

**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restriction on

Perfluorohexane sulfonic acid (PFHxS) including its salts and related substances

**Non-confidential**

**ECHA/RAC/** **RES-O-0000006739-59-01/F**

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

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| **Substance name** | **EC number** | | **CAS number** | |
| Perfluorohexane sulfonic acid  (PFHxS), its salts and related  substances | | - | | - |

13 March 2020

General Comments and answers to specific information requests

## Specific information requests:

1. The production, use and import of PFHxS, its salts and related substances[[1]](#footnote-2)

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:

1. The concentrations of PFHxS present in parts per billion, and whether it is present as an impurity or intentionally added
2. Description of the use or function
3. Quantities used and whether quantities will remain stable, increase or decrease in the future and over what time-frame?
4. Information regarding the potential risks to the environment (e.g. quantified release estimates)
5. 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)
6. 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
7. Costs for substituting PFHxS.

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

1. 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:

1. the concentrations of PFHxS present in parts per billion, and whether it is present as an impurity or intentionally added
2. Description of the use, if any
3. Quantities used and whether quantities will remain stable, increase or decrease in the future and over what time-frame?
4. Information regarding the potential risks to the environment (e.g. quantified release estimates)
5. 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)
6. 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
7. Costs for substituting PFHxS or removing the impurity from the products.
8. 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:

1. Additional details of alternatives to PFHxS, indicating whether they are technically and economically feasible and challenges of switching to these alternatives
2. Non-fluorinated alternatives, particularly if they have lower risk profiles than PFHxS
3. 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).

