**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restrictions on

**Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances**

**Non-confidential**

**ECHA/RAC/RES-O-0000006229-70-02/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** |
| PFOA, its salts and PFOA-related substances | 206-397-9 | 335-67-1 |

11 September 2015

General Comments and answers to specific information requests

## Specific information requests:

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).

1. 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.

1. 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 C7F15- as a structural element, including its salts, (except C7F16, C7F15Cl or C7F15 Br) which do not have the potential to degrade to PFOA?
* Substances having linear or branched perfluorooctyl derivatives with the formula C8F17- as a structural element, including its salts, (except C8F18, C8F17Cl, C8F17Br, C8F17-SO2X', C8F17-C(=O)OH or C8F17-CF2-X' (where X'=any group, including salts)) which do not have the potential to degrade to PFOA?

1. 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?

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| **Ref.** | **Date/type/Org.** | **Comments** |
| **1198** | **Date:** 2015/01/07 14:04  **Type:** Individual  **Country:** Sweden  **Company name confidential:** **No** | **General Comments:**  Does this proposal include polymers according to the definition in REACH? | |
| **Dossier submitter response:**  Yes also polymers are included if they contain PFOA or PFOA-related substances. | |
| **RAC Rapporteurs comments:**  The RAC opinion makes it clear that the restriction is intended to include polymers that are made using PFOA/PFOA-related substances (rather than those that contain them as an unintentional contaminant from other substances). | |
| **SEAC Rapporteurs comments:**  We agree with the Dossier submitter. | |
| **1200** | **Date:** 2015/01/27 17:44  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes**  **Privacy comment:** We have phased out PFOA and PFOS from our supply chain. We do not use PFOA any more. Some of our water repellent finishes use PFC, but this is C6 chemistry. | **General Comments:**  We have phased out PFOA and PFOS from our supply chain. We do not use PFOA any more. Some of our water repellent finishes use PFC, but this is C6 chemistry. | |
| **Answer to specific info request 1:**  We have phased out PFOA and PFOS from our supply chain. We do not use PFOA any more. Some of our water repellent finishes use PFC, but this is C6 chemistry. | |
| **Answer to specific info request 2:**  We have phased out PFOA and PFOS from our supply chain. We do not use PFOA any more. Some of our water repellent finishes use PFC, but this is C6 chemistry. | |
| **Answer to specific info request 3:**  Not applicable | |
| **Answer to specific info request 4:**  No impact. We have phased out PFOA and PFOS from our supply chain. We do not use PFOA any more. Some of our water repellent finishes use PFC, but this is C6 chemistry. | |
| **Dossier submitter response:**  Thank you very much for your comment. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that C6 chemistry represents an important alternative to PFOA-related substances, and that the proposed restriction must not prevent the continued production and use of such substances. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1201** | **Date:** 2015/02/10 18:35  **Type:** Individual  **Country:** Sweden  **Company name confidential:** **No** | **General Comments:**  One concern of mine about the current EU PFOA proposal is how to ensure analytical peformance at a level of 2 ppb over the whole range of PFOA related substances in various articles and mixtures? I would welcome a discussion in this matter. My own experience also reported as a peer review paper (2010) report detection limits of PFAS from 0,1 ng/g to 20 ng/g. Maybe there are improved lab practices now. | |
| **Dossier submitter response:**  The lack of standard analytical methods does not automatically imply that a very low threshold is not possible at later stage (which is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation).  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  A restriction is a motive for the EU Commission to induce the development of analytical methods if they are necessary for the enforcement. Thus, it seems to be possible to also establish method detection limits at a low ppb range for other matrices e.g. articles and formulations in the near future. Moreover, it seems to be very likely that standardized methods will soon be available once they are required by law. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the analytical detection limit is a practical issue that needs to be considered for the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. | |
| **1202** | **Date:** 2015/02/15 11:42  **Type:** Individual  **Country:** Sweden  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  In my view as a scientist there are challenges to set a restriction limit of 2 ppb of all PFOA related substances in chemical mixtures and articles for a number of reasons  1. We have no validated international analytical methods (EN/ISO) for per and polyfluorinated substances  2. There are considerable datagaps of a wide range of PFOA related substances that would be excluded in any legal follow up by the enforcable authority meaning that noone can for sure say that they comply with these restrictions.  3. This restriction proposal include residues in so called short chain fluorochemical Products that are feasible alternatives to PFOS compounds for various acceptable purposes and specific exemptions such as metal plating where 6:2 FTS is used, If these alternatives are banned for the reason of 2 ppb residues it would conflict the total phase out of PFOS compunds in EU (ongoing for the Stockholm Convention) which would mean that EU has to keep on using PFOS compounds beyond 2015.  4. A mandated work to develop an EN standard method for longchain per and polyfluorinated substances is in progress in CEN, TC248/WG26 (EC restricted substances). The outcome of this work where LOQ are for a range of PFOA related substances would be a guideline for the coming restriction on PFOA and related substances and taken into serious consideration what can really be achieved since noone wants to keep these substances in society but restrictions have to be realistic as well which they are not today from a scientific perspective.  As lead author for the Stockholm Convention I enclose a range of reports that reflect my comments and additionally a presentation of a major research Project SUPFES.  Yours sincerely  **<removed>**, senior researcher | |
| **Dossier submitter response:**  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of C8 substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  The DS proposed a structural formula to include all possible substances which can degrade to PFOA. This is in line with the restriction on PFOS. In our view there is no reason to alter the scope of the proposed restriction.  The lack of standard analytical methods does not automatically imply that a very low threshold is not possible at later stage (which is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation).  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  A restriction is a motive for the EU Commission to induce the development of analytical methods if they are necessary for the enforcement. Thus, it seems to be possible to also establish method detection limits at a low ppb range for other matrices e.g. articles and formulations in the near future. Moreover, it seems to be very likely that standardized methods will soon be available once they are required by law. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree that a revision of the concentration limit is necessary in order to allow the use of alternatives to PFOA-related substances. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1203** | **Date:** 2015/02/17 16:07  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes** | **General Comments:**  We import and blend aqueous based fluorocarbon emulsions for application to textiles and paper as a finish to impart water, oil and stain repellent properties.  The products we import are sourced globally, REACH registered and are of C6 and C8 chain chemistry.  Our EU / global customers who use these products range from textile manufacturers supplying the retail industry for consumer goods (outdoor clothing, tents, umbrellas, etc) to technical manufacturers who supply fabric for professional end use (military, workwear, police and fire protective wear, healthcare).  Whilst the majority of retail end use fabrics can be treated with C6 type fluorocarbon to a sufficient performance standard it is not the case with the professional market.  There is still a requirement by the industry for C8 type fluorocarbon to maintain performance standards which would otherwise fail using C6 technology.  Norway recognised this by imposing their PFOA restriction on consumer goods only thereby providing exemption for professional clothing treated with higher PFOA loadings. The major point here is that this type of technical fabric is very much geared towards personal protection fabrics, for use in areas such as the oil industry, firefighters, police and military uniforms and protective equipment. This as mentioned has a large element of personal protection with the potential to provide lifesaving properties to the treated articles.  We would request the same consideration for continued use of C8 fluorocarbon to maintain performance standards and to retain business in the professional sector.  We are certain you will receive evidence to support this from numerous organisations that still require the C8 type products in order to maintain performance standards set by industry or else set by them to establish a performance / commercial advantage.  The ECHA proposed blanket limit of 2 ppb PFOA would affect our business and many other suppliers and users of C8 fluorocarbons resulting in € millions of lost business to countries such as Russia, India, and China which have not agreed to restrict PFOA use.  For example many tenders would be lost if C8 were to be banned within the EU.  Our suppliers of C6 fluorocarbon emulsion state the PFOA content in the mixture to be less than 5 ppb PFOA. Typical chemical add on levels to fabric are 5 - 10 % on weight of fabric.  The proposed restriction would allow fabric to be finished with C6 chemical however import of the chemical would not be allowed.  Our suppliers of C8 fluorocarbon emulsion state PFOA content in the mixture to be less than 0.5 ppm PFOA. Typical chemical add on levels to fabric are 2 – 20 % on weight of fabric depending on durability and type of repellency standard.  The proposed restriction would not allow import of C8 chemical or C8 treated fabric.  Based on the figures quoted by the manufacturers for PFOA content within their fluorocarbon emulsions, as described above, we take exception to the extravagant figure quoted on page 211 (appendix B.2.2.5) where it states that 1000 – 10,000 tons of PFOA and PFOA related substances are imported on 350 million DWR jackets. This would be correct for PFOA related substances eg. Fluorocarbon emulsion however the focus is on PFOA so your estimate wrongly includes PFOA and is misleading.  Considering the proposed restriction is based on PFOA then a more accurate figure would be as follows (assuming C8 chemical is applied to the fabric)  1 jacket = 1 m2  C8 fluorocarbon emulsion contains < 0.5 mg / kg PFOA (manufacturers figure)  Typical application of 10 grams fluorocarbon applied to 1 m2  Therefore 1 m2 contains < 0.000005 g PFOA  350,000,000 jackets x 0.000005 = < 1.75 kg PFOA  This 1.75 kg quantity of PFOA contained within 350 million DWR jackets is significantly lower than the 1000 – 10,000 tons quoted. | |
| **Dossier submitter response:**  The DS is grateful for the comments made and will take it into further consideration when revising the background document.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain PFAS. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier Submitter considers a derogation for non-professional textiles not reasonable. The Dossier Submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier Submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  Considering your information we believe that also for outdoor clothing, tents, umbrellas alternatives are available. Moreover, since those items may directly emit residual amounts of PFOA and PFOA-related substances into the environment we do not agree with derogation for this use. | |
| **RAC Rapporteurs comments:**  RAC notes that the proposed restriction may affect the performance standards of personal protection fabrics for professionals. As these are a source of environmental exposure for PFOA-related substances, a derogation is not supported from a risk perspective (the calculation provided refers to PFOA content only, and the comment notes that a higher amount of PFOA-related substances are present in C8 emulsions). | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We recognizse that the performance of short chain alternatives may not yet be sufficient for use in protective professional textiles and we support a transitional period of 6 years to give more time for the development of alternatives. We also see it necessary that the state of the art will be examined in 5 years and that any necessary changes to the scope of the restriction will be made at that point in time. | |
| **1204** | **Date:** 2015/02/18 16:56  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** The Socio Economic Assessment has been submitted confidentially for competitive reasons, and to preserve intellectual property. | **General Comments:**  This company is in general fully supportive of a PFOA regulation for Europe and it has done already a lot to eliminate PFOA from its products.  However, it has three concerns about the proposed restrictions:  1. The proposed 2ppb limit: The economic and practical feasibility of conducting measurements to ensure compliance with a limit as low as 2ppb would be extremely difficult. Raising the threshold would be easier and considerably more cost efficient, both for companies to demonstrate compliance and for authorities to enforce the limit.  2. The timeframe involved: Whereas substitute materials are now readily available for many general applications, it will not be possible to have completely eliminated PFOA from some specialized products which have to undergo rigorous testing and complex approval processes within the proposed time frame. It would mean that specialized products would not be available on the European market for a significant period of time.  3. Products already in the supply chain: The proposal goes some way towards addressing products already in the supply chain within the context of second-hand articles. However, in the case of many specialized products, there are very complex supply chains which mean that new products are put into service up to five years after they are placed on the EU market. The proposal would mean that many products already in the EU would have to be removed after the effective date of the restriction.  A Socio Economic Assessment has been submitted confidentially for competitive reasons, and to preserve intellectual property. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration for potential derogations.  The Dossier submitter is grateful for the new information and will check if it is useful for the SEA.  The restriction involves the placing of the market of articles containing PFOA and PFOA-related substances. Thus, articles which are already on the market are not affected. It is not the aim of the DS to restrict second hand articles.  The lack of standard analytical methods does not automatically imply that a very low threshold is not possible at later stage (which is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation).  Different analytical methods and measured data (see chapter E, Appendix B.2.2 and E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA-related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  A restriction is a motive for the EU Commission to induce the development of analytical methods if they are necessary for the enforcement. Thus, it seems to be possible to also establish method detection limits at a low ppb range for other matrices e.g. articles and formulations in the near future. Moreover, it seems to be very likely that standardized methods will soon be available once they are required by law. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future.  The issues about products in the supply chain are related to socio-economic factors since such products can still give rise to emissions in the long-term. The attachment (and further information provided separately during the public consultation process) demonstrates that environmental emissions of PFOA present in implantable medical devices are very low (so the environmental risk is also likely to be low). This might not be the case for all medical devices. From a risk perspective, RAC therefore supports a derogation for implantable medical devices only, at the present time. | |
| **SEAC Rapporteurs comments:**  Thank you for the information and the profound discussion in the attached confidential document. We have taken it into account when assessing whether derogation or a higher limit value as regards these products is justifiable. We also agree that a revision of the general concentration limit is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1205** | **Date:** 2015/02/18 21:01  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  FluoroCouncil  **Org. country:** United States  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  The Global Industry Council for FluoroTechnology (FluoroCouncil) appreciates this opportunity to provide comments on the “Annex XV Restriction Report: Proposal for a Restriction for Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances” (PFOA restriction proposal) published by the European Chemicals Agency for public comment.  The FluoroCouncil is a global membership organization representing the world’s leading manufacturers of fluoropolymers, fluorotelomers, and other fluorinated surfactants and surface property modification agents. The FluoroCouncil has a fundamental commitment to product stewardship and, as part of its mission, addresses science and public policy issues related to FluoroTechnology, including PFOA and related long-chain substances.  All members of the FluoroCouncil were early adopters of the 2010/2015 PFOA Stewardship Program, the global partnership between the U.S. Environmental Protection Agency (EPA) and industry based on voluntary corporate goals to reduce human and environmental exposure to PFOA and higher homologues by globally eliminating those chemicals from facility emissions and product content by the end of 2015. The FluoroCouncil has also been focused on facilitating the successful transition from long-chain fluorinated chemicals, including PFOA and related long-chain substances, to alternative fluorochemistries at a global level.  For a broad range of applications, short-chain chemistry presents the only alternative providing the same performance properties. The transition to alternative short-chain chemistry is ongoing for downstream users, and even though not fully completed, the remaining economic cost of the transition will therefore be manageable. An effective restriction of PFOA and PFOA-related substances would be a useful tool for completion of this process.    In order to allow for an effective restriction, however, the following principles must be applied:  • Restriction should cover the target substances but not have consequences outside its intended scope.  • Threshold should be set on a level which eliminates the manufacturing, use and placing on the market of long-chain substances while still allowing manufacturing, use and placing on the market for the essential alternatives.  • The threshold must be compatible with standardised, robustly repeatable, analytical techniques that minimise false positives available in Member States to allow a proper enforcement of the restriction. In this regard, FluoroCouncil believes that multiple thresholds are essential with a clear distinction between PFOA and PFOA-related substances. Limits of quantification that are possible vary from product to product.  FluoroCouncil is of the view that the above mentioned principles are not applied in the draft restriction proposal, for the reasons elaborated in our response to the four specific information requests.  The threshold of 2 ppb applicable for all substances in scope and all types of products would mean a de facto ban of all short-chain alternatives and fluoropolymers made without PFOA. With current analytical technology, it would show false-positive results against “clean” products, and would even catch certain products that were made without fluorochemicals at all but were contaminated somewhere in the logistics chain, causing great reputational and economic damage to European industry. For more information on FluoroCouncil’s concerns with the proposed threshold, see the more detailed comments provided in response to Question 4.  In addition, there needs to be further clarification on the scope in order to avoid the inclusion of substances not intended to be restricted.  If the restriction would be implemented as currently proposed, it would cause severe damage to the European manufacturing industry without any additional benefits for the environment and human health.  The FluoroCouncil commends Germany and Norway for developing the PFOA restriction proposal to build upon the progress of the Stewardship Program by regulating the manufacture, use, and commerce of PFOA and related long-chain substances. | |
| **Answer to specific info request 1:**  FluoroCouncil member companies believe that they have introduced alternatives, based on short-chain chemistry, that are suitable for substantially all applications. Similarly, FluoroCouncil member companies have developed processing aids alternatives allowing for the manufacturing of fluoropolymers without PFOA. Based on our understanding, absent short-chain chemistry, there are broad industrial sectors that do not have acceptable alternatives.  Since the year 2000, this industry has seen an increased effort in developing new products that can deliver the same performance as the products they replace. For example, in 2006 eight chemical companies joined the global voluntary US EPA Product Stewardship Program [http://epa.gov/oppt/pfoa/pubs/stewardship/index.html] committing to phasing-out of PFOA, precursor chemicals that can break down to PFOA, and related higher homologue chemicals. FluoroCouncil member companies invested over €500 million in the development of alternative products that offer the same high-performance benefits with improved environmental and human health profiles (See, e.g., Environ report, available at http://fluorocouncil.com/PDFs/Assessment-of-POP-Criteria-for-Specific-Short-Chain-Perfluorinated-Alkyl-Substances.pdf). The investments also include the deployment of state-of-art emission control equipment to minimize any potential impact on workers and the environment. The new fluorinated alternative offerings went through extensive testing and qualification steps in the value chain and gained market acceptance.  In addition, FluoroCouncil member companies have engaged in an extensive dialogue with downstream users to encourage the application of best environmental practice and the use of best available technologies when applying the alternatives. Considering all efforts taken to deploy the alternatives, the total cost to the value chain can be estimated as many multiples of that investment.  In parallel, non-fluorinated alternatives entered the market but, according to feedback from our downstream users, these do not bring all the unique performance attributes of fluorinated products and can only be used in a limited number of non-demanding applications.  The table C.1-1 lists non-fluorinated alternatives for several industry branches, such as: construction, fire-fighting, textile, polymerization processing aids. Non-fluorinated alternatives have particularly been promoted for use in textiles and firefighting foam. However, only the fluorinated alternatives are fully assessed while the non-fluorinated alternatives are only listed as "exist". We would suggest that the authorities perform a full assessment of all available alternatives according to the REACH guidance document. Data on availability, functionality, toxicology and environmental impact, and economic feasibility of non-fluorinated alternatives are available and should be taken into account in the assessment of alternatives to PFOA and PFOA-related substances.  Regarding the assessment of alternatives, substantial scientific data clearly shows that 6:2 FTOH, the short-chain methacrylate and acrylate and short-chain PFCAs, such as PFHxA are not bioaccumulative in aquatic ecosystems, For example, PFHxA has been shown to rapidly eliminate in multiple mammalian species and is not detected in the vast majority of human biomonitoring studies conducted. (Martin et al., 2003a,b; Conder, et al., 2008; Russell et al., 2013) These facts show unequivocally that short-chain PFCAs are very different from PFOA in their biology.  In addition, we would encourage authorities to take account of a report conducted by ENVIRON International Corporation evaluating the persistent organic pollutant (POP) characteristics of several short-chain fluorinated chemicals. The conclusions of the report read as follows:  “Based on the data reviewed for each substance (i.e., the raw materials, the commercial product, and the potential degradation products), none of the substances meet all of the criteria required to be classified as a POP and none of the substances meet more than one criterion. […] In the case of the Methacrylate Polymer, although there was very little pertinent data, because polymer molecules in general are too large to cross biological membranes, they are of low toxicity, and would, therefore, not be expected to trigger the toxicity criterion for identification of a POP. More data were available for the fluorotelomer raw materials (i.e., 6:2 FTOH, 6:2 FTAC, and 6:2 FTMAC) and their degradation product, PFHxA. While PFHxA may persist in the environment, PFHxA, 6:2 FTOH, 6:2 FTAC, and 6:2 FTMAC are rapidly metabolized and eliminated from mammalian systems. None of these materials appear to bioaccumulate or biomagnify based on laboratory data and available field monitoring data, and none show severe toxicity of the types that would warrant designation as POPs. Lastly, although 6:2 FTOH may be subject to long-range atmospheric transport, 6:2 FTAC and 6:2 FTMAC are not likely to be transported long distances in the environment. Additional data are necessary to determine if PFHxA meets the Annex D 1 (d) (ii) persistence criteria based on concentrations of “potential concern” in remote environments.”  Therefore, to state that the short-chain PFCAs “differ only in the number of fluorinated carbon atoms” (p. 129) from PFOA is not supported by the available scientific data.  Relevant references:  • ENVIRON, 2014. “Assessment of POP Criteria for Specific Short-Chain Perfluorinated Alkyl Substances”, 3, available here: http://fluorocouncil.com/PDFs/Assessment-of-POP-Criteria-for-Specific-Short-Chain-Perfluorinated-Alkyl-Substances.pdf  • Martin et al., 2003a. Dietary accumulation of perfluorinated acids in juvenile rainbow trout (Oncorhynchus mykiss). Environ Toxicol Chem 22(1), 189-95.  • Martin et al., 2003b. Bioconcentration and tissue distribution of perfluorinated acids in rainbow trout (Oncorhynchus mykiss). Environ Toxicol Chem 22(1), 196-204.  • Conder et al., 2008. Are PFCAs Bioaccumulative? A Critical Review and Comparison with Regulatory Criteria and Persistent Lipophilic Compounds. Environmental Sci. Technol. 42(4), 995-1003.  • Russell et al., 2013. Elimination kinetics of perfluorohexanoic acid in humans and comparison with mouse, rat and monkey. Chemosphere 93(10), 2419-2425.  Furthermore, in table C.2.1, properties of an organic acid are compared to properties of an alcohol. It would be more appropriate to compare the alcohols 8:2 FTOH to 6:2 FTOH, and the acids PFOA to PFHxA. | |
| **Answer to specific info request 2:**  Because leading manufacturers proactively and voluntarily prompted the phase out of PFOA and related long-chain chemicals years before this restriction proposal, significant research, development, and capital expenditures associated with the alternatives have already been invested. While these expenditures have already been made and, therefore, will not be impacted by this proposal, it is important that the total costs associated with this transition are recognized.  FluoroCouncil member companies have invested over €500 million of R&D and capital expenditures into the development of alternative polymerization aids and short-chain products and emission control technology. This figure does not include the transition and qualification costs for downstream users to replace PFOA and its related substances, which varied significantly up to over €1,000,000 per use per company, depending on the application. While the FluoroCouncil cannot provide specific costs per use, we believe the total costs to downstream customers for testing, recalibration, etc. are many times greater than the investment made by FluoroCouncil member companies.  It is important that the proposal portrays the full costs associated with the transition to alternatives to PFOA and related chemicals, even if all of those costs will not be an outcome of the proposed restriction because industry worked proactively to address these chemicals of concern in advance of regulation. The transition to alternative short-chain chemistry is ongoing for downstream users, and even though not fully completed, the remaining economic cost of the transition will therefore be manageable. An effective restriction of PFOA and PFOA-related substances would be a useful tool for completion of this process.  It is critical that thresholds are set at levels allowing the use of fluorinated alternatives, and yet preventing the placing on the market of articles treated with long-chain chemistry as well as unprocessed fluoropolymers manufactured with PFOA. The currently proposed single threshold of 2ppb covering PFOA and PFOA-related substances would severely limit the use of fluorinated alternatives and therefore lead to a demand for derogations for a majority of uses from the restriction. To the best of our knowledge, there exist no other alternatives providing the required performance.  Furthermore, contrary to the assumption made in the restriction dossier on page 166, the current restriction proposal will only induce change for fluoropolymer dispersions that are shipped to Europe in an unsintered form. Therefore, further action needs to be taken to ensure that fluoropolymers made with PFOA outside Europe, are not allowed into the EU market. Such actions are needed to eliminate the EU demand for fluoropolymers made using PFOA, which remain the major sources of global environmental releases of PFOA. One option could be to require documentation confirming that PFOA was not used in the production.  With reference to the substances listed in Appendix B.1, FluoroCouncil member companies are committed to phase out the use of these substances by the end of 2015. Some of these (8:2 FTOH, 8:2 FTAC, and 8:2 FTMAC) are commonly used in the manufacture of long-chain fluorinated polymers and will most probably continue to be used by non-FluoroCouncil members mainly in China, India and Russia. | |
| **Answer to specific info request 3:**  C7F15-COOH is PFOA and is already covered by the restriction (same CAS Number 335-67-1).  There has been no showing that any other C7 substance can degrade to PFOA and, therefore, they should be outside the scope. C8F17- as a structural element, including its salts, degrades to PFOA and should remain in scope.  As an additional comment, C8F17-CF2-X' describes fluoropolymers that are end capped with fluorine. If the polymer chain has a different terminal group, then the formula for those fluoropolymers would not start with C8F17.  In order to avoid any confusion, we would suggest that all fluoropolymers with fluorine in their backbone be expressly excluded from the scope of the restriction dossier. | |
| **Answer to specific info request 4:**  While it is possible to identify products where a 2 ppb threshold for PFOA-only could apply, FluoroCouncil has not identified any applications where this threshold could be applied for PFOA-related substances. A single threshold cannot be applied to all fluoropolymer and fluorotelomer products. These products may have a range of detection and quantification limits, which could span several orders of magnitude. As a result, thresholds for substances within scope must be developed on a product by product basis, such as:  • Short-chain products (intermediates and fluorinated polymers mixtures)  • Articles treated with short-chain products  • Fluoropolymers  The reasons why a 2 ppb threshold for PFOA and PFOA-related substances is not acceptable are:  • A threshold of 2 ppb applicable for all substances in scope and all types of products would mean a de facto ban of all short-chain alternatives and fluoropolymers made without PFOA.  • Under current state-of-art manufacturing practice, it is not possible to ensure a level below 2ppb for all substances to be restricted.  • The threshold should be set at a level of quantification that must be applicable and enforceable by Member States.  • Analytical methods are matrix dependent.  • Such a low threshold would increase probability of encountering false positives.  • As we have been informed by one of our customer groups, for articles in commerce, trying to certify an absence of contamination at the 2 ppb level would be impossible.  • No single methodology available to detect such a low threshold for all substances within the scope of the dossier. However, of the 16 methods listed in table A.E.2-1 only 5 have a LOQ of less than 2 ppb, despite the quoted results relating only to PFOA. In addition, it is misleading to compare the work needed to develop standardized methods for PFOA to the method under development for PFOS where the threshold is substantially higher (i.e. 100.000 times higher in articles).  • The proposed threshold is inconsistent with approaches proposed in Norwegian PFOA restriction and existing PFOS POP restriction.  The proposed threshold would result in a significant economic burden for authorities and on the value chain for implementation and ongoing monitoring.FluoroCouncil supports the development of a European standardized method for the enforcement of the restriction.  Given the current lack of data on the different substances in scope for the various matrices, it is not possible to identify suitable thresholds at this point.  FluoroCouncil will continue to assess the possibility to define workable thresholds that would allow an efficient restriction of PFOA (and related substances) without limiting the use of short-chain alternatives.  FluoroCouncil members aim to submit further information within the six months period of the public consultation. | |
| **Dossier submitter response:**  Answer 1:  The Dossier Submitter is grateful for the new information and will check if it is useful for the SEA.  The evaluation of all alternatives is not appropriate in our point of view, since the number of substances and technologies is high. It was important to show that there are alternatives available on the market. We assessed some example substances which seemed to be mainly used as alternatives.  Answer 2:  The Dossier Submitter is grateful for the new information on investment costs incurred by industry to switch to short-chain alternatives and will consider it in the further development of the Background Document.  It is not our aim to restrict the short-chain alternatives or fluoropolymers made without PFOA with this restriction proposal. However, intentional use of PFOA and PFOA related substances needs to be avoided. According to REACH, emissions of PBT substances have to be minimised.  The Dossier Submitter has revised the proposed concentration limit to ensure that short-chain PFAS and fluoropolymers made without PFOA can be manufactured and used.  It is not our aim to restrict the manufacturing and use of PTFE with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers.  Answer 3:  The DS is grateful for the comments made and will check if it is useful for altering the scope.  Answer 4:  The lack of standard analytical methods does not automatically imply that a very low threshold is not possible at later stage (which is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation).  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover from researchers point of view who also responded during the public consultation, analytical methods are already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  With political pressure and also the will to spend money, it seems to be possible to the Dossier Submitter to also establish method detection limits at a low ppb range for other matrices e.g. articles and even formulations in the near future. Moreover, it seems to be very likely that standardized methods will soon be available once they are required by law.   * Human Health   The FluoroCouncil (FC) comments, in the attachment, on the quality and the consistency with other available studies of the underlying studies for the DNEL calculations.  Comments to the use of study by Macon et al. (2011) for DNEL setting on mammary gland development:  According to FC “*The selected human health studies are inappropriate for DNEL derivation (…).* *The selected toxicological study by Macon et al. (2011) is based on a method that has not been validated for regulatory risk assessment, hence inappropriate for DNEL derivation. Other studies, including studies using humanized mouse models, did not support the finding by Macon et al. (2011) even though the dose level was substantially higher (Albrecht et al., 2013).*” Furthermore, FC states that *“The findings of Macon et al. (2011) are inconsistent with those of White et al. (2009), which reported effects at a much higher dose level (≥3 mg/kg), and Albrecht et al. (2013), which found no differences in the average length of mammary gland ducts and the average number of terminal end buds per mammary gland per litter in female pups following a maternal dose of 3 mg/kg.”* FC also states that “*Although the mammary gland effect is important, this effect has only been reported in mice and not rats or primates. Use of the LOAEL dose descriptor (0.01 mg/kg/d; mammary gland development) and the corresponding internal concentration (285 ng/mL) from Macon et al. (2011) for DNEL derivation is inconsistent with another key risk assessment from the US EPA (February 2014, draft).”*  According to Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health chapter R.8.1.2.1 Data requirements, REACH also requires that any other relevant hazard information that is available (i.e. on other endpoints and/or from other test and non-test methods) is taken into account.  As discussed in the dossier, several different mice strains have shown developmental changes in mammary gland, mostly reduced development after in utero exposure to PFOA. Especially at late GA exposure which seems to be a sensitive window of exposure. Full GA exposure in the Macon et al., 2009 study showed stunted mammary gland development up to adulthood (PND 84). Albrecht et al. 2013 have only looked at one dose (3 mg/kg bw/day through gestation) and one time point (PND21) when analyzing mammary gland development making it difficult to evaluate these results. In fact, table 5 in the Albrecht paper show a mean reduced TEB/gland in the humanized PPAR alfa mice after PFOA exposure. However, it has been debated whether PPARa is involved in the MOA of PFOA-mediated reduced mammary gland development at all. In addition, mammary gland development was not the main scope of the Albrecht-paper.  Different mice strains may respond differently to PFOA exposure and postnatal development of mammary gland should thus be checked at several post natal time points with different doses of exposure . Some studies show abnormal mammary gland development at peripubertal exposure of 5 or 10 mg PFOA/kg bw/day. Some mice strains are more sensitive than others to PFOA effects and/or the effects in the mammary gland are dependent upon the timing of exposure (peripubertal vs in utero). However, a recent study by Tucker et al. (2015) confirms that in utero exposure to PFOA stunts the developing mammary gland of two different mice strains. Furthermore, early PFOA exposure alters the mammary gland in the mice without changing other pubertal endpoints. The lowest dose where these effects occurred was 0.01 mg/kg bw/day.  In general, rat is not a good species to work with as PFOA has a very short half-life in rats, especially in female rats. Therefore, mice with longer PFOA half-life is a better choice and used for health hazard assessment in this dossier.  It is stated clearly in the draft U.S. EPA’s review of the human health effects of PFOA from February 2014 that we may not cite or quote the review.  Comments to use of study by Steenland et al. (2010) for DNEL setting on increase in total cholesterol and LDL:  FC comments in the attachment states that *“(…) to date data, mostly cross-sectional, are insufficient to draw firm conclusion that PFOA increases cholesterol. The strength of the association between PFOA and cholesterol varies by study, and there is no monotonic response. Studies with lower range of exposure levels have larger change in cholesterol per unit change in PFOA. For example, Nelson et al. (2010) reported 10 mg/dL change in cholesterol per 5 ng/mL change in PFOA in a cross sectional study of a representative sample of the U.S. population. On the other hand, Sakr et al. (2007) reported 1 mg/dL change in cholesterol per 1,000 ng/ml change in PFOA in a longitudinal study of occupational exposure. Besides, the associations between PFOA and increased cholesterol in humans contradict with animal studies from multiple species where PFOA decreases serum lipids, not increases (Lau et al. 2007).*  *In addition, an important controlled phase I clinical trial in humans (Macpherson et al., 2010) was not included in this report in which oral dose equivalent to plasma PFOA level ranging from 30,000-600,000 ppb results in a reduction in LDL-cholesterol at the highest exposure level of PFOA.*  *(…)*  *Steenland et al. (2009) reported 11 mg/dL change in cholesterol per 340 ng/mL change in PFOA among workers. However, in another occupational cohort study including 3 different manufacturing sites, Olsen et al. (2007) did not find any statistically significant association between PFOA exposure and total cholesterol (≥ 200 mg/dL) or low-density lipoproteins (LDL≥130 mg/dL). Olsen et al. (2007) expressed total cholesterol and LDL based on clinical identification of metabolic syndrome in their study; therefore, the study has the advantage of addressing the significant clinical implication of the results. In addition, PFOA is not lipophilic, and any potential mechanism by which PFOA might be related to cholesterol in humans is not known (Steenland et al., 2009).”*  The C8 science panel including Dr. Steenland and Dr. Fletcher state that there is a probable link between PFOA and cholesterol increase. PFOA resembles fatty acids and have shown in animal studies to interfere with the lipid metabolism as discussed in the dossier. The probable link is also justified by the fact that both cross sectional and longitudinal studies show a statistical significant association with PFOA and cholesterol. The epidemiological studies performed by the C8 science panel have been conducted in different ways, and similar association has been confirmed in other cohorts worldwide as well (Zheng XW et al., 2015, Geiger SD et al., 2014, Starling AP et al., 2014). In a recent study of Fisher et al., 2014, published after writing the restriction proposal, found in 2700 Canadian citizens a weak association with cholesterol at low PFOA concentrations, but only in unweighted models.  We have also referred to studies were no association was found and they were mainly high exposed fluorochrome workers with fewer participants (200-300) or the clinical trial of Macpherson.  The Macpherson human trial was conducted on very few (44) patients with median age of 63. These patients had advanced cancer and this may have implications on interpretation of the results. However, these results also support the possible non-monotonic dose response were low dose exposure of PFOA leads to an increase of LDL, while a high exposure dose reduces LDL in the blood.  PFOA is a fatty acid mimetic in that it interacts with fatty acid homeostasis and/or a fatty acid mediated pathway. This has been demonstrated in Vanden Heuvel (1996) where it was shown that different nuclear hormone receptors were activated by PFOA and how this compared to natural fatty acid activation of the same receptors. Thus, lipid metabolism is affected in rodents and may underpin a MOA for the cholesterol-effect seen in humans, although they differ from rodents.  Comments to the use of study by Fei et al. (2007) for DNEL setting on reduced birth weight:  FC comments in the attachment that *“Two review studies that included the study by Fei et al. (2007) concluded that there is not sufficient evidence to suggest a possible decrement in birth weight associated with PFOA exposure (Steenland et al., 2010; Olsen et al., 2009). A more recent review study by Johnson et al. (2014) that was discussed in this report concluded there is “sufficient” evidence that developmental exposure to PFOA reduces fetal growth, but do not cite data sufficient to this conclusion. These authors reviewed 9 studies in which 7 (80%) of them are cross-sectional studies. Results from 5 (60%) of these 9 studies were not statistically significant, which included two recent studies that were not included in the two previous reviews, a nested case-control study by Whitworth et al. (2012) and a cross-sectional study by Chen et al. (2012). This review did not evaluate the pharmacokinetics of PFOA among pregnant women. The inverse association between birth weight and PFOA reported in the current literature may be confounded by maternal glomerular filtration rate (Morken et al., 2014), as mentioned in the report. In addition, the review approach by Johnson et al. (2014) is a new method, and its utility has not been validated for different environmental chemicals or for regulatory risk assessment.*  *Even if these selected health outcomes are proved to be causal, they are not clinically significant. In the study by Fei et al. (2007), a decrement of 10.6 g (95% CI: 0.5-20.8) in birth weight per 1 ng/mL change in PFOA exposure was reported. However, this study did not find the same association for low birth weight (LBW; <2,500 g), a significant clinical outcome that has direct consequences for infant mortality and morbidity compared to that of birth weight (Wilcox 2001). In a community-based study with high exposure to PFOA, Savitz et al. (2012) did not find a statistically significant association between 100 ng/mL increased in PFOA exposure and term LBW. Birth weight is measured on a continuous scale; therefore, any moderate-size studies would have sufficient statistical power to detect small decrements, and the results reflect only the normal distribution range of birth weight (Savitz, 2007).”*  There are both animal data and several epidemiological studies supporting the positive association between PFOA and reduced birth weight. The weight of evidence approach used in the meta study by Johnson et al., 2014 is well performed. The glomerular filtration rate is discussed in the proposal as well as in the Johnson-study where they refer to another meta study that they performed (Lam et al., 2014). The meta-study could have been used for DNEL-setting, however we chose the Fei-study due to the blood withdrawal at early GA (first trimester) and the fact that this study is large (1400 mothers). Since the blood was drawn at the first trimester, the glomerular filtration rate (GFR) is a less significant confounder (Morken et al., 2014), compared to other studies were the blood was drawn late in pregnancy or even after birth. Even though several studies adjusted for GFR they still obtained an association between PFOA and reduced birth weight (Morken et al. 2014, Vesterinen HM. 2014, Verner et al. 2015). A more thorough description of the Fei-study is added to the background document. The significance of glomerular filtration rate was also described in the proposal.  Comments on assessment factors:  The FC comments in the attachment states that *“(…) evidence from human studies on PFOA is limited for DNEL derivation. Even if there is sufficient evidence from human studies, the approaches for DNEL derivation for human studies are conservative. (…)The DNEL derivation for decrease in foetal birth weight (Table B.5-7) is based on human adults >18 yrs (Fei et al., 2007). The assessment factors (AFs) applied for the intra-species difference of 6 for the general population is extremely conservative since the study is representative of the general population. Therefore, no assessment factor is needed for the general population or the worker. This would result in sum AF of 3 for both workers and general population instead of 9 and 18, respectively.”*  The assessment factors used were based on default factors (5 for workers and 10 for the general population) from the Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health chapter R.8.1.2.1. These were reduced to 6 (general pop) and 3 (workers) since the cohort represents the general population but not the young <18 years of age or the very old.  Comments on exposure assessment for fluoropolymer workers:  FC comments in the attachment that *“The exposure estimates from both external dose and internal dose approaches are based on PFOA manufacturing processes (Kaiser et al., 2010) which do not reflect the current exposure scenario in the EU where there is no PFOA manufacturing facility as indicated in the Dossier. Therefore, the exposure estimate for PFOA manufacturing workers is irrelevant in the EU.*  *If applied, exposure estimates based on manufacturing processes only reflect an extreme worst case exposure scenario, and the exposure assessment approaches are conservative (Section B.5.3.2.1, Table B.5-10). Kaiser et al. (2010) indicates that waste sumps should be kept above pH 7 to avoid the vaporization of PFOA; therefore, the monitoring data from the sump pump area with pH adjusted to 7 (0.001 mg/m3) would be a reasonable worst case exposure scenario for PFOA manufacturing today. In addition, workers would not be expected to spend 6 hrs/day standing near the sump, and the concentration would dissipate as one moves away from the sump assuming adequate ventilation in the processing areas. Assuming a worst case scenario of 4 hrs standing near the sump (0.001 mg/m3) with an inhalation rate of 1.4 m3/hr, the equivalent intake from inhalation of occupational air is 0.006 mg/day (or 86 ng/kg bw/day) which is considerably less than the range of 490-7900 ng/kg bw/day stated. In addition, arithmetic mean of serum/plasma concentrations was used for exposure estimate instead of geometric mean which is less influenced by extreme values. For example, if geometric mean of serum/plasma concentrations (1,130 ng/mL) was used for Decatur and Antwerp locations (Olsen et al, 2003), the equivalent overall mean intake of PFOA is 131 ng/kg/day which is less than half of the 298 ng/kg/day stated.”*  According to comment no. 1395, there is fluoropolymer production in EU where a PFOA-related substance is “*an unavoidable fraction*”. There is no information on the pH in the waste sumps, hence we can only use the data presented by Kaiser et al. (2010). The length of workday (hour) in “Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health” is 8 hours/day.  Comments on exposure assessment for general population:  FC comments in the attachment that *“Biomonitoring data for general U.S. and Canadian populations were not considered for human exposure assessment. In the U.S., there is a declining trend of PFOA exposure among the general population from 1999 to 2010 (U.S. DHS, 2009).”*  The biomonitoring data for the general populations in U.S. and Canada are not considered relevant for this proposal. The aim of this proposal is to demonstrate that action on a (EU) Community-wide basis beyond any measures that are already in place is necessary, ref. REACH Article 69 (4). | |
| **RAC Rapporteurs comments:**  RAC notes the criticisms of the DNELs used in the original dossier, and agrees that the underlying evidence is not sufficiently reliable. DNELs have therefore been based on reliable animal data in the RAC opinion.  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk that cross-contamination might cause failures above the proposed 2 ppb limit is also noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future.  RAC notes the statement that fluoropolymers made using PFOA are the major sources of global environmental releases of PFOA, and the suggestion to use a form of certification to avoid this. RAC notes that certification is not a REACH instrument, and it is unclear which actor(s) would be responsible for the certification procedure. Certificates could, however, be a good additional voluntary measure to help demonstrate compliance and promote the use of fluoropolymers made without PFOA.  RAC agrees with the request for all fluoropolymers with fluorine in their backbone to be expressly excluded from the scope of the restriction dossier (so that the proposal only addresses those substances with PFOA-related side chains). This is mentioned in the opinion.  RAC notes that a single low threshold cannot be applied to all fluoropolymer and fluorotelomer products for a variety of reasons. RAC has proposed a slightly higher limit than the DS, partially based on this issue. | |
| **SEAC Rapporteurs comments:**  Thank you for the information and the indication of the magnitude of investments made for the voluntary phase out.  We agree that revision of the proposal to ensure that short-chain alternatives are allowed to be used is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1206** | **Date:** 2015/02/20 16:25  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  TEGEWA e.V.  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  As requested by ECHA, TEGEWA submits these comments in due time before 1 March 2015 to allow first discussions in ECHA´s Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC). TEGEWA would like to reserve its right to submit a more detailed comment by 17 June 2015.  TEGEWA supports the approach to restrict the use of PFOA and PFOA- related substances in textile applications but objects to the restriction in its current version. Rationale:  • The report mentions that the most important substitutes for PFOA and PFOA-related substances are short-chain PFASs. Due to the proposed limit in chemical formulations of 2 ppb such alternatives are not available.  • This would lead to a loss of technical textiles (e.g. personal protective equipment) with requested repellent properties.  • The lack of robust analytical methods will not allow companies to prove compliance. But also Member State authorities will have no tools to enforce the restriction. | |
| **Answer to specific info request 1:**  The proposed threshold of 2ppb in mixtures and articles puts a direct ban to the placing on the market and use of the most important short-chain alternatives as well as articles treated with short-chain alternatives.  According to calculations, a PFOA-content below 2 ppb in chemical mixtures might be achievable in future, but a limit of 2ppb for PFOA- related substances (e. g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate) is definitively not feasible.  The threshold should be set at a level that safeguards the placing on the market of short-chain alternatives, namely intermediates, mixtures, and articles treated with short-chain alternatives.  It takes time to provide a realistic estimation of a threshold on treated textile based on the possible C8 fraction in commercial C-6-formulations. We would like to refer to our detailed comments that will be submitted by 17 June 2015.  Thresholds must be supported by robust analytical methods that must be uniformly applicable by industry and enforceable by Member State authorities. Methods with detection level in the 2 ppb range are currently not available for all of the C8 substances in scope of the restriction dossier. | |
| **Answer to specific info request 2:**  It is mentioned in the dossier that short chain PFASs are the most important alternatives for PFOA and PFOA-related substances. In fact, at least regarding textile applications this information is misleading. Due to the proposed limit in chemical formulations of 2 ppb, short-chain PFASs compliant to this limit are not available on the market. Therefore the presented calculations were carried out on a false basis.  Taking into account that short chain PFASs are not compliant the restriction proposal would cause a ban for technical textiles with a sufficient repellent (especially for oil, stain and chemicals) effect which is requested e. g. for personal protective equipment. Affected would be  - Bullet-proof vests for police and armed forces  - Apparel for fire fighters  - Protective work wear against chemicals in chemical and other industries  - Certain textiles used in clinics with requests for repellence of blood  - Automotive textiles  - Insulation products for vehicles  - Specific products for coating textiles (e.g. tents) | |
| **Answer to specific info request 3:**  No information available at TEGEWA. | |
| **Answer to specific info request 4:**  In view of the 2ppb limit for PFOA and PFOA-related substances in chemical formulations there will be no short-chain PFASs available as substitutes for the C-8-compounds. A PFOA-content below 2 ppb might be achievable in future, but a limit of 2ppb for PFOA-related substances (e. g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate) is not feasible.  • Analytical methods to quantify the PFOA-content in textiles are available but it is very questionable that these methods are robust enough to determine whether the PFOA-content in a textile article is below 2 ppb or not and to decide whether an article is compliant or not.  • There are no analytical methods available to quantify PFOA- related substances (e. g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate) in textile articles according to the limit of 2ppb.  • Analytical methods to quantify PFOA and related substances in chemical formulations according to the 2ppb limit are not available.  • It has to be taken into account that the task is not to detect a specific substance in a given clear solution but to extract the specific fluoro chemical out of a matrix with a million times excess of other fluorinated substances and to detect it with a accuracy that allows the decision that the product is compliant or not.  • Experiences from ongoing work to develop test methods for PFOS cannot be transferred to testing of PFOA and PFOA related substances because the threshold of 2 ppb is so much lower as for PFOS.  • Therefore, chemical companies, textile companies and textile brands will not be in the position to prove compliance of their products (both formulations and articles). Member State authorities will have no tools to enforce the restriction. | |
| **Dossier submitter response:**  The DS is grateful for the comments made.  Answer 1:  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier Submitter has revised the proposed concentration limit to ensure that short-chain chemistry can be manufactured and used.  The lack of standard analytical methods does not automatically imply that a very low threshold is not possible at later stage (which is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation).  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  A restriction is a motive for the EU Commission to induce the development of analytical methods if they are necessary for the enforcement. Thus, it seems to be possible to also establish method detection limits at a low ppb range for other matrices e.g. articles and formulations in the near future. Moreover, it seems to be very likely that standardized methods will soon be available once they are required by law.  Answer 2:  According to manufacturers of C6 substances and formulations all uses of C8 can be replaced by short-chain alternatives. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier Submitter considers a derogation for non-professional textiles not reasonable. The Dossier Submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  Answer 4:  Please see answers 1 and 2 above. | |
| **RAC Rapporteurs comments:**  The comment raises an interesting point about the ability to develop the existing PFOS analytical method for use with PFOA/PFOA-related substances when the limit of detection is so much higher than the proposed 2 ppb limit. RAC has no information about this. See also response to Comments 1200-1204. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that revision of the proposal to ensure that short-chain alternatives are allowed to be used is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances.  See also response to Comment 1203. | |
| **1207** | **Date:** 2015/02/23 10:57  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  I&P Europe - Imaging and Printing Association e.V.  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:** | |
| **Answer to specific info request 1:**  • Technical and economic information on continued critical uses in the photographic industry for which alternatives are not available and/or the performance of alternatives is not considered adequate – information on quantities used.  o The photographic industry has reduced its use of PFOA over 91% since 2000 and spent tens of millions euros in the process. However, replacement of the remaining uses, which we estimate to be 0.3 t/yr for the EU(annex 1), has proven to be a difficult problem.  I&P Europe members have conducted extensive research into alternatives to PFOA or PFOA related substances (further in this text referred to as “PFOA’s”). While many applications of PFOA’s have been eliminated, a small number of critical uses remain, amounting to a total continued use of about 0.3 t/yr in the EU. According to an estimate developed by the German and Norwegian authorities this accounts for less than 0.0054% of the total use in the EU. In addition, I&P Europe member companies have taken many steps to eliminate the exposure to and the release of the remaining PFOA’s. Based upon this combination of factors, we believe that the continuing critical uses of these substances in those conventional photographic products do not present a significant environmental or health concern.  I&P Europe members have undertaken their own research and development to find substitutes for PFOA’s. Where alternatives have been validated for the manufacturing of photographic products, they are already in use by the photo imaging industry. The alternative products are unique to each company and are proprietary. Research into alternatives to PFOA’s is continuing for the remaining uses. Forecast numbers indicate a further reduction to about 0.12 t/yr in 2015 and 0.088 t/yr in 2016, amounting to a further reduction of the use of PFOA’s in the photographic industry to respectively 96.4% and 97.5% since 2000. While even further reduction remains the target, it is expected that this will potentially be at increasingly high cost ratio and with increasingly limited chances for success, as only the difficult applications and the smaller niche applications remain.  The primary barrier to complete elimination of the use of PFOA’s at this time remains technical. However, the cost of research and development is also a relevant consideration, since this investment represents a significant financial burden during a time when the imaging industry is focused on the creation of innovative new digital imaging technologies. As a matter of fact the economic cost associated with substitution of PFOA’s in the few remaining critical photographic uses has in most cases become prohibitive, the small remaining critical uses being niche products in markets that I&P Europe members anticipate to further decline.  Non availability of PFOA’s for the manufacture of the remaining critical imaging products will also adversely affect involved customer groups including healthcare and military. In view of the healthcare sector for example, it could be financially challenging for hospitals and doctor's offices with tight budget restraints to invest in new technologies necessitated by discontinuation of current conventional photographic products during the proposed phase out period of 18 months. Moreover it appears that EU Member States with a relatively higher amount of such photographic products in the medical area are Italy, Spain, Portugal, Greece and a number or east European countries.  Also in view of the healthcare sector discontinuation of current conventional photographic medical products because of the non availability of PFOA’s will impact EU Member States where keeping hard copy images in medical files is a legal requirement, such as e.g. in France.  In view of the above, I&P Europe members believe that an exemption which is not restricted in time would be appropriate for the few critical uses of PFOA or PFOA related substances remaining in the photographic industry. In this respect it is useful to point out that the surfactants used by I&P Europe member companies are in most cases already in stock and can no longer be commercially obtained, so that a derogation without time limit would allow them to be used up.  Accordingly, the photo imaging industry respectfully requests that in the further process of the Annex XV Restriction Proposal the language for a RMO 1b approach that provides a derogation with no time limit for the remaining critical uses of PFOA, its salts or PFOA related products by the photographic industry will be supported. Any production ban or restriction on the use of PFOA related materials would have the effect of prohibiting the manufacture of these critical imaging products, without accomplishing any significant benefit to the environment or human health.  The photographic imaging industry does not manufacture PFOA, its salts or related substances, and must purchase the necessary materials from suppliers (EU and non-EU). From the purchased PFOA’s photographic product manufacturers then create mixtures, for internal use only. The photographic industry does not sell PFOA, its salts or PFOA related substances nor preparations containing these materials, although some companies may transport mixtures between plant sites.  The concentration of PFOA related substances will be greater than 2 ppb in the purchased or imported materials and in the subsequently manufactured mixtures for internal use in the production process of the end materials. Therefore any wording for a restriction of the type described in RMO 1b, i.e. the phase out of PFOA and PFOA related substances over 18 months with possible exemptions including photographic applications, should allow I&P Europe members to store the small quantities of purchased materials and use these internally to prepare the diluted materials required for manufacturing photographic imaging end products.  o PFOA’s are essential for the application of coating layers during the manufacture of some remaining conventional photographic products, i.e. products in which the image formation is based on silver halide technology: they have multiple functions, serving  1. as surfactants,  2. as static control agents,  3. as dirt repellents during coating operations,  4. as friction control agents,  5. and to provide adhesion control of coated layers.  PFOA’s are unique in that they provide the combination of all these properties in one molecule, without any adverse effects on photographic performance.  As static control agents, PFOA’s are needed to prevent damage to the sensitized photographic layers and thus prevent product damage or even waste.  These substances not only provide performance features necessary for the manufacture and use of conventional photographic products, they also provide important safety features by controlling the build-up and discharge of static electricity.  The ability of PFOA’s to control surface tension is a critical aspect of the use of these materials as coating aids. In order to function, imaging materials must be coated with multiple thin layers at high speed – some having as many as 18 thin layers containing up to 200 chemicals and with an overall total thickness of about 0.11 mm. During the coating process the chemicals in these layers should not mix. The PFOA related materials play a key role in minimizing manufacturing waste by contributing to the technology for creating coatings of high complexity in a highly consistent manner. The coating aid must allow the rapid uniform spreading of the layers so that irregularities in the coatings are avoided. Any irregularity in coating thickness makes conventional imaging materials unusable and increases manufacturing waste significantly. Coating aids must also not be photoactive and thus not interfere with the imaging process, otherwise unacceptable fogging or speed effects may occur in the end material.  • Information regarding the potential risks to the environment or to human health via the environment associated with continued Uses by the Imaging Industry in critical photographic uses.  o What is the Potential for Occupational Exposure to PFOA during Manufacturing of photographic materials?  Potential occupational exposure to PFOA’s in the manufacturing of conventional photographic products is estimated to be extremely low for a number of reasons including:  1. PFOA’s are not volatile and used as working solutions in water;  2. exposure during preparation of coating formulations is avoided because employees are provided with protective clothing, eye shields, gloves and, in some operations, respirators;  3. after preparation of the coating mixtures, the solutions are transferred via automatic piping from the mix preparation area to the production area where they are added to coating machines that handle the actual application of the coating mixtures. Human intervention is minimal, because coatings must be conducted in a clean environment with restricted access to coating machines.  o What is the Potential for Environmental Release of PFOA during Manufacturing?  Environmental releases from the manufacturing of conventional photographic products are estimated to be extremely low for a number of reasons including:  1. the small amounts of PFOA related materials added during the coating stage of the photographic product (0.1-0.8 µg/cm2) have beneficial effects throughout the life of the product. Therefore the PFOA related material must predominantly remain in the product for the product to perform adequately;  2. manufacturing facilities for photographic materials either have incineration capability on-site or use incineration facilities available through off-site contracts. Wastes containing PFOA’s may arise from a variety of sources. In all cases, these waste streams are managed appropriately to minimize the potential for exposure and release to the environment.  Wastes from Coating Operations  Wastes from coating are disposed of through high temperature incineration. This waste category has been estimated as 1-3% of the total PFOA material in analogy with former data for PFOS developed in the course of the former regulatory process for PFOS. Coating materials that are unused but excess are sent for silver recovery by incineration at high temperature. This category of waste may account for 5-28% of the total amount of PFOA’s used, again in analogy with former PFOS data.  Some companies may use PFOA related substances in the overcoat layer. Whereas the overcoat does not contain silver (as opposed to photographic emulsion layers), any excess is not sent for silver recovery by incineration but rather treated in a large STP. This quantity of PFOA-related substance is estimated to be well below 1 kg per year and is further declining because of market trends.  Wastes from Finishing Operations  The finishing stage involves slitting the rolls of film that are up to several metres wide into sizes appropriate for the product type. The wastes from this process are all solid and are either incinerated directly or incinerated after recovery of silver and PET (polyethylene terephthalate) film base and other materials. Ultimately, all waste from finishing is incinerated, accounting for an estimated 5-25% of the total of PFOA chemicals.  Wastes from Photo-processing Operations  I&P Europe member companies no longer use PFOA’s in their photo-processing solutions.  During the wet processing of any photographic film or paper containing PFOA’s, we would anticipate very little PFOA chemical being released.  This is confirmed by analytical data yielding a PEC/PNEC of 0.000 24 << 1 in the wash section of a wet film processor for medical film, which constitutes a worst case example, and a PEC/PNEC = 0. 000 000 010 << 1 at the emission point of that processor in a typical hospital setting in Germany\*\*.    \*\*: reference “Use of PFOA in critical photographic applications” – presentation at the Workshop on PFOA and its Ammonium salt. Production, use, risk – 4 May 2010, slide 10  o What is the Potential for Customer Exposure of PFOA during Product Use?  Exposure potential is expected to be very low because:  1. the concentration of PFOA related materials in coatings is very small and in the range of 0.1-0.8 µg/cm2. Moreover the PFOA-related material will not all be on the surface of the coating, as it is included in one or more crosslinked layers of the coating, not applied as a surface treatment;  2. images must be handled as little as possible in order to preserve image quality (i.e. absence of finger prints, scratches, dirt, grease).  o What is the Potential for Environmental Release of PFOA during Product Use?  Environmental releases originating from photographic products are estimated to be very low.  The imaging industry aggressively recycles hundreds of millions of kilogrammes of manufacturing and post-customer waste annually, including solvents, PET, and silver. Because of the high value of silver, I&P Europe members have developed highly effective processes to recover as much used and waste photographic material as possible in order to recover the precious metal.  Consumer film and paper (except for small amounts of materials returned by photofinishers) are usually not returned to the manufacturer. Consumers typically store their film and printed images indefinitely and usually across generations. Materials that are discarded are usually disposed of in municipal solid waste systems. The proportion of municipal waste that is incinerated will vary considerably on a national and local level.  Recycling of commercial film may be carried out with several goals in mind: recovery of silver; recovery of film base material (PET); and protection of intellectual property or sensitive information. For film that is constructed on a PET base, the emulsion layers are separated using enzymes or chemicals, the PET base is separated and sent for recovery, and the emulsion solutions are either biologically treated or chemically treated with a flocculant, precipitated, dried and are in both cases subsequently incinerated at high temperature to produce an ash that is used for recovery of silver. Film that is not on a PET base is incinerated directly at high temperature to recover the silver. For commercial (e.g., entertainment, industrial x-ray, graphics arts, and printing) and medical imaging industries, film materials are collected by a small number of registered organizations who are responsible for the secure destruction of the film in order to protect private information or intellectual property. The materials are incinerated and the silver and other raw materials are recycled as described above.  Any waste solvents are incinerated in hazardous waste incinerators. To treat wastewaters, most recyclers have primary treatment facilities on-site so as to maximize silver recovery; sludges from primary treatment facilities are collected and used for silver recovery. Recycling operations located at manufacturing sites also have secondary wastewater treatment systems where sludges are collected and incinerated at high temperatures.  o Conclusion  As stated above, the total amount of PFOA related materials required for continued uses in the remaining critical applications in the photographic industry is estimated to account for less than 0.0054% of the total use in the EU. In addition, the occupational exposure to and environmental releases of PFOA related materials associated with continued uses in photographic products are controlled and pose no unacceptable risk to human health or the environment. | |
| **Answer to specific info request 2:**  • Information on other costs of the restriction in the Photographic Industry.  I&P Europe members have conducted extensive research into alternatives to PFOA or PFOA related substances (further in this text referred to as “PFOA’s”). While many applications of PFOA’s have been eliminated, a small number of critical uses remain, amounting to a total continued use of about 0.3 t/yr in the EU. According to an estimate developed by the German and Norwegian authorities this accounts for less than 0.0054% of the total use in the EU. In addition, I&P Europe member companies have taken many steps to eliminate the exposure to and the release of the remaining PFOA’s. Based upon this combination of factors, we believe that the continuing critical uses of these substances in those conventional photographic products do not present a significant environmental or health concern.  Where alternatives have been validated for the manufacturing of photographic products, they are already in use by the photo imaging industry. The alternative products are unique to each company and are proprietary. Research into alternatives to PFOA’s is continuing for the remaining uses, however at potentially high cost ratio and with limited chances for success, as only the difficult applications and the smaller niche applications remain.  The primary barrier to complete elimination of the use of PFOA’s at this time remains technical. However, the cost of research and development is also a relevant consideration, since this investment represents a significant financial burden during a time when the imaging industry is focused on the creation of innovative new digital imaging technologies. Costs to substitute PFOA’s typically amount to 500-1000 kEuro for a single photographic material. As a matter of fact the economic cost associated with substitution of PFOA’s in the few remaining critical photographic uses has in most cases become prohibitive, the small remaining critical uses being niche products in markets that I&P Europe members anticipate to further decline.  Non availability of PFOA’s for the manufacture of the remaining critical imaging products will also adversely affect involved customer groups including healthcare and military. In view of the healthcare sector for example, it could be financially challenging for hospitals and doctor's offices with tight budget restraints to invest in new technologies necessitated by discontinuation of current conventional photographic products during the proposed phase out period of 18 months. Moreover it appears that EU Member States with a relatively higher amount of such photographic products in the medical area are, Italy, Spain, Portugal, Greece and a number or east European countries.  Also in view of the healthcare sector discontinuation of current conventional photographic medical products because of the non availability of PFOA’s will impact EU Member States where keeping hard copy images in medical files is a legal requirement, such as e.g. in France.  In view of the above, I&P Europe members believe that an exemption which is not restricted in time would be appropriate for the few critical uses of PFOA or PFOA related substances remaining in the photographic industry. In this respect it is useful to point out that the surfactants used by I&P Europe member companies are in most cases already in stock and can no longer be commercially obtained, so that a derogation without time limit would allow them to be used up.  Accordingly, the photo imaging industry respectfully requests that in the further process of the Annex XV Restriction Proposal the language for a RMO 1b approach that provides a derogation with no time limit for the remaining critical uses of PFOA, its salts or PFOA related products by the photographic industry will be supported. Any production ban or restriction on the use of PFOA related materials would have the effect of prohibiting the manufacture of these critical imaging products, without accomplishing any significant benefit to the environment or human health.  • Information on which of the substances (PFOA-related) are most relevant in terms of production/use volumes.  The photographic industry uses PFOA related substances in a small number of critical uses, amounting to a total continued use of about 0.3 t/yr in the EU(annex1), accounting for less than 0.0054% of the total use in the EU.  Annex 1 provides a consolidated table showing the small amounts of PFOA related substances still used in the EU. Information on the exact chemical identity of PFOA related substances are proprietary as these substances are unique to each company. | |
| **Answer to specific info request 3:**  I&P Member companies do not have new information in this respect. | |
| **Answer to specific info request 4:**  • Information on the possible impact of the proposed concentration limit of 2 ppb regarding the use of short-chain PFASs with PFOA/PFOA-related substances as impurities.  I&P Europe members are aware that a number of manufacturers of PFOA-related substances have undertaken a move to shorter fluorinated chain elements (eg within the U.S. Environmental Protection Agency 2010/15 PFOA Stewardship Program). However, information from one supplier indicates that some of these shorter-chain substances would fall within the proposed scope because of the presence of traces of C7 or C8 perfluorinated chains. In other words, substances designed as alternatives to those covered by the proposed restriction would themselves be banned as a result of the 2 ppb limit.    In view of this and of the information provided under question 1, I&P Europe members believe that an exemption which is not limited in time would be appropriate for the few critical uses of PFOA or PFOA related substances remaining in the photographic industry.  Similar to PFOA’s, the photographic imaging industry does not manufacture short-chain PFASs and must purchase the necessary materials from suppliers (EU and non-EU). From the purchased materials photographic product manufacturers then create mixtures, for internal use only, that for some companies may be transported between plant sites..  Also similar to PFOA’s the concentration of PFOA related substances will be greater than 2 ppb in some of these purchased or imported shorter-chain substances and in the subsequently manufactured mixtures for internal use in the production process of the photographic end materials. Therefore any wording for a restriction of the type described in RMO 1b, i.e. the phase out of PFOA and PFOA related substances over 18 months with possible exemptions including photographic applications, should allow I&P Europe members to store the small quantities of purchased materials and use these internally to prepare the diluted materials required for manufacturing photographic imaging end products.  • Information on The availability of analytical methods including the limit of quantification of those methods in relevant matrices.  With respect to the availability of analytical methods in relevant matrices I&P Member companies are not aware of the existence of standardized methods for the analysis of PFOA in photographic materials (matrix: multiple layers of crosslinked gelatin). | |
| **Dossier submitter response:**  The DS is grateful for the new information and will take it into further consideration for granting possible derogations.  Request 1  Risk management measures regarding human health and environment are in place. Furthermore, photo industry is a minor user of PFOA and PFOA-related substance with further decreasing trend. Emissions during service life of the photographic material are considered negligible. Therefore, the Dossier Submitter would agree with a derogation.  Request 2  See our response to request 1. The Dossier Submitter is grateful for the new information on substitution costs in photographic material and the market conditions of these applications. We will consider it in the further development of the Background Document.  Request 4  It is not our aim to restrict the short-chain alternatives with this restriction proposal. Concentrations of PFOA and PFOA-related substances are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain PFAS can be manufactured and used. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that remaining use in the photographic sector is for niche applications that are declining, the supplied amounts of PFOA are relatively low (e.g. 88 kg by 2016, which is lower than the amount assumed in the previous BD) and that process wastes are (in general) incinerated. On this basis, the risk appears to be low and the requested derogation seems justified. Whether this is open-ended or time-limited will depend on the desire of the Commission to provide continued pressure to seek alternatives.  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternative substances. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that taking into account the low emissions (due to low and still decreasing volumes used and the risk management measures applied) and the anticipated socioeconomic consequences of the restriction, derogation seems appropriate for photographic coatings. We have reflected this in our draft opinion. | |
| **1208** | **Date:** 2015/02/23 22:26  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  DuPont de Nemours International Sàrl  **Org. country:** Switzerland  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  All DuPont comments are included in the attached non-confidential document (Section IV).  Best regards, **<removed>** | |
| **Dossier submitter response:**  The DS is grateful for the comments made.  Most of the comments are minor corrections of the wording and the Dossier submitter decided not to adopt most of the proposals made. The newly published data from a mice study on 6:2 FTOH has been included in the background document. REACH Annex XII is by now quoted in chapter B.4.1.2 in the background document. The hypothesis made by the stakeholder regarding degradation of fluorotelomer acrylates and methacrylates and polymers of not being a significant source of PFOA in the environment is not supported by information provided in the background document. Unfortunately, no references have been included underpinning the statement by the commenter. | |
| **RAC Rapporteurs comments:**  RAC notes that most of the comments in the attachment are relatively minor corrections of the BD text. One comment that “numerous modelling studies which have summed up the global PFOA mass balance from known and postulated sources ... indicate that polymer degradation is unlikely to be a significant contributor to PFOA in the environment” contradicts the statements in the BD, but is not supported by any specific data. A subsequent comment states that “emissions of PFOA resulting from biodegradation of side-chain fluorinated polymers are 4-7 t/a (citing two papers by Russell et al., which are included in the BD), and RAC does not consider this to be insignificant. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. | |
| **1209** | **Date:** 2015/02/24 17:03  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** The socio-economic assessment has been submitted under the reference number 62836ab3-1417-416d-9c5c-999702909eb7 confidentially for competitive reasons, and to preserve intellectual property. The same applies to this position paper. | **General Comments:**  This is a position paper related to the already submitted socio-economic assessment (SEA). | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration for potential derogations.  The lack of standard analytical methods does not automatically imply that a very low threshold is not possible at later stage (which is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation).  Different analytical methods and measured data (see chapter E, Appendix B.2.2 and E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA-related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  A restriction is a motive for the EU Commission to induce the development of analytical methods if they are necessary for the enforcement. Thus, it seems to be possible to also establish method detection limits at a low ppb range for other matrices e.g. articles and formulations in the near future. Moreover, it seems to be very likely that standardized methods will soon be available once they are required by law. | |
| **RAC Rapporteurs comments:**  RAC notes the request for derogation for certain medical devices. The amounts of PFOA that may be emitted from the products produced by this company appear trivial, but RAC does not have a thorough understanding of emissions from the whole sector. As such, from a risk perspective, RAC only supports a derogation for implantable medical devices at the present time. Derogation for other types of medical device is more of a matter for SEAC. See also response to comment 1204. | |
| **SEAC Rapporteurs comments:**  Thank you for all the valuable information you have submitted. | |
| **1210** | **Date:** 2015/02/25 11:56  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  AEQCT  **Org. country:** Spain  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  As Spanish Association of Chemical and Colourist Textiles we represent the 80% of national companies and we would like to express our concern on the information issued by you about limiting the content of PFOA to 2 ppb, both in chemical and ending products.    This restriction not only affects to PFOA but also to all those substances than can degrade to PFOA.    As far as we know, the analysis to detect the limit of 2 ppb of PFOA and particularly of all those substances that can degrade to PFOA is not possible. It is so because actually there is no effective testing method against this specification, also not on clothing items, for which a control of this material treated and imported in USA cannot be analysed correctly.    We think that this proposal of resolution can severely affect to:    • Competitiveness of companies associated with our organization  • It would suppose a loss of manufactured product and value creation  • It would impact on employment deprivation of a significant portion of workers in companies dealing with fluorocarbon items | |
| **Answer to specific info request 1:**  In Spain we think that 15 million metres are handled with this range of products and that at around 400 direct workers could be affected.    For all mentioned above, and from AEQCT, we would like to intercede in order to set more real limits to the PFOA content and also more suitable to the market needs.    This could be reached with products of more reduced supply chain (e.g. C6) compared with the current C8 fluorocarbon items. They would also allow to be controlled in a more real and effective way.    For our associated companies, you must consider that the change from C8 to C6 represents an additional cost which runs from 500 and 700 Th€. This cost is already assumed but a new increase could lead to unwanted and irreversible decisions for our industry. | |
| **Answer to specific info request 4:**  As far as we know, the analysis to detect the limit of 2 ppb of PFOA and particularly of all those substances that can degrade to PFOA is not possible. It is so because actually there is no effective testing method against this specification, also not on clothing items, for which a control of this material treated and imported in Europe cannot be analysed correctly. | |
| **Dossier submitter response:**  The DS is grateful for the comments made.  The Dossier Submitter is grateful for the new information and will take it into further consideration on potential derogations.  The Dossier Submitter is grateful for the new information on costs to downstream users to switch to short-chain alternatives and will consider it in the further development of the Background Document.  The lack of standard analytical methods does not automatically imply that a very low threshold is not possible at later stage (which is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation).  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  A restriction is a motive for the EU Commission to induce the development of analytical methods if they are necessary for the enforcement. Thus, it seems to be possible to also establish method detection limits at a low ppb range for other matrices e.g. articles and formulations in the near future. Moreover, it seems to be very likely that standardized methods will soon be available once they are required by law. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment and the indication of the range of anticipated costs from the change from C8 to C6. We agree that the 2 ppb limit is not feasible and we support higher concentration limits (25 ppb for PFOA and its salts, 1000 ppb for PFOA-related substances). | |
| **1212** | **Date:** 2015/02/26 04:22  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  JEITA  **Org. country:** Japan  **Country:** Japan  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  We believe that covered substances should be identifiable by identifiers and therefore be manageable and that thresholds for them should be justifiable via appropriate risk assessment and be reasonable and feasible both for authorities and for industry.  More concretely, when PFOA and its related substances would be restricted, covered substances should be specified by identifiers such as EC number or CAS number. For concrete example, it would be as follows:  Perfluorooctanoic acid (PFOA) and individual salts and esters of PFOA (CAS No. 335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5)  In addition, proposed threshold doesn’t seem to be based on appropriate risk assessment and socio-economic impact assessment. We strongly believe that appropriate threshold should be set based on risk assessment and socio-economic impact assessment under REACH. From the point of view of risk, the difference between current measures for PFOS and proposed restriction on PFOA would not be able to be justified.  In addition, we consider that the level on which whole supply-chain could control substances would be the same as threshold of PFOS under EU POPs Regulation (for chemicals/mixtures:10ppm; for articles: 0.1%; and for textile/ coating:0.1µg/m2).  The details and justification of our proposal are as follows.  a) Necessity of the identifiable way of specifying chemical substances  When PFOA and its related substances would be restricted, we believe that covered substances should be specified by identifiers such as EC number or CAS number.  We consider that it would not be legally effective to restrict broad chemical substance group which cannot be identified by identifiers such as EC number or CAS number. It would be extremely difficult for any stakeholders, especially downstream users and manufacturers of articles in supply-chain, to control group of chemical substances which cannot be specified in concrete and clear way and to comply with such legal requirements. On the other hand, regulators would not be able to implement such unclear legal requirement in an appropriate manner. We don’t necessarily oppose against the restriction of PFOA, but are afraid that proposed restriction would not be reasonable and feasible as law.  b) Issues on the way of specifying covered chemical substances and its possible impacts  To restrict not only PFOA but also all C7F15 substance groups with extremely severe threshold (2ppb) is not realistic. It's as same as to restrict almost all fluoro polymer compounds. For example, it is said that PTFE is decomposed thermally at ≥360°C. Once the fluoro polymer, not only PTFE, is partially decomposed, there is a possibility of forming C7F15 substance groups in fluoro polymer. If the supplier manufactures the parts or material without PFOA, there is a concerning of contamination of PFOA produced by thermal or other decomposition.  That is, manufacturers of articles would have to control not only infinitesimal impurity in materials but also infinitesimal results of decomposition in production process in supply-chain and infinitesimal migration from object or equipment used in production process. This is unreasonable and impracticable as a legal requirement to restrict contents of substances in final products.  When PFOA and its related substances would be restricted, we believe that covered substances should be concretely identified, like Norwegian PFOA restriction under “Regulations relating to restrictions on the manufacture, import, export, sale and use of chemicals and other products hazardous to health and the environment (Product Regulations)” , as follows:  Chapter 2. Restricted substances and preparations  Section 2-32  perfluorooctanoic acid (PFOA) and individual salts and esters of PFOA (CAS No. 335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5)  c) Issues of current proposed restriction from the point of view of practice  Considering measures across whole supply-chain, the level on which whole supply-chain could control substances would be the same as threshold of PFOS under EU POPs Regulation:  - in chemicals (substances and mixtures)：equal to or below 10 mg/kg (0,001 % by weight; 10ppm);  - in semi-finished products or articles, or parts thereof: 0,1 % by weight (in considering exposure from articles); and  - for textiles or other coated materials：1µg/m2 of the coated material.  Possible problems expected from current proposed restriction are listed as follows. It would be too difficult for downstream stakeholders in supply-chain to meet current proposal. Among others, it would be practically impossible to check the information on impurity and decomposition at ppb level by communication through global supply-chain. Especially, because fluorocarbon polymers (not PFOA) are relatively used in wide range in EE industry, if infinitesimal impurity should be checked, huge number of possible materials and parts would have to be investigated in detail.  - When considering not only impurities remaining in raw materials but also the decomposition product which occurs in process of manufacture and the infinitesimal amount of contamination which shift from other product, supply-chain cannot control them.  - As a fact, about information delivery of chemical substances in the world-wide supply-chain, the information such as "impurities remaining in raw materials under 1000ppm","decomposition product" and " infinitesimal amount of contamination" has not been delivered enough even with existing structure such as SDS.  - For manufactures producing products using a large number of materials, they cannot judge whether they can use the material without an appropriate analysis method. So, they cannot control these products appropriately.  Practically speaking, the proposed threshold is not feasible value at which all the stakeholders from supplier of materials (manufacturing and selling fluorocarbon polymers) to downstream manufacturers in supply-chain (those who processing articles, parts-manufacturers or manufactures of final complicated product) could responsibly control and assure contents of substances. Even if each supplier of chemical material had guaranteed it in SDS at the time of product shipment, end-downstream manufacturer in supply-chain cannot ensure the proposed threshold given all possibilities of pollution or impurity incorporation in transit or processing. Especially, because fluorocarbon polymers (not PFOA) are relatively used in wide range in EEE industry, if infinitesimal impurity should be checked, huge number of possible materials and parts would have to be investigated in detail. So, we cannot even begin to imagine the greatness of confusion and influence that the whole supply-chain receives.  It should be considered that strict threshold of PFOA than that of PFOS may significantly increase burden for industry.  d) Issues of current proposal about object substances and setting method of threshold  In REACH, the threshold of regulation should be decided based on "risk assessment" and "socio-economic impact assessment" suitably. But, at the viewpoint of risk, nobody may justify the need to manage much strictly than current management level of PFOS. Moreover, it will be discussed later in detail, conclusion of the evaluation in this dossier is entirely different from that of EFSA (food security organization in Europe) which PFOA's regulation in food is unnecessary. We would like ECHA to take a real look at the reason why the conclusion of the evaluation in this dossier is so different from that of EFSA.  The authorities mind the uses of PFOA in Q1、but this does not make sense. That is, as current designated method of substances and threshold, we cannot use any fluororesin ("elimination of all fluororesin" virtually) because they cannot be controlled in supply- chain". If so, the negative impact to give whole society is immeasurable. That's why we think that the authorities should adopt rational policy option after doing the socio-economic impact assessment with calculating not only "alternative cost for PFOA" but also "total social cost for not using every fluororesin" and "benefit". | |
| **Answer to specific info request 1:**  Please see our general comments above. | |
| **Answer to specific info request 2:**  We checked the proposed dossier and recognized following issues. We sincerely would like to ask ECHA to consider these points and to assess risk and socio-economic impact appropriately, when ECHA would review the appropriateness of the proposed restriction. At the same time, we strongly believe that ECHA should consider the consistency with the existing reports and policy by the other EU authority thoroughly.  a) Incomplete Socio-Economic analysis  We consider especially following issues in proposed dossier as problematic:  i. Socio-Economic analysis is incomplete;  ii. Benefit estimation for the proposed restriction on human health and environment is lacking; and  iii. It should be valuated for the rational socio-economic analysis.  i. There is NO valuation for the benefit of the proposed restriction, accordingly socio-economic consideration is incomplete. Using production volume as a proxy for the benefit is insufficient for the rational socio-economic analysis, and just "SVHC candidate" is not sufficient reason to draw conclusion for the proposed restriction. Allowing evaluation based on these insufficient rational will leads decision based on mere hazard, and is not in conformity with Article 68 of REACH which requires risk based restriction consideration.  ii. Proposed amendment: For human health, disability adjusted life years (DALYs) and/or quality adjusted life years (QALYs) should be derived for selected endpoints used to draw DNELs for the calculation of RCRs. For environmental impact, willingness to pay (WTP) and/or direct economical value such as revenue from fishery should be evaluated.  iii. There is NO cost estimation for controlling PFOA along long and complex supply- chain. Proposed restriction requires controlling PFOA for wide variety of final products from household goods, textiles, table/kitchen ware to electric/electronic products, and required control level, 2 ppb is far beyond current analytical technology available for these products, so estimated cost just for the chemical analysis will be extremely huge, if not prohibitive. Furthermore, investigation along long and complex supply-chain requires huge cost, in general, and total cost for controlling PFOA at 2 ppb will not be affordable for the society.  b) Inconsistency to Food contaminant control policy  Smallest DNEL of 0.3 ng/ml of internal dose, correspond to 0.035 ng/kg bw(body weight)/day in external dose is used for risk characterization in the proposed dossier, and the DNEL is far less than TDI of 1500 ng/kg bw/day referred in the EFSA report. Furthermore, it is much smaller than estimated daily dietary intake 31.5 ng/kg bw/day (highest 95th percentile estimate for toddler).  Such great deviation of limit values such as DNEL or TDI and critical risk characterization for the estimated exposure level should be extremely carefully investigated to avoid any inconsistency between EU policies.  As stated in the proposed restriction dossier, EFSA have already evaluated the risk of PFOA as food contaminant. EFSA have used TDI of 1500 ng/kg bw/day (external dose) for their evaluation, on the other hand, proposed restriction dossier using DNEL for general population of child 0.3 ng/mL (internal dose) for the evaluation. Converting the internal dose to external dose in accordance with the equation of DP = CP x (ln2/(T1/2 days) x Vd) in the restriction dossier, DNEL 0.3 ng/ml for general population of child is 0.035 ng/kg bw/day in external dose, and the value is much smaller than that of TDI of EFSA.  Furthermore, the DNEL 0.035 ng/kg bw/day in external dose is much smaller than estimated daily dietary intake used in the EFSA report, stating;  "For PFOA, the highest upper bound mean exposure estimates for the adult population (4.3 ng/kg bw/day) represented 0.3 % of the TDI while the highest 95th percentile estimate (7.7 ng/kg bw/day) represented 0.5 % of the TDI. In toddlers, the age class having the highest exposure, the same parameters represented 1.1 % and 2.1 % of the TDI, respectively."  European Food Safety Authority, Perfluoroalkylated substances in food: occurrence and dietary exposure, EFSA Journal 2012;10(6):2743  http://www.efsa.europa.eu/en/efsajournal/doc/2743.pdf  This will have a great impact on the food administration in EU, and adequacy for the selection of limit value such as TDI or DNEL should be thoroughly investigated for all relevant legislative areas to avoid unreasonable inconsistency between them.  c) Related information on risk assessment : the legislative actions by the U.S. EPA  The U.S. EPA published a proposed Significant New Use Rule (SNUR) on “Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances” in January 21, 2015. Some articles would be covered under the proposed SNUR, but SNUR covers “intended use” and does not require any strict control of contamination or impurity.  We cannot believe that there are major differences in the usage or risk of PFOA between the EU and the U.S. The materials and data from the U.S. EPA should be checked, and appropriate policy option based on the appropriate assessment should be considered.  (References)  40 CFR Part 721[EPA-HQ-OPPT-2013-0225; FRL-9915-63] RIN 2070-AJ99  Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule  http://www.gpo.gov/fdsys/pkg/FR-2015-01-21/pdf/2015-00636.pdf | |
| **Answer to specific info request 3:**  We are final product (article) manufacturers and don't have data on this issue. | |
| **Answer to specific info request 4:**  a) Possible impact of the proposed concentration  Generally, the measurement of ppb (ng/g) level corresponds to the ultra-trace analysis. In order to obtain a reliable data at this low level, the experts are strongly required the knowledge of analytical chemistry, especially for contamination control. It seems to be impossible for general industrial manufactures or suppliers to analyze such a low concentration level of PFOA as daily control. Unreliable data would cause a misunderstanding and confusion through the supply-chain.  “ANNEX XV PROPOSAL FOR A RESTRICTION – Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances (on 16 pages) “mentioned that:  The threshold of 2 ppb is derived from  - the quantification limit of PFOA and lead substances of PFOA-related substances in analytical methods.  LOD (Limit of Detection) or LOQ (Limit of Quantification) depends on the analytical equipment. This threshold as 2 ppb is no meaning unless specific analytical methods are shown. Additionally, when LOQ is calculated, the background should be considered.  As described in Document 1, the biggest challenge in establishing the ultra-trace analysis of PFOS / PFOA is the reduction of contamination. Yamashita et al identified the systematic contamination source for PFOS and PFOA from laboratory environment to analytical instrument in order to reduce contamination. Especially, many fluorocarbon polymers (such as tube, seal, filter and so forth) are often used for the analytical instrument. PFOS or PFOA eluting as impurities from these fluorocarbons polymers is called as a system blank (contamination is due to the analytical instrument) and it is a serious problem for PFOS or PFOA analysis at ultra-trace level.  In general, LC / MS is used to measure PFOA. The ppb level of PFOA elution can occur easily. Considering these contamination, threshold of 2 ppb is virtually impossible.  b) The availability of analytical methods  Only international standards have been developed by ISO / TC147. The title is ISO 25101:2009“Water quality -- Determination of perfluorooctanesulfonate (PFOS) and perfluorooctanoate (PFOA) -- Method for unfiltered samples using solid phase extraction and liquid chromatography/mass spectrometry”  Target samples are drinking water, groundwater or surface water (river water, sea water, etc.). PFOS (2.0 ng / L ~ 10000 ng / L) and PFOA (10 ng / L (~ 10000 ng / L) are guaranteed for quantitative analysis. However, this method requires a large amount of the target sample (more than 1L). This method cannot apply to the consumer products directly.  Furthermore, LC/MS/MS, which is specified in this ISO standard is expensive analytical equipment and has not been spread worldwide yet.  In order to widely spread the measurement techniques that require such advanced technology, it is essential to establish the ultra-trace analysis technique that can confirm by global users.  At least, QA / QC (Quality Assurance and Quality Control) should be carried out by LC/MS which is relatively popular in the global users. The appropriate LOD and LOQ should be established for PFOA.  (References)  1. N. Yamashita et al: Analysis of perfluorinated acids at part-per-quadrillion levels in seawater using liquid chromatography-tandem mass spectrometry, Environ. Sci. Technol., 38(21), 5522-5528 (2004).  2. <http://www.iso.org/iso/catalogue_detail.htm?csnumber=42742> | |
| **Dossier submitter response:**  The Dossier Submitter is grateful for the comments made. According to REACH emissions of PBT substances have to be minimised, thus manufacturing, use and import of PFOA and PFOA-related substances needs to be avoided.  Request 1 and 3  The Dossier Submitter proposed a structural formula to include all possible substances which can degrade to PFOA. This is in line with the restriction on PFOS and the stewardship program of the US-EPA on long chain PFASs. In our view there is no reason to alter the scope of the proposed restriction.  The Dossier Submitter has revised the proposed concentration limit, but we strongly disagree with the same threshold as for PFOS because intentional use of PFOA and related substances cannot be excluded.  Request 2:  The Dossier Submitter is grateful for the new information and will check if it is useful for the SEA.  With regard to item a) of your comment, we would like to highlight the following issues:  The benefits of the proposed restriction have been considered in Section F 1.2 of the Annex XV report. As the concerns related to PFOA and PFOA-related substances are based on their PBT properties it is not possible to reliably quantify the risk or physical damage caused by these substances. Hence, the benefits of the proposed restriction cannot be quantified in terms of avoided risk or damage. In order to still get an indication of the benefits of the proposal, the emissions reduced are used as a proxy of the benefits. This approach is in line with the approach of SEAC to evaluate restriction proposals and applications for authorisation for PBT substances (available at <http://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpvb_substances_seac_en.pdf>). Furthermore, it is important to consider that in REACH PBT/vPvB substances are to be minimised as practically and technically possible based on their inherent properties.  As the restriction proposal is addressing the PBT concern related to PFOA and PFOA-related substances it is in our view not appropriate to carry out a quantitative human health impact assessment including an assessment of QALYs and DALYs. Such an assessment would also be very difficult owing to the lack of data to quantify the impacts and to derive related economic values.  In the Background Document we will include further information to underpin the benefits assessment of the proposal including available data from WTP studies.  We agree that the costs to control compliance with the restriction within complex supply chains are a relevant economic impact of the proposal. These costs have not been quantified due to lack of reliable data.  Request 4:  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available..   * Human Health   The evaluations of PFOA from EFSA are presented in chapter B.5.1.11 of the restriction dossier. The TDI estimated by EFSA was adopted in 2008 and a vast amount of new scientific literature has been published on possible PFOA associated health effects since then. These were not taken into account by EFSA. In our opinion, the data presented in the REACH Annex XV restriction proposal supports a reason for concern.  A vast amount of literature indicating health effects at low blood concentrations of PFOA are important to include in the dossier as well, in making the dossier balanced for the public. If we omit them that would make the dossier unbalanced. We believe there is a weight of evidence for concern in the low dose/blood concentration area as well, especially for the unborn child, which supports a restriction. | |
| **RAC Rapporteurs comments:**  RAC notes the proposal to use specific identifiers for substances intended to be within scope, but the DS has highlighted that many polymers are also sources, and some other industry stakeholders favour an open-list approach, which has already been used for PFOS.  RAC also notes the suggestion to use a limit value that is the same as PFOS under the EU POPs Regulation. This is attractive as it would provide a level of consistency with an existing restriction of a PBT substance. However, the DS points out that this would still allow PFOA to be used in polymer manufacture, which is not desirable. Nevertheless, RAC notes the comment that the proposed limit of 2 ppb is unrealistic, especially as PFOA might be formed through thermal decomposition during processing and this may bring a very large number of substances within scope. In addition, sample contamination is also a real possibility. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future.  The EFSA conclusion is based on risks to human health from food consumption, whereas the restriction proposal is primarily based on environmental risks arising from the PBT properties of the substance for which a safe threshold cannot be reliably established. | |
| **SEAC Rapporteurs comments:**  Thank you for the information.  We agree with the Dossier submitter that the benefits of the proposed restriction cannot be quantified in terms of avoided risk or damage. Using emissions as a proxy of the benefits is the approach supported by SEAC in this situation.  We agree that a revision of the concentration limit is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1213** | **Date:** 2015/02/26 10:45  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes** | **General Comments:**  This is an amendment to comments submitted yesterday. Those comments had reference dbed54e3-8002-4489-95e4-c4df5587a772. | |
| **Answer to specific info request 4:**  **<removed>** offers the following letter as its preliminary comments for the public consultation to the proposed Annex XV restriction report on Perfluorooctanoic Acid (PFOA), its salts and related substances, published on Dec. 17th, 2014 on the ECHA website.  Introduction:  As a result of its decision in May 2000 to phase out of the production and use of C-8 compounds, **<removed>** no longer manufactures perfluorooctanyl compounds. The company ceased the manufacture and use of the vast majority of these compounds within approximately two years of the phase-out announcement, and ceased all manufacturing and the last significant use of this chemistry by the end of 2008. Through its raw material composition identification processes associated with **<removed>**’s policies covering the use of all persistent and bio-accumulative materials, **<removed>** has, on occasion, identified the presence of precursor chemicals in materials received from suppliers that ultimately degrade to PFOA, PFOS, or similar compounds. Upon such identification, **<removed>** works to find alternatives for such materials. This voluntary phase-out of long chain perfluorinated materials by **<removed>** has delivered significant results in the reduction of PFOA in the manufacturing processes of **<removed>**. **<removed>** continues to support reasonable measures to further reduce the use of PFOA and related substances. Despite that commitment on the part of **<removed>**, we have significant reservations regarding a broad-based 2 ppb limit as the most effective way to achieve that objective. **<removed>** believes that regulation of PFOA should be practical and based on risk-benefit analysis.  **<removed>** has reviewed the human health assessment in the dossier and will be providing detailed comments pertaining to the lack of scientific merit on the proposed DNELs and RCRs, which were derived based on a mammary gland development study in mice as well as the statistical associations of cholesterol and lower birth weight with exposures to PFOA from two cross-sectional epidemiological studies. These comments will be relevant to risk / benefit considerations in the proposal.  The proposed Annex XV restriction, published on Dec. 17, 2014, raises concerns for **<removed>** products based on fluorochemical technology as well as its customers and downstream users.  Discussion:  **<removed>** has replaced long chain (C8) perfluorinated chemical building blocks with shorter chain (C4, for example) perfluorinated building blocks and no longer manufactures fluoropolymers using PFOA (salts). However, production of fluorochemical products that do not contain PFOA above the proposed 2 ug/kg threshold may be beyond the limits of **<removed>**´s available technology. In addition, the proposed 2 ug / kg regulatory threshold is at the limits of (non-standardized) analytical technology. Therefore, achieving conformance with the proposed threshold would be very challenging.  Even when PFOA or PFOA-related substances are not intentionally manufactured, processed or used in the manufacturing of fluoropolymers, they may still be present in low quantities. The proposed restriction could create an inordinate need for analytical work along the value chain. Many fluoropolymer processors are mid-sized companies, using a variety of processing methods and conditions. Analysis at this low level of detection would be complex and not justified based the low quantities of PFOA involved.  In our view, a threshold based regulation should have analytical methods that are clearly defined. Sample selection, sample preparation, test methodology, test method quality management, quality standards for laboratories, and easy access to the test for all stakeholders should be clearly understood.  Analytical methods to quantify the PFOA content in surface treatments (hard surface coatings, textiles) are available, but it is very questionable that these methods are robust enough to determine whether the PFOA content in a textile article is below 2 ppb and thus to decide whether an article is compliant or not. Fluoropolymers include elastomers, thermoplastic materials, PTFE, additives, coatings, etc., and these different materials also require different analytical techniques. Currently there is no standard analytical method for all these product forms and matrices. Reliable analytical methods will be challenging for the proposed 2 ppb target.  Therefore, chemical companies, and the converting industry (textile mills, fabric and finished good producers and other coatings or surface treatment formulators) are not in a position to prove compliance of their products (formulations and articles). Member state authorities would have no valid tools to enforce the restriction.  Based on these facts, **<removed>** believes that the proposed 2 ppb restriction level is problematic not only with the achievable manufacturing technology, but also with analytical capabilities.  The significant socio-economic value of fluorochemistry and fluoropolymers is evident from their diverse applications. The proposed restriction would effectively create a ban for technical textiles, as well as consumer textiles having sufficient repellency (especially for oil and chemicals) properties. These properties are specifically needed for personal protective equipment. Some affected areas in textiles include:  - Bullet proof vests for police and armed forces;  - Apparel for fire fighters;  - Protective work wear for chemicals in the chemical and other process industries; and  - Certain textiles used in medical applications requiring repellence of blood.  Fluorochemistry is also used in a wide variety of specialized industrial, commercial, and consumer applications. Specific applications include mining and oil well surfactants, acid mist suppressants for metal plating and electronic etching baths, as well as aftermarket furniture and textile treatments to name a few. In addition, it is difficult to replace fluorochemical based emulsifiers in coatings, metal treatment and other specialty applications by replacement with hydrocarbon products while achieving a similar level of efficiency (low application concentration) and surface tension properties.  Fluoropolymers are widely used in automotive, aerospace, data communication, semiconductor manufacturing, energy generation and storage as well as chemical processing, oil and gas exploration and many, many others. For illustration, essentially all modern gasoline engines are dependent on fluoropolymers for their function. Some of the benefits resulting from chemical resistance over a broad temperature range are safety (e.g. cars, heavy duty equipment or airplanes), environmental protection (emission reduction and corrosion prevention), energy use reduction (low friction applications) and fire protection (via architecture or wire & cable).  Conclusion:  Because of the successful voluntary stewardship effort, the possible unintentional presence of small quantities of PFOA in fluoropolymers, the significant overall analytical challenges, and the remarkable range of benefits to safety, environment, and quality of modern life, **<removed>** respectfully requests that the option is considered whereby fluoropolymers (and the articles made from them) be exempt from the proposed restrictions, if they are made without the use of PFOA or PFOA related substances. As for the other uses of fluorochemicals, **<removed>** suggests basing any limit for PFOA on a risk based assessment and supported by the available toxicological data and not merely on an assumed 2 ppb analytical detection limit capability. We believe that this step would not undermine ECHA’s overall objective of real reductions in PFOA and related substances, but enhance it by making it more workable and enforceable.  **<removed>** intends to provide additional detailed comments and appreciates your consideration. | |
| **Dossier submitter response:**  The Dossier Submitter is grateful for the comments made  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised. Hence a risk based assessment is not appropriate under REACH.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  According to other manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chainC6 chemistry. Since a shift to short-chain- chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the manufacturing and use of fluoropolymer with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing fluoropolymers. Fluoropolymers manufactured without PFOA are already available on the market and will not be affected by the proposed restriction. | |
| **RAC Rapporteurs comments:**  RAC notes that the proposed limit of 2 ppb may be beyond the limits of available technology in terms of both production (since unintentional contamination is hard to avoid) and chemical analysis. In particular, RAC agrees that a standardised analytical method that can be used for a variety of treated materials will be an important component of the risk management of PFOA. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future.  RAC notes the widespread use of fluoropolymers, which creates both a variety of benefits but also a widespread source of PFOA. The request to explicitly derogate fluoropolymers made without the use of PFOA or PFOA-related substances (and the articles made from them) has not been accepted. Whilst RAC agrees that such a derogation could avoid unnecessary chemical analysis, other administrative means can be used to enforce the restriction, and the scope is clear. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that a revision of the concentration limit is necessary to ensure that the continued use of the short-chain alternatives will be allowed. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances.  We recognize that the performance of short chain alternatives may not yet be sufficient for use in protective professional textiles and we support a transition period of 6 years to give more time for the development of alternatives. We also see it necessary that the state of the art will be examined in 5 years and that any necessary changes to the scope of the restriction will be made by the Commission. | |
| **1214** | **Date:** 2015/02/26 17:26  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes** | **General Comments:**  Proposal to restrict PFOA and precursor products - Annex XV PFOA PFOA salts and related substances  Dear Sir /Madam  As manufacturers of specialist protective fabrics that require not only water, but more importantly oil & chemical repellence for the protection and safety of workers and individuals in key industry segments i.e. Oil & Gas, Chemical industries and Military, we would like to point out some findings of our research and our concerns regarding the draft proposals.  It is our understanding that the restriction will remove from the EU market all so called C8 fluorocarbons that can be applied to textiles i.e. have various groups that allow for an aqueous application.  It is our understanding that the proposal suggests that either non fluorinated type chemistry or so called C6 fluorocarbons are thought to be able to give similar technical performances.  We have the following concerns:   In specific cases we have found that the C6 fluorocarbons or other non-fluorinated chemical based repellents do not meet the technical specifications required to offer wearer safety in critical work environments.   The vast majority of analysis carried out on fabrics is related to the sport/leisure and fashion industry segments where historically fluorocarbons were used for imparting water repellence and easy clean finishes. Alternative chemistries suggested in the proposal would be technically suitable for sports/leisure end uses but not suitable for protective clothing requiring oil and chemical resistance/repellence. Imposing the restrictions would lead to a reduction in the performance and safety of specialised protective wear for millions of wearers.   Specifically there are technical gaps to the requirements for the UK Defence Ministry for soldiers uniforms for oil, petrol and improvised ignition sources leading either to under performance in repellence and/or reduced flame retardancy due to a higher retained flammable substance in risk situations.   Specifically there seem to be technical gaps to tests regarding the repellency of certain biological agents having oil like properties for soldiers CBRN (chemical, biological, radiation, nuclear) protective clothing and supporting equipment.   Specifically there are technical gaps for performance for the oil industry for both light and heavy fractions leading to higher flammable liquid retention and thereby reduced flame retardant performance of the fabrics.   Specifically the reduced performance in the chemical industry where wearers need to be protected from chemical splash to prevent injury will undoubtedly result in a significant increase in the number of workplace injuries and fatalities.   Socio economic factors   As exporters to countries outside of the EU we will face socio economic discrimination as our finished products will be significantly more costly (estimated at 30%) and show lower performance than our none-EU competitors but even for sale in the EU it may be that the none EU competitors will have access to chemistry that is not allowed in the EU due to the blanket 2 ppb restriction.   It is, in our experience, unlikely that our export customers will accept a premium price for our manufacture on the basis of the improved environmental profile alone, when the key objective is personal safety and saving lives.  We see the restriction as having a limited effect and will lead to an export of the problem to other countries with a probable overall negative impact on the global pollution levels as the manufacture will move out of EU and will be re-imported as finished articles and at a greater overall pollution. The EU authorities seem to want to rely on declarations and very limited testing of imported articles as a means of controlling the problem.  This type of cause and effect has already been seen in the textile industry through many years of loss of local production and as a consequence very high pollution levels in Asian and other countries leading to an overall increase of pollution worldwide due to inadequate regulation. In this case it was driven caused by socio economic factors (people wanting cheaper clothing and by the marketing driven change in expectations of fashion clothing).  A far more effective measure to reduce the effect from the textile industry as a whole would be to review the textile article types that contain PFOA and impose restrictions on articles that do not require fluorocarbon finishes e.g. water repellent clothing for sports/leisure where there are technically suitable alternatives. At this current time the benefits in terms of protection and safety for oil/chemical and military end and the lives saved using fluorocarbon far outweighs the environmental benefits.  One final area of concern is the lack of clarity and reliability on the method of testing to 2ppb on repellent fabrics as there does not yet seem to be a recognised method of test. Please can you confirm the test methods, degree of accuracy as this is still unclear. Any restrictions would lead to our customers requesting proof of compliance from ourselves. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction for textile applications because they are a major source of PFOA exposure, but shares concerns that the proposed restriction may affect the performance of personal protection fabrics for professionals. No information was provided in the comment about the likely level of emissions of PFOA/PFOA-related substances from these applications. The request for exemptions cannot be supported from an environmental risk perspective, but RAC can support longer transitional periods for safety critical applications, such as PPE (which perhaps could be subject to a review clause).  RAC also acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future.  See also response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for the information.  We recognize that the performance of short chain alternatives may not yet be sufficient for use in protective professional textiles and we support a transitional period of 6 years to give more time for the development of alternatives. We also see it necessary that the state of the art will be examined in 5 years and that any necessary changes to the scope of the restriction will be made at that point in time. | |
| **1215** | **Date:** 2015/02/26 18:49  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Switzerland  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Values given in the confidential attachment are CBI as they refer to our production location, produced volumes, impurity level or plant emission estimations | **General Comments:**  Our company welcomes the initiative of Germany and Norway to propose a restriction of PFOA and PFOA-related substances under REACH. We are a signatory company of the US EPA PFOA Stewardship Programme and as such we are committed to phasing out PFOA and C8 production by the end of 2015.  However, our company is very much concerned that the restriction proposal may not only ban the manufacturing of PFOA and PFOA-related substances but would also ban the manufacturing of short-chain fluorotelomer alternatives (or “C6” substances), although for most applications they are the main alternatives known to date to the C8 PFOA-related substances. We welcome the fact that the restriction proposal considers the possibility of a derogation for the “production of short-chain fluorinated alternatives” (as part of Risk Management Option 1b, p.158).    C8 FRACTION AS UNAVOIDABLE BYPRODUCT IN THE C6 PRODUCTION PROCESS  The need for a derogation is due to the fact that the first step of the production of short-chain fluorotelomer alternatives, the so-called “telomerisation process”, leads to the production of an unavoidable fraction of C8 substances belonging to the PFOA-related substances to be restricted. Importantly, neither PFOA, nor PFOA-related substances are “used” in the manufacturing of C6 substances. The C8 fraction is an unintentional byproduct occurring during production. It is an isolated intermediate, it is not a commercial product. The amount of this C8 residual fraction has been continuously reduced in the course of past years to XX% [please refer to point 1 in the confidential attachment]. The derogation should cover the unintended manufacturing of a fraction of C8 Iodide and ethyl iodide (C8F17-I; C8F17-CH2-CH2-I) as isolated intermediate during the C6 telomerization process.  OUR PLANT IS THE ONLY SITE IN EU DOING TELOMERISATION  Our plant in Germany is the only site within the EU where the telomerization process takes place, more generally the only production site in the EU where the entire production process of C6 alternatives takes place. All the other manufacturers of short-chain alternatives worldwide do telomerization outside Europe, importing to Europe the (post-telomerization) short-chain products.  C6 PRODUCTION UNDER STRICTLY CONTROLLED CONDITIONS.  All steps of C6 production take place under strictly controlled conditions as defined in REACH. All intermediates have been registered accordingly. The main SCC components can be described as follows:  - All production units are linked by closed pipes  - Between the units there are tanks buffering the products  - In all units emissions are handled with either adsorption, incineration or waste water technology  - Waste disposal of fluorine containing products takes place by a special waste incineration company  - All production people are supervised, trained and skilled personnel  - All procedures are well documented and most of them are controlled by a process control system  - Ongoing monitoring in order to ensure continuous improvement  FULL SWITCH TO C6 PRODUCTION BY THE END OF 2015  As a signatory of the US EPA Stewardship Programme, we are committed to phasing out C8 production (as such, not related to C6 production) by the end of 2015. After that date, our company will convert to full C6 production. As a result of the conversion to full C6 production, the only C8 fraction that will be produced will be the unavoidable C8 residual fraction related to C6 production.  For a production of C6-based fluorotelomers at our EU site of XX (please refer to point 2 in the confidential attachment), according to our estimates, this will represent PFOA emissions of XX and C8 emissions (sum of all C8) of XX per year (please refer to point 3 in the confidential attachment).  REWORK OF THE C8 FRACTION  As mentioned, our company has been working on a R&D project in order to rework the C8 residual fraction into C6 production. The technology has shown promising results and it is expected to be investigated and approved at the end of 2015. The derogation should also allow for the reprocessing of the C8 fraction back into C6 production under strictly controlled conditions.  IMPACTS OF A BAN ON C6 MANUFACTURING  The consequences of an absence of derogation will be far reaching. Our plant would have to cease its activity leading to several hundred job losses (from production, R&D, marketing and sales). It would result in the loss of the unique European site for know-how and innovation in fluorochemistry. A planned several million euro investment would have to be cancelled. Such a decision would furthermore place the EU chemical industry in a competitive disadvantage, as non EU-producers will not be impacted by the restriction. More information is provided in our response to Question 2.  SUMMARY ON SCOPE AND NEED FOR A DEROGATION  The derogation should cover both the unintended manufacturing of a fraction of C8 Iodide and ethyl iodide (C8F17-I; C8F17-CH2-CH2-I) as isolated intermediate during the C6 telomerization process, and the reprocessing of that fraction back into C6 production, provided the entire process takes place under strictly controlled conditions”.  Without such a derogation, the C6 production in the EU would have to stop leading to significant impacts in terms of employment and placing European industry at a competitive disadvantage, whereas the production of C6 fluorotelomer alternatives would take place under strictly controlled conditions with minimal emissions of C8 substances. Therefore, we believe that the socio-economic impacts of a ban of C6 alternatives would be significantly disproportionate compared to its limited environmental benefits.  THRESHOLD OF 2ppb AND ANALYTICAL METHODS  In addition, our company is concerned by the proposed single threshold of 2ppb for PFOA and PFOA-related substances. A threshold of 2ppb applicable for all substances in scope and all types of products would technically mean a de facto ban of C6 alternatives and of articles treated with C6 alternatives.  The threshold should be set at a level of quantification that safeguards the placing on the market of C6 alternatives and that must be applicable by industry and enforceable by Member States on the basis of robust analytical methods with proven repeatability and reproducibility (please refer to our response to question 4 for more information).  Thus, one can conclude that without a derogation for C6 manufacturing and without appropriate thresholds, the REACH restriction of PFOA and PFOA-related substances will not achieve its desired effect to the extent of even contradicting REACH restriction principles according to which a restriction “shall take into account the socio-economic impact of the restriction, including the availability of alternatives” (Art. 68 (1)).  The hereby contribution aims to provide an overview of our key messages in support of a derogation for the manufacturing of C6 production as well as a revised 2ppb threshold. Our company will submit a more detailed input within the second half of the public consultation period. | |
| **Answer to specific info request 1:**  Our company believes that the short-chain fluorotelomer alternatives can deliver the same performance as the long-chain products they replace.  We are a signatory company of the US US EPA Product Stewardship Program [http://epa.gov/oppt/pfoa/pubs/stewardship/index.html] which is committed to phasing-out PFOA, precursor chemicals that can break down to PFOA, and related higher homologue chemicals. As other signatories, our company has also made significant investments (over €15 million over the past years) in the development of fluorotelomer alternative products that are suitable for substantially all products with improved environmental and human health profiles (See, e.g., Environ report, available at http://fluorocouncil.com/PDFs/Assessment-of-POP-Criteria-for-Specific-Short-Chain-Perfluorinated-Alkyl-Substances.pdf). | |
| **Answer to specific info request 2:**  Our company is concerned that the restriction dossier does not provide an assessment of the socio-economic impacts that would be induced by a ban on the manufacturing of short-chain fluorotelomer alternatives. We would like to underline that such impacts will be far reaching. If no derogation is granted, our EU plant will have to close down, resulting in over XX direct job losses from production, R&D, marketing and sales (please refer to point 4 in the confidential attachment) and stopping a planned €XX investment (please refer to point 5 in the confidential attachment) in the rework of the C8 fraction and C6 production technology. Furthermore, it should be highlighted that non-EU producers will not be impacted by the REACH restriction. If the only EU supplier of C6 were to be forced to cease production, European downstream users in textile and paper sectors will have to rely entirely on imports from non-EU countries. We may argue that it will be more difficult to prevent imports of C6 commercial products possibly produced under less rigorous environmental conditions, and with a higher risk of non-compliance with the restriction on C8 content. We are also concerned that a REACH restriction that would ban the manufacturing of the main alternatives to the target substances could have a knock-on effect, choking off investments in innovation and know-how in the European chemicals sector. Therefore, statements in the restriction dossier (p. 176) such as “The proposed restriction is not expected to have major effects on employment”, or […]it is not expected that there will be a significant loss (or gain) in employment in the EU due to the closing down and/or relocation of business activities”, are not correct and ignore the impacts of not granting the derogation for short-chain alternatives manufacturing. | |
| **Answer to specific info request 3:**  We have no specific contribution to provide to that question | |
| **Answer to specific info request 4:**  Our company is concerned by the proposed single threshold of 2ppb for PFOA and PFOA-related substances. Under current state-of-art manufacturing practice it is not possible to ensure a level below or equal to 2ppb for all substances and all products to be restricted for the following reasons:  - C8 impurity levels in intermediates and mixtures are not the same. Different thresholds for C6 transported intermediates and mixtures are needed.  - No single methodology available to detect such a low threshold for all substances within the scope of the dossier.  - Analytical methods are matrix dependent.  - Such a low threshold of 2ppb would increase probability of encountering false positives.  While we are confident about our PFOA levels (please refer to point 6 in the confidential attachment] at this stage, in the absence of validated analytical methods for PFOA-related substances, we cannot provide levels that would apply to each individual substance to be restricted and to all products in scope.  Furthermore, the proposed threshold is inconsistent with approaches proposed in Norwegian PFOA restriction and existing PFOS POP restriction.  Any threshold should be set at a level of quantification that safeguards the placing on the market of C6 alternatives and that must be applicable by industry and enforceable by Member States on the basis of robust analytical methods with proven repeatability, reproducibility, and taking into account the risk of cross-contamination. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  General comments  According to Art. 68 (1) of REACH on site isolated intermediates are exempted from restriction. Therefore derogation for unintended manufacturing of a fraction of C8 Iodide and ethyl iodide (C8F17-I; C8F17-CH2-CH2-I) as isolated intermediate during the C6 telomerization process, and the reprocessing of that fraction back into C6 production is not necessary.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  Request 1  The Dossier submitter is grateful for the comments made.  Request 2  As it is not our intention to ban short-chain alternatives (see our response above), the revised concentration limit will allow to use these substances to substitute PFOA and PFOA-related substances. With this condition, we consider the socio-economic assessment in the Annex XV report to be generally valid.  Request 4  The Dossier submitter is grateful for the comments made and will consider it when revising the threshold values for PFOA and PFOA-related substances.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that C6 chemistry represents an important alternative to PFOA-related substances, and that the proposed restriction must not prevent the continued production and use of such substances.  RAC notes the DS’s response that restriction does not apply to on-site isolated intermediates, and has recommended a derogation for intermediates transported and used under strictly controlled conditions (since the risks are likely to be similar).  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future.  RAC also notes the suggestion to use the same limit value as PFOS under the EU POPs Regulation. This is attractive as it would provide a level of consistency with an existing restriction of a PBT substance. However, this would still allow PFOA-related substances to be present in polymers, which is not desirable since they are a source of widespread environmental exposure. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that revision of the proposal to ensure that the continued use of short-chain alternatives will be allowed is necessary. Derogation for transported isolated intermediates is foreseen in this regard. We also support higher general concentration limits (25 ppb for PFOA and its salts, 1000 ppb for PFOA-related substances). | |
| **1216** | **Date:** 2015/02/27 11:12  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  EPCG - European Pulp and Paper Chemicals Group  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  As requested by ECHA, EPCG submits these comments in due time before 1 March 2015 to allow first discussions in ECHA´s Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC). EPCG would like to reserve its right to submit a more detailed comment by 17 June 2015.  EPCG supports the approach to restrict the use of PFOA and PFOA- related substances in paper applications but objects to the restriction in its current version. Rationale:  • The report mentions that the most important substitutes for PFOA and PFOA-related substances are short-chain PFASs. Due to the proposed limit in chemical formulations of 2 ppb such alternatives are not available.  • The lack of robust analytical methods will not allow companies to prove compliance. But also Member State authorities will have no tools to enforce the restriction. | |
| **Answer to specific info request 1:**  The proposed threshold of 2ppb in mixtures and articles puts a direct ban to the placing on the market and use of the most important short-chain alternatives as well as articles treated with short-chain alternatives.  According to calculations, a PFOA-content below 2 ppb in chemical mixtures might be achievable in future, but a limit of 2ppb for PFOA- related substances (e. g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate) is definitively not feasible.  The threshold should be set at a level that safeguards the placing on the market of short-chain alternatives, namely intermediates, mixtures, and articles treated with short-chain alternatives.  It takes time to provide a realistic estimation of a threshold based on the possible C8 fraction in commercial C-6-formulations. We would like to refer to our detailed comments that will be submitted by 17 June 2015.  Thresholds must be supported by robust analytical methods that must be uniformly applicable by industry and enforceable by Member State authorities. Methods with detection level in the 2 ppb range are currently not available for all of the C8 substances in scope of the restriction dossier. | |
| **Answer to specific info request 2:**  It is mentioned in the dossier that short chain PFASs are the most important alternatives for PFOA and PFOA-related substances. In fact this information is misleading. Due to the proposed limit in chemical formulations of 2 ppb, short-chain PFASs compliant to this limit are not available on the market. Therefore the presented calculations were carried out on a false basis. | |
| **Answer to specific info request 3:**  No information available at EPCG. | |
| **Answer to specific info request 4:**  a) In view of the 2ppb limit for PFOA and PFOA-related substances in chemical formulations there will be no short-chain PFASs available as substitutes for the C-8-compounds. A PFOA-content below 2 ppb might be achievable in future, but a limit of 2ppb for PFOA-related substances (e. g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate) is not feasible.  b) • Analytical methods to quantify the PFOA-content in paper are available but it is very questionable that these methods are robust enough to determine whether the PFOA-content in a textile article is below 2 ppb or not and to decide whether an article is compliant or not.  • There are no analytical methods available to quantify PFOA- related substances (e. g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate) in paper articles according to the limit of 2ppb.  • Analytical methods to quantify PFOA and related substances in chemical formulations according to the 2ppb limit are not available.  • Experiences from ongoing work to develop test methods for PFOS cannot be transferred to testing of PFOA and PFOA related substances because the threshold of 2 ppb is so much lower as for PFOS.  • Therefore, industry will not be in the position to prove compliance of their products (both formulations and articles). Member State authorities will have no tools to enforce the restriction. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  Request 1 and 2:  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  Request 4:  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that revision of the proposal to ensure that the continued use of the short-chain alternatives are allowed is necessary. We support higher concentration limits (25 ppb for PFOA and its salts, 1000 ppb for PFOA-related substances). | |
| **1217** | **Date:** 2015/02/27 11:38  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes**  **Attachment confidential:** **No** | **General Comments:**  Dear Sirs,  Following the publication of the restriction dossier entitled, “Annex XV Restriction Report Proposal for a Restriction, Substance name: Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances” **<removed>** would like to offer the following comments as part of the initial public consultation period. **<removed>** will be submitting a more comprehensive response prior to the conclusion of the extended consultation period in June.  **<removed>** supports the reduction in the overall environmental impact of fires, and of firefighting foams for use at emergency incidents and during training exercises. It is our goal to work with regulatory bodies to reduce the environmental footprint of our products, whilst improving their performance. The proposed level of 2ppb for PFOA and PFOA-related substances is at such a level to prevent the sale, use and movement of raw ingredients throughout the EU for the production of short-chain (C6) fluorochemical based foams, as listed in section C1 as a viable alternative (Identification of potential alternative substances and techniques).  It is the recommendation of **<removed>** that an impurity level be implemented which prevents the manufacture and use of long-chain (C8) based foams, whilst allowing the manufacture and use of short-chain alternatives.  Further comments have been submitted to each consultation question.  For and on behalf of **<removed>**,  Yours Sincerely,  **<removed>**  Global Product Manager – Firefighting Chemicals | |
| **Answer to specific info request 1:**  With regards to technical information for alternatives; C6 based foams offer a viable alternative to C8 based foams, as highlighted in section C1. With the current level of 2ppb for PFOA and PFOA-related substances, this is so low as to effectively ban the very alternative identified within the Dossier. Section C1 also identifies non-fluorinated alternatives, however their performance to-date has not consistently met the performance of fluorinated foams and therefore cannot be considered a viable alternative throughout the EU for all applications. EN1568 part 3 and 4 test results show that broadly speaking, fluorinated AFFF foams show a performance grade of 1A/1A/1A/1A/1A/1A whilst most fluorine free “alternatives” have performance levels of 3B, and in some cases, not tested against all water qualities and/or fuels. C6 chemistry based foams retain their performance whilst, in some cases, drastically reducing the amount of fluorinated components required contrary to what the Dossier lays out on page 171.  It is the recommendation of **<removed>** that an impurity level be implemented which prevents the manufacture and use of long-chain (C8) based foams, whilst allowing the manufacture and use of short-chain alternatives. | |
| **Answer to specific info request 2:**  Due to the timing constraints of the preliminary deadline, it has not been possible to collate sufficient evidence based data to answer this question. **<removed>** is working closely with EU and international representative bodies to ensure the Committees are furnished with adequate data. | |
| **Answer to specific info request 3:**  Our response to Q3 is more of a comment about language used throughout the Dossier. The fluorotelomer alcohol (8:2 FtOH) has been identified in the proposal for restriction not only as a related substance to PFOA, but also as a precursor whose breakdown in the environment can lead to the formation of PFOA. Furthermore the transport properties of 8:2 FtOH are such that it is considered to be significantly responsible for the global distribution of PFOA.  Because of the role of 8:2 FtOH it is important to distinguish between uses for perfluorinated chemicals where it is either a deliberately added component or unwanted by-product, and those where it plays no part whatsoever.  The latter is particularly so for the AFFF surfactants that are included in firefighting products and is clearly demonstrated by the reaction pathway shown. Consequently it can be seen that those AFFF surfactants used in fire-fighting products are not a source of 8:2 FtOH. | |
| **Answer to specific info request 4:**  Information has been requested from various suppliers to **<removed>** in order to submit a full and considered response to this point, however prior to the deadline for submission, information was only forthcoming from one. Early indications suggest that raw material procurement for the production of fluorinated firefighting foams will be effectively banned under the current limit of 2ppb.  Analytical methods for testing fluorosurfactant chain lengths within a finished firefighting foam matrix is challenging and **<removed>** will strive to provide further information prior to the conclusion of the consultation period. Preliminary investigations show that the foam matrix must be diluted for analysis, preventing a LOD of 2ppb, but rather 10-100ppm. Investigations are continuing.  It is the recommendation of **<removed>** that an impurity level be implemented which prevents the manufacture and use of long-chain (C8) based foams, whilst allowing the manufacture and use of short-chain alternatives. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short- chain products are already in the trace level range. With the revised concentration limit proposed it is ensured that short- chain chemistry and consequently fire-fighting foams based on short- chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short- chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb. RAC is concerned about contradictory claims about the possibility of using fluorine-free foams at airports and for oil installations, but efficacy is an issue for SEAC.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We recognise the problems relating to PFOA and PFOA-related substances being found as impurities in short-chain alternatives. We consider it vital also from the proportionality perspective that short-chain alternatives will continue to be available. RAC and SEAC suggest general limit values of 25 ppb for PFOA and 1000 ppb for PFOA-related substances. SEAC further suggests that for firefighting foams, the 1000 ppb level would be applied to both PFOA and PFOA-related substances. | |
| **1218** | **Date:** 2015/02/27 12:38  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** This response is confidential (CBI) as it derives from analyses of our company’s commercial products and revealing this information to competitors would undermine our company’s intellectual property and thus our commercial interests (article 4 paragraph 2 of Regulation (EC) No 1049/2001 applies). | **General Comments:**  The company wishes to submit comments regarding the suitability of the proposed concentration limit of 2 ppb and to share its experience on applicable analytical methods. | |
| **Answer to specific info request 4:**  It should be noted with respect to textiles treated with Telomer based polymeric products that textile mills may process, during a transition period, both long-chain telomer based products and short chain alternatives. This, as well as historic production with long-chain products, could cause cross contamination exceeding the proposed concentration limit. The Commission is requested to consider this under transitional arrangements. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comment made.  The Dossier submitter is aware that contamination can take place. However, according to REACH emissions of PBT substances have to be minimised. Unfortunately no values for the contamination of PFOA have been provided. Therefore the Dossier submitter cannot take this into consideration when proposing new threshold values.  comment to confidential attachment:  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short- chain PFAS can be manufactured and used. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the issue of contamination of samples is an important issue, that may be particularly problematic if the selected limit is very low. A standardised analytical method also needs to be established for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information especially on the feasible limit value. We agree that a revision of the concentration limit is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances; these values are understood to be feasible more generally for the different sectors affected. | |
| **1219** | **Date:** 2015/02/27 13:21  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United States  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Disclosure or permitting access to any of the information contained in the document attached to this Section V would undermine the protection of the commercial interests including intellectual property of **<removed>** Company and its subsidiaries. | **General Comments:**  An extension of the restriction to 2020 is requested to allow for the phase out of our commercial use of a PFOA-related substance.  Despite a significant substitution effort, a viable alternative has not been identified.  As proposed, the restriction would force customers to invest in new equipment. Most small to medium enterprises (SME) typically cannot readily absorb the replacement costs. Revenue and labor impacts can be expected. Existing equipment would need to be scrapped before reaching its end of life (E0L). This would be environmentally counterproductive.  In addition, alternative technologies have different, but significant health and environmental impacts.  Specific information is included in the confidential attachment. | |
| **Answer to specific info request 1:**  Information has been provided in confidential section and contains information about specific uses, substitution efforts, and volumes of the substances. | |
| **Answer to specific info request 2:**  We do not consider the presented calculations to be representative of our commercial use.  Costs specific to our use, including financial impacts to SME’s are included in the confidential attachment. | |
| **Answer to specific info request 3:**  No. | |
| **Answer to specific info request 4:**  We are concerned that the proposed 2 ppb threshold limit will be difficult to verify for fluoropolymers and alternative fluorosurfactants that may be used in our products.  We understand that alternative thresholds are currently being evaluated by the FluoroCouncil and support the development of matrix-specific thresholds and better-defined analytical protocols for verification. | |
| **Dossier submitter response:**  Request 1:  Considering the decreasing amounts and the short transition period requested the Dossier submitter would agree to grant a longer transitional period for the described commercial use.  Request 2  Thank you for the new information. We will consider it in the further development of the Background Document. We agree that the conditions of the specific use reported so far are not reflected in the assessment of economic impacts of the restriction proposal in the Annex XV report.  Request 4  It is not our aim to restrict the short chain alternatives and fluoropolymers manufactured without PFOA with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS and fluoropolymers manufactured without PFOA can be manufactured and used. | |
| **RAC Rapporteurs comments:**  No information has been provided to indicate that the uses of the respondent are low risk, and the (confidential) tonnage involved is not insignificant. RAC therefore cannot support a derogation on the basis of low risk. However, RAC notes that this company requests a derogation until the end of 2020, which would delay emission reduction but may be acceptable from a socio-economic perspective. RAC considers that the alternative proposal for a low volume exemption, whilst dealing with a use that should reduce in time, would not provide any regulatory pressure to transition away from this chemistry.  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. There seems to be a clear decreasing trend in emissions approaching zero within a short period of time, and the costs from advanced replacement of the printers in use would seem relatively high. Taking into account the information provided in the confidential attachment and that phase-out is already well underway, SEAC supports an extended transitional period of 5 years for this use. | |
| **1219b** | **Date:** 2015/02/27 14:08  **Type:** BehalfOfAnOrganisation  **Org. type:** National NGO  **Org. name:** Swedish Society for Nature Conservation  **Org. country:** Sweden  **Company name confidential:** **No** | **General Comments:**  Swedish Society for Nature Conservation (SSNC) agrees with the dossier authors that an EU restriction is the best way to protect humans and wildlife from PFOA and PFOA-related substances, since many imported consumer articles contain PFOA or PFOA-related substances.  SSNC would like to stress the importance with an EU restriction to further decrees the PFOA levels found in humans and wildlife. PFOA are found in all humans (1) and it is transferred to the unborn child, as well as to infants via the mothers’ milk (2).  SSNC sees a problem with substitution to other per- and polyfluorinated substances, since it is likely that they also are persistent (3). Only substances shown not to be persistent should be allowed as substitutes.  Examples of substitutions can be found on SubsPort:  <http://www.subsport.eu/case-stories/374-EN>  <http://www.subsport.eu/case-stories/362-EN>  <http://www.subsport.eu/case-stories/234-EN>  <http://www.subsport.eu/case-stories/184-EN>  <http://www.subsport.eu/case-stories/070-EN>  References:  1) Temporal changes (1997-2012) of perfluoroalkyl acids and selected precursors (including isomers) in Swedish human serum. Gebbink WA, Glynn A, Berger U. Environmental Pollution 199 (2015) 166-173.  2) Endocrine disrupting properties of perflorooctanoic acid. White SS, Fenton SE, Hines EP. J Steroid iochem Mol Biol. 2011 October; 127(1-2): 16-26.  3) A modeling assessment of the physicochemical properties and environmental fate of emerging and novel per- and polyfluoroalkyl substances. Gomis MI, Wang Z, Scheringer M, Cousins IT. Sci Total Environ. 2015 Feb 1;505:981-91. doi: 10.1016/j.scitotenv.2014.10.062. Epub 2014 Nov 8. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the information provided.  The Dossier submitter is aware that the short- chain PFAS are also persistent. However, persistence alone is not sufficient to identify substances of very high concern under REACH. The data set available today does not allow a thorough PBT assessment. Therefore, these substances will be assessed during the substance evaluation.  We have included the information from Gebbink et al. (2015) on the increased human serum levels of linear PFOA between 1997 and 2012 in the background document. | |
| **RAC Rapporteurs comments:**  The restriction cannot specify which substances should be used as substitutes. Alternative substances that pose a lower level of hazard/risk are clearly preferable to the use of PFOA and related substances. High persistence is undesirable from an environmental view point, but this does not in itself make substances harmful. Nevertheless, RAC would welcome further research into the hazards and risks of all alternative substances. | |
| **SEAC Rapporteurs comments:**  Thank you for the information on non-persistent alternatives. The hazard/risk levels of alternatives were considered qualitatively when assessing the proposed restriction. | |
| **1221** | **Date:** 2015/02/27 15:00  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  PlasticsEurope  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  Driven by the successful PFOA voluntary stewardship effort, the significant analytical challenges, and because they enable a remarkable span of benefits to safety, environment, and quality of modern life, PlasticsEurope requests that ECHA consider an option whereby fluoropolymers (and the articles made from them) be exempt from the proposed restrictions, if they are manufactured without the use of PFOA or PFOA related substances. It is believed that this step would not undermine ECHA’s overall objective of real reductions in PFOA and related substances. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comment made.  It is not our aim to restrict the manufacturing and use of PTFE or other fluoropolymers with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers. PTFE manufactured without PFOA is already available on the market and will not be affected by the proposed restriction. | |
| **RAC Rapporteurs comments:**  RAC notes the widespread use of fluoropolymers, which creates both a variety of benefits but also a widespread source of PFOA, and therefore supports the aim of the DS. The request to explicitly derogate fluoropolymers made without the use of PFOA or PFOA-related substances (and the articles made from them) has not been accepted. Whilst RAC agrees that such a derogation could avoid unnecessary chemical analysis, other administrative means can be used to enforce the restriction, and the scope is clear  RAC notes the suggestion to require manufacturers of fluoropolymers to abide by a certification scheme. RAC notes that certification is not a REACH instrument, and it is unclear which actor(s) would be responsible for the certification procedure. Certificates could, however, be a good additional voluntary measure to help demonstrate compliance and promote the use of fluoropolymers made without PFOA.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We agree with the Dossier Submitter regarding the scope. | |
| **1222** | **Date:** 2015/02/27 15:16  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Guarniflon SpA  **Org. country:** Italy  **Company name confidential:** **No** | **General Comments:**  Guarniflon, as a producer of fluorinated polymers, fluorinated surfactants and as a transformer of PTFE, declare its interest to submits the comments to the restriction proposal on Perfluorooctanoic acid (PFOA), its salts and PFOA- related substances, before 1 March 2015. Guarniflon would reserve it´s right to submit a more detailed comment by 17 June 2015.  Guarniflon is informed of the potentially risk of PFOA and PFOA related substances, and supports the restriction of the use of these substances, but challenge the presented restriction for following reasons:  - Restriction report proposal mentions that the most important substitutes for PFOA and PFOA related substances are short-chain PFASs. Due to the proposed limit in chemical formulations of 2 ppb such alternates are not available.  - The lack of robust analytical methods will not allow companies to prove compliance. Member state authorities will have no tools to enforce the restriction. | |
| **Answer to specific info request 1:**  As mentioned in the reports the alternatives to PFOA- related substances are short-chain PFASs. In these last years Guarniflon increased the portfolio of the C6 fluorocarbon range, but the limit of 2ppb in mixtures would ban these products from the market. A limit of 2ppb for PFOA related substances is not sustainable.  Our fluorinated polymers are usually used in a concentration of 10% w/w (approximately 2,5% of active matter), and our fluorinated surfactants are used in a concentration of 0,01-0,1% w/w (active matter). In these concentration the final mixture can respect the limit of 2ppb but is necessary to have a robust analytical methods with a LOD below or equal to 2ppb. This method a LOD in the 2 ppb range are currently not available for all C8 substances in scope of the restriction dossier. | |
| **Answer to specific info request 2:**  As mentioned Guarniflon alternatives for PFOA and PFOA-related substances are C6 fluorocarbons. We agree on the estimated increase of the cost of 20% indicated in the report. But we want to underline that to have the same performance is necessary to use more C6 fluorocarbons than C8 fluorocarbons in coating applications. | |
| **Answer to specific info request 3:**  No information available | |
| **Answer to specific info request 4:**  Limit of 2ppb for PFOA and PFOA related substances in chemical formulations would eliminate from the market the majority of the alternative products already available as substitutes for the C-8-compounds.  There are no analytical methods available to quantify PFOA related substances in textile and stone articles treaded with fluorocarbon products, according to the limit of 2ppb.  Analytical methods to quantify PFOA and related substances in chemical formulations according to the 2ppb limit are not available. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the information provided.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  It is not our aim to restrict the short chain alternatives and fluoropolymers manufactured without PFOA with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFASs and fluoropolymers manufactured without PFOA can be manufactured and used. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that revision of the proposal to ensure that short-chain alternatives are allowed to be used is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1223** | **Date:** 2015/02/27 16:36  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Mineralölwirtschaftsverband  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  1. Allgemeines  Die Feuerwehren in der Mineralölindustrie setzen bei der Brandbekämpfung in Raffinerien, Tanklagern und Ölterminals Schaumlöschmittel ein, in denen per- und polyfluorierte Tenside enthalten sind. Der bevorzugte Schaumtyp für die Brandbekämpfung in der Erdölindustrie sind Konzentrate, die eine sehr gute „Rückbrand“-Resistenz besitzen, sehr gute Fließverhalten aufweisen, darüber hinaus über schnelle Löscheigenschaften verfügen und die gültigen Umweltschutzstandards einhalten.  Aufgrund der Lagerung und Verarbeitung von sehr großen Mengen an brennbaren Flüssigkeiten in der Mineralölindustrie müssen vor der Beschaffung von Schaumlöschmitteln, die in Raffinerien, Tanklagern und Ölterminals zum Einsatz kommen sollen, deren Eignung nach bestimmten europäischen Normen und Brandtestverfahren überprüft und zudem die Eignung der Schaumlöschmittel möglichst bei realen Brandbekämpfungen nachgewiesen worden sein. Infolge der gerade in den letzten Jahren gestiegenen Umweltschutzstandards (PFOS Beschränkung) lassen sich die Feuerwehren vor einer Beschaffung von Schaumlöschmitteln deren Zulassung und Einhaltung der Umweltschutzstandards durch den Schaummittellieferanten bescheinigen.  Weitere Informationen entnehmen Sie bitte der anhängenden Stellungnahme. | |
| **Dossier submitter response:**  See comment 1237 (= comment 1223 in English) | |
| **RAC Rapporteurs comments:**  - | |
| **SEAC Rapporteurs comments:**  - | |
| **1224** | **Date:** 2015/02/27 17:19  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  UNITEQ SA  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  The limit proposed of 2 ppb (part per billion) for limitations on PFOA and precursors is not only unrealistic but dangerous as it undermine a technology that as demonstrate its efficiency in fighting dangerous fire. During the last few years, the industry has put enormous effort to phase out PFOA and bring the new C6-agent in place. This new proposal will affect our industry even more as it will bring a lot of problems in term of quality control (the limit of detection are much high the limitation proposed) even when using new C6-agent, no member supply of the chain will be able to guarantee the compliance with this proposal.  We do not support this proposal | |
| **Answer to specific info request 4:**  The limit proposed of 2 ppb (part per billion) for limitations on PFOA and precursors is not only unrealistic but dangerous as it undermine a technology that as demonstrate its efficiency in fighting dangerous fire. During the last few years, the industry has put enormous effort to phase out PFOA and bring the new C6-agent in place. This new proposal will affect our industry even more as it will bring a lot of problems in term of quality control (the limit of detection are much high the limitation proposed) even when using new C6-agent, no member supply of the chain will be able to guarantee the compliance with this proposal.  We do not support this proposal | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comment made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short- chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short- chain chemistry and consequently fire-fighting foams based on short -chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1225. | |
| **1225** | **Date:** 2015/02/27 17:29  **Type:** Individual  **Country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No**    **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  Fabrik chemischer Präparate von Dr. Richard Sthamer GmbH Co. KG  22113 Hamburg  Germany  27.02.2015  Response to specific Information Requests  ANNEX XV PROPOSAL FOR A RESTRICTION – Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances (17 October 2014)  Worldwide, fire fighting foam concentrates based on fluorotelomeric surfactants fulfill the highest safety standards (e.g. EN 1568, ICAO, IMO, UL 162, FM, LASTFire). They are used to fight fire incidents, which massively impact human life and the environment. One of these risks are large liquid fires, which need special technical framework to make sure that the hazards for human life are significantly minimised and that the complete environmental impact of toxic and cancerogenic emissions are reduced.  The enforcement of the proposed restrictions on PFOA will, with no alterations, lead to a formal ban of AFFF fire fighting foams in high risk areas like refineries, chemical industry, tank storage farms, airports and large fixed extinguishing systems. Fluorine free products are not suitable for all kind of poor foaming applications, like monitor application, water sprinkler systems etc.. By now many of these areas cannot be protected with fluorine-free foam concentrates. An adequate fluorine-free „drop-in“ alternative for AFFF does not exist (as shown in table C.1-1 of part C of the proposal).  In contrast to section B.4.4.3.1, which states „Environmental release from fire-fighting foams: PFOA-related substances are used in aqueous fire-fighting foams (AFFF), which are mostly directly applied outside, reaching the sewage system or/and leach into soil and groundwater“, fire fighting foams are merely an emergency instrument. By far the largest part of the fire fighting foams are stored for 10-25 years for this emergency which will typically never take place and will be disposed off unused. Only a small part is actually used to fight scale fires. PFAS-containing fire fighting foams therefore do not contribute to a constant emission of PFOA/PFOA-related substances into the environment.  Between 2006 and 2011, manufacturers as well as users of fire fighting foams have replaced their PFOS-based stocks by PFOS-free products having high financial, technical, and environmental impacting efforts (due to cleaning and disposal). AFFF, based on mainly C6 chemistry with only smallest parts of C8 and impurities of PFOA, were purchased instead, or, when having less critical risks, fluorine-free foams if appropriate. Following the restrictions of EU directive 122/2006/EU stating a maximum of 50 mg/kg PFOS and later on of EU regulation 757/2010 which states a maximum of 10 mg/kg PFOS, it was difficult for manufacturers as well as for users to reach this threshold because of cross-contamination of the new foam concentrate with the old one. Even at thresholds 5000 times higher than for the planned PFOA regulation, it was not in each case successful to clean the sites of large production facilities and fixed firefighting systems with a reasonable effort due to the strong surface adhesive properties of PFOS.  The proposed threshold of 2 µg/kg for PFOA and PFOA-related substances is, in our opinion, not at all possible to achieve for the technical applications of fire fighting foams. The production of AFFFs based on currently available C6-fluoro telomeric raw materials in our production plant, fulfilling the proposed threshold, is not possible. The enforcement of this proposal with the said threshold would result in a total ban of all PFAS-containing fire fighting foams.  This ban would result in the complete disposal of all PFAS-containing fire fighting foam concentrate stocks and the complete dismantlement of all production sites and fixed extinguishing systems to prevent cross-contamination. In terms of sustainability, these measures should be put into question. A huge number of emergency plans and fire protection concepts based on the application and the specific properties of AFFF cannot be further used.  We are nor aware of any reproducible and validated analytical method for the determination of 2 µg/kg PFOA and PFOA related substances in the matrix of PFAS-containing fire fighting foam concentrates.  We herewith formulate a formal protest against the „ANNEX XV PROPOSAL FOR A RESTRICTION – PERFLUOROOCTANOIC ACID (PFOA), PFOA SALTS AND PFOA-RELATED SUBSTANCES“ based on the following reasons:  • A 2 µg/kg threshold for PFOA and PFOA-related substances in fire fighting foams cannot be followed in terms of raw materials and cross-contamination  • There is no reproducible and validated analytical method to determine 2 µg/kg PFOA and PFOA-related substances in PFAS-containing fire fighting foams  • High ecological and economical impact because of missing fluorine-free alternatives for PFAS-containing fire fighting  • High safety risks in the case of a big fire emergency because of missing equivalent large scale tested and proved fluorine free alternatives for PFAS-containing fire fighting foams  • Disposal of all PFAS-containing fire fighting foams as well as dismantled production sites and fixed extinguishing systems  Fabrik chemischer Präparate von Dr. Richard Sthamer GmbH Co. KG  22113 Hamburg  Germany | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comment made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short- chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that C6short- chain chemistry and consequently fire-fighting foams based on short -chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting-agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier Submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short- chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC notes that many firefighting foams are disposed of unused, but when they are used they can contaminate the local environment directly, as pointed out by the DSDS. Therefore a sufficiently long transition period is needed to avoid the unnecessary disposal of existing stocks, but care must also be taken in their use.  RAC is concerned about contradictory claims about the possibility of using fluorine-free foams at airports and for oil installations, but efficacy is an issue for SEAC.  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb. RAC also notes that cross-contamination of new foam concentrates with old ones (including from existing equipment such as storage tanks) may be problematic if the limit is too low.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information.  We agree that fluorine-free firefighting foams seem not to be currently suitable for use in all situations, and that it is important to ensure that short-chain fluorinated foams will be available when needed.  We acknowledge the difficulties that would be incurred by the necessity to replace the PFOS-free foams recently acquired. We propose derogation for firefighting foams already in stock; we note that emissions deriving from those are partly theoretical because they might not be needed before the expiry date and would be destroyed unused.  We recognise the problems relating to PFOA and PFOA-related substances being found as impurities in short-chain alternatives. We consider it vital also from the proportionality perspective that short-chain alternatives will continue to be available. RAC and SEAC suggest general limit values of 25 ppb for PFOA and 1000 ppb for PFOA-related substances. SEAC further suggests that for firefighting foams, the 1000 ppb level would be applied to both PFOA and PFOA-related substances. | |
| **1226** | **Date:** 2015/02/27 17:39  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Italy  **Company name confidential:** **Yes** | **General Comments:**  Our Company purchases and uses PERFLUOROOCTYL-IODIDE C8F17-I (CAS. 27619–97-2) as an Isolated and transported intermediate, for the production of perfluorinated waxes that find their main application as ski waxes in winter sports market segment. Perfluorinated waxes also have a minor market application as special lubricants in electronics.  For the above mentioned market segments, no valid alternative to these molecules, able to guarantee similar performances, are presently available.  Quantity of Perfluorooctyl-iodide used by our Company is in the range of 1500 Kg/y, for a production of a similar quantity of waxes. This quantity represents a market share of about 50% worldwide.  This business represents roughly 20% of total turnover of the Company.  The restriction on this molecule at European level, will imply total production displacement of ski waxes outside Europe, with advantages only for non-european manufacturers. In fact the restriction will impact on the raw material (perfluoroctyl iodide) and not on the final waxes (that will be imported in Europe after their production). Obviously no environmental benefit will be obtained on final utilization of ski waxes. | |
| **Answer to specific info request 1:**  Perfluorooctyl-iodide is a chemical intermediate used by our Company for its chemical transformation in perfluorocarbons via a dimerization process.  These perfluorocarbons are solid products at different melting points; they are very stable compounds and do not show any degradation process during their service life to PFOA.    Average annual consumption of perfluorooctlyl iodide in our company is in the range of 1500 Kg/y with a similar production annual quantity of pefluorinated waxes.  Our company has no evidence that during this chemical transformation perfluorooctlyl iodide is degraded into PFOA (or related compounds).  These perfluorocarbons are commercialized by our company as ski waxes, very effective as anti-friction agents in alpine and cross-countries winter sports.  They are also manufactured for electronic industry as lubricant.  None of these applications are listed in the dossier for the restriction proposal.  Perfluorocarbons have a very special behaviour due to the unique feature of organic fluorine compounds that are non reactive and absolutely inert towards all the other substances. These characteristics explain their extraordinary performance as sliding agents and lubricants.  This unique performance is far higher than the ones that can be achieved with the alternative of non fluorinated hydrocarbons.  It can be easily assessed that these fluorinated compounds have no alternative versus the achievement of similar performances. | |
| **Answer to specific info request 2:**  Specific use of perfluorinated compounds, such those related to ski waxes application that our company commercialize, is not included in the above mentioned markets.  No valid alternative is presently available for our company ski waxes, and thus no cost estimation for their substitution can be reasonably envisaged. | |
| **Answer to specific info request 3:**  Our company has no evidence that during this chemical transformation perfluorooctlyl iodide is degraded into PFOA (or related compounds) at least at the level of 2 ppb mentioned in the proposed regulation. | |
| **Answer to specific info request 4:**  In the chemistry world the requisite of 2 ppb limit of a substance in a correlated substance can be considered quite unfeasible.  Introduction of such a restrictive limit (2 ppb) that would also apply to short chain PFAs, will impact dramatically on the global market of perfluorinated compounds, including those identified as alternative to long chains.  In addition after a long time of production and consumption of PFOA all products still have a background content of PFOA at the level of some ppm. Overtime this level will be naturally reduced.  This restrictive limit shows also an evident technical issue.  According to our knowledge and experience, PFOA (and related substances) detectable content in fluorinated compounds, is higher by at least 2 orders of magnitude versus the envisaged limit.  At the best of our knowledge, determination of PFOA at a level of 2 ppb, in perfluorinated hydrocarbons media, are not today available. While for PFOA related substances determination references are not reported (also in the restriction proposal document). This concept is supported and confirmed by the fact that in Table A.E.2-2 a number of analytical methods are listed where detection limits, in similar perfluorinated media (fluorotelomers), are in the range of 2500 ppb.  Several additional concerns related to the analityc performance to take under consideration are:  1-Transform methods with the suitable sensitivity as a routinely analytic methodology available in industrial and public labs  2-Validate the methods in every type of matrices where PFOA and PFOA-related substances have to be detected  3-Inter-laboratory test alignment at this limit level. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for this new information.  According to Nielsen et al.,2014 perfluorooctlyl iodide can be degraded to PFOA.  Ski waxes are a completely open application, leading to direct environmental emissions According to manufacturers of short chain alternatives all uses of C8 can be replaced by short-chain chemistry. Therefore, the DS does not agree with a derogation for this use.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC notes that the tonnage of perfluorooctyl iodide used for this application is relatively high, but that the company claims that the resulting perfluorocarbons do not degrade during their service life (as ski waxes and lubricants in the electronic industry). The content of residual PFOA-related substance impurities is not mentioned, so no information has been provided to confirm that this is a low risk use (and ski waxers are known to be exposed to PFOA, as described in the BD).  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information.  We agree that the concentration limit initially proposed (2 ppb) is not feasible. RAC and SEAC suggest limit values of 25 ppb for PFOA and 1000 ppb for PFOA-related substances to allow the use of alternatives to PFOA-related substances. SEAC also took into account RAC considerations about the risk of this use. | |
| **1227** | **Date:** 2015/02/27 19:10  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  European Semiconductor Industry Association  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  Please find enclosed a first set of preliminary comments from the European Semiconductor Industry association to the ECHA consultation as requested by the rapporteurs of the ECHA’s Risk assessment and Socio-economic analysis committees by March 1 2015 to facilitate their further discussion. The industry will provide further final input before the June 17th 2015 deadline. | |
| **Answer to specific info request 1:**  Please find enclosed a first set of preliminary comments from the European Semiconductor Industry Association to the ECHA consultation as requested by the rapporteurs of the ECHA’s Risk assessment and Socio-economic analysis committees by March 1 2015 to facilitate their further discussion. The industry will provide further final input before the June 17th 2015 deadline.  The Semiconductor manufacturing industry produces semiconductor devices (microchips) and uses PFOA as a constituent in a number of chemical manufacturing process formulations. The industry uses these formulations in a very specialized manufacturing process step, called photolithography. Within the industry manufacturing process (in photolithography), are critical applications of PFOA where no alternatives exist currently for all uses. (as per Appendix C , Table A.C.1.1 Potential alternatives and technologies in the annex XV proposal) The industry and its supply chain are aware of the concerns regarding these chemicals, and have already made efforts where technically feasible to eliminate PFOA from the manufacturing process formulations. Currently however for the critical photolithography uses there are no adequate technically feasible alternatives that can be used as drop-in replacements for all applications. ESIA believes that RMO 1b should be considered as appropriate especially for sectors that require exemptions due to critical use where substitution is technically unfeasible and where the use and emissions are well managed.  Quantities Used  Overall the semiconductor industry is a very minor volume user of PFOA in photolithography. It was estimated at less than 0.05t/year for critical photolithography uses across the entire European industry in 2010  Waste Streams and Potential Risk  The potential risk to the environment and human health is managed in semiconductor use through stringent risk management measures implemented in the manufacturing factories. There is no release to the work place due to the use of closed systems. Solvent waste is collected at the factories and sent for incineration. There is very minimal release to the environment in wastewater. Based on estimated figure of photolithography usage per annum of 0.05t in 2010 overall emissions through wastewater based on expert engineer knowledge of the process technology and processing waste stream would give rise to an estimated 4kg per annum for the entire sector. This is a conservative estimation – a very worst case scenario.  PFOA / Semiconductor manufacturing equipment  Semiconductor manufacturing equipment used in the semiconductor factories to make the semiconductor device or (microchip) and production installations (piping) have parts made of fluoropolymer and fluorotelomer material that may contain PFOA and related substances. Fluoropolymers are needed in parts of semiconductor manufacturing equipment and /or installations due to their specific material properties (in order to withstand heat and/or certain chemicals). Examples include o-rings, gaskets and surface coatings. The semiconductor industry and our suppliers of manufacturing equipment are investigating further on this issue. This manufacturing equipment would be classified as ‘articles’ under REACH and are typically supplied from companies operating outside of the EU.    Semiconductor device manufacturing is one of the most complex and sophisticated manufacturing technologies in the world. The process of building a 3-dimensional nano-scale structure on a silicon or other wafer can require typically over 500 process steps and uses over 100 different types of equipment supplied by many equipment manufacturers and sub-suppliers. The manufacturing equipment are highly complex machines. To give scale of the issue the industry could have in the region of 100,000 replaceable spare parts for servicing the manufacturing equipment per European semiconductor manufacturing company. Therefore assessing the full impact of the article aspect of the restriction proposal will be a complex and time consuming process. We have started the process of reviewing and surveying our supply base and hope to have a better picture at a later time this summer. | |
| **Answer to specific info request 2:**  No cost analysis has been performed on small volume users like semiconductor industry in the annex XV dossier. Due to the high tech nature of semiconductor production compared to 5 sectors/markets that have been assessed in the annex XV dossier the costs from these other sectors cannot be extrapolated to the semiconductor sector and as such are not representative for semiconductor industry. Industry is currently examining these elements and hopes to provide further input.  Despite significant R&D in recent years, currently there are no drop in replacement substances for all uses of PFOA in photolithography, which provide the critical functionality and equal performance required. The process of technology implementation, test and approvals and final replacement is not simple. The semiconductor industry needs to continue using PFOA as long as no suitable drop in alternatives are industrially available. A restriction for PFOA in photolithography in Europe has the potential to undermine semiconductor production and future innovation in Europe, as the photolithography process is at the heart of leading edge semiconductor manufacture. At the same time a restriction will not provide significant improvements in human health or environmental aspects attributable to the semiconductor footprint as volume used and emissions are very low.  Semiconductor manufacturing relies on a highly complex supply chain, of which most suppliers of manufacturing equipment tools (as well as of specialty chemicals) are located outside the EU, such as the U.S. or Japan.  The semiconductor industry has a good track record of reducing materials and since the early 2000s and has now implemented almost complete replacement for PFOS. For non-critical and for new semiconductor manufacturing processes PFOS free chemistry is used. This process has taken time however due to the critical nature of the process involved. | |
| **Answer to specific info request 4:**  Semiconductor industry would have some concerns on the concentration limit approach here as a user of manufacturing equipment (articles). The 2ppb limit seems not practical in an industrial setting. The industry’s supply chain is predominantly outside Europe and the industry operates globally and would favour harmonisation at global level of ppm levels. In addition analytical methods would be very difficult to demonstrate compliance at these levels. Besides, given the enormous amount of equipment and auxiliary parts in a semiconductor manufacturing fab that could be affected, demonstration of proof would give rise to a disproportionate administrative and analytical burden and would entail extremely high cost. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made. We will consider them when revising the Background Document.  According to REACH emissions of PBT substances have to be minimised. Therefore the threshold needs to be as low as possible. We received information from a standard laboratory that there are no differences in the costs for analysing PFOA and related substances in the ppb range vs. the ppm range.  Risk management measures regarding human health and environment are in place. Furthermore, semiconductor industry is a minor user of PFOA related substances. There are very low emissions into the environment. Therefore, the Dossier submitter would agree with a longer transitional period for the remaining critical uses in photolithography.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC notes the relatively low releases of PFOA-related substances used in the semi-conductor industry, and RAC has recommended derogation on the basis of low risk.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. The volumes and emissions seem to be low and risk management measures in place. We support derogation for mixtures used in semiconductor photolithography processes as reflected in our draft opinion. | |
| **1228** | **Date:** 2015/02/27 20:45  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Fire Fighting Foam Coalition, Inc.  **Org. country:** United States  **Company name confidential:** **No** | **General Comments:**  The Fire Fighting Foam Coalition (FFFC) appreciates this opportunity to provide comments on the “Annex XV Restriction Report: Proposal for a Restriction for Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances” (PFOA restriction proposal) published by the European Chemicals Agency. FFFC is a non-profit trade association whose members are manufacturers of fire fighting foam agents and their fluorochemical components.  FFFC fully supports the goal of minimizing the environmental impact of fire fighting foam. We are currently working with the US Environmental Protection Agency to finalize best practice guidance on foam use, and in 2013 submitted proposed revisions to international foam standards focused on proper containment and treatment of foam discharges and the use of non-fluorinated alternatives for training and testing. At the same time FFFC members are working diligently to reformulate all of their fluorinated foam products to use short-chain (C6) fluorochemicals with reduced environmental impacts in response to the EPA PFOA Stewardship Program. An effective restriction of PFOA and PFOA-related substances in Europe would be a useful tool for completion of this process.  However, FFFC has very serious concerns that the proposed threshold of 2 ppb for PFOA and PFOA-related substances cannot be achieved in the production of fire fighting foam concentrates and would result in a de facto ban on the use of fluorinated foams. As fluorinated foams are the most effective agents currently available to protect life, high-value property and the environment from the risk of flammable liquid fires in military, oil and gas, municipal, and aviation applications, such a result would have an extremely negative impact on fire safety in Europe.  FFFC recommends that a practical threshold of the impurity level of PFOA and its related substances be set for firefighting foam that eliminates the manufacture and use of foams with long-chain substances while still allowing the manufacture and use of short-chain alternatives. The proposed impurity level of 2 ppb is currently impossible to achieve due to the limitation of the current fluorotelomer manufacturing technology. FFFC plans to submit additional information on this issue prior to the end of the consultation in June. | |
| **Answer to specific info request 1:**  Fire fighting foams containing short-chain (C6) fluorotelomer surfactants provide highly effective and available alternatives to foam with PFOA-related long-chain substances. However, the proposed threshold of 2 ppb for PFOA and PFOA-related substances cannot be met in the manufacture of fire fighting foam and would result in a de facto ban on the use of fluorinated foams. While fluorine-free foams can provide an alternative in some applications, they are not currently able to provide the same level of fire suppression capability, efficiency, flexibility, and scope of usage. A ban on the use of fluorinated foams could leave users in important applications such as military, petrochemical, and aircraft rescue and fire fighting without adequate fire protection.  Data presented at the 2013 Reebok conference and the 2011 SUPDET conference show that fluorinated foams are more effective at extinguishing flammable liquid fires than fluorine-free foams . Fluorine-free foams can require up to three times more foam for a given size fire than AFFF agents , which produces increased amounts of runoff and potentially a greater environmental impact. In addition, there are issues for fluorine-free foams related to compatibility and viscosity. Whereas most AFFF agents are compatible and different brands can be mixed in the same equipment, fluorine-free foams are generally not compatible and cannot be mixed with other types of foam agents. This can cause issues for fixed fire protection systems and military applications. Fluorine-free foams are also more viscous than AFFF agents, and this can cause problems for proportioning equipment.  References  A New High Performance Newtonian Fluorine-Free Foam, Manual Acuna, VS Focum, presented on March 19, 2013 at the 5th Reebok International Foam Conference and Extinguishment and Burnback Tests of Fluorinated and Fluorine-free Firefighting Foams with and without Film Formation, Bradley Williams, Timothy Murray, Christopher Butterworth, Zachary Burger, Ronald Sheinson, James Fleming, Clarence Whitehurst, and John Farley, Naval Research Laboratory, Washington, DC, presented at the 2011 SUPDET Conference.  Sealability Properties of Fluorine-Free Fire Fighting Foams by Ted Schaefer, Bogdan Dlugogorski, and Eric Kennedy, University of Newcastle (2007) | |
| **Answer to specific info request 4:**  The proposed concentration limit of 2 ppb for PFOA and PFOA-related substances would result in the unavailability of fire fighting foams based on the use of short-chain PFASs. It would act as a de facto ban on the use of fluorinated foams, which could leave users in important applications such as military, petrochemical, and aircraft rescue and fire fighting without adequate fire protection.  FFFC recommends that a specific threshold be set for fire fighting foams at a level that eliminates the manufacture and use of foams with long-chain substances while still allowing the manufacture and use of essential short-chain (C6) alternatives. FFFC plans to submit additional information on this issue prior to the end of the consultation in June.  PFOA and its related substances in firefighting foams can be quantified. However, currently available analytical methods, especially those used in the commercial service labs, are not reliable enough to assure the necessary reproducibility and repeatability (inter-lab consistency). The major technical issue is the matrix effect, and firefighting foam is a highly concentrated matrix of various types of fluorosurfactants and hydrocarbon surfactants. Another serious issue is the use of PFOA-contaminated water for the formulation of foam concentrates. The quantification limit also greatly depends on the matrix and the currently claimed detection limits by the qualified service labs, from a few ppb to a few tenth of a ppb, are based on analytical test protocols developed mainly for simple matrices such as drinking and ground water samples. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short- chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short -chain chemistry and consequently fire-fighting foams based on short chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short -chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We recognise the problems relating to PFOA and PFOA-related substances being found as impurities in short-chain alternatives. We consider it vital also from the proportionality perspective that short-chain alternatives will continue to be available. RAC and SEAC suggest general limit values of 25 ppb for PFOA and 1000 ppb for PFOA-related substances. SEAC further suggests that for firefighting foams, the 1000 ppb level would be applied to both PFOA and PFOA-related substances. | |
| **1229** | **Date:** 2015/02/28 00:07  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Dynax Corporation  **Org. country:** United States  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  February 27, 2015  Submitted via online form at: https://comments.echa.europa.eu/comments\_cms/AnnexXVRestrictionDossier.aspx?substancename=Perfluorooctanoic%20acid%20%20  Re: Annex XV Restriction Report: Proposal for a Restriction for Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances (17 October 2014)  Dynax is happy to provide comments and suggestions on the above restriction proposal published by the ECHA for public comments.  Dynax is one of the major global manufacturers of fluorotelomer-based surfactants and fluorochemical foam stabilizers to the fire fighting foam industry. Fluorosurfactants and fluorochemical foam stabilizers are the essential key components in firefighting foams. Various types of fluorinated foams, from protein-based to synthetic aqueous film forming foams, are most effective and versatile in extinguishing flammable liquid fires. Fluorochemicals in these foams provide these key properties: fuel repellency that minimizes the fuel contamination of the foam, low surface tension that is required for the formation of aqueous film on the fuel surface, heat stability that prevents the foam from breaking up against heat.  Dynax fully supports ECHA’s objectives of restricting the impact of PFOA and its long chain precursors on the environment. In fact, in compliance with the EPA’s 2015 PFOA Stewardship Program, Dynax has already phased out the production of C8-based fluorosurfactants at the end of 2014, a full year ahead of the 2015 deadline.  Dynax, however, cannot support the proposed restriction limit of 2 ppb for PFOA and its precursors. The inability of the industry, especially the fire fighting industry, to meet this extremely low threshold is mainly due to the limitation of the current state of the art fluorotelomer manufacturing processes. The 2 ppb threshold limit will effectively ban the use of fluorotelomer intermediates, fluorosurfactants, and fluorinated firefighting foams.  To illustrate, perfluorohexyl ethyl iodide (C6F13CH2CH2-I) is the common starting material used to produce fluorotelomer-based surfactants. The four largest producers of this intermediate are DuPont, Archroma (ex-Clariant), Asahi and Daikin both in Japan. PFOA and its precursors (≥C8) are undesired impurities and the intermediates produced by these companies contain varying levels of these impurities from ppm to sub-ppm levels. Dynax’s fluorosurfactants and fluorochemical foam stabilizers are all derived from a high purity starting material containing sub-ppm level of impurities. The trace levels of these impurities get further diluted during our single or multi step manufacturing processes. These impurity levels are further reduced when our customers, firefighting foam manufacturers, use certain small percentages of our products in their foam concentrates, some use more, some less.  However, the single 2 ppb restriction limit of the impurities proposed for all phases of the production of fluorosurfactants, as explained above, is impossible to meet according to the current technology.  Dynax would like to provide further info/data to ECHA before the comment period is over in June, 2015.    Dynax Responses to Specific Information Requests  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?  The short chain (≤C6) fluorotelomer surfactants have been around since the early 1980’s for use in the fluorinated foams alongside with the so called “PFOS foams.” PFOA has always been an impurity, and it was never used as an active component in what is erroneously termed as “PFOA foams.” The fire fighting foam industry has already accepted the short chain (≤C6) fluorotelomer surfactants as an alternative to the longer chain (≥C8) PFOA-related fluorosurfactants and has been making great efforts to make the transition before the 2015 deadline of the EPA’s PFOA Program. Some of our customers have already made the successful transition to produce new C6-based foams. Some others are expected to make the transition before the deadline.  The C6 alternatives have been shown as effective and efficient in formulating various types of fire fighting foams as the long chain PFOA precursors. For example, all C6-based fluorinated foams were demonstrated to pass and exceed the fire test requirements of the US Mil-F-specification which is known to be the most difficult fire test standard in the world.  Fluorine-free foams (F3), despite commercial claims otherwise, have proven to be a non-viable alternative technology. For example, none of the currently available F3 foams on the market have qualified for the ICAO Level C standard at the designated use level, the latest and toughest among the ICAO standards, let alone US Mil-spec. Other issues, such as aquatic toxicity, operational issues with fire fighting mechanism, further make F3 foams less viable as an alternative.  • Please note that information regarding sectors that involve higher amounts used are particularly welcomed (e.g. textiles).  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?  As previously mentioned, the proposed threshold limit of 2 ppb for the impurity levels of PFOA and PFOA-related substances would virtually ban the use of fluorotelomer intermediates, fluorosurfactants and fluorinated firefighting foams.  Dynax strongly recommends a restriction limit on the PFOA and its precursor impurity levels that is practical and consistent with the current state of the art fluorotelomer production processes.  • The availability of analytical methods including the limit of quantification of those methods in relevant matrices?  The current analytical methods for the quantification of PFOA and its precursor levels are not robust enough to muster the necessary requirements of reproducibility and repeatability. The main analytical issue is the complex matrix of the highly concentrated fluorosurfactant products, and the complex foam matrices consisting of various types of fluoro- and hydrocarbon surfactants on the other. These complex matrices interfere with the quantification of the impurity analytes.  Some certified commercial analytical labs do claim the quantification limit to be ppb and sub-ppb levels. However, the analytical protocols they use are designed for ground/drinking water samples, relatively simple matrices.  \*\*\* | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternativesproducts are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain chemistry and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC notes the statement that PFOA is an impurity rather than an active component in fire fighting foams.  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We recognise the problems relating to PFOA and PFOA-related substances being found as impurities in short-chain alternatives. We consider it vital also from the proportionality perspective that short-chain alternatives will continue to be available. RAC and SEAC suggest general limit values of 25 ppb for PFOA and 1000 ppb for PFOA-related substances. SEAC further suggests that for firefighting foams, the 1000 ppb level would be applied to both PFOA and PFOA-related substances. | |
| **1230** | **Date:** 2015/02/28 02:49  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:**  AFIRM Group  **Org. country:** United States  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Thank you for the opportunity to comment on the REACH Annex XV dossier submitted by Germany and Norway proposing a restriction on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances. The proposal raises several important issues, and AFIRM seeks to contribute information and insight to aid in ECHA’s deliberations. AFIRM may be supplementing these comments with additional information prior to the 15 June 2015 deadline  The Apparel and Footwear International RSL Management (AFIRM) Group was established in 2004; its mission is to reduce the use and impact of harmful substances in the apparel and footwear supply chain. Members include adidas-Group, Asics, Bestseller, C&A, Carhartt, ESPRIT, Gap Inc., Gymboree, H&M, Hugo Boss, J.Crew, LACOSTE, Levi Strauss & Co., New Balance, Nike, Pentland, PUMA, PVH, s.Oliver, and VF Corporation. Since its founding, AFIRM has developed tools to assist the supply chain in implementing restricted substance lists (RSLs) and has presented training on chemical management to over 3200 individuals during RSL Seminars (see www.afirm-group.com for the tools and specifics on the seminars).  AFIRM members understand the importance of reducing and working towards eliminating intentional use of PFOA, its salts and PFOA-related substances (‘PFOA’) in textile and footwear manufacturing. We believe that an incrementally phased-in limit based on feasibility and socio-economic assessments will support all industries in this challenging undertaking. At present, AFIRM members manage and monitor PFOA through their respective Restricted Substance Lists (RSLs) and are working with suppliers to replace their use and decrease concentrations of them in manufacturing and finished products. Some members have been restricting and testing for PFOA in their products since 2006. The result has been the accumulation of data and experience concerning the extent to which these chemicals are utilized in different stages of the supply chain, their existence as unintended contaminants in apparel and footwear materials, and the challenges that exist in decreasing their wide use and incidental occurrence.  AFIRM members have studied the proposed legislation and believe that clarification of several points is needed: the legislation’s scope and implementation, the test method, and whether a full socioeconomic assessment across all industry sectors has been performed with appropriate consideration of the incredibly low limit proposed. The most important goals for AFIRM members in submitting these comments are to ensure that any new restriction can be feasibly implemented within their international supply chains and to prevent legal uncertainty.  A. SUGGESTED RESTRICTION  Comment:  I. REQUEST FOR CLARIFICATION. To avoid confusion in implementation, we recommend that ECHA clarify the following items:  a. Scope of Restriction. Does the proposed PFOA restriction apply to the total concentration in the finished article or to specific components of the article?  b. Test Method. We recommend that ECHA specify a validated and internationally recognized test method before finalizing a restriction on PFOA. No validated method currently exists, and implementing a restriction without one would result in significant uncertainty in compliance and enforcement for the regulated business community.  II. THRESHOLD LIMIT VALUE (TLV). The 2ppb proposed limit is incredibly low and located in the scientific area of so-called “Ultra-Trace Analytics.” Analytical technology can quantify substance concentrations down to this level, but highly sophisticated equipment not widely available is needed. However, at these ultra-trace concentrations, results are not consistently repeatable, especially in the absence of a validated test method as in the case of PFOA. According to one AFIRM member’s outreach to an analytical expert, even with the highest level of due diligence, the variation of results among different laboratories has been found to be a factor of 65 for PFOA specifically. With the potential for this much variability, this ultra-trace concentration limit should not be the basis for determining the legal status of millions of imported products every year into the European Union. The uncertainty created for compliance with and enforcement to such a low limit will result in substantial commercial disruption.  III. CONTAMINATION. As discussed in the ECHA Dossier, PFOA and related substances are used in a wide variety of applications, which makes complete avoidance of cross-contamination a profoundly challenging task, even for leading apparel and footwear brands that have restricted PFOA for years. The risk that cross-contamination will cause widespread failures above the proposed 2ppb limit is a certainty. Potential sources of contamination include:  - Overseas production facilities have phased out the use of long-chain PFCs for some customers who require it, but not others. These facilities have contaminated equipment that will easily result in apparel and footwear products with trace levels of PFOA above the proposed limit.  - Since PFOA is very persistent in the environment, trace background concentrations in fresh water sources may contain enough PFOA to contaminate finished products in exceedance of the proposed limit.  - Fire-fighting substances, such as those used in fire extinguishers, may contaminate production facilities with enough PFOA to cause manufactured goods to exceed the proposed limit.  - At the limit proposed, laboratory testing equipment can contain trace concentrations of PFOA that will result in false-positive test results for the samples being tested.  To mitigate the confusion and uncertainty caused by cross-contamination, we recommend that ECHA adjust the proposed limit upward to focus on restricting intentional use of PFOA and related substances.  IV. TIMELINE FOR REDUCTION. Regardless of what final limit ECHA settles on, we strongly recommend that this restriction be implemented by incremental decreases over time. This strategy was successfully applied in the United States Consumer Products Safety Improvement Act, where restricted levels of lead in children’s products were incrementally decreased from 600 ppm to 100 ppm over the course of several years, with the final limit pending assessment of technological feasibility. Likewise, the specifics regarding the limit and timeline for each decrease in the case of this PFOA restriction would be most appropriately determined by independent feasibility and socio-economic assessments. This approach of incremental decreases would assist the greater industry in reducing intentional PFOA use and contamination by allowing the supply chain to focus efforts on the more significant uses on a priority basis. This in turn will make it more practical and possible to tackle the lesser known, smaller, and more difficult to identify uses and sources of contamination later on. Furthermore, incrementally decreasing the limit will allow for the appropriate establishment of a validated test method. We therefore suggest an initial TLV of 500 ppb in apparel and footwear products, with an incremental decrease to 100 ppb within 5 years.  SUMMARY:  • AFIRM members understand the importance of reducing and working towards elimination of intentional use of PFOA, its salts and PFOA-related substances in footwear and textile manufacturing. We believe this restriction should be implemented by incrementally decreasing the acceptable limit over time to support all industries in this challenging undertaking.  • The specifics regarding the limits and corresponding timelines for each decrease would be most appropriately determined by independent feasibility and socio-economic assessments.  • Clarification of the test method is imperative to ultimately allow for the identification, reduction and substitution of PFOA, its salts and PFOA-related substances, and being able to demonstrate compliance.  • Among AFIRM members, opportunities for the most rapid reduction in PFOA in the supply chain occurred when these substances were restricted from intentional use. Further reduction will take time, considering the wide range of their existing usage, a full understanding of every possible usage further up the supply chain, and the control of sources of cross-contamination.  Again, thank you for the opportunity to comment. Please let me know if you have any questions.  Sincerely,  **<removed>**  Director, Apparel and Footwear International RSL Management Group (AFIRM) | |
| **Answer to specific info request 1:**  Carrier-foil applications, industrial anti-stick treatments/sprays, high performance durable water repellent (DWR) work-wear/personal protective equipment (PPE), fire-fighting chemicals. Potential risks should be marginal compared with other applications in the cosmetic or food sector | |
| **Answer to specific info request 2:**  The intentional usage in our direct operational sphere/production allocations is controlled by our RSL programs, cost impacts are manageable. To avoid any kind of ultra-trace impurity or cross-contamination, costs may raise significantly and out of proportion to any benefit gained. | |
| **Answer to specific info request 3:**  NONE | |
| **Answer to specific info request 4:**  As described earlier, a limit of 2ppb is in the area of Ultra Trace Analytics will result in legal uncertainties about product marketability and liability and will result in significant commercial disruption. This includes the very likely occurrence of false-positives during spot checks of market surveillance authorities e.g.  The existence of a validated test method is imperative before any chemical can be properly integrated into REACH/Annexes. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new comments made.  Ia: Scope of Restriction. The Dossier submitter revised the thresholds and proposes different thresholds for e.g. formulations and final articles.  IB and II:  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  III contamination:  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross-contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  IV. TIMELINE FOR REDUCTION.  The Dossier submitter does not agree with the proposed incremental decreases over time. Industry has now been informed about the proposed restriction and can already take measures to minimise the content of PFOA and PFOA-related substances in their articles. The proposed threshold value seems not to be justified by the Dossier submitter, since no data were provided (such as volumes and, substances used).  However, the Dossier submitter has revised the proposed threshold to ensure that short-chain alternatives are allowed to be used. | |
| **RAC Rapporteurs comments:**  RAC notes the request for an incrementally phased-in concentration limit, and clarity about whether the restriction will apply to the total concentration in the finished article or to specific components of the article. RAC has recommended that the wording regarding articles is consistent with existing legislation on PFOS.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk that cross-contamination might cause failures above the proposed 2 ppb limit is also noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. This could be part of a phased approach. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that a revision of the concentration limit is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1231** | **Date:** 2015/02/28 18:14  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  **<removed>**  **Org. country:** Italy  **Company name confidential:** **Yes** | **General Comments:**  We do not support the draft for the following reasons:  1.1 Impurities  1.1.1 Raw materials  Basically the given threshold equals to what in chemistry is called HPLC-quality level meaning an extremely high purity level. It is foreseeable that the industry will not be able to meet this low level of C8-impurities due to factors like carry over contamination for materials being made in the same plants which used to make C8 and higher. No manufacturer of Fluorochemicals at present can guarantee to get even close to that level, hence the implication would be an immediate discontinuation of AFFF-Foams at the risk of not having any suitable replacement.  Internal flushing experiments with a stainless steel vessel which was used for expansion testing gave a contamination with F-Surfactants in clean fresh water of 0,094mg/kg equaling to 94µg/kg hence 94ppb.  1.1.2 Finish Products  Obviously if raw materials will suffer from carrying impurities of C8 and higher beyond the 2ppb limit foam concentrates made of those will as well provided the content in the raw materials is high enough (which we have to assume basing on the experiment and in lieu of lacking other data).  1.1.3 Hardware:  To meet the requirements of this norm a major part of all installations would have to be replaced: manufacturing plants for agents and the corresponding raw materials as well as extinguishing systems (!). This will have the immediate consequence that a huge number of facilities will have significant downtimes to be able and reinstall new systems as far as necessary plus will obviously have to burden huge investment as well as large volumes of contaminated materials.  1.2 Disposal:  1.2.1 Foam concentrates:  If the threshold comes in force as is written in the current proposal basically >90% of all stocks of firefighting foam agents will have to be disposed of within the transition period. This will be several hundred thousand metric tons of foam agents. In addition to that a volume multiple times that much of rinse water will also have to be disposed of.  At present the only way for a safe disposal is incineration. That again means a volume of fuels consumed to burn the aqueous solutions and the water which is reportedly 1,5-2times the aqueous waste volume.  It is also not clear if the current landscape of suitable incineration capacities (quite a few will not be able to burn Fluorine containing waste for material incompatibility with the installed ovens and gas handling technology) will be able to burden that waste volume.  1.2.2 Contaminated Water:  Obviously since parties along the supply chain will at least try to wash their hardware installations to at least try and avoid replacement huge volumes of water at a comparatively low contamination level (yet by far too much for the drain) will also show up on the disposal market.  This will significantly add to the complexity as this water needs to be incinerated.  1.3 Analytics  1.3.1 Limits of Detection (LOD):  It needs to be noted that foam agents do show very strong matrix effects caused by the surfactants and other ingredients. That said the LOD in foam agents and premixes at present is at ~50ppb at best which is 25 times more than the proposed threshold.  1.3.2 Repeatability/Error:  Current analytics of Fluorochemicals in foam agents or premixes have typical error ranges of ±50-100% for an individual lab and up to several 100% for inter-lab comparison. This can lead into liability issues hence law suits if the found values are around the limit. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain products are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain chemistry and consequently fire-fighting foams based on ashort-chain alternatives can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other firefighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1225. | |
| **1232** | **Date:** 2015/02/28 19:16  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Eucomed and EDMA  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Eucomed, the European medical technology association and EDMA, the European Diagnostic Manufacturers Association welcome the opportunity to provide the below set of preliminary comments to ECHA in order to meet the preferred ‘early’ deadline of 1 March. With these preliminary remarks, Eucomed and EDMA would also like to register their interest as impacted stakeholders.  Please note that Eucomed and EDMA are still in the process of analysing where PFOA is used in the medical device and in vitro diagnostic (IVD) medical device industries and assessing the potential impact of the restriction proposal. Therefore this contribution should be considered as preliminary only: Eucomed and EDMA will be following up to this consultation with a more in depth contribution by the deadline of 17 June.  Please refer to the attached document for more remarks noted. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration for potential derogations.  The Dossier submitter proposed a structural formula to include all possible substances which can degrade to PFOA. This is in line with the restriction on PFOS and the stewardship program of the US-EPA on long chain PFASs. In our view there is no reason to alter the scope of the proposed restriction.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  The Dossier submitter is aware that contamination can take place especially in long supply chains. Therefore, the revised threshold as proposed by the Dossier submitter takes these contaminations into account. However, according to REACH emissions of PBT substances have to be minimised. The Dossier submitter therefore urges industry to reduce the content of PFOA and PFOA related substances as far as possible. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC also notes the comments about likely unintentional contamination of products, and that Regulation (EC) No. 850/2004 uses a limit of 0.1% w/w in articles and parts, and excludes substances occurring as an unintentional trace contaminants. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future.  RAC notes the suggestion that the proposed transitional period of 18 months might be too short for complex supply chains and products that are subject to stringent regulatory requirements, and that an exemption is requested for medical devices. No information has been provided about emissions from the whole sector. As such, from a risk perspective, RAC only supports a derogation for implantable medical devices at the present time. Derogation for other types of medical device is more of a matter for SEAC.  RAC also notes the suggestion to specifically include the use of lead substances for enforcement purposes in the legal text. The specification of CAS numbers for all substances within scope of the restriction would not address polymers, and would be inconsistent with the approach adopted for PFOS. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Taking into account all information submitted during the public consultation of the restriction dossier we support derogation for implantable medical devices and an extended transitional period for most other medical devices.  We also agree that a revision of the concentration limit is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1233** | **Date:** 2015/02/28 21:08  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** The confidential information disclosed in the response above is proprietary, containing technically and commercially-sensitive information which is known only to the company on whose behalf this submission is made, its legal advisor and a small number of relevant customers. It is not currently in the public domain and the company has no intention or desire to make it public. Accordingly, it must not be released into the public domain by virtue of this submission.  The company on whose behalf this information is submitted has invested significant investment (in terms of both time and resources) in research and development to produce its C8F17-X based chemistry coating process. Disclosure of the confidential information would allow an association to be made between the coating process and PFOA which would prejudice this company’s investment as it would allow this company’s competitors to associate the substance with the coating process and potentially allow its competitors to replicate the process as well as affording them a significant public relations opportunity. Disclosure of this information would substantially and potentially irretrievably harm this company’s commercial interests and competitive market position.  We and our client consider that the claim for confidentiality has been sufficiently justified. Our client expressly reserves the right to withdraw and/or redact this submission in the event that its confidentiality cannot be guaranteed. If you consider that, following a review of the claim, further information is required please let us know and we will be happy to provide it. | **General Comments:**  Response to ECHA’s Information Note to the Proposed Restriction of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances. Prepared by ERM for a UK confidential client.  Our client’s process polymerises C8F17-X monomer to a 2nm-4µm covalently-bonded water- and oil-repellent nano-coating. The monomer as supplied is a PFOA-related substance through impurity. Coating produces trace PFOA impurity to 40 ppm.  No commercially-available substance screened delivers performance equivalent to the C8F17-X monomer. Its supplier considers no manufacturer’s C6 material able to meet 2ppb PFOA.  The restriction would have significant economic impact with little quantifiable benefit. Estimated impacts over 10 years for coating smartphones (SP) (70% of our client’s market) are  • European consumer damaged products replacement costs 2015-2024 - €1,638m NPV  • gross profit loss 2015-2024 - €554m NPV  • upstream supplier gross profit loss 2015-2024 - €17m NPV  • EU employee annual earnings loss from unemployment 2015-2024 - €0.7m NPV  • total costs related to our client’s activities >€2.2bn NPV.  Dermal contact presents negligible risk in occupational exposure and consumer scenarios and to the public as product users, because:  • sealed chambers prevent operator exposure to process monomers, with negligible waste  • coating PFOA impurity concentration is low  • individuals’ exposure to coating releases via abrasion is limited  • dermal absorption is minimal  • the coating’s contribution to total intake compared to occupational exposure is negligible, although higher than dietary exposure  • consumer products use contributes insignificantly to occupationally exposed workers’ overall intake  • risk to the general public is adequately controlled compared to authoritative bodies’ derived no-effect levels  Nano-coating environmental impacts are limited compared to benefits. Across SP life cycles  • SP treatment emissions are negligible, adding <1% to production emissions  • a high proportion of SP are recycled, driven by precious metal content  • coatings thermally decompose in smelting or incineration for materials recovery  • where landfilled, polymer coating half-life is 33-112yrs before it degrades to a fluorotelomer alcohol  Production dominates SP life cycle environmental impacts. Coating protects SPs from corrosion and water damage, providing greater reliability and durability. Potential benefits associated with 55m SPs treated are  • >1m damaged SP returns to the manufacturer prevented  • >52,000t CO2e emissions from producing replacement SP avoided  • reduction of >150 tonnes of electronic waste (assuming SPs average 150g)  If all 1.8bn SP shipped worldwide annually were nano-coated, estimated waste and carbons savings are  • >34m SP prevented from being returned to the manufacturers  • >1.7mt CO2e saved each year through reduced production emissions  • electronic waste reduction of 5,100 tonnes | |
| **Answer to specific info request 1:** | |
| **Answer to specific info request 2:** | |
| **Answer to specific info request 3:** | |
| **Answer to specific info request 4:** | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information provided.  For the Dossier submitter the available information does not seem to justify derogation for this use. According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain chemistry has already taken place and time remains until the restriction enters into force, the development of alternatives can be already started / use of alternative substances already tested. Especially for a growing market as the smart phone market which entails higher emissions of these PBT substances, the Dossier submitter considers derogation for this use not reasonable. | |
| **RAC Rapporteurs comments:**  RAC notes that coating smartphones using current C8 technology leads to a PFOA impurity of 40 ppm in the coating itself. RAC acknowledges that environmental emissions from this specific use are likely to be very small during service life and at disposal. Whilst such a specific use could be granted a derogation from a risk assessment perspective, RAC is concerned that this would be a piecemeal approach to the issue of fluoropolymer contamination (especially as many other individual polymer uses might involve low emissions, but collectively the emissions will be higher). In practice it would be simpler to raise the threshold limit. RAC has proposed a slightly higher limit than the DS which will be applicable to all polymers made with PFOA or related substances, which should ensure that this collective source is subject to significant emission reduction.  RAC also notes that the comments flag a further degradation study for polymers that is not currently in the background document: Washington JW, Jenkins TM, [Rankin](http://pubs.acs.org/action/doSearch?ContribStored=Rankin%2C+K) K and Naile JE (2015). Decades-scale degradation of commercial, side-chain, fluorotelomer-based polymers in soils and water. Environ. Sci. Technol., 49, 915–923. | |
| **SEAC Rapporteurs comments:**  Thank you for the information.  Information on the effect of the assumed deterioration of quality due to switching to alternative substances on the end product is very limited. A scenario comprising such an option could have been enlightening. Now information on how much quality would actually suffer and what would be the consequences then is very limited.  We note that finding new alternatives could require the synthesis of new precursors and we understand that this might be time-consuming. We also note that several years will have been available for R&D before the proposed restriction would enter into force. SEAC also proposes to extend the general transitional period to 36 months to allow investigation and introduction of suitable alternatives.  RAC and SEAC propose concentration limit of 25 ppb for PFOA and 1000 ppb for PFOA-related substances. These values are considerably higher than the limit value originally proposed by the Dossier Submitter and are expected to solve any problems relating to impurities. | |
| **1234** | **Date:** 2015/03/02 10:37  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes** | **General Comments:**  We are manufacturers of Textiles for the Fire Fighting Garments that need high repelancey against chemical contamination. An increase in performance can not be acheived using C6 technology compaired to C8. This band will make all current fabrics lacking against the EU and ISO plus national standards, and the current desire by the end users to increase the frequency of washing and decontamination, which C6 technology will fail. This would greatly increase the risk of garments not performing or meeting the standard(s) and increasing the risk of injury or death during active service. | |
| **Answer to specific info request 1:**  There is still a requirement by the industry for C8 fluorocarbon technology to maintain performance standards which would otherrwise fail using C6 technology.  Norway has recognised this by imposing their PFOA restriction on consumer goods only, thereby providing exemption for professional clothing treated with higher PFOA laodings. The major piont here is that this type of technical fabric is very much gear towards PPE fabrics, for use such as in the oil and firefighters, police and the military. This C8 flourocarbon technology mentined has a large element of perdsonal protection with the potential to provide life saving properties to the treated articles.  We could request the same consideration to continued use of C8 fluorocarbon to maintain peformance standards and to retain business in the professional sector. Current value ot the business is £3.5million T/O employing 125 personnel. | |
| **Answer to specific info request 2:**  Current T/O £3.5 million  Employing 125 personnel in manufacturing in Textiles in the UK.  Currently this ban would affect the competitive ability of the company to remain viable after 2018.  The ECHA proposed blanket limit of 2 ppb PFOA would effect our business and many others suppliers and users of C8 fluorocarbons resulting in £millions of lost business to countries such as Russia, India and China which have agreed to restrict PFOA use.  For exampple many tenders will be lost if C8 were to be banned within the EU. | |
| **Answer to specific info request 3:**  Our suppliers of C6 fluorocarbon emulsion state the PFOA content in the mixture is less than 5 ppb. Typical chemical add on levels to fabrics at 5-10% on weight of fabric. The proposed restriction would allow the fabric to be finished with C6 however import of the Chemical would not be allowed.  Our suppliers of C8 fluorocarbon emulsion state PFOA content in the mixture to be less than 0.5 ppm PFOA. Typical chemical add on levels to fabric ar 2-20% on weight of fabric depending on durability and type of repellancy standard. The proposed restriction would not allow import of C8 chemical or C8 treated fabric. | |
| **Answer to specific info request 4:**  Based on teh figures quoted by the manufacturer for PFOA content within their flourocarbon emulsions, as described above, we take exception to the extravagant figure quoted on page 211 (appendix B2.2.5) where it states that 1000-10,000tons of PFOA and PFOA related substances are imported on 350 million DWR jackets. This would be correct for PFOA related substances eg: fluorocarbon emulsion however the focus is on PFOA so your estimate wrongly includes PFOA and is misleading.  Considering the proposed restriction is based onb PFOA then a more accurate figure would be as follows ( Assuming C8 chemical is applied tot he fabric)  1 x Jacket = 1m2  C8 FLUOROCARBON emulsion contains <0.5mg / kg PFOA (manufacture)  Typical application of 10grams fluorcarbon applied 1m2  Therefore 1m2 contains <0.000005g = <1.75kg PFOA  This 1.75kg quantity of PFOA contained within 350 million DWR jackets is signiificantly lower than 1000-10,000 tons quoted. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.    It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used. | |
| **RAC Rapporteurs comments:**  RAC notes that C6 compounds may contain up to 5 ppb of PFOA, as well as the claim that C6 technology will not allow certain fire fighting garments to meet EU, ISO and other national standards, and the current desire by the end users to increase the frequency of washing and decontamination, which will lead to loss of C6 substances (and therefore presumably an increased need for re-treatment or replacement). This is a matter for SEAC.  RAC supports the restriction for textile applications in general because they are a major source of PFOA exposure, but shares concerns that the proposed restriction may affect the performance of personal protection fabrics for professionals. RAC notes that the DS has not commented on the amounts estimated in DWR jackets, but although the estimate of 1.75 kg is very low, RAC has no information about the reliability of this value, or its applicability to the wide range of other types of safety critical fabrics that are on the market. The request for exemptions therefore cannot be supported from an environmental risk perspective, but RAC can support longer transitional periods for safety critical applications, such as PPE (which perhaps could be subject to a review clause). | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We recognise that the performance of short chain alternatives may not yet be sufficient for use in protective professional textiles and we support a transitional period of 6 years to give more time for the development of alternatives. We also see it necessary that the state of the art will be examined in 5 years after the entry into force and that any necessary changes to the scope of the restriction will be made at that point in time. | |
| **1235** | **Date:** 2015/03/02 11:04  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Rudolf Group  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  Comments of Rudolf Group for Annex XV restriction report Perfluorooctanoic acid (PFOA), PFOA salts and PFOA related substances  A) General Comments  As requested by ECHA, Rudolf Group submits these comments to allow first discussions in ECHA`s Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC). Rudolf Group welcomes the initiative of Germany and Norway to propose a restriction of PFOA and PFOA-related substances under REACH. However, Rudolf Group is very much concerned that the restriction proposal may not only ban the manufacturing of PFOA and PFOA-related substances but would also ban the manufacturing of short-chain fluorotelomer alternatives (or “C6” substances), although for most applications they are the main alternatives known to date to the C8 PFOA-related substances. We welcome the fact that the restriction proposal considers the possibility for exemptions for textile applications requiring high technical performance (as part of Risk Management Option 1a , p 157).Rudolf Group is a worldwide operating supplier in the textile finishing industry. We are market leader for hydrophobic finishes, that are not based on substances that contain perfluorinated groups. Our products are highly water-repellent. But this product class generally do not achieve all the unique performance attributes of fluorinated products and can only be used in a limited number of applications. Therefore it is necessary to have alternatives available based on short-chain perfluorinated chemistry to ensure the production of technical textiles for several areas. (For more information see detailed comments provided to Question 1) The threshold of 2 ppb would mean a de facto ban of all short-chain alternatives and fluoropolymers made without PFOA, too. As mobile fluorine compounds have been used for years PFOA is ubiquitously detectible, even in water. Together with the lack of robust analytical methods to quantify PFOA in the range of its detection limit it is not possible for companies to prove compliance. (For more information see detailed comments provided to Question 4)  Specific information requests  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? - Please note that information regarding sectors that involve higher amounts used are particularly welcomed (e.g. textiles)  Answer 1:  Rudolf Group has introduced alternatives, based on short-chain perfluorinated chemistry, that are suitable for substantially all applications, e.g. outdoor, military and technical textiles, protective clothing, lab coats, safety belts, tarpaulins and awnings, etc. Rudolf Group also developed a hydrophobic finishing, that is not based on substances that contain perfluorinated groups. This product class generally achieves highly water-repellent effects against aqueous soiling substances. But it does not achieve all the unique performance attributes of fluorinated products (e.g. oil, chemical or blood repellency) and can only be used in a limited number of applications. Therefore it is necessary to have alternatives based on short-chain chemistry to ensure the production of technical textiles for the following areas:  Automotive textiles  Insulation products  Filter materials for oil and fuel filtration  Specific products for coating textiles (e.g. tents)  Bullet-proof vests for police and armed force  Protection clothing, like work wears for oil drilling, fire fighting, military and surgery  For the mentioned articles, in particular protection clothing, which are essential for human safety and health, the use of perfluorinated polymers is crucial.  The table C.1-1 lists non-fluorinated alternatives for several industry branches, such as fire-fighting, insulation, textile. However, only the fluorinated alternatives are fully assessed, while the non-fluorinated alternatives are only listed „exist“.  The currently proposed threshold of 2 ppb covering PFOA, PFOA salts and PFOA related substances would ban the use of fluorinated alternatives. Traces of PFOA and PFOA related substances in the ppb range are not completely avoidable, because the C8 fraction is an unintentional byproduct occuring during C6 production process. We want to point out, that the amount of this C8 residual fraction has been continuously reduced in the course of past years.  The short-chain perfluorinated polymers have the following advantage: They can not break down to PFOA or PFOA related substances.  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:  e. g. surface treatment of textiles (PFOA-related substances)  Would you consider the presented calculations to be representative for use?  Do you have information of the restriction which might not be included in the dossier?  Answer 2:  Rudolf Group is working to phasing out C8- fluorocarbon polymer production by the end of 2015. After that date, Rudolf Group will convert completely to C6-based chemistry. Rudolf Group has made significant investments in the development of short-chain perfluorinated alternatives that are suitable for all applications with improved environmental and human health profiles. Thus, one can conclude that without a derogation for C6 manufacturing and without appropriate thresholds, the REACH restriction of PFOA and PFOA-related substances will not achieve its desired effect to the extent or is even contradicting REACH restriction principles according to which a restriction “shall take into account the socio-economic impact of the restriction, including the availability of alternatives” (Art. 68 (1)).  According to our current state of knowledge no raw material supplier for C6-fluorocarbon monomers can at present guarantee a PFOA content below 2 ppb. Traces of PFOA and PFOA related substances in the ppb range are not completely avoidable, because the C8 fraction is an unintentional byproduct occuring during C6 production process. We want to point out, that the amount of this C8 residual fraction has been continuously reduced in the course of past years. If the EU supplier of C6 were to be forced to cease production, European downstream users, e.g in textile sectors, will have to rely entirely on imports from non-EU countries.  Rudolf Group is concerned that the restriction dossier does not provide an assessment of the socio-economic impacts that would be induced by a ban on the manufacturing of short-chain fluorotelomer alternatives. Rudolf Group would like to underline that such impacts will be far reaching. If no derogation for C6-based chemistry is granted, the German plant will have to close down, resulting in direct job losses from production, R&D, marketing and sales of C6 chemistry. We are also concerned that a REACH restriction that would ban the manufacturing of the main alternatives to the target substances could have a knock-on effect, choking off investments in innovation and know-how in the European chemicals sector. Therefore, statements in the restriction dossier (p. 176) such as “The proposed restriction is not expected to have major effects on employment”, or […]it is not expected that there will be a significant loss (or gain) in employment in the EU due to the closing down and/or relocation of business activities”, are not correct and ignore the impacts of not granting the derogation for short-chain chemistry.  Question 3: Information about perfluoroheptyl derivates or perfluorooctyl derivates which do not have the potential to degrade to PFOA?  Answer 3:  No information available at Rudolf Group  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?  Answer 4:  A 2 ppb threshold for PFOA and PFOA related substances is not acceptable for the following reasons:  As mobile fluorine compounds have been used for years, PFOA is ubiquitously detectible in the range of ppb, e.g  a) PFOA content (in groundwater in Bavaria, near Gendorf, 2007 und 2008) up to 5 ppb ( see Bayerisches Landesamt für Umwelt under the following link  http://www.lfu.bayern.de/analytik\_stoffe/analytik\_org\_stoffe\_perfluorierte\_chemikalien/pfoa\_gendorf/index.htm )  b) a study of the environmental specimen bank (Umwelt Probenbank des Bundes) shows 1,5 – 13 ppb PFOA in blood plasma of german population ( see brochure – chemicals – per- and polyfluorinated chemicals – avoid of entry, protect environment of Umweltbundesamt Germany)  Therefore a threshold in the range of the ubiquitously existing content does not allow to decide, whether a product itself contributes to the release of further PFOA or not.  • There are currently no analytical methods available to quantify PFOA and PFOA related substances in textile articles or chemical formulations at the 2 ppb limit. Additional you first have to extract the specific fluoro chemical out of a matrix with a million times excess of other fluorinated substances.  Therefore there is currently no method available to allow companies to prove compliance of their product with this threshold of 2 ppb. But, also Member State authorities will have no tools to enforce the restriction.  • Such a low threshold of 2 ppb would increase probability of encountering false positive results.  According to our current state of knowledge no raw material supplier for C6-fluorocarbon monomers can at present guarantee a PFOA content below 2 ppb.  Furthermore, the proposed threshold is inconsistent with approaches proposed in the Norwegian PFOA restriction and existing PFOS POP restriction.  Any threshold should be set at a level of quantification that safeguards the placing on the market of C6 alternatives and that must be applicable by industry and enforceable by Member States on the basis of robust analytical methods with proven repeatability, reproducibility, and taking into account the risk of cross-contamination. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that C6 chemistry represents an important alternative to PFOA-related substances, and that the proposed restriction must not prevent the continued production and use of such substances.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). In addition, unintentional contamination of samples might be a problem if the limit is too low. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that revision of the proposal to ensure that short-chain alternatives are allowed to be used is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances.  As regards protective professional textiles we recognise that the performance of short chain alternatives may not yet be sufficient for all applications and we support a transitional period of 6 years to give more time for the development of alternatives. We also see it necessary that the state of the art will be examined in 5 years and that any necessary changes to the scope of the restriction will be made at that point in time. | |
| **1236** | **Date:** 2015/03/06 10:55  **Type:** BehalfOfAnOrganisation  **Org. type:** Regional or local authority  **Org. name:**  Fire Department Bremen City  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  The targeted retriction creates insurmountable problems in the field of fire fighting | |
| **Answer to specific info request 1:**  1.  Problem:  Specifically existing riscs of fire can currently only capable with AFFF fire-extinguishing substances. These keep PFOA.  There are no no substitutes, here is no alternative to AFFF. To control these scenarios highly efficient AFFF are needed to prevent damage to human lifes and the environment .  Solution:  Compliance exemptions for Fire Services would be a solution.  2.  problem:  Existing extinguishing systems including tanks could not be cleaned sufficiently to come in a future use of PFOA-free extinguishing agents below the target limit of 2 ppb PFOA.  All plants and tanks should be discarded and replaced with new one. These disposals weigh the environmental performance significantly.  Solution:  The limit of 2 ppb should be raised. | |
| **Answer to specific info request 2:**  see above | |
| **Answer to specific info request 3:**  see above | |
| **Answer to specific info request 4:**  see above | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain chemistry and consequently fire-fighting foams based on short-chain alternatives can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain chemistry, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1225. | |
| **1237** | **Date:** 2015/03/09 15:20  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Mineralölwirtschaftsverband  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **Previous comment n. 1223**  **General Comments:**  supporting our comment from February 27th,  reference number 4c37b65a-a393-4397-a893-5c1d43516de9  we provide comments and analysis document as attached in English. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain chemistry and consequently fire-fighting foams based on short-chain chemistry can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other firefighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of firefighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain chemistry, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  RAC appreciates the technical explanation for the reasons why fire-fighting foams contain perfluorinated substances, their long service life (up to 30 years), and the difficulties faced with meeting the existing PFOS restriction.  See also response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see response to Comment 1225. | |
| **1239** | **Date:** 2015/03/10 13:40  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  EURATEX  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  EURATEX supports the intention to limit the emissions of PFOA. The European textile industry do no longer use PFOA for considerable time now however, the main issue our industry have is PFOA in the final articles as a contamination/impurity from the use of PFOA substitutes.  Fluorinated substances are necessary for a range of uses in textiles and related articles i.e. police, fire fighters and military uniforms; technical textile for automotive, filtering material, seals in buildings etc.  In more general terms fluorinated substances are used for the kind of applications and products that gives the EU textile industry the competitive edge.  PFOA have been substituted by the C8 chemistry but on the basis of industry tests, we know that the contamination/impurity with PFOA is a reality. On this basis our industry started for some years now intensive efforts to substitute the C8 chemistry and we came to the conclusion that many of the uses are substitutable but unfortunately not all.  For some applications the substitute (C6 chemistry know to have less residues of PFOA) are not able to comply with the performance criteria of many standards and clients requirements.  Because of the 2ppb threshold recommended, even the substitute of C8 ( C6 chemistry) would no longer be available. Even if it guaranties less PFOA residues, it will not meet the 2ppb threshold in the final articles.  The 2ppb threshold will mark the end of an important segment of the EU textile industry with a shift to production outside the EU with all its socio-economic consequence for Europe.  To this end EURATEX would seek a reconsideration of the 2ppb threshold coupled with an exemption for certain applications and products for which the C8 is the only viable alternative today until such time technical progress will allow for its substitution.  To this end, the following uses are to be considered (this is non exhaustive list as we are still investigating):  • Clothes for the police including the need for fuel repellence to protect against Molotov cocktails  • Bullet-proof vests for police and armed forces  • Clothes for fire fighters  • Clothes for the military  • Clothes for ambulance services  • Clothes for all workers in the chemical industry  • Air and liquid filtering materials, Filter media for industrial dust  • Blood repellent textiles in medical uses  • Transdermal tapes/plats  • Different textiles in the automotive and in the aviation industry ranging from convertible tops in cars to tapes, seals, friction linings, Insulation products etc  • Sun protection (outdoor use, the longevity would be minimized, the aging process would be quicker without the repelling finishing, a damage for the sustainability!)  • Seals in the building industry  • Tarpaulin in ships  • Outdoor furniture (longevity!)  • Tents, also for military use  • Table linen with a stain prof  • Lifting and carrying strap  • Medical textiles  • Heavy duty protective wear  • Strong dyn. Water repellence  • Exhaust air cleaning filters  According to our R&D for these types of articles they are no alternatives yet to meet the required performance criteria. All the test alternatives are worse in their effect on textiles and in their efficiency as you need more chemicals load for a worse effect. At the same time, we have no information about any fluorinated substances which do not have the potential to degrade to PFOA.  As far as the level of PFOA contamination in the articles, it ranges between 50 and 100 ppb according to laboratory tests carried out by our industry. the 8:2 fluortelmomeralcohol is much more problematic because of the lack of analytical method. The existing methods are also questionable and they are not considered to be robust enough for determining a 2ppb threshold. This is important for compliance purpose. For the related substances, no analytical methods exists which add to the industry problems.  To conclude, the 2 ppb threshold will ban not only PFOA but also all related substances including the C6 chemistry. Although the later guaranty a lower contamination level, it is not viable as an alternative to a wide range of textile applications and products for which only C8 chemistry allow to meet the performance criteria required by the standards imposed by our clients. Moreover, no analytical methods to allow enforcement and compliance are available to date for the 2ppb.  To this end, the threshold must be revised and an exemption for certain uses/articles must be granted. Euratex remains available for further discussions on any of the points and arguments raised here. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  Considering your information we believe that also for sun protection, tarpaulin in ships, Outdoor furniture, tents, etc. alternatives are available. Moreover, since those items may directly emit residual amounts of PFOA and PFOA-related substances into the environment we do not agree with derogation for these uses. | |
| **RAC Rapporteurs comments:**  RAC notes the long list of textile applications for which substitutes for C8 technology are said to be unavailable, which is contradicted by the DS. RAC supports the restriction for textile applications because they are a major source of PFOA exposure, but shares concerns that the proposed restriction may affect the performance of personal protection fabrics for professionals. No information was provided in the comment about the likely level of emissions of PFOA/PFOA-related substances from these applications. The request for exemptions cannot be supported from an environmental risk perspective, but RAC can support longer transitional periods for safety critical applications, such as PPE (which perhaps could be subject to a review clause).  RAC also notes that residual PFOA levels in articles are in the range 50 – 100 ppb.  RAC acknowledges that C6 chemistry represents an important alternative to PFOA-related substances, and that the proposed restriction must not prevent the continued production and use of such substances.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that revision of the proposal to ensure that short-chain alternatives are allowed to be used is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances.  We recognise that the performance of short chain alternatives may not yet be sufficient for use in protective professional textiles and we support a transitional period of 6 years to give more time for the development of alternatives. We also see it necessary that the state of the art will be examined in 5 years and that any necessary changes to the scope of the restriction will be made at that point in time. | |
| **1240** | **Date:** 2015/03/11 12:49  **Type:** BehalfOfAnOrganisation  **Org. type:** National NGO  **Org. name:**  Unabhängiger Tanklagerverband UTV e.V.  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:** | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration. | |
| **RAC Rapporteurs comments:**  Thank you for the information. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1249** | **Date:** 2015/03/19 07:10  **Type:** BehalfOfAnOrganisation  **Org. type:** Regional or local authority  **Org. name:**  Queensland Department of Environment & Heritage Protection  **Org. country:** Australia  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Ongoing government Policy drafting and consideration. | **General Comments:**  Relevant information from other jurisdictions on proposed management controls for composition and use fluorochemical products. | |
| **Answer to specific info request 1:**  n/a | |
| **Answer to specific info request 2:**  Negative impacts to human health, the environment and economic assets such as food and water quality must be considered if there is a failure to control emissions. | |
| **Answer to specific info request 3:**  No | |
| **Answer to specific info request 4:**  n/a | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration. | |
| **RAC Rapporteurs comments:**  The comment is noted. The attachments concern a variety of issues surrounding policy towards the use of fire-fighting foams in Australia. RAC notes the preference for a limit of 50 ppm (or 73 ppm expressed as free PFOA equivalents) in such foams. However, since this is a potentially significant source of environmental exposure, RAC has not recommended any derogation for this use, but recognises that there are socio-economic factors for SEAC to address. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1251** | **Date:** 2015/04/02 17:27  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  FESI  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  The Federation of the European Sporting Goods Industry (FESI) represents approximately 1,800 sports manufacturers (85% of the European market) through its twelve national sporting goods associations, its special groupings and its directly-affiliated member companies. FESI’s constituency accounts for a European turnover of 66 Billion Euro Annually and employs approximately 640.000 EU Citizens. FESI is a long-term, experienced partner and contributor to both national and EU-wide consultation processes.  The sporting goods industry, as mediator between the users (sports people), the regulatory and standardisation world and the global supply chain has a natural interest in robust and reliable standards and protocols as this improves the public’s confidence in and positive perception of the sector. This ultimately helps to elevate consumer satisfaction.  Therefore FESI thanks ECHA for providing the opportunity to comment on the REACH Annex XV dossier submitted by Germany and Norway proposing a restriction on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances. The proposal raises several important issues, and FESI seeks to contribute information and insight to aid in ECHA’s deliberations. After a thorough membership consultation, FESI comes to the same conclusion as the comments submitted previously by the AFIRM group and fully endorses their input as re-produced below..  The Federation of the European Sporting Goods Industry (FESI) Sustainability Committee was established in 2008; its mission is to be the link between the sporting goods industry and the European Authorities on Environmental and Sustainability policies.;. FESI is made up of sporting goods manufactures as well as the European Outdoor Group (EOG) and 12 National Sporting Goods Associations Representing: Austria, Czech Republic, Denmark, Croatia, France, Germany, Greece, Italy, Netherlands, Spain, Turkey and the United Kingdom.  As expressed in the AFIRM paper, FESI members understand the importance of reducing and working toward eliminating intentional use of PFOA, its salts and PFOA-related substances (‘PFOA’) in textile and footwear manufacturing. We believe that an incrementally phased-in limit based on feasibility and socio-economic assessments will support all industries in this challenging undertaking. At present, FESI members manage and monitor PFOA through their respective Restricted Substance Lists (RSLs) and are working with suppliers to replace their use and decrease concentrations of them in manufacturing and finished products. Some members have been restricting and testing for PFOA in their products since 2006. The result has been the accumulation of data and experience concerning the extent to which these chemicals are utilized in different stages of the supply chain, their existence as unintended contaminants in apparel and footwear materials, and the challenges that exist in decreasing their wide use and incidental occurrence.  FESI members have studied the proposed legislation and believe that clarification of several points is needed: the legislation’s scope and implementation, the test method, and whether a full socioeconomic assessment across all industry sectors has been performed with appropriate consideration of the incredibly low limit proposed. The most important goals for FESI members in submitting these comments are to ensure that any new restriction can be feasibly implemented within their international supply chains and to prevent legal uncertainty.  A. SUGGESTED RESTRICTION  Comment:  I. REQUEST FOR CLARIFICATION. To avoid confusion in implementation, we recommend that ECHA clarify the following items:  a. Scope of Restriction. Does the proposed PFOA restriction apply to the total concentration in the finished article or to specific components of the article?  b. Test Method. We recommend that ECHA specify a validated and internationally recognized test method before finalizing a restriction on PFOA. No validated method currently exists, and implementing a restriction without one would result in significant uncertainty in compliance and enforcement for the regulated business community.  II. THRESHOLD LIMIT VALUE (TLV). The 2ppb proposed limit is incredibly low and located in the scientific area of so-called “Ultra-Trace Analytics.” Analytical technology can quantify substance concentrations down to this level, but highly sophisticated equipment not widely available is needed. However, at these ultra-trace concentrations, results are not consistently repeatable, especially in the absence of a validated test method as in the case of PFOA. According to a FESI and AFIRM member’s analytical experts, even with the highest level of due diligence, the variation of results among different laboratories has been found to be a factor of 65 for PFOA specifically. With the potential for this much variability, this ultra-trace concentration limit should not be the basis for determining the legal status of millions of imported products every year into the European Union. The uncertainty created for compliance with and enforcement to such a low limit will result in substantial commercial disruption.  III. CONTAMINATION. As discussed in the ECHA Dossier, PFOA and related substances are used in a wide variety of applications, which makes complete avoidance of cross-contamination a profoundly challenging task, even for leading apparel and footwear brands that have restricted PFOA for years. The risk that cross-contamination will cause widespread failures above the proposed 2ppb limit is a certainty. Potential sources of contamination include:  - Overseas production facilities have phased out the use of long-chain PFCs for some customers who require it, but not others. These facilities have contaminated equipment that will easily result in apparel and footwear products with trace levels of PFOA above the proposed limit.  - Since PFOA is very persistent in the environment, trace background concentrations in fresh water sources may contain enough PFOA to contaminate finished products in exceedance of the proposed limit.  - Fire-fighting substances, such as those used in fire extinguishers, may contaminate production facilities with enough PFOA to cause manufactured goods to exceed the proposed limit.  - At the limit proposed, laboratory testing equipment can contain trace concentrations of PFOA that will result in false-positive test results for the samples being tested.  To mitigate the confusion and uncertainty caused by cross-contamination, FESI recommends that ECHA adjust the proposed limit upward to focus on restricting intentional use of PFOA and related substances.  IV. TIMELINE FOR REDUCTION. Regardless of what final limit ECHA settles on, we strongly recommend that this restriction be implemented by incremental decreases over time. This strategy was successfully applied in the United States Consumer Products Safety Improvement Act, where restricted levels of lead in children’s products were incrementally decreased from 600 ppm to 100 ppm over the course of several years, with the final limit pending assessment of technological feasibility. Likewise, the specifics regarding the limit and timeline for each decrease in the case of this PFOA restriction would be most appropriately determined by independent feasibility and socio-economic assessments. This approach of incremental decreases would assist the greater industry in reducing intentional PFOA use and contamination by allowing the supply chain to focus efforts on the more significant uses on a priority basis. This in turn will make it more practical and possible to tackle the lesser known, smaller, and more difficult to identify uses and sources of contamination later on. Furthermore, incrementally decreasing the limit will allow for the appropriate establishment of a validated test method. We therefore suggest an initial TLV of 500 ppb in apparel and footwear products, with an incremental decrease to 100 ppb within 5 years.  SUMMARY:  • FESI members understand the importance of reducing and working towards elimination of intentional use of PFOA, its salts and PFOA-related substances in footwear and textile manufacturing. We believe this restriction should be implemented by incrementally decreasing the acceptable limit over time to support all industries in this challenging undertaking.  • The specifics regarding the limits and corresponding timelines for each decrease would be most appropriately determined by independent feasibility and socio-economic assessments.  • Clarification of the test method is imperative to ultimately allow for the identification, reduction and substitution of PFOA, its salts and PFOA-related substances, and being able to demonstrate compliance.  • Among FESI members, opportunities for the most rapid reduction in PFOA in the supply chain occurred when these substances were restricted from intentional use. Further reduction will take time, considering the wide range of their existing usage, a full understanding of every possible usage further up the supply chain, and the control of sources of cross-contamination.  Again, thank you for the opportunity to comment. In case you need any clarifications please do not hesitate to contact us.  Sincerely,  Jerome Pero  Eu Policy Director,Federation of the European Sporting Goods Industry(FESI) | |
| **Answer to specific info request 1:**  Carrier-foil applications, industrial anti-stick treatments/sprays, high performance durable water repellent (DWR) work-wear/personal protective equipment (PPE), fire-fighting chemicals. Potential risks should be marginal compared with other applications in the cosmetic or food sector | |
| **Answer to specific info request 2:**  The intentional usage in our direct operational sphere/production allocations is controlled by our RSL programs, cost impacts are manageable. To avoid any kind of ultra-trace impurity or cross-contamination, costs may raise significantly and out of proportion to any benefit gained. | |
| **Answer to specific info request 3:**  NONE | |
| **Answer to specific info request 4:**  As described earlier, a limit of 2ppb is in the area of Ultra Trace Analytics will result in legal uncertainties about product marketability and liability and will result in significant commercial disruption. This includes the very likely occurrence of false-positives during spot checks of market surveillance authorities e.g.  The existence of a validated test method is imperative before any chemical can be properly integrated into REACH/Annexes | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new comments made.  Ia. Scope of Restriction. The Dossier submitter revised the thresholds and proposes different thresholds for e.g. formulations and final articles.  IB and II:  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  III contamination:  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA related substances because of cross contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  IV. TIMELINE FOR REDUCTION.  The Dossier submitter does not agree with the proposed incremental decreases over time. Industry is has now been informed about the proosed restriction and can already take measures to minimise the content of PFOA and PFOA related substances in their articles. The proposed threshold value seems not to be justified by the Dossier submitter, since no data were provided (such as volumes and, substances used).  However, the Dossier submitter has revised the proposed threshold to ensure that short-chain alternatives are allowed to be used. | |
| **RAC Rapporteurs comments:**  RAC notes the request for an incrementally phased-in concentration limit, and clarity about whether the restriction will apply to the total concentration in the finished article or to specific components of the article. RAC has recommended that the wording regarding articles is consistent with existing legislation on PFOS.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk that cross-contamination might cause failures above the proposed 2 ppb limit is also noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. This could be part of a phased approach. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that a revision of the concentration limit is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1252** | **Date:** 2015/04/10 12:36  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Jack Wolfskin GmbH & Co. KGaA  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  Jack Wolfskin understands the importance of reducing and working towards eliminating international use of PFOA, its salts and PFOA-related substances in textile and footwear manufacturing. We are steadily changing our DWR finishes to non-fluorinated chemistry. At present, Jack Wolfskin manages and monitors PFOA through its Restricted Substances List (RSL), implementing input stream management systems in the supply chain, and working with suppliers to replace fluorinated DWR finishes. We have restricted PFOA in our products since 2007. The result has been the accumulation of data and experience concerning the extent to which these chemicals are utilized in different stages of the supply chain, their existence as unintended contaminants in apparel and footwear material, and the challenges that exist in decreasing their wide use and incidental occurrence. | |
| **Answer to specific info request 1:**  Jack Wolfskin uses DWR (Durable Water Repellent) finishes for outdoor clothing and shoes. Short chain and non-fluorinated chemicals are available on the market. Non-fluorinated chemicals do not provide oil repellency. Short-chain fluorinated formulations often contain contaminants higher than the proposed limit of 2 ppb. | |
| **Answer to specific info request 2:**  The intentional use is controlled by our RSL regulation for which costs are manageable. The control of impurities or cross-contamination at trace level might imply high costs due to changes of processes, settings and equipment at the manufacturing site. This is applicable for short-chain as well as non-fluorinated alternatives. Higher costs might also occur when performing tests at ultra-trace level due to a more complex handling of testing equipment (e.g. necessity of intense cleaning to eliminate traces), as well as sophisticated testing equipment which might not commonly be available in commercial labs used by the industry around the world. | |
| **Answer to specific info request 3:**  None. | |
| **Answer to specific info request 4:**  The use of long-chain fluorinated substances in same manufacturing site might lead to cross-contaminations in the finished product. As to our knowledge, also short-chain fluorinated chemistry contains PFOA and PFOA-related substances as impurities. As the chemical industry cannot ensure that traces are below 2ppb coming from by-products during production, these amounts are likely to be found in finished products.  Additionally, the detection in the area of ultra-trace analytics can cause an increase in false-positive results, which makes it difficult to assume liability and hence ensure marketability of products. It is necessary to have validated test methods in place - not only in specialized laboratories but also in commercial laboratories used by the industry - so that test results are comparable and conclusive. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  Thank you for the information on compliance control costs. According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross-contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced, although acknowledging the costs involved to ensure compliance with the proposed restriction. These compliance control costs could not be quantified due to lack of reliable data. Hence, their relevance compared to the overall substitution costs is difficult to assess. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that C6 chemistry represents an important alternative to PFOA-related substances, and that the proposed restriction must not prevent the continued production and use of such substances.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk that cross-contamination might cause failures above the proposed 2 ppb limit is also noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that the low concentration limit might entail high costs and consider that a revision of the limit value is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1253** | **Date:** 2015/04/10 14:31  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  bluesign technologies ag  **Org. country:** Switzerland  **Company name confidential:** **No** | **General Comments:**  bluesign technologies (hereinafter: bluesign) would like to take the opportunity to contribute information and insight to the public consultation on the REACH Annex XV restriction for perfluorooctanoic acid (PFOA), its salts and related substances, published on December 17th, 2014 on the ECHA website. As important as such restriction is, bluesign believes that in its current form the proposal includes several significant shortcomings.  The bluesign® system is the solution for a sustainable textile production, whose aim is to eliminate harmful substances right from the beginning of the manufacturing process and set and control standards for an environmentally friendly and safe production. Together with our system partners we have committed to remove long-chain chemistry from the textile supply chain. This resulted in a usage ban for long-chain C8 repellents in textile manufacturing of our system partners starting from January 01, 2015. As such, the PFOA restriction proposal not only supports bluesign’s decision to eliminate long-chain perfluorinated chemicals, but it should also ensure ongoing access to products made with shorter chain (e.g. C6 or C4) alternatives.  The current proposal, however, calls for certain provisions that are of main concern for bluesign technologies:  • The proposed threshold of 2 ppb for each substance in scope of the restriction may be beyond the limits of current state-of-the-art analytical technology. In order to quantify substance concentrations down to this level highly sophisticated, not widely available and very expensive equipment is needed. For such ultra-low concentrations and due to the fact that no validated method exists to date, the variation of results between different laboratories can be significant.  • Analytical techniques do not exist for all materials and analytes subject to the restriction. In addition, the already existing analytical methods are not yet standardized. The accuracy of currently available analytical techniques varies and often cannot reliably detect 2 ppb of PFOA or related substances, which creates a substantial risk of false positives.  • There exist a risk of cross-contamination of shorter chain chemistry. The background levels of PFOA in the environment, which can for example be traced back to historical emissions or to current emissions in major producing countries, can readily contaminate articles produced with shorter chain chemistry. Additionally, the same production facilities manufacture products for customers, who have already phased out the use of long-chain PFCs and for those who have not. All of the above could lead to positive testing of PFOA and thus restriction of articles, which were actually not manufactured with PFOA or related substances.  • Short chain chemistry is endangered by the proposed threshold limit. Even though a PFOA-content below 2 ppb in chemical products might be achievable for C6 chemistry, it is not feasible to obtain this limit for PFOA-related substances (e.g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate).  • The proposed restriction would also effectively create a ban for technical textiles and consumer textiles made with short chain substitutes, which require sufficient repellency (oil, chemicals) properties not possible to obtain with non-fluorine chemistry. The affected products include among others:  - Protective work wear in medical, chemical, oil and other process industries  - Textiles used in certain medical applications (e.g. blood repellency properties)  - Apparel for fire fighters and armed forces  - Outdoor equipment and apparel | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross-contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that C6 chemistry represents an important alternative to PFOA-related substances, and that the proposed restriction must not prevent the continued production and use of such substances.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk that cross-contamination might cause failures above the proposed 2 ppb limit is also noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see response to Comment 1235. | |
| **1254** | **Date:** 2015/04/22 10:04  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Swedavia AB  **Org. country:** Sweden  **Company name confidential:** **No** | **General Comments:**  Swedavia AB wants to highlight that the company has used a fluorine-free fire-fighting foam for several years at the company’s airports in Sweden, for example at Stockholm Arlanda Airport.  The fluorine-free fire-fighting foam, Moussol-FF 3/6, fulfills the requirements according to ICAO (International Civil Aviation Organization).  MPA Dresden GmbH issued a certificate in the 5th of August 2009; to certify conformity of the tested foam concentrate, designation Moussol-FF 3/6, with the requirements for performance of level B according to table 8E.1, Appendix 8E : 2004-5 of ICAO Airport Service Manual, Part 1. Certificate number 2009-F-2536/Sth 79.  MPA Dresden GmbH is an Independent fire protection competence center and serves as a testing, inspection and certification centre, as well as a consulting engineering office for constructional, organisational and supervisory fire protection (the information about the company MPA Dresden GmbH is copied from the company’s homepage). | |
| **Dossier submitter response:**  Thank you very much for the information of using fluorine-free fire-fighting foam. | |
| **RAC Rapporteurs comments:**  RAC notes, contrary to claims made by several other fire-fighting foam organisations, that a fluorine-free fire-fighting foam appears to be available for use at airports. RAC does not know if this product can be used for any oil fire, whether it can be supplied in sufficient quantities for all relevant applications in the EU, nor its composition (so cannot comment on whether it is more or less hazardous). The efficacy of such products compared with fluorinated foams is an issue for SEAC. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. SEAC considered this information together with other comments submitted regarding fluorinated and non-fluorinated alternatives, their efficacy and availability. Overall it seems that there are applications where fluorine-free foams available today are not suitable. See also response to Comment 1225. | |
| **1255** | **Date:** 2015/04/24 09:55  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes** | **General Comments:**  Our company is active in the production of functional textiles for personal protection equipment, of which a vast majority is treated with fluoro containing chemicals (already based on the C6 chemistry) to achieve oil, chemical and water repellency.  This represents about 60% of our turn-over. The proposed threshold of 2 ppb in the active substance will lead to the cancellation of this product range, which means the end of our business.  Note that our company employs more than 800 people. There is no doubt that this proposed restriction will lead to an economical and social disaster in the ppe supply chain.  Moreover, human lifes amonst the end-users (police, firemen,...)will be at stake.  For the moment a 1 ppb ON THE FABRIC is achievable with the existing C6 fluorochemisry. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used. | |
| **RAC Rapporteurs comments:**  RAC notes the concern for functional textiles for PPE, and that 1 ppb appears to be achievable on the final fabric (but not in the substance used to treat the fabric). | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see reply to Comment 1235. | |
| **1256** | **Date:** 2015/04/24 11:25  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Riedel Textil GmbH  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  Not possible, you should look first at the correlations before you design rules. | |
| **Dossier submitter response:**  See Comment 1257. | |
| **RAC Rapporteurs comments:**  - | |
| **SEAC Rapporteurs comments:**  - | |
| **1257** | **Date:** 2015/04/24 11:35  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Riedel Textil  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  A) General Comments  As requested by ECHA, TEGEWA submits these comments in due time before 1 March 2015 to allow first discussions in ECHA´s Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC). TEGEWA would like to reserve its right to submit a more detailed comment by 17 June 2015.  TEGEWA supports the approach to restrict the use of PFOA and PFOA- related substances in textile applications but objects to the restriction in its current version. Rationale:  The report mentions that the most important substitutes for PFOA and PFOA-related substances are short-chain PFASs. Due to the proposed limit in chemical formulations of 2 ppb such alternatives are not available.  This would lead to a loss of technical textiles (e.g. personal protective equipment) with requested repellent properties.  The lack of robust analytical methods will not allow companies to prove compliance. But also Member State authorities will have no tools to enforce the restriction.  B) Specific information requests  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  2  alternatives are not available and/or the performance of alternatives is not considered adequate?  Please note that information regarding sectors that involve higher amounts used are particularly welcomed (e.g. textiles)  The proposed threshold of 2ppb in mixtures and articles puts a direct ban to the placing on the market and use of the most important short-chain alternatives as well as articles treated with short-chain alternatives. According to calculations, a PFOA-content below 2 ppb in chemical mixtures might be achievable in future, but a limit of 2ppb for PFOA- related substances (e. g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate) is definitively not feasible. The threshold should be set at a level that safeguards the placing on the market of short-chain alternatives, namely intermediates, mixtures, and articles treated with short-chain alternatives.  It takes time to provide a realistic estimation of a threshold on treated textile based on the possible C8 fraction in commercial C-6-formulations. We would like to refer to our detailed comments that will be submitted by 17 June 2015. Thresholds must be supported by robust analytical methods that must be uniformly applicable by industry and enforceable by Member State authorities. Methods with detection level in the 2 ppb range are currently not available for all of the C8 substances in scope of the restriction dossier.  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:  e. g. surface treatment of textiles (PFOA-related substances)  3  Would you consider the presented calculations to be representative for your use?  Do you have information of the restriction which might not be included in the dossier? It is mentioned in the dossier that short chain PFASs are the most important alternatives for PFOA and PFOA-related substances. In fact, at least regarding textile applications this information is misleading. Due to the proposed limit in chemical formulations of 2 ppb, short-chain PFASs compliant to this limit are not available on the market. Therefore the presented calculations were carried out on a false basis.  Taking into account that short chain PFASs are not compliant the restriction proposal would cause a ban for technical textiles with a sufficient repellent (especially for oil, stain and chemicals) effect which is requested e. g. for personal protective equipment. Affected would be - Bullet-proof vests for police and armed forces - Apparel for fire fighters - Protective work wear against chemicals in chemical and other industries - Certain textiles used in clinics with requests for repellence of blood - Automotive textiles - Insulation products for vehicles - Specific products for coating textiles (e.g. tents)  Question 3: Information about perfluoroheptyl derivatives or perfluorooctyl derivatives which do not have the potential to degrade to PFOA? No information available at TEGEWA.  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?  4  In view of the 2ppb limit for PFOA and PFOA-related substances in chemical formulations there will be no short-chain PFASs available as substitutes for the C-8-compounds. A PFOA-content below 2 ppb might be achievable in future, but a limit of 2ppb for PFOA-related substances (e. g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate) is not feasible.  The availability of analytical methods including the limit of quantification of those methods in relevant matrices? Analytical methods to quantify the PFOA-content in textiles are available but it is very questionable that these methods are robust enough to determine whether the PFOA-content in a textile article is below 2 ppb or not and to decide whether an article is compliant or not.  There are no analytical methods available to quantify PFOA- related substances (e. g. 8:2 fluorotelomer alcohol, fluorotelomer acrylate) in textile articles according to the limit of 2ppb.  Analytical methods to quantify PFOA and related substances in chemical formulations according to the 2ppb limit are not available.  It has to be taken into account that the task is not to detect a specific substance in a given clear solution but to extract the specific fluoro chemical out of a matrix with a million times excess of other fluorinated substances and to detect it with a accuracy that allows the decision that the product is compliant or not.  Experiences from ongoing work to develop test methods for PFOS cannot be transferred to testing of PFOA and PFOA related  5  substances because the threshold of 2 ppb is so much lower as for PFOS.  Therefore, chemical companies, textile companies and textile brands will not be in the position to prove compliance of their products (both formulations and articles). Member State authorities will have no tools to enforce the restriction. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk that cross-contamination may cause failures above the proposed 2 ppb limit is also noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see reply to Comment 1235. | |
| **1258** | **Date:** 2015/04/28 18:35  **Type:** Individual  **Country:** Belgium  **Company name confidential:** **No** | **General Comments:**  Dear Madam,  Dear Sir,  the use of PFOA (used in water repellent products) is needed to guarantee a good protection against chemicals (EN13034). The only way to guarantee is the use of C6 spray that contain PFOA, due to lack of good alternatives.  Best regards,  Frederik | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFAS can be manufactured and used. | |
| **RAC Rapporteurs comments:**  RAC notes the generic comment about textiles. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see reply to Comment 1235. | |
| **1259** | **Date:** 2015/05/07 18:46  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Eurofeu  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  We are representing the subsection for firefighting agents of EuroFeu, the European umbrella organization of the national trade associations of the fire protection industries.  Although we do support the need for a restriction of PFOA and PFOA-related substances, we do not support the current draft version due to the inapplicable proposed threshold level. | |
| **Answer to specific info request 1:**  Foam agents are designed to meet international standards (ISO 7203; EN 1568; IMO; ICAO; UL162; …) and basically are used to save lives and property in cases of fire. The application scenarios stretch from a burning car on the roadside to a burning fuel storage tank with >100m diameter. In particular in the high risk areas (chemical and petrochemical industry) the foam agents used are referred to as AFFF (aqueous film forming foams) and contain Fluorosurfactants bringing the performance of the agent to a level suitable for fighting these extreme fires.  Fluorosurfactants used in AFFF are chemicals consisting of one or more per- or polyfluorinated molecular groups with typical chain lengths varying from four to over ten carbons. The key function of these chemicals is the suppression of vapours and emulsion of fuel into the foam blanket (emulsion of fuel into the foam blanket could cause a fast collapse or even burning of the foam blanket hence loss of firefighting properties). This function is essential to a foam agent’s fire performance to a point that fires above a certain size cannot be successfully fought without AFFFs .  The major Fluorochemical producers in Europe, the US and Japan are all signatories of the so-called EPA Product Stewardship Program – a voluntary agreement between the manufacturers of Perfluorochemicals and the US-American Environmental Protection Agency EPA - that aims at completely eliminating the use and emission of PFOA by the end of 2015. Alternatives developed to replace C8-based chemicals are commonly referred to as short-chain (C6-based) chemicals.  Currently used AFFFs contain Fluorosurfactants consisting almost exclusively of C6-based telomer chains (6 perfluorinated carbon plus a two carbon spacer to the rest of the molecule). However, they may also contain trace amounts of impurities consisting of longer chains such as C8 telomeres. It should be noted that PFOA was never used as an active substance in firefighting foam agent technology but can again be present in trace amounts as contaminant from the manufacturing process of fluorotelomers..  It is important to note that C8-chemistry was used along the entire AFFF supply chain beginning from manufacturers of Fluorochemicals, transporters, manufacturers of firefighting agents, warehouses and installations of end users that have now converted to C6-chemistry. Furthermore, perfluorinated C8-chemicals has a strong tendency to adsorb to surfaces. Since that bonding is quite stable this behavior leads to a slow bleed out into liquids which get into contact with those contaminated surfaces. Even extensive rinsing and cleaning will not remove 100% of C8-contamination. This basically means that contamination of new C6-based AFFF by their predecessors is likely to happen and as a consquence will lead to C6-based products that will very likely exceed the proposed threshold 2 ppb which is not limited to PFOA but includes all PFOA-related substances considered as precursors. | |
| **Answer to specific info request 2:**  Basically the given threshold equals to an extremely high purity level beyond what is common for technical or even analytical grade of purity for chemical substances. It is foreseeable that the industry will not be able to meet this low level of C8-impurities due to factors like carry over contamination for materials being made in the same plants which used to make C8 and higher. No member of the supply chain at present can guarantee to get even close to the proposed level of 2ppb (parts per billion). That said one has to assume that even modern C6-based foam agents will carry C8-contamination beyond 2ppb.  If the threshold comes in force as currently proposed basically >90% of all stocks of firefighting foam agents will have to be disposed of within the transition period. This will be several hundred thousand metric tons of foam agents. In addition to that a volume of rinse water multiple times the foam volume will also have to be disposed of.  At present the only way for a safe disposal is incineration which means each liter of water or foam agent to be incinerated requires a corresponding minimal amount of fuel (reportedly 1,5-2times the volume).  It is also not clear if the current landscape of suitable incineration capacities (quite a few will not be able to burn Fluorine containing waste for material incompatibility with the installed ovens and gas handling technology) will be able to burden that waste volume. | |
| **Answer to specific info request 4:**  1.1 Impurities  1.1.1 Raw materials  Basically the given threshold equals to an extremely high purity level beyond what is common for technical or even analytical grade of purity for chemical substances. It is foreseeable that the industry will not be able to meet this low level of C8-impurities due to factors like carry over contamination for materials being made in the same plants which used to make C8 and higher. No member of the supply chain at present can guarantee to get even close to the proposed level of 2ppb (parts per billion). That said one has to assume that even modern C6-based foam agents will carry C8-contamination beyond 2ppb.  1.1.2 Finished Products  Obviously if the raw materials (Fluorosurfactants and –polymers) suffer from C8-contamination at a high enough level this will carry through into the finished fire fighting foams as well and still exceed the threshold. It can be safely assumed that all foam agents containing Fluorochemicals and many of the fluorine free ones in the field will carry contaminations of some perfluorinated C8-chemistry above 2µg/kg. The implication would be an immediate discontinuation (and disposal) of all AFFF-Foams at the risk of not having any suitable replacement.  1.1.3 Hardware:  To meet the requirements of this norm a major part of all installations would have to be replaced: The ability of C8-based Fluorochemicals to strongly bond to surfaces contaminates those surfaces to the extent that even extensive washing will not take out enough material to stay below the threshold. This affects manufacturing plants for agents and the corresponding raw materials, storage facilities for foam agents as well as extinguishing systems (!). This will have the immediate consequence that a huge number of facilities will have significant downtimes to reinstall new systems as far as necessary plus will obviously have to burden huge investment as well as large volumes of contaminated materials.  1.3 Analytics  1.3.1 Limits of Detection (LOD):  It needs to be noted that foam agents do show very strong matrix effects caused by the surfactants and other ingredients. That said the LOD in foam agents and premixes at present is at 50-20ppb at best which is 25-10 times more than the proposed threshold.  1.3.2 Repeatability/Error:  Current analytics of Fluorochemicals in foam agents or premixes have typical error ranges of ±50-100% for an individual lab and up to several 100% for inter-lab comparison. This can lead into liability issues hence law suits if the found values are around the limit. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain chemistry and consequently fire-fighting foams based on short-chain chemistry can be manufactured and used. Contaminations in existing extinguishing systems are considered, too. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1225. | |
| **1260** | **Date:** 2015/05/08 00:38  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Outdoor Industry Association - Chemicals Management Working Group  **Org. country:** United States  **Company name confidential:** **No** | **General Comments:**  Thank you for the opportunity to comment on the REACH Annex XV dossier submitted by Germany and Norway proposing a restriction on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances.  Outdoor Industry Association Chemicals Management Working Group (OIA CMWG) members understand the importance of reducing and working towards eliminating intentional use of PFOA, its salts and PFOA-related substances (‘PFOA’) in textile and footwear manufacturing, in step with work needed to determine safer and functionally relevant alternatives.  While the OIA CMWG does not have the detailed hazard, risk and test expertise to draft our own unique comments, we do have a very strong market perspective. Our members align with the high-level points of concern as articulated and submitted by the Apparel and Footwear International RSL Management Group (AFIRM) and supported by the Federation of the European Sporting Goods Industry (FESI.) These points include:  • The OIA CMWG has an understanding of the importance of reducing and working towards elimination of intentional use of PFOA, its salts and PFOA-related substances in footwear and textile manufacturing. We believe this restriction should be implemented by incrementally decreasing the acceptable limit over time to support all industries in this challenging undertaking.  • The proposed limit of 2 ppb for determining the legal status of millions of products imported every year into the European Union would cause substantial commercial disruption as analytical results today are not consistently repeatable.  • The specifics regarding the limits and corresponding timelines for each decrease would be most appropriately determined by independent feasibility and socio-economic assessments.  • Clarification of the test method is imperative to ultimately allow for the identification, reduction and substitution of PFOA and being able to demonstrate compliance.  • Opportunities for the most rapid reduction in PFOA in the supply chain have occurred when these substances were restricted from intentional use. Further reduction will take time, considering the wide range of their existing usage, a full understanding of every possible usage further up the supply chain, and the control of sources of cross-contamination.  Background:  Outdoor Industry Association (OIA), founded in 1989, is the premier global trade association for the outdoor products and services industry, with 1,300 member companies globally. Based in Boulder, Colorado, USA, with an office in Washington, DC, USA, OIA’s member companies include Adidas Outdoor, Arc’Teryx, Burton Snowboards, Mountain Equipment Co-op, Outdoor Research, Patagonia, REI, New Balance, The North Face, Timberland, and W.L. Gore.  OIA’s Sustainability Working Group (SWG) was founded in 2007 to address issues of product and supply chain environmental and social responsibility in a pre-competitive, collaborative manner. Today, the OIA SWG is 200+ companies strong and serves as a model for other industries and sectors to proactively address their shared supply chain challenges. The flagship work product of the OIA SWG, the Eco Index, was adopted by the Sustainable Apparel Coalition (along with materials sustainability data contributed by Nike) as the basis for the Higg Index, an assessment tool now being adopted by 40% of the global apparel and footwear supply chain.  Under the OIA SWG, the Chemicals Management Working Group (CMWG) was formed in 2011 in partnership with the Sustainable Apparel Coalition to specifically address issues related to chemicals management in the shared global supply chains of apparel, footwear, accessories, and gear. The mission of the OIA CMWG is to drive continuous improvement and innovation in chemicals management practices, to accelerate the development and use of “Sustainable Chemistry” (“Green Chemistry”) practices.  The goals of this group include providing outdoor and apparel companies with education around the properties of various chemical treatments, to establish a shared baseline of understanding within the industry; collecting information on existing chemical treatment options; establishing a shared landscape of chemical treatment use cases and performance requirements; and, ultimately seeking to replace existing chemistries with less hazardous alternatives, while upholding necessary performance requirements and avoiding “regrettable substitutions.”  Today, the CMWG has around 135 individual members - stakeholders from the outdoor and fashion industries and throughout the value chain. In addition to developing measurement tools for the industry including the Chemicals Management Module of the Higg Index, in 2012, the OIA CMWG also began a working group specifically dedicated to exploring the use of perfluorinated chemistries in the industry and promoting informed sourcing decisions, given their widespread use for water repellency in performance outerwear as well as for stain repellency in fashion/uniform apparel.  Again, we thank you for the opportunity to comment. Please let me know if you have any questions.  Sincerely,  Beth Jensen, Director of Corporate Responsibility and the OIA Chemicals Management Working Group  Outdoor Industry Association  4909 Pearl East Circle, Suite 300, Boulder, Colorado, 80301 USA | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The Dossier submitter does not agree with the proposed incremental decreases over time. Industry has now been informed about the proposed restriction and can already take measures to minimise the content of PFOA and PFOA-related substances in their articles.  However, the Dossier submitter has revised the proposed threshold to ensure e.g. that short-chain alternatives are allowed to be used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC notes the request for an incrementally phased-in concentration limit.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk that cross-contamination might cause failures above the proposed 2 ppb limit is also noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. This could be part of a phased approach. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that a revision of the concentration limit is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1261** | **Date:** 2015/05/11 17:58  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes** | **General Comments:**  **<removed>** members make extensive use of coatings which contain low levels of PTFE waxes. The suppliers of waxes are unable to guarantee that PFOA and associated substances whilst generally not being used as starting substances would be below a 2 ppb compositional limit. Our concern is that the proposed limit could impact on the availability of these waxes with consequent problems of ensuring supply of coatings containing these waxes. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the manufacturing and use of PTFE with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers. PTFE manufactured without PFOA is already available on the market and will not be affected by the proposed restriction. | |
| **RAC Rapporteurs comments:**  RAC notes the comment that suppliers of PTFE waxes are not able to guarantee PFOA concentrations below 2 ppb, but there is insufficient detail to evaluate this further. RAC also notes the intention of the DS. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Your concern with regard to PTFE waxes is noted. Overall we think that the concentration limit of 2 ppb is not appropriate. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1263** | **Date:** 2015/05/13 17:56  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  CEPE  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  The 2 ppb limit is much too low. Specific exemptions or a much higher level should minimize the impact on our industry. | |
| **Answer to specific info request 1:**  See under Q4. | |
| **Answer to specific info request 2:**  See under Q4. | |
| **Answer to specific info request 3:**  No information | |
| **Answer to specific info request 4:**  PFOA is not used as such as a substance in paints and printing inks. However, the proposed low limit of 2 ppb poses three main issues:  1. Contaminations.  The proposed 2 ppb limit is much too low to take into account possible contamination. Looking upwards in our supply chains we can see uncountable possibilities where such contamination might come from. It is possible that such traces may be found even in products where no fluorinated raw materials are intentionally added at all.  2. Use of PTFE waxes. Also, PTFE waxes are used and may contain PFOA impurities.  Many printing inks and varnishes contain a low level (ca. 0.1 - 1%) of a PTFE wax to modify the surface and slip/friction characteristics of the print. If these PTFE waxes contain even low levels of PFOA, there will be difficulty in meeting a 2 ppb limit. It will also be difficult to make such analyses with the required level of analytical sensitivity. If such a limit is introduced, then, without an exemption for PTFE, it would likely mean that no PTFE wax could be used, removing a vital ink additive, even though it is only used at a low level, and does not intentionally contain PFOA. In the past some specialty inks contained PFOA based surfactants to impart particular characteristics; however, since the concerns about PFOA and PFOS these have been replaced. We do not think that there would be an issue with prohibiting PFOA for such uses. However, with regard to impurity in PTFE, either a specific exemption or a much higher allowable level is necessary to avoid significant issues with up to 50% of all printing inks and varnishes (Total EU value of the printing ink Industry, see EUPIA website in 'statistics': 1 million tons of inks and 3 billion euros of value). Removing theses waxes would not solve the problem of contamination at the proposed very low level.  In can coating (200 000 tons/year of can coatings sold in Europe) the PTFE wax imparts good abrasion, scuff, scratch and tooling resistance in a can coating formulation. The PTFE is usually added to the formulation as a blend with other waxes such as polyethylene and or carnauba. This combination provides a best balance of properties in terms mobility (including can to can slip) and abrasion resistance. The PTFE wax is added to overprint varnishes which are subsequently applied to DWI beer and beverage aluminum cans. During the can making process the applied varnish film will undergo a series of tooling operations as the neck and flange are formed on the can body. The PTFE wax is a key component in providing the applied varnish surface with the scuff, toughness and abrasion performance. The PTFE component of the lubricant system also enhances the abrasion resistance of the applied varnish film which is essential for can transportation through the production line, along with the filling operation. The PTFE wax is also a key component in offering good transportation of the filled cans to the required destination. This is particularly important when long distance or global transportation is required. If PTFE lubricant was a raw material that was withdrawn from the market place and subsequently banned for its inclusion into beer beverage overprint varnishes then potentially a high volume of business could be affected with subsequent loss of volume and profit on a well-established business. The removal of PTFE from the approved raw materials list could also potentially have subsequent knock on issues with the ability to successfully manufacture 2 Piece beer and beverage cans and the impact on a global market. This would have a particularly severe impact if alternative lubricants could not be identified as suitable replacements. Any potential loss of business would significantly impact on the profit of the given business and may result in a change of strategy which in turn could affect many jobs within the industry.  3. With reference to the Coil Coatings business (also 200 000 tons/year of EU sales) i.e. structural building, white goods, etc. One of the polymer types used is Polyvinylidene fluoride (PVDF). Therefore there may be residual PFOA present.  In conclusion if this proposed limit of 2ppb PFOA was implemented, this would have a huge impact to the printing ink, the Can Coatings business & the Coil Coatings industry, as the raw materials which we purchase based on PVDF & PTFE would not meet this limit and because even when these raw materials are not used we see multiple possible sources of contamination in the supply chain. Therefore there would be a significant loss of business. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the manufacturing and use of PTFE with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers. PTFE manufactured without PFOA is already available on the market and will not be affected by the proposed restriction.  The Dossier submitter is aware that contamination can take place especially in long supply chains. Therefore, the revised threshold as proposed by the Dossier submitter takes these contaminations into account. However, according to REACH emissions of PBT substances have to be minimised.  The Dossier submitter therefore urges industry to reduce the content of PFOA and PFOA related substances as far as possible. | |
| **RAC Rapporteurs comments:**  RAC acknowledges the importance of PTFE and polyvinylidene fluoride in the coatings industry, and notes the comment that PTFE waxes may not be able to attain PFOA concentrations below 2 ppb. Fluoropolymers are an important source of PFOA in the environment, but RAC notes the intention of the DS, and believes that a higher concentration limit would avoid the problem.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk that cross-contamination might cause failures above the proposed 2 ppb limit is also noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. This could be part of a phased approach. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that a revision of the concentration limit is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1266** | **Date:** 2015/05/19 12:57  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Switzerland  **Company name confidential:** **Yes** | **General Comments:**  **<removed>** make extensive use of coatings containing low levels of PTFE waxes. The suppliers of waxes currently seem to be not able to guarantee that PFOAs and related substances whilst generally not used as starting substances will finally reach the proposed 2 ppb compositional limit. Our concern is that this could have the potential to impact on the availability of the PTFE waxes with a consequent issue of supply of coatings containing these waxes | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the manufacturing and use of PTFE with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers. PTFE manufactured without PFOA is already available on the market and will not be affected by the proposed restriction. | |
| **RAC Rapporteurs comments:**  RAC notes the comment that suppliers of PTFE waxes are not able to guarantee PFOA concentrations below 2 ppb. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment, your concern is noted. | |
| **1269** | **Date:** 2015/05/21 03:26  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Willson Consulting  **Org. country:** Australia  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  These restriction proposals fall well beyond the UK Environment Agency guideline of 10ppm for PFOS contamination of firefighting foams. 50ppm would seem a suitable restriction level for PFOA in this context as 2ppb seems unduly onerous and beyond the level of risk. | |
| **Answer to specific info request 2:**  The proposed restriction will effectively ban the use of all fluorinated foams probably, from use within the EU. Economic impacts will be great as evidence suggests that large fires will not be controlled as quickly, will be slower to extinguish, be prone to sudden and unpredictable flashbacks which could cause incident escalation, increase risk to life safety of emergency responders, increase property damage, increase business interruption and put more jobs at risk of potential loss. | |
| **Answer to specific info request 3:**  The proposed restriction level will only enable fluorine free foams to be used in future. These have been shown to have no fuel shedding capabilities, have high detergent levels which attract volatile hydrocarbon fuels into the foam bubble structure, leading to unexpected, sudden and unpredictable flare ups and flashovers which are a danger to firefighters, casualties and other responders through the clean up period, High detergent levels mean greater aquatic toxicity concerns in the environment, particularly when slower control and extinction mean more foam and water resources are required (sometimes three times more), which could have major impacts on aquatic life in receiving water bodies, oil separators and sewage treatment plants. | |
| **Answer to specific info request 4:**  Since there is inevitable trace contamination from PFOA through the reaction process in short chain fluorotelomers the proposed 2ppb level will prevent their use, despite compliance with the US EPA PFOA Stewardship program's purity compliance. When UK Environment agency set a restriction limit of 10ppm for PFOS in foam concentrates, 2ppb is unrealistic for PFOA which is generally recognised as being less harmful, so a 50ppm restirction level would seem to be more appropriate and in line with existing levels. Queensland has recently proposed this level for PFOA in their Draft Management of Foam policy. | |
| **Dossier submitter response:**  Thank you very much for the new information.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain chemistry and consequently fire-fighting foams based on short-chain can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain chemistry, further development and also acceptance on fluorine-free alternatives is necessary.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  Even if PFOA is not listed as persistent organic pollutant (POP) as PFOS, it is a substance of very high concern based on its PBT properties and toxicity for reproduction (and a candidate for listing in Stockholm Convention). Therefore, PFOA should not be regarded as less harmful to humans and the environment, compared to PFOS. We strongly disagree to use the same or even higher threshold as for PFOS. Furthermore, we have received many responses stating that a lower threshold than 50 ppm is possible. | |
| **RAC Rapporteurs comments:**  RAC does not agree with the statement that “PFOA is generally recognised as being less harmful than PFOS”, since although PFOS appears more bioaccumulative, both meet the Annex XIII criteria so are considered to pose a non-threshold hazard. There is therefore no risk-based argument for use of a higher threshold in fire-fighting foams than that for PFOS.  RAC notes the claim that the proposed restriction may affect all fluorinated foams if the limit remains at 2 ppb. However, since this is a potentially significant source of environmental exposure, RAC has not recommended any derogation for this use, but recognises that there are socio-economic factors for SEAC to address, such as the efficacy of fluorine-free foams. RAC cannot assess the statement that fluorine-free foams may pose “greater aquatic toxicity” due to high detergent levels without further information (noting that fire water can contain many other substances besides detergents that may be hazardous to the environment).  See also response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We take note of your comment mentioning that F-free foams may pose efficiency problems and be hazardous for firefighting personnel, but will also consider other information submitted in this consultation stating that they are currently used in several airports in the EU and outside the EU. Please see also response to Comment 1225. | |
| **1270** | **Date:** 2015/05/21 18:38  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  IBENA Textilwerke GmbH  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  IBENA is a textile weaving mill specialised in the development and manufacturing of fabrics for personal protection equipment (ppe) for fire fighters, police and military service men, SAR personnel, industry workmen. Almost all endusers require their ppe to provide water and oil repellency. This is vital with burning liquids in a fire or with Molotov cocktails. It is also vital with NBC protection suits to function properly.  The combination of water and oil repellency is only achievable with fluorinated products. Alternatives based on silicone, urethane or PVC products may achieve water repellency but do not provide oil repellency.  IBENA is supporting the elimination of PFOAs by way of transition from fluorinated C8 compounds to C6 compounds i.e. replacement of harmful long-chain fluoro-chemicals with harmless short-chain fluoro-chemicals. The current restriction proposal for PFOA and PFOA related substances, however, is making this transition impossible. The reason is that said harmless short-chain fluoro-chemicals will inevitably contain traces of PFOA related substances, in particular 8:2 fluorotelomer alcohol and fluorotelomer acrylate. These traces from manufacturing processes can not be reduced to a level below the suggested 2 ppb threshold. When applied to a textile fabric as finish the threshold may or may not be met, as typically, the application is 0,01% only – however, there is no reliable and commercially available testing method available. So there is no sound way to prove compliance.  As a consequence, the use of harmless C6 short-chain fluoro-chemicals would become impossible, leaving firefighters and police and service men exposed to risk from burning liquids or NBC agents. Hence, the proposed restriction of PFOA and PFOA-related substances would create a significant threat to the health of fire fighters, police- and military service men.  For IBENA as a company, we would see 40% of our total business at risk, which means the a vital threat for the company with 300 employees as a whole.  We therefore strongly suggest to (a) create exemptions for related substances such as 8:2 fluorote-lomer alcohol and fluorotelomer acrylate and/or (b) products for the manufacture of PPE and/or (c) raise the threshold from 2 ppb to 5 ppm, in line with the widely accepted Ökotex standard. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances. | |
| **RAC Rapporteurs comments:**  See responses to Comments 1214 and 1279.  RAC notes the suggestion to exempt products for the manufacture of PPE and/or raise the threshold from 2 ppb to 5 ppm, in line with the Ökotex standard. However, specific exemptions for PFOA-related substances such as 8:2 fluorotelomer alcohol and fluorotelomer acrylate are not desirable from a risk perspective as they are sources of PFOA in the environment. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1271** | **Date:** 2015/05/22 08:51  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Wacker Chemie AG  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Chemical substances. | **General Comments:**  We only use fire-fighting foams (PFOA-related substances). No limitation of content of the PFOA to 2 ppb before a new foam agent is developed with the same quality (features). | |
| **Answer to specific info request 1:**  We store approximately 40 tons of fire-fighting foam. | |
| **Answer to specific info request 2:**  We only use fire-fighting foams (PFOA-related substances)in case of fires of Silan or other chemical liquids. | |
| **Answer to specific info request 3:**  We only use fire-fighting foams. | |
| **Answer to specific info request 4:**  Our foam Agent is stored in fire engines and stationary systems. For many installations would it be impsoosible to clean it. New installations would be riquired! High Investment costs! | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain chemistry and consequently fire-fighting foams based on short-chain chemistry can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other firefighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain chemistry, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  RAC notes the comment that cleaning of existing fire equipment will be very difficult to achieve a very low PFOA contamination level.  See also response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the comment. We recognize that contamination would be a problem at the 2 ppb level. Please see response to Comment 1225. | |
| **1272** | **Date:** 2015/05/22 11:36  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  AFPé2i  **Org. country:** France  **Company name confidential:** **No** | **General Comments:**  Proposal for Comments for Annex XV restriction report on PFOA  General comments: AFPé2i France  We are representing the French Trade Association AFPé2i (Association Française des Professionnels de l’Equipement d’Incendie et d’Intervention - whose members are manufacturers and distributors of fire fighting foam agents), a subsection of FFMI (Fédération Française des Métiers de l’Incendie), state member of EUROFEU.  Dedicated to save lives and properties in cases of fire, Foam Agents are used in all kind of fire situations, from the small flammable liquid spillage to the huge fuel tank storage facilities fires. Fire fighting foams are the best available extinguishing agents for the petrochemical industry, civil aviation, military, general industry, fire brigades, warehouses, etc... involving flammable liquids risks. They are designed to meet the highest international standards (ISO 7303, EN 1568, IMO, ICAO, UL 162, Lastfire…). In the high risk areas, the most effective foam agents used to protect lives and properties are referred to as AFFF (aqueous film forming foam), which contain Fluorosurfactants bringing their performance to a level suitable for fighting these extreme fires. The key function of these chemicals is the suppression of vapours and emulsion of fuel into the foam blanket which could cause a fast collapse or even the burning of the foam blanket and hence loss of the agent’s fire fighting properties. This function is essential to a foam agent’s fire performance up to a point where fires above a certain size cannot be successfully controlled and extinguished without AFFF’s.  AFPé2i is supporting the objective of minimizing the environmental impact of fire fighting foams. The major Fluorochemical producers in Europe aim at completely eliminating the use and emission of PFOA by the end of 2015. Alternatives developed to replace C8-based chemicals are commonly referred to as short-chain (C6-based) chemicals. Foam manufacturers have been working diligently to reformulate all of their fluorinated foam products to use short chains (C6) fluorochemicals focusing on improved containment and treatment of foam discharges. | |
| **Answer to specific info request 1:**  Therefore, currently used AFFFs contain Fluorosurfactants consisting almost exclusively of C6-based telomers chains. However, they may also contain trace amounts of impurities consisting of longer chains such as C8 telomeres. Even if PFOA was never used as an active substance in fire fighting foam agent technology, it can again be present in trace amounts as contaminant from the manufacturing process of C8-based fluorotelomers. In this respect it is important to note that C8-chemistry was used along the entire AFFF supply chain, from manufacturers of Fluorochemicals, to transporters, manufacturers of fire fighting agents, warehouses and installations of end users that have now converted to C6-chemistry. Furthermore, perfluorinated C8-chemicals has a strong tendency to adsorb to surfaces. Since that bonding is quite stable this behaviour leads to a slow bleed out into liquids which get into contact with those contaminated surfaces.  Even extensive rinsing and cleaning operations will not remove 100 % of C8-contamination. Basically, this means that contamination of new C6-based AFFF by their predecessors is likely to happen, and consequently will lead to C6-based products that exceed the proposed threshold of 2 ppb which is not limited to PFOA, but includes all PFOA-related substances considered as precursors. | |
| **Answer to specific info request 4:**  Although AFPé2i does support the need for a restriction of PFOA and PFOA-related substances, we have serious concerns that the proposed threshold level could be effectively achieved in the production of fire fighting foam concentrates. As a consequence, we do not support the current draft version due to the proposed threshold level which is perceived as inapplicable for the following reasons:  1.1.1 Impurities  1.1.1 Raw materials  Basically, the 2 ppb threshold equals to an extremely high purity level. It is reasonable to anticipate that the industry will not be able to meet this low level of C8-impurities due to the potential contamination of the current C6-based materials being produced in the same plants used to manufacture C8-based concentrates. Considering the supply chain at this moment, it is likely that nobody can guarantee to get even close to the proposed level of 2ppb (parts per billion). As a consequence, we can assume that recently manufactured C6-based foam agents could be contaminated by C8 traces beyond 2 ppb.  1.1.2 Finished Products  If the raw materials (Fluorosurfactants and polymers) are impacted by C8 contamination at a level exceeding the threshold, this will impact the finished fire fighting foams as well. It can be assumed that all foam agents containing Fluoro-chemicals, and many of the fluorine free ones in the field, will carry contamination traces of some perfluorinated C8-chemistry above 2µg/kg. AFPé2i concern is that the proposed threshold of 2 ppb for PFOA and PFOA related substances will not be achieved in production, and cause an immediate ban / discontinuation (and disposal) of all AFFF-Foams. As long as AFFF foams are the most effective fire fighting agent currently available, such discontinuation would have an extremely negative impact on fire safety. At this point in time, we have not proven alternative product or technology available as suitable and safe drop in / replacement.  1.1.3 Hardware  To meet the requirement of this proposed threshold, a major part if not all fire protection installations / equipments would have to be replaced. The ability of C8-based Fluorochemicals to strongly bind to surface results in a contamination that even intensive washing will not be able to remove efficiently resulting in contamination levels above the threshold .  This will definitely affect foam agents manufacturing plants and their corresponding raw materials storage facilities, as well as extinguishing systems (!). This will have the immediate consequence that a huge number of facilities will have significant downtimes to invest in reinstallation of new fire protection systems and handling/disposal of huge volumes of contaminated water and materials.  1.2 Disposal:  1.2.1 Foam concentrates:  If the 2 ppb threshold comes in force as currently proposed, basically > 90% of all stocks of fire fighting foam agents will have to be disposed within the transition period. This will represent several hundred thousand metric tons of foam agents. In addition, one will also have to contain and dispose the cleaning and rinsing water, corresponding to multiple times the aforementioned volumes of foam agents.  For the time being, the only process for a “state of the art” safe disposal is incineration. This means that each litter of foam agent or contaminated water has to be contained, collected and incinerated. This requires a corresponding minimal amount of fuel (reported 1,5-2 times the volume). It is also not clear if the current availability of required incineration capacities (quite a few will not be able to burn Fluorine containing waste for material incompatibility with the installed ovens and gas handling technology) will be in a position to handle that huge waste volume.  1.2.2 Contaminated water:  Obviously since parties along the supply chain will try at least to wash and clean their hardware installations in order to avoid their replacement, huge volumes of water at a comparatively low contamination level (yet by far too much for the drain) will also show up on the disposal market. This will significantly add to the complexity and costs of the process, this waste needing to be incinerated too.  1.3 Analytics  1.3 1 Limits of Detection (LOD)  Foam agents do show very strong matrix effects caused by surfactants and other ingredients. The LOD in foam agents and premixes at present is at 50-20ppb at the best which is 25-10 times more than the proposed threshold.  1.3.2 Repeatability/Error:  Current analysis of Fluorochemicals in foam agents or premixes present typical error ranges of ±50-100% for an individual lab and up to several 100% for inter-lab comparison. This can lead to liability issues and potential law suits should the level found be under the limits. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain chemistry and consequently fire-fighting foams based on short-chain chemistry can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1225. | |
| **1273** | **Date:** 2015/05/25 12:45  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  ANIE Federazione  **Org. country:** Italy  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  ANIE is the Italian Federation of electrotechnical and electronic industries that represents more than 1.200 companies with a combined turnover of 56 billion € and 410.000 workers.  Referring to Annex XV report, recently submitted for the Restriction of perfluorooctanoic acid (PFOA) and related substances, we would like to express our concern as end-users.  As ANIE we are aware of the characteristics of PFOA, which identify the substance as toxic for reproduction and PBT, and we share the will of the institutions to improve the environment and health protection at EU level. However, we believe that any future restriction should be formulated by providing appropriate exemptions and timing.  In reference to what stated in the report, concerning risks on possible PFOA emissions in end of life phase, is necessary to remember that Directive 2012/19/EU on waste electrical and electronic equipment - WEEE II lays down measures of recovery, separate collection and proper disposal for all electrical and electronic equipment (EEE) thus minimizing any risk of emissions related to improper disposal.  Nowadays more than 4 kg per inhabitant per year of WEEE are recovered and recycled in Europe1 under best available techniques, thanks to the extended responsibility of producers that provide adequate financing of weee management cycle.  Therefore, according to the consideration listed via attachment, we ask to support the exemption from the proposed restriction for the semiconductor industry and, if it would not be possible to exempt equally the usage of fluoropolymers for the electrotechnical and electronic industry, at least provide an adequate phase-out period of PFOA related substances.  Technically speaking the proposed threshold of 2 ppb in mixtures and articles, besides not being feasible, puts a direct ban to the placing on the market even of articles produced with short-chain alternatives. Unless this threshold will not be augmented, industry will need to quickly research new alternative materials. However such kind of substitution will concern the entire reevaluation of the supply chain to find and approve new suppliers and raw materials that could be not available in few time.  Eventually it should be noted that any transition period must be proposed taking into account the time needed to "clean up" a long and complex supply chain from PFOA containing materials. Such products, even with a substance contents over the threshold values, were already put on the market and stored in the warehouses of manufacturers and distributors. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  Risk management measures regarding human health and environment are in place. Furthermore, semiconductor industry is a minor user of PFOA related substances. There are very low emissions into the environment. Therefore, the Dossier submitter would agree with a longer transitional period for the remaining critical uses in photolithography. | |
| **RAC Rapporteurs comments:**  RAC notes that legislation is in place for the proper disposal of some (though not necessarily all) types of electrical and electronic equipment.  RAC has recommended an exemption for the semiconductor industry in view of the low emissions (and consequently environmental risk).  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb. The risk that cross-contamination might cause failures above the proposed 2 ppb limit is also noted, requiring time to resolve given the complex nature of supply chains. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. The volumes and emissions seem to be low and risk management measures in place. Also socio-economic costs caused by the restriction would seem to be disproportionate. Taking into account all information submitted during the public consultation of the restriction dossier we support derogation for mixtures used in semiconductor photolithography processes as reflected in our draft opinion.  We also agree that revision of the proposal more generally to ensure that short-chain alternatives are allowed is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances.  SEAC also proposes to extend the general transitional period to 36 months to allow introduction of suitable alternatives. | |
| **1274** | **Date:** 2015/05/25 21:37  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  FEC, the European Federation of Cookware , Cutlery and Houseware Producers and Brands  **Org. country:** France  **Country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No**    **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** commercial interests of a natural or legal person, including intellectual property, | **General Comments:**  FEC is the European Federation of Cookware , Cutlery and Houseware Producers and Brands.  FEC represents about 150 brand owners & producers of articles, that use for part of their products coatings, plus manufacturers of coatings (non-stick PTFE and other).  Since years PFOA is not used in the preparation of non-stick food contact coatings or in articles made by FEC members. Members of FEC switched to alternatives. Any eventually detected PFOA should be due to background contamination or NIAS type impurities. EFSA, BfR and AFSSA have confirmed that exposure to PFOA via food or food contact materials (cook- and bakeware with a non-stick coating) is “negligible” and “highly unlikely to exceed health-based guidance values”.  The proposal to limit the content in any material or finished product to 2 ppb, is unworkable and would be detrimental for the whole industry. Due to background contamination it is unworkable even for those that have never used and will never use any PFOA to prepare any of their coatings or articles. Realistic threshold levels which have to be much higher than 2 ppb could be measured in “materials or substances” but it is be nearly impossible to measure them in complex finished articles made of different components, matrices and layers.  FEC proposes that  - products mostly for food contact have not to be tested for PFOA content under this restriction  - food contact articles have to be tested for conformity with EU PFOA food contact migration limits  - houseware articles even when not for food contact do not have to be PFOA content tested  - because 2 ppb is unworkable this threshold should be revised upward for coating manufacturers  - inside the EU all coating applicators have to receive from their coating suppliers a “certificate that no PFOA was used” in the manufacturing of the coating.  - To make sure that no distortion of competition takes place, a certificate of meeting the EU legal requirements for a coating applied outside the EU must be required for any finished item coming into the EU in order to proof that imports into the EU meet the same high standards, even when manufactured outside the EU.  The enclosed FEC PFOA position paper gives an overview on how FEC would like to have the requirements revised . More details and technical explanations are given in the separate attached detailed document that further explains the position of FEC and that should be taken into consideration together with FEC’s position paper. | |
| **Answer to specific info request 1:**  See the enclosed FEC PFOA position paper and the separate attached detailed document that further explains the position of FEC and that should be taken into consideration together with FEC’s position paper. | |
| **Answer to specific info request 2:**  See the enclosed FEC PFOA position paper and the separate attached detailed document that further explains the position of FEC and that should be taken into consideration together with FEC’s position paper. | |
| **Answer to specific info request 3:**  See the enclosed FEC PFOA position paper and the separate attached detailed document that further explains the position of FEC and that should be taken into consideration together with FEC’s position paper. | |
| **Answer to specific info request 4:**  See the enclosed FEC PFOA position paper and the separate attached detailed document that further explains the position of FEC and that should be taken into consideration together with FEC’s position paper. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  It is not our aim to restrict the fluoropolymers manufactured without PFOA with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed restriction to ensure that fluoropolymers manufactured without PFOA can be manufactured and used.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Therefore, the Dossier submitter does not agree with a derogation for Food Contact Materials and Food Contact Articles. | |
| **RAC Rapporteurs comments:**  RAC acknowledges that other institutions in the EU have given an opinion about human health risks due to PFOA exposure via food, but the basis of this proposal is environmental hazard.  RAC notes that “high temperatures during PTFE sintering (curing) make sure that non-stick surfaces of cookware are put on the market without PFOA” and notes the calculations in the confidential attachment which suggest that residual PFOA in non-stick coatings and articles will be significantly below 1 tonne/year (assuming a content of 10 ppm as a worst case). However, RAC has concerns about emissions at all points in the life cycle of polymer products.  RAC also notes the request for a derogation for the food contact materials and articles. RAC acknowledges that migration limit testing is required for consumer protection purposes, but this is not the same as ensuring that environmental emissions are well controlled.  RAC acknowledges that the industry will need sufficient time to make the transition to any limit that is imposed by the restriction (depending what that limit is), but this is a socio-economic issue.  RAC notes the suggestion to require supplier certification that “fluoropolymers have not been manufactured using PFOA” for coating applicators. Certification is not a REACH instrument, and it is unclear which actor(s) would be responsible for the certification procedure. Certificates could, however, be a good additional voluntary measure to help demonstrate compliance and promote the use of fluoropolymers made without PFOA.  RAC notes the comment that “emissions into the environment are almost entirely due to the resin manufacturers”, but the DS has demonstrated that emissions can occur from several parts of the life cycle and from numerous products, not just the fluoropolymer manufacturing stage. However, RAC would agree that stopping the use of PFOA in fluoropolymer manufacture globally would be a significant step forward in the risk management of this substance.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk that cross-contamination might cause failures above the proposed 2 ppb limit is also noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree that a revision of the concentration limit is necessary as the contaminants might be a problem at the 2 ppb level. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances.  SEAC also proposes to extend the general transitional period to 36 months to allow introduction of suitable alternatives and depletion of the relevant materials from supply chains. | |
| **1275** | **Date:** 2015/05/29 00:19  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:**  Water Research Institute - National Research Council of Italy  **Org. country:** Italy  **Company name confidential:** **No**  **Attachment confidential:** **No**    **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  In 2010–2013 Water Research Institute of the National Research Council of Italy (IRSA-CNR) carried out extensive and intensive monitoring campaigns of 12 perfluoroalkyl acids (PFAA) in the main Italian river basins. IRSA-CNR sampled about 35 rivers, belonging to the basins of rivers Po, Adige, Brenta, Arno and Tevere, which cover more than 40% of the national surface area. The work was funded by the Italian Ministry for the Protection of Environment, Territory and Sea (MATTM, Divisione V, Direzione generale per le valutazioni ambientali) within the project “PFAS Project: Valutazione del Rischio Ambientale e Sanitario associato alla contaminazione da sostanze perfluoro-alchiliche (PFAS) nel Bacino del Po e nei principali bacini fluviali italiani”. The aim of the PFAS Project (http://www.irsa.cnr.it/ShPage.php?lang=it&pag=PFAS) was to map the occurrence and emissions of PFAA in the main Italian rivers, highlighting hotspots correlated with specific sources and industrial emissions. The results of the whole project were collected in a final report (in Italian): Polesello et al., “Realizzazione di uno studio di valutazione del Rischio Ambientale e Sanitario associato alla contaminazione da sostanze perfluoro-alchiliche (PFAS) nel Bacino del Po e nei principali bacini fluviali italiani. Relazione finale”, IRSA-CNR, Rome 2013.  In the project IRSA-CNR highlighted the PFAA pattern in surface waters released by the use of everyday products, and IRSA-CNR fingerprinted the discharges of specific industrial sites such as fluorochemical and fluoropolymer plants and tannery and textile industrial districts. In the same basins drinking waters and groundwaters were also analysed. The complete results have already been discussed in three recently published papers (Castiglioni et al., 2015; Valsecchi et al., 2015; Mazzoni et al., 2015).  Castiglioni S, Valsecchi S, Polesello S, Rusconi M, Melis M, Palmiotto M, Manenti A, Dávoli E, Zuccato E (2015). Sources and fate of perfluorinated compounds in the aqueous environment and in drinking water of a highly urbanized and industrialized area in Italy. Journal of Hazardous Materials, 282: 51‐60. https://www.researchgate.net/profile/Sara\_Valsecchi/contributions  Mazzoni M, Polesello S, Rusconi M, Valsecchi S (2015). Investigating the occurrence of C8‐based perfluorinated substitutes for in Italian waters, NORMAN Bulletin on Emerging Substances, issue N°4. http://www.norman‐network.net/?q=NORMAN%20Bulletin  Valsecchi S, Rusconi M, Mazzoni M, Viviano G, Pagnotta R, Zaghi C, Serrini G, Polesello S (2015). Occurrence and sources of perfluoroalkyl acids in Italian river basins. Chemosphere, 129: 126‐134. https://www.researchgate.net/profile/Sara\_Valsecchi/contributions  Because there was evidence of significant sources of PFOA in Northern Italy and PFOA is not included in the Priority List for WFD (2000/60/EC) and thereby no Environmental Quality Standard (EQS) for PFOA is established at European level, the Italian government established a Working Group on Environmental Quality Standard (EQS) for PFAA in order to include some of them in the list of national specific pollutants (Ministerial Decree 260/2010) for surface water monitoring and classification in the context of the Water Framework Directive (2000/60/EC) The substances have been chosen by considering the statistical distribution of concentrations and frequency of detection in the Italian surface and ground waters. The substances in the list included perfluorooctanoic acid (PFOA) and related short chain (number of carbon < 7) perfluorocarboxylic acids such as perfluorobutanoic acid (PFBA), perfluoropentanoic acid (PFPeA) and perfluorohexanoic acid (PFHxA). Perfluorobutanesulphonic acid (PFBS), which is a common substitute of perfluorooctanesulphonic acid (PFOS), has been included too.  For each of these substances a dossier has been prepared which collects available data on regulation, physico-chemical properties, emission and sources, occurrence, acute and chronic toxicity on aquatic species and mammals, including humans. Dossiers for single compounds are added to this public consultation as confidential files.  The standards have been derived according to European guideline for the derivation of Environmental Quality Standard (EQS). The EQS for PFOA is determined by the secondary poisoning protection goal which is related to the bioaccumulative property of the substance.  EQS proposed for superficial and transition waters and quality goals for ground water are presented in Tables 1 and 2 respectively. | |
| **Answer to specific info request 1:**  In the recent survey carried out in the framework of the PFAS Project (reported above in the General Comments) by IRSA-CNR on the occurrence and sources of perfluoroalkyl acids (PFAA) in the main Italian river basins allowed to identify industrial hot spots correlated with specific sources and industrial emissions. Results of this survey can support the evaluation of the potential risks to the environment or to human health via the environment related to different uses reported in Table C.1-1  Urban emissions. PFAA are present in many consumer products of daily use and thereby the urban conglomerations can be considered point and diffuse (by run-off) sources of these compounds for the receiving water bodies. Domestic emission factors (EF) of 10 µg/day per capita for total PFAA and 5 µg/day per capita for PFOA were calculated, averaging outputs of three different WWTPs of Milano, characterised by low industrial component (< 4%) (Castiglioni et al., 2015).  Fluorochemical and fluoropolymer plants. In the studied basins we identified two plants which produce fluorochemical intermediates and fluoropolymers. The Fluoropolymer plant, sited in Piedmont on the river Bormida, in the Po basin, is the most significant source of PFOA and short chain PFCAs (PFPeA and PFHxA). Maximum PFOA concentrations of 6.5 µg/L were measured in the river Bormida from July 2008 to July 2013. No trend of reduction of PFOA use in fluoropolymer production was detected from 2008 to 2013.  The second important plant is located in Trissino, Vicenza province, Veneto region and produces fluorinated molecules, such as PFOA and PFBS. The plant discharges into the municipal WWTP whose output is then mixed with the outputs of four other WWTPs and carried by a single sewer pipeline (called Collettore ARICA) to the river Fratta-Gorzone. PFAA composition of the river water and the WWTP effluents are very similar to the composition of the effluent discharged by the fluorochemical plant, with the main fluorocompounds being PFBS (68%), PFHxA (11%), PFOA (10%) and PFPeA (8%).  Use of PFAA in specific industrial applications. A very favourable situation for distinguishing the emissions of textile and tannery activities is present in the river Arno basin (Tuscany, Italy). Along the river course there are two specific districts, well spaced from each other and close to the principal course of the river. The textile district of Prato, whose WWTPs discharge into the tributaries Bisenzio and Ombrone, is a significant source of PFOA and short and long chain PFCAs (especially PFHxA and PFDA), while the contribution of perfluoro alkylsulfonates (PFSAs) is more limited. In contrast, a significant input of PFSAs, mainly PFBS, comes from the tannery district in the province of Pisa, a few kilometers from the mouth of the Ano river.  In Table 3 results of the this survey are summarised: mean water PFOA concentrations in river water receiving industrial discharges and in ground- or drinking water are reported according to industrial activity.  As already well known fluorochemical and fluoropolymer productions are the main sources of PFOA in surface and ground waters: PFOA concentrations can be some thousands of ng/L. However, both textile districts (Tuscany) and textile cluster (Lombardy) can cause significant levels of PFOA (hundreds of ng/L) in water bodies that receive the industrial discharges.  Comparing concentrations of PFOA in environmental waters impacted by specific industrial activities (Table 3) and the Italian proposed Environmental Quality Standard for PFOA (100 ng/L for Inland surface waters, Table 1) it is clear that fluorochemical and fluoropolymer plants, as well as textile activity, cause harmful levels of PFOA in the environment.  It is important to underline that aquifers collected in the areas impacted by the fluoropolymer and fluorochemicals plants, as showed in table 3, can reach µg/L levels of PFOA. In Veneto these high concentrations were also present in drinking waters and obliged the water managers to apply treatment systems (carbon adsorption columns) to many wells in the Region, with an extra-cost for drinking water production and distribution. The situation in Veneto is described in the website of the local Environmental Agency (http://www.arpa.veneto.it/temi-ambientali/acqua/file-e-allegati/documenti/acque-interne/pfas/pfas/?searchterm=pfas). | |
| **Dossier submitter response:**  Thank you very much for the new information. We will take it into further consideration. | |
| **RAC Rapporteurs comments:**  RAC appreciates the additional information on the widespread contamination of the Italian environment (including drinking water aquifers) from domestic sources, textile manufacturing and individual fluorochemical and fluoropolymer plants. This provides further support for a wide-ranging restriction. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1276** | **Date:** 2015/05/30 19:54  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes** | **General Comments:**  The following summarizes **<removed>**’s review conclusions of the health hazard assessment for the ECHA Annex XV Restriction Report for PFOA (dated 17 October 2014). **<removed>** will be submitting detailed comments on this aspect of the dossier before the close of the comment period on 17 June 2015.  It is **<removed>**’s view that the Derived No Effect Levels (DNELs) and Risk Characterization Ration (RCRs) chosen for the PFOA dossier health hazard assessment are not scientifically justifiable based on the selected evidence for: (1) delayed mammary gland development in mice (Macon et al. 2011), (2) increased total cholesterol and LDL in human serum (Steenland et al. 2009), and (3) a reduction in birth weight in humans (Fei et al. 2007). Specifically:  • There is strong scientific evidence to warrant against using the mouse mammary gland data reported by Macon et al. on the basis of; flawed study design, use of subjective endpoints, and erroneous data interpretation. In addition, inconsistent mouse mammary gland data reported by others reflected a lack of robustness and questionable biological significance of this endpoint.  • The use of data from Steenland et al. to infer a causal association between exposure to PFOA and increased total cholesterol:  o Disregards the fact that a cross-sectional study cannot infer temporality,  o Discounts viable alternative explanations,  o Dismisses the lack of risk for heart disease and stroke observed in several occupational and community studies, and  o Does not consider the striking contrary evidence of hypolipidemia reported in a Phase I human clinical trial with high administered dosages of PFOA that is consistent with the animal evidence.  • The dossier erroneously assumes that PFOA reduces birth weight based on findings from Fei et al. and a meta-analysis (Johnson et al. 2014; Lam et al. 2014), neither of which are adjusted for the major confounding effect of glomerular filtration as recently demonstrated in a published PBPK model by Verner et al. (2015).    Overall, the dossier’s PFOA human health hazard assessment was not an in-depth critical analysis of both the toxicological and epidemiological literature. The assessment appears to be biased, as reflected by omission of contradictory evidence, exclusion of important data leading to alternative conclusions, and, most importantly, a failure to critically synthesize the literature in the weight of the evidence review for these three health-based outcomes. **<removed>** believes that a holistic and critical review of the extensive mammalian hazard data for PFOA will significantly change the calculated DNEL’s and RCR’s in the dossier. We urge the dossier reviewers and other stakeholders to review and consider **<removed>**’s full comments on this topic.  References:  Johnson PI, Sutton P, Atchley DS, et al. 2014. The Navigation Guide-Evidence-Based Medicine Meets Environmental Health: Systematic Review of Human Evidence for PFOA Effects on Fetal Growth. Environ Health Perspect 122:1028-1039.  Lam J, Koustas E, Sutton P, et al. 2014. The Navigation Guide-Evidence-Based Medicine Meets Environmental Health: Integration of Animal and Human Evidence for PFOA Effects on Fetal Growth. Environ Health Perspect 122:1040-1051.  Verner MA, Loccisano AE, Morken NH, et al. 2015. Associations of Perfluoroalkyl Substances (PFASs) with Lower Birth Weight: An Evaluation of Potential Confounding by Glomerular Filtration Rate Using a Physiologically Based Pharmacokinetic Model (PBPK). Environ Health Perspect DOI: 10.1289/ehp.1408837 | |
| **Dossier submitter response:**  Thank you for your comments on our human health risk assessment. The Fluorocouncil commented on the same endpoints. We therefore refer to our responses to Comment 1205. | |
| **RAC Rapporteurs comments:**  See response to Comment 1205. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1277** | **Date:** 2015/06/02 16:02  **Type:** BehalfOfAnOrganisation  **Org. type:** National NGO  **Org. name:**  FIA  **Org. country:** United Kingdom  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  By way of introduction we are the UK Fire Industry Association, which is a member of the subsection for firefighting agents of EuroFeu, the European umbrella organization of the national trade associations of the fire protection industry. We appreciate the opportunity to comment on the draft proposal to restrict the use of PFOA and its pre-cursors to 2ppb or less. Our interest in this matter is on the grounds that per-fluorinated chemicals in general, of which PFOA is a particular example, are used extensively in the formulation of foam agents. | |
| **Answer to specific info request 2:**  To meet the requirements of this proposal a major part of all installations would have to be replaced. The ability of C8-based fluorochemicals to strongly bond to surfaces contaminates those surfaces to the extent that even extensive washing will not remove enough material to stay below the threshold. This affects manufacturing plants for foam agents and the corresponding raw materials, as well as bulk storage facilities for foam agents and their associated extinguishing systems.  To replace such a diversity of plant and equipment would result in a significant and burdensome capital investment on manufacturers and end users alike. There would also be the issue of the delay between the de-commissioning of redundant plant and the introduction of its replacement to take account of.  It is also envisaged that many hundreds of in-service portable foam extinguishers within Europe will have to be disposed of and replaced, simply because the levels of cleanliness required to make them conform to this ruling will not be attainable. The replacement costs are likely to be exorbitant.  A quick calculation as an example: we estimate that there are around 4 million foam extingiushers in France and the UK and they would all have to be replaced as you will not be able to get the residual levels below 2ppb, the average lowest cost per unit is euro 25 the cost to replace them is euro 100,000,000. if you scale this up for the rest of europe the cost increase by orders of magnitude | |
| **Answer to specific info request 4:**  Although we support the need for a restriction of PFOA and PFOA-related substances, we do not support the current draft version for the following reasons:  1.1 Impurities  1.1.1 Raw materials  The proposed threshold equates to an extremely high purity level beyond what is normally achievable for technical or even analytical grade chemical substances. It is predicted that the industry will not be able to meet this low level of impurities due to contamination resulting from being made in the same plant used to make C8 and higher homologues. No manufacturer at present can guarantee to get even close to the proposed level of 2ppb (parts per billion).  1.1.2 Finish Products  If the raw materials (fluorosurfactants and fluoropolymers) suffer from C8-contamination at a high enough level this will carry through into the finished fire-fighting foams as well and consequently exceed the threshold. It can be safely assumed that all foam agents containing fluorochemicals and many of the fluorine free ones in field use will carry contamination by some perfluorinated C8-chemistry above 2ppb. The implication would be an immediate discontinuation (and disposal) of all fluorochemical foams with the attendant risk of not having any equivalent replacements available.  1.1.3 Hardware:  To meet the requirements of this proposal a major part of all installations would have to be replaced. The ability of C8-based fluorochemicals to strongly bond to surfaces contaminates those surfaces to the extent that even extensive washing will not remove enough material to stay below the threshold. This affects manufacturing plants for foam agents and the corresponding raw materials, as well as bulk storage facilities for foam agents and their associated extinguishing systems.  To replace such a diversity of plant and equipment would result in a significant and burdensome capital investment on manufacturers and end users alike. There would also be the issue of the delay between the de-commissioning of redundant plant and the introduction of its replacement to take account of.  It is also envisaged that many hundreds of in-service portable foam extinguishers within Europe will have to be disposed of and replaced, simply because the levels of cleanliness required to make them conform to this ruling will not be attainable. The replacement costs are likely to be exorbitant.  1.2 Disposal:  1.2.1 Foam concentrates and contaminated waste:  If the threshold comes in force as currently proposed it is reckoned that >90% of all stocks of firefighting foam agents will have to be disposed of within the transition period. This will constitute several hundred thousand metric tons of foam agents. In addition to that a further volume, multiple times that of rinse water, will also have to be disposed of.  At present the only way of safe disposal is by high temperature incineration which means each litre of water or foam agent to be incinerated will require a corresponding amount of fuel that is reportedly 1.5-2 times as much.  It is also not clear if there is sufficient incineration capacity within Europe to be able to cope with the influx of foam and contaminated water to be destroyed.  1.3 Analytics  1.3.1 Limits of Detection (LOD) and repeatibility:  Foam agents exhibit very strong matrix effects caused by interferences from other surfactants and formulation ingredients. This could result in many false positives for samples that are actually in compliance with the ruling.  Furthermore, the proposed threshold of 2ppb is at the very limit of detection for PFOA which will cast uncertainty on the accuracy of any analytical determination.  It is highly unlikely that commercial laboratories will be able to detect PFOA at such a low level with any degree of confidence, and between laboratories the large error range will be such as to make any inter-lab comparisons meaningless.  Precedence:  Europe has already introduced legislation in the form of the POPs regulations (EU 757/2010), limiting the threshold of PFOS to 10 ppm NOT 2ppb. This has effectively set a precedent for PBT materials, and for the sake of consistency it should also be applied to PFOA.  Although PFOS is generally considered to be more hazardous than PFOA, it is the latter to which the more demanding limit is being applied. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other firefighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier Submitter. These stocks should only be used for emergency cases and not for exercises.  Even if PFOA is not listed as persistent organic pollutant (POP) as PFOS, it is a substance of very high concern based on its PBT properties and toxicity for reproduction (and a candidate for listing in Stockholm Convention). Therefore, PFOA should not be regarded as less harmful to humans and the environment, than PFOS. We strongly disagree to use the same threshold as for PFOS because intentionally use of PFOA and related substances could not be excluded. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We recognise that contamination of installations would be a problem at the 2 ppb level. Please see response to Comment 1225. | |
| **1278** | **Date:** 2015/06/04 12:13  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  COCIR  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  COCIR , the European Association of the Radiological, Electromedical and Healthcare IT Industry, is pleased to submit the attached contribution to the public consultation on a REACH restriction proposal for PFOA.  The objective of the contribution is to highlight the specific needs of the medical technology sector regarding the ban or restriction of a substance, in particular the time needed for collecting information and for the technical adoption of alternatives.  COCIR considers that “RMO 1b: Phase out of PFOA and PFOA related substances over 18 months including possible exemptions” is the most appropriate option and that a general exemption for medical devices should be granted for a minimum period of 5 years.  This contribution is complemented by the COCIR study on the RoHS ban of phthalates (attached) which provides evidence to support the considerations and requests highlighted in this paper. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration for potential derogations.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC notes the request for a general exemption for medical devices for a minimum period of 5 years, partly due to the difficulties in communicating information in the supply chain, and also the testing requirements for such devices. No information has been provided about emissions. As such, from a risk perspective, RAC only supports a derogation for implantable medical devices at the present time. Derogation for other types of medical device is more of a matter for SEAC.  Generic concerns about analytical testing difficulties, enforceability, exclusion of alternatives due to trace presence of PFOA and risk of cross contamination are noted. RAC has proposed a slightly higher limit than the DS based on such considerations, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see response to Comment 1232. | |
| **1279** | **Date:** 2015/06/04 17:25  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** Ich erkläre hiermit, dass die oben angeführten Informationen mit Bezugnahme auf Artikel 4 (2) der 1049/2001/EG vertraulich sind und eine Verbreitung wirtschaftlcihe Interessen unseres Unternehmens unterwandern | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  "Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh"  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available.  see above | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction for textile applications because they are a major source of PFOA exposure, but shares concerns about the technical feasibility of alternatives for the professional sector. The request for exemptions cannot be supported from an environmental risk perspective, but RAC can support longer transitional periods for safety critical applications, such as PPE (which perhaps could be subject to a review clause).  RAC acknowledges that the proposed restriction must not prevent the continued production and use of alternatives to PFOA-related substances, which may be affected by a limit of 2 ppb. With a realistic choice of limits, derogations should not be needed for this reason.  RAC acknowledges that the analytical detection limit and availability of standardised analytical methods are practical issues that need to be considered for the application of the restriction threshold(s). The risk of cross-contamination might cause failures above the originally proposed 2 ppb limit is also noted. Whilst RAC agrees with the DS that the restriction can be an incentive to develop analytical methods, there has to be a realistic prospect of the development of a reliable method within an appropriate time frame to provide legal certainty for all actors. RAC has proposed a slightly higher limit than the DS based on such considerations, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1280** | **Date:** 2015/06/05 12:40  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Spengler & Fürst GmbH & Co. KG  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:** | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short chain alternatives all uses of C8 can be replaced by short chain chemistry. Since a shift to short chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  The Dossier submitter is grateful for the new information and will take it into further consideration on potential derogations.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1281** | **Date:** 2015/06/05 12:40  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Spengler & Fürst GmbH & Co. KG  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:** | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1282** | **Date:** 2015/06/05 15:09  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  German Airports Association (ADV)  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  Rejection of a 2 ppb limit for PFOA and related substances  Withdrawing the Proposal of Germany and Norway | |
| **Answer to specific info request 1:**  The Rescue and Firefighting Services (RFFS) are crucial to airport operations. Their equipment and procedures are based on numerous national and international regulations. The performance requirements for RFFS especially for extinguishing agents are written down in ICAO provisions and have recently been transferred to European provisions by EASA. For saving lives the use of extremely efficient agents are essential in an emergency.  AFFF (Aqueous Film Forming Foam) agents are able to form a thin layer of water between a flammable liquid such as kerosene and the stable thick layer of extinguishing foam, because they contain fluorinated surfactants. This thin layer of water may float up to 30 meters and makes AFFF foams very resistant to re-ignition, very effective thus providing a corridor for evacuation for passengers escaping an aircraft. Only those agents are able to continuously re-cover a burning area even if people, vehicles or wind cause gaps in the foam layer.  The aforementioned fluorinated surfactants in extinguishing foams consist of two mayor groups, perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA). | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain alternatives can be manufactured and used. Contaminations in existing extinguishing systems are considered, too. We strongly disagree to use the same threshold as for PFOS because intentionally use of PFOA and related substances could not be excluded.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of firefighting foam and those stock foams are only used in an emergency case where no other firefighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see response to Comment 1225. | |
| **1283** | **Date:** 2015/06/05 21:43  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  "Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh"  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1284** | **Date:** 2015/06/08 11:03  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  NOVA Textil-Beschichtung GmbH  **Org. country:** Germany  **Company name confidential:** **No**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  1. Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh  2. As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  3. The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  1. The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  2. As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  3. Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  4. The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  1. As the textile industry doesn't use PFOA and related substances no additional information is available.  2. see above | |
| **Answer to specific info request 4:**  1. According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  2. The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross-contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1285** | **Date:** 2015/06/08 11:31  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents. | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh. | |
| **Answer to specific info request 2:**  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1286** | **Date:** 2015/06/08 11:40  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  bvfa  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:** | |
| **Answer to specific info request 1:**  see non-confidential attaxchment | |
| **Answer to specific info request 2:**  see non-confidential attachment | |
| **Answer to specific info request 3:**  see non-confidential attachment | |
| **Answer to specific info request 4:**  see non-confidential attachment | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier Submitter. These stocks should only be used for emergency cases and not for exercises. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see response to Comment 1225. | |
| **1287** | **Date:** 2015/06/08 14:34  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes** | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies. | |
| **Answer to specific info request 3:**  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1288** | **Date:** 2015/06/08 15:17  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  - e.g.:the DIN EN 13034 (protection against liquid chemicals) is in sections not achieveable.The standard has to be define to lower performance. This is an tecnical regress.  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACH  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available.  see above | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1289** | **Date:** 2015/06/08 15:46  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short chain PFAS can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1290** | **Date:** 2015/06/08 16:59  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in impregnated foam products PFOA and related substances are not being used but only occur as impurities in processing agents. | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications of impregnated joint sealing tapes and dynamic water- and oil-repellency of other polymer foam applcations.  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh | |
| **Answer to specific info request 2:**  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover. Furthermore we are no longer able to ensure lifetime performance as requested from construction industry.  We are highly specialized on niche-products. The sales are strongly connected with the performance of fluorinated products. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance. | |
| **Answer to specific info request 3:**  As we do not use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile and related production and placing on the market of textile and impregnated foam articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information.  The use of impregnated joint sealing tapes and dynamic water- and oil-repellency of other polymer foam applications is new to the Dossier submitter. Unfortunately no data on the amount of PFOA and related substances used was provided, neither the substances used were named. Because of the limited information provided, derogation seems not to be justified.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross-contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1291** | **Date:** 2015/06/08 17:21  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  "Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh" | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1292** | **Date:** 2015/06/08 18:06  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Gesamtverband der deutschen Textil- und Modeindustrie e. V.  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  "Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh"  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1293** | **Date:** 2015/06/09 12:41  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1294** | **Date:** 2015/06/09 16:00  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes** | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  As the alternatives on the market do not fit the demand the higher risk is losing a part of turnover. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree that a revision of the limit value is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1295** | **Date:** 2015/06/09 20:37  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Cookware Manufacturers Association  **Org. country:** United States  **Company name confidential:** **No** | **General Comments:**  The Cookware Manufacturers Association represents a majority of the producers of cookware and bakeware in the U.S., Canada and Mexico. Our members export products to the EU, import products from the EU and from Southeast Asia, particularly China, and produce products domestically within the U.S., Canada and Mexico. Our members combine to sell some $3.5 billion annually to consumers and employ several thousands of production workers both within the U.S. and abroad. More than half of this amount is in products with nonstick surfaces. Exports of U.S. produced cookware and bakeware to Europe in 2014 amounted to some $300-million at retail. Imports from EU countries to the U.S. amounted to $135-million.  Fluoropolymer-based nonstick coatings are an important part of the cookware and bakeware products. 95% of aluminum cookware has a nonstick finish and more than 50% of all cookware and bakeware combined is sold to consumers with nonstick finishes. Sol-gel (so-called “ceramic”) nonstick finishes are only about 25% of the market and this percentage is declining in the U.S. Nonstick finishes enable consumers to cook with reduced amounts of oils and fats and are a significant contributor to “healthy eating.”  The CMA is opposed to the current ECHA proposed threshold for PFOA of 2 parts per billion (ppb). This threshold has been proposed without any risk assessment or valid methods in place for determining the existence of PFOA in a consumer product. The CMA believes that environmental contamination at ports could easily render false positives, resulting in economic hardship for the industry and consumers alike. The proposed level of 2 ppb, we believe, could be found in background dust and general environmental conditions thereby contaminating the object being tested.  Fluoro-product industries are reducing their reliance on long-chain substances in favor of short-chain materials, no matter where they are located. Serum blood concentrations of PFOA and similar compounds are going down. We believe the proposed threshold is ill advised and likely to cause confusion and economic hardship to both producers and consumers. | |
| **Dossier submitter response:**  It is not our aim to restrict the fluoropolymers manufactured without PFOA with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed restriction to ensure that fluoropolymers manufactured without PFOA can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1274. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1274. | |
| **1296** | **Date:** 2015/06/10 09:06  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential interests of our company | **General Comments:**  1. We would like to state clearly, that the resolution of the dossier brings far-reaching consequences which are too hard for many companies. Particularly PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  2. There are no alternatives mentioned in the dossier which could achieve satisfactory properties for the applications listed below:  - coatings- sun protection  - Printing and its chemical pretreatment  - air filtration (e.g. for cars)  -personal protective equipment    We could not produce any more the desired quality like sustainability and persistence which become more and more important.  Personal protective equipment needs higher rubbing and abrasive durability. People or worker depend on protective equipment would not as be protect any more as now. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1297** | **Date:** 2015/06/10 14:02  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Textilausrüstung Roessing GmbH  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents.  To avoid misunderstandings. We are supporting the replacement of harmful PFOA and related substances but  with a suggested Limit of 2 ppb we are very close to a prohibition of efficient and longlasting water and oil repellent effects on a wide range of use- and helpful textiles. | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers.  For Textilausrüstung Roessing GmbH it´s essential to offer a reliable water- and oilrepellent technologie. A restriction like this is a dangerous threat for our Company and more than 95 employees. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs.  In our opinion it is necessary to raise the threshold to 5 - 8 ppm. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1298** | **Date:** 2015/06/11 09:53  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes** | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  The alternatives lack  - dynamic oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands. | |
| **Answer to specific info request 2:**  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1299** | **Date:** 2015/06/11 10:46  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes** | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for personal protective equipment  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  In the industry of personal protective equipment for example the whole product Group of industrial washable chemical resistant textiles would dissapear from the market due to the lack of alternative substances that reach the relevant requirements.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1300** | **Date:** 2015/06/11 10:47  **Type:** Individual  **Country:** Germany  **Company name confidential:** **No**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. | |
| **1301** | **Date:** 2015/06/11 10:54  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes** | **General Comments:**  Please find below our general comments on the proposal:  1. PFOA is a component of Aqueous Film Forming Foam (AFFF), the predominant fire fighting foam in use in the UK. Many if not all Major Accident Hazard sites have significant stocks as part of their inventories for emergency planning measures as required under Seveso III (implemented as Control of Major Accident Hazards [CoMAH] in the UK).  2. AFFF is particularly important when fighting alcohol/Ethanol fires (or fires in which these are present).  3. Our view is that AFFF is the most effective foam to use for alcohol/Ethanol fires. Other foams free of PFOA may be available, but these may potentially pose additional health or environmental risks.  4. One alternative to AFFF is Fluorine-free foam, however this is felt to be less effective in tackling liquid hydrocarbon fires.  5. In summary, we believe that a restriction on the use of PFOA in fire fighting foam (AFFF) represents an increase in risks to business, the environment and to people. | |
| **Answer to specific info request 1:**  Please refer to our general comments provided in section A | |
| **Answer to specific info request 2:**  Please refer to our general comments provided in section A | |
| **Answer to specific info request 3:**  Please refer to our general comments provided in section A | |
| **Answer to specific info request 4:**  Please refer to our general comments provided in section A | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The use of PFOA and PFOA-related substances in AFFF is not necessary. Alternatives based on short-chain chemistry are available and widely used. It is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Please see response to Comment 1225. | |
| **1302** | **Date:** 2015/06/11 14:57  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Fedustria  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  Fedustria is the federation of the Belgian textile, wood and furniture industries and represents consequently the Belgian textile companies. The Belgian textile companies are specialised in interior textiles (i.e. carpets, upholstery fabrics, …) and technical textiles (i.e. medical textiles, protective clothing, outdoor textiles …). More and more textiles need to have extra functionalities such as repellence to water, oil, stain, … Characteristics for which fluorinated substances are essential in order to have a permanent character.  Fedustria supports the initiative of Germany and Norway to restrict PFOA and PFOA-related substances. However we are very much concerned that the proposed threshold of 2 ppb applicable for all substances in scope and all types of products would mean a de facto ban of fluorinated alternatives. | |
| **Answer to specific info request 1:**  Short-chain fluorinated alternatives are the only viable alternatives for most textile applications  The main properties of fluorinated chemicals that are essential for textiles are: water repellence, oil repellence and permanency. Oil repellence can only be reached by fluorinated chemicals. So far no valid alternative exists and this despite years of R&D. For water repellence, substitutes can be used but the problem with these substitutes is that they are not permanent. After washing the repellence disappears, which is of course a huge problem for e.g. protective clothing.  Most often, protective clothing is being rented by industrial laundries who take full responsibility for the clothing offered to their customers. Consequently, these textile service companies need a guarantee that the properties of the protective clothing are permanent for at least a certain time.  In most cases protective clothing should be (industrial) washable for 25 - 50 times.    Standards for protective clothing can only be reached by fluorinated alternatives  The high performance properties for oil- and water repellence required for protective clothing and other technical textiles can only be reached by fluorinated alternatives. Protective clothing is regulated very strictly. European Standards have been established in order to reach a high level of protection against different kinds of dangers.  It is worthwhile to mention two European Standards for protective clothing that require chemical repulsion:  • standard EN 13034 for protective clothing against liquid chemicals – performance requirements for protective clothing offering limited protective performance against liquid chemicals;  • standard EN469 for protective clothing for firefighters – performance requirements for protective clothing for firefighting.  For some very wetting chemicals like o-xylene and butan-1-ol (which are explicitly described in the standard), it is very difficult to meet the criteria of the standards. Even with the C8-technology it is not always obvious to meet the criteria and this after minimum 5 washing cycles.  With the C6-technology it will even be more difficult. Most probably, the protective clothing will need a re-impregnation after each washing in order to be sure to meet the criteria after washing.  The standards require that the repellence should be higher than 80% and no penetration may occur through the different layers.  Alternatives may not have detrimental effects on other required properties  It should be stressed that protective clothing needs to be “multi-functional”. Apart from oil- and water repellent, the textile needs in most cases also to have flame retardant and anti-static properties. Textiles companies have experience in reaching multi-functional properties by using fluorinated alternatives in combination with chemicals for the other properties.  Using other chemistry for oil- and water repellence might have a detrimental effect on the flame retardant property of textiles due the reaction of the different kinds of chemistry.  It is of utmost importance to have a stable and permanent balance of the different functional properties of protective textiles. Consequently, it is highly questionable whether all the requirements of the standards for protective clothing will still be achievable when fluorinated chemicals could no longer be used. | |
| **Answer to specific info request 2:**  The threshold of 2 ppb means the end for high end technical textiles in Europe  The threshold of 2 ppb that is being proposed in the restriction and which is applicable for all substances and all types of products, means a de facto ban of fluorinated alternatives. Even short-chain alternatives could no longer be used as they all contain traces of PFOA and PFOA related substances above the threshold value of 2 ppb.  The consequence of the proposal will be that the production of water and oil repellent textiles would no longer be possible in Europe. A major part of the production of technical textiles, which is the spearhead sector of textiles, would disappear. The economic and social impact would be tremendous. In Belgium 130 companies with in total 7.600 employees are involved in technical textiles. Technical textiles represents 40% of the Belgian textile industry.  By imposing unrealistic thresholds on the short-chain PFAS’s (as C6-chemicals) , the production of high end textiles would shift towards non-European countries, where fluorinated chemicals can still be used. However, the production in these countries is likely to take place under less stringent conditions, which will result in important releases to the environment. As PFOA is a PBT substance with potential for long-range transport, this release might be wide dispersive! Consequently, the outcome of the restriction proposal would be opposite as what was intended, namely reducing the overall existence of PFOA. | |
| **Answer to specific info request 4:**  Threshold value should be realistic and evidence based  Short-chain PFAS’s still contain traces of PFOA above the threshold value of 2 pbb, which is due to the production process. In the future the production process may be optimised so that traces of PFOA can be limited below 2 ppb. However the threshold value of 2 ppb is not feasible at all for the PFOA-related substances present in short-chain PFAS’s.  Consequently the concentration limit of 2 ppb for PFOA and PFOA-related substances means that short-chain PFAS’s can no longer be placed on the European market and/or used.  The threshold value of 2 ppb could apply for PFOA only on textiles. Textile companies have already experience with restrictions for PFOA only, as they have to comply with the Norwegian PFOA-restriction. Moreover PFOA is also a substance that is restricted by the textile ökotex-label. The threshold for PFOA in the ökotex-label is < 1 µg/m².  At the moment it is impossible for the textile companies to give a comment on the threshold values for the PFOA-related substances , as these substances have never been assessed so far. Moreover due to the absence of validated analytical methods for PFOA-related substances, it is impossible to do well-founded statements on these parameters.  Any threshold should be set at a level of quantification that safeguards the placing on the market of both short-chain PFAS’s and textiles treated with these short-chain alternatives. Moreover the threshold must be applicable by industry and enforceable by Member States on the basis of robust analytical methods with proven repeatability and reproducibility. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration on potential derogations.    According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC notes the comment that oil repellence in textiles can only (currently) be achieved with fluorinated chemicals, and that alternatives that offer water repellence are not permanent and can be removed by washing (leading to a need for re-impregnation), which is a problem for some types of PPE that are designed to meet harmonised safety standards. RAC also notes that the use of some alternatives might interfere with other aspects of the textile, such as flame retardancy.  RAC also notes current requirements to comply with the PFOA restriction in Norway (which has a higher limit than the proposal) as well as the limit for the ökotex-label. RAC acknowledges that the textile industry does not appear to have reliable information on levels of PFOA-related substances. The general lack of information on actual emissions from textiles means that RAC is unable to consider any derogations from a risk perspective.  See also responses to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1303** | **Date:** 2015/06/11 17:02  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  DIGITALEUROPE  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  DIGITALEUROPE, the association representing the digital technology industry in Europe, welcomes the opportunity to comment on the Annex XV Restriction Report: Proposal for a Restriction for Perfluorooctanoic acid (PFOA), PFO salts and PFO-related substances, published on 17 October 2014.  While PFOA is usually not directly contained in electronic products, Fluoropolymers are base plastic materials used in a wide variety of electronic applications. As downstream users of Fluoropolymers, we do not have a direct influence on the upstream process of chemicals used for manufacturing Fluoropolymers. Irrespective of whether long chained perfluorinated substances such as PFOA or their short chained alternatives are used for manufacturing of Fluoropolymers, thermal or other decomposition will highly likely lead to trace contamination with PFOA. While these impurities of PFOA are contained in very low concentrations, the proposed threshold of 2ppb would lead to a de facto restriction of all Fluoropolymers.  For the ICT and consumer electronics industry, the use of Fluoropolymers is key to the functionality of many product applications. Examples include lithium-ion battery chemistry and wire coatings on transformers and in power supplies coated with Fluoropolymers. Fluoropolymers are used as a low-loss material for high frequency applications like communications chips and printed circuit boards. The same is valid for other electronic parts such as electrical switches, electromagnetic solenoid valves, transducers, magnetic separators, electrical insulators and capacitors. Fluoropolymers are also used in structural components of electronic products, such as washers and gaskets; anywhere where heat, electrical isolation and chemical resistance are needed.  For these Fluoropolymer applications there are neither alternatives nor substitutes. The proposal to restrict PFOA and PFOA-related substances at 2 ppb for articles therefore presents a serious concern for our industry.  In the light of the above, DIGITALEUROPE proposes to include in the restriction a derogation for fluoropolymers, thus excluding fluoropolymers from the scope. This is will ensure that (unintended) consequences outside the intended scope will not occur. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict fluoropolymers manufactured without PFOA with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the restriction proposal to ensure that fluoropolymers manufactured without PFOA can be manufactured and used. | |
| **RAC Rapporteurs comments:**  The RAC view is that fluoropolymers as such should not be included in the restriction, but that the specific use of PFOA as a process chemical in the production of fluoropolymers should be stopped. It is a challenge to find a threshold level that stops the specific use of PFOA as a process aid but still allows some trace level contamination with PFOA, and hopefully the proposed limits will do that. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Taking into account all information submitted during the public consultation of the restriction dossier we support derogation for mixtures used in semiconductor photolithography processes as reflected in our draft opinion.  We also agree that revision of the proposal more generally to ensure that short-chain alternatives are allowed is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances.  SEAC also proposes to extend the general transitional period to 36 months to allow introduction of suitable alternatives and depletion of the relevant materials from supply chains. | |
| **1304** | **Date:** 2015/06/11 17:10  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1305** | **Date:** 2015/06/11 17:18  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  British Safety Industry Federation  **Org. country:** United Kingdom  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  The proposed restriction in PFOA will have an adverse effect on the performance of some items of Personal Protective Equipment (PPE). | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made showing that manufacturing of functional fabrics (PPE) is possible without PFOA and related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and trace level contamination. Thanks for indicating that “Raising the threshold (e.g. 25 ppb) would not result in any producer being able to use PFOA in their manufacturing process, but would be much easier for companies to demonstrate compliance and authorities to enforce the limit.” This has been recognised in the opinion. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see response to Comment 1235. | |
| **1306** | **Date:** 2015/06/11 19:56  **Type:** Individual  **Country:** Norway  **Company name confidential:** **No**  **Attachment confidential:** **No**    **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Documents with detailed information on used substance in the production of our product, some patent pending and intellectual property.  Solberg can be contacted for further information and confidentiality issues | **General Comments:**  The Solberg Company wishes to submit comments in support of the use of fluorine-free foam. Solberg has been commercially supplying non-fluorinated foam under the RE-HEALINGTM brand name since 2006. The product line has been developed to provide foams with fire performance equal to or better than the performance observed with commercially available fluorine containing foams. We include in this package information the supporting fire performance of products as defined by various international fire testing specifications including; Underwriters Laboratories, Inc. (UL) Standard 162, Factory Mutual (FM) 5130, European Normative 1568 parts 3 and 4, International Civil Aviation Organization (ICAO) dated 2014, the latest edition of International Maritime Organization (IMO), and the Large Atmospheric Storage Tank Fire Test (LASTFire).  Further descriptive information will be found in submitted file:"Solberg Comments ECHA Annex XV, as part of the public.zip file | |
| **Answer to specific info request 1:**  Solberg is fully compliant to the production of Fire Fighting Foam with the proposed PFOA limit of 2 ppb | |
| **Answer to specific info request 2:**  Solberg doesn't have to make investments to comply with proposed restriction of PFOA. | |
| **Answer to specific info request 3:**  Solberg is not using any chemicals which can degrade or Bio-degrade to PFOA | |
| **Answer to specific info request 4:**  Solberg production of Foam concentrate and other related products will not contain, nor biodegrade to possible PFOA molecules above the proposed limit of 2 ppb | |
| **Dossier submitter response:**  Thank you for the support and the new information on fluorine-free alternatives, especially the information that fluorine-free firefighting foams are already used at airports and refineries in Europe.  We will take the information into further consideration. | |
| **RAC Rapporteurs comments:**  Thanks for the information about fluorine free fire-fighting foams meeting international fire standards. See also response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Considering all information submitted during the public consultation it seems that fluorine-free firefighting foams seem not to be suitable for use in all situations at the current level of state of the art, and that it is important to ensure that short-chain fluorinated foams will be available when needed. See also response to Comment 1225. | |
| **1307** | **Date:** 2015/06/11 21:35  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  "Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh  "The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available.  see above | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1308** | **Date:** 2015/06/12 08:43  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We are manufacturer of workwear as well PPE products. For guaranteeing a chemical resistance, a stable PFC quality is necessary. For the security function the PFC quality even has to be renewed. A prohibition of PFOA means for the workwear sector, that there is no appropriate riot gear available. | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available.  see above. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account.The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1309** | **Date:** 2015/06/12 10:16  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes** | **General Comments:**  In protective clothing repellent finishes are used for different applications. Not all the applications are mentioned in the available documents. Therefor further work needs to be done to make sure that a large amount of workers would no longer be properly protected against the risks they face because of this limitation. | |
| **Answer to specific info request 1:**  In protective clothing repellent finishes are used for different applications. Can be for water repellence as described in the table with applications. However these finishes are very often used for (light) protection against liquid chemicals. This application is not included in the table. Protective clothing is subject to the Directive on Personal Protective Equipment (89/686). This type of protection is used on fire fighting clothing (harmonised standards EN 469) as a first barrier against chemicals, but also in industry as chemical protection type 6 (harmonised standard EN 13034). This type 6 protection is widely used in different types of industry where the risk of contact with chemicals is limited but not completely excluded. With this protection, the wearer has some time to go away from the risk and take off the clothing while the chemical remains on the surface of the clothing. To achieve this type of repellence, fluorocarbon finishes are applied to the fabrics used to produce the clothing, but also during the life cycle of the clothing the finish has to be reapplied to maintain the required level of protection. In practice this is done after each wash cycle. Both the textile and the textile service industry are shifting from C8 to C6 chemistry at the moment. This includes studies being done at the moment on the effectiveness of the C6 chemistry in all steps of the chain. So far, the results are promising, even if the C6 requires stricter conditions for activation, which certainly during the reapplication process leads to extra burdens for the textile service companies. | |
| **Answer to specific info request 4:**  One element that needs attention is the amount of ‘impurities’ in the C6 based products on the market for this application. Indeed it seems that there are some traces of C8 to be found in the C6 solutions and the limit of 2 ppb is unrealistically low. To determine a realistic limit, the manufacturers of the solutions offered to e.g. the textile services have to be consulted (e.g. Christeyns, Ecolab). | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration on potential derogations.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1310** | **Date:** 2015/06/12 10:31  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Concordia Textiles  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  In protective clothing repellent finishes are used for different applications. Not all the applications are mentioned in the available documents. Therefor further work needs to be done to investigate that a large amount of workers would no longer be properly protected against the risks they face because of this limitation. | |
| **Answer to specific info request 1:**  In protective clothing repellent finishes are used for different applications. Can be for water repellence as described in the table with applications. However these finishes are very often used for (light) protection against liquid chemicals. This application is not included in the table. Protective clothing is subject to the Directive on Personal Protective Equipment (89/686). This type of protection is used on fire fighting clothing (harmonised standards EN 469) as a first barrier against chemicals, but also in industry as chemical protection type 6 (harmonised standard EN 13034). This type 6 protection is widely used in different types of industry where the risk of contact with chemicals is limited but not completely excluded. With this protection, the wearer has some time to go away from the risk and take off the clothing while the chemical remains on the surface of the clothing. To achieve this type of repellence, fluorocarbon finishes are applied to the fabrics used to produce the clothing, but also during the life cycle of the clothing the finish has to be reapplied to maintain the required level of protection. In practice this is done after each wash cycle. Both the textile and the textile service industry are shifting from C8 to C6 chemistry at the moment. This includes studies being done at the moment on the effectiveness of the C6 chemistry in all steps of the chain. So far, the results are promising, even if the C6 requires stricter conditions for activation, which certainly during the reapplication process leads to extra burdens for the textile service companies. | |
| **Answer to specific info request 4:**  One element that needs attention is the amount of ‘impurities’ in the C6 based products on the market for this application. Indeed it seems that there are some traces of C8 to be found in the C6 solutions and the limit of 2 ppb is unrealistically low. To determine a realistic limit, the manufacturers of the solutions offered to e.g. the textile services have to be consulted (e.g. Christeyns, Ecolab). | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.    According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1311** | **Date:** 2015/06/12 10:55  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes** | **General Comments:**  Our company has decided to develop only PFOS/PFAS free products for the electronic industry more than 10 years ago and since then we did not promote any PFOS/PFAS containing products at all  in the EU market. However there are still some PFOS/PFOA containing products used by our EU customers in the electronic industry. The substances are not enclosed in the final products.  Such products are often used in a wide range of different processes to manufacture/produce a variety of devices/products at our customers’ level in supply chain. We know from previous experience during phase out of lithographic products that 18 months is too short for our customers to find a suitable alternative, test, qualify this alternative material and subsequently qualify the change at their end customers. For that reason we strongly recommend to expand the transition timeline to at least 3 years. | |
| **Answer to specific info request 4:**  The restriction proposal refers to PFOA related substances with unspecified chemical structures; this makes it nearly impossible to demonstrate compliance with the restriction based on analytical data. Analytical methods need to be sensitive in regard to the individual chemical structure as well as in regard to the medium the substances are presented in. In addition, if all the potential methods need to have a detection limit of <= 2 ppb, costs of development of appropriate methods will be significant.  Furthermore, substitution efforts for already developed alternative fluoro-components as substitutes for PFOA and PFOA-related substances could be in vain due to the risk that substances in scope of the restriction might be present as impurity above the challenging limit of 2 ppb. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The Dossier submitter proposed a structural formula to include all possible substances which can degrade to PFOA. This is in line with the restriction on PFOS and the stewardship program of the US-EPA on long chain PFASs. In our view there is no reason to alter the scope of the proposed restriction.  Risk management measures regarding human health and environment are in place. Furthermore, semiconductor industry is a minor user of PFOA related substances. There are very low emissions into the environment. Therefore, the Dossier submitter would agree with a longer transitional period for the remaining critical uses in photolithography.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction (with a derogation for semi-conductor manufacture), but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination. Longer implementation times than 18 months could be discussed, but it is noted that a large-scale substitution from C8 to C6 has already been performed suggesting that substitution is possible and could in general be performed rather quickly. It is not clear from this comment if the applications discussed concern niche markets or not. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see response to Comment 1303. | |
| **1312** | **Date:** 2015/06/12 12:31  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Switzerland  **Company name confidential:** **Yes** | **General Comments:**  Comments made in this form are to cover protective clothing finishes used in protecting people from chemical exposure (industrial workers), heat and flame protection (water and chemical exposure of industrial workers, fire fighters, security personnel, etc.) in their work environments. There protective clothings need to meet requirements linked to norms and standards to meet the essential safety requirements of the PPE Directive (89/686. In protective clothing repellent finishes are used for different applications. Not all the applications are mentioned in the available documents. Therefore further work needs to be done to make sure that a large amount of workers would no longer be properly protected against the risks they face because of this limitation. | |
| **Answer to specific info request 1:**  In protective clothing repellent finishes are used for different applications. Can be for water repellence as described in the table with applications. However these finishes are very often used for (light) protection against liquid chemicals. This application is not included in the table. Protective clothing is subject to the Directive on Personal Protective Equipment (89/686). This type of protection is used on fire fighting clothing (harmonised standards EN 469) as a first barrier against chemicals, but also in industry as chemical protection type 6 (harmonised standard EN 13034). This type 6 protection is widely used in different types of industry where the risk of contact with chemicals is limited but not completely excluded. With this protection, the wearer has some time to go away from the risk and take off the clothing while the chemical remains on the surface of the clothing. To achieve this type of repellence, fluorocarbon finishes are applied to the fabrics used to produce the clothing, but also during the life cycle of the clothing the finish has to be reapplied to maintain the required level of protection. In practice this is done after each wash cycle. Both the textile and the textile service industry are shifting from C8 to C6 chemistry at the moment. This includes studies being done at the moment on the effectiveness of the C6 chemistry in all steps of the chain. So far, the results are promising, even if the C6 requires stricter conditions for activation, which certainly during the reapplication process leads to extra burdens for the textile service companies.  The threshold of 2 ppb applicable for all substances in scope and all types of products would mean a de facto ban of all short-chain alternatives used in repellent finishes made without PFOA. With current analytical technology, it would show false-positive results against “clean” products, and would even catch certain products that were made without fluorochemicals at all but were contaminated somewhere in the logistics chain. Therefore a sensible limit should be included such as 250 to 500 ppb. | |
| **Answer to specific info request 2:**  As a fiber and textile provider this is difficult to quantify although a number of our customers are coming to us to with worries of not meeting norms and the potential frequent need of re-impregnation (every 50 washes to every wash). This means added cost and potentially reduction in comfort (increased heat exhaustion risks) for users of the PPE. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  RAC notes the proposal of an alternative limit of 250-500 ppb, but lacks a specific rationale for selecting these levels.  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1313** | **Date:** 2015/06/12 13:28  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  "Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh" | |
| **Answer to specific info request 2:**  Wie oben erwähnt hat sich die Textilindustrie in Deutschland auf Nichenprodukte spezialisiert. Die Verkäufe deutscher Hersteller von technischen Textilien beliefen sich in 2013 auf 6 Mrd. EUR. Ein Verbot fluorierter Produkte, die in Spuren PFOA und verwandte Stoffe enthalten, führen zu einen Niedergang der Wirtschafts- und Innovationskraft, was die Gefahr einschließt, dass Textilunternehmen ihre Konkurrenzfähigkeit und Existenzgrundlage verlieren. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  Nach Informationen unserer Lieferanten übersteigt der Anteil an PFOA und verwandten Verbindungen in den Hilfsmitteln für die Textilindustrie die Grenze von 2 ppb bei weitem. Deshalb entspricht dieser Grenzwert einem Verbot für die textile Produktion und das Auf-den-Markt-bringen von textilen Produkten. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1314** | **Date:** 2015/06/12 14:40  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Bundesverband Betrieblicher Brandschutz; Werkfeuerwehrverband Deutschland e.V.  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:** | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other firefighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC notes the information that the concentration of PFOA is in the order of 1 ppm in many current foams.  See also response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We recognise that contamination would be a problem at the level of 2 ppb. See also response to Comment 1225. | |
| **1315** | **Date:** 2015/06/12 14:38  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  3M Belgium  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Please find attached detailed comments by 3M on the ECHA PFOA Annex XV Restriction Report Health Assessment.  Questions on this submission can be directed to Philippe Hoff (phoff@mmm.com), 3M EMEA Product EHS&R Specialist or Michael J. Falco (mjfalco1@mmm.com), 3M Materials EHS&R Manager. | |
| **Dossier submitter response:**  Mammary gland development:  The Fluorocouncil also commented on this endpoint. We therefore refer to our responses to comment no. 1205.  3M furthermore comments that *“There is strong scientific evidence against using the mouse mammary gland data reported by Macon et al. on the basis of flawed study design, use of subjective endpoints, and erroneous data interpretation. In addition, inconsistent mouse mammary gland data reported by others reflected questionable biological significance of this endpoint”*  We disagree that the study design of Macon et al. (2011) was flawed. According to Macon et al. (2011) “*The dams were observed by veterinary staff and study personnel for signs of stress such as lack of weight gain or aggressiveness. None were observed.*” We also disagree that there is a use of subjective endpoints, cfr. Figure 1 of the article that presents the female offspring mammary gland whole mounts to allow the reader to assess the results. Furthermore, in our view, the observed change in the development of the mammary gland that was demonstrated in several different studies is of biological significance.  Effects on human cholesterol levels:  The Fluorocouncil also commented on this endpoint. We therefore refer to our responses to comment no. 1205  The lack of observed correlation in epidemiological studies between disease and stroke from PFOA exposure is described in the background document.  Reduced birth weight:  The Fluorocouncil also commented on this endpoint. We refer to our responses to comment no. 1205.  3M furthermore comments that the “*report needs to address GFR (Glomerular Filtration Rate) as a substantial confounder (…) of the association between prenatal PFOA exposure and birth weight.*” The glomerular filtration rate is discussed in chapter B.5.1.9.1.2 of the report. This has been responded to in comment no.1205. GFR is also discussed in the Johnson-study where they refer to another meta study that they performed (Lam et al., 2014).  Verner et al., 2015 concludes “Results of our simulations suggest that a substantial proportion of the association between prenatal PFAS and birth weight may be attributable to confounding by GFR and that confounding by GFR may be more important in studies with sample collection later in pregnancy.” They also state; “Our results also suggested that GFR had less influence on PFAS levels in maternal plasma early in pregnancy.”  This possible confounding mechanism has been discussed in the dossier and this is one of the reason why we chose the Fei-study as an indicative for lower birth weight association since sample collection was performed in the first trimester. | |
| **RAC Rapporteurs comments:**  Thanks for the comments on the human health risk assessment. RAC shares the view that some of the proposed end-points are currently not sufficiently robust to be used for a quantitative risk assessment. However, the animal data on developmental toxicity is relevant and RAC supports using them. RAC also notes that this animal data has been used by regulatory agencies worldwide in setting different types of limit values. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1316** | **Date:** 2015/06/12 16:43  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes** | **General Comments:**  In protective clothing repellent finishes are used for different applications. Not all the applications are mentioned in the available documents. Therefor further work needs to be done to make sure that a large amount of workers would no longer be properly protected against the risks they face because of this limitation. | |
| **Answer to specific info request 1:**  In protective clothing repellent finishes are used for different applications. Can be for water repellence as described in the table with applications. However these finishes are very often used for (light) protection against liquid chemicals. This application is not included in the table. Protective clothing is subject to the Directive on Personal Protective Equipment (89/686). This type of protection is used on fire fighting clothing (harmonised standards EN 469) as a first barrier against chemicals, but also in industry as chemical protection type 6 (harmonised standard EN 13034). This type 6 protection is widely used in different types of industry where the risk of contact with chemicals is limited but not completely excluded. With this protection, the wearer has some time to go away from the risk and take off the clothing while the chemical remains on the surface of the clothing. To achieve this type of repellence, fluorocarbon finishes are applied to the fabrics used to produce the clothing, but also during the life cycle of the clothing the finish has to be reapplied to maintain the required level of protection. In practice this is done after each wash cycle. Both the textile and the textile service industry are shifting from C8 to C6 chemistry at the moment. This includes studies being done at the moment on the effectiveness of the C6 chemistry in all steps of the chain. So far, the results are promising, even if the C6 requires stricter conditions for activation, which certainly during the reapplication process leads to extra burdens for the textile service companies. | |
| **Answer to specific info request 2:**  As the proposed limitation practically bans the use of fluorocarbons as repellent finish for protective clothing, this means not only more expensive alternatives but also less effective finishes on the products. This of course has an economic impact on the manufacturers and textile care companies. But even more important as the alternatives are less efficient it will force employers to revise their choices of protective clothing. Either they will use less effective clothing, which can lead to increased numbers of accidents and health issues. Or if they want to maintain at least the same level of protection, they will need to use more expensive clothing using different technologies (e.g. coating or laminate) - this will have a huge economic impact on those companies. | |
| **Answer to specific info request 4:**  One element that needs attention is the amount of ‘impurities’ in the C6 based products on the market for this application. Indeed it seems that there are some traces of C8 to be found in the C6 solutions and the limit of 2 ppb is unrealistically low. To determine a realistic limit, the manufacturers of the solutions offered to e.g. the textile services have to be consulted (e.g. Christeyns, Ecolab). | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration on potential derogations.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1317** | **Date:** 2015/06/13 19:49  **Type:** Individual  **Country:** Spain  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  The use of PFOA and related compounds in a wide range of products for industrial, textile, food, construction materials and domestic use, among others, produce direct accumulation in humans through ingestion, breathing or direct contact. Moreover, the discharge and disposal of PFOA-containing products affect the quality of the environment and residues are subsequently bioaccumulated in organisms, both aquatic and terrestrial.  Since 2009, our research group has studied the presence of PFOA, along with other perfluorinated compounds in several environmental matrices and in human blood. It is notorious that all samples analysed contained traces of PFOA, thus indicating its widespread distribution in the environment and impact in humans. To briefly summarize the findings, we have found that:  - PFOA was present in coastal seawaters collected along the NE Mediterranean and that river waters and in second instance Wastewater Treatment Plant (WWTPs) effluents through marine emissaries were the main contributors to the load of PFOA to the sea (Sánchez-Avila, 2010).  - PFOA was detected in crabs and in insect larvae although other freshwater invertebrates (e.g. oysters) did not present traces of this compound. Levels were detected at the 0.14-4.3 ng/g fresh weight (Fernández-Sanjuan, 2010).  - PFOA was accumulated in WWTPs sludge from Spain and Germany at levels from 0.12 to 1.21 ng/g dry weight, with slight increases from primary to anaerobic digested centrifuged sludge, contributing to the release of PFOA to agricultural land in case sludge is used as fertilizer (Gómez-Canela, 2012).  - Among 5 perfluorinated compounds studied in entire gull eggs (used as bioindicator of contamination) collected in National and Natural Parks of the Iberian Peninsula, perfluorooctane sulfonate (PFOS) was the only compound detected and no traces of PFOA were found (Vicente, 2012), although PFOA was detected when analysing the yolk in 1 out of 10 egg clutches studied (Vicente, 2014).  - PFOA was detected systematically in blood from Catalan residents at 0.07 to 1.08 ng/mL, indicating that exposure is generalized in both laboratory workers and in the general population (Gómez-Canela, 2015).  - When determining the effects of PFOA using the human placental choriocarcinoma cell line JEG-3 at concentrations simulating the levels in human blood, PFOA was able to exert endocrine disruption on the cellular P450 aromatase (CYP19 activity) and was able to produce changes in the lipid profile of JEG-3 cells exposed to 0.6 and 6 µM of a mixture of perfluoroalkyl and polyfluoroalkyl substances (Gorrochategui, 2014).  According to the widespread presence of PFOA at the effects it might cause at low concentrations, the restriction proposal of PFOA at 2 ppb level seem to be adequate and that special attention has to be given to:  - Its use in food contact material, where the use of PFOA can have direct health effects due to migration to foodstuff.  - The toxicity and effects of mixtures of and perfluoroalkyl and polyfluoroalkyl substances.  - Effects on endocrine disruption and lipid alteration, considering the bioavailable fraction.  Taken together, PFOA is present in both environmental and human samples and can trigger negative endocrine disruption effects and alterations in the lipid composition in cells. Therefore, their exposure should be minimized by restricting the levels allowed in consumer’s products. It should also be considered that PFOA substitutes can have similar or other effects which cannot be left apart.  However, comparing the proposal for the restriction of 2 widely used surfactants, nonylphenol (NP) and PFOA, the levels are very different. For PFOA the proposal for restriction is of 2 ppb and for NP, a value of 0.01% (100 µg/g) has been set for textiles (proposal for restriction of NP) and 0.1% (1000 µg/g) in other products (DIRECTIVE 2003/53/EC). The very restrictive level for PFOA compared to NP, which has been identified as highly estrogenic and toxic, should be well evidenced according to toxicological studies.  References  - Gómez-Canela C., Fernández-Sanjuan M, Farrés M, Lacorte S, Factors affecting the accumulation of perfluoroalkyl substances in human blood, Environmental Science and Pollution Research, in press, 2015.  - Vicente J, Sanpera C, García-Tarrasón M, Pérez A, Lacorte S, Perfluoroalkyl and polyfluoroalkyl substances in entire clutches of Audouin’s gulls from the ebro delta, Chemosphere, (2014), 119, S62-S68, 2015.  - Gorrochategui E, Pérez-Albaladejo E, Casas J, Lacorte S, Porte C, Perfluorinated Chemicals: Differential toxicity, inhibition of aromatase activity and alteration of cellular lipids in human placental cells, Toxicology and Applied Pharmacology, 277, 124-130, 2014.  - Gómez-Canela C, Barth JAC, Lacorte S, Occurrence and fate of perfluorinated compounds in sewage sludge from Spain and Germany. Environmental Science and Pollution Research, 19, 4109-4119, 2012.  - Vicente J, Bertolero A, Meyer J, Viana P, Lacorte S, Distribution of perfluorinated compounds in Yellow-legged gull eggs (Larus michahellis) from the Iberian Peninsula. Science of the Total Environment, 416,468-475, 2012.  - Fernández-Sanjuan M, Meyer J, Damásio J, Faria M, Barata C, Lacorte S, Screening of perfluorinated chemicals (PFCs) in various aquatic organisms. Analytical Bioanalytical Chemistry, 398, 1447-1456, 2010.  - Sánchez-Ávila J, Meyer J, Lacorte S, Spatial distribution and sources of Perfluorochemicals in the NW Mediterranean Sea. Environmental Pollution, 158 (9), 2833-2840, 2010.  - Proposal for a restriction nonylphenol and nonylphenolethoxylates in textile COMMISSION REGULATION (EU) No …/.. of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") as regards nonylphenol ethoxylates.  - DIRECTIVE 2003/53/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2003 amending for the 26th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (nonylphenol, nonylphenol ethoxylate and cement). | |
| **Answer to specific info request 1:**  No information available on these issues. | |
| **Answer to specific info request 2:**  No information available on these issues. | |
| **Answer to specific info request 3:**  No information available on these issues. | |
| **Answer to specific info request 4:**  - Short chain PFASs are being present in the environment at increasing concentrations since PFOS restrictions. The capability to determine the bioavailable fraction producing an effect is of outmost importance to determine risks. Therefore, while PFOA might be restricted, the study of effects of short-chain PFASs to be used as PFOA substitutes must be performed to ensure that the replacement does not produce a higher risk.  - The method detection limit (MDL) of PFOA for water samples is of 0.04 ng/L (Sánchez-Ávila et al., Environ. Pollut. 158, 2010), in biological matrices the MDL is of 0.11 ng/g ww (Fernández-Sanjuan, ABC 398, 2010) and in sludge of 0.10 ng/g dw (Gómez-Canela, ESPR 19, 2012). Liquid chromatography coupled to tandem mass spectrometry is needed to unequivocally determine PFOA with high sensitivity and precisely. Using this technique, it should not be a problem to determine concentrations of 2 ppb in consumer products. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration.  The reported PFOA blood concentrations from Spain are in the range we already use in chapter B.5.3.6. We have included the submitted information on the effects that PFOA has on the human placental choriocarcinoma cell line JEG-3 in the revised background document. | |
| **RAC Rapporteurs comments:**  Thanks for the extensive information. The widespread occurrence of a PBT-substance is of concern and reasons for a restriction, although for practical reasons the RAC would support a limit value higher than 2 ppb. The restriction will concern PAP-substances, thereby reducing the exposure via foodstuffs. We have noted the concern for mixture effects, and support the need for further studies of the fluorinated alternatives. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1318** | **Date:** 2015/06/15 10:40  **Type:** Individual  **Country:** Hong Kong  **Company name confidential:** **No** | **General Comments:**  The limit of 2 ppb appears unreasonably low compared to current limits set e.g. for known carcinogens with more critical exposure scenarios such as toys or drinking water. | |
| **Answer to specific info request 1:**  no comment | |
| **Answer to specific info request 2:**  no comment | |
| **Answer to specific info request 3:**  no comment | |
| **Answer to specific info request 4:**  A limit of 2 ppb means entering the field of ultra-trace level analytics. Typical laboratories for product testing work with equipment and methodologies that allow determination in the trace level range from 1 to 1000 ppm.  No standard method for the given matrix is known to reproducibly achieve a LoQ (Limit of Quantification) of 2 ppb. In case a standard method can successfully be developed, it’s application will be limited to a small number of specialized laboratories due to high investment cost and required expertise.  Additionally it needs to be considered that between the regulatory limit and analytical LoQ a certain safety margin (ideally with the LoQ 5~10-fold lower than the regulatory limit) is advisable to account for unavoidable uncertainties.  An increased limit of 2 ppm could be considered analytically feasible with state-of-the-art equipment, ensuring test method become broadly available. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to REACH emissions of PBT substances have to be minimised. Therefore the threshold needs to be as low as possible.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities. Whilst RAC agrees with the DS that the restriction can be an incentive to develop analytical methods, there has to be a realistic prospect of the development of a reliable method within an appropriate time frame to provide legal certainty for all actors. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that a revision of the concentration limit is necessary. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. | |
| **1319** | **Date:** 2015/06/15 11:15  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  - Diesel- / Winter-Diesel repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh | |
| **Answer to specific info request 2:**  Economic Impact:  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  Calculations:  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Any other costs:  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  Information on which of the PFOA-related substances:  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  Information on linear and branched substances C7F15:  As the textile industry doesn't use PFOA and related substances no additional information is available.  Information on linear and branched substances C8F17:  see above | |
| **Answer to specific info request 4:**  Possible impact of 2ppb Limit:  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  New limits should be set in a way that the use C6-chemistry is not affected (also in the future).  Analytical methods:  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short- chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised. The Dossier submitter has revised the proposed concentration limit to ensure that short- chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1320** | **Date:** 2015/06/15 11:34  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  VdS Schadenverhütung GmbH  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  summary of the attachment:  The maximum permissible value of PFOA in the restriction proposal will have severe influence on the effectiveness of extinguishing systems using fluorinated foaming agents (AFFF – aqueous film-forming foams). The present concepts for fixed extinguishing systems require the use of fluorinated foaming agents for special risks and/or materials in order to ensure efficient firefighting.  This refers especially to fixed fire extinguishing systems in the industrial sector used for the protection of “storage and processing of flammable liquids” like alcohols and related substances, fuels and aviation petrol, as well as for the “storage of plastics” like polypropylene, polyethylene or similar products where the proportioning of fluorinated foaming agents to the water is indispensable to secure their effective extinguishment.  All fluorinated foaming agents available on the market today contain a concentration of PFOA which is 300-600 times higher than the designated maximum permissible value.  Alternative foaming agents, with comparable effectiveness which would comply to the restriction proposal, are not available at present and will not be available in the foreseeable future. In implementing this restriction proposal with the mentioned limit values, effective hazard control in the mentioned scenarios would no longer be possible, with all possible consequences for the population, for the safety of workers, the environment and also for the availability of industrial sites.  For the mentioned reasons VdS requests the following:  1. The rejection of the restriction proposal to introduce a limit of 2 ppb for "PFOA and related substances" on the manufacturing, use and placing on the market. This restriction is disproportionate and could not be met even with great effort. It is 5000-fold below the threshold of the PFOS restriction of 10,000 ppb (10,000 µg/kg).  2. Should it be necessary, for reasons incomprehensible to VdS, to introduce a restriction of "PFOA and related substances”, we hereby apply to exclude the use in stationary extinguishing systems. This must apply as long as foaming agents equivalent to today's fluorinated but PFOS-free extinguishing agents are not available.  3. In any case, we request that the implementation of a restriction of "PFOA and related substances" includes a limit that guarantees the continued use of all foaming agents stockpiled in stationary extinguishing systems until 27/06/2031. This represents a 20-year reuse after the restriction of PFOS from 27.06.2011 and subsequently newly purchased foaming agents. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other firefighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier Submitter. These stocks should only be used for emergency cases and not for exercises.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1225. | |
| **1321** | **Date:** 2015/06/15 14:17  **Type:** BehalfOfAnOrganisation  **Org. type:** European institution  **Org. name:**  European Aviation Safety Agency  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  The Aerodrome Section (FS.4.3)of the European Aviation Safety Agency would like to indicate hereby its availability to advise you in your work during the analysis of the consultation and policy formation regarding PFOA substances.  It has been indicated to us by the aerodrome industry that the proposed restriction to the concentration of PFOA and its salts to equal or less than 2 ppb may eliminate the possibility of using AFFF in fire fighting especially when used in aircraft accidents by aerodrome's rescue and fire fighting services. The current AFFF (performance levels B and C)are the first choice to knock down kerosene fire in short time and prevent re-ignition after passengers walking through foam above kerosene, fire fighters running or fire fighting vehicles driving through, due to its film-forming capabilities.  The other available foam is performance level A, which however contains high concentrations of heavy metals (mainly cadmium). Since there are so far no widely available other types of foams having the same performance characteristics as AFFF levels B and C, any possible restriction could degrade the operational efficiency of rescue and fire fighting services at aerodromes.  For this reason it might be necessary to either exclude rescue and fire fighting services from the proposed requirements to substantially limit PFOA in extinguishing foams or to allow sufficient time to the industry to develop foams that have similar operational efficiency, while meeting the proposed requirements. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The use of PFOA and PFOA-related substances in AFFF is not necessary. Alternatives based on short-chain chemistry are available and widely used. It is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAScan be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We note that several comments submitted during this public consultation state that C6 alternatives perform well in AFFF.  We consider it important to be ensured that short-chain alternatives will be allowed to be used. Therefore we support higher concentration limits (25 ppb for PFOA and its salts, and 1000 ppb for PFOA-related substances in general for all uses. For firefighting foams however we suggest to apply the 1000 ppb limit for both PFOA and its salts and PFOA-related substances). | |
| **1322** | **Date:** 2015/06/15 14:34  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  "Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh"  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover. | |
| **Answer to specific info request 3:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles. | |
| **Answer to specific info request 4:**  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1323** | **Date:** 2015/06/15 14:57  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  3M Zwijndrecht - Belgium  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  3M provided the same feedback towards the European Safety Federation (ESF)secretary general mr Henk Vanhoutte (see attachment)  Conclusion:  Because of the successful voluntary stewardship effort, the possible unintentional  presence of small quantities of PFOA in fluoropolymers, the significant overall  analytical challenges, and the remarkable range of benefits to safety, environment, and  quality of modern life, 3M respectfully requests that the option is considered whereby  fluoropolymers (and the articles made from them) be exempt from the proposed  restrictions, if they are made without the use of PFOA or PFOA related substances. As  for the other uses of fluorochemicals, 3M suggests basing any limit for PFOA on a risk  based assessment and supported by the available toxicological data and not merely on  an assumed 2 ppb analytical detection limit capability. We believe that this step would  not undermine ECHA’s overall objective of real reductions in PFOA and related  substances, but enhance it by making it more workable and enforceable.  3M intends to provide additional detailed comments and appreciates your  consideration. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the manufacturing and use of PTFE with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers. PTFE manufactured without PFOA is already available on the market and will not be affected by the proposed restriction.  The Dossier submitter has revised the proposed concentration limit, but we disagree to set the limit based on the toxicological data because intentional use of PFOA and PFOA-related substances cannot be excluded.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  The RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other products.  The RAC view is that fluoropolymers as such should not be included in the restriction, but that the specific use of PFOA as a process chemical in the production of fluoropolymers should be stopped. It is a challenge to find a threshold level that stops the specific use of PFOA as a process aid but still allows some trace level contamination with PFOA, and hopefully the proposed limits will do that. The limits also have to be chosen not to affect the use of C6 chemistry. Whilst RAC agrees with the DS that the restriction can be an incentive to develop analytical methods, there has to be a realistic prospect of the development of a reliable method within an appropriate time frame to provide legal certainty for all actors. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1324** | **Date:** 2015/06/15 15:07  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company. | **General Comments:**  We would like to state clearly,that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  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?  Comment: Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  a) Personal protective equipment:  For the various applications (police,fire- and rescue authorities and workers in the chemical industry) the persons wearing this protective clothings will be less protected and therefore more endangered in the future due to the significant worsening technical effects of the alternative products such as dynamic water- and oil repellency, washing / water fastness and rubbing / abrasive durability.  b) Clothes ant tents for military use:  Comment: See above  c) Materials for sun protection an building protection:  By using alternative products which have worse performances,  the durability and longevity is significantly at risk and the aging process would be quicker. This is a slump in the sustainability of the materials that is being intended by the ECHA.  Could you specify the quantities used?  Comment: As mentioned above processing agents contain PFOA and/or related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The information supplied by SDS do not contain details regarding PFOA and/or related substances. Alternative processing agents -if possible at all- must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  Could you provide information regarding the potential risks to the environment or to human health via the the environment related to any of these uses?  Comment: The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  Economic impacts  Comment: The Textile industry in Germany is highly specialized on niche-products, which meets the highest requirements as mentioned above. The sales of German producers of technical textiles reached around 6 billion € in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  For our company a loss of about 15% in turnover may result.  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?  Comment: As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Do you have information on any other costs of the restristriction, which might not be included in the dossier?  Comment: Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  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.  Comment: The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  Do you have information on substances having linear or branched perfluoroheptyl derivatives with the formula C7F15- as a structural element, including its salts, (except C7F16, C7F15Cl or C7F15 Br) which do not have the potential to degrade to PFOA?  Comment: As the textile industry doesn't use PFOA and related substances no additional information is available.  Information to degradation of C8 and related substances to PFOA  Comment: See above. | |
| **Answer to specific info request 4:**  Do you have information on the possible impact of the proposed concentration limit (2 ppb) 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?  Comment: According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  Do you have information on the availability of analytical methods including the limit of quantification of those methods in relevant matrices?  Comment: The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasize, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1325** | **Date:** 2015/06/15 15:17  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Finland  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Protection of our company's interests | **General Comments:**  Our company is conscious that the long-chain telomer chemistry must be replaced,and it has done already a lot to eliminate PFOA from its products.  However, it has three concerns about the proposed restriction:  1. The proposed 2ppb limit: The economic and practical feasibility of conducting measurements to ensure compliance with a limit as low as 2ppb would be extremely difficult.  2. The timeframe involved: The proposal goes some way towards addressing products already in the supply chain and that would still be present by the time of the enforcement of the restriction.  3. The Social and Economical Assessment: the proposed threshold of 2 ppb applicable for all substances in scope and all types of products would put a direct ban to the placing on the market of short-chain alternatives (C6 alternatives) and thus causing severe damage to our paper mills, not excluding the risk of ceasing their activity, resulting in several hundred job losses direct and indirect (from production, R&D, sales & marketing, …) in various EU countries. | |
| **Dossier submitter response:**  Thank you for the new information provided. We will consider it in the further development of the Background Document.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.    It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The restriction involves the placing on the market of articles containing PFOA and PFOA-related substances. Thus, articles which are already on the market are not affected.  Industry has now been informed about the proposed restriction and can already take measures to minimise the content of PFOA and PFOA-related substances in their articles. Therefore we see no problem with the shelf life of products already in the supply chain. A longer transistional time does not seem to be justified. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination. Longer implementation times than 18 months could be discussed, but it is noted that a large-scale substitution from C8 to C6 has already been performed suggesting that substitution is possible and could in general be performed rather quickly. We note the concern for products in the supply chain and also note the response from the DS that articles which are already on the market are not affected. Whilst RAC agrees with the DS that the restriction can be an incentive to develop analytical methods, there has to be a realistic prospect of the development of a reliable method within an appropriate time frame to provide legal certainty for all actors. | |
| **SEAC Rapporteurs comments:**  Thank you for the information submitted including information on shelf-lives of concerned articles and the indications of the anticipated costs. We agree that a revision of the concentration limit is necessary to ensure that short-chain alternatives are allowed to be used. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances.  SEAC also proposes to extend the general transitional period to 36 months to give more time to the introduction of suitable alternatives and to allow depletion of the affected materials from supply chains. | |
| **1326** | **Date:** 2015/06/15 16:34  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Schümer Textil GmbH  **Org. country:** Germany  **Company name confidential:** **No**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  We are a company producing high-grade apparel for fire services in Austria and Germany. These textiles have to comply with regulations such as ÖBFV-RL KS03 and KS04 or DIN EN 469.  These regulations demand high requirements according to water- and oil-repellency standardized in ISO 4920 / EN 24920 / EN 13034 Type 6 / EN ISO 6530. These are also needed for industrial purposes and can only be fulfilled with long-chain fluorine products.  Furthermore a high rate of protection is needed in areas like protective wear for police and army. If persons get wet and in contact with burning oil (Molotow-Coctails) they would scald themselves, oils could penetrate the clothing, ignite and burn the persons wearing them.  Especially for the applications mentioned above we need exemptions to use a chemistry that provides best personal protection.  "Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh"  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see response to Comment 1235. | |
| **1327** | **Date:** 2015/06/15 17:23  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Assotende/FederlegnoArredo (italian association of furnishing producers)  **Org. country:** Italy  **Company name confidential:** **No** | **General Comments:**  Assotende represents the Italian producers of curtains, blinds and shades, both for indoor and outdoor use, and is part of FederlegnoArredo, the Italian association of woodworking, furniture and furnishing industries. Our association supports in general the intention to limit the emissions of PFOA in the environment. Our member companies do not use PFOA, but this substance is a contamination in fluorinated substances, which are necessary for a wide range of uses in the textile industry, including the textiles used in curtains for indoor and outdoor use, e.g. awnings, pergolas, sails, canopies.  Our products are in use worldwide, a few of our companies are world leaders with their products. For this reason our member companies had started intensive efforts to substitute the so called C8 chemistry because of the known contamination with PFOA. Many of the uses are substitutable, but not all, because the substitutes are not able to fulfill all specifications of our clients. The substances, which are more or less able to substitute the C8 chemistry, are the shorter chain, the so called C6 chemistry, which has - according the information of the chemical industry – less residues of PFOA.  The central problem now is the fact, that the restriction proposal not only includes the PFOA, but also the “related substances” – and these substances are still a contamination also in the C6 chemistry. So if this restrictions proposal would be realized, even the substitutes for the C8 chemistry would no longer be available on the market and many specifications of our clients would no longer be accomplished.  This would not only be a hard damage to the competitiveness of the European textile industry, but also an endangering of all the people. The problem is not only the fact, that our companies cannot use the C6 chemistry any longer, but these kinds of textiles would furthermore no longer be available on the European market, because the restriction proposal also includes the import of articles. We support this circumstance, because this would prevent a shift of the production to Far East, but again, these textiles, which are absolutely necessary i.e. as in textiles used for furnishing and structural elements such as shades, curtains and pergolas. | |
| **Answer to specific info request 1:**  In our sector (furniture and furnishings), the following uses would be hardly damaged through a restriction of PFOA and especially of the related substances:  • Sun protection (curtains and shades for outdoor use, awnings, pergolas, sails, canopies, the longevity of which would be minimized, the aging process would be quicker without the repelling finishing, a damage for the sustainability)  • Outdoor furniture (longevity)  Several of our companies are making high amounts of these kinds of textiles, so they would be hardly damaged, if they would no longer be able to fulfil the requirements in the specifications of their clients. According their R&D, there are no alternatives to the PFC-Chemistry! They have tried hard, but all alternatives are worse in their effect on the textile and in their efficiency (you need more chemicals for a worse effect). | |
| **Answer to specific info request 2:**  Concerning the economic impacts on the market “surface treatment” of textiles the consequences would be harder than estimated, because according the answers of our companies a few of them would be endangered in their existence. | |
| **Answer to specific info request 3:**  We have no information about fluorinated substances, which do not have the potential to degrade to PFOA. | |
| **Answer to specific info request 4:**  the threshold of 2 ppb is very critical, not only for the PFOA, but especially for the related substances. According the answers of laboratories, which test regularly textiles for PFOA their actual detection limit is 100 ppb (laboratory 1) and 50 ppb (laboratory 2) only for PFOA. The 8:2 fluortelomeralcohol is much more problematic, because the asked laboratories have not analytical method!!!! So analytical methods to quantify the PFOA content in textiles are available, but it is very questionable, that these methods are robust enough to determine whether the PFOA content in a textile article is below 2 ppb or not and to decide whether an article is compliant or not. For the related substances no analytical methods are obviously available! So it would be impossible to make sure, that textiles produced in Far East will be compliant to these EU requirements – and the competitiveness of the EU companies will be worse again….. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised. The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  Considering this information we believe that also for sun protection and outdoor furniture alternatives are available. Moreover, these items may directly emit residual amounts of PFOA and PFOA-related substances into the environment and we do not agree with derogation for these uses. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other product. The limits have to be chosen not to affect the use of the C6 chemistry. Longer implementation times for some critical uses are supported. Whilst RAC agrees with the DS that the restriction can be an incentive to develop analytical methods, there has to be a realistic prospect of the development of a reliable method within an appropriate time frame to provide legal certainty for all actors. | |
| **SEAC Rapporteurs comments:**  In accordance with the RAC rapporteurs, SEAC rapporteurs share the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of alternatives. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. We also suggest a longer transition period (36 months) to allow for the development of alternatives where necessary. | |
| **1328** | **Date:** 2015/06/15 17:46  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** protection of confidential information relating to product performance and identity of disclosed contacts. | **General Comments:**  response to request for additional information provided as confidential attachment | |
| **Dossier submitter response:**  Thank you for responding to the ECHA request.  We will take it into further consideration when revising the background document. | |
| **RAC Rapporteurs comments:**  Thanks for the useful information. See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for this important information.  We recognise that the performance of short chain alternatives may not yet be sufficient for use in protective professional textiles and we support a transitional period of 6 years to give more time for the development of alternatives. We also see it necessary that the state of the art will be examined in 5 years and that any necessary changes to the scope of the restriction will be made at that point in time.  Derogation is not seen as a preferable solution because of high emissions. | |
| **1329** | **Date:** 2015/06/15 18:19  **Type:** MemberState  **MS name:** Belgium  **Country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  please find in the enclosed document the Belgian comments. | |
| **Dossier submitter response:**  Thank you for your support.  The Dossier submitter proposed a structural formula to include all possible substances which can degrade to PFOA. This is in line with the restriction on PFOS and the stewardship program of the US-EPA on long chain PFASs. In our view there is no reason to alter the scope of the proposed restriction.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other product. Longer implementation times or derogations have been discussed for PPE-textiles, but so far there is little specific information available from the PC to assist in these discussions. RAC acknowledges the problems for enforcement with the large scope, but the scope is supported by the analysis performed by RAC regarding emission potentials. | |
| **SEAC Rapporteurs comments:**  SEAC also shares concerns about the 2 ppb threshold, and recognise concerns about the proportionality of the proposal for safety critical uses or if alternatives would no longer be available. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. We also suggest a longer transitional period generally (36 months) and specifically for protective professional textiles (6 years) to allow for the development of alternatives where necessary. | |
| **1330** | **Date:** 2015/06/16 06:14  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  The Japan Federarion of Medical Devices Associations  **Org. country:** Japan  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  JFMDA wishes to submit the following comments in response to the invitation for public input on the proposed REACH restriction for PFOA. We hope that our comments will contribute to effective and appropriate implementation of the restriction for PFOA.  Our comments can be summarized as follows: in the case of medical devices which play important roles in helping to maintain human health, we request allowance of a suitable period of time for implementation of the proposed restriction, similar to the grace period allowed for RoHS, etc. The basic reason for this request is that additional time is needed for investigation of the current situations, verification of alternative techniques, and application to and approval by the relevant authorities.  General Comments  a) Period for obtaining information on PFOA-containing components  Medical device manufacturers are not in possession of complete information about all of the "components that contain PFOA at concentrations of 2 ppb or more and less than 1000 ppm" that are used in medical devices; therefore, they need time to investigate the matter for each of their numerous suppliers across various industry sectors.  PFOA is restricted under regulations such as REACH SVHC and the Norwegian Product Control Regulations. The threshold in those regulations is 1000 ppm (article) and not 2 ppb. Consequently, our suppliers are not legally required to report to medical device manufacturers regarding electronic components that contain PFOA at concentrations of 2 ppb or more and less than 1000 ppm.  This means there is a possibility that components containing PFOA at concentrations of 2 ppb or more and less than 1000 ppm are being used without medical device manufacturers having been informed of this fact. Accordingly, a grace period from two to three years is required to enable compilation of sufficient information about these components.  b) Switch to PFOA-free components  For medical device manufacturers to identify which components contain PFOA and then switch to PFOA-free components, they need additional time for exploring and developing alternative components, verifying their quality, and applying for marketing approval. Since medical devices are required to have high safety levels, examination of quality and securing of marketing approval from the relevant authorities/independent third parties takes a long time—at least five years until a device is approved and can be used in clinical practice. Hence, a timeline mandating enforcement of the restriction within 18 months after its promulgation is far too short and, therefore, unrealistic.  c) Characteristics of medical devices  Long life-cycles and high-mix/low-volume production are factors that characterize medical devices. They also have to meet high quality and safety standards because patients’ lives may depend on their efficacy and reliability. For those reasons, the process of switching to PFOA-free components in all types of medical devices demands longer lead-times compared to the requirements for other types of finished equipment.  Since medical devices are often produced in lower volumes than other types of general-use devices, the amounts of PFOA-containing components are estimated to be smaller than those in devices manufactured for other industries. Furthermore, medical devices are strictly controlled from their in-use phase through final disposal. Therefore, compared to other industries, the amounts used and disposed of illegally are estimated to be smaller, resulting in relatively less impact on the environment and human health. In other words, imposing a restriction on medical devices is not a matter of great urgency, and delaying enforcement to a later date than for other products would be beneficial to society compared to the disadvantages of their complete removal as patients depend on these devices to maintain their health or even to preserve their lives.  d) Request  - We request that thresholds be set at realistic levels in consideration of the impacts on the environment and human health, and of actual detection capability.  - We request that enforcement of the restrictions for medical devices be delayed for at least four years after enforcement of the restrictions on PFOA-containing components and other finished equipment using PFOA-containing components. | |
| **Answer to specific info request 1:**  As shown in our General Comments, presumably manufacturers of finished equipment might not have information on the large number of components containing PFOA at concentration of 1000 ppm or lower. | |
| **Answer to specific info request 2:**  Even within the limited scope of medical equipment, it is not possible to estimate the extent of any economic impacts due to lack of comprehensive information on the current status of use of PFOA. | |
| **Answer to specific info request 3:**  We have no information on such substances. | |
| **Answer to specific info request 4:**  We have no information on analytical methods for PFOA. Even within the limited scope of medical equipment, it is not possible to estimate the impacts of low concentration limits due to no comprehensive information on the current status of use of PFOA. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration for potential derogations. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other product. From a risk perspective, RAC only supports a derogation for implantable medical devices at the present time. Derogation for other types of medical device is more of a matter for SEAC. | |
| **SEAC Rapporteurs comments:**  In accordance with the RAC rapporteurs, SEAC rapporteurs share the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of alternatives. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. Relating to medical devices specifically please see response to Comment 1232 | |
| **1331** | **Date:** 2015/06/16 09:52  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  I&P Europe - Imaging and Printing Association  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** The protection of commercial interests of member companies including intellectual property would be undermined. | **General Comments:**  Additional information to the ongoing public consultation on the PFOA restriction proposal, as requested by the ECHA PFOA Restriction Team in email dated 9 June 2015.  Question 1: Could you please specify which PFOA-related substances are exactly required/used in the remaining critical applications in the photographic industry?  Members of the I&P Europe association require and use the following PFOA-related substances in remaining critical applications:  - The CAS No used are provided as a separate confidential document.  Question 2: Could you please specify which substances used are not volatile? Are risk management measures also in place for volatile substances?  All PFOA-related substances required in the remaining applications of Member companies of I&P Europe are not volatile. No volatile substances are used.  Question 3: According to the information submitted “it could be financially challenging for hospitals and doctor's offices with tight budget restraints to invest in new technologies necessitated by discontinuation of current conventional photographic products during the proposed phase out period of 18 months”  Could you describe a bit more in details the photographic products/ technologies for healthcare?  Photographic products for healthcare: the PFOA substances are used in different types of film.  First hardcopy film, used to make a copy of a medical view.  Such medical hardcopy films include  - high-density, high-contrast dry processing films offering optimum image quality for digital mammography. Such films are specially developed to meet the high optical density requirements demanded by digital mammography. With its high maximum density (Dmax > 3.7), even the most subtle grey-level changes required for mammography applications can be visualized (diagnosis of breast cancer);  - dry processing film specially developed to produce the very highest diagnostic-quality grayscale hardcopies with high Dmax and contrast. It gives the same clear, high-quality results as wet laser film, but with all the advantages of dry technology: no wet processing, no darkroom and no chemicals.  Key benefits of medical hardcopy films include  - Clear and sharp images.  - Excellent image stability.  - No wet processing, darkroom or chemicals.  - Secure archiving up to 20 years.  An other film type are the classic AgX screen film applications, including dental films  ( intra-and extra-oral films).  Question 4: Could you briefly describe also the photographic products/technologies used for military purposes?  Photographic products for military purposes are AgX based films used in high speed cameras with high resolution for aerial applications.  Uses in aerial photography include black and white or color films for airborne image capture for use in civil mapping and military strategic applications. Also photographic panchromtic glass plates for photogrammetry, archival dupe film, surveillance camera films and traffic infringement films. | |
| **Dossier submitter response:**  Thank you for responding to the ECHA request.  We will take the information provided into further consideration when revising the background document. | |
| **RAC Rapporteurs comments:**  Thanks for the detailed information. In the view of RAC, the emissions from the photographic sector seem negligible, which in combination with the use pattern warrants a derogation. | |
| **SEAC Rapporteurs comments:**  Thank you for the detailed information. We agree that taking into account the low emissions (due to low and still decreasing in volumes and the risk management measures applied) and the anticipated socio-economic consequences of the restriction, derogation seems appropriate for this use. We have reflected this in our draft opinion. | |
| **1332** | **Date:** 2015/06/16 12:30  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  IBENA Textilwerke GmbH  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Following my submission of May 21st.  Ref.:eeed6a64-0c6a-4fb8-b9d5-b5b46306d817  I have received a request for additional information and I like to answer the questions raised as follows:  In order to analyse in details the issues highlighted in your comment, we kindly ask you to submit some additional information by June, 17th via public consultation.  1. Would you consider feasible to move to C6 compounds for manufacturing any kind of PPE? (e.g. being the threshold 5 ppm?)  unfortunately, the scope for the use of C6 compounds for manufacturing PPE is fairly limited. Most PPE (Firefighters, Police, Military, SAR but also Industrial) requires performance levels that can not be reached with C6 chemistry or that can only be reached prior to first washing. The weak point of C6 compounds is the lack of washing resistance or permanency. To mend this deficiency, the respective PPE may be re-impregnated by adding an agent on laundering. This C6 agent will react under the temperature of ironing and form an new repellent film. It has to be pointed out though, that not only the outer shell fabric will receive a coating but the membranes, liners and other compounds of the garment as well. As a result, breathability and moisture retention and transport capabilities of the garment will suffer. Besides, a significant share of the agent added to the washing machine will be released into the sewage after washing. We do not consider this practice as a reasonable one in the context of sustainability and environmental care.  2. Could you specify/describe which are the standards and the performances required for PPE? (e.g. Ökotex standard)  General standards and performance levels for PPE are defined in EN 344 or EN/ISO 13688. Specific standards and performance levels are laid out in Norms like EN469 (typical for firefighters). Here, specific levels for water and chemicals repellency are defined as well as the methods for testing the same (EN/ISO 4920 and EN/ISO 6530 respectively).  3. Could you specify whether there is any kind of PPE for which safety requirements and/or harmonised standards cannot be met using the C6 or other alternatives? And which chemicals are currently used to produce these specific PPEs (i.e. which PFOA-related substances are used)? Amount (tons)?  Specific requirements that can not at all be met using C6 compounds are e.g. those requested by German police (TLP = " ") and German military. The requirements mentioned above (EN 469) can only be met by product prior to washing as finishes based on C6 compounds do not provide the necessary wash fastness. Today C8 compounds are used to achieve such level of performance. However, we can not provide data or estimates on volumes, as PFOAs or related substances are contained as impurities or trace-substances.  4. Could you specify how much time would you need to complete the transition to C6 (i.e. transition period)?  Transition to C6 is not seen as a reasonable option as it would leave firefighters, policemen, military service men and industrial workers without adequate protection – lest one reverts to frequent re-impregnation, with the disadvantages for the clothing and the environment described above under (1)  5. Would you have additional costs to complete the transition to C6 compounds? If so, could you please give an estimation?  Transition to C6 is not seen as a reasonable option as it would leave firefighters, policemen, military service men and industrial workers without adequate protection – lest one reverts to frequent re-impregnation, with the disadvantages for the clothing and the environment described above under (1) | |
| **Dossier submitter response:**  Thank you for responding to the ECHA request.  We will take the information provided into further consideration when revising the background document. | |
| **RAC Rapporteurs comments:**  Thanks for the detailed information, which contributes constructively to the discussion about potential derogations for PPE. See also response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for the information.  As regards protective professional textiles we support a longer transitional period of 6 years to give more time for the development of alternatives. We also see it necessary that the state of the art will be examined in 5 years and that any necessary changes to the scope of the restriction will be made at that point in time. | |
| **1333** | **Date:** 2015/06/16 12:48  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Schmitz-Werke GmbH + Co. KG  **Org. country:** Germany  **Company name confidential:** **No**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company. | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents. | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - automotive and aviation industry  - sun protection / building industry  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Through the use of alternative products the mode of action is worse and the longevity of the awning fabrics will be massively compromised. The consequence is a severe deterioration in the sustainability of our products. Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh.  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available.  Information to degradation of C8 and related sbst. to PFOA see above. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  SEAC takes note of the concerns expressed. We agree that the 2 ppb limit is not feasible and we support higher concentration limits (25 ppb for PFOA and its salts, 1000 ppb for PFOA-related substances). We also propose a transitional period of 6 years for protective professional textiles to give more time to the introduction of alternatives. | |
| **1334** | **Date:** 2015/06/16 12:54  **Type:** MemberState  **MS name:** Germany  **Company name confidential:** **No** | **General Comments:**  Die in dem genannten Vorschlag vorgegebenen Grenzwerte für Perfluoroktansäure (PFOA) treffen die Feuerwehren bei der Anwendung von fluorhaltigen Schaumlösch-mitteln in einem unvertretbaren Maß. Sie sind bei der Bekämpfung von Bränden mit Problemstoffen auf fluorhaltige Schaumlöschmittel angewiesen, um eine effektive Brandbekämpfung durchführen zu können. Darüber hinaus sind sie im industriellen Be¬reich bei der Bevorratung und Verarbeitung in stationären Löschanlagen für eine wir¬kungsvolle Brandbekämpfung unerlässlich.  Diese am Markt befindlichen fluorhaltigen (AFFF)-Schaummittel beinhalten alle einen Anteil von PFOA der die vorgesehenen Grenzwerte um das Vielfache (1.000-fache) übersteigt. Andere, gleichwertige Schaumlöschmittel, stehen wohl auch in absehbarer Zeit nicht zur Verfügung. Bei der Umsetzung des Vorschlags mit den vorgesehenen Grenzwerten würde eine wirkungsvolle Gefahrenabwehr nicht mehr möglich sein. Und dies mit allen denkbaren Folgen für die Bevölkerung, für die Sicherheit der Arbeitnehmer, für die Umwelt und auch für die Verfügbarkeit von Industriestandorten.    Löschmittel werden bewusst und zielgerichtet eingesetzt, also zugeschnitten auf den Einsatzauftrag und abgewogen auf einen wirkungsvollen Einsatzerfolg, wie auch auf die Vermeidung von Folgeschäden. Wenn es im Rahmen der Brandbekämpfung zwingend nötig wird, Löschmittel einzusetzen die als Nebenwirkung negative Folgen auf die Um¬welt haben, so ist das vorher sehr sorgfältig geprüft worden.  In industriellen Bereichen, besonders in der chemischen und der pharmazeutischen Pro¬duktion, aber auch in der Kraftfahrzeugindustrie bei der Bevorratung leicht entzündlicher Produkte und auf Verkehrswegen müssen besondere Löschmittel vorgehalten werden, mit denen bei einem Brand eine nachhaltige Löschwirkung erreicht werden kann.  Die heute schon für Schaumlöschmittel vorgegebenen Grenzwerte werden ins-besondere bei fluorhaltigen Produkten ständig überprüft und kontrolliert. Bevorratung und Ausbildung erfolgt unter Einhaltung der notwendigen Umweltanforderungen.  Schon nach dem PFOS-Verbot gab es bei vielen Anwendern von Schaumlöschmitteln große Probleme den geltenden Grenzwert (10.000 μg/kg) einzuhalten. Trotz sehr auf¬wendiger Reinigung von Behältern/Anlagen kam es zum Eintrag von PFOS in die neuen Schaumlöschmittel.  Eine Begrenzung des „PFOA and related substances“ -Gehaltes auf 2 ppb (2 μg/kg) ist fern jeder Praxis, analytisch nicht messbar und würde die Feuerwehren als Anwender von Schaumlöschmitteln vor unlösbare Probleme und rechtliche Konsequenzen stellen.  Die heute zum Einsatz kommenden fluorhaltigen Schaumlöschmittel werden entweder in mobilen Anlagen (Löschfahrzeugen der Feuerwehren) und/oder in stationären An-lagen mit Vorratstanks, Rohrleitungen, Pumpen und Zumischeinrichtungen sowie in Schaummittelcontainern bevorratet. Nach den beim PFOS-Beschränkungsverfahren ge¬machten Erfahrungen wäre es nicht möglich, diese mobilen und stationären Einrich-tungen soweit zu reinigen, dass die vorgegebenen Grenzwerte eingehalten werden könnten. Gleichzeitig muss man dann davon ausgehen, dass neu eingefüllte Löschmittel kontaminiert werden.    Wir fordern Planungssicherheit bei der Beschaffung dieser doch langlebigen Lösch-mittel. Am Markt sind polyfluorierte Chemikalien in verschiedenster Form vorhanden. Die Schaumlöschmittel spielen aus unserer Sicht dabei eine untergeordnete Rolle. Aber aus¬gerechnet hier, wo es auch bei Einsatz von fluorhaltigen Löschmitteln um die Sicherheit der Bevölkerung geht, soll in einer nicht nachvollziehbaren Art und Weise den Feuer¬wehren ein unverzichtbares Produkt zur Gefahrenabwehr genommen werden.  Der DFV ist selbstverständlich sehr daran interessiert, den Eintrag von Fluorchemikalien in die Umwelt zu vermeiden. Dazu tragen z.B. auch Abstimmungen mit dem Umwelt¬bundesamt bei, die sich z.B. mit der erfolgten Veröffentlichung eines gemeinsamen Merkblatts „Fluorhaltige Schaumlöschmittel umweltschonend einsetzen“ belegt. Diese Informationen und Inhalte gelten bei den Feuerwehren als eine Art Pflichtenheft.  Wir beantragen deshalb  1. Die Ablehnung des Antrags auf Einführung einer Begrenzung des „PFOA and related substances“ -Gehaltes auf 2 ppb (2 μg/kg)  2. Sollte es aus für die Feuerwehren nicht nachvollziehbaren Gründen notwendig werden eine solche Begrenzung der „PFOA and related substances“ einzu¬führen, beantragen wir hiermit, die Feuerwehren davon auszunehmen. Diese muss solange gelten, bis gleichwertige Schaumlöschmittel verfügbar sind wie die heutigen fluorhaltigen, aber PFOS-freien, Löschmittel.  3. In jedem Fall beantragen wir, dass bei der Umsetzung einer Begrenzung für „PFOA and related substances“ ein Grenzwert eingeführt wird, der die Weiter-nutzung aller bei den Feuerwehren bevorrateten Schaummittel bis zum 27. Juni 2031 garantiert. Dieser Grenzwert sollte oberhalb von 10.000 μg/kg liegen. Dies stellt eine 20-jährige Weiternutzung nach der Verbotsgrenze für PFOS zum 27. Juni 2011 und der daraufhin neu beschafften Schaumlöschmittel dar. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  SEAC takes note of the concerns expressed. Please see response to Comment 1225. | |
| **1335** | **Date:** 2015/06/16 13:37  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  ETSA - European Textile Services Assoc  **Org. country:** Belgium  **Company name confidential:** **No** | **General Comments:**  ETSA represents the interests of laundry groups servicing workwear and protective clothing to a wide variety of industries and business-to-business end-users throughout Europe. Our industry accounts for approximately €11 billion in annual turnover in Europe, and over 130,000 jobs.  When workwear and protective clothing are regularly washed in laundries, they often need surface re-treatment with C6 chemical finishes to ensure barrier properties (in terms of repellency and penetration) to protect wearers.  These C6 chemical finishes may contain tiny amounts of PFOA and related substances.  Alternatives to these chemical finishes are not currently available on the market.  If textile service companies are no longer allowed to use these substances, this would result in wearers having to use coated or laminated fabrics instead. In turn, this would result in (1) higher costs for companies using these garments, (2) lower wearer comfort due to lack of breathability of the garments, (3) greater physiological strain for wearers, and (4) shorter periods during which the garment could be worn (due to lower comfort). All of this with significant economic cost.  Sectors which are most likely to be affected:    Chemical industry  Oil and gas  Mechanical and plant engineering  Metallurgy  Printing  Automotive  Recycling  Paper and packaging  Waste disposal  Shipbuilding  Plastics  Construction  Fire and emergency services  Public utilities  Military  Logistics and haulage  Airports and seaports | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See responses to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  We agree that a revision of the concentration limit is necessary to ensure that short-chain alternatives are allowed to be used. Please see response to Comment 1235. | |
| **1336** | **Date:** 2015/06/16 15:45  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  LEIA Laboratories  **Org. country:** United Kingdom  **Company name confidential:** **No**  **Attachment confidential:** **No**    **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  We are a company offering services for fire fighting industry. We recommend the banning of PFOA, and in general of all PFCs, for the following reasons. We have been testing PFCs-free products and we know that there are efficient options on the market. PFOA is already history, as most of the manufacturers have already taken steps to way out of this technology and offer now the ''C6'' technology. We still think that this new ''C6'' is not a long term answer, as it does not offer the same level of performance of the previous family ''C8''. We recetly tested a PFC-free additive to replace AFFF in extinguishers, and we have seen that the product complies with the EN3 tests. It is likely that the new technology will be successful in other standard fro fire performance. So why should we keep an high contaminating technology when new product without PFC are now available on the market. At latest exhibition in Hannover, a manufacturer (3F) presented its PFC-free products which are matching the demand for efficient, standard complying and environmental safr products ? We strongly support that PFOA should be banned. | |
| **Answer to specific info request 1:**  Portable extinguishers : million units sold yearly in Europe: now available product FREDEX SF approved in Germany and complying with EN3 | |
| **Dossier submitter response:**  Thank you for the information on fluorine-free fire-fighting foam alternatives. We will take it into further consideration. | |
| **RAC Rapporteurs comments:**  Thanks for the information. The availability of fluorine-free fire-fighting foams is noted, as is other PC comments on the need for fluorinated foams for specific uses.  See also response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. SEAC notes the existence of F-free foams. Considering all information submitted during the public consultation it seems that fluorine-free firefighting foams seem not to be suitable for use in all situations at the current level of state of the art, and that it is important to ensure that short-chain fluorinated foams will be available when needed. See also response to Comment 1225. | |
| **1337** | **Date:** 2015/06/16 16:01  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  TEXTILCOLOR GmbH  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  TEXTILCOLOR supplies the textile industrie with textile auxiliary agents. Fluorocarbon resins are in our sales program for more than 25 years. Other suppliers have used it for even longer. They are well accepted by the industry due to their unique properties and created a tremendous technological break through. In textile industry PFOA is not used as a substance itself, but it is necessary to produce fluorocarbons of the C8 range and appears as a residual impurity. This range has been produced for a long time. In the early 90's I think the 3M company published that the substance had been found in the blood of workers who produced different substances with those educt but they found no adverse effects and the workers were in good health. Meanwhile the C8 range - although the best product regarding its performance - were substituted by the C6 chemistry, where PFOA only appears as an unavoidable byproduct. A restriction as indicated in a range of 2 ppb means to prohibit fluorocarbon completely! No substitutes are available! No substance or preparation provides the required properties regarding durability (permanence), water repellency, oil repellency, repellency of dirt and other substances like blood, chemicals, infectious material etc. Prohibition of these substances will definitely mean a regress of the gained acquisition in textile development. Therefore the demand for a restriction should be denied, also bearing in mind that the entry into the environment in Europe is very low. Relocation of the production into Asian States will not improve the global impact and will weaken our own industry in Europe. | |
| **Answer to specific info request 1:**  Alternatives are much worse in performance, durability (permanence), abrasion resistance and do not have oil repellent or dirt repellent properties. On the contrary alternative water repellents mostly attract dirt and oil! So production of medical clothes, safety clothing (fire fighter protection, bulletproof jackets) belts and ropes, material for ships, planes, trains, cars, outdoor apparel, military equipment etc. as well as the whole carpet industry will definitively suffer from this restriction. Therefore we ask for rejection of the demand for restriction! | |
| **Answer to specific info request 2:**  Information according to associations of the textile industry estimates the loss for the textile industry alone at 6 billion Euros per year only in Germany. The damage the industry has to bear will continue and loss of jobs or even the shutdown of companies will have to be feared. Regions with specialized industry (e.g. carpet, filter manufacturing etc.) will suffer substantially. Textile industry provides innovation only with high performance auxiliaries - if this is missing competitiveness and turnover and its existence especially in Europe will be endangered, as Europe is a technology exporting region. | |
| **Answer to specific info request 3:**  Our company does not produce PFOA or related substances but uses fluorocarbon resins for water, oil and soil repellent finishing products which as polymer preparations are assumed to be of high stability, most probably eliminable from the waste water by precipitation, adsorption and flocculation and/or precipitation but not by degradation, at least not within the short time it is biologically available in a sewage treatment plant. | |
| **Answer to specific info request 4:**  2 ppb as a restriction limit means no products based on polyfluorinated organic products for the textile industry any more!(see above). We are not in the position to detect such small amounts reliably. As far as we know the methods still are not approved up to now. Nevertheless, if the restriction should be accepted, no products could be prepared within this limit. Investigations and research for purification as well as analytics would be extremely expensive if feasible at all, so we assume that this technology will die in Europe. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances. | |
| **RAC Rapporteurs comments:**  See responses to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  We agree that a revision of the concentration limit is necessary to ensure that short-chain alternatives are allowed to be used. Please see response to Comment 1235. | |
| **1338** | **Date:** 2015/06/16 16:51  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Infraserv GmbH & Co. Höchst KG  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  In facilities of the chemical and pharmaceutical industry like ours a broad variety of flammable liquids (polar ones, like alkohols or ketones, and unpolar ones, like hydrocarbons) are used in production buildungs and stored in appendant tankfarms. For the fire protection of this facilities (producing life-saving pharmaceuticals for Europe and the World), the employees working in here, the people in the neighborhood and the environment stationary fire extinguishing systems are installed widely. | |
| **Answer to specific info request 1:**  Fire fighting foam / buildings (production and Research) in chemical and pharmaceutical industry. | |
| **Answer to specific info request 2:**  Fire fighting foam | |
| **Answer to specific info request 3:**  see allready in the other documents or PNEC e.g.  http://www.lfu.bayern.de/analytik\_stoffe/loeschschaeume/doc/pfc\_bewertungsleitlinien\_03\_2013.pdf | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting-agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the garanteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  SEAC takes note of the concerns expressed. Please see response to Comment 1225. | |
| **1339** | **Date:** 2015/06/16 16:52  **Type:** BehalfOfAnOrganisation  **Org. type:** National NGO  **Org. name:**  German Fire Services Association (Deutscher Feuerwehrverband DFV)  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No**    **Privacy comment:** N/A. No confidential information submitted. | **General Comments:**  The proposal’s threshold limits for perfluorooctanesulfonic acid (PFOA) adversely affect fire brigades in their use of fluorochemical foam extinguishing agents to an unreasonable extent. To fight fires involving hazardous substances, the fire brigades depend on of fluorochemical foam extinguishing agents to ensure effective fire fighting. PFOAs are also indispensable in the industry for storing and processing in fixed fire suppression installations to ensure effective fire fighting.  Aqueous Film Forming Foams (AFFF) available on the market include a percentage of PFOA up to a 1000 times higher than the proposed threshold. Other foam extinguishing agents with similar characteristics are not likely to become available any time soon. Implementing the proposal with the threshold limits included would make effective hazard prevention impossible, along with the corresponding consequences for the population, occupational safety, the environment and the availability of industrial locations.  To ensure efficient firefighting, we apply for the following:  a) Rejection of the proposal to limit the content of PFOA and related substances to 2 ppb (2 μg/kg)  b) If, however and for reasons beyond our comprehension, it should become necessary to introduce such a limitation of PFOA and related substances, we hereby apply to exclude the fire brigades from such a limitation. This exclusion must apply as long as there are no other foam extinguishing agents available that have similar characteristics as today’s fluorochemical but PFOS-free extinguishing agents.  c) In any case, we hereby apply to introduce a threshold limit when restricting PFOA and related substances that allows fire brigades to continue using their stored foaming agents until 27 June 2031. Such a threshold should be higher than 10,000 μg/kg. This way, the fire brigades would be given a period of 20 years to continue using the foam extinguishing agents they had to acquire due to the ban of PFOS in 2011. | |
| **Answer to specific info request 1:**  Aqueous Film Forming Foam (AFFF) is designed for generating low and medium expansion fire extinguishing foam. AFFF forms foam very readily and is therefore also suitable for use as medium expansion foam and in foam/water sprinkler systems. The high water releasing capacity favours film formation, increases flowability, reduces the extinction time and cools the source of fire. The aqueous film extinguishes fires even in areas not yet reached by the foam and prevents reignition should the foam blanket get ruptured. Unlike other foam agents AFFF is oil-repellent (oleophobic), i.e. it does not load itself with petroleum products and is, therefore ideal for sub-surface foam application. Compared to other foam agents and owing to its high foam density long throwing distances are achieved.  Other foam extinguishing agents with similar characteristics are not likely to become available any time soon.  Not using AFFF foam agents would cause major problems in effective hazard prevention and fire suppression. | |
| **Answer to specific info request 2:**  Since there are no extinguishing agents with appropriate effectiveness available at the moment, there is no replacement especially for AFFF products.  Therefore substitution costs can not be provided. | |
| **Answer to specific info request 3:**  As far as we know there are no extinguishing agents available that could replace AFFF foam agents at the moment. | |
| **Answer to specific info request 4:**  The Aqueous Film Forming Foams (AFFF) available on the market include a percentage of PFOA up to a 1000 times higher than the proposed threshold.  After the PFOS ban many users had great difficulties to meet the new threshold limit of 10,000 μg/kg. Despite extensive cleaning of containers/installations, a release of PFOS into the new foam extinguishing agents could not be avoided.  Limiting the content of PFOA and related substances to 2 ppb (2 μg/kg) is wholly impractical since such a threshold could not be analytically measured and would create unsolvable problems along with the corresponding legal consequences for fire brigades as users of these foam extinguishing agents.  The fluorochemical foam extinguishing agents used today are either stored in mobile installations (fire appliances) and/or in stationary fire suppression systems with storage tanks, pipes, pumps and mixing devices as well as in containers for foaming agents. From the experience fire services gained from the PFOS restriction procedure it is known that it would be impossible to clean these mobile and stationary installations in a way that the proposed threshold limits could be met. At the same time, it can be expected that any newly refilled extinguishing agents will also be contaminated. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternative products are already in the trace level range. With the revised concentration limit proposed it is ensured thatshort-chain alternatives and consequently fire-fighting foams based on short-chain PFASs can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFASs, further development and also acceptance on fluorine-free alternatives is necessary.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  SEAC takes note of the concerns expressed. Please see response to Comment 1225. | |
| **1340** | **Date:** 2015/06/16 16:58  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Verband der Automobilindustrie e. V.  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  see supporting document (attachment) | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  Use of PFOA in articles:  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  It is not our aim to restrict the manufacturing and use of PTFE with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers. PTFE manufactured without PFOA is already available on the market and will not be affected by the proposed restriction.  Spare parts:  As stated above we have revised the proposed concentration limit of 2 ppb. Taking this into account, we conclude from your comment that the proposed restriction will not impact the manufacture and placing on the market of spare parts for vehicles already in use.  Second-hand/recycling:  The restriction is focussing on the placing on the market of new articles containing PFOA and PFOA-related substances. Thus, articles which are already on the market are not affected. It is not the aim of the Dossier submitter to restrict second hand articles and recycling of articles.  Fire-fighting foam:  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternative products are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFASs can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting-agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the garanteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other products.  The intention is that the C6 chemistry should not be affected by this restriction. Furthermore, the view of RAC is that fluoropolymers as such should not be included in the restriction, but that the specific use of PFOA as a process chemical in the production of fluoropolymers should be stopped. It is a challenge to find a threshold level that stops the specific use of PFOA as a process aid but still allows some trace level contamination with PFOA, and hopefully the proposed limits will do that.  We note the information that the concentration of PFOA is in the order of 1 ppm in all current fluorine-based foams. RAC acknowledges that fluorinated foams might be needed for specific circumstances (e.g. burning fuels), but also notes comments in the PC indicating that fluorine-free foams also meet the requirement for such fires. Considering the direct environmental releases from fire-fighting foams, there are reasons to minimise the content of PFOA in foams. Since this is a potentially significant source of environmental exposure, RAC has not recommended any derogation for this use, but recognises that there are socio-economic factors for SEAC to address. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC agrees that a revision of the concentration limit is necessary to ensure that short-chain alternatives are allowed to be used. We support limit values of 25 ppb for PFOA and its salts, and 1000 ppb for PFOA-related substances.  Adapting the thresholds is considered a potential way to keep the proposed restriction proportionate, and avoiding exemptions when the C6 alternatives provide the desired function.  We also propose derogation for the placing on the market of spare parts for automobiles that are in stock at the date of entry into force of the restriction. | |
| **1341** | **Date:** 2015/06/16 16:59  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Bergans of Norway  **Org. country:** Norway  **Company name confidential:** **No** | **General Comments:**  We welcome clear, strict EU regulations on PFOA and its related substances, but there must be detailed description of which analytical methods to be used for testing on each product category, that these analytical methods are readily available globally and that the treshhold is set at the credible limit in accordance with available analytical methods as well as accounting for the existance of impurities. Furthermore, a clear timeline for phase out must be defined. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  Different analytical methods and measured data (see chapter E, Appendix B.2.2 and E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA-related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  A restriction is a motive for the EU Commission to induce the development of analytical methods if they are necessary for the enforcement. Thus, it seems to be possible to also establish method detection limits at a low ppb range for other matrices e.g. articles and formulations in the near future. Moreover, it seems to be very likely that standardized methods will soon be available once they are required by law.  A timeline for phase out/derogations will be defined. | |
| **RAC Rapporteurs comments:**  Whilst RAC agrees with the DS that the restriction can be an incentive to develop analytical methods, there has to be a realistic prospect of the development of a reliable method within an appropriate time frame to provide legal certainty for all actors. | |
| **SEAC Rapporteurs comments:**  SEAC takes note of the comment and the response from the Dossier Submitter. SEAC proposes a general transitional period of 36 months. Furthermore, specific transitional periods are proposed by SEAC for some individual applications. | |
| **1343** | **Date:** 2015/06/16 18:05  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - sewing threads  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh | |
| **Answer to specific info request 2:**  As the alternatives on the market do not achive the good performance the higher risk is losing the innovative power and will endanger the competitiveness and existance of many Textile companies. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  We agree that a revision of the concentration limit is necessary to ensure that short-chain alternatives are allowed to be used. Please see response to Comment 1235. | |
| **1344** | **Date:** 2015/06/16 18:21  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  COPACEL (Paper Industry)  **Org. country:** France  **Company name confidential:** **No** | **General Comments:**  PFOA-related substances are used in paper and board industry as wetting agents, adhesives, lubricants, detergents and emulsifiers. The inclusion of PFOA and PFOA related substances in annex XVII could be problematic for some paper and board mills. Indeed, for some paper products,the performance of available alternatives is not considered adequate. | |
| **Answer to specific info request 1:**  For some specific paper productions, the performance of available alternatives is not considered adequate. Morevover, the deadline for the implementation of the restriction (18 months) is not not enough to change and to validate all processes. | |
| **Answer to specific info request 4:**  The concentration limit of 2 pbb has been proposed without a real impact assessment study. This 2 ppb threshold cannot be acceptable in absence of reliable, robust and standatised measurement methods. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments. However only very limited information on the use of PFOA and related substances was provided. No information on the critical uses, on volumes and substances were delivered. Therefore, derogation or the extension of the transitional period does not seem to be justified. | |
| **RAC Rapporteurs comments:**  RAC agrees with the DS that the information provided were too limited to be a basis for discussing delays or derogations.  Whilst RAC agrees with the DS that the restriction can be an incentive to develop analytical methods, there has to be a realistic prospect of the development of a reliable method within an appropriate time frame to provide legal certainty for all actors. | |
| **SEAC Rapporteurs comments:**  SEAC notes and shares the concern with the thresholds, but more information would be needed to understand for which paper products and why the proposed restriction could be problematic. Please see also reply to Comment 1325. | |
| **1345** | **Date:** 2015/06/16 18:27  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Italy  **Company name confidential:** **Yes** | **General Comments:**  Our company produces fabrics for awnings and for outdoor furnishing and it is Italian market leader and one of the most important players of international market.These type of fabrics require the use of finishing products based on fluorine substances that are able to give them the features of oil and water repellency that can ensure the fabric retaining its original look and its technical features for a long time (longevity) . The restriction proposal concerning PFOA and related substances means to cancel this type of business or , at least , to have a product completely different and no able to fulfil the requirements of the customers | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry.  Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances. Considering this information we believe that also for awnings and outdoor furnishing alternatives are available. Moreover, since awnings and outdoor furnishings may directly emit residual PFOA and related substances into the environment we do not agree with derogation for these uses.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  It would have been useful with information on what type of fluorinated substances are used by this company, and why other alternatives do not work. The intention is that the C6 chemistry should not be affected by this restriction.  See also response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  SEAC agrees that a revision of the concentration limit is necessary to ensure that short-chain alternatives are allowed to be used. We support limit values of 25 ppb for PFOA and its salts, and 1000 ppb for PFOA-related substances.  It would have been useful to have further justification why alternatives do not bring the desired functionality for the case of awnings and outdoor furniture. We however suggest a longer general transitional period (36 months) to allow for the development of alternatives. | |
| **1346** | **Date:** 2015/06/16 19:34  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Dow MF Produktions GmbH&Co OHG  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Dow asks for an exemption of PFOA use in fire-fighting foams: Dow urges that an exemption should be granted for PFOA that is contained in fire-fighting foams that are used in fire protection systems in the chemical industry. As required by the EU Seveso III Directive, this will help prevent major incidents and protect the health of people and the environment. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The use of PFOA and PFOA-related substances in AFFF is not necessary. Alternatives based on short-chain chemistry are available and widely used. It is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  SEAC takes note of the concerns expressed. Please see response to Comment 1225. | |
| **1347** | **Date:** 2015/06/16 19:33  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Attachment confidential:** **No**    **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  We are a company supporting and advising various customers with our more than 20 years personal experience and technical knowledge in the fire-fighting business at detailed level background. Most recently we supported a company in Germany to approve the worlds first fluoro-free fire extinguishers, which is a major change in the fire-industry and a result of several years of research and technological development. The products have been show on most recent world leading fair Interschutz in Hannover and - due to the manufacturer - the interest of the industry, as well as the operators in these new products was extremely high and positive. Due to this new products available on the market from various manufacturers and the technology exchange to other foams we recommend the banning of PFOA and of all PFCs, as we don’t see further demand for this technology in most market segments. As we clearly see the evidence, that the foam manufacturers can transform and develop these products further to current performance-levels in a very foreseeable future, the use of persistent and accumulative products should be banned to stop polluting the planets recourses. As well we see a strong interest of the operators in changing to fluoro-free solutions, as they are liable for the environmental damage caused by the unnecessary use of fluoro-contaminated foams. We strongly recommend a move to sustainability with chemicals. | |
| **Dossier submitter response:**  Thank you for the information on fluorine-free fire-fighting foam alternatives. We will take it into further consideration. | |
| **RAC Rapporteurs comments:**  Thanks for the information. The availability of fluorine-free fire-fighting foams is noted, as is other PC comments on the need for fluorinated foams for specific uses.  See also response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  The availability of the fluorine-free alternatives is noted. Considering all information submitted during the public consultation it seems that fluorine-free firefighting foams are not suitable for use in all situations at the current level of state of the art, and that it is important to ensure that short-chain fluorinated foams will be available when needed. See also response to Comment 1225. | |
| **1348** | **Date:** 2015/06/16 19:46  **Type:** BehalfOfAnOrganisation  **Org. type:** Trade union  **Org. name:**  Eurofeu  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  This is to extend an earlier comment I have handed in on behalf of EUROFEU beginning of May 2015.  In the earlier comment we were not able to provide a proposal for a limiting value istead the one proposed by Germany and Norway. In the appropriate below section you will fined that proposal now as we have agreed upon a figure we believe is realistic for our industry. | |
| **Answer to specific info request 4:**  We want to also point out that the analytical testing of PFOA and its precursors is very difficult in the matrix of foam concentrates or -dilutions as we have been advised by accredited analytical laboratories.  Because of strong matrix effects the true limit of detection lies significantly above the proposed 2ppb plus a high error rate.  We believe that analytical methods will yet have to be developed to reliably measure the true content of the constituents in the proposal.  We have elaborated in our earlier statement on the adsorbtion behavior of PFOA and its precursors.  Therefore we are convinced that to date the value of 2ppb cannot be met by our industry and as well cannot be measured in our products.  We propose a limit of 1000ppb (1ppm) per per each affected constituent of the group of chemicals in the proposal (PFOA and its precursors) in foam concentrates. We also believe that over the coming years we will be able to bring this number down significantly. | |
| **Dossier submitter response:**  Thank you for the proposed threshold. We will take it into further consideration.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  Thanks for the proposal. The analytical problems are acknowledged, and the proposed 1 ppm limit is noted. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  We thank and take note of the proposed 1 ppm threshold. It was taken into account when suggesting limit values for firefighting foams. | |
| **1349** | **Date:** 2015/06/16 19:50  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:**  Wirtschaftskammer Österreich  **Org. country:** Austria  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  See document attached. | |
| **Answer to specific info request 1:**  See document attached. | |
| **Answer to specific info request 2:**  See document attached. | |
| **Answer to specific info request 3:** | |
| **Answer to specific info request 4:**  See document attached. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The Dossier submitter proposed a structural formula to include all possible substances which can degrade to PFOA. This is in line with the restriction on PFOS and the stewardship program of the US-EPA on long chain PFASs. In our view there is no reason to alter the scope of the proposed restriction.  General:  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  Fire-fighting foam:  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternative products are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFASs can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFASs, further development and also acceptance on fluorine-free alternatives is necessary.  Textiles:  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  Analytical method:  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other products. The intention is that the C6 chemistry should not be affected by this restriction. The general lack of information on actual emissions from textiles means that RAC is unable to consider any derogations from a risk perspective. The concern for how the use of fire-fighting foams might be affected (depending on the choice of limit values) by the restriction is noted. From a risk perspective, RAC cannot support a derogation for such foams, but recognises that there are socio-economic considerations for SEAC. | |
| **SEAC Rapporteurs comments:**  SEAC takes note of the concerns expressed. As reflected by our response to several comments related to textile and fire-fighting foams, we share the concern that the proposed restriction should not impede the use of C6 alternatives in these sectors. We propose longer transitional periods for PPE textiles and a higher limit value for PFOA in fire-fighting foams, along with derogation for firefighting foams in stock. We agree that account has to be taken of the social benefits provided by these applications. | |
| **1350** | **Date:** 2015/06/16 21:58  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Association of th eTextiel and Clothing Industry of Northwest Germany  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  As association of 240 member companies, which are producing in Europe and also import textiles and clothing from all over the world we would like describe the consequences of the Annex XV restriction report in its present form. Our industry does NOT use PFOA and the related substances mentionned in the restriction report, they are unwanted impurities in the chemistry we need to give our textiles a repellent effect - this includes not only the water repellency, but also the repellency against blood in medical textiles, fuel for clothing for policemen, chemicals in the chemical industry, dirt in many uses, just mentionning a few examples. We will describe all known uses later. With the information, that PFOA is critical in its properties and that this substance is unwanted part of the so called C8-chemistry our industry has spent a lot of time and money in its R&D departments to substitute the C 8-Chemistry against the supposed "better" C6-chemistry. And this was not easy! It is now necessary to use more "chemistry", because the C6-chmeistry is less effectiv, and the results are worse. OK, it is not critical to become wet much faster, if the water repellent properties of an outdoor jacket is worse, but the lower effects in PPE, which protects the people, sometimes saving their lifes, are a serious problem. Now the situation has changed: based on the available Annex XV dossier it will be impossible in future to use even the C6-chemistry, because the dossier extend the expected retricition of PFOA to a lot of other "related substances", which are also unwanted imputities in the C6- chemsitry, which we could not use any longer, if the restriction will be realised unchanged. The consequneces in many parts would be a disaster for the safety of many people and a massive decrease in the sustainability of many outdoor textiles and textiles, which are in use in environmental protection and in the building industry. Due to the fact, that the restriction report also regards the imported textiles, which is to advocate, if there would exist methods to analyse the imported textiles (which doues NOT exist for PFOA and the related substances to find 2 ppb) and to prevent a loss in competitiveness for the Europain industry, all these textiles would not be available on the market within the EU. So performing the socio economic analysis all these uses and the consequences had to be considered!!!  What we really need are realistic, higher allowed concentration of the related substances for these uses, which are necessary for human health and for the sustainability of textile products. | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below - and the C6 chemistry is NO alternative, because it will no longer be available due to higher amounts of the "related substances" than 2 ppb!!:  - personal protective equipment for police, fire fighters, workers in the many industry branches, military, offshore workers, motorcycle equipment, expeditions equipment  - filtration purposes, especially for aggresive gases and fluids, but also for dust - which is more and more needed to fulful IED requirements!  - medical uses as protection against blood to prevent infections  - automotive and aviation industry: many "unseen" parts of cars and airplanes are textiles, mostly nonwoven engine compounds, a few parts of tyres, which are highly water repellent; also the lightweight textile convertable tops need a heavy dynamic rain repellent!  - sun protection / building industry: in this use the sustainability of many parts would be less, because the humidity would damage these parts of the building; sealing material would age faster and lose their properties  - lifting and carrying belts e.g. for helmets (again PPE!), backpacks and in the equipment for mountaineers  - fuel cells: innovations in alternative energy sources, which need a good resitance against hydrolysis and acid conditions  All of the alternatives lack  - washing and water fastness  - rubbing and abrasive durability  - dynamic water-/oil-repellency  - chemical repellency  - stability in hydrolysis  The wanted properties in repellent effects are part of many technical standards, DIn-standards, customer requirements, which our undustry would no longer be able to fulfl. For example:  - EN 469 for firefighters  - EN ISO 6530 liqid chemicals  - EN 13034 PPE liquid chemicals  - ISO 9865 PPE water repellency  - AATCC TM 42, AATCC TM 130, AATCC TM 118 , requirements for water and oil repellency  - AATCC TM 118 oil repllency in the automotive industry  Many of the standards are part of the contracts with our clients, so our industry would not be able to deliver textiles according the requirements anymore.  Concerning the potential risks to enviroment and human health we have to refer to the toxicologists in the chemical industry. But we would like to point, that many of the produts are very durable textiles, not least because of the repellent properties, so the release to the environment is less compared to other substances used in the textile industry.  Concerning the | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  According a survey, which we made in the last weeks we have member companies, which would lose up to 80 % of their turmover (specialist in PPE, specialist in filters, specialist in sunprotection, specialist in car compoments), so their future would be unsure. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  Regarding the existing analytical methods and the detection limits on many, many reports, which we have received from our member companies the detection limit is just now far away from 2ppm. The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. So a repeated measuer would cause high costs without giving the safety,that a textile is according the restriction! | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for the details on the various applications of treated textiles. We agree that a revision of the concentration limit is necessary to ensure that short-chain alternatives are allowed to be used. Please see response to Comment 1235. | |
| **1351** | **Date:** 2015/06/16 23:01  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Arent Fox LLP  **Org. country:** United States  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  This firm represents a manufacturer of durable, easy-to-care-for fabrics used primarily in indoor and outdoor harsh environments. That manufacturer opposes the proposed blanket 2 ppb threshold concentration for PFOA and PFOA-related substances in substances, mixtures and articles for reasons set for the below, and believes it would be extremely harmful to its efforts to continue to produce and sell durable fabrics that the public has come to rely upon for a variety of important uses.  General Comments:  (A) Multiple problems with proposed restriction limit of 2 ppb. In order to best serve the objective of protecting human health and the environment, a threshold concentration for PFOA and PFOA-related substances in substances, mixtures and articles must be scientifically sound and capable of implementation. Unfortunately, based on the information presented, it appears that the proposed 2 ppb threshold cannot meet either test. Section A.3.3.4 states that the overall aim of the restriction is that concentrations of these substances “need to be zero”, but since a threshold of zero “might not be technically feasible” the next best thing is to set the threshold at the limit of quantitation (LOQ) of certain analytical methods “reported in the literature”, i.e., a one-size-fits-all value of 2 ppb for all substances and all applications. This approach is untenable for a significant number of reasons, among which are the following:  • In an ideal world, a concentration of zero for any unwanted contaminant would be the goal. However, for most contaminants such a goal is unachievable, and attempts to reach it are impracticable and, in many cases, unnecessary. Instead, comprehensive risk assessments and cost/benefit analyses should be performed in order to arrive at scientifically sound and practicable thresholds that are still protective of human health and the environment.  • The thresholds resulting from such assessments and analyses may well vary from substance to substance, and from one application to another. It is highly improbable that all assessments and analyses would result in a single threshold value.  • It should be recognized that LOQs are substance-specific and matrix-specific in addition to being method-specific. Again, there can be no one-size-fits-all LOQ covering all target substances and matrices.  • Any PFOA-related substance covered by this proposed restriction should be identified by CAS registry no. and/or EC no. so that all affected parties are clear as to exactly which substances are covered by the proposed restriction.  • No threshold value should become a regulatory requirement, or should even be proposed, until there is a fully validated and internationally recognized analytical test method designed to achieve it on a routine basis.  • Such a method must be validated for PFOA and specific PFOA-related substances in specific matrices. Multiple methods, or multiple modifications of a single method, may be necessary to cover all such substances and matrices.  • Any such test method should be capable of being performed on an affordable and timely basis by routine industrial, commercial and regulatory testing laboratories without the need for highly expensive instrumentation.  • No threshold value should be set so low that there could be significant interferences or false positive results from fluorinated compounds in the general environment or in components of laboratory instrumentation or other laboratory equipment.  • No threshold value should be set so low that it threatens the viability of the short-chain (C6 and C4) substitutes for C8 chemistry that have been, and continue to be, introduced into the market as a result of lengthy, cooperative efforts between industry and government regulators.  • Table A.E.2-1 lists just two published analytical methods applicable to textiles, and both are very limited in scope.  • The first cited method is by Mawn et al. (2005) from DuPont (USA). This method is listed in Table A.E.2-1 as having an LOQ of 1 ppb for a water extract and 2.5 ppb for a methanol extract, apparently derived using a polyester textile control. However, while it had the lowest LOQ, the water extraction method was shown to be very inefficient when applied to a carpet sample, since it achieved only a 60% extraction even after 24 hours on a wrist-action shaker. The optimum results were obtained using methanol (with a higher LOQ), but a 24-hour extraction with a wrist-action shaker was found to give better results than either a 2-hour shaker extraction or a 1.5-hour pressurized-fluid extraction. Analysis was by LC/MS/MS, expensive instrumentation that is not available in many laboratories. Thus, this method may be unsuitable for routine analysis in multiple laboratories. Moreover, analysis was only for PFOA, so its applicability to PFOA-relates substances is unknown.  • The second of the two cited methods is by Lv et al. (2009) from Tianjin, China. The analysis was for only PFOA and PFOS, using less expensive instrumentation (GC/MS) than Mawn at al., but requiring pressurized fluid extraction optimized by response surface methodology and followed by solvent removal and then derivatization by silylation. Testing of the method was limited to two PTFE gasket samples from a single manufacturer, and three different textiles (cotton, linen and nylon) from a single dress manufacturer. Table A.E.2-1 states that the LOQ was 1.6 ppb, but that is misleading, since it was was actually the detection limit, and only for PFOA; the detection limit for PFOS was significantly higher (13.9 ppb). Moreover, the LOQ might be much higher than the detection limit. Again, this method may be unsuitable for routine analysis in multiple laboratories, and its applicability to PFOA-relates substances is unknown.  • No methods are referenced for analysis of PFOA-related substances in textiles.  (B) Lack of performance equivalence of fluorinated alternatives for some applications. The proposed 2 ppb threshold value in substances, mixtures and articles is based partly on the general assumption that not only will nearly all C8 applications have switched over to C6 or non-fluorinated chemistry in the very near future, but that performance equivalence will be generally achieved with C6 chemistry, albeit at somewhat higher cost. However, the restriction report itself concedes that this will often not be true, at least in the case of textiles:  • A straightforward 1:1 exchange of C8 fluorocarbon products with C6 and C4 products is not possible.  • A greater quantity of treatment of fluorinated treatment material is required with short-chain fluorocarbons, and those C6 and C4 products are also more expensive than C8 products.  • Water repellency performance is lower with short-chain products in at least some applications.  • Oil and soil repellency performance is definitely lower with short-chain products, and resistance to abrasion may be lower.  • For some textile materials, including technical textiles, the required performance may be simply unachievable with short-chain fluorocarbon substitutes.  (C) Questionable DNELs selected for PFOA. As presented in the Restriction Proposal, ECHA’s Derived No-Effect Levels (DNELs) for PFOA appear to be greatly at odds with the Tolerable Daily Intake (TDI) value of 1.5 µg/kg bw/day derived for PFOA as recently as 2008 by the European Food Safety Authority (EFSA). While we understand that ECHA had the benefit of a few additional studies published since 2008, three of the five DNELs calculated by ECHA for both workers and the general population (Tables B.5-8 and B.5-9) were derived from studies also reviewed by EFSA (mouse studies by Lau et al., 2006, and by Abbot et al., 2007, and a human study by Fei et al., 2007).  Moreover, the lowest DNEL of all derived by ECHA was 0.3 ng/mL (internal value) for the general population, equivalent to an external value of 0.035 ng/kg bw/day, which is more than 40,000 times lower than EFSA’s TDI of 1.5 µg/kg bw/day. The DNEL was based on a report of reduced birth weight from the epidemiological study by Fei et al. (2007). However, while it also reviewed this study of 1400 births in Denmark, EFSA did not consider it for derivation of a TDI presumably because, as it noted, “maternal plasma levels of PFOA were inversely associated with birth weight but not with risk of low birth weight (<2500 g) or small for gestational age” (emphasis added).  Similarly, for the next-lowest DNEL, ECHA selected a single epidemiological study not available to EFSA (Steenland et al., 2009) that identified an association between PFOA and cholesterol levels in residents living near a fluorochemical plant. The difference in total cholesterol between the 10% with the lowest serum PFOA levels and the 10% with the highest level was only 11 mg/dL, or about 5% variation. EFSA, on the other hand, had already reviewed at least eight such PFOA-cholesterol studies and reported that while three of them also found a positive association, five others found no such association. The most recent study considered by EFSA (Olsen and Zobel, 2007), had investigated fluorochemical production workers at three locations in Europe and the USA, and had concluded that “PFOA was not statistically associated with total cholesterol or low-density lipoproteins.”  Thus, ECHA appears to have been selective in its consideration of studies on which to base its DNELs, and to have based the lowest DNELs on effects of questionable significance. It is very disconcerting that two European regulatory bodies would derive such highly disparate human exposure limits for PFOA within such a short time span.  Answer to specific info request 1:  Information on applications for which alternatives are not available and/or the performance of alternatives is not considered adequate. Listing of references to fluorinated alternatives for textiles in Table C.1-1 (“Overview of available fluorinated and non-fluorinated alternatives for different branches”) is limited to a single type of textile, outdoor clothing. The proposed 2 ppb concentration limit is based partly on the general assumption that nearly all C8 applications will have switched over to C6 or non-fluorinated chemistry in the very near future and that performance equivalence will be generally achieved with C6 chemistry. While that expectation might possibly be met for general-purpose outdoor clothing, there are no indications that it has been demonstrated for specialized outdoor textile applications, especially for articles that may be exposed to significant quantities of rainfall and for which specific performance parameters must be met. Examples include camping gear, covers for outdoor and marine equipment, outdoor furniture, exterior architectural textiles, and geotextiles. The lack of demonstrated performance with fluorinated alternatives also applies to specialized safety equipment such as fire-fighters’ uniforms, bullet-proof vests, and various hospital and other medical textiles. These concerns are reinforced by Table A.C.1-1 (“Potential alternatives and technologies”), which lists the following disadvantages associated with the use of short-chain fluorinated repellant chemistries (C6 or C4) as alternatives to C8 in the textile industry:  • Not as effective as those with long-chain chemistries, particularly in repelling oil;  • More expensive than C8;  • Not applicable for all textile materials;  • Applying higher amounts of finishes  • Challenges in the production, formulation and technical properties of water and oil-repellent agents based on C4 and C6 chemistry;  • A simple 1:1 exchange of the former C8 base fluorocarbon products by C6 and C4 products is not possible  • Do not fulfill the sum of all requirements[, namely]:  o Very high water-repellency;  o Combined soil, oil and chemical repellency;  o Resistance to abrasion;  o High durability to washing;  (The reference is to Stakeholder Consultation 2013/14 and ZDHC P05 Project Team, 2012.) In addition, Section F.2.3 states: “For technical textiles the change to alternatives could result in a loss in product quality, which could be decisive for the utility of the respective product.”  Answer to specific info request 2:  Information on economic impacts of switching to fluorinated alternatives. For surface treatment of textiles, not only are fluorocarbon alternatives more expensive than the C8 products they are replacing, but a greater quantity of the short-chain alternatives are required, further increasing the costs of substitution. This is acknowledged in the Annex XV Restriction Report. For example, Section C.2.4 states:  “However, in general ≤ C6-based fluorotelomer chemistry is more expensive, i.e. higher volumes must be applied to achieve the same technical performance and costs of ≤ C6-based fluorotelomer products are higher (see chapter F for details).”  This is further confirmed in Section F.2.3, which also indicates that an additional cost could result from increased demand caused by the substitution requirements outstripping supply:  “Short-chain fluorinated polymers are considered as the most probable alternatives to be used instead of PFOA-related substances. They have a similar performance regarding water repellence. However, a larger amount (10 – 20 %) of substance is needed to achieve comparable water repellent properties of the fabric/leather. Furthermore, consulted companies stated that overall the oil repellence of textiles treated with short-chain alternatives is poorer. In addition to the increased loading, industry stated that short-chain fluorinated polymers are more expensive to produce owing to extra processing (filtration) to remove impurities. Also, due to the general trend to switch to short-chain PFASs market demand is increasing. Industry indicated that this could lead to higher costs of short-chain fluorinated polymers of up to 20%.”  Answer to specific info request 3:  Information on substances which do not have the potential to degrade to PFOA. No information.  Answer to specific info request 4:  Information on the availability of analytical methods. For the multiple reasons listed in the General Comments, we believe that a general 2 ppb concentration limit for both PFOA and PFOA-related substances is impracticable, and threatens the viability of the short-chain (C6 and C4) alternatives for C8 chemistry that have been, and continue to be, introduced into the market as a result of lengthy, cooperative efforts between industry and government regulators. No such limit should become a regulatory requirement, or should even be proposed, until there is a fully validated and internationally recognized analytical test method designed to achieve it on a routine basis. Such a method (or methods) should first be validated for PFOA and specific PFOA-related substances in specific matrices. Also, any such test method(s) should be capable of being performed on an affordable and timely basis by routine industrial, commercial and regulatory testing laboratories without the need for highly expensive instrumentation. Moreover, no threshold value should be set so low that there could be significant interferences or false positive results from fluorinated compounds in the general environment or in components of laboratory instrumentation or other test equipment. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  PFOA is a PBT substance. According to REACH emissions of PBT substances need to be minimised.    The Dossier submitter proposed a structural formula to include all possible substances which can degrade to PFOA. This is in line with the restriction on PFOS and the stewardship program of the US-EPA on long chain PFASs. In our view there is no reason to alter the scope of the proposed restriction.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  Considering your information we believe that also for camping gear, covers for outdoor and marine equipment, outdoor furniture, exterior architectural textiles, and geotextiles alternatives are available. Moreover, since those items may directly emit residual amounts of PFOA and PFOA-related substances into the environment we do not agree with derogation for this use.   * Human Health   The evaluations of PFOA from EFSA are presented in chapter B.5.1.11 of the restriction dossier. For further details, see our response to comment no. 1212. | |
| **RAC Rapporteurs comments:**  Thanks for the very extensive and informative comments. RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other products. The intention is that the C6 chemistry should not be affected by this restriction. The general lack of information on actual emissions from textiles means that RAC is unable to consider any derogations from a risk perspective.  See also response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  We agree that a revision of the concentration limit is necessary to ensure that short-chain alternatives are allowed to be used. We support limit values of 25 ppb for PFOA and its salts, and 1000 ppb for PFOA-related substances. We also suggest a longer transitional period (36 months) to allow for the development of alternatives. We also take note of your comment emphasising some information on substitution costs in the restriction dossier.  As regards protective professional textiles we recognise that the performance of short chain alternatives may not yet be sufficient for all applications and we support a transitional period of 6 years to give more time for the development of alternatives. We also see it necessary that the state of the art will be examined in 5 years and that any necessary changes to the scope of the restriction will be made by the Commission at that point in time. | |
| **1352** | **Date:** 2015/06/17 03:13  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Fire Fighting Foam Coalition, Inc.  **Org. country:** United States  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  FFFC fully supports the goal of minimizing the environmental impact of fire fighting foam. However, as noted in our preliminary submission of February 27, FFFC has very serious concerns that the proposed threshold of 2 ppb for PFOA and PFOA-related substances cannot be achieved in the production of fire fighting foam concentrates and would result in a de facto ban on the use of fluorinated foams. As fluorinated foams are the most effective agents currently available to protect life, high-value property and the environment from the risk of flammable liquid fires in military, oil and gas, municipal, and aviation applications, such a result would have an extremely negative impact on fire safety in Europe. In our preliminary submission, FFFC recommended that a practical threshold of the impurity level of PFOA and PFOA-related substances be set for firefighting foam that eliminates the manufacture and use of foams with long-chain substances while still allowing the manufacture and use of short-chain alternatives. At the same time we noted that the measurement of these substances in foam is technically difficult due to matrix effects, and available analytical methods (especially those used in the commercial service labs) are not reliable enough to assure the necessary reproducibility and repeatability. Based on these two factors and taking into consideration the information currently available to foam manufacturers, FFFC recommends an initial threshold of 1,000 ppb per analyte be set for fire fighting foam concentrates. We believe this level is low enough to ensure the elimination of long-chain substances in foam without restricting the use of essential short-chain alternatives. It is our understanding that over time the levels of long-chain contaminants in short-chain fluorochemicals are likely to decrease and the ability to measure them is likely to improve, so FFFC would support inclusion of a phased in reduction based on future circumstances. | |
| **Dossier submitter response:**  Thank you for the proposed threshold. We will take it into further consideration.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC notes the information that the concentration of PFOA is in the order of 1 ppm in all current fluorine-based foams, and the suggestion of using a limit of 1 ppm limit per analyte. RAC has proposed a slightly higher limit than the DS, partially based on analytical issues, and has recommended that the Commission takes due account of analytical developments in future.  See also response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree that revision of the proposal to ensure that short-chain alternatives are allowed to be used is necessary. For firefighting foams we propose a limit value of 1000 ppb for both PFOA and its salts and PFOA-related substances. See also response to Comment 1225. | |
| **1353** | **Date:** 2015/06/17 08:13  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Wacker Chemie AG  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Protection of Commercial interests. | **General Comments:**  See comments in Attachment. | |
| **Answer to specific info request 1:**  See comments in Attachment. | |
| **Answer to specific info request 2:**  See comments in Attachment. | |
| **Answer to specific info request 3:**  See comments in Attachment. | |
| **Answer to specific info request 4:**  See comments in Attachment. | |
| **Dossier submitter response:**  Thank you for responding to the ECHA request We will take the information into further consideration. | |
| **RAC Rapporteurs comments:**  Thanks for the information. Because of the confidential comment, RAC can only note the possibilities to use available stocks of fire fighting foam in the future.  See also response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the technical and economic information, it has been taken into consideration. | |
| **1354** | **Date:** 2015/06/17 08:16  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Willy Bogner GmbH & Co. KGaA  **Org. country:** Germany  **Company name confidential:** **No**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Dossier submitter response:**  Thank you for the comment. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Please see response to Comment 1235. | |
| **1355** | **Date:** 2015/06/17 10:41  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Ireland  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Release of the information regarding the costs and effects of possible restriction of PFOA-related substances to the commenting company would give competitors an unfair advantage in the market as the items demonstrate our company’s business model and strategy. The release of such information could thereby cause harm to the competitive position of the commenting company and would therefore substantially undermine our company’s commercial interests.  In addition, the document contains forward looking statements, whose release to the public needs to comply with relevant stock market rules and regulations.  Third parties, including competitors could beneficiate from the specific information about the commenting company’s manufacturing processes that is presented in the document that are either highly confidential or secret information, and protected as the commenting company’s trade secrets. Although all IC manufacturers have their own fabrication processes, competitors could utilize the information by optimizing their own processes. This would not only ultimately cause harm to competitiveness of the commenting company but also divulge our company’s intellectual property, potentially causing an irreparable damage to the commenting company’s IP assets.  The information related to the cost and effects to the commenting company in case of restriction and manufacturing processes will remain confidential indefinitely. | **General Comments:**  The European semiconductor manufacturers have made great efforts to reduce the amount of PFOA (Perfluoro Octanoic Acid) and PFOA-related substances in their processes. However, the commenting company, as well as the European semiconductor industry, is still highly dependent on some PFOA-related substances in its Integrated Circuit (IC) manufacturing processes. These substances are used in the pattern formatting process called photolithography as a surfactant and as a photoacid generator in the anti-reflective coating and photoresist applications. Because of the extremely developed high volume manufacturing of ICs, which is one of the most technologically advanced and complex industrial fabrication processes, replacing PFOA-related substances in the process is very difficult. Photolithography is the only method the industry knows at the moment to fabricate the nanoscale structures necessary for modern ICs. The functions of PFOA-related substances are essential within this process.  Even if a theoretical alternative to PFOA-related substances is found, replacing them in the ARC and resists solution in the fabrication process would be an immense effort in terms of both money and time. The product development and re-qualification of the many dozens of highly integrated and interdependent process steps could take years to finish in the commenting company’s European factory. Taking into consideration the relatively fast pace of technological development and high rate of innovations in the industry, by the time the replacement would be done, the technology would already be outdated. The more logical approach for the industry would be attempting the substitution in the next generation technology under development. In addition, there is currently a lot of collaborative research with the industry and academia on developing next generation lithography technologies that include extreme ultraviolet photolithography and directed self-assembly technology, which could make the use of PFOA-related substances unnecessary in future.  PFOA-related substances used in semiconductor manufacturing are used inside enclosed processes in highly controlled environment together with extensive use of risk management measures. Exposure to workers during substance loading and equipment maintenance activities are minimised by the use of engineering controls, personal protective equipment, local exhaust ventilation and good working practises. The substances are used in strictly enclosed process together with abatement systems that prevent emissions, including fugitive emissions being released to environment. Waste solutions containing PFOA are collected to general solvent waste tanks and destroyed by incineration. Only a small portion of PFOA is released to wastewater. In conclusion the commenting company’s use of the PFOA-related substances should be considered to be under strictly controlled conditions and the risks to workers and environment are controlled to a minimal level.  The European Semiconductor Industry Association has estimated a release factor of 3.8% of PFOA-related substances as the industry average. Based on an ESIA EU semiconductor member company survey, total use of PFOA-related substances in the sector is estimated at 19 kg per year. Using the 3.8% estimate, a total of 0.722 kg of PFOA-related substance may be released to the environment annually by the sector. Using the industry emission factor of 3.8% provides a conservative estimate for the commenting company, and derives an annual release of 19 grams of PFOA-related substances to the environment.  If the restriction proposal was to enter into force with an 18 month transitional timeline, the European semiconductor manufacturers will be impacted heavily. The impacts of the commenting company’s “no-exemption” scenario are analysed with an input-output model. It is a tool which best captures the overall economic impact to the local supply chain and business community. Due to the lack of time, despite the joint effort by ESIA, similar analysis at the sector level was not possible. Therefore, the results of the current impact analysis was extrapolated to get an idea of the impacts at the sector level. To summarize, the semiconductor industry’s economic impact of the ‘no-exemption’ scenario on the European society is an annual loss of at least €550 million in gross value add for a period of 4 to 6 years. In other words, European society needs to pay at least €762 million per year in order to prevent one kilogram of PFOA-related substances released to the environment. For the commenting company, the price is even higher, at approximately €28,380 million per kg. Compared to the cost effectiveness of between 4 and 3,500 with a central estimate of 734 € per kg for PFOA-related substances used as the decision criteria for the proposal restriction, the proposed regulatory measure is clearly disproportionate in semiconductor industry’s case.  The wider economic impacts of the ‘no-exemption’ scenario include a deterioration of attractiveness of the EU as an investment location due to the uncertainty the measure would create in terms of further regulation that might jeopardise the sector’s ability to manufacture in the EU.  In addition, the commenting company fully supports the comments provided to the PFOA restriction public consultation from ESIA and DIGITALEUROPE relating to the impact on semiconductor lithography chemistries as well as the impact of parts or ‘articles’ used in semiconductor manufacturing equipment, although the articles question is not addressed under the remit of this report.  In conclusion, there is currently no alternative for the use of PFOA-related substances for many photolithography applications in the European semiconductor industry. The current use can be considered under strictly controlled conditions and risks are minimized. The socio-economic impact of the proposed restriction would be very negative to the European semiconductor industry. In addition, the semiconductor industry has a good track record in demonstrating its ability to phase out hazardous chemicals, having made substantial progress towards phasing out PFOA and PFOS. The commenting company and the European semiconductor industry support the premise of the proposed restriction, however, the authority is urged with good reason to grant an exemption for the use of PFOA-related substances in the photolithography process in the production of semiconductors, with a review period of 10 years. The sector is confident that PFOA-related substances will be phased out as technically viable alternatives are found and able to be qualified in the various process steps. | |
| **Answer to specific info request 1:**  Please refer to the attached confidential document for answer to this question. | |
| **Answer to specific info request 2:**  Please refer to the attached confidential document for answer to this question. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration on potential derogations.  Risk management measures regarding human health and environment are in place. Furthermore, semiconductor industry is a minor user of PFOA related substances. There are very low emissions into the environment. Therefore, the Dossier submitter would agree with a longer transitional period for the remaining critical uses in photolithography. | |
| **RAC Rapporteurs comments:**  Thanks for the detailed information. In the view of RAC, the emissions from the semiconductor industry (photolithograpy) seem negligible, which in combination with the use pattern supports a derogation. | |
| **SEAC Rapporteurs comments:**  Thank you for the information and economic impact assessment provided. More details on how economic figures have been arrived at could have been useful, however, based on the available information SEAC proposes a derogation for mixtures used in semiconductor photolithography processes given the possible disproportionate socio-economic impacts to the sector. Please see response to Comment 1303. | |
| **1357** | **Date:** 2015/06/17 10:42  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  BWF Offermann, Schmid & Co. KG  **Org. country:** Germany  **Company name confidential:** **No**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company . | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents. | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh.  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Please see response to Comment 1235. | |
| **1358** | **Date:** 2015/06/17 11:08  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Verband TEGEWA e.V.  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  The comments included in the attachment should be understood as additional to the ones TEGEWA already submitted on February 20, 2015. The ECHA PFOA Restriction Team asked us some additional questions which we are answering here. TEGEWA is supporting the approach to restrict the use of PFOA and PFOA-related substances in textile applications but objects to the proposed threshold of 2ppb. The thresholds should be set at a level that safeguards producing and placing on the market of short-chain alternatives, namely intermediates, mixtures and articles treated with short-chain alternatives. | |
| **Answer to specific info request 1:**  Already answered in February 2015, please see attachment for further information. | |
| **Answer to specific info request 2:**  Already answered in February 2015, please see attachment for further information. | |
| **Answer to specific info request 3:**  Already answered in February 2015, please see attachment for further information. | |
| **Answer to specific info request 4:**  Already answered in February 2015, please see attachment for further information. | |
| **Dossier submitter response:**  Thank you for responding to the ECHA request.  We will take the information provided into further consideration. | |
| **RAC Rapporteurs comments:**  Thanks for the useful and detailed information. We note the statement that a limit of 1-5 ppm for PFOA and a higher limit for the PFOA-related substances will enable nearly any kind of PPE (with some exceptions) to be manufactured using short-chain fluorochemistry. However, the general lack of information on actual emissions from textiles means that RAC is unable to consider any derogations from a risk perspective.  See also response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for the information especially proposing thresholds. It was taken into consideration in the assessment of concentration limits. Please see also response to Comment 1235. | |
| **1359** | **Date:** 2015/06/17 11:43  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  AFPé2i  **Org. country:** France  **Country:** France  **Company name confidential:** **No** | **General Comments:**  Proposal for Comments for Annex XV restriction report on PFOA  Additional comments: AFPé2i France  We are representing the French Trade Association AFPé2i (Association Française des Professionnels de l’Equipement d’Incendie et d’Intervention - whose members are manufacturers and distributors of fire fighting foam agents), a subsection of FFMI (Fédération Française des Métiers de l’Incendie), state member of EUROFEU.  AFPé2i has sent to the ECHA his general comments in the Public Consultation on the restriction proposal on PFOA and PFOA related substances on May 22nd 2015.  We have been invited by your note June 11th to answer to some additional questions, via public consultation, in particular referring to a reasonable threshold expressed in “X” ppb or ppm for PFOA and PFOA related substances.  Our comment May 22nd was “although AFPé2i does support the need for a restriction of PFOA and PFOA-related substances, we have serious concerns that the proposed threshold level could be effectively achieved in the production of fire fighting foam concentrates. As a consequence, we do not support the current draft version due to the proposed threshold level (2ppb) which is perceived as inapplicable”.  As a member of EUROFEU, AFPé2i supports the proposal to suggest a value of 1.000 ppb for each affected substance as defined in the proposal to Annex IX (PFOA and precursors) in the foam concentrate, and suggestion to work on decreasing that number in the coming years as new technologies become available.  AFPé2i  France  June 17th 2015 | |
| **Dossier submitter response:**  Thank you for responding to the ECHA request.  We will take the information provided into further consideration. | |
| **RAC Rapporteurs comments:**  The information is noted. | |
| **SEAC Rapporteurs comments:**  Thank you for providing a proposal. It has been taken into consideration. Please see response to Comment 1225. | |
| **1360** | **Date:** 2015/06/17 11:47  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  WIRTEX Wirtschaftsverband Textil Service  **Org. country:** Germany  **Company name confidential:** **No**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  The alternatives lack  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh.  Quantities used:  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  Potential risks:  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  economic impacts:  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  substitution costs:  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  costs of the restriction:  "In the field of personal protective equipment (PPE) type 6 chemical protection is commonly used in the industry.    Especially in following sectors:    Chemical industry  Oil and gas  Mechanical and plant engineering  Metallurgy  Printing  Automotive  Recycling  Paper and packaging  Waste disposal  Shipbuilding  Plastics  Construction    Fire department  Public utilities  Military  Emergency services    Logistics  Airports  Seaports  Haulage    To achieve the chemical protection necessary for type 6, fabrics are treated with a so-called C6-chemistry finish. This C6-chemistry may contain impurities of PFOA and continue to fall under the definition of „related products“. Alternatives to these products are not currently available. In particular, the oleophobic and hydrodynamic properties can not be achieved by alternative products.    One consequence of a limitation of these type 6 products would be that coated or laminated fabrics must be used instead. These products have significantly lower wearer comfort, due to a higher water vapor resistance. The result would be a much greater physiological strain for workers forced to wear these garments or a significant reduction of the working time. The economic costs would be significant.  "  related substances:  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  analytical methods:  "The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs.  A threshold value of 2 ppb requires extremly ambitious analytical methods. A threshold value of 2 ppb correlates with the actual possible limit of quantification for textiles. This means a significant risc for wrong-positive measuring results. It is not possible to ensure reliable analytical results whether the threshold value is met." | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account.The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1361** | **Date:** 2015/06/17 11:48  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  - chemical protection  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-limit. The informations supplied by SDS do not contain details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Besides flame and arc-flash protection, we meet our customers’ expectations for PPE with a solid and reliable chemical protection. An ample majority of our products emphasize on such characteristics and offer protection against dangerous chemicals and provide security while handling chemical products. All such attributes can only be provided using certain proportions of chemical substances, including PFOA related ingredients.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available.  see above | |
| **Answer to specific info request 4:**  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1362** | **Date:** 2015/06/17 12:16  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Sattler AG  **Org. country:** Austria  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Protection of commercial interests | **General Comments:**  We would like to state that in textile industry PFOA and related substances are not being used as such. Therefore these occur as impurities in our processing agents only. A 2ppb limit would be equivalent to an entire interdiction of these fluorinated processing agents. Adequate non fluorinated substances are not sufficient due to not satisfactory properties for our demanding applications. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other products. The intention is that the C6 chemistry should not be affected by this restriction. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1363** | **Date:** 2015/06/17 12:21  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  SEMI Europe  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  SEMI, the global industry association representing the manufacturing supply chain for the micro-/nano-electronics and related industries (including photovoltaic/solar, LED, flat panel display etc.), thanks ECHA for the opportunity to comment on the proposed restriction of PFOA, PFOA salts and PFOA-related substances.  SEMI’s core members are the companies that produce and supply the manufacturing equipment and the materials used to manufacture micro-/nano-electronics (e.g. semiconductors, also known as chips), solar cells, LED etc.  SEMI has evaluated the Annex XV dossier and the accompanying ECHA information note. SEMI would like to outline its concerns and recommendations. SEMI is also providing additional information in response to ECHA’s specific requests.  SEMI recommends to ECHA that:  • The semiconductor industry use should be granted a 10 year exemption, followed by a review to determine if an exemption extension is required.  • The proposed restriction on articles should be limited to the uses that have been evaluated in the restriction dossier.  • The possible use in articles embedded in semiconductor manufacturing equipment should not be in the scope of the proposed restriction, as this is an industrial use with risk management measures in place to control exposure and is therefore not comparable to the articles evaluated in the Annex XV dossier.  • The substances in scope need to be defined more clearly and in an exhaustive manner.  • No restriction should be imposed in cases where no existing proven analytical method already exists.  • The concentration limit should be raised by several orders of magnitude to a level that can be implemented and enforced with an existing technically proven analytical method.  • No single concentration limit should be adopted for all PFOA and PFOA-related substances. The limit should be set based on reasonable detection limits for specific classes of materials.  SEMI has the following concerns with the proposed restriction:  1. The semiconductor industry use should be exempted  SEMI recommends that the semiconductor industry use is exempted from the proposed restriction and is reviewed in 10 years to assess the need for a prolongation.  PFOA and PFOA-related substances are used in chemical formulations during specialized manufacturing steps (lithography) of the semiconductor manufacturing process. Over the past years the industry has moved away from uses of PFOA itself to alternative substance that give less concern based on current knowledge. There are no technically feasible alternatives for all critical uses in photolithography.  The volumes used in the semiconductor industry in Europe are very small.  The chemical formulations containing PFOA and PFOA-related substances are used in an industrial setting and are subject to strict handling controls to prevent exposure during all stages of the manufacturing process.  Restricting the use of PFOA or PFOA-related substances in the semiconductor industry would have a significant negative impact on Europe’s capacity to manufacture semiconductors. It would also impact the manufacturing supply chain operating in Europe (companies manufacturing semiconductors, companies supplying manufacturing equipment, companies supplying the materials used to manufacture semiconductors) and require a significant investment in research and development, testing and validation to identify and introduce alternative substances that provide the same level of technical capability, reliability and safety.  More detailed feedback is provided in SEMI’s responses to Questions 1 and 2.  2. The proposed restriction may impair efforts to replace PFOA and PFOS in the semiconductor industry  The vague definition of PFOA-related substances, coupled with the low concentration limit, may impact precursors and bring into scope the alternative substances that the semiconductor industry has adopted in its efforts to substitute PFOA and PFOS. When moving away from PFOS or PFOA to shorter- chain perfluorinated compounds, there may be impurities of PFOA and PFOS. If these alternatives are now being brought into question by the proposed restriction, continuing industry efforts to phase out PFOA and PFOS will be stalled, as industry tries to clarify what substances are in scope and identify whether alternatives to the alternatives exist.  More detailed feedback is provided in SEMI’s response to Questions 3 and 4.  3. Articles restriction should be limited to the uses evaluated in the dossier - use in articles that are parts of semiconductor manufacturing equipment should not be in scope of the proposed restriction.  SEMI’s core membership includes companies producing and supplying the machines used to manufacture semiconductors (electronic chips) and other related technologies (e.g. photovoltaic/solar, LED, flat panel displays etc.)  SEMI members believe that PFOA and PFOA-related substances may be contained in components, i.e. parts, of such manufacturing machines (e.g. in o-rings, seals or tubing). SEMI members would need to survey their global supply chain to confirm the presence of PFOA and PFOA-related substances in these parts. There are several thousand individual parts in a single manufacturing tool in the semiconductor industry. The specific parts that may contain PFOA and PFOA-related substances are sourced deep in the supply chain.  Manufacturing equipment used in different industries may also use these articles.  SEMI recommends that the restriction on articles is limited to the uses in articles evaluated in the Annex XV dossier. This possible use of PFOA and PFOA-related is a separate potential use in industrial settings, not evaluated in the Annex XV dossier and not comparable to the uses that have been evaluated in the dossier. The use in articles embedded in semiconductor manufacturing equipment should not be in the scope of this restriction proposal.  The use in parts embedded in semiconductor manufacturing equipment is not comparable to the uses in articles listed in the dossier, i.e. in paper, textiles and leather, fire fighting foams and in paints and ink. The articles SEMI is referring to are used in industrial settings, so there is no exposure to consumers nor do they end up in the typical household waste stream. Exposure to workers and the environment is controlled through strict processes for maintenance and repair and for waste disposal.  A restriction on use in these parts would have a significant impact on the companies that produce and supply semiconductor manufacturing equipment: survey their global supply chain several levels upstream, invest in research, testing and validation to introduce alternatives that guarantee the same level of technical capability and safety. On the other hand, a restriction of these articles would have little environmental and health benefit, as risk management measures are in place to prevent exposure to workers and the environment.  More detailed feedback is provided in SEMI’s response to Questions 1 and 2.  4. The scope of the proposed restriction is not clear  The definition of the restricted substances is not clear. It is therefore not easy for SEMI members to evaluate the extent to which they may be impacted by the proposed restriction and provide feedback to the specific information requests made by ECHA.  It will also be difficult to apply and enforce the restriction in practice throughout the supply chain if it is not clear what substances industry should aim to identify and restrict.  More detailed feedback is provided in SEMI’s response to Question 3.  5. The proposed concentration limit is too low  SEMI has significant concerns about the proposed 2ppb limit. SEMI does not believe analytical methods currently exist to cover the entire scope of the proposed restriction, i.e. all proposed substances used both in articles and as formulations in manufacturing.  A low concentration limit that is technically impossible to detect cannot be applied and cannot be enforced, thereby undermining the value of the proposed restriction.  SEMI is also concerned that setting such a low limit would lead to the restriction of substances that unintentionally contain traces of PFOA or PFOA-related substances as ubiquitous impurities.  More detailed feedback is provided in SEMI’s response to Question 4. | |
| **Answer to specific info request 1:**  a/ Regarding use in the semiconductor industry  SEMI recommends that the semiconductor industry use is exempted from the proposed restriction, with a review in 10 years to assess the need for an extension.  PFOA or PFOA-related substances are used in small quantities in specialized manufacturing steps (principally lithography) of the semiconductor manufacturing process. Over the past years the industry has moved away from uses of PFOA itself where technically feasible to alternative substance that give less concern based on current knowledge. There are no technically feasible alternatives for all critical uses in photolithography.  The volumes used in the semiconductor industry in Europe are small, as is stated in the restriction dossier and as outlined by the European Semiconductor Industry Association (ESIA) in their submission.  Regarding the potential risks to the environment and human health of the semiconductor industry use, SEMI would like to correct a statement made in the Annex XV restriction dossier (section B.4.4.2.3 – page 67) that “…emissions from the end-of-life stage, when electronics are not properly disposed, cannot be excluded.” During lithography PFOAs are used as part of the chemical formulation in a manufacturing process – the chemical formulation is subsequently not present in the finished product (i.e. the die patterned finished wafers).  The chemical formulations containing PFOA and PFOA-related substances are used in an industrial setting and are subject to strict handling controls. There is no release to the workplace during production due to the use of closed systems, so worker exposure is prevented. Solvent waste containing PFOA/PFOA-related substances is typically collected at the factories and sent for incineration at temperatures where PFOA is fully destroyed, thus preventing potential emission to the environment. There is very minimal release to the environment in wastewater. SEMI supports the contribution of the European Semiconductor Industry Association (ESIA) on the risk management measures and exposure levels.  b/ Regarding use in articles in semiconductor manufacturing equipment  SEMI would like to highlight an additional possible use of PFOA and PFOA-related substances in articles in the context of manufacturing equipment that has not been evaluated in the Annex XV dossier.  PFOA and PFOA-related substances may be contained in components, instruments and sub-assemblies of semiconductor manufacturing equipment, for example in o-rings, seals or tubing due to their chemical resistance properties. PFOA and PFOA-related substances may also be present in these components as unintended additives or breakdown products or in residual quantities associated with the fluorocarbons used in their manufacture.  SEMI currently has no confirmation on the presence of PFOA and PFOA-related substances in these parts, nor any information on the possible quantities. Equipment manufacturers need to query their supply chains to confirm whether the substances are present in the components and if so, in what quantities. There are several thousand individual components in a medium-sized piece of semiconductor manufacturing equipment, and these substances could appear in components that are sourced very deep in the supply chain (i.e. beyond tier 1 and 2). Additionally, many components that may include PFOA and/or PFOA-related substances are minor and not directly specified by the equipment supplier. Semiconductor equipment manufacturers source globally from a complex multi-tiered supply chain over which they have little influence.  Such components would presumably also be used in the manufacturing equipment of other industries, where the equipment is in contact with process chemistry and require resistance to such chemistry.  The use in parts embedded in semiconductor manufacturing equipment is not comparable to the uses in articles listed in the Annex XV dossier, i.e. in paper, textiles and leather, fire fighting foams and in paints and ink.  The articles SEMI is referring to are not available to consumers; they are embedded in industrial machinery that is used in industrial settings. Risk management measures are in place to prevent exposure to workers and the environment: maintenance and repair is undertaken by trained professionals. At end of life, as these parts are in contact with process chemistry during the manufacturing process, they would be disposed of as hazardous waste, usually by incineration, thereby preventing release to the environment.  Semiconductor manufacturing equipment has a long life-span and a high intrinsic value. It is therefore returned to specialized companies (whether the original equipment manufacturer or secondary market operators) for refurbishment and resale, rather than being disposed of and would not end up in typical household waste streams.  SEMI therefore recommends that the proposed restriction on articles should be limited to the uses in articles that have been evaluated in the Annex XV dossier.  The use in articles embedded in semiconductor manufacturing equipment should not be in the scope of the proposed restriction on use in articles. A restriction of these articles would have little environmental and health benefit, as risk management measures are in place to prevent exposure to workers and the environment. | |
| **Answer to specific info request 2:**  - About Europe’s semiconductor manufacturing supply chain  The semiconductor manufacturing industry, more widely known as the micro and nano-electronics industry, employs 250,000 people, representing around 8% of the industrial jobs in Europe, and contributes 10% of European GDP.  An additional 105,000 people are employed in the supply chain, specifically in companies that manufacture and supply the manufacturing tools and the materials used to manufacture semiconductors. Over 80% of these companies are small and medium-sized enterprise.  The EU acknowledges the strategic importance of the semiconductor manufacturing supply chain as a Key Enabling Technology and is implementing a dedicated strategy for micro- and nano-electronics with a target of doubling Europe’s share of the global market by 2020. The strategy aims to facilitate industry investments in research and manufacturing of € 100 Billion by 2020-2025. The EU is devoting over € 1.6 Billion of research and innovation funding between 2014-2020, and an additional € 2.B Billion is available from national and regional funding sources in Europe. The industry is also at the heart of the EU Digital Single Market Strategy: to achieve digital sovereignty Europe must also have technological sovereignty and ensure it owns the critical technologies needed in this digital era.  In 2015, SEMI forecasts that investment in new manufacturing infrastructure and equipment in Europe will reach 2,94 Billion US Dollars, and investment in materials used to manufacture semiconductors will be worth 3.22 Billion US Dollars.  - Regarding the socio-economic impact of restricting the use in the semiconductor industry  Not granting an exemption for the semiconductor industry use would have a significant impact on Europe’s capacity to manufacture semiconductors and on the companies active in the supply chain. This is a high-tech, high-precision and research intensive manufacturing industry, that has already made efforts and transitioned away from PFOA where this is technically feasible. Identifying alternative substances is a lengthy process, that requires an important and lengthy investment in research and development for material suppliers and for semiconductor device manufacturers, followed by a testing and validation period before new process chemistry can be introduced to the manufacturing process.  Manufacturing equipment could also be impacted by a change in process chemistry. Equipment manufacturers and their suppliers would need to test the new process chemistry on their machines and where necessary invest in research to develop new technologies to accommodate the new chemistry. This new technology would then be subject to a testing and validation process, to ensure safety, reliability and quality production to the customer’s specifications.  - Regarding the socio-economic impact of restricting the use in articles:  A blanket ban of all potential uses in articles, including articles used in industrial settings where risk management measures are in place to prevent exposure, would have little benefit to human health and the environment but would incur a significant cost to the industry.  Following a survey of SEMI members, the majority of respondents currently only suspect that PFOA and/or PFOA-related substances may be present in components of the manufacturing equipment. A survey of the global supply chain, going several tiers upstream in the chain, is required to confirm their presence and, if so, in what quantities.  Based on our experience with other material content regulations, e.g. RoHS, REACH and conflict minerals, this is likely to take at least 3 years. Semiconductor equipment manufacturers source globally from a multi-tiered complex supply chain over which they have little influence. They would rely on their supply chain to source compliant articles and may also need to introduce independent testing to ensure compliance, as they source from a global, non-semiconductor and non-EU specific supply chain that may be uninformed or not cooperative.  If components were found to contain PFOA and/or PFOA-related substances, equipment manufacturers would need to identify compliant alternatives based on design and end-user requirements. The total time frame for identifying non-compliant parts and then testing, validating and introducing alternative components is estimated to require no less than 3-5 years. The actual length depends on the complexity of the equipment, in terms of how many components and sub-assemblies it contains. These alternatives would be subject to testing, including design verification and long-term reliability and compatibility testing, as necessary. Changes to the manufacturing equipment are subject to customer approval, and the customers would need to be notified of the proposed change and be provided with documentation confirming that their requirements are satisfied.  Exemptions would need to be obtained for secondary market operations, to avoid the creation of unnecessary waste and allow the equipment to fulfill its full useful life. Semiconductor manufacturing equipment has a long life span of no less than 15-20 years and a high intrinsic value, and hence secondary market operations in Europe represent an important part of the semiconductor manufacturing equipment market. Substitution with compliant parts is not automatic and requires research, testing and validation to ensure equivalent technical capability and safety. | |
| **Answer to specific info request 3:**  SEMI believes that the current definition is too generic and that the specific substances that are in scope, as well as the exempted substances, need to be more clearly defined:  • Materials suppliers use fluorinated substance telomers as precursors to other substances, and it is currently unclear to what extent all fluorinated telomers are being regulated.  • the “X” in the chemical nomenclature is too generic, “C8F17-X” can be interpreted in many different ways.  • CAS or EIC numbers are often not included in the restriction dossier, and this can add to the sense of ambiguity.  • it is unclear to what extent products that degrade to PFOA, defined in the proposal as PFOA- related substances, are in scope.  SEMI believes the current definition is too generic and does not provide sufficient guidance as to what substances are in scope of the proposed restriction.  Below examples of questions arising from the definitions:  a) C7F15-X  What if X = some other non carbon to carbon bonded moiety, e.g. ether, ester; it is not clear that it would degrade to PFOA. If X = CH2-C(R)(R’)-X’ it is not clear it would degrade to PFOA but maybe to PFNA.    b) C8F17-X  What if X = some other non carbon to carbon bonded moiety, e.g. ether, ester; it is not clear that it would degrade to PFOA.  It appears from section B4.1.2.1 (page 37-39) of this proposal that only C8F17-CH2-CH2-CO2H or C8F17-CH2-CR=O will degrade to generate a small amount of PFOA, the functionality of CH2-CH2-CO2H appears to be necessary for the degradation reaction pathway.  We would suggest that the definition identifies more groups that “X” can be as well as what “X” cannot be. The challenge with the current definition is that as it is so generic very few substances of C7F15- or of C8F17- are exempt and yet we feel there are some substances falling into scope (as above) that are not intended for capture.  X needs to be defined as which functional groups actually give rise to PFOA upon degradation.  C7F15-CH2-X where X is a non carbon-carbon bond  C8F17-CH2-CH2-CO2R (R =H or ester), C8F17-CH2-CO2R (R = H or ester), C8F17-CH2-CHO | |
| **Answer to specific info request 4:**  SEMI is deeply concerned about the proposed 2ppb PFOA threshold limit.  Such a low threshold would bring into scope of the proposed restrictions substances that unintentionally contain restricted contaminants. SEMI supports the following statement of the FluoroCouncil: “A persistent substance such as PFOA may be ubiquitously present, and testing for substances at these truly trace contamination levels would result in false positives and unrepeatable analytical results, especially when there are not validated analytical test methods for all matrices, as is the case with PFOA. Such a low limit threshold would result in such routine test failures as to represent a de facto ban on products and articles that are not made with the regulated substances, including alternatives that are now relied on in multiple industries and have been reviewed and approved by regulatory agencies as replacements for PFOA and related substances.”  To SEMI’s knowledge, there are currently no known established methods to detect fluorinated substances in articles and formulations at this level. SEMI believes it is not appropriate to extrapolate from possible existing methods for one kind of chemistry and assume these can be applied to a different kind of chemistry.  The lack of analytical methods to ensure compliance with the proposed concentration limit then raises the question of how to enforce the proposed restriction. Downstream industry can try to impose the limit and request confirmation in the form of a report from a certified lab as it sources from its upstream supply chain. However, we are not confident that labs are currently in a position to certify at this low level. National authorities enforcing the proposed regulation would encounter the same enforcement problem. SEMI believes that there is no value in a restriction that cannot be enforced by industry and where compliance cannot be checked by the competent authorities.  The Dossier lists twelve scientific studies in Tables A.E.2-1 and A.E.2-2, which report quantification limits for PFOA and PFOA-related substances. All these studies use some form of chromatography / mass spectrometry to estimate detection limits. Three of these studies (Mawn, Lu, and Knepper) detect PFOA and PFOA-related substances at or below 2ppb.  We have reviewed these three studies and don’t disagree with their conclusions on the 2ppb quantification limits. But we do question whether the analytical methods used in these studies can be repeated and / or replicated under the wide variety of substrates and formulations likely found in the semiconductor environment.  To conduct chromatography / mass spectrometry, samples containing possible PFOA materials must be prepared in some sort of solution along with a solid matrix. If done properly, chromatography / mass spectrometry can detect very low limits of certain materials. The challenge is that some materials containing PFOA are more difficult to prepare (extraction, matrix effect etc.) for chromatography / mass spectrometry than others. In this case, sampling method variables are likely to reduce the ability of chromatography / mass spectrometry to detect PFOA at 2ppb.  Materials containing PFOA-related substances may frequently be contaminated with low levels of other fluorinated materials which are difficult to account for as they may be residual substances resulting from previous stages of manufacturing processes.  Many of the studies, including those with detection limits of 2ppb, use sampling preparation methods that are extremely easy to conduct. Many of these studies use PFOA containing textiles (e.g. carpet fibers), where the PFOA molecules are not strongly bound to the carpet fiber substrate. Preparing these carpet fibers containing PFOA for chromatography / mass spectrometry is a relatively straight-forward process.  Preparing more complicated PFOA-related articles or formulations for chromatography / mass spectrometry, is likely to be more challenging and increase the detection thresholds. For example, PFOA-containing solid articles such as O-Rings where the PFOA is strongly bound to or embedded in a larger substrate, would be more difficult to prepare for chromatography / mass spectrometry, resulting in a less robust ability to detect the PFOA. The same complexities are also relevant for liquid formulations where the PFOA materials are mixed with other materials in a liquid matrix. This would also apply for PFOA-related substances that have not been added intentionally to the formulation, as for example by contamination.  Ultimately, SEMI questions whether the analytical methods used in these three studies (Mawn, Lu, and Knepper) are repeatable and replicable under a wide variety of substrate materials. One of the authors (Mawn) agrees with this notion and concludes “for routine application of these methods to a large number of sample sets differing in chemical and physical compositions, a complete validation for each sample type is not practical or possible”. We note that this study is not directly related to total extraction of PFOA but limits itself to possible environmental exposure.  Other than the three studies referenced in the Dossier, SEMI is not aware of any publically available reference methods to detect PFOA or PFO-related substances at 2ppb in articles or formulations. We are also not aware of any existing and validated international analytical methods (EN/ISO) for PFOA or PFOA-related substances.  We are aware that the Latvian government is currently working on an EN standard method to detect long-chain per-fluorinated substances (under CEN, TC248/WG26). But we have not located any publically available information that would allow us to better understand the development of this standard.  Based on the sampling challenges with the three studies (Mawn, Lu, and Knepper) used to detect PFOA at or below 2ppb and the fact that no clear standardized methods currently exist, SEMI questions whether detecting PFOA at 2ppb threshold is even possible and enforceable in a regulatory setting.  Based on the fact that detecting PFOA at 2ppb is not currently practical in a regulatory setting, SEMI urges ECHA to substantially raise the detection limit by some orders of magnitude. Furthermore, SEMI urges ECHA to not adopt a single threshold limit for all PFOA-related materials. The threshold should be set based on reasonable detection limits for specific classes of materials.  Finally, SEMI urges ECHA to work with standards development organizations to come up with a set of robust analytical methods for PFOA detection that could be used in a regulatory setting. As part of this standard-setting, some focus should be on extraction and detection methods that are applicable and environmentally relevant. The extraction methodology also needs to be relevant to the products being analyzed. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration on potential derogations.  Risk management measures regarding human health and environment are in place. Furthermore, semiconductor industry is a minor user of PFOA related substances. There are very low emissions into the environment. Therefore, the Dossier submitter would agree with a longer transitional period for the remaining critical uses in photolithography.  The Dossier submitter proposed a structural formula to include all possible substances which can degrade to PFOA. This is in line with the restriction on PFOS and the stewardship program of the US-EPA on long chain PFASs. In our view there is no reason to alter the scope of the proposed restriction.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  Thank you for the detailed information. RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other products. In the view of RAC, the emissions from the semiconductor industry seem negligible, which in combination with the use pattern warrants a derogation. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree that a revision of the concentration limit seems necessary to ensure that short-chain alternatives are allowed to be used. Given the evident disproportionate socio-economic impacts to the sector we support derogation for mixtures used in semiconductor photolithography processes. Please see also response to Comment 1303. | |
| **1364** | **Date:** 2015/06/17 12:23  **Type:** Individual  **Country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No**    **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Both reports contain a detailed breakdown of life-cycle costs which may allow competitors to draw conclusions on BASF's profitability (Art. 4(2)). In addition, data on potential damage in the scenarios investigated may give hints on suitable targets for sabotage (Art. 4(1)). BASF, therefore, requests confidential treatment of the reports. | **General Comments:**  Dear Sir or Madam,  please ignore our previous comments for ANNEX XV restriction report of this morning (9:55 cest). In section V - confidential attachment - we had to replace the documents by new ones.  Please see non confidential attachment in section IV. Details on eco-efficiency analysis in Confidential Attachment section V. | |
| **Answer to specific info request 1:**  See non confidential attachment in section IV. | |
| **Answer to specific info request 2:**  For more details on the use of fire-fighting foams see non confidential attachment in section IV. | |
| **Answer to specific info request 4:**  See non confidential attachment in section IV. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  Thanks for the comments and the information. See also response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see response to Comment 1225. | |
| **1365** | **Date:** 2015/06/17 12:55  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Assosistema  **Org. country:** Italy  **Company name confidential:** **No** | **General Comments:**  In protective clothing repellent finishes are used for different applications. Not all the applications are mentioned in the available documents. Therefor further work needs to be done to make sure that a large amount of workers would no longer be properly protected against the risks they face because of this limitation. | |
| **Answer to specific info request 1:**  In protective clothing repellent finishes are used for different applications. Can be for water repellence as described in the table with applications. However these finishes are very often used for (light) protection against liquid chemicals. This application is not included in the table. Protective clothing is subject to the Directive on Personal Protective Equipment (89/686). This type of protection is used on fire fighting clothing (harmonised standards EN 469) as a first barrier against chemicals, but also in industry as chemical protection type 6 (harmonised standard EN 13034). This type 6 protection is widely used in different types of industry where the risk of contact with chemicals is limited but not completely excluded. With this protection, the wearer has some time to go away from the risk and take off the clothing while the chemical remains on the surface of the clothing. To achieve this type of repellence, fluorocarbon finishes are applied to the fabrics used to produce the clothing, but also during the life cycle of the clothing the finish has to be reapplied to maintain the required level of protection. In practice this is done after each wash cycle. Both the textile and the textile service industry are shifting from C8 to C6 chemistry at the moment. This includes studies being done at the moment on the effectiveness of the C6 chemistry in all steps of the chain. So far, the results are promising, even if the C6 requires stricter conditions for activation, which certainly during the reapplication process leads to extra burdens for the textile service companies. | |
| **Answer to specific info request 4:**  One element that needs attention is the amount of ‘impurities’ in the C6 based products on the market for this application. Indeed it seems that there are some traces of C8 to be found in the C6 solutions and the limit of 2 ppb is unrealistically low. To determine a realistic limit, the manufacturers of the solutions offered to e.g. the textile services have to be consulted (e.g. Christeyns, Ecolab). | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1366** | **Date:** 2015/06/17 13:15  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  European Semiconductor Industry Association  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  The European Semiconductor Manufacturing Industry is an extremely minor user of PFOA related substances within its manufacturing processes. As outlined in the draft restriction dossier, the semiconductor industry requests an exemption to allow for continued use of these compounds in photolithography formulations based on disproportionate socioeconomic impact of a ban would have on the industry. The semiconductor industry requests a 10 year exemption for semiconductor photolithography use, followed by a review to determine if an exemption extension is required.  These substances are used due to their high technical functionality in speciality formulations in the industry manufacturing process called photolithography. Over the past number of years the European semiconductor industry has been transitioning away from uses of PFOA itself in photolithography. However based on upstream industry information the industry now uses some substances that are newly brought within scope of this draft restriction as PFOA-related substances.  These PFOA –related substances remain critical for the industry as there are no adequate technically feasible alternatives that can be used as replacements for all applications.  Any potential environmental releases are well managed by the semiconductor industry. This is due to careful collection of the used liquid, typically followed by solvent waste incineration. There is very minimal emissions release to wastewater containing PFOA related substances (3.8% of total usage). There are no emissions to air arising from their use. In addition, these substances do not remain on the finished patterned semiconductor wafer. Stringent risk management measures are implemented in the manufacturing factories. There is no release to the work place environment during production due to the use of closed systems.  European semiconductor industry has a long history of responsible use of perfluorinated substances and has made significant efforts and progress to transition to perfluorinated substances of lower chain lengths (short chain Perfluoro Carboxylic Acids (PFCAs) and Perfluoro Sulphonic Acids (PFSA) alternatives) that give less concern based on current knowledge.  In response to question 2, ESIA has outlined a table and figure explanation that is not visible in the online text format and so which will be inserted as an attachment- which provides a summary comparison of the health, environmental and socio-economic implications of the restriction with and without an exemption for photolithography in the semiconductor manufacturing industry | |
| **Answer to specific info request 1:**  The Semiconductor manufacturing industry produces semiconductor devices (microchips). PFOA related substances are used in very minor quantities at low concentrations in some speciality formulations in a semiconductor industry manufacturing step called photolithography. These substances are critical to this manufacturing step due to their high technical functionality (as per Appendix C , Table A.C.1.1 Potential alternatives and technologies in the annex XV proposal). The industry and its photolithography formulation supply chain are aware of the concerns regarding these chemicals, and have already made substantial efforts where technically feasible to eliminate them from the manufacturing process formulations. Over the past number of years the European semiconductor industry has been transitioning away from uses of PFOA itself in photolithography. Currently however for the critical photolithography uses there are no adequate technically feasible alternatives for PFOA related substances that can be used as replacements for all applications. European Semiconductor Industry Association (ESIA) believes that RMO 1b (as per Section E.1.2 of the Annex XV restriction proposal) should be considered as appropriate especially for sectors that require exemptions and a longer transition time (effective date) due to remaining critical uses where substitution is technically unfeasible, where the use in absolute terms is very low, emissions are well managed and substances subject to restriction do not remain in the final product.    Page 157 E2.2.1.2.2 Technical Feasibility  There are no feasible alternatives for all critical uses in photolithography  Quantities Used  Overall the semiconductor industry is a very minor volume user of PFOA related substances in photolithography. The industry has been transitioning away from PFOA itself in recent years. Within the timeframe of the ECHA public consultation, the European Semiconductor Industry Association conducted a survey of its members to estimate the total amount (kg) of PFOA and PFOA related substances contained in European semiconductor photolithography chemical products in 2014. Members in turn reviewed their suppliers and the amounts received were aggregated at sector level. The resulting total was 19 kg of PFOA related substances, which is the best estimate of use within the sector available currently It should be noted that this estimate is based on responses from ESIA member companies. It can be possible that there may be some minor users of in scope substances outside of the ESIA membership.    Referencing the OECD Emission Scenario Document on Photoresist use in the Semiconductor Industry , which estimates emissions at between 1 and 7%, and based on further refinement using expert judgement from semiconductor industry manufacturing process engineers, a conservative emission factor for the sector is calculated as 3.8%. Applying this emission factor results in 0.7kg of PFOA-related substances being attributed to emissions to wastewater in 2014. This value accounts for 0.001 % of total estimated emissions (with reference to Table F.1-1: Estimated annual use volumes and emissions of PFOA (red) and PFOA-related substances (blue) in the annex XV proposal page 163).  Waste Streams and Potential Risk  PFOA related substances are used in very small quantities as an ingredient at low concentration in photoresist and ARCs (Anti-reflective coatings) chemical formulations in semiconductor photolithography. The potential risk to the environment and human health is managed in semiconductor manufacturing through stringent risk management measures implemented in the manufacturing factories.  The semiconductor manufacturing industry sector has implemented stringent risk management measures and safety practices to prevent release of chemicals during all stages of the manufacturing process including the waste stage.  There is no release to the work place during production due to the use of closed systems, thus preventing worker exposure.  Inside the semiconductor wafer manufacturing clean room, the presence of uncontrolled particles, as well as of chemical vapours and gases constitutes an unacceptable risk from a safety and health and a production perspective. This risk is controlled through the application of closed system manufacturing equipment which are installed in a cleanroom environment. Automated chemical delivery systems are installed to create a barrier between workers and the process and protect against chemical and physical hazards in the work environment.  Solvent waste containing PFOA related substances is typically collected at the factories and sent for incineration at temperatures where PFOA related substances are fully destroyed, thus preventing potential emission to the environment. There is very minimal release to the environment in wastewater.  Page 67 - Paragraph B 4.4.2.3 Environmental release from the semiconductor industry  The paragraph B 4.4.2.3 relating to environmental emissions from the EU semiconductor industry states: “…Since the substances are enclosed in the product, emissions during the use phase are considered negligible…”  ESIA disagrees with the statement. PFOA related substances do not remain enclosed in the die patterned finished wafer. ESIA recommends to remove this statement from this section of the report. In addition there are no emissions to air arising from the manufacture of semiconductors due to low use and low volatility of photolithography formulations. VOC treatment systems are in place at semiconductor manufacturing fabs that would treat any potential emissions of PFOA and related substances. Environmental release category 5 (ERC5) has been attributed to use in semiconductor manufacturing fabs with an associated 50% release factor. This is inaccurate as the substances do not remain enclosed in the die patterned finished wafer and the release factor is significantly lower. The more accurate characterisation of ERC for semiconductor manufacturing is, therefore, ERC 4. The release factor based on expert engineer research is 3.8%. as a conservative figure.  Semiconductor manufacturing equipment  Semiconductor manufacturing equipment used in the semiconductor factories to make the semiconductor device (microchip) and production installations (piping) have parts made of fluoropolymer and fluorotelomer material that may possibly contain substances within the scope of this restriction dossier. Semiconductor manufacturing equipment companies and their suppliers could be impacted by a potential restriction on articles, as parts, instruments and sub-assemblies of semiconductor manufacturing equipment which may contain fluoropolymer and fluorotelomer material, for example in O-rings, seals or Teflon tubing, due to their chemical resistance properties. This manufacturing equipment would be classified as ‘articles’ under REACH and are typically supplied from companies operating outside of the EU.  Semiconductor device manufacturing is one of the most complex and sophisticated manufacturing technologies in the world. The process of building a 3-dimensional nano-scale structure on a silicon or other wafer can require typically over 500 manufacturing process steps and uses over 100 different types of equipment supplied by many equipment manufacturers and sub-suppliers. The manufacturing equipment are highly complex machines. To give scale of the issue the industry could have approximately 100,000 replaceable spare parts for servicing the manufacturing equipment per European semiconductor manufacturing company. These substances could appear in parts that are sourced very deep in the upstream supply chain. Therefore assessing the full impact of the article aspect of the restriction proposal will be a complex and time consuming process. The industry would need further information from upstream tiers of the global supply chain to confirm the presence of these substances in equipment parts  It is worth noting that semiconductor manufacturing equipment will not end up in any typical household waste stream. The equipment machinery has a high capital value and a long life cycle. Semiconductor manufacturing equipment is typically reused and resold. In terms of potential exposure the industry would recommend that the scope of article provisions in the restriction proposal dossier should be narrowed to focus on consumer articles only where there is a high exposure potential for the environment and humans and where the risk management is not in place.  The semiconductor industry would recommend that the proposed restriction risk management option on use in articles be limited to the markets and uses that have been evaluated in the restriction dossier. | |
| **Answer to specific info request 2:**  No cost analysis has been performed on small volume users like semiconductor industry in the annex XV dossier. Due to the high tech nature of semiconductor production compared to 5 sectors/markets that have been assessed in the annex XV dossier the costs from these other sectors cannot be extrapolated to the semiconductor sector and as such are not representative for semiconductor industry.  The economic impact to the semiconductor industry was not assessed as part of the Annex XV restriction proposal. For the semiconductor industry it is not only a question of substitution cost but of finding alternatives. Despite significant R&D in recent years there are still some photolithography applications containing minute quantities of PFOA related substances for which replacements have not yet been identified.  The photolithography process which patterns the micro/nano circuitry of the device is at the heart of semiconductor manufacturing. Variance from company technology, process line, product line, technology node (size of transistor), and photolithography process step within a process line means that there is not one unique process photolithography step but hundreds of photolithography applications requiring varying chemical formulations. Depending on the technical challenges and performance criteria in question, PFOA related substances may be required as a surfactant or photo acid generator in some photolithography applications both in photoresists and in anti-reflective coatings.  The table below provides a summary comparison of the health, environmental and socio-economic implications of the restriction with and without an exemption for photolithography in the semiconductor manufacturing industry  Impact Exemption for Semiconductors No Exemption for Semiconductors Comment  Human Health Adequate control using risk management measures – no health impact to workers or to consumers. Adequate control using risk management measures – no health impact to workers or  to consumers. No health benefit to workers or to consumers arising if there is no semiconductor exemption.  Environment Worst case scenario 0.7 kg per annum of PFOA related substances are emitted to wastewater across Europe until all uses are replaced. No air emission due to low volatility of PFOA related substances and abatement in place. Waste containing PFOA related substances are typically sent to incineration Some PFOA related substances uses may be replaced over time. For others the equivalent manufacturing will likely be relocated to outside the EU, a corresponding proportion of the 0.7kg/annum will be emitted elsewhere globally. Significant materials and energy use to transfer some production outside the EU. Any significant environmental benefit arising from no exemption is highly questionable as on a global basis some of the emissions will still exist.  As a proportion of the emissions from the substances in scope across the EU in industry and in historic articles, the PFOA related emissions from the semiconductor portion can be regarded as insignificant.  Economic Significant costs to identify, develop and qualify feasible alternatives. Impact will vary across the sector up to 100% reliant and in certain examples manufacturing would temporarily not be able to operate within the EU. In other examples manufacturers may have reduced capacity to manufacture until replacements are invented, implemented and requalified. Customer commitments may not be met leading to significant financial impacts. The impacts of non-use are significant In certain cases production leakage to factories outside the EU that without such legislative measures would not take place.  Social Continued provision of highly skilled jobs in the EU in the semiconductor industry. EU Jobs may be at risk as well as EU jobs in linked industry upstream and downstream activities. Future EU investment confidence would be damaged leading to loss of future investment and therefore a loss in jobs. There is a desire to maintain highly skilled jobs within the EU.  Wider Economic Overall, micro- and nano-electronic components and systems enable the generation of at least 10% of GDP in the world. There may be a negative impact on the EU semiconductor sector and associated supply chain. There will be nervousness to invest the large amounts of capital required to build a semiconductor fabrication plant, Europe’s position as a global competitor in the semiconductor sector may be damaged. The importance of the semiconductor sector in the EU has been recognised by the Commission as a Key Enabling Technology (KET) and is essential for jobs and growth in the EU. A European strategy for micro and nanoelectronics components and systems was announced in 2013. This EU strategy facilitates industry investments of 100 billion euros and to help create 250,000 jobs in Europe up to 2020. The EU and member states and regions are currently implementing the European Industrial Strategic Roadmap  Overall comparison The semiconductor industry’s risk management measures are shown to protect human health and the environment. There is no impact on consumers as the product (microchip) does not contain PFOA related substances. The negative impacts of an exemption are considered to be relatively small and will be addressed in the industry’s continued efforts over time as research is conducted to identify, develop and qualify replacements. The negative impacts of no exemption for the semiconductor industry are considered to be high and will lead to production leakage to non-EU countries in certain circumstances. Some semiconductor companies will suffer significant financial damage. The analysis supports the case for an exemption for the semiconductor industry until such time as the industry has identified developed and qualified replacements for PFOA related substances.  Socio-Economic Impacts of no Semiconductor Sector Exemption  If no exemption for the semiconductor industry is granted within the PFOA restriction proposal, there will be severe economic impacts for the sector in the EU. The extent of this impact will vary across the sector. One large manufacturing centre is entirely reliant on the use of minor amounts of PFOA related substances and would temporarily not be able to operate within the EU; production would most likely be moved to a non-EU location with the potential loss of over four thousand direct highly skilled jobs and €550 million annual GVA (gross value add) to the economy. This manufacturing centre which has recently completed a €3 billion plant upgrade to run a new technology would suffer immense financial damage. Other semiconductor factories across the EU may no longer be able to operate at maximum capacity until replacements are invented, implemented and re-qualified. Customer commitments may not be met, leading to significant financial impact. There may be a longer term negative impact on the EU semiconductor sector as there will be a lack of confidence to invest the large amount of capital required to build a semiconductor fabrication plant (typically > €1billion) in the EU in the future. Europe’s position as a global competitor in the semiconductor sector may be damaged.  The US EPA has proposed a Significant New Use Rule (SNUR) under TSCA to limit future use of the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (LCPFAC and PFAS substances), including PFOA and PFOA-like substances. However, EPA cannot propose a SNUR for an ongoing use and is seeking comments on whether there are any ongoing uses of the substances covered by the proposed rule. Semiconductor use of PFOA and PFOA-like substances is ongoing, and these uses will fall outside of the scope of the rule when finalized. Granting an exemption for EU semiconductor manufacturers until such time as alternatives are available will ensure that the EU is not disadvantaged in terms of global competitiveness. Furthermore ESIA urges ECHA and the EC to work in conjunction with their counterparts at the US EPA to enable consistency in terms of the scope of any exemption granted.  PFOA Related Substance Criticality in Photolithography  Photolithography is the process which generates the lines, holes and patterns on the wafer which form the circuit after processing in other modules. It is generally the technology limiter in all semiconductor processes. It is the patterning resolution of the photolithography process which determines how many chips can be made from one wafer and how fast the transistors on the chip can run. Photolithography is the most capital intensive part of the process flow and is usually the most critical for production output. PFOA related substances are used in some photoresists anti reflective coatings (ARCs)  Two types of equipment linked together for leading-edge applications  • “Track” which coats the wafer with photoresist and develops away the exposed resist  • “Scanner” which exposes the resist in a masked pattern using laser light source  Photoresists -The photoresist coat process takes place in the track. First a primer is applied to the wafer to increase the adhesion of photoresist. Then during coat, photoresist is dispensed onto the wafer. The wafer is spun at high speed so that the photoresist spreads evenly across the wafer surface. Each resist is a custom designed blend designed for the particular layer, wavelength, substrate reflectivity and thickness required. Finally, during bake the resist is dried by removing solvent to produce a mechanically stable film. The biggest challenges are coverage over uneven surfaces, thickness, pattern defects and particle contamination. PFOA related compounds are used here as a surfactant to improve coverage and uniformity and also to change the absorption and refractive index.  During exposure the Wafer is exposed chip by chip in the scanner using a product and layer specific photomask. It usually uses 248nm or 193nm laser source. The key process challenges are lens focus, resolution and lens distortion. The critical application of PFOA related substances here are as PAG (photo acid generator) in some resists which is converted to a photo acid by the light.  Anti-Reflective Coating - Bottom ARC layers are spun onto the wafer prior to resist coating. They are used to reduce the reflectivity variation of a substrate much like “anti-reflective” glass. This stops “notching” in the pattern caused by reflection from underlying layers. PFOA related substances are used to improve film forming properties and adjust refractive index (RI). It is essential that the RI of ARC is square root of the RI of photoresist. This specification narrows down available alternatives only to substances that are chemically closely related to the substances currently in use.  Once the photolithography process step is complete the wafer is moved to an implant, dry etch or wet etch process step where the photoresist-covered areas are protected from the process as the exposed areas will be etched or implanted according to the pattern defined in the photolithography step. Once the etching or implanting is complete the remaining photoresist is stripped of the wafer in an oxygen plasma chamber. This process of patterning is repeated several times (in the range between 20 and 60, according to technology) with the manufacturing process to build up the layers of features of the transistors and interconnects that finally becomes an array of microchips on the silicon wafer.  PFOA related substances have excellent surfactant properties as well as being very stable molecules that are able to withstand the aggressive chemical and high temperature and energy environments that a wafer is exposed to during post lithography processing.  In general the industry is moving towards shorter-chain PFCA and PFSA compounds but due to the technical demands of process shorter chain molecules do not in every case deliver the required performance.    Substitution challenges requiring extended timelines for exemption  Despite significant R&D in recent years, currently there are no replacement substances for all uses of PFOA related substances in photolithography, which provide the critical functionality and equal performance required. Once a replacement is found the process of technology implementation, test and approvals and final replacement is not simple. The semiconductor industry needs to continue using these substances as long as no suitable alternatives are industrially available. A restriction without adequate timelines for transition for PFOA related substances in photolithography in Europe has the potential to undermine semiconductor production and future innovation in Europe.  The industry would underline the economic cost of final replacement and requalification for the end industrial user is enormous when considering the final PFOA related substances amounts used. This is because once a replacement substance has been identified it is not a ‘drop-in’ substitution. Each photolithography step has unique process performance criteria and has to be re-designed and qualified individually. Sometimes a chemistry change can give rise to the requirement for a photomask re-design. Mask re-design is a hugely onerous process as a large amount of specialised programming support is required to implement the revised optical proximity corrections which are integrated into the mask pattern. Furthermore changes in the photolithography process step can have upstream or downstream effects requiring re-design of additional process steps such as etching, stripping, cleaning and others. The industry will require an exemption to ensure the final remaining uses of PFOA related substances are not restricted in a disproportionate way. An effective date such as 18 months after entry into force would mean that a considerable amount of European semiconductor manufacturing may not be able to continue manufacturing. This ‘non-use’ scenario would have a very damaging effect on the industry without any commensurate benefit for environment and human health accruing from the non-use by the semiconductor sector.  ESIA requests a 10 year exemption for semiconductor photolithography use followed by a review to determine if an exemption extension is required for the semiconductor industry where no proven substitute exists for all applications. ESIA would underline this message to the socio economic analysis committee for their consideration comparing the ‘non-use’ scenario where no exemption would apply and an ‘applied for use’ scenario which outlines the impact of an exemption for the semiconductor industry.  The technology pipeline for semiconductor process development is typically of 10 years duration.  To appreciate the process of innovation in the semiconductor industry, it is important to understand two parallel dynamics that are at work. First, the semiconductor product (’microchips’) cycles tend to be very short. The products that are sold today are not expected to meet customer needs for long periods of time, an expectation that any consumer who owns and then upgrades his or her home computer can appreciate. Second, the technology development cycles, in contrast, often take a long time. Because of the complexity of the products and associated production processes, a major innovation can take years to bring to market. Manufacturers of electronic devices, working in conjunction with their materials and equipment suppliers, must typically proceed through multiple stages of research, technology integration, demonstration and manufacturing ramp-up to achieve a process change effectively. One technology development cycle typically takes around 10 years from fundamental research to production ramp up.  Since the PFOA related substances play a fundamental function to some remaining photolithography processes as described and they are used in multiple steps, the replacement of the PFOA related substances should be considered as a technology development, instead of mere product development. Therefore if a semiconductor manufacturing company were to start this technology development by the end of 2015 when the proposed restriction was decided, it will take around 10 years for the alternative technology into use Totally new, disruptive technology where the function of the perfluoroalkylated substances (including shorter chain alternatives) currently performing in the photolithography process will be superseded for the patterning of the smallest dimensions is not envisaged for another 20 years. Based on past experience, the chance of finding a theoretical alternative to PFOA related substances for all photolithography applications by the time of the restriction enters into force is very low.  Figure 1: Semiconductor Material Development Cycle    The semiconductor industry has a good track record of addressing materials of concern and since the early 2000s and has now implemented almost complete replacement for PFOS over a 10 year period as well as significantly reducing use of PFOA. For non-critical and for new semiconductor manufacturing processes PFOS free chemistry is used. This process has taken time due to the critical nature of the process involved, however past replacement timelines are not necessarily an indication of future performance and so a time limited exemption without a review period, may likely not be prudent or workable. | |
| **Answer to specific info request 3:**  ESIA cannot comment on question 3. | |
| **Answer to specific info request 4:**  The threshold of 2ppb would mean a de facto ban on of all the short chain PFCA and PFSA alternatives in photolithography. These are the substances which the semiconductor industry is transitioning into for its photolithography critical manufacturing processes since the last 15 years due to the regulatory concerns with PFOS and now PFOA.  Semiconductor industry would have concerns on the concentration limit approach as a user of manufacturing equipment articles containing fluoropolymers that may have been made in the upstream supply chain using in scope substances. The 2ppb limit seems not practical in an industrial setting. The industry’s upstream supply chain is predominantly outside Europe and the industry operates globally and would favour harmonisation at a global level in line with analytical method capabilities for complex matrices. As of today, it is our understanding that there are limitations to analytical methods to demonstrate compliance at levels as low as 2ppb.  Besides, given the enormous amount of equipment and auxiliary parts in a semiconductor manufacturing fab that could be affected, demonstration of proof would give rise to a disproportionate administrative and analytical burden and would entail extremely high cost if at all possible. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration on potential derogations.  Risk management measures regarding human health and environment are in place. Furthermore, semiconductor industry is a minor user of PFOA related substances. There are very low emissions into the environment. Therefore, the Dossier submitter would agree with a longer transitional period for the remaining critical uses in photolithography. We have included in the background document the information that workplace exposure in the semiconductor industry does not take place.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  Thanks for the detailed information. RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict with respect to analytical possibilities and potential trace level contamination of other products. In the view of RAC, the emissions from the semiconductor industry seem negligible, which in combination with the use pattern warrants a derogation. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree that a revision of the concentration limit seems necessary to ensure that short-chain alternatives are allowed to be used. Given the evident disproportionate socio-economic impacts to the sector we support derogation for mixtures used in semiconductor photolithography processes. Please see also response to Comment 1303. | |
| **1367** | **Date:** 2015/06/17 13:54  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes**  **Privacy comment:** I hereby declare by reference to Article 4 (2) of regulation 1049/2001/EC that the information submitted above is confidential and disclosure would undermine commercial interests of our company. | **General Comments:**  If this dossier were legally implemented in its current form, it would have serious consequences for the textile industry in Germany and Europe and therefore our company and its 60 employees in Germany.  We think the current initiative not only to be undifferentiated but also an imminent danger for our company. The envisaged restriction is among other things so alarming, because it has a major effect on a European level. In order to prove oneself as a producer of textiles in Germany against the global competition, to secure and create jobs, one has to exert oneself and make tremendous investments in innovation, quality and environmental orientation anyhow. Because of the envisaged restriction in Europe we feel not only deprived of our working base in the short term, but also considerably discriminated against in comparison to competitors in less restricted countries, e.g. in Asia.  Our company considers its survival radically endangered by the current proceedings. On-site production would no longer be possible if the restrictions were implemented. The aim should be developing repeatable and comprehensible limit values in a European task force first, in order to then develop new technical performance specifications together with official and normative authorities. | |
| **Answer to specific info request 1:**  The dossier contains restrictions in the field of textile auxiliaries, as well as in the field of goods treated or materials produced with those auxiliaries. The restrictions mentioned in the PFOA-dossier, which are basically a total ban, affect our company directly, since we produce functional textiles for authorities, personal protective equipment and technical applications.  Our company is already implementing the current standards and, among other things, the complete switch to C6-technology at great cost. If now, within a very short period of time, the new C6-technology were banned too, we would be deprived of our central working basis. Moreover the chemical supply industry does not offer any corresponding substitutes.  These materials are used in a large part (approx. 80%) of our product portfolio, for personal protective equipment, clothing for authorities in all European countries (e.g. police, fire department, THW, emergency services), medical applications (reusable products for surgery gowns and drapes) leisure and outdoor clothing, protective footwear and shoes for authorities, technical applications like special products for producing lightweight production parts for airplanes or wind turbines.  The current official specifications and standard requirements for personal protective clothing are in line with the hazards of the particular application area. They give a realistic and practical image of the performance. When using substitutes that are currently available, the protection requirements would have to be considerably lowered. The protective effect against wet, cold, bacteria, viruses, dirt, oil, heat, flame and other external influences in connection with care durability and physiological stress reduction (breathing activity) would be significantly lower or no longer be existent in this combination respectively.  The alternatives mentioned in the dossier are not sufficient, as they do not possess satisfying features for the application areas listed below. Among other things the alternatives lack fastness to washing, water, rubbing, adherence, dynamic water and oil repellence.  If the dossier were implemented, protection of the everyday worker due to his/her clothing could no longer be guaranteed and workplace safety, which has to be obliged according to legal requirements, would have to be completely rearranged. The elimination of the so-called C8-chemicals already led to deterioration in these systems. | |
| **Answer to specific info request 2:**  Even if the standards regarding the protective effect of e.g. turnout gear were lowered, the implementation would take 3-5 years and involve an investment of aprox. 5 Mio. € by our company. | |
| **Answer to specific info request 4:**  Within the scope of the envisaged restriction, a very low limit value of 2 ppb in functional textiles is depicted. During discussions with our partners in independent testing institutes, experts have already raised the basic question if these requirements are even measurable, since the necessary analytics are not sufficient in accordance with the current state of the art. The analytical methods mentioned in the dossier are not coordinated, which is why we doubt that repeated measurements will lead to resilient results. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the information  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree that a revision of the concentration limit is necessary to ensure that short-chain alternatives are allowed to be used. We support limit values of 25 ppb for PFOA and its salts, and 1000 ppb for PFOA-related substances. We also suggest a longer transitional period (36 months) to allow for the development of alternatives where necessary. Please see also response to Comment 1235. | |
| **1368** | **Date:** 2015/06/17 14:26  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Finavia Corporation  **Org. country:** Finland  **Company name confidential:** **No** | **General Comments:**  The airport operators are in responsible for rescue services at the airports. Well educated Rescue Services, effective rescue equipments and fire extinguishers have a crucial role in saving lives in aircraft accidents. In those situations every second counts. Aircraft fuel tanks full of kerosene may cause enormous fires which can’t be extinguished without proper fire fighting foams. Fluorinated surfactants make extinguisher spread evenly onto burning fuel layer and suppress fire by preventing oxygen access. So far fluorine free surfactants have not been as effective as fluorine containing ones. It is very important that in fuel burning accidents the most effective extinguishers could be in use and that way saving lives. The use of fluorine containing AFFF (Aqueous Film Forming Foam) agents should be allowed in fuel burning accidents as long as there isn’t as effective options. In fire fighting rehearsals it is possible to use non-fluorine agents or even just water.  The proposed concentration limit for PFOA and PFOA-related substances is 2 ppb (2 µg/kg). The limit value is extremely low comparing to PFOS which limit value is 10 ppm (10 mg/kg; EU regulation 757/2010). The limit value for PFOA and its derivatives should be taken into reconsideration. By the comments given by chemical manufactures there is a threat that also primarily short-chain fluorine compounds containing AFFF products would be banned because they contain long-chain fluorine substances as impurities. That is intolerable consequence as far as there aren’t alternatives effective enough.  If PFOA and PFOA-related substances containing AFFF agents are forbidden and they are not allowed to use even in fuel burning accidents should the transition time be reasonable. Taken into account the utilization time (the best before date) of AFFF is quite long and the fact there is no proper alternatives, 18 months for transition time is absolutely too short. Chemical manufactures should have time enough to develop substitute compounds which are in fire extinguishers as effective as fluorine compounds. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the guaranteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. We agree that revision of the proposal to ensure that short-chain alternatives are allowed to be used is necessary. Please see response to Comment 1225 | |
| **1369** | **Date:** 2015/06/17 14:59  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United States  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Disclosure or permitting access to any of the information contained in the document attached to this Section V would undermine the protection of the commercial interests including intellectual property of **<removed>** and its subsidiaries. | **General Comments:**  An extension of the restriction to 2020 is requested to allow for the phase out of our commercial use of a PFOA-related substance. Despite a significant substation effort, a viable alternative has not been identified. As proposed, the restriction would force customers to invest in new equipment. Most small to medium businesses (SMB) typically cannot readily absorb the replacement costs. Revenue and labor impacts can be expected. Existing equipment would need to be scrapped before reaching its end of life (E0L). This would be environmentally counterproductive. In addition, alternative technologies have different, but significant environmental impacts. Additional specific information is included in the confidential attachment. | |
| **Answer to specific info request 1:**  Information has been provided in confidential section in the previous submission. Here we answer specific questions received from ECHA and provide more information about the volume of the substance. | |
| **Dossier submitter response:**  Considering the decreasing amounts and the short transition period requested the Dossier submitter would agree to grant a longer transitional period for the use described. | |
| **RAC Rapporteurs comments:**  The information is noted. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Taking into account all information submitted during the public consultation of the restriction dossier, SEAC supports a longer transitional period of 5 years for certain printing inks to allow the move to alternatives while avoiding excess premature replacement of equipment. | |
| **1370** | **Date:** 2015/06/17 15:07  **Type:** MemberState  **MS name:** Sweden  **Country:** Sweden  **Company name confidential:** **No** | **General Comments:**  The Swedish Chemicals Agency (KEMI) welcomes the restriction proposal from Norway and Germany. KEMI agrees with the dossier submitters that an EU wide restriction is the best way to handle PFOA and PFOA-related substances, due to the fact that many imported articles contain these substances.    KEMI agrees that the only way to reduce PFOA in the environment is to include all substances that have the potential to degrade to PFOA to some extent. Therefore KEMI welcomes the broad scope including all precursors to PFOA. KEMI agrees that substances with a certain perfluorinated carbon chain length (those described in the scope by the dossier submitter) should be included in an upcoming restriction. It would not be possible to investigate the degradation path for each potential precursor. If there are no degradation studies it should, by default, be enough to observe the chemical structure of the PFOA-related substance in question, whether to include it or not in the scope. Even if only a small percentage of the PFOA-related substance will degrade to PFOA, this degradation product is a PBT substance for which it is not possible to establish a safe level of exposure. As far as technically and practically possible emissions should be minimised (see REACH recital 70).  PFOA and PFOA-related substances are used in many different applications (described by the dossier submitters). Even if there is less effective or no proper alternative today it might not be appropriate to make exemptions. If considering exemptions it is important to describe why this use is necessary. It is important to put that in perspective to the risk. Exemptions should only be warranted if the user can give specific technical reasons, based on facts. Only claiming that there are no suitable alternatives should not be enough! In addition, a derogation should always include a time limit to endorse the development of suitable alternatives.    The alternatives described by the dossier submitters are mainly other highly fluorinated substances with shorter perfluorinated chain lengths. These substances are (based on what we know today) not as bioaccumulative as PFOA. However (as also stated by the dossier submitters) they are equally persistent in the environment and cannot be degraded under biotic or abiotic conditions. KEMI sees the proposed restriction as an important step on the way (restricting a group of PBT-substances), and further down the line all of the extreme persistent highly fluorinated substances should be considered for regulatory actions. | |
| **Dossier submitter response:**  Thank you very much for your support. | |
| **RAC Rapporteurs comments:**  The support is noted. | |
| **SEAC Rapporteurs comments:**  The support is noted. | |
| **1371** | **Date:** 2015/06/17 15:43  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** The confidential information disclosed in the response attached is proprietary, containing technically and commercially-sensitive information which is known only to the company on whose behalf this submission is made, its legal advisor and a small number of relevant customers. It is not currently in the public domain and the company has no intention or desire to make it public. Accordingly, it must not be released into the public domain by virtue of this submission.  The company on whose behalf this information is submitted has invested significant investment (in terms of both time and resources) in research and development to produce its C8F17-X based chemistry coating process. Disclosure of the confidential information would allow an association to be made between the coating process and PFOA which would prejudice this company’s investment as it would allow this company’s competitors to associate the substance with the coating process and potentially allow its competitors to replicate the process as well as affording them a significant public relations opportunity. Disclosure of this information would substantially and potentially irretrievably harm this company’s commercial interests and competitive market position.  We and our client consider that the claim for confidentiality has been sufficiently justified. Our client expressly reserves the right to withdraw and/or redact this submission in the event that its confidentiality cannot be guaranteed. If you consider that, following a review of the claim, further information is required please let us know and we will be happy to provide it. | **General Comments:**  Please find within the confidential attachment a response to ECHA's request for additional information prepared by**<removed>** for a UK confidential client. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made. We will take it into further consideration. | |
| **RAC Rapporteurs comments:**  Thanks for the confidential information. | |
| **SEAC Rapporteurs comments:**  Thanks for the confidential information. It was taken into account i.a. when assessing suitable transition periods. | |
| **1372** | **Date:** 2015/06/17 15:44  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** The information submitted contains people's names, surfactant details within our products and our change plan from C8 to C6 along with time-frames. | **General Comments:**  - | |
| **Answer to specific info request 1:**  Performance of fluorine free alternatives are not yet able to consistently meet the minimum performance standards required of life-safety products whereas C6 based alternatives consistently do. | |
| **Answer to specific info request 2:**  The economic impact of the proposed 2ppb upper limit would force many EU based manufacturers to close. | |
| **Answer to specific info request 4:**  A detection level of 2ppb within a fire fighting foam matrix or the raw ingredients is currently unobtainable and so could not be enforced. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  The information is noted. We share the concern that the 2 ppb limit is too strict with respect to analytical possibilities, especially in fire-fighting foams. However, since this is a potentially significant source of environmental exposure, RAC has not recommended any derogation for this use, but recognises that there are socio-economic factors for SEAC to address. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC understands that the 2 ppb limit could prevent the use of C6 alternative fluorinated foams, and considers that revision of the proposal to ensure that short-chain alternatives are allowed to be used is necessary. Issues with analytical methods are also noted. Please see also response to Comment 1225. | |
| **1373** | **Date:** 2015/06/17 16:36  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes** | **General Comments:**  In protective clothing repellent finishes are used for different applications. Not all the applications are mentioned in the available documents. Therefor further work needs to be done to make sure that a large amount of workers would no longer be properly protected against the risks they face because of this limitation. | |
| **Answer to specific info request 1:**  In protective clothing repellent finishes are used for different applications. Can be for water repellence as described in the table with applications. However these finishes are very often used for (light) protection against liquid chemicals. This application is not included in the table. Protective clothing is subject to the Directive on Personal Protective Equipment (89/686). This type of protection is used on fire fighting clothing (harmonised standards EN 469) as a first barrier against chemicals, but also in industry as chemical protection type 6 (harmonised standard EN 13034). This type 6 protection is widely used in different types of industry where the risk of contact with chemicals is limited but not completely excluded. With this protection, the wearer has some time to go away from the risk and take off the clothing while the chemical remains on the surface of the clothing. To achieve this type of repellence, fluorocarbon finishes are applied to the fabrics used to produce the clothing, but also during the life cycle of the clothing the finish has to be reapplied to maintain the required level of protection. In practice this is done after each wash cycle. Both the textile and the textile service industry are shifting from C8 to C6 chemistry at the moment. This includes studies being done at the moment on the effectiveness of the C6 chemistry in all steps of the chain. So far, the results are promising, even if the C6 requires stricter conditions for activation, which certainly during the reapplication process leads to extra burdens for the textile service companies. | |
| **Answer to specific info request 4:**  One element that needs attention is the amount of ‘impurities’ in the C6 based products on the market for this application. Indeed it seems that there are some traces of C8 to be found in the C6 solutions and the limit of 2 ppb is unrealistically low. To determine a realistic limit, the manufacturers of the solutions offered to e.g. the textile services have to be consulted. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used. | |
| **RAC Rapporteurs comments:**  See response to Comments 1214 and 1279. The general lack of information on actual emissions from textiles means that RAC is unable to consider any derogations from a risk perspective. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1374** | **Date:** 2015/06/17 16:38  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:**  European Environmental Bureau (EEB)  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  The European Environmental Bureau (EEB) supports the restriction of PFOA and PFOA related substances, and would like to provide additional information on; adverse effects of PFOA, formation of PFOA from the degradation of other fluorinated substances, the content of PFOA and its precursors in textile articles as well as the environmental and health concerns related to shorter chained fluorinated substances proposed as alternatives. Finally, we also provide further information on possible safer alternatives for the use of PFOA in textiles. | |
| **Answer to specific info request 1:**  See attachment | |
| **Answer to specific info request 2:**  See attachment | |
| **Answer to specific info request 3:**  See attachment | |
| **Answer to specific info request 4:**  See attachment | |
| **Dossier submitter response:**  Thank you for your support.  The study by Grandjean et al. (2011) states that elevated exposures to PFCs were associated with reduced humoral immune response to routine childhood immunizations in children aged 5 and 7 years. A clear connection between PFOA exposure and reduced vaccine response was not demonstrated; “*However, a weakness is the close correlation between PFOA and PFOS, which makes mutual PFC adjustment difficult. Structural equation models suggest that the joint effects of major PFCs were stronger than those that could be ascribed to single compounds, and it is therefore possible that each of the major PFCs contribute to the effects.”* The possible immunotoxic effects of PFOA were therefore not mentioned in the proposal. | |
| **RAC Rapporteurs comments:**  The support is noted. Thanks for the information. RAC is aware of studies both in animals and epidemiological studies suggesting effects of PFAS on the immune system. At present, although of concern, it is felt that it is difficult to use this information in a quantitative way in a risk assessment. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  SEAC takes note of the information regarding alternatives and acknowledges this is a source of uncertainty regarding the cost-effectiveness of the proposed restriction. | |
| **1375** | **Date:** 2015/06/17 16:50  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:**  Health and Environment Alliance (HEAL)  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Summary of uploaded comments on Human Health Hazards. There are several epidemiological studies which suggest harmful effects in humans including both cross-sectional and longitudinal studies regarding metabolic, developmental and reproductive endpoints. This is of particular concern given the extremely long half-life of these chemicals in humans and widespread exposure. In addition, meta-analyses regarding the effects of developmental perfluorochemical exposure conclude that PFOA adversely affects human health due to evidence of decreased fetal growth in both human and nonhuman mammalian species.  These types of analyses are similar to those currently being used to direct human medical care, i.e. evidence-based medicine, and provide a means to integrate different studies and evaluate a whole body of evidence including statistical analyses. These types of analyses should be given considerable weight and their findings indicate that developmental exposures to these chemicals are of particular concern.  A particular issue arising from the epidemiological studies on metabolism is whether there are non-monotonic dose response relationships for the effects being studied.  The associations found or diseases or conditions implicated include: gestational diabetes, cholesterol / lipid levels which have implications for atherosclerosis, heart disease, pregnancy-induced hypertension or preeclampsia; sperm concentrations & sperm counts; serum testosterone in adolescent girls with implications for polycystic ovary syndrome, metabolic disorders, cardiovascular disease; and various fetal growth indicators and birth outcomes including: birth weight, length of gestation; abdominal circumference and birth length; gestational age, birth size; preterm birth, gestational age, head circumference; and finally risk of overweight at 20 years of age. | |
| **Dossier submitter response:**  Thank you for your comments.  We have addressed most of the epidemiological studies that you mention in your comment. We have also noted that it seems to be non-monotonic dose response relationships for some of the effects. Cfr. Chapter B.5.1.6.3; “*the epidemiological studies of the general populations report larger shifts in cholesterol per unit change in PFOA compared to the occupational studies.*” | |
| **RAC Rapporteurs comments:**  Thanks for the information on effects of PFOA on human health. At present, although of concern, it is felt that it is difficult to use this information in a quantitative way in a risk assessment. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. | |
| **1376** | **Date:** 2015/06/17 16:49  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** France  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** This response is confidential (CBI) as it derives from analyses of our company’s commercial products and revealing this information to competitors would undermine our company’s intellectual property and thus our commercial interests (article 4 paragraph 2 of Regulation (EC) No 1049/2001 applies). | **General Comments:**  With regards to the Proposed Restriction Dossier entitled, “Annex XV Restriction Report Proposal for a Restriction, Substance name: Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances” we submit the following comments. | |
| **Answer to specific info request 1:**  Fluorine free alternatives should not be seen as a “one size fits all” drop-in replacement to fluorinated products due to the reduction in performance and limitations of use according to EN1568 pt 3 & 4 and EN13565-2. | |
| **Answer to specific info request 2:**  An impurity limit for firefighting foam concentrates should be set which would permit existing companies to continue trading through the responsible production of C6 based foam concentrates. | |
| **Answer to specific info request 4:**  The impurity limit for firefighting foam concentrates should be set at 1,000ppb per analyte as there is no quantitative method to test to such a low LOQ of 2ppb within a firefighting foam matrix. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  Request 1:  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary.  Request 2:  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Request 3:  Thank you for the proposed threshold. We will take it into further consideration.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  Thanks for the constructive comments, suggesting an enforceable and realistic limit of 1 ppm for each analyte in fire fighting foams. However, since this is a potentially significant source of environmental exposure, RAC has not recommended any derogation for this use, but recognises that there are socio-economic factors for SEAC to address. | |
| **SEAC Rapporteurs comments:**  Thank you for proposing a threshold, it will be taken into account. SEAC understands that the 2 ppb limit could prevent the use of C6 alternative fluorinated foams and considers that revision of the proposal to ensure that short-chain alternatives are allowed to be used is necessary. Please see also response to Comment 1225. | |
| **1377** | **Date:** 2015/06/17 16:49  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Eurofins Product Testing A/S  **Org. country:** Denmark  **Company name confidential:** **No** | **General Comments:**  I represent Eurofins Product Testing as part of Eurofins Scientific. We have 17.000 employees across more than 200 laboratories in 35 countries worldwide. We perform commercial analyses for a wide range of industries and our annual revenue in the group as of 2015 is 1.4 billion Euro. We are in favour of the proposed restriction. | |
| **Answer to specific info request 2:**  We predict a potential for innovation in non-fluorinated/alternative types of material. We expect that we can | |
| **Answer to specific info request 4:**  We have made some research, and we estimate that it is possible for us to develop a method for the detection of PFOA and PFOA precursors down to 2 ppb. Our interest in developing the method is that we believe that there is an economic growth potential for us in testing chemicals like PFOA in consumer products. All our compliance methods are validated, which ensures equal competition in the market. | |
| **Dossier submitter response:**  Thank you very much for your support. | |
| **RAC Rapporteurs comments:**  The support is noted. It is useful to get an estimate of the time needed to develop the analytical methods, noting that methods for one or more lead substances may be required along with PFOA. It will be important to ensure repeatability and the minimization of interferences, especially given the large number of matrices that might need to be sampled. RAC has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  The information and support is noted. | |
| **1378** | **Date:** 2015/06/17 16:51  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:**  CTIF - International Association of Fire and Rescue Services, Hazmat Commission  **Org. country:** Austria  **Company name confidential:** **No**  **Attachment confidential:** **No**    **Privacy comment:** The joint statement from CTIF and FEU was writen under strong discussion and cooperation between our to organisations.  CTIF is the International Association of Fire and Rescue Services since more than 110 years.  We have at this time 36 member countries and most of them are from the European Union.  We are representing around 5 million fire fighters all over the world and protecting with them a population of one billion people.  FEU is the Federation of the European Union Fire Officers Associations representing senior fire service leaders out of 22 EU countries + Norway.  FEU expresses the opinion on any matter associated with fire service management, fire safety, fire fighting, disaster management, rescue and other emergency operations within the European Union and outside. | **General Comments:**  This draft regulation is absolutely not acceptable from the fire fighters perspective and will lead to a huge cost impact for fire brigades, both private as public.  As there are no alternatives, fire fighting without PFOA foams endangers the life of citizens in airplanes, workers in production plants, tank farms and above all fire fighters who have to respond those fires. Safety cannot longer be guaranteed in case of a fire. We will get fatalities and huge environmental disasters.  Representing the fire services and the fire fighters, we firmly ask you to review this amendment or to make an exception for the use of PFOA containing firefighting foams, till there are fully tested alternative products that can completely fulfil the same safety and tactical standards | |
| **Answer to specific info request 1:**  Please look at our enclosed joint statement from CTIF and FEU "20150617\_PFOA foam\_joint paper\_CTIF\_FEU.pdf" under IV. Non-confidential attachments | |
| **Answer to specific info request 2:**  Please look at our enclosed joint statement from CTIF and FEU "20150617\_PFOA foam\_joint paper\_CTIF\_FEU.pdf" under IV. Non-confidential attachments | |
| **Answer to specific info request 3:**  Please look at our enclosed joint statement from CTIF and FEU "20150617\_PFOA foam\_joint paper\_CTIF\_FEU.pdf" under IV. Non-confidential attachments | |
| **Answer to specific info request 4:**  Please look at our enclosed joint statement from CTIF and FEU "20150617\_PFOA foam\_joint paper\_CTIF\_FEU.pdf" under IV. Non-confidential attachments | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The use of PFOA and PFOA-related substances in AFFF is not necessary. Alternatives based on short-chain chemistry are available and widely used. It is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  SEAC is conscious that alternatives need to remain available and affordable for this critical use of PFOA and PFOA-related chemicals. Please see response to Comment 1225. | |
| **1379** | **Date:** 2015/06/17 16:57  **Type:** BehalfOfAnOrganisation  **Org. type:** International organisation  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** The attached file contains CBI information such as names, suppliers and other company names/information. | **General Comments:**  Our company supports the reduction in the overall environmental impact of fires, and of firefighting foams for use at emergency incidents and during training exercises. It is our goal to work with regulatory bodies to reduce the environmental footprint of our products, whilst improving their performance. The proposed level of 2ppb for PFOA and PFOA-related substances is at such a level to prevent the sale, use and movement of raw ingredients and finished product throughout the EU for both long-chain (C8) and short-chain (C6) fluorochemical based foams, which are listed in section C1 as a viable alternative (Identification of potential alternative substances and techniques). | |
| **Dossier submitter response:**  Thank you for the information and the proposed threshold. We will take it into further consideration. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for proposing a threshold. SEAC understands that the 2 ppb limit could prevent the use of alternative fluorinated foams and considers that revision of the proposal in this regard is necessary. Please see response to Comment 1225. | |
| **1380** | **Date:** 2015/06/17 18:21  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** United Kingdom  **Company name confidential:** **Yes** | **General Comments:**  We do not contest the need for a restriction, however, we do not believe it is practically possible to place a 2 ppb limit on Perfluorooctanoic acid (PFOA, CAS 335-67-1, EC 206-397-9), salts and related substances, particularly for downstream users. We do not actually manufacture PTFE, and as a downstream user we do not have the capability to obtain detailed information on the manufacturing process and have to rely upon representations from our suppliers. Our suppliers’ standard protocol is to issue letters stating that to the best of their knowledge, they do not expect PFOA to be present in the materials that they supply. We feel this limit is unreasonable for the following reasons:  • As an ISO 9000 company, we must rely upon certificate of analysis and/or other statements of quality from our suppliers. It would be unreasonable to expect a downstream user to test each raw material for impurities. After having consulted with our suppliers, many feel they do not have the technical means to provide us with data indicating that there is less than 2 ppb of PFOA (and its salts) present in the materials they supply to us.  • There is currently no reliable or standardized method to measure PFOA content at low levels (ppm). Accurate analysis at ppb levels would be difficult in practice, and the use of currently available methods in many cases could result in a false positive. This could be further confounded as PFOA is known to be found in the normal environment. With such a low restriction limit as 2 ppb, even if it were possible to quantify down to 2 ppb (for all substances covered by the restriction in a variety of matrices), it is likely that external interferences could also introduce false positives. Therefore, we feel that it would be impossible to demonstrate that we are compliant.  Based on these points, we do not feel that the proposed limit is attainable, in terms of practicality and monitoribility, nor will its effectiveness prove more beneficial than the measures already taken voluntarily by industry. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  It is not our aim to restrict the manufacturing and use of PTFE with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers. PTFE manufactured without PFOA is already available on the market and will not be affected by the proposed restriction.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  We share the concern that the 2 ppb limit is too strict with respect to analytical possibilities. A higher limit is needed. Whilst RAC agrees with the DS that the restriction can be an incentive to develop analytical methods, there has to be a realistic prospect of the development of a reliable method within an appropriate time frame to provide legal certainty for all actors. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree that the 2 ppb limit is not feasible and we support higher concentration limits (25 ppb for PFOA and its salts, 1000 ppb for PFOA-related substances). | |
| **1381** | **Date:** 2015/06/17 18:23  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  EPBA - European Portable Battery Association  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  See attachment under IV | |
| **Answer to specific info request 1:**  See attachment under IV | |
| **Answer to specific info request 2:**  See attachment under IV | |
| **Answer to specific info request 3:**  See attachment under IV | |
| **Answer to specific info request 4:**  See attachment under IV | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information.  To the best of our knowledge PVDF is possible to be manufactured without PFOA and PFOA related substances (see e.g. http://www.epa.gov/opptintr/pfoa/pubs/arkemaresponse.pdf)  It is not our aim to restrict the manufacturing and use of fluoropolymers such as PTFE and PVDF with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers. PVDF manufactured without PFOA is already available on the market and will not be affected by the proposed restriction. | |
| **RAC Rapporteurs comments:**  The restriction will not affect the manufacturing and use of fluoropolymers, but the intention is to restrict the use of PFOA and its salts for the manufacture of fluoropolymers. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  Note is taken of concerns regarding threshold value and transitional period. | |
| **1382** | **Date:** 2015/06/17 18:27  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  FluoroCouncil  **Org. country:** United States  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Detailed comments are provided in the attached document. | |
| **Dossier submitter response:**  The DS is grateful for the comments made.  The proposals for thresholds, scope and certification for PFOA free fluoropolymers will be evaluated and taken into further consideration.  The Dossier submitter is grateful for the new information on costs of switching to alternatives and will consider it in the further development of the Background Document.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  PFOA and PFOA related substances were identified by the ECHA Member State Committee as PBT substances in [June 2014](http://echa.europa.eu/documents/10162/86f13df6-a078-475c-b0b2-2eb9536ebc5d). According to REACH Annex I, section 6.5, 2nd paragraph the emissions of these should therefore be as low as possible in order to protect humans and the environment. It is therefore not feasible to derive a threshold value for PFOA and PFOA related substances relying on the use of a human health risk assessment.   * Human Health   The toxicology value (RfD) proposed by USEPA (2014) in its recent Draft Health Effects Document cannot be used as a DNEL, since US EPA states clearly that the draft report may not be cited or quoted. | |
| **RAC Rapporteurs comments:**  The lack of standardized analytical methods for all substances and in all matrices should not be a reason to stop the restriction, as the restriction can trigger development of analytical methods. However, RAC has sympathy for a step-wise procedure with lowering of limits as the methods are being developed and improved. RAC welcomes the information on the new thermolysis method that can be used to distinguish C8 from C4-C6 chemicals. RAC has recommended that the Commission takes due account of analytical developments in future. The proposal to include C8 methacrylate monomer and C8 acrylate monomer as lead/indicator substances is noted. The RAC opinion has clarified that polymers with a fluorinated backbone are outside the scope of this restriction. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  The cost information provided by FluoroCouncil Members on developing alternatives is not caused by the proposed restriction. However, it is considered as relevant background information. The qualitative information provided on reformulation costs has been considered by SEAC in its opinion.  SEAC considered the possibility to derogate the manufacture of fluoropolymers based on a voluntary scheme, but found that the revision of the concentration limits avoided the need for a specific derogation. | |
| **1383** | **Date:** 2015/06/17 18:30  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Currenta  **Org. country:** Germany  **Company name confidential:** **No** | **General Comments:**  Vorbemerkung  Mit großer Sorge verfolgt Currenta, der größte deutsche Chemieparkmanager und –betreiber die anhaltende Diskussion um die Grenzwerte von PFOA und PFOA-verwandte Stoffen auf Grund der sich daraus etwaig ergebenden Einschränkungen der Gefahrenabwehr.  Die Currenta GmbH & Co. OHG ist Manager und Betreiber der drei Chempark-Standorte Leverkusen, Dormagen und Krefeld-Uerdingen.  Das Joint-Venture von Bayer und Lanxess bietet den 70 angesiedelten CHEMPARK-Partnern auf rund elf Quadratkilometren mehr als 1.000 chemienahe Dienstleistungen an. Dazu zählen unter anderem Energieversorgung, Umweltdienstleistungen, Sicherheit, Infrastruktur, Analytik, Ausbildung, Logistik und Instandhaltung. Teile dieser Leistungen werden von den rund 5.300 Mitarbeitern der Currenta und den beiden Tochtergesellschaften Chemion und Tectrion auch für externe Kunden erbracht.  Das Geschäftsfeld Sicherheit der Currenta ist neben vielen weiteren Aufgaben für die operative Gefahrenabwehr innerhalb der Standorte verantwortlich. Durch die Vernetzung der Gefahrenabwehrphilosophie der Werkfeuerwehr mit der Löschtechnik der Betriebe nutzt die Currenta vorhandene Synergien für eine effektive Bearbeitung von Schadenlagen. Dazu gehört ein verantwortungsbewusster Umgang mit Schaummitteln, ohne die Brände in der chemischen Industrie nicht effektiv zu bekämpfen sind.  Ca. 330 Werkfeuerwehrleute sorgen an den drei Standorten für die notwendige Abdeckung des von den Aufsichtsbehörden geforderten personellen Sicherheitsniveaus.    Von Deutschland und Norwegen vorgeschlagene Beschränkung der Perfluoroctansäure (PFOA), ihre Salze und PFOA – verwandte Stoffe  „PFOA and PFOA-related substances“  1. Allgemeines  Die Feuerwehren setzen bei der Brandbekämpfung in Chemieanlagen und Tanklagern Schaumlöschmittel ein, in denen per- und polyfluorierte Tenside enthalten sind. Der einzig geeignete Schaumtyp für die Brandbekämpfung in der chemischen Industrie sind Konzentrate, die eine sehr gute „Rückbrand“-Resistenz aufweisen, darüber hinaus über schnelle Löscheigenschaften verfügen und die gültigen Umweltschutzstandards einhalten.  Aufgrund der Lagerung und Verarbeitung von sehr großen Mengen an brennbaren Flüssigkeiten in der chemischen Industrie müssen vor der Beschaffung von Schaumlöschmitteln, die in Chemieanlagen und Tanklager zum Einsatz kommen sollen, deren Eignung nach bestimmten europäischen Normen und Brandtestverfahren überprüft und zudem die Eignung der Schaumlöschmittel möglichst bei realen Brandbekämpfungen nachgewiesen worden sein. Infolge der gerade in den letzten Jahren gestiegenen Umweltschutzstandards (PFOS Beschränkung) lassen sich die Feuerwehren vor einer Beschaffung von Schaumlöschmitteln deren Zulassung und Einhaltung der Umweltschutzstandards durch den Schaummittellieferanten bescheinigen.  2. Eignung von Schaumlöschmitteln  Als Testverfahren für Schaumlöschmittel werden u. a. die europäischen Normen EN 1568-3 für nichtpolare Brennstoffe und EN 1568-4 für polare Brennstoffe genutzt und zusätzlich die von international tätigen Mineralölunternehmen aus der jahrzehntelangen Erfahrungen heraus entwickelten Brandtestverfahren, die sog. LASTFIRE-Tests.  Nach der o. g. EN 1568-3 und EN 1568-4 geprüfte und zugelassene Schaumlöschmittel erreichen eine sog. Löschleistungsstufe, die auf ihren Löschleistungs- und Rückbrandeigenschaften beruht. Für einen Schwerschaum für nicht-polare Brennstoffe (EN 1568-3) bestehen drei Löschleistungsstufen (I, II, III) und vier Rückbrandbeständigkeiten (A, B, C, D), wobei die Löschleistungsstufe IA die höchste (beste) Stufe ist. Für einen Schwerschaum für polare Brennstoffe (EN 1568-4) bestehen zwei Löschleistungsstufen (I, II) und drei Rückbrandbeständigkeiten (A, B, C).  Die Tests nach LASTFIRE und der europäischen EN 1568 ergänzen sich somit gegenseitig, so dass die Feuerwehren in der chemischen Industrie sehr großen Wert auf Einhaltung und Erfüllung beider Testverfahren legen. Darüber hinaus wurde die Eignung verschiedener Schaumlöschmittel auch in größeren Brandversuchen in der Vergangenheit getestet so z. B. bei Tankbrandversuchen in Ungarn und in den USA bzw. es liegen in Einzelfällen auch Ergebnisse aus weltweiten realen Tankbränden vor.  3. Löscheinrichtungen und Löschtaktik, Toxizität  Von der Einhaltung der Umweltschutzstandards, der Klassifizierung nach Normen und insbesondere den Testergebnissen von kleineren bzw. größeren Brandversuchen hängt die Beschaffung der eingesetzten Schaumlöschmittel in der chemischen Industrie ab.  Aus diesen Rahmenbedingungen heraus haben sich in den letzten 30 bis 40 Jahren die sog. AFFF-Schaummittel (AFFF = aqueous film forming foam) als die am besten geeigneten Schaumlöschmittel in der chemischen Industrie durchgesetzt. AFFF-Schaumlöschmittel sind aufgrund ihrer enthaltenen Fluortenside in der Lage, zwischen der brennbaren Flüssigkeit und dem eigentlichen Schaum einen hauchdünnen Wasserfilm zu bilden, auf dem der Schaum auf der brennenden Oberfläche bis zu 30 m weit fließt. Durch diesen Wasserfilm sind die AFFF-Schaumlöschmittel sehr rückzündungssicher, sehr löschwirksam und bieten der Löschmannschaft dadurch einen größtmöglichen Schutz bei der Brandbekämpfung.  Durch die Entwicklung und weite Verbreitung der AFFF-Schaumlöschmittel haben sich in den letzten 25 Jahren auch die technische Ausrüstungen von Chemieanlagen und das taktische Vorgehen der Feuerwehren in solchen Fällen wesentlich verändert. Wurde in den 70iger Jahren noch sehr viel Wert auf stationäre Löschanlagen gelegt, sind es heute meist große mobile Löscheinrichtungen, die ihre Wirkung nur im Zusammenspiel mit den Löscheigenschaften der AFFF-Schaumlöschmittel und der speziellen Einsatztaktik der Feuerwehr erzielen. Ohne den Einsatz dieser mobilen Großbrandbekämpfungseinrichtungen und der AFFF-Schaumlöschmittel sind Tankbrände, Brände in Chemieanlagen, große Flächenbrände unterhalb von verfahrenstechnischen Anlagen, Brände von Tankschiffen und Eisenbahnkesselwagen nicht zu löschen und somit der Schutz der Umwelt und der Gesundheit (z. B. bei toxischen Holdups) nicht zu gewährleisten.  4. PFOS Beschränkung und deren Folgen  Nach Festsetzung des europaweit gültigen Grenzwertes für PFOS von 10.000 µg/l waren viele Feuerwehren in der chemischen Industrie im Jahr 2010/2011 gezwungen, die PFOS haltigen Schaumlöschmittel gegen PFOS freie Mittel auszutauschen. Die alten Schaumlöschmittel mussten entsorgt werden und die Lageranlagen für Schaumlöschmittel vor der Lagerung der neuen Mittel aufwändig gereinigt werden. Die dabei angefallenen Spülwässer wurden ebenfalls entsorgt.  5. Einsatz fluorfreier Schaumlöschmittel  Im Jahr 2010/2011 standen viele Feuerwehren vor der Frage, ob fluorfreie Produkte ebenfalls die gleiche Löschleistung erbringen können wie ein AFFF.  Wie oben bereits beschrieben, wird für Schaumlöschmittel durch Tests gemäß EN 1568-3 und EN 1568-4 eine Löschleistungsstufe ermittelt. Die so ermittelte Löschleistungsstufe geht anschließend in die Berechnungen sog. Aufgaberaten nach EN 13565-2 ein, wo rechnerisch in Abhängigkeit von einem Brandszenario ermittelt wird, welche Schaumlöschmittelmengen zum Löschen und damit zur Beherrschung des Brandszenarios erforderlich sind.  Nach EN 13565-2 sind Schaumlöschmittel der Löschleistungsstufe 3A bis 3D nicht zur Brandbekämpfung von großen Kohlenwasserstoffmengen geeignet und aus diesem Grund wird in der Norm kein Berechnungsfaktor für derart eingestufte Schaumlöschmittel genannt.  Einige der fluorfreien Schaumlöschmittel sind nach EN 1568-3 in der Löschleistungsstufe 3D eingestuft und somit für den Einsatz bei Tankbränden, Tankauffangraumbränden, Bränden in verfahrenstechnischen Anlagen, Tankschiff- und Eisenbahnkesselwagenbränden nicht geeignet. Andere fluorfreie Produkte erfüllten nicht die kompletten LASTFIRE-Tests bzw. fielen bei praktischen Löschversuchen z. B. an einem recht kleinen Tank von 9 m Durchmesser bereits durch.  Die Erfahrung der letzten Jahre zeigt zudem, dass die fluorfreien Schaumlöschmittel gerade bei Bränden an Anlagen der chemischen Industrie nicht das eingehalten haben, was versprochen wurde und daher einige Betriebe die fluorfreien Produkte bereits wieder ausgetauscht und durch ein AFFF-Schaumlöschmittel ersetzt haben.  6. Haltbarkeit von Schaumlöschmittel  Die Erfahrung zeigt, dass Schaumlöschmittel durchaus eine Haltbarkeit von weit über 20 Jahren erreichen. Zum Teil sind heute noch Schaumlöschmittel im Einsatz, die vor 1990 gekauft wurden. Ihre löschwirksame Eignung wird nach den Vorgaben der EN 13565-2 einmal jährlich durch eine Analyse nachgewiesen.  So kann heute davon ausgegangen werden, dass die in 2010/2011 aufgrund der PFOS Beschränkung neu beschafften Schaumlöschmittel durchaus über das Jahr 2031 hinaus ihre löschwirksame Eignung beibehalten und eingesetzt werden können.  7. Anforderungen der Feuerwehren  Im Zuge der PFOS Beschränkung hat es in den Jahren 2010 und 2011 mehrere Fachgespräche unter Beteiligung verschiedener Behörden, Schaummittelproduzenten, Feuerwehren und Forschungsinstitute zusammen mit dem Umweltbundesamt in Deutschland gegeben. Unter anderem wurde ein gemeinsames Merkblatt unter Beteiligung des Umweltbundesamtes“, des Deutschen Feuerwehrverbandes e.V. „DFV“ und des Bundesverbandes Technischer Brandschutz e.V. „bvfa“ zum umweltschonenden Einsatz fluorhaltiger Schaumlöschmittel erstellt , das in den deutschen Feuerwehren bekannt ist und an dessen Empfehlungen sich die Feuerwehren halten.  Leider ist es den Forschungsinstituten und Schaummittelproduzenten bisher nicht gelungen, ein Ersatzmittel für die AFFF-Schaumlöschmittel und den in der chemischen Industrie vorliegenden Spezialanwendungen zu entwickeln. Die heute bekannten „Ersatz“-Schaumlöschmittel weisen nicht einmal ansatzweise die benötigten Eigenschaften der AFFF-Schaumlöschmittel auf und können daher nicht bei Bränden großer Kohlenwasserstoffmengen und beim Abdecken toxischer Substanzen in der chemischen Industrie eingesetzt werden.  Ohne den Einsatz der heute vorgehaltenen AFFF-Schaumlöschmittel ist der Brandschutz, Umweltschutz und Gesundheitsschutz derzeit in der chemischen Industrie und bei Transportunfällen nicht zu gewährleisten.  8. PFC-Analytik  Es gibt z. Z. keine Möglichkeit, die von Deutschland und Norwegen beantragte PFOA-Verbotsschwelle von 2 ppb (2 µg/kg) in Schaumlöschmitteln sicher und reproduzierbar zu analysieren. Die Matrix der Schaumlöschmittel ist dafür viel zu komplex. Es gibt kein standardisiertes Verfahren für die PFOS/PFOA-Analytik in Schaummitteln um die 2 µg/kg nachweisen zu können.  Die Reproduzierbarkeit der PFOS/PFOA-Analytik zwischen unterschiedlichen Laboren liegt z. T. bei einigen 100%. Bei einigen der aufgeführten Schaumlöschmittel wurden die Schaummittelproben parallel in verschiedenen Laboren auf die gängigsten PFCs analysiert. Dabei wurde die v. g. Abweichung bei einigen PFCs sehr deutlich. Der Fehler innerhalb eines Labors liegt bereits zwischen 35 und 50%.  9. PFOA Begrenzung  Schon nach dem PFOS-Verbot gab es bei vielen Anwendern von Schaumlöschmitteln große Probleme, den geltenden Grenzwert (10.000 µg/kg) einzuhalten. Infolge nicht ausreichend gereinigter Behälter/Anlagen kam es zum Eintrag von PFOS in die neuen Schaumlöschmittel.  Eine Begrenzung des „PFOA and related substances“ -Gehaltes auf 2 ppb (2 µg/kg) ist fern jeder Praxis, analytisch nicht messbar und würde die Anwender von Schaumlöschmittel vor unlösbaren Problemen und rechtlichen Konsequenzen stellen.  Die heute zum Einsatz kommenden fluorhaltigen Schaumlöschmittel werden in stationären Anlagen mit Behältern, weit verzweigten Rohrleitungen, Pumpen und Zumischeinrichtungen sowie in mobilen Anlagen wie Feuerwehrfahrzeugen und Schaummittelcontainern bevorratet. Nach den beim PFOS-Beschränkungsverfahren gemachten Erfahrungen, wird es nicht möglich sein diese stationären und mobilen Einrichtungen derart zu reinigen, dass eine Kontamination der neuen Löschmittel vermieden wird.  Die Feuerwehren würden unweigerlich vor einem Legal Compliance Problem stehen, denn ein derart niedriger Grenzwert wäre wahrscheinlich nur durch Neubau sämtlicher Schaumlöschmittelsysteme erreichbar. Somit stellt der Grenzwert von 2 ppb (2 µg/kg) eine unverhältnismäßige Anforderung dar.  Ferner wird die Werkfeuerwehr Chempark im Rahmen des Transport-Unfall-Informations- und Hilfeleistungssystem (TUIS) von öffentlichen Feuerwehren bei Einsätzen mit Chemikalien angefordert, um diese mit Fachwissen und organisatorischen und technischen Komponenten zu unterstützen. Dazu gehört auch die Bereitstellung von speziellem Löschschaum (z.B. alkoholbeständigem Schaummittel), ohne die eine erfolgreiche und effiziente Gefahrenabwehr nicht möglich ist. Ein Eintrag von Schaummittel außerhalb des Chemparks ist in diesem Rahmen nicht auszuschließen. Mit den jetzigen zur Verfügung stehenden Schaummitteln ist bei Anpassung der Grenzwerte auf 2 ppb eine Grenzwertüberschreitung im öffentlichen Raum zu rechnen. Die rechtlichen und ökonomischen Konsequenzen sind nicht abzusehen.  Wir sind nicht daran interessiert, Fluorchemikalien mit den im Brandfall eingesetzten Schaumlöschmitteln in die Umwelt zu bringen. Wir haben die Einführung des PFOS-Grenzwertes von 10.000 µg/kg mitgetragen und die hoch belasteten Schaumlöschmittel mit erheblichem finanziellen Aufwand ausgetauscht.  Zum Schutz und zur Sicherheit der Nachbarn unserer Anlagen, der Menschen, die in unseren Anlagen arbeiten, und unserer Verarbeitungs-, Lager- und Verladeanlagen müssen wir einen effektiven und wirkungsvollen Brandschutz sicherstellen, der letztendlich durch die Betrachtung eines integrierten Ansatzes auch dem Umweltschutz erheblich zu Gute kommt.  Unabhängig davon hat die chemische Industrie die Vorgehensweisen bei Großschadensfällen bezüglich ihrer Umweltrelevanz untersucht und mit Hilfe der Ökoeffizienzanalyse nachgewiesen, dass effiziente Maßnahmen mit fluorhaltigen Schaumlöschmitteln nachhaltig zum Schutz der Umwelt beitragen.  Diese gesamtheitlichen Aufgaben sind derzeit nur mit wirkungsvollen Löschsystemen und Löschtaktiken sowie die darauf abgestimmten AFFF-Schaumlöschmittel sicher zu stellen.  Aus den v. g. Gründen beantragen als Unternehmen:  a. Ablehnung des 2 ppb Grenzwertes für “PFOA and related substances“  Der Grenzwert für „PFOA and related substances“ von 2 ppb (2 µg/kg) ist unverhältnismäßig und liegt um das 5000 fache unterhalb der Verbotsschwelle für PFOS von 10.000 ppb (10.000 µg/kg).  b. Übergangszeit bis zum 27.06.2031  Falls unausweichlich eine „PFOA and related substances“ Begrenzung erforderlich sein sollte, beantragen wir einen Grenzwert, der die Weiternutzung aller in unseren Werken bevorrateten Schaummittel bis zum 27.06.2031 garantiert. Dies stellt eine 20 jährige Weiternutzung nach der für uns relevant gewordenen Verbotsgrenze für PFOS zum 27.06.2011 und der daraufhin im Jahr 2011 neu beschafften Schaumlöschmittel dar.  c. Verlässliche Rahmenbedingen  Wir lehnen es ab, nach Umstellung wegen der Einführung eines PFOS-Grenzwertes, schon wenige Jahre später die Schaumlöschmittel aufgrund der Begrenzung eines weiteren PFCs auszutauschen. Es sind einige hundert PFCs am Markt verfügbar und es kann daher nicht sein, dass alle paar Jahre die Schaumlöschmittel wegen der scheibchenweisen Begrenzung eines weiteren PFCs getauscht werden müssen. Wir benötigen verlässliche Rahmenbedingungen zur Beschaffung und Nutzung von Schaumlöschmitteln um die Sicherheit in und um unsere Industrieanlagen zu gewährleisten.  d. Einstellung des Antrages von Deutschland und Norwegen  Aufgrund fehlender Alternativen zu den heutigen AFFF-Schaumlöschmitteln beantragen wir die Einstellung des PFOA-Verbotsverfahrens bis zum Vorliegen geeigneter alternativer Löschmittel. Die heute zur Gefahrenabwehr vorgehaltenen Schaumlöschmittel enthalten nur noch einen Bruchteil der PFOS- und PFOA-Konzentrationen wie vor dem PFOS-Verbot im Jahr 2011. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The threshold should be as low as possible, since the use will directly lead to environmental emissions and severe damage as it can be seen from a lot of damage events/remediation sites. When the environment around fire drill sites has been polluted with PFOA and PFOA-related substances, remediation costs for these sites are high. Moreover, it is impossible to capture 100% of the released PBT substances. Since areas spilled with fire-fighting foam are usually rather large it is impossible in most cases to exchange the contaminated soil completely. Over the time remaining residuals bound in soil will leach into the underlying ground water. Thus, a major part of the released PFOA and PFOA-related substances will remain in soil and groundwater, even after remediation steps have been applied.  Nevertheless, it is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting-agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the garanteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC is conscious that short chain alternatives need to remain available and affordable for this critical use of PFOA and PFOA-related chemicals. SEAC supports a limit value of 1000 ppb for both PFOA and its salts and PFOA-related substances. Monitoring costs have also been considered by SEAC. Please see also response to Comment 1225. | |
| **1384** | **Date:** 2015/06/17 18:33  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes** | **General Comments:**  We would like to state clearly, that Textile industry PFOA and related substances are not being used but only occur as impuities in processing agents | |
| **Answer to specific info request 1:**  As mentioned above processing agents contain PFOA and related substances only as impurities. Due to cross-staining there is no product on the market, that is compliant to the 2 ppb-Limit. The informations supplied ba SDS do not contain Details regarding PFOA and / or related substances. Alternative processing agents - if possible at all - must be used in multiple amounts compared to common fluorine processing agents while not achieving the necessary properties and demands. | |
| **Answer to specific info request 2:**  The Topic "related substances" is new for the Textile industry, we have no Information regarding this Point. Pleas refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional Information is available. | |
| **Answer to specific info request 4:**  According to Information provided ba our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb Limit by far. So this Limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced. | |
| **RAC Rapporteurs comments:**  The information is noted. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree that the 2 ppb limit is not feasible and we support higher concentration limits (25 ppb for PFOA and its salts, 1000 ppb for PFOA-related substances). | |
| **1385** | **Date:** 2015/06/17 18:35  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Switzerland  **Company name confidential:** **Yes**  **Attachment confidential:** **No** | **General Comments:** | |
| **Answer to specific info request 1:**  **<removed>** (as other industries part of the semiconductor manufacturing industry sector) produces semiconductor devices (microchips). PFOA related substances are used in very minor quantities (total of 13kg/y in all Europe locations) at low concentrations (500 ppm max) in some speciality formulations in a semiconductor industry manufacturing step called photolithography. These substances are critical to this manufacturing step due to their high technical functionality (as per Appendix C , Table A.C.1.1 Potential alternatives and technologies in the annex XV proposal) The industry and its photolithography formulation supply chain are aware of the concerns regarding these chemicals, and have already made substantial efforts where technically feasible to eliminate them from the manufacturing process formulations. Over the past number of years the European semiconductor industry has been transitioning away from uses of PFOA itself in photolithography. Currently however for the critical photolithography uses there are no adequate technically feasible alternatives for PFOA related substances that can be used as replacements for all applications. **<removed>** believes that RMO 1b should be considered as appropriate especially for sectors that require exemptions and a longer transition time (effective date) due to remaining critical uses where substitution is technically unfeasible, where the use in absolute terms is very low, emissions are well managed and substances subject to restriction do not remain in the final product. More over the exemption should be granted for a period of 10 years and should be followed by a review to determine if an extension is required. Unavailability of alternatives is welle known since it is reported in the annex XV proposal (page 157 E2.2.1.2) - There are no feasible alternatives for all critical uses in photolithography  PFOA related substances were introduced due to regulatory concerns on previous used PFOS substances, that **<removed>** has completely removed from the photolithography chemistry used in European sites, since 2012. PFOA related substances are used in older and newer technologies. Therefore the search of alternatives linked exclusively to regulatory issues could make vain years of technology development and significant advantage gained versus non EU competitors. Moreover it will induce costs on the EU companies that non EU competitors are not requested to afford.  There is very minimal release to the environment in wastewater. Based on collected figures from European sites located in France and Italy the photolithography usage per annum ofapprox. 13kg/ythe overall, emissions through wastewater based on expert engineer knowledge of the process technology and processing waste stream would give rise to about 0.5 kg/y  Page 67 - Paragraph B 4.4.2.3 Environmental release from the semiconductor industry  It is incorrect to say that PFOA related substances remain enclosed in the final semiconductor product, the device. They do not. This reference needs to be removed from this section of the report. There also are no emissions to air possible from the end of life stage as there are no PFOA-like substances contained in the semiconductor device. In addition there are no emissions to air arising from the manufacture of semiconductors due to low use and low volatility of photolithography formulations. VOC treatment systems are in place that would treat any potential emissions of PFOA and related substances. Environmental release category 5 (ERC5) has been attributed to this use with an associated 50% release factor. This is inaccurate as the substances do not remain in the final product and the release factor is significantly lower. The more accurate characterisation of correct ERC for semiconductor manufacturing is, therefore, ERC 4. The release factor based on expert engineer research is 3.8%. as a conservative figure.  Overall the emission estimated at 0.5 kg/y is representing the 0.014 % of the post 2015 total estimated emissions (with reference to Table F.1-1: Estimated annual use volumes and emissions of PFOA (red) and PFOA-related substances (blue) in the annex XV proposal). | |
| **Answer to specific info request 2:**  No cost analysis has been performed on small volume users like semiconductor industry in the annex XV dossier. Due to the high tech nature of semiconductor production compared to 5 sectors/markets that have been assessed in the annex XV dossier the costs from these other sectors cannot be extrapolated to the semiconductor sector and as such are not representative for semiconductor industry.  **<removed>** European sites would have a major impacts in case the restriction would be approved as such. For France and Italy it would imply a possible relocation of manufacturing activities to non European sites that could lead to thousands of jobs cut and reduction of ability to contribute to European Economy. For Malta there would be a domino effect due to missing European front end activities, as much as the 15 % of the whole current employment and billing capacity. There may be a longer term negative impact on **<removed>** future investment ad missing credibility from customers, linked to possible missed commitment. Europe’s position as a global competitor in the semiconductor sector may be damaged. | |
| **Answer to specific info request 4:**  The threshold of 2ppb would mean a de facto ban on of all the short chain Fluorinated compounds alternatives in photolithography. These are the substances which the semiconductor industry is transitioning into for its photolithography critical manufacturing processes since the last 15 years due to the regulatory concerns with PFOS and now PFOA and PFOA related substances. A ban is dis proportionate.  Semiconductor industry would have concerns on the concentration limit approach as a user of manufacturing equipment articles containing fluoropolymers that may have been made in the upstream supply chain using in scope substances. The 2ppb limit seems not practical in an industrial setting. A dedicated threshold for each article category would probably be a suitable way. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  Risk management measures regarding human health and environment are in place. Furthermore, semiconductor industry is a minor user of PFOA related substances. There are very low emissions into the environment. Therefore, the Dossier submitter would agree with a longer transitional period for the remaining critical uses in photolithography. | |
| **RAC Rapporteurs comments:**  Thanks for the detailed information. In the view of RAC, the emissions from the semiconductor industry (and photolithograpy) seem negligible, which in combination with the use pattern warrants a derogation. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1303. | |
| **1386** | **Date:** 2015/06/17 18:56  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Eucomed and EDMA  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  In additiona to the preliminary comments submitted on 28 February 2015 - Eucomed, the European medical technology association and EDMA, the European Diagnostic Manufacturers Association welcome the opportunity to provide input to ECHA on the proposed restriction of the manufacturing, use and placing on the market of Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances.  Use of PFOA and related substances in Medical Devices  The proposed substances for restriction are used as non-polymeric substances or as part of side-chain fluorinated polymers, such as fluoroacrylate polymers. The Annex XV Restriction report has already identified the following uses in generic components that can end up in a Medical Device:  • Cable and wiring  • Electronics (insulators, solder sleeves, vapour phase soldering media),  • The photographioc and imaging industry (e.g. g. when using traditional black and white film in Xray photography)  • Medical Articles (non-woven medical garments, Surgical patches cardiovascular grafts, raw material for implants in the human body; stain- and water-repellents for surgical drapes and gowns)  A quick survey within the membership of Eucomed and EDMA identified some additional uses in components that (possibly) contain PFOA’s. The presence of the PFOA is related to the use of polymers such as PTFEs. These polymers are used in medical devices for their specific properties, such as:  • chemical resistant tubing,  • heat resistant wiring  • lubricative coatings on metals,  • lubricative coatings on plastics.  The above mentioned components result in application within a wide range of medical devices including sensors, cardiovascular devices, protection tubing, implants and orthopaedic devices. Within the timeframe of this consultation it is not feasible to generate a complete overview of the applications, possible substitutes and costs of substitution for the entire sector.  Medical devices that are placed on the market are in most cases articles. The experience with the inclusion of medical devices within scope of the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) shows that minimum 18 months are required to initially collect information on relevance of a new substance proposed for a ban/restriction, due to the complexity of the supply chain as well as its global nature.  Additional challenges to the proposed restriction of PFOA, its salts and PFOA-related substances compared to those under the RoHS Directive are twofold:  1) PFOA’s are not intentionally added by the medical device manufacturers, but a remaining building block of the used substances of the components (polymers)  2) The extreme low threshold of 2 ppb.  PFOA’s as a remaining substance in the building block of components  Medical device manufacturers count up to 11000 suppliers and 5 to 7 tiers. Most of the supply chain moreover is located outside Europe thus making the collection of information even more difficult and slower. Production of PFOA has ceased in the EU and decreased dramatically in the US and Japan under a voluntary program. However, the main component production is outside of Europe and may use PFOA (produced in China and India) as raw material input for the production of the applied polymers.  Need for safer and more workable threshold  The European medical technology industry is concerned that the proposed threshold of 2 ppb is extremely limited and not proportionate to the objective of eliminating PFOA from the end product. The proposed limit value for articles is extremely low especially when seen in comparison with the threshold values adopted in the Regulation (EC) No. 850/2004 and its amendment 757/2010/EC addressing PFOS. The existing threshold value of PFOS in Regulation 757/2010/EC is 0,001% w/w (= 10 ppm) which is compared to the proposed 2 ppb 500 times higher.  Measuring a level as low as 2ppb would represent a significant technical and costly challenge for manufacturers. Although most of them have sophisticated testing equipment available, they are not able to measure to such an extremely low threshold. On the market available tests with the lowest detection limit, Q-TOF GC/MS, has a limit around and above the proposed threshold (2-3 ppb).  No manufacturers will have in-house testing and consequently, most of them would be unable to conduct their own in-house measurements to confirm compliance. They would either have to invest very heavily or would have to rely on external laboratories. Very few laboratories in Europe are capable of performing this destructive test (costing around 450 Euro per sample, not taking into account the costs of the destructed product). Full testing of the components of a complex product may cost up to 450.000 euro.  Furthermore, a threshold of 2ppb dramatically increases the risk of cross-contamination at the manufacturing site by trace amounts even to other parts, although the concerned substances may not actually be used in the manufacturing of a specific part. Taking into account complex supply chains, and the increased risk of false positives setting such an exceptionally low threshold could be highly detrimental to the reputation of companies who have acted diligently and taken all reasonable care in eliminating PFOA from their products. A safer and more workable threshold should therefore be set.  Availability of alternatives and time required for substitution  As a full overview of the presence of PFOA and all potentially PFOA-related substances in medical technology is not fully known today (taking into account this extremely low threshold), alternative assessment has not been performed. Alternatives may be available for most if not all of the applications. However, the substitution of substances within the medical device sector is very different from the same processes in any other sector.  Stringent EU regulatory requirements under directives 93/42/EC and 98/79/EC mean that a change in materials which could impact the reliability of a device will trigger its evaluation as a new device. When a substitution of any substance is required, this may require redesign, additional testing for reliability and for patient safety and the need to obtain the data to gain the approval in the EU and in the rest of the world. This can take many years especially if the change in design is significant which may occur when a new substance restriction is proposed.  Identification of concerned materials and suppliers, especially in case of complex active medical devices, is additionally impeded by the facts that validated analytical methods are missing (e.g. p.153 of the PFOA ANNEX XV RESTRICTION REPORT regarding PFOA-related substances) and that not all substances in scope of the proposed restriction are currently known (at the same place). Therefore, confirmation of compliance with the proposed substance restrictions materials, especially in case of complex active medical devices, will require extensive efforts, time and cost for manufacturers to collect substance information within the supply chain and to perform chemical analysis.  A longer transition period will be required to ensure the continued supply of crucial medical technologies. The transition to new substances or materials should not be taken as a trivial exercise for medical devices and IVDs. The period required for transitioning from one raw material to another is therefore longer and more complex for medical technologies than would be required for e.g. traditional consumer products.  To give an example – the experience of one company that already started to phase out PFOA’s substances (until the existing threshold), estimated that the phase out of PFOA to the level of the proposed 2ppb threshold would take up to 15 years and would result in the phase out of cumulative 1 gram of PFOA over 15 years (from now until 2030) in all products.  Definition and analytics / Clearer identification of substances – The current proposal from Germany and Norway lacks clarity in terms of substance identification and nomenclature. The proposed restriction bears serious legal uncertainty because validated analytical methods are currently missing and even not all substances in scope of the proposed restriction are currently known (p.153 of the PFOA Annex XV Restriction Report). The proposed use of three lead substances for enforcement of the restriction of PFOA-related substances (p.154 of the PFOA Annex XV Restriction Report) should become part of the restriction's and limit value's definitions in Annex XVII. Additionally, the CAS numbers of the substances concerned need to be clearly identified to allow the restrictions to be implemented in a harmonised and timely manner by manufacturers across the European single market and to ensure that it can be properly enforced by the responsible authorities.  Conclusion  The proposed restriction as it is defined in the Annex XIV report is not a feasible task for the medical device industry, for the following reasons:  • Lack of baseline situation  The low threshold and the unclarity on the substance identification and nomenclature make it impossible to assess the present baseline situation of the presence of PFOA and related substances above 2 ppb in medical devices.  • Unknown need for and availability of substitutes  As the baseline situation is unknown, it is impossible to define the need and availability for substitutes and identification of required exemptions.  • Extremely low threshold of 2 ppb  It is practically not possible to guarantee absence of the substances above the extremely low threshold of 2 ppb, since the threshold is below the most accurate commercially available testing methods.  Therefore, EDMA-Eucomed believe that in order to ensure that suitable alternative materials can be found, properly tested for medical conformity and to meet regulatory requirements, medical devices and IVDs would require an exemption from the proposed restriction for an initial period of time, at least comparable with the one used under Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment 1 July 2011. | |
| **Answer to specific info request 1:**  PFOA, its salts and PFOA-related substances are used as intermediate in the manufacturing process of PTFEs. These PTFE are used in several applications that ultimately result in the use in medical devices and in vitro diagnostic medical devices - as an article with its specific properties. Examples of different uses and applications are the following:  1) chemical resistant tubing,  2) heat resistant wiring  3) lubricative coatings on metals,  4) lubricative coatings on plastics.  Within the timeframe of this consultation it not feasible to generate a complete overview of the applications, possible substitutes and costs of substitution for the entire sector. EDMA and Eucomed collected feedback from their Members on order to develop input to this consultation. The examples in Table 1 attached to the general statement, present some initial information on the uses of PFOA, its salts and PFOA-related substances and identification of possible alternatives for medical devices and in vitro diagnostic medical devices. Medical Devices that are placed on the market are in most cases articles. The articles may consist of one, one to ten to numerous multiple sized components. | |
| **Answer to specific info request 2:**  The data in the restriction report is not sufficiently representative the medical device sector. Medical device industry manufactures complex products within a global supply chain. According to our understating at EDMA and Eucomed, the presence of PFOA, its salts and PFOA-related substances in medical devices, is limited to the presence in the components as a residual substance, initially used as building block or intermediate in a synthesis process that ultimately leads to another substance (often a polymer). The sector never places the PFOA as substance or in a mixture on the market.  These characteristics and the proposed low threshold of 2 ppb require a thorough assessment of supply chains of the suspected components and identification of the concentration of PFOA in polymers that may contain this substance as residual substance. Such an assessment is impossible within the timeframe of this consultation. The assessment of the economic impact will require first a solid baseline study that identifies where the PFOA is still present as residue in components, secondly an evaluation of alternatives to PFOA used as intermediate to manufacture the required substances and thirdly the costs of an assurance system to comply with the low threshold of 2 ppb. | |
| **Answer to specific info request 3:**  EDMA and Eucomed are not in a position to provide technical feedback to the question on degradation of PFOA-related substances. However, the proposed restriction of PFOA-related substances bears serious legal uncertainty because validated analytical methods are currently missing and even not all substances in scope of the definition of PFOA-related substances are currently known. | |
| **Answer to specific info request 4:**  From a downstream user perspective, the restriction with a concentration limit of 2 ppb would require implementation of costly solutions for the supply chain risk management approach in order to identify the possible components that contain PFOA and its related substances at the level of concentration exceeding 2 ppb. Complementary to this approach additional testing would be required. The available testing methods for products in the market are listed in Table 2, included in the attached general statement.  The compliance cost of a restriction control programme will depend on the complexity of the products, the materials at risk and the transparency of the supply chain of all components. If a company cannot exclude the presence of PFOA by means of a qualitative supply chain risk assessment, destructive testing will be required. The cost consequences are in-house managerial costs and testing costs.  Costs for a multimaterial product sold in all Member States will be high, but cannot be estimated within the timeframe of this consultation for our sector. On top of that, the lowest detection limit of the Q-TOF GC/MS test of 2-3 ppb’s, will not give a 100% assurance of absence of PFOA and all potentially PFOA-related substances above the 2 ppb threshold. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the new information and will take it into further consideration for potential derogations.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available.  The Dossier submitter proposed a structural formula to include all possible substances which can degrade to PFOA. This is in line with the restriction on PFOS and the stewardship program of the US-EPA on long chain PFASs. In our view there is no reason to alter the scope of the proposed restriction. | |
| **RAC Rapporteurs comments:**  The problems for the medical sector are noted. RAC supports the restriction, but shares the concern that the 2 ppb limit is too strict, e.g. with respect to analytical possibilities. With a higher limit value, there will hopefully be less problem. In any case, from a risk perspective, RAC supports a derogation for implantable medical devices. Derogation for other types of medical device is more of a matter for SEAC. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC also takes note of the technical problems associated with the 2ppb threshold, of longer transitional periods that might be required, and of potential cost of testing (but we believe this problem will be relieved when the threshold is moved up). We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances.  SEAC proposes to extend the general transitional period to 36 months to give more time to the introduction of suitable alternatives and to allow depletion of the affected materials from supply chains.  See also response to Comment 1232. | |
| **1387** | **Date:** 2015/06/17 18:56  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  ACEA  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>** | **General Comments:**  see supporting document | |
| **Dossier submitter response:**  It is not our aim to restrict the manufacturing and use of PTFE with this restriction proposal. Our aim is to restrict the use of PFOA and its salts for manufacturing PTFE and other fluoropolymers. PTFE manufactured without PFOA is already available on the market and will not be affected by the proposed restriction.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised. The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  The restriction involves the placing on the market of articles containing PFOA and PFOA-related substances. It is not the aim of the Dossier Submitter to restrict second hand articles for which a derogation is proposed. Consequently, articles which are already in their end use are not affected.  Fire-fighting foam is stockpiled to be prepared for the emergency case. The Dossier submitter assumes that fire-brigades responsibly handle the use of fire-fighting foam and those stock foams are only used in an emergency case where no other fire fighting-agents are applicable. Thus, the Dossier submitter concludes that most of the stock will not be used at all until the garanteed time frame for use by the manufacturer ends. Thus, for stocks of fire-fighting foam agents containing PFOA or PFOA-related substances above the proposed threshold, a longer transition time is proposed by the Dossier submitter. These stocks should only be used for emergency cases and not for exercises. | |
| **RAC Rapporteurs comments:**  The intention of the restriction is not to limit the use of C6 chemistry or PTFE, and the limits therefore have to be chosen in a sensible way not to do that. With realistic limits, the concerns expressed in the confidential comment will be limited. The concern for spare parts in stock is noted. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  The concern related to the 2 ppb limit is noted. We agree that the limit value should be higher and we support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. We also support derogation for spare parts for automobiles in stock when the restriction enters into force. | |
| **1388** | **Date:** 2015/06/17 19:28  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Germany  **Company name confidential:** **Yes** | **General Comments:**  We would like to state clearly, that in Textile industry PFOA and related substances are not being used but only occur as impurities in processing agents. | |
| **Answer to specific info request 1:**  Alternatives mentioned in the dossier are not sufficient due to not satisfactory properties for the applications as listed below:  - personal protective equipment  - filtration purposes  - medical uses  - automotive and aviation industry  - sun protection / building industry  - lifting and carrying belts  The alternatives lack  - washing / water fastness  - rubbing / abrasive durability  - dynamic water-/oil-repellency  Therefore we would like to refer to the exemptions mentioned in RMO 1b of the restriction proposal and strongly ask for adding them to the current proposal of Annex XVII REACh.  The Textile industry has no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 2:**  The Textile industry in Germany is highly specialized on niche-products as mentioned above. The sales of German producers of technical textiles reached around EUR 6 bn in 2013. So a ban on fluorinated products containing trace impurities of PFOA and related substances will lead to a decrease of economic and innovative power and will endanger the competitiveness and existance of many Textile companies.  As the alternatives on the market do not fit the demand the higher risk is losing a significant part of turnover.  Chemical and Textile industry invested a large amount of money within the last five to ten years to substitute or at least minimise the content of PFOA in the applications used for the effects mentioned above. This process is still in progress.  The topic "related substances" is new for the Textile industry, we have no information regarding this point. Please refer to chemical suppliers. | |
| **Answer to specific info request 3:**  As the textile industry doesn't use PFOA and related substances no additional information is available. | |
| **Answer to specific info request 4:**  According to information provided by our suppliers processing agents used in the textile industry contain amounts of PFOA and related substances exceeding the 2 ppb limit by far. So this limit is equivalent to an entire interdiction of textile production and placing on the market of textile articles.  The analytical methods mentioned in the dossier are not approved so we doubt that repeated measurements would be able to lead to reliable results. We would like to emphasise, that analytical measurements in a range of 2 ppb will lead to extraordinary high costs. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  According to manufacturers of short-chain alternatives all uses of C8 can be replaced by short-chain chemistry. Since a shift to short-chain-chemistry has already taken place and time remains until the restriction enters into force, the Dossier submitter considers derogation for non-professional textiles not reasonable. The Dossier submitter would agree with a longer transitional period for the remaining uses of C8 chemicals in the professional sector. However, we would like to stress that one manufacturer of personal protection equipment stated to be able to manufacture these items without PFOA and PFOA-related substances.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The Dossier submitter has revised the proposed concentration limit to ensure that short-chain PFASs can be manufactured and used.  According to REACH emissions of PBT substances have to be minimised. Regarding the cross-contamination, no information was provided on the concentrations of PFOA and PFOA-related substances because of cross-contamination. The revised threshold as proposed by the Dossier submitter takes contaminations in the trace level range into account. The Dossier submitter believes that there are possibilities to avoid cross- contamination, e.g. only those facilities could be used which have faced out PFOA and PFOA-related substances completely. Moreover, the Dossier submitter is of the opinion that these measures are manageable to achieve within the transitional period until the restriction is enforced.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  See response to Comment 1279. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see response to Comment 1235. | |
| **1389** | **Date:** 2015/06/17 19:46  **Type:** Individual  **Country:** Denmark  **Company name confidential:** **No** | **General Comments:**  Please take into account relevant information on adverse effects in humans as revealed by epidemiological studies. In particular, the evidence on immunotoxicity should be properly considered. Here's the link to the most recent article that cites several previous reports: http://www.ehjournal.net/content/14/1/47/abstract. | |
| **Dossier submitter response:**  Thank you drawing our attention to this very recent article. The authors state that the immunotoxic effects cannot be explained by a single PFAS. Cfr. our response to Comment 1374. | |
| **RAC Rapporteurs comments:**  Thanks for providing the reference. RAC is aware of studies both in animals and epidemiological studies suggesting effects of PFAS on the immune system. At present, although of concern, it is felt that it is difficult to use this information in a quantitative way in a risk assessment. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1390** | **Date:** 2015/06/17 20:06  **Type:** Individual  **Country:** United States  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Thank you for the opportunity to comment on the proposed restriction of PFOA and its precursors. As an environmental scientist I am aware of the persistent, bioaccumulative, and toxic characteristics of PFOA and support the proposed restriction. Although I am not qualified to speak to the likely economic impacts of the restriction, I am familiar with the environmental health hazards posed by these compounds and feel I have a responsibility as a researcher to voice my concerns.  The scientific literature documenting the problematic nature of long-chain perfluorocompounds continues to grow. PFOA breaks down very slowly, if at all, in the environment (1), and is spread throughout the globe via atmospheric and oceanic circulation (2). It is present at measurable levels in human blood (3) and breast milk (4) and is transferred from mothers to fetuses through the placenta (5). Epidemiological studies have linked exposure to this chemical to high cholesterol (6), pregnancy-induced hypertension and preeclampsia (7), testicular cancer and kidney cancer (8), thyroid disease (9), autoimmune disease (10), and reduced immune function (11) in humans. For all of these reasons, the manufacture of PFOA and related substances, even as incidental byproducts of other production processes, has adverse consequences for human and environmental health around the world.  I agree with the authors of the proposed restriction that the hazard profile of PFOA also applies to PFOA-related substances (i.e., substances that are expected to degrade to PFOA under environmentally relevant conditions). Including these PFOA precursors in the restriction will be key to ensuring the rule’s effectiveness. Studies performed at the University of California Berkeley using an assay developed to simulate relevant environmental breakdown processes have shown the importance of considering PFOA precursors. For example, conversion of precursor compounds to PFOA accounted for a mean of 37% of PFOA measured in stormwater runoff from the San Francisco Bay region (12) and 48% of PFOA measured in firefighting foam products from one U.S. manufacturer (13).  Opponents of the proposed restriction claim that including PFOA-related substances under the rule is too onerous. They argue that analytical methods do not exist to quantify all such compounds and that the rule should be limited to specific compounds identified by a CAS number. This argument is flawed for the following reasons. Firstly, the analytical assay mentioned in the previous paragraph, developed by Houtz and Sedlak (12), is capable of measuring both PFOA and it’s precursors simultaneously. The method has already been adopted by other academic laboratories, and its relative simplicity lends itself well to adoption by commercial labs. Secondly, to the best of my knowledge there is currently no comprehensive inventory of PFOA precursors to draw upon in creating a list. Finally, limiting the scope of the restriction to a discrete list of compounds will open the door for manufacturers to use regrettable substitutions, i.e., novel compounds that are not covered in the restriction but that differ only trivially from known PFOA precursors. | |
| **Answer to specific info request 4:**  Opponents of the restriction argue that the proposed 2 ppb limit for PFOA should be raised to the 10 ppm level that is specified in the EU restriction on PFOS. This argument fails to consider that the PFOS restriction was written nearly a decade ago and that significant advances have been made in analytical capability in that time.  Another argument invoked against the proposed restriction is that the required control level of 2 ppb is far beyond current analytical technology. In my opinion, this is wrong. For instance, PFOA has been measured by LC-MSMS in the matrices muscle, blood, plant-based feed, etc. with an LOD of 0.2 µg/kg [14]. Standardized methods exist for the analysis of PFOA in unfiltered water samples [15] and for the analysis of PFOA in water, sediment, and biota [16]. The method detection limits for PFOA have been reported with 1.2 pg/L (0.0000012 ppb) for seawater [17], 10 pg/g dry weight (0.01 ppb) for sediment [18], and 0.144 ng/g-1 wet weight (0.144 ppb) for biota samples (blood) [19].  I agree with many critics of the proposed rule that limiting PFOA to less than 2 ppb will require significant efforts by manufacturers. However, I consider this an argument in favor of the proposed rule, not against it. | |
| **Dossier submitter response:**  Thank you very much for the support. | |
| **RAC Rapporteurs comments:**  The support is noted. It is agreed that analysis of 2 ppb is possible, but the question is if it is possible in all matrices. RAC would favour a process with enforceable limits and where tighter limits are set as the analytical possibilities increases and the LOQs decreases (provided that remains proportional to the risk). RAC has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for the information submitted. We support limit values of 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. However, SEAC is also in favour of a revision of the restriction after 5 years, in particular to assess if tighter limits are justified and enforceable. | |
| **1391** | **Date:** 2015/06/17 20:12  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  Zentralverband Oberflächentechnik/ Federal Association of Surface Treatment  **Org. country:** Germany  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  Eine weitere Regulierung von PFOS, seiner Salze oder anderer in der Branche genutzter fluorierter Tenside stellt die Galvano- und Oberflächentechnik vor derzeit unlösbare verfahrenstechnische Probleme. Zu beachten ist, dass die galvano- und oberflächentechnische Branche von kleinen und mittelständischen Firmen geprägt wird. Der bisherige regulatorische Druck aus verschiedenen Richtungen auf diese Ausnahme- und Querschnittsbranche führt bereits jetzt in produzierenden Betrieben der Oberflächenbeschichtung zu einer Überforderung und erzeugt zunehmenden Unmut in der EU zu produzieren.    Weiterhin ist der im Beschränkungsvorschlag formulierte Grenzwert von 2 ppb weder messtechnisch mit angemessenem Aufwand und der benötigten Zuverlässigkeit und Genauigkeit zu überwachen noch in Galvaniken im Produktionsablauf überhaupt technisch einzuhalten. Ein Grenzwert von 2 ppb wird deshalb als vollkommen unrealistisch abgelehnt.  Das Beschränken (Restriktion) der Herstellung, des Inverkehrbringens und des Verwendens der beschriebenen Verbindungen und ihrer Salze und weiterer Stoffe, die ein C7F15-Strukturelement aufweisen, als solches, als Bestandteil anderer Substanzen, in Gemischen oder Artikeln wird aus Sicht der Galvano- und Oberflächentechnik abgelehnt, da bereits die bestehende Rechts- und Regulierungslage als hinreichend erachtet. Zudem stehen die negativen Folgen der Beschränkung für den Arbeits- und Umweltschutz in einer unangemessenen Relation zum etwaigen Nutzen. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made. However, the proposed restriction is not on PFOS but on PFOA. To the best of our knowledge electroplating is not affected by the restriction proposed. | |
| **RAC Rapporteurs comments:**  We lack reliable information that electroplating is a relevant sector for this restriction. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We also think electroplating is not affected since PFOS is not object of the proposed | |
| **1392** | **Date:** 2015/06/17 20:38  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:**  National Food Institute, DTU-Food  **Org. country:** Denmark  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  DTU Food supports and welcomes this restriction, as a means to lower the global overall exposure of humans and environment to PFOA and its precursors, whether they are released during the production, use, disposal or reappear in recycled products. | |
| **Answer to specific info request 2:**  DTU Food has been contacted by five companies (one Czeck food producer, one Finish paper material company, two Danish retailer, one commercial laboratory) who are interested in making/using alternative non-fluorinated paper and textile coatings - for them a restriction of PFOA and PFOA precursors is seen as an economic growth potential.  A Danish retailer (COOP) has phased out fluorinated coatings in all their own products in the Nordic countries, and judge that there is no extra cost associated with buying products not containing fluorinated chemistry. The only product they so far cannot find a non-fluorinated replacement for is microwave popcorn bags, which they have chosen not to sell in Denmark, until they find a solution that is non-fluorinated. | |
| **Answer to specific info request 3:**  To our knowledge all of these substances have the ability to degrade to PFOA, biotically or abiotically. | |
| **Answer to specific info request 4:**  Please see the attached document for further information on methods.  It has been voiced that “It is impossible to manufacture industrial and/or consumer products under 2 ppb (2 µg/kg)”, with so-called short-chain fluorochemicals, and that PFOA levels typically are around 10-50 ppb. For industrial products, short-chain PFAS based products labeled “PFOA-free” frequently contain PFOA and precursors at levels up to 0.01% (106 ppb). In our view, this labeling is not acceptable at current PFOA levels, and dishonest marketing. It might not be possible with the current technology, but then synthesis and cleaning processes must be improved. As an example, PFOA can be removed from PTFE polymers for food contact, by sintering (heating) the final product. If this is not possible for some processes, other non-fluorinated alternatives could be considered as an option. Products without persistent substances are also more in line with the circular resource economy, which the EU supports: Since persistent compounds which accumulate, might lower the grade of the recycled product to the extent that the resource must be destroyed, as in the case of recycled products containing PFOS > 50 ppb (EU commission regulation nr. 1342/2014, applying from the 18th of June, 2015). Reducing these levels to 2 ppb is admittedly a challenge, and at the same time the root cause for the strong need for this restriction, not a reason to halt it.  It is possible to measure PFOA at the 2 ppb level:  • PFOA has been measured by LC-MSMS in the matrices muscle, blood, plant-based feed, etc. with an LOD of 0.2 µg/kg [3]  • PFOA has been measured down to 1.25 ug/kg (1.25 ppb) in paper at Oregon State University (unpublished data). Comparable recovery and limits of quantification were obtained for 33 other PFAS including PFOA precursors.  • Standardized methods exist for the analysis of PFOA in unfiltered water samples (ISO/DIS25101) [7] and for the analysis of PFOA in water, sediment, and biota (ICES, International Council for the Exploration of the Sea) [8]. The method detection limits for PFOA have been reported with 1.2 pg/L (0.0000012 ppb) for seawater [9], 10 pg/g dry weight (0.01 ppb) for sediment [10], and 0.144 ng/g-1 wet weight (0.144 ppb) for biota samples (blood) [11].  • At DTU Food we can measure PFOA in paper and board has an LOD of 0.03 µg/L (corresponding to 0.01 ng/cm2 or 0.1 µg/m2 or 0.001 µg/g paper) in our validated enforcement method based on online SPE-UHPLC-QTOF MS method (not yet published)  It is possible to convert PFOA-precursors to PFOA in products and will be possible to measure 2 ppb levels soon  • A method to oxidize PFOA precursors to PFOA in run-off water and in soil has already been developed by Houtz & Sedlak [4], [5] and is described below in the section “Chemical oxidation as a path to quantifying total PFOA and PFOA-precursors: towards a standardized method for enforcement”.  • A recent modification of Houtz & Sedlak [4] using the micro liquid-liquid extraction of Allred et al. [13] was applied to select papers and textiles by the Field Laboratory at Oregon State University. Analyses of 15 papers and 9 textiles produced significant levels of perfluoroalkyl carboxylates (C4-C18) upon oxidation. Unknown, unidentified precursors comprised 60%-98% of the highly fluorinated substances on the select papers and textiles tested.  • A large commercial laboratory (Eurofins) has judged that it is ‘highly likely with the right equipment to reach the 2 ppb limit in all relevant matrices’, with the Houtz & Seldak method [4],[5] as a starting point using LC-MSMS. They say that they “are interested in developing this method, if the restriction gets approved.”. They will comment this, and that it would be a financial benefit to them if the restriction is passed. All developed compliance methods will be accredited.  Harmonized methods:  • Sweden has initiated the development of a new CEN standard within the Technical Committee TC248/WG26, “EC restricted substances in textiles” that specifies a test method for detection and quantification of extractable long chain perfluorinated and polyfluorinated substances in textile products that include long chain per- and poly-fluorinated compounds from C7 – C14 are used in soil and water repellent finishes [12].  • There is currently an initiative to make a horizontal CEN method for PFOA and PFOA precursors, in textile, leather and paper and board, and contact to other CEN groups such as for food contact plastics (TC194) could be considered.  1. Scheringer, M., X. Trier, I.T. Cousins, P.d. Voogt, T. Fletcher, Z. Wang and T.F. Webster, Helsingor statement on poly- and perfluorinated alkyl substances (PFASs). Chemosphere, 2014. 114: p. 337-9.  2. Blum, A., S.A. Balan, M. Scheringer, X. Trier, G. Goldenman, I.T. Cousins, M. Diamond, T. Fletcher, C. 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Yeung, S. Taniyasu, Y. Horii, P.K.S. Lam, R. Ebinghaus, Partitioning behavior of per- and polyfluoroalkyl compounds between pore water and sediment in two sediment cores from Tokyo Bay, Japan. Environ. Sci. Technol., 2009, 43: 6969–6975.  11. L. Ahrens, U. Siebert, R. Ebinghaus, Total body burden and tissue distribution of polyfluorinated compounds in harbor seals (Phoca vitulina) from the German Bight. Mar. Pollut. Bull., 2009. 58: 520–525.  12. CEN/TC 248/WG 26 N 349 AND 350  13. Allred, B. M., Lang, J.R., Barlaz, M. A., Field, J.A., Orthogonal zirconium diol/C18 liquid chromatography-tandem mass spectrometry analysis of poly and perfluoroalkyl substances in landfill leachate. J.Chromatogr. A, 2014. 1359: p. 202-211. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the support. | |
| **RAC Rapporteurs comments:**  The support is noted. There are analytical methods that can measure 2 ppb, but the question is if it is possible in all matrices, for all compounds, and by all commercial labs. Thanks for the many references. The RAC would favour a process with enforceable limits when the regulation enters into force (at least for many of the substances), and tighter limits set later as the analytical possibilities increases and the LOQs decreases (provided this remains proportional to the risk). RAC has recommended that the Commission takes due account of analytical developments in future. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC takes notes of the information that show ongoing development, but also pays attention to technical and economic feasibility of analytical methods at the end of the transitional period of the proposed restriction. | |
| **1393** | **Date:** 2015/06/17 23:03  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:**  FEU Federation of European Union Fire Officiers Association  **Org. country:** Luxembourg  **Company name confidential:** **No**  **Attachment confidential:** **No** | **General Comments:**  This draft regulation is absolutely not acceptable from the fire fighters perspective and will lead to a huge cost impact for fire brigades, both private as public.  As there are no alternatives, fire fighting without PFOA foams endangers the life of citizens in airplanes, workers in production plants, tank farms and above all fire fighters who have to respond those fires. Safety cannot longer be guaranteed in case of a fire. We will get fatalities and huge environmental disasters.  Representing the fire services and the fire fighters, we firmly ask you to review this amendment or to make an exception for the use of PFOA containing firefighting foams, till there are fully tested alternative products that can completely fulfil the same safety and tactical standards. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the comments made.  The use of PFOA and PFOA-related substances in AFFF is not necessary. Alternatives based on short-chain chemistry are available and widely used. It is not our aim to restrict the short-chain chemistry with this restriction proposal. Concentrations of PFOA and PFOA-related substances in short-chain alternatives are already in the trace level range. With the revised concentration limit proposed it is ensured that short-chain alternatives and consequently fire-fighting foams based on short-chain PFAS can be manufactured and used. Contaminations in existing extinguishing systems are considered, too.  We also received comments which show that fluorine-free alternatives with comparable performance exist. Fluorine-free fire-fighting foams are already used at airports in Germany and Northern Europe. Furthermore, petroleum oil and gas producers in the North Sea as well as refineries in Europe (and outside Europe) are replacing fluorinated fire-fighting foam with fluorine-free fire-fighting foam.  Even if the threshold will allow fire-fighting foams based on short-chain PFAS, further development and also acceptance on fluorine-free alternatives is necessary. | |
| **RAC Rapporteurs comments:**  See response to Comment 1225. | |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC is conscious that alternatives need to remain available and affordable for this critical use of PFOA and PFOA-related chemicals. Please see response to Comment 1225. | |
| **1394** | **Date:** 2015/06/18 00:06  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:**  United States Environmental Protection Agency  **Org. country:** United States  **Company name confidential:** **No** | **General Comments:**  US EPA appreciates the human health and environment concerns outlined by Germany and Norway on Perfluorooctanoic acid (PFOA). EPA has also been investigating and taking action on long-chain perfluoroalkyl carboxylate chemicals (including PFOA) because of their persistent, bio-accumulative, and toxic properties.  Long-chain PFCs are found world-wide in the environment, wildlife, and humans. They are bioaccumulative in wildlife and humans, and are persistent in the environment. They are toxic to laboratory animals and wildlife, producing reproductive, developmental, and systemic effects in laboratory tests. To date, significant adverse effects have not been found in the general human population. However, given the long half-life of these chemicals in humans (years), it can reasonably be anticipated that continued exposure could increase body burdens to levels that would result in adverse outcomes.  In its domestic context, the US has been pursuing a number of risk management actions on PFOA and its related chemistries.  In 2006, EPA and the eight major companies in the industry launched the 2010/15 PFOA Stewardship Program. Through this, the companies committed to reduce global facility emissions and product content of PFOA and related chemicals by 95 percent by 2010, and to work toward eliminating emissions and product content by 2015. As of this writing, participating companies are on track to phase-out the chemicals by the end of 2015 and have successfully developed over 150 alternatives. Companies’ progress towards meeting the 2015 phase-out goal has been made available by EPA. The 2014 annual progress report, which reflects 2013 data, is available at http://www.epa.gov/oppt/pfoa/pubs/stewardship/preports8.html.  EPA remains concerned about LCPFCs being produced by companies that are not participating in the stewardship program and intends to take further action to address those concerns. On December 30, 2009, EPA posted an action plan on LPFCs available at: http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/pfcs.html. The LCPFCs action plan outlines actions that would further reduce exposure to LCPFCs by addressing their use in products from sources other than the eight companies participating in the stewardship program.  Building off of these activities, on January 15, 2015 EPA proposed a Significant New Use Rule under TSCA for LCPFACs. The aim of this action is to ensure that perfluorinated chemicals that have been phased out do not re-enter the marketplace without review, and is in part in anticipation of the 2015-phase-out deadline.  The proposed Significant New Use Rule requires that anyone who intends to import LCPFACs, including in products, or domestically produce or process these chemicals for any new use submit a notification to EPA at least 90 days before beginning the activity. This notice will provide the agency with an opportunity to evaluate the new use and, if necessary, take action to prohibit or limit the activity.  This is not our first action of this nature. EPA has previously issued other SNURs on perfluorinated chemicals: In 2013, EPA issued a final Significant New Use Rule for use of perfluorinated chemicals in carpets and carpet aftercare products. EPA has also issued other Significant New Use Rules on perfluorinated chemicals, including perfluorooctane sulfonate (PFOS) and perfluoroalkyl sulfonates (PFAS) that were voluntarily phased-out of production.  In addition to its domestic efforts, EPA appreciates the collaboration we have been able to share with the EU and its member states to date on PFOA related chemistries in international fora. For example, we appreciate the work conducted beneath OECD’s former Existing Chemicals Task Force to create the joint Hazard Assessment of Perfluorooctane Sulfonate (PFOS) and its Salts (2000) as well as the more recent information gathering and exchange work being conducted by the Global PFC group created under SAICM and supported by OECD and UNEP.  We welcome the European Commission’s recently submitted comments on the proposed SNUR, and hope that we can have further conversations about our respective approaches towards risk management.  US EPA would appreciate further bilateral technical discussions on PFOA with the EU. We believe that both the US and the EU might benefit from an exchange of information regarding the regulatory activities under consideration by each jurisdiction, including the proposed restriction from Germany and Norway on PFOA, its salts, and PFOA-related substances. | |
| **Dossier submitter response:**  The Dossier submitter is grateful for the support and welcomes further bilateral technical discussions with US-EPA. | |
| **RAC Rapporteurs comments:**  Thanks for the detailed information. | |
| **SEAC Rapporteurs comments:**  Thank you for the information. | |
| **1395** | **Date:** 2015/06/18 00:57  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Switzerland  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Contains information related to production processes, volumes and impurity level regarded as confidential information | **General Comments:**  The below comments intend to supplement our first contribution to the public consultation submitted on 26 February.  We welcome that the restriction dossier considers the possibility of a derogation for the “manufacturing of short-chain fluorinated alternatives”. We propose to qualify “short-chain fluorinated alternatives” as “short-chain fluorotelomer alternatives” as this refers more precisely to the scope of substances which is the object of our derogation request.  “Short-chain fluorotelomer alternatives” (or “C6” alternatives) are the main alternatives known to date to C8 PFOA-related substances. They are mainly used in professional textile and paper applications.  The need for a derogation for the manufacturing of short-chain fluorotelomer alternatives is due to the fact that the telomerisation process, which corresponds to the state of the art manufacturing process for those alternatives, leads to an unavoidable fraction of C8 perfluorooctyl iodide (Heptadecafluoro-1-iodooctane, CASN 507-63-1), hereinafter referred to as C8 iodide. We are the only production site in the European Union where this telomerisation process, and more generally the entire cycle of C6 production, takes place.  Once produced during telomerisation, the unavoidable C8 fraction is then separated from C6 substances by destillation. It becomes a C8 iodide isolated intermediate.  We have been working on an R&D project in order to rework this side C8 fraction back into TFE gas, which in turn is used to produce C6 alternatives, and this under strictly controlled conditions. The technology has shown promising results (please refer to confidential Annex for more information). This process would ensure that potential emissions deriving from the C8 side fraction are reduced to their lowest possible level, while offering an economically viable solution for this C8 fraction. Furthermore, it follows the objective of the European Union to move towards a circular economy, including through sustainable recycling.  We therefore believe that a derogation for the manufacturing of short-chain fluorotelomer alternatives, due to the unintentional production of C8 fraction, should also allow the reprocessing of this C8 fraction for the purpose of C6 manufacturing, under strictly controlled conditions.  More information on C6 production steps, C8 impurity levels in respective intermediates and commercial mixtures, are provided in the confidential annex to this contribution.  Furthermore, in our first contribution, we voiced concerns regarding the single threshold of 2ppb for PFOA and PFOA-related substances as posing a direct threat, not only to the manufacturing but also the placing on the market of short-chain fluorotelomer intermediates and mixtures as well as articles treated with these products. In line with the FluoroCouncil, we support a two-step approach to achieving the objectives of the restriction while providing a workable and cost-effective implementation (see question 2 for further detail). | |
| **Answer to specific info request 2:**  In our previous contribution, we underlined the fact that the socio-economic impacts that would be induced as a consequence of the closure of the plant had not been assessed in the restriction dossier. We insisted in particular on the impacts on employment (number of job losses) and future investments (several millions of Euro of investments that would have to cease).  We also mentioned that the closure of the plant would place EU C6 fluorotelomer industry and related downstream sectors using C6 at a competitive disadvantage compared to non-EU companies, as production outside of the EU would be allowed to continue.  Furthermore, we would like to stress that the telomerization process is a local process, that depends on the availability of the TFE gas as raw material. This gas is unstable, it can’t be transported easily (transportation would require its liquefaction and stabilization). Therefore it must be processed on the site of its synthesis. Closing down the only production site in Europe of C6 intermediates and mixtures would further limit their availability for downstream users, making it more complicated for them to transition from C8 to C6. This would contradict the objective of the restriction to phase out the use of C8 products. Also, it would mean that all European C6 users would depend on C6 intermediates originating from outside Europe. | |
| **Answer to specific info request 4:**  The various intermediates occurring during C6 production, as well as final C6 mixtures, do not only exceed the threshold of 2ppb of a single substance for PFOA and PFOA-related substances, but have different C8 impurity levels. C8 impurity levels depend on the stage of the process. Intermediates can be only on-site, or on-site and/or transported intermediates depending on whether they are used for further production steps on site or sold as transported intermediates under strictly controlled conditions. All our intermediates have been registered under REACH accordingly.  Furthermore, any threshold needs to be set based on validated analytical methods in order to be applicable by industry and enforceable by Member States.  In the absence of such methods at present, and in line with the position of the FluoroCouncil, our company is member of, we recommend to follow a two-step approach with regard to thresholds for fluorotelomers:  Step 1: Adopt an analytical method that distinguishes C8/long-chain intermediates, mixtures and articles containing them from their C6/short-chain alternatives – such a method is already available, please refer to second FluoroCouncil’s contribution for the description of the method.  Step 2: Adopt thresholds to restrict PFOA and PFOA-related substances in alternative products or articles treated or made with them once standardised analytical methods have been developed. The relevant analytes could include: PFOA, 8:2 FTOH, C8 methacrylate monomer and C8 acrylate monomer. For each relevant analyte, different thresholds should be established for the following specific matrices:  • Fluorotelomer-based mixtures  • Fluorotelomer-based products  • Articles treated with fluorotelomer-based products | |
| **Dossier submitter response:**  Thank you for the additional information. We will take it into further consideration.  According to Art. 68 (1) of REACH on site isolated intermediates are exempted from restriction. Therefore derogation for unintended manufacturing of a fraction of C8 Iodide and ethyl iodide (C8F17-I; C8F17-CH2-CH2-I) as isolated intermediate during the C6 telomerization process, and the reprocessing of that fraction back into C6 production is not necessary.  It is not our aim to restrict the short-chain alternatives with this restriction proposal. However, intentional use of PFOA and PFOA-related substances needs to be avoided. According to REACH emissions of PBT substances have to be minimised.  The current lack of standard analytical methods does not automatically imply that it is not possible to have a standardized methods with a detection limit low enough to enforce the restriction at later stage. This is supported by a number of researchers and an analytical laboratory who submitted information in the public consultation~~)~~.  Different analytical methods and measured data (see chapter E and Appendix E of the background document) are already available showing that methods are available for different matrices in the low ppb range. Moreover, from researchers point of view who also responded during the public consultation, an analytical method is already available to measure PFOA and PFOA related substances simultaneously. This method (included in the background document) could be further developed in the near future and may already be the first step of a standardized method.  Furthermore, a stakeholder reported ongoing work of developing an EN standard method for PFOA and some PFOA-related substances (as well as other PFASs) in textiles. This information is by now also included in the background document.  Overall, it seems to be very likely that standardized methods will soon be available. | |
| **RAC Rapporteurs comments:**  The information is noted. RAC confirms that according to Art. 68 (1) of REACH ‘on-site isolated intermediates’ are exempt from restriction. | |
| **SEAC Rapporteurs comments:**  Thank you for comments and answer.  SEAC finds it essential at this point that the manufacture and use of short chain fluorinated alternatives will continue to be allowed. We have reflected this in our draft opinion and we believe that the justification is now also clear in this regard. | |
| **END OF AXV PC COMMENTS** | | | |