NORWAY PROPOSES A RESTRICTION ON PERFLUOROHEXANE-1-SULPHONIC ACID (PFHxS), ITS SALTS AND RELATED SUBSTANCES[1]

Summary[2]

The Annex XV report outlines a proposal to restrict the manufacture or placing on the market of PFHxS (linear or branched), its salts or related substances[3] (abbreviated in this note to 'PFHxS'); and as a constituent of another substance, in a mixture or in articles. This follows the inclusion of PFHxS and its salts in the REACH Candidate List because of its very persistent and very bioaccumulating (vPvB) properties. Monitoring data indicates that PFHxS, along with PFOS and PFOA, is the most frequently detected perfluorinated substance in human blood samples worldwide. PFHxS is ubiquitously detected in environmental samples. PFHxS will leach from contaminated sites, such as airports and training areas for firefighters and can be a long-term source of contamination to underlying groundwater and drinking water.

From the information available there appears to be no current intentional uses of PFHxS within the EU, but historically it has been used in textiles because of its water and oil repellence properties and also in fire-fighting foams. Alternatives to PFHxS have therefore been found, many of which are fluorine-free. Today it may still be present as an impurity of perfluorooctanesulphonic acid (PFOS) in the limited applications still permitted. The restriction is necessary to avoid the possibility that PFHxS is used as a regrettable substitute when entry 68 of Annex XVII of REACH (Perfluorooctanoic acid) becomes effective in 2020 and to reduce the environmental emissions of the substances present in articles and mixtures imported to the EU. Derogations[4] are included in the proposal to ensure consistency with other EU legislation.

The costs associated with this restriction proposal to EU producers and importers of articles are considered negligible. This EU-wide measure may be a first step for global action.

The public consultation on this proposed restriction will start on **19/06/2019** and end on **19/12/2019**.

When responding to the public 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

[1] The information note has been prepared based on the Annex XV report submitted by ECHA.
[2] An elaborated summary of the proposal is presented on pages 1 to 6 of the Annex XV report.
[3] PFHxS-related substances are substances that based upon their structural formulae are considered to have the potential to degrade or be transformed to PFHxS – see section 1.1.2 of the report.
[4] Derogations are for PFHxS as an impurity in PFOS and for concentrated fire-fighting foam mixtures.

below) and time their submissions accordingly (multiple submissions are possible throughout the consultation)

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 public consultation. This early submission would also allow the information to be considered at the appropriate time. 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 public 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.

	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 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 public consultation. Adopt the final opinion.

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. It is available here: https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c.

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 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 web form.

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

1. <u>The production, use and import of PFHxS, its salts and related substances</u>[5]

   The manufacture, use or import of PFHxS (as a substance, constituent of another substance, mixture or article) is described in Annex A of the report and is summarised above (see summary section). In addition to this, are you aware of any present or future intentional or unintentional use (impurities) of PFHxS, either in the EU, or imported to the EU e.g.in articles? If such uses exist, for example in fluoropolymers (including fluoroelastomers) please provide the following:

   a) the concentrations of PFHxS present in parts per billion, and whether it is present as an impurity or intentionally added

   b) Description of the use or function

[5] PFHxS, its salts and related substances is abbreviated in this note to 'PFHxS'.

c) Quantities used and whether quantities will remain stable, increase or decrease in the future and over what time-frame?

d) Information regarding the potential risks to the environment (e.g. quantified release estimates)

e) Whether the concentrations present will exceed the threshold values in column 2, paragraph 2 of the proposed entry in Annex XVII (p1 of the Annex XV report)

f) Technical and economic information for these applications or uses, for which alternatives are not available and/or the performance of alternatives are not considered adequate

g) Costs for substituting PFHxS.

The above information is also needed from the industry if a time-limited derogation is to be considered.

2. Perflurobutanesulphonic acid (PFBS) and PFOS

In the Annex XV report there is limited information that the manufacture of PFBS and certain limited uses of PFOS may contain impurities of PFHxS. PFBS is known to be manufactured and used as well as imported to the EU in articles. Certain limited uses of PFOS are also permitted in the EU by Regulation (EC) No 850/2004. If not already covered in (1) above, please provide information on:

a) the concentrations of PFHxS present in parts per billion, and whether it is present as an impurity or intentionally added

b) Description of the use, if any

c) Quantities used and whether quantities will remain stable, increase or decrease in the future and over what time-frame?

d) Information regarding the potential risks to the environment (e.g. quantified release estimates)

e) Whether the concentrations present will exceed the threshold values in column 2, paragraph 2 of the proposed entry in Annex XVII (p1 of the Annex XV report)

f) Technical and economic information for these applications or uses, for which alternatives are not available and/or the performance of alternatives are not considered adequate

g) Costs for substituting PFHxS or removing the impurity from the products.

3. Alternatives

The Dossier Submitter summarises alternatives to PFHxS in Annex E.2 and explains that alternatives must already be in use in the EU because there are no intentional uses. Nevertheless, please provide information on:

a) Additional details of alternatives to PFHxS, indicating whether they are technically and economically feasible and challenges of switching to these alternatives

b) Non-fluorinated alternatives, particularly if they have lower risk profiles than PFHxS

c) Articles that would no longer be available in the EU anymore once the proposed restriction becomes effective. Please name the article (types), purposes of use, and origins.

4. Exposure and trend data

In addition to what is provided in sections 1.1.5 - 1.1.7 and Annex B.9., please provide any environmental or human health exposure and/or trend data for PFHxS, its salts and related substances (full reference or links to the reports is appreciated).

The final opinions of both Committees are scheduled to be available by June 2020. 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 public consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion in month nine of the process.

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