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| **Ref.** | **Date/type/Org.** | **Comments** |
| **2347** | **Date:** 2019/07/10 11:32  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** <redacted>  **Org. country:** United Kingdom  **Company name confidential:** Yes  **Attachment:** | **Comment:**  - |
| **Answer to specific info request 4:**  Please see attached spreadsheet with surface water data for PFHxS anion |
| **Dossier submitter response:**  Thank you for submitting the data. We have included them in chapter B.4.3.1 of the Background Document. |
| **RAC Rapporteurs comments:**  Noted, thank you. |
| **SEAC Rapporteurs comments:**  Thank you for the information. |
| **2396** | **Date:** 2019/08/13 20:38  **Content:**  Scope or restriction option analysis;  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** European Environmental Bureau  **Org. country:** Belgium  **Attachment:** | **Comment:**  CHEMTRUST, EEB AND IPEN COMMENTS TO THE ANNEX XV RESTRICTION REPORT PROPOSAL FOR THE RESTRICTION OF PFHxS  August, 13th, 2019  GENERAL COMMENTS  The undersigning organisations support the dossier submitters conclusion on the need to restrict the use of PFHxS (Justification for restricting PFHxS (summary P3-6)):  Long-term impact potential on human health and the environment:  PFHxS is one of the worst PFAS in terms of persistence:  P39: “The human elimination half-life for PFHxS is > 7 years which is the longest of all perfluoroalkyl and polyfluoroalkyl substances (PFAS) for which data are available”  P154 “Due to their vPvB properties, minimizing the use of PFHxSs is an urgent priority. There are indications that PFHxS is likely to lead to significant adverse human health effects. Furthermore, since these substances persist and accumulate in humans and wildlife they may be impossible to remove if serious health concerns should be documented in the future.”  To prevent regrettable substitution:  PFHxS is a well know substitute for PFOS and in some cases PFOA:  P 26 (and subsequent detailed information in the section): “ There is evidence that PFHxS has been (and is being) used as a substitute for PFOS and PFOA in a number of applications around the World. PFHxS (and related substances) are known to be technically feasible substitutes for PFOA (and PFOS) in a number of applications (Kemi, 2017), including several where current uses of PFHxS appears minimal”  P3 “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.”  To regulate imported articles:  P5: “No current intentional uses of PFHxS, its salts or related substances within the EU were reported during the stakeholder consultation or call for evidence.”  P5: “a REACH restriction is proposed that will regulate imported articles containing PFHxS, its salts and PFHxS-related substances.”  However, the undersigning organisations would like to provide comments regarding the concentration limit of PFHxS in mixture or article < 25 ppb (i.e. 25 μg/kg) and 1000 ppb proposed in the restriction dossier and the derogation for fire-fighting foam mixtures that were placed on the market before [date - 18 months after the entry into force of this Regulation] and are to be used, or are used in the in the production of other fire-fighting foam mixtures.”  THE CONCENTRATION LIMIT IN MIXTURES OR ARTICLES SHOULD BE 2 PPB IN ORDER TO AVOID INTENTIONAL USE OF PFHxS.  As described in the Restriction Report Annex A.2., PFOA has been used in a wide variety of applications in the past in the EU and elsewhere. All of these are also potential new uses of PFHxS as an alternative to PFOA, unless PFHxS is restricted. For example:  Page 55 Restriction report: PFOA, however, was detected in most of the items (most of which were manufactured in China but also Vietnam and Bangladesh). This is of relevance because limit values on PFOA will soon apply to such articles and are likely to promote a switch to alternatives, of which PFHxS is, technically,one.  The limited set of test results of PFHxS in some consumer products presented in the dossier, show that PFHxS has been detected in concentrations below 25 ppb in several samples.  As stated in the Restriction Report on page 38, “Analytical methods for the detection of PFHxS are reported in the literature which can be used to measure PFHxS and PFASs in general in almost all environment all media.” Two methods are highlighted that have a level of quantification of 0.06 ppb.  PFHxS has been shown to be released through air emissions and leachates from landfills. Taken together with several warnings that that even relatively small annual emissions can quickly produce a large stock in the environment. (see e.g. P39 and 41), it is both crucial and feasible to keep concentrations at a minimum.  The proposed concentration limit of 25 ppb in the Restriction Report mirrors the final PFOA restriction decision by the Commission. However, it should be noted that the Dossier submitter of the PFOA restriction proposal put forward a threshold of 2 ppb for PFOA and PFOA related substances in order to ensure that these substances were not intentionally applied in these uses. The dossier included a summary of test methods showing that it is possible to achieve quantification limits for PFOA and some PFOA-related substances of 2 ppb.  The final limit of 25ppb that was finally adopted by the Commission was the result of the RAC and SEAC Committees who, following claims by industry stakeholders on the lack of availability of testing methods, changed in their opinion the scope of the PFOA restriction proposal.  Hence, noting the need to minimize potential PFHxS emissions as well as the availability of well-recognized analytical methods with low (0.6 ppb) detection limits, 2 ppb is a feasible limit that would prevent the intentional use of PFHxS and therefore the continued environmental releases of PFHxS at manufacturing sites, during use of mixtures and articles and during waste management.  In addition, the proposed limit of 1000 ppb for the sum of PFHxS related substances should be reduced by the same factor to at least 80 ppb or lower.  NO DEROGATION FOR FIRE-FIGHTING FOAMS (FFF) SHOULD BE INCLUDED  The derogation will allow the continued releases of PFHxS to the environment  Use of PFAS-containing fire-fighting foams is a direct route into the environment that has already contributed to contamination of soil, groundwater, drinking water, humans and the environment in countries all over the world.  Therefore, any FFF containing PFHxS should not be derogated but be destroyed in an environmentally sound manner. For developing countries, UNIDO has recommended a variety of effective non-combustion techniques, including methods suitable for PFAS destruction such as gas phase chemical reduction and ball milling (UNIDO, 2007). The updated general technical guidelines for the environmentally sound management of wastes consisting of, containing or contaminated with persistent organic pollutants (POPs) under the Basel Convention lists Gas Phase Chemical Reduction as capable of destroying all POPs. Electrochemical oxidation has been demonstrated to destroy C4 – C8 PFAAs.1  The restriction does not extend retrospectively to FFF already purchased and stockpiled for the purpose of fighting fires and includes no obligation to destroy the stocks. Therefore PFHxS-bearing FFF could still be used years after the restriction come into force. P126 of the dossier mentions that fluorine based FFF have shelf lives of several decades:  P126: “fluorine containing firefighting foams having shelf lives typically between 10 years and 20 years (to a maximum of 30 years)”  Moreover, even if PFHxS is not currently intentionally used in FFF in the EU, it was the case historically (meaning that there might be stocks out there, however, possibly not too far from their expiring date).  P5: “Historical (pre-2000) use of PFHxS included apparel and leather (20%), carpets (60%), fabric and upholstery (15%), coatings (0.4%) and -fire-fighting foams (5%)”  Overall benefits to human health and the environment of destroying the stock of PFAS FFF should be considered.  An initial proposal from the Dossier submitter to remove all fire-fighting foams from stocks which exceed the 25ppb limit for mixtures was discarded for economic reasons:  P124: “The second discarded restriction option is a requirement to remove all fire-fighting foams which exceed the 25ppb limit for mixtures from stock. This restriction option would require testing and destruction by incineration of existing stocks of PFAS based foams, estimated at around 31 240 tonnes. As described in Annex A.2.9, this option would reduce the annual PFHxS emissions by a maximum of 3 kg per year. The risk reducing potential of this option is not proportional to the societal costs it would encompass.”  The societal costs are refered to the avoided environmental releases of 3kg per year of PFHxS, but the destruction of the estimated 31240 tonnes of existing stocks of PFAS based foams could potentially correspond to several tonnes of other PFAS of high concern (including PFOA and PFOS). Therefore, even if the impact on PFHxS reduction might not be so high, the overall benefits to human health and the environment of destroying the stock of PFAS FFF should be considered.  Also, remediation of contaminated sites is extremely expensive and should be taken into account. A Nordic Council of Ministers assessment estimates that PFAS remediation costs at the European level are expected to be in the hundreds of millions of euros at a minimum ranging from 821 million – 170 billion euros in the 31 EEA Member Countries and Switzerland.2 The report also noted links between PFHxS exposure and several health endpoints that also carry costs. Annual health impact-related costs in Nordic countries due to PFAS exposure were estimated to be 52 – 84 billion euros. The authors note that exposures are rarely limited to a single substance PFAS and they share similar properties.  Fire-Safety Regulators, Scientists, & Industry Representatives Call for a Global Ban on PFAS Chemicals with No Loopholes for Toxic Fire Fighting Foams  Last 24 April 2019, industry fire-safety experts from the oil and gas and aviation sectors joined with firefighter trade unions to urge governments to protect human health and the environment with a global ban PFAS chemicals and to reject loopholes for its use in firefighting foams.https://ipen.org/news/fire-safety-regulators-scientists-industry-representatives-call-global-ban-pfas-chemicals-no  A recent PFAS study of a large cohort of Australian firefighters found significant elevations of PFAS blood levels, far in excess of the general population in Australia (IPEN, 2019):  P34: “Levels for PFOS, PFHxS and PFOA in the blood of a significant proportion of firefighters are well above levels in the gener-al population raising concerns about potential consequenc-es for human health. Of particular concern is the increased likelihood of certain cancers developing or being promoted given that firefighters are also exposed to a combination of other chemicals that can have adverse health effects that may be enhanced synergistically by PFAS exposure.”  “The exposure of the workforce and in particular firefighters to PFAS is of growing concern globally with evidence emerging that this is not just a legacy issue for earlier generations of workers but a continuing issue with no obvious source.”  “The highest levels of PFOS and PFHxS in Australian firefighters were an order of magnitude higher compared to the general populations in both Australia and Canada (Rotander et al. 2015).”  Fluorine-free FFF are available at no higher cost and demonstrate similar performance  The Draft risk management evaluation from the Persistent Organic Pollutants Review Committee of the Stockholm Convention (POPRC) states:  147. The regular assessment of alternatives to PFOS under the Stockholm Convention has revealed that alternatives are available for all potential applications which could also be relevant for PFHxS, its salts and related compounds.  Alternatives include both fluorinated and non-fluorinated substances as well as alternative (non-chemical) technical solutions. Information on availability, accessibility and price of alternatives, as well as information on regulatory measures and use in different countries, reveal that the socioeconomic costs of implementing a ban and/or restriction on the use of PFHxS are considered small and are outweighed by the benefits of an elimination/ regulation. High costs are estimated for remediation of contaminated sites, such as old and current fire-fighting foam training sites and airports, landfills for industrial waste, and hazardous waste, as well as for the removal of PFASs, including PFHxS, from drinking water and water sources affected by PFHxS (and other PFASs) contamination.  No need for exemptions have been identified at a global level  The Draft risk management evaluation from the Persistent Organic Pollutants Review Committee of the Stockholm Convention (POPRC), after consultation with governmental bodies, industry, academia and NGOs recommends taking global action on PFHxS without exemptions, not even for FFF:  150. Having decided that perfluorohexane sulfonic acid (CAS No. 355-46-4, PFHxS), its salts and PFHxS-related compounds are likely as a result of their long-range environmental transport to lead to significant adverse human health and/or environmental effects such that global action is warranted; having prepared a risk management evaluation and considering the management options and noting the information on the availability of alternatives; [the  POPs Review Committee recommends, in accordance with paragraph 9 of Article 8 of the Convention, the Conference of the Parties to the Stockholm Convention consider listing and specifying the related control measures for perfluorohexane sulfonic acid (CAS No. 355-46-4, PFHxS), its salts and PFHxS-related compounds in Annex A without exemptions.]  Therefore, the derogation for PFHxS FFF should not be included in the EU restriction as it will hinder efforts to regulate these chemicals at the global level. |
| **Dossier submitter response:**  Thank you for your extensive comments. We welcome discussions on strict limit values and the proposed derogations in the PFHxS REACH restriction.  Limit values:  The proposed limit values of 25 ppb for PFHxS and 1000 ppb for PFHxS-related substances are identical to the agreed limit values for PFOA and PFOA related substances under the REACH regulation. We have no information that intentional use of PFHxS or PFHxS-related substances will be possible with these limit values.  Limit values of 25 and 1000 ppb are furthermore proposed to apply for PFOA and PFOA related substances in the POPs regulation (see Annex to Draft delegated regulation – Ares (2019)6890180). In comparison, the current limit values for PFOS in the POPs regulation (Regulation 2019/1021) is 10 000 ppb for mixtures (=10 mg/kg) and 1 000 000 ppb for articles (=0.1 %).  The restriction proposal on C9-C14 PFCAs (See table 1 of Final Background document for the PFCA restriction) proposes limit values of 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related substances. These limit values were based upon information submitted by industry during the development of the restriction proposal. Despite repeated and exhaustive stakeholder consultation as part of the preparation of this dossier no similar information was possible to obtain for PFHxS.  To illustrate possible consequences of setting different limit values for PFHxS in the REACH restriction proposal, a worst case estimation shows that a limit value of 2 ppb might reduce the total current yearly European emissions of PFHxS from textiles by approximately 5 kg, that is from 20 kg to 15 kg, cfr. table 5 and information on imports of textiles in chapter A.2.8:   |  |  | | --- | --- | | *Concentration limit for PFHxS in textiles* | *Resulting total amount of PFHxS emissions from textiles* | | 2 ppb | (2 ppb \* 252 042 tonnes=) 0,5 kg | | 25 ppb | (25 ppb \* 252 042 tonnes=) 6,3 kg |   This estimate based upon the scarce information that is available.  Derogation for fire-fighting foams:  The restriction proposal regulates the manufacture or placing on the marked of new fire-fighting foams or fire-fighting foam concentrates containing PFHxS.  The proposed derogation in 4 b) concerns the dilution of concentrated fire-fighting foam mixtures by an end-user. (See also the explanatory note to the proposed entry; *"The dilution of concentrated fire-fighting foam mixtures by an end-user is defined as manufacture of a mixture in REACH. This particular use is exempted from the restriction in point 4 (b)."*)Within the REACH-framework, we could not demonstrate proportionality of a PFHxS restriction on the old fire-fighting foam concentrates that were placed on the market within the EEA before the entry into force of the proposed regulation.  As documented in chapter A.2.9 and specifically table 17 of the dossier for details, based on available data, the total EU Stockpile of fire-fighting foams or fire-fighting foam concentrates is estimated to contain between 0,48 and 3,06 kg of PFHxS. The use of old PFHxS containing fire-fighting foams for testing and training exercises by industry is estimated to result in yearly emissions of between 0,039 and 0,245 kg of PFHxS in EEA, see chapter A.2.9 and table 17 for details. Please apologise for the mistake we made in Annex E.1.2.2 ("*As described in Annex A.2.9, this option would reduce the annual PFHxS emissions by a maximum of ~~3~~ 0,039 and 0,245 kg per year.*"). This will be corrected in the background document for the restriction. To our knowledge, PFHxS is not used in new PFAS containing fire-fighting foam or fire-fighting foam concentrates. New PFAS containing fire-fighting foam or fire-fighting foam concentrates contain 6:2 FTS and its derivatives which are PFHxA-precursors.  The cost of replacing the European stockpile of old fire-fighting foams or fire-fighting foam concentrates that contains maximum 3 kg PFHxS in total for the EEA, can roughly be estimated to be between 68 million and 305 million € per kg PFHxS. These costs by far exceeds replacement costs described in Table A2-1 of SEAC/24/2014/04 where the maximum replacement cost for Mercury was 2 million US $. The estimated costs do not include the costs related to collecting and destructing the fire-fighting foams or fire-fighting foam concentrates and cleaning equipment that has contained it. Therefore, we were not able within the REACH-framework to demonstrate proportionality of regulating PFHxS in the European stockpile of old fire-fighting foams or fire-fighting foam concentrates. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  Both limit values, 25/1000 ppb and 2/80 ppb, have been discussed in RAC. The opinion of RAC is that the benefit in terms of reduced emissions with the lower 2/80 ppb values are marginal, but that the lower limit value would be more difficult to enforce. RAC therefore supports the proposal of 25/1000 ppb of the Dossier Submitter.  For fire-fighting foams, RAC is of the opinion that placing new foams on the market containing PFHxS could pose a risk for substantial emissions, although the likelihood of import of such foams is considered low. RAC therefore is if the opinion that the transitional period for a restriction on such import should be as short as practically possible from entry into force. For existing legacy foams in the EU, estimated to totally between 0.5 – 3 kg, RAC consider this amount low in relation to already emitted PFHxS (e.g. 2.1 tonnes/year during 1990-2010) and in relation to other current emissions sources, and that testing and destruction of such foams would not significantly reduce the risk. However, while the contribution of existing old AFFFs to the overall risk is considered low, RAC is of the opinion that the use of such foams for training exercises should be avoided, if possible, and the old AFFFs should be collected and properly disposed of if used for training and/or testing. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  Concentration limits: We understand that the 25 ppm limit is sufficient to prevent intentional use. As to unintentional use, it is impurities in imported articles and fire-fighting foams that may be affected.  For imported articles there could be some (limited) positive effect in terms of benefits, but with associated costs (that are expected to mostly fall upon companies outside the EU).  Fire-fighting foams produced by telomerisation are not expected to contain any PFHxS, and the ones produced by electrochemical fluorination, according to the dossier, contain it at levels that exceed the 25 ppb limit. A change in the limit value is therefore not expected to make any difference in terms of benefits. However, according to experts, a 2 ppb limit would be difficult to monitor in fire-fighting foams by the analytical methods available. This would complicate enforcement and incur extra costs.  Overall, the proposed change does not appear economically feasible from the SEAC perspective.  Derogation for fire-fighting foams: Based on earlier experience in evaluating restriction proposals on similar substances, SEAC expects that applying the restriction to fire-fighting foams already placed on the market would entail high costs over a relatively short period of time.  We have pointed out in the opinion the high concentrations of PFHxS in firemen’s blood.  It is interesting that the POPRC considers *that the socioeconomic costs of implementing a ban and/or restriction on the use of PFHxS are considered small and are outweighed by the*  *benefits of an elimination/ regulation (for inclusion in the Annex A of the Stockholm Convention)*. As regards PFHxS, its salts and the related substances, costs indeed appear negligible (there is no intentional use in the EEA even today) and alternatives are available, but this is not necessarily the case for PFASs more generally. From the SEAC perspective, some doubts remain on whether the performance of the available alternatives is currently sufficient for some special cases (tank farms etc). Also, information available on the health and environmental impacts of the non-fluorinated alternatives is scarce and also pointing at possible concern. |
| **2404** | **Date:** 2019/08/15 10:21  **Content:**  Scope or restriction option analysis;  Information on alternatives  **Type:** MemberState  **Country:**  Germany | **Comment:**  The German CA welcomes the restriction proposal regarding perfluorohexanesulfonic acid (PFHxS), its salts and related substances.  In general, we support the limitation of further emissions of perfluorinated substances (vPvB) into the environment.  PFHxS is discussed to become subject of the POP Convention. We agree that a restriction under REACH efficiently addresses an EU-wide risk and that it will assist the global regulation for POPs Convention.  In the proposal, reference is made to Regulation (EC) No 850/2004, which lists specific exemptions for the use of PFOS and its salts. This regulation has recently been updated (Regulation (EC) No. 2019/1021) also with regard to these exemptions (in the update, the use of PFOS in "mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems" is the only remaining exemption). Therefore, the reference in the PFHxS restriction proposal should also be updated and refer to the latest version of the POP Regulation. |
| **Answer to specific info request 3:**  In addition, to our knowledge, there are fluorine-free, chemical alternatives, e.g. alkane sulfonates, for hard chromium (VI) plating available on the market, as well as effective , technical solutions to minimize aerosol emission, e.g. galvanic bath covers or air extraction systems. It might be worthwhile to consider a reassessment of alternatives in the restriction after a short period of time, e. g. five years. |
| **Dossier submitter response:**  We appreciate your support.  The background document will be corrected in line with the current version of the EU POPs regulation.  PFHxS is an impurity in PFOS used as mist suppressant for hard chromium plating. The POPs regulation foresees that the Commission shall review the derogation for PFOS as mist suppressant for hard chromium plating as soon as new information is available. This will directly affect PFHxS, since any changes to the POPs regulation on PFOS will apply automatically to PFHxS, see 4 a). |
| **RAC Rapporteurs comments:**  Noted, thank you. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  Thank you for pointing out the recast of the POP regulation. The SEAC opinion refers to the new version.  Thank you for pointing out the availability of alternatives as regards mist suppressants in hard chromium plating. While convincing information on the suitability of the available alternatives in all the different situations is missing, we agree that it looks promising that alternatives could soon be used in more and more situations. We have noted this in the opinion. |
| **2410** | **Date:** 2019/08/16 15:44  **Content:**  Scope or restriction option analysis;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Mineralölwirtschaftsverband  **Org. country:** Germany | **Comment:**  PFHxS is contained as impurity in concentrates for fire fighting foams needed to extiguish large fires of fuels containing biofuels. Analysis of fire fighting foams are contained in the informative material geared to PFOA uploaded separately. Nevertheless, comments to PFOA in the files likewise apply to PFHxS. According to Information from foam producing companies, there is no alternative for perfluorinated chemicals in this application to be expected. The Derogation foreseen as number 4. (b) needs to be unlimited in time. |
| **Dossier submitter response:**  Thank you for sharing your view on fire-fighting foams.  According to the fire-fighting foam producers, PFHxS and PFHxS-related substances are not present as impurities in new fire-fighting foams. Analyses of 14 fire-fighting foams revealed that all foams contained 6:2 FTS, while 10 of the foams did not contain PFHxS (KEMI, 2017). 6:2 FTS is a PFHxA-precursor. Non-fluorinated fire-fighting foam alternatives are also available and used within most sectors, see chapter A.2.9 of the proposal for details.  It is therefore not justified to introduce a permanent derogation for the manufacture or placing on the market of PFHxS or PFHxS-related substances in concentrated fire-fighting foam mixtures that are to be used, or are used in the in the production of other fire-fighting foam mixtures.  Old fire-fighting foams (AFFF) that were placed on the market before the entry into force of the restriction containing PFHxS or PFHxS related substances as an impurity is not within the scope of the restriction proposal. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is of the opinion that there is no need for a permanent derogation for PFHxS-containing fire-fighting foams, as no such new foams are currently being placed in the EU market. The amount of PFHxS in existing remaining stocks of fire-fighting foams containing PFHxS are considered low in relation to already emitted PFHxS and current emissions of PFHxS and are therefore accepted to be derogated from the restriction. However, RAC advises to collect and properly dispose any such foams used for testing and training. |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We agree with the Dossier Submitter’s response.  We also point out possible difficulties in finding non-fluorinated alternatives with sufficient performance in some special kinds of fires in the opinion. |
| **2751** | **Date:** 2019/11/06 17:53  **Type:** MemberState  **Country:**  Sweden  **Attachment:** | **Comment:**  - |
| **Dossier submitter response:**  Thank you for your general support to the restriction proposal and for drawing our attention to the very recent study by Schultes et al. (2019) on temporal trends of, amongst others, PFHxS in Baltic Cod. The results have been included in chapter 1.1.6 and 4 of the Background Document.  We appreciate your comments to the proposed limit values, transitional period and derogation for old fire-fighting foam. The EEB has also commented on the limit values and derogations. We therefore refer to our responses to comment no. 2396 above  Acknowledging that we have not identified any manufacture or placing on the market of new fire-fighting foams or fire-fighting foam concentrates containing PFHxS within the EEA, we support your view that the 18 months transitional period is not necessary. |
| **RAC Rapporteurs comments:**  Thank you for your comments. RAC is also of the opinion that an 18 months transitional period for placing new fire-fighting foams on the market could open a window for import of such foams and should be avoided. The recommendation from RAC is that this transitional period should be as short as practically possible.  Both limit values, 25/1000 ppb and 2/80 ppb, has been discussed in RAC. The opinion of RAC is that the benefit in terms of reduced emissions with the lower 2/80 ppb values are marginal, but that the lower limit value would be more difficult to enforce. Although a limit of quantification of 0.06 ppb is presented in the Background Document, this does not apply to all matrices and the Background Document has been revised accordingly. RAC therefore supports the proposal of 25/1000 ppb of the Dossier Submitter. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  Fire-fighting foams: We agree that an 18-month transition period could leave the door open for imports of PFHxS-containing foams for 18 months and transitional period should be as short as possible.  Concentration limits: We note that there are indeed some analytical methods that allow determination of concentrations of even below 2 ppb. However, those are not applicable to all matrices. We understand that 2 ppb would be difficult for fire-fighting foams at least, and 25 ppb would be more feasible. Further, it appears that 25 ppb will be stringent enough to prevent intentional use. Therefore, we do not support lowering the limit value to 2 ppb. |
| **2787** | **Date:** 2019/12/06 16:04  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Environment Agency  **Org. country:** United Kingdom | **Comment:**  We have included a summary of analytical results from water quality monitoring undertaken by the Environment Agency in England in 2018 and 2019. |
| **Answer to specific info request 4:**  Analysis of aquatic media undertaken by the Environment Agency in 2018 and 2019 has provided the following statistics for environmental PFHxS concentrations:  Median measured concentration at 1 sewage treatment works final effluent was 0.570 μg/L (maximum 0.620 μg/L, n = 7);  Median measured concentration at 32 river sampling sites was 0.170 μg/L (95-percentile 0.558 μg/L, n = 744);  Median measured concentration at 24 estuarine or coastal sampling sites was 0.0205 μg/L (95-percentile 0.510 μg/L, n = 136);  Median measured concentration at 167 groundwater sampling sites was 0.0380 μg/L (95-percentile 1.64 μg/L, n = 211).  These statistics are not necessarily representative of PFHxS levels in England, but provide an indication of widespread occurrence in the aquatic environment.  The proportion of samples with positive detection was high, over 85% in all media. The Level of Detection was 0.005 μg/L. |
| **Dossier submitter response:**  Thank you for submitting the data. We have included this information in chapter B.4.3 of the Background Document. |
| **RAC Rapporteurs comments:**  Noted, thank you. |
| **SEAC Rapporteurs comments:**  Thank you for the information. |
| **2886** | **Date:** 2019/12/19 12:37  **Content:**  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Environment Agency  **Org. country:** United Kingdom | **Comment:**  We are submitting analytical data on behalf of the Centre for Environment, Fisheries and Aquaculture Science (Cefas). |
| **Answer to specific info request 4:**  Analysis of pooled (n=5) liver samples from fish caught off the UK coast in 2018 has provided the following statistics for PFHxS concentrations (wet weight):  Median measured concentration in Dab (Limanda limanda) was 0.115 μg/Kg (95-percentile 0.210 μg/Kg, n = 70);  Median measured concentration in European plaice (Pleuronectes platessa) was 0.0956 μg/Kg (maximum = 0.124 μg/Kg, n = 5);  Measured concentrations in Whiting (Merlangius merlangus) were below the Level of Detection of 0.05 μg/Kg (n=4).  Liver samples from 95 Harbour Porpoises (Phocoena phocoena) stranded or bycaught in UK coastal waters from 2012-17 contained a median measured PFHxS concentration of 0.424 μg/Kg (95-percentile 2.801 μg/Kg) (wet weight).  Liver samples from 50 adult European Otters collected in the UK from 2007-09 contained a median measured PFHxS concentration of 7.09 μg/Kg (95-percentile 42.03 μg/Kg) (wet weight). |
| **Dossier submitter response:**  Thank you for submitting the data. We have included them in chapter B.4.3.5 of the Background Document. |
| **RAC Rapporteurs comments:**  Noted, thank you. |
| **SEAC Rapporteurs comments:**  Thank you for the information. |

1. PFHxS, its salts and related substances is abbreviated in this note to ‘PFHxS’. [↑](#footnote-ref-2)