related substances from coated building and construction materials.

5) Fire-fighting foams (all relevant sectors, including defence sector):

a) Have you already shifted from PFHxA, its salts and/or related substances to fluorine-free foams or are you planning to shift to those alternative foams?

- If yes:
  - In which area did you or are you planning to shift to fluorine-free foams (e.g.: seagoing units, storage of fuel)?
  - How long did the transition to fluorine-free foams take you or how long will it approximately take to perform the transition?
  - What are/were the challenges when performing such a transition? E.g., when using the same equipment, are the residues of PFHxA, its salts and/or related substances in the equipment posing a technical challenge in relation to the concentration limit proposed?

- If no:
    - Please, specify whether you have moved from PFHxA, its salts and/or related substances to a foam containing other fluorinated substances.
    - Please, provide information on the volumes and value of the stocks you may have on fluorinated foams in general and more specifically on foams containing PFHxA, its salts and/or related substances.
    - Please, provide information on the volumes of fire-fighting foams containing PFHxA, its salts and/or related substances currently in use in your equipment? Please, provide any information on the handling, release mitigation and waste management instructions relevant for estimating the releases and evaluating the socio-economic impacts.
    - Why did you decide not to shift to fluorine-free foams or, more specifically, to foams free of PFHxA, its salts and/or related substances?
    - What changes are necessary to allow the transition to fluorine-free foams from PFHxA, its salts/related substances? Are you already taking measures to achieve such changes? How long will it take until respective measures are in place to allow a transition to fluorine-free foams?

b) Hand-held fire extinguishers: please, provide information on the volumes and concentrations of PFHxA, its salts or related substances you use in the extinguishers, the use sectors using extinguishers containing these substances, current handling, release mitigation and waste management instructions, and any other information which would be relevant for estimating the exposures and the socio-economic impacts of the proposed restriction?

c) Are you using aqueous film-forming foams (AFFF) containing PFHxA, its salts and/or related substances for training purposes? If yes, please specify why.

d) Are you using AFFF containing PFHxA, its salts and/or related substances for testing purposes? If yes, please specify why.

6) Other uses (cleaning, cosmetics, waterproofing agents, polishing products, floor waxes, food contact materials, etc.) including uses in consumer products:

- Please provide any information you may hold on tonnages used of these mixtures and of the identity of the substances (within the scope of this restriction and/or any fluorinated substance).

Substitution and alternatives, all sectors:

7) Are you aware of any alternative fluorine-free substances or technologies for the uses of PFHxA, its salts and related substances?

8) For uses where substitution is regarded as being impossible:

- What is the use?
- What are the main obstacles to substitution?
- Please describe the consequences that would result from the proposed restriction and provide information about the costs associated to these consequences.

9) For uses where substitution is possible now, or uses where substitution is not possible now, but it is expected to become possible within a short to medium timeframe:

- What is the use?
- What transitional period would be needed for this use?
- Please describe the technical and economic consequences that would result from the proposed restriction if the transitional period were as requested, and provide information about the costs associated to these consequences.
- What would be the consequences of a shorter transitional period? What would be the costs associated to that?
- Would investments to enable new processes etc. be needed? If so, please provide information about the costs of these investments.

10) For uses where substitution would be possible but is expected to lead to a lower quality of products or lower performance:

- What is the use?
- Please describe the impacts on the quality/performance of the products.
- If possible, please provide an estimate of the economic impacts that could be expected on an annual basis.

Uses where we would in particular need the above information in relation to substitution:

- Performance of fluorinated polymers and fluoropolymers within the scope of the proposal, compared to fluorine-free alternatives in various uses of these polymers. What are the cost implications if substitution is required?
- Performance loss of textiles or membranes in case of substitution to fluorine-free alternatives. What would be the impacts of substitution in non-woven textiles used in the automotive and aerospace sectors, medical textiles, textiles for worker protection and membranes for treatment of effluents?

11) PFAS-based alternatives:

Note to the version 2 of this information note: we have deleted 7:2 FTOH. This substance is not relevant as it is covered by the PFOA restriction.

Previously, the PFOA restriction led to the replacement of the 8:2 FTOH technology by 6:2 FTOH. Are you aware of the usability of alternative fluorotelomer substances (e.g. ~~7:2 FTOH,~~ 4:2 FTOH, etc.) or other fluorinated substances (e.g. perfluoroalkyl ether carboxylic acids) in the different processes that now rely on 6:2 FTOH?

12) Costs

- If for your use/sector the Dossier Submitter has provided a concrete cost assessment, do you agree with the assumptions and costs used? If not, please provide additional data and evidence to support it.
- The Dossier Submitter proposes annual reporting on the use of PFHxA, its salts and PFHxA-related substances in the production of personal protective equipment (PPE), non-woven medical textiles and impregnation agents (see paragraph 10 of the proposal entry) and the quantities and substitution efforts for fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances (paragraph 12 of the proposal entry). Are there costs associated with that reporting requirement?

13) Analytical methods

Note to the version 2 of this information note: this is a new question.

Are you aware of a method for chemical analysis of PFHxA, its salts and related substances present in a matrix relevant for the restriction proposal? Do you develop or intend to develop such a method?

The final opinions of both Committees are scheduled to be available by 25/03/2021. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII of the REACH Regulation.

The Dossier Submitter and the Rapporteurs will all respond to the issues raised in the consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion in month nine of the process.