

GERMANY, IN COLLABORATION WITH SWEDEN, PROPOSES A RESTRICTION ON C9-C14 PERFLUOROCARBOXYLIC ACIDS (PFCAS), THEIR SALTS AND RELATED SUBSTANCES (PRECURSORS)

Summary

Germany, in collaboration with Sweden, is proposing a restriction on the manufacturing, use, placing on the market and import of C9-C14 PFCAs (PFNA, PFDA, PFUnDA, PFDoDA, PFTTrDA, PFTeDA), their salts and precursors^{1,2}

The public consultation on this proposed restriction will start on 20/12/2017 and ends on 20/06/2018. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome early comments, by 16/02/2018, to assist them in their evaluation of the proposal.

SUGGESTED RESTRICTION

Scope

The proposal restricts the manufacturing of C9-C14 PFCAs, their salts and related substances within the EU. Further, the proposal restricts the use, placing on the market and import of C9-C14 PFCAs, their salts and related substances as substances on their own, in a mixture or in an article or parts thereof in a concentration equal to or above 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related substances. The restriction becomes effective 18 months from the entry into force of the restriction.

Exemptions are proposed for:

- (i) C9-C14 PFCAs, their salts and related substances that occur as unintended by-products during the manufacturing of other fluorochemicals with a carbon chain equal to or shorter than eight carbon atoms,
- (ii) A substance that is to be used, or is used as a transported isolated intermediate, following the strictly controlled conditions provided for in Article 18(4)(a) to (f) of the REACH Regulation, and
- (iii) The production of, or placing on the market in articles, or any parts thereof before the restriction becomes effective.

Reasons for action

No manufacturers or users of C9-C14 PFCAs have been identified by the dossier submitters in the EU and only one importer of C9-C14 PFCAs has been identified. The restriction for PFOA, its salts and PFOA-related substances³ will become effective in 2020 and this restriction is intended to prevent a switch by industry using PFOA-based substances ('C8

¹ C9-C14 PFCA related substances (also called precursors) can be transformed to in the environment to C9-C14 PFCAs

² The information note has been prepared based on the Annex XV report prepared by Germany in collaboration with Sweden.

³ Commission Regulation (EU) 2017/1000 of 13 June 2017.

chemistry') to longer chain PFCAs ('C9-14 chemistry') to fulfil the same role in the end products. PFOA has been used because of its special properties such as high friction resistance, dielectric properties, resistance to heat and chemical agents, low surface energy, as well as water, grease, oil, and dirt repellence.

Alternatives to C9-C14 PFCAs and PFOA are currently being used. These alternatives include other per- and polyfluorinated substances, i.e. perfluorohexanoic acid-based substances ('C6 chemistry') and fluorine-free substances. Stakeholders have reported in the EU that C9-C14 PFCAs have occurred as an impurity in per- and polyfluorinated chemicals containing a carbon chain of less than nine carbon atoms e.g. PFOA-based substances. PFOA-based substance manufacture ceased in the EU in 2015, but as a result of the previous manufacture C9-C14 PFCAs have been released into the environment via various exposure pathways e.g. manufacturing of the substances, processing, use and at the waste stage.

During the manufacturing of the alternative C6 perfluorohexanoic acid -based substances, longer chain C9-C14 PFCAs and related substances still occur as unintended by-products. For this reason a derogation for this manufacture is given in the proposed restriction. Based on information from industry, after further processing the mixtures placed on the market contain less than the threshold values that have been included in the proposed restriction (25 ppb for the sum of C9-C14 PFCAs and their salts, or 260 ppb for the sum of C9-C14 PFCA related substances) or the substance is used as a transported isolated intermediate.

PFCAs are synthetic compounds and their hazard profile is well known. C9-PFCA and C10-PFCA as well as their sodium and ammonium salts are listed in Annex VI of the CLP Regulation as Carc. 2 and Repr. 1B and can cause damage to human health. In addition, C9-C14 PFCAs are bioaccumulative and belong to the most persistent chemical substances known thus they were added to the Candidate List as substances of very high concern (SVHCs) under REACH. C9-C14 PFCA related substances can be transformed to C9-C14 PFCAs in the environment and hence are included within the scope of the proposed restriction. Due to these properties they are very likely to cause severe and irreversible adverse effects to the environment and to human health if their releases are not minimised.

PFCAs themselves do not undergo any further abiotic or biotic degradation under environmentally relevant conditions. They have a high water solubility (compared to other PBT substances) leading to relatively high mobility in water bodies and between different environmental compartments. They can also be transported over long distances via the atmosphere and aquatic environment. As a result they are found ubiquitously in the environment, even in remote areas, as confirmed in biomonitoring data from polar species such as polar bears and seals, as well as in human body fluids such as serum and breast milk.

Consequences of the action

No intentional uses in the EU and only one importer of articles containing C9-C14 PFCAs have been identified by the dossier submitters hence there are few impacts to assess. Consequently, a quantitative valuation of the potential benefits associated with the proposed restriction has not been possible. However, the proposed restriction will prevent

potential future releases of intentionally used C9-C14 PFCAs, their salts and related substances into the environment. The potential compliance costs for industry (if any) are described based on the cost estimates for switching from 'C8 chemistry' to 'C6 chemistry' reported in the PFOA restriction report.

Enforcement costs are estimated to be lower than on average because these costs can be shared with the enforcement costs connected with the implementation of the PFOA restriction. However there is uncertainty related to the extent of the use of C9-C14 PFCAs in imported articles which may influence the enforcement costs.

SPECIFIC INFORMATION REQUESTED

Several specific elements have been addressed in the public consultation to gather relevant information, if available, from stakeholders.

1. The only confirmed intentional use/import of C9-C14 PFCAs or related substances identified in the restriction report is for semiconductor industry. C9-C14 PFCAs are potential alternatives to PFOA. The proposed restriction would prevent industry switching to C9-C14 PFCAs after the PFOA restriction enters into force.

Are you aware of any other present or future intentional uses either in the EU, or outside the EU for articles imported 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)
- c) Technical and economic information on those applications or uses, for which alternatives are not available and/or the performance of alternatives is not considered adequate. This should include information on potential alternative substances or technologies and justification of why they are not feasible.

The above information would be particularly welcomed from the semiconductor and the cosmetic industries and if a time-limited derogation is necessary.

2. According to the restriction report, the proposed thresholds (25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related substances) allow the continued use of alternatives to C9-C14 PFCAs, e.g. based on 'C6 chemistry', where C9-C14 substances may be present as impurities.

Are you aware of uses of other substances (e.g. substances with a carbon chain longer than 14) in the EU or in imported articles, that would be affected by the proposed restriction due to concentrations of impurities of C9-C14 PFCAs that are higher than the proposed thresholds? If such uses exist, please provide the following:

- a) Description of the use
- b) Quantities present as impurities and related concentrations, and information regarding the potential risks to the environment (e.g. quantified release estimates)

- c) Technical and economic information on those applications or uses, for which alternatives are not available and/or the performance of alternatives is not considered adequate. This should include information on potential alternative substances or technologies and justification of why they are not feasible.
3. The restriction report foresees a derogation for the manufacture of C9-C14 PFCAs, their salts or related substances where these occur as an unintended by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 8 atoms. Please describe technical or economic reasons why this by-product fraction cannot be avoided.
4. Are C9-C14 PFCAs, their salts or related substances found in recycled materials and at what concentrations? How would the recycling sector be impacted by the proposed restriction?

Comments preferably by 16/02/2018

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 20/12/2017. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 20/06/2018, the rapporteurs of RAC and SEAC would appreciate receiving comments by 16/02/2018 to assist them in the early stages of the opinion development process .

The final opinions of both Committees are scheduled to be available by 20 December 2018. 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 the Annex XVII of the REACH Regulation.

Further information on the purpose, objectives, and process of the public consultation on restriction proposals is available in the Public Consultation Guidance

http://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf