

**Committee for Socio-economic Analysis (SEAC)**

**Response to comments on the SEAC draft**

**Opinion**

**on the Annex XV dossier proposing**

**restriction on**

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

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| Substance name | EC number | CAS number |
| Perfluorooctanoic acid | 206-397-9 | 335-67-1 |

### 4 December 2015

Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. SEAC has concluded that there is a need for a derogation for certain uses. For some other sectors, SEAC does not consider derogations justified under the revised transitional period (36 months) and concentration limits (25 ppb for PFOA and its salts, 1000 ppb for PFOA-related substances). In case further derogations seem necessary, the affected parties are invited to submit substantiated socio-economic information (including substantiated quantitative information on costs of complying and/or on emissions reduced) to justify their case.

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 217 | **Date/Time:** 2015/10/07 11:09  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  Belgium  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  We agree with the position of SEAC concerning  - concentration limits (25 ppb i.o. 2 ppb PFOA)  - transitional period | |
| **SEAC Rapporteurs response:**  Thank you for your comment. | |
| 218 | **Date/Time:** 2015/10/13 11:36  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  I&P Europe - Imaging and Printing Association  **Org. country:**  Germany  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  The European Imaging and Printing Association (I&P Europe) appreciates the invitation to provide its response to the Public Consultation on the draft SEAC opinion on the Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances prepared by the German and Norwegian authorities. The membership of I&P Europe includes all of the major manufacturers of photographic products within the European Union.  I&P Europe notes that the draft SEAC opinion takes into account the documented arguments provided by the photographic sector regarding the particular case of the few critical uses of PFOA or PFOA related substances remaining in the photographic industry.  Hence the draft opinion is supported by I&P Europe members. | |
| **SEAC Rapporteurs response:**  Thank you for your support. | |
| 219 | **Date/Time:** 2015/10/30 12:58  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Mineralölwirtschaftsverband  **Org. country:**  Germany  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  As already stated in our comment provided 2015/02/27 the PFOA limit of 2 ppb as drafted in the original draft of this restriction would be applicable even to impurities. Such impurities could be found even in fire-fighting systems that previously contained PFOA containing foam and that were cleaned after phase-out of PFOA.  SEAC draft opinion is taking care of this problem by raising the limit considerably, which we fully support. | |
| **SEAC Rapporteurs response:**  Thank you for your comment. | |
| 221 | **Date/Time:** 2015/11/05 17:21  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  EUROFEU  **Org. country:**  Germany  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  I am writing to you as the chairman of the EUROFEU section Fire Fighting Agents (FFA).  EUROFEU is the umbrella organization of the national trade associations of the European fire protection industry currently consisting of 5 sections (Fixed Extinguishing Installations, Mobile Equipment, Portable Fire Extinguishers, Sprinkler and Fire Fighting Agents).  The section FFA represents European manufacturers of firefighting agents namely the national associations AGORIA (Belgium), BVFA (Germany), FFMI (France), FIA (UK), ANIMA UMAN (Italy) and ANAF (Luxemburg). These associations cover the vast majority of manufacturers of firefighting foam agents in Europe including some globally active organizations.  It is the mission of FFA to be the voice of Europe’s firefighting agents industry upstream and downstream to other organizations and legislators and promote good practice in particular through compliance with European Standards and legislation to ensure best practice and quality of existing and future fire protection technologies.  EUROFEU’s section FFA welcomes and fully supports the current SEAC proposal in its draft “Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances” dating September 10th, 2015, on pages 13 and 14 of an individual threshold value of 1000ppb for PFOA and each related substance.  We have however noted that the proposed wording for the restriction text (pages 4-6, particularly paragraph 5d) seems to differ from the corresponding justification on the pages 13 and 14 of the same document:  The derogation proposed in 5d) on page 6 leaves it unclear if the threshold value is to be applied on the content of the entire group of chemicals specified as PFOA and related substances or on each individual representative of that group. The justification speaks of 1000ppb per individual substance. This was addressed to ECHA accordingly for awareness.  Based upon the respective correspondence between ECHA’s Risk Management Implementation Unit and EUROFEU’s FFA as well as with other members of the industry it is our understanding that SEAC has acknowledged the need to revise the derogation proposal accordingly to clarify the intended threshold limit in firefighting foams to be 1000ppb per each individual substance as defined in the restriction.  EUROFEU’s FFA welcomes and supports the derogation 5c) allowing the use of those firefighting foams which are already on the market at the time the restriction enters into force. This derogation greatly helps securing a continuous fire protection in high risk areas and a seamless transition towards alternative foam agents. It was however noted that SEAC’s proposal does not clarify how foam agent stocks shall be handled:  A significant volume of foam agents is stored on industrial sites to supply mandatorily required fix installed fire protection systems or as an emergency stock in moveable large volume containments (trailers, skids, etc.). In order to keep the corresponding fire protection systems fully operational at any point in time a defined volume of foam agent must be stored on site.  Any consumption of that stored volume must be restored to the required minimum storage volume (in Europe typically defined by EN-Standards). It is hence a critical requirement to backfill a foam storage containments with fresh foam agent in any case of partly consumption of the stored (old) foam agent.  This practice leads to backfilling existing stock volumes (which are already on the market hence exempted according to paragraph 5c and 5d of the recent draft of the regulation in SEAC’s recent opinion document) with new foam agents (which have to comply to the restriction). The draft proposal by SEAC does not specify how the resulting mixture will be classified: will the stock volume remain exempted as it was before backfilling or will it be considered new?  We therefore propose to add a specification to paragraph 5 as new subparagraph e:  5. By way of derogation, paragraph 1 shall not apply to:  “e) Fire Fighting Foam concentrates which are stored by users in designed fixed installation volumes and emergency stocks at the point in time this restriction enters into force for a transition period of fifteen years.”  RAC’s point of concern that existing stock may be used up in training scenarios leading into groundwater contamination has been noted. We like to point out that over the course of the past years since the negative impact of PFOS was discovered the industry has developed a strong focus on the environmental impact of its products. Proactive collaboration with national and international agencies and NGO’s have led to a high and still growing awareness within the industry and from there also to its client base – the users of firefighting foams.  Through trainings and educational programs the practice which in the past has been leading to groundwater contaminations is meanwhile almost obsolete. Today’s best practice recommendations from the industry require selective use of foam agents, use of alternate eco-friendly liquids wherever possible, safe disposal of firewater runoff and foam concentrate waste and no use of foam agents if containment is not guaranteed.  We are continuously working with the users of firefighting foams to educate them on safe use of firefighting foam agents, fluorinated or not. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Regarding the concentration limit, the aim is indeed that the threshold applies to each chemical under scope. The text in the entry has been modified to be consistent with the justification section.  On the possibility to continue using existing stocks when subsequently mixed with new fire foams, we agree that the continued use of these mixtures should be allowed, and we have proposed an amendment to the opinion.  We also note the information on the current practice regarding training. We have reflected it in the entry of the restriction. | | |
| 222 | **Date/Time:** 2015/11/05 20:12  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  AFIRM  **Org. country:**  United States  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  The Apparel and Footwear International RSL Management (AFIRM) Group appreciates SEAC’s scientifically sound socio-economic analysis of the proposed restriction on Pentadecafluorooctanoic acid (PFOA), its salts and PFOA-related substances. We welcome this opportunity to further contribute to the public consultation process by providing comments on the draft opinion of 10 September 2015.  These comments reference and elaborate on our 28th February 2015 comments submitted during the initial ECHA outreach on the REACH Annex XV dossier submitted by Germany and Norway.  We concur with many of the recommended changes proposed in SEAC’s opinion, in particular the modified concentration limits, longer transitional periods and certain derogations. We also welcome the important clarification that a key prerequisite for this restriction is that it not jