Information note

Germany and Norway propose a restriction on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances[1]

Summary

Germany and Norway have submitted a report proposing a restriction on the manufacturing, use and placing on the market of Perfluorooctanoic acid (PFOA) and its salts, also including substances that may degrade to PFOA (PFOA-related substances), in concentrations equal to or greater than 2 ppb. The proposed restriction also covers articles containing these substances.

PFOA is a persistent, bioaccumulative, and toxic substance (PBT). Due to these properties it may cause severe and irreversible adverse effects on the environment and human health. Based on their PBT and CMR properties, PFOA and its salt (APFO) have been identified as substances of very high concern (SVHC) under REACH.

In general, PFOA-related substances are defined as fluorinated substances that are expected to degrade to PFOA under environmentally relevant conditions. Therefore, the hazard profile of PFOA applies to these substances as well.

PFOA and a number of PFOA-related substances are found ubiquitously in the environment – also in remote areas – since they can be transported over long distances via water and air. This results in findings in rivers, oceans, drinking water, the atmosphere and biota. Moreover, PFOA is present in human blood of the general population. Human exposure takes place via the environment, e.g. consumption of drinking water and food, ingestion or inhalation of contaminated indoor dust (resulting from the use of consumer products).

ECHA launches the public consultation on this proposed restriction today, which will end on 17 June 2015. However the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome any early comments by 1 March 2015, to assist them in the first discussions of this restriction proposal.

General Remarks

The Annex XV restriction report, prepared by Germany and Norway, has been published on ECHA's website. A public consultation on the proposed restriction is open for a period of six months[2] to allow stakeholders[3] to submit comments or additional information (such as peer reviewed articles, monitoring data and business information) relevant to the proposal. Specific questions on certain aspects of the proposed restriction have also been posed. Comments are invited from stakeholders from both the EU and the rest of the world.

[1] The information note has been prepared based on the Annex XV report prepared by Germany and Norway.
[2] The duration of the public consultation is six months according to Article 69(6) of REACH.
[3] Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities.

An additional, 60 day, public consultation of the draft SEAC opinion will be held at a later stage of Committee opinion making.

The opinions of RAC and SEAC will take into account the comments received in the public consultation. ECHA will reply to these comments and publish the responses, together with the comments of the Committees and Rapporteurs, on its website.

More information on the restrictions process can be found at: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/restriction

It should also be understood that:

- in case there is little information on costs submitted during public consultation, SEAC will understand by this that the concern from Industry is low and that the Restriction could normally be considered proportional.
- where derogations have been proposed by the Dossier Submitter, which have been fully assessed in the Annex XV dossier, they are within the scope of the proposal and will be assessed by RAC and SEAC. Therefore such derogations could potentially be withdrawn, if not sufficiently justified and so it is advised that respondents affected by such derogations give information to either justify the derogation or to withdraw it.
- new derogations may also be added during the opinion making if they are fully justified through either risk or socio-economic arguments (also see specific information requested).

Suggested restriction

Germany and Norway have submitted a report proposing a restriction on the manufacturing, use and placing on the market of:

- Perfluorooctanoic acid (PFOA, CAS 335-67-1, EC 206-397-9), including its salts.
- Any other substance having linear or branched perfluoroheptyl derivatives with the formula C_7F_{15}-[4] as a structural element, including its salts, except those derivatives with the formula C_7F_{15}-X where X= F, Cl, Br.
- Any other substance having linear or branched perfluorooctyl derivatives with the formula C_8F_{17}- as a structural element, including its salts, except those derivatives with the formula C_8F_{17}-X, where X= F, Cl, Br or, C_8F_{17}-SO_2X', C_8F_{17}-C(=O)OH or C_8F_{17}-CF_2-X' (where X'=any group, including salts).

[4] The structural element referred to here is C_7F_{15}-; to degrade to PFOA (C_7F_{15}-COOH) the structural element should be further linked to an additional C atom (i.e. C_7F_{15}C-). Any comments on clarifying this issue would be welcomed in the Public Consultation. It is the intention that those compounds having the potential to degrade to PFOA will be in the final scope of the proposed restriction.

The proposed restriction covers the manufacturing, use and placing on the market of these substances (derivatives of C8 and C7) as a substance, as a constituent of other substances, or in mixtures, if the concentration is equal or greater than 2 ppb.

Articles containing these substances in concentrations equal to or greater than 2 ppb are also proposed to be restricted.

PFOA and PFOA-related substances provide special properties, such as high friction resistance, dielectrical properties, resistance to heat and chemical agents, low surface energy, as well as water, grease, oil and dirt repellency. They are used in a wide range of industrial applications as well as consumer products: in fluoropolymer and fluoroelastomer production, photographic industry, surfactants in the semiconductor industry, surfactants in fire-fighting foams, wetting agents and cleaning agents, in sensor technology and medical technology, textiles and leather products, paper and cardboard products (including food packaging), paints and lacquers (including exterior and interior architectural paints), cookware, skiwax, etc. Overview of major uses can be found in Chapter B.2.2 and Appendix B.2.2: uses of PFOA and PFOA-related substances of the restriction report.

For some uses there are indications that a substitution of PFOA and PFOA-related substances is economically and/or technically challenging and an exemption might be needed. However according to the restriction report, so far there is not enough evidence available in order to propose exemptions for any specific uses (also see specific information requested).

The restriction proposal contains a derogation for the second hand market and a transitional period of 18 months after the entry into force.

Reasons for action

PFOA is a persistent, bioaccumulative and toxic (PBT) substance, which means that it persists in the environment and may have irreversible adverse effects on the environment and human health in the long term. PFOA has the potential for environmental long-range transport, which makes emissions of PFOA a transboundary pollution problem. In addition, PFOA is toxic for reproduction (category 1B) and has been shown e.g. to affect cholesterol levels in humans.

Since the uses of PFOA and PFOA-related substances are wide dispersive, and consumer articles and mixtures containing these substances are placed on the market in all EU Member States, EU wide action is necessary to eliminate emissions of PFOA and PFOA-related substances. National regulatory action cannot adequately minimise emissions of PFOA including PFOA-related substances. As a consequence, risk management action needs to be taken on an EU wide basis. The review clause on PFOA and related substances that was included in the former Directive 2006/122/EC imposing restrictions on perfluorooctane sulfonates (PFOS), also acknowledges the need to manage the risks of PFOA on a community-wide basis.

Based on the analysis presented in the Annex XV report, it is concluded that a restriction is the most appropriate Union-wide measure.

Consequences of the action

The proposed restriction will eliminate all emissions and related exposures of PFOA to both humans and the environment stemming from manufacturing and use of PFOA and PFOA-related substances and articles in the EU (except any emissions resulting from potentially derogated uses). As the actual impact for humans and the environment of reduced PFOA exposure cannot be described in quantitative terms, the overall benefit of the restriction cannot be quantified. However, reduced emissions are used as a proxy of the benefits of the proposed restriction. For the emissions and cost calculations in the restriction report, the annual use and imports of 18 tonnes of PFOA and 775-4420 tonnes of PFOA related substances have been used.

Short-chain (≤ C6) PFASs (perfluoroalkyl and polyfluoroalkyl substances) are alternatives that are available on the market and already used as substitutes of PFOA and PFOA-related substances. The use of short-chain PFASs as well as fluorine-free alternatives will entail additional costs due to their higher price (compared to PFOA and PFOA-related substances) or higher quantities that have to be used to achieve a similar technical performance. The total substitution costs are estimated to be between €2 - 160 million per year with a central estimate of €36 million per year. This range reflects the high uncertainties related to the cost estimates, which mainly originate from diverging information received from industry as well as publically available sources on substitution costs, but also from uncertainties related to the estimated volumes of PFOA and PFOA-related substances used.

SPECIFIC INFORMATION REQUESTED

A number of specific elements are addressed in the Public Consultation to gather relevant information, if available, from stakeholders:

Question 1: PFOA and PFOA-related substances are used in a wide range of industrial applications as well as consumer products. Based on the information in Table C.1-1 (*overview of available fluorinated and non-fluorinated alternatives for different branches)* and Appendix C Table A.C.1-1 (*potential alternatives and technologies*), could you:

- Provide technical and economic information on any application or use (identified or not identified in the restriction dossier) for which alternatives are not available and/or the performance of alternatives is not considered adequate?
- Specify the quantities used?
- Provide information regarding the potential risks to the environment or to human health via the environment related to any of these uses?

Please note that information regarding sectors that involve higher amounts used are particularly welcomed (e.g. textiles).

Question 2: Economic impacts of the proposed restriction have been assessed for the uses and supply chains, representing the major current applications of PFOA and PFOA-related substances. The following markets have been assessed:

- ✓ manufacture of fluoropolymers (PFOA)
- ✓ surface treatment of textiles (PFOA-related substances)
- ✓ surface treatment of paper (PFOA-related substances)
- ✓ manufacture and use of fire-fighting foams (PFOA-related substances)
- ✓ coatings and printing inks (PFOA-related substances).

In addition the potential impact of the proposed restriction on the photographic and the semiconductor industry were discussed without providing explicit cost estimates for these sectors. The cost estimates were based on differences in price and the loading required to achieve the requested performance.

- Would you consider the presented calculations to be representative for your use? If not, do you have specific information on the substitution costs in your application?
- Do you have information on any other costs of the restriction which might not be included in the dossier?
- Information on which of the substances (PFOA-related) are most relevant in terms of production/use volumes is also invited. Some examples of PFOA-related substances are given in Appendix B.1 of the restriction report.

Question 3: The environmental and human health concern on the manufacturing and use of PFOA-related substances is based on their possible degradation to PFOA. Do you have information on:

- Substances having linear or branched perfluoroheptyl derivatives with the formula C_7F_{15}- as a structural element, including its salts, (except

C_7F_{16}, $C_7F_{15}Cl$ or C_7F_{15} Br) which do not have the potential to degrade to PFOA?

- Substances having linear or branched perfluorooctyl derivatives with the formula C_8F_{17}- as a structural element, including its salts, (except C_8F_{18}, $C_8F_{17}Cl$, $C_8F_{17}Br$, C_8F_{17}-SO_2X', C_8F_{17}-C(=O)OH or C_8F_{17}-CF_2-X' (where X'=any group, including salts)) which do not have the potential to degrade to PFOA?

Question 4: The proposed restriction includes a concentration limit of 2 ppb. Do you have information on:

- The possible impact of the proposed concentration limit regarding the manufacture, use and placing on the market of the short-chain PFASs, or other substances and articles with PFOA/PFOA-related substances as impurities?
- The availability of analytical methods including the limit of quantification of those methods in relevant matrices?

Comments preferably by 1 March 2015

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 17 December 2014. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 17 June 2015, the rapporteurs of RAC and SEAC would appreciate receiving comments by 1 March 2015 to assist them in the detailed discussion of the restriction proposal in the March 2015 plenary meetings.

The final opinions of both Committees are scheduled to be available by 17 December 2015. ECHA will send these two opinions to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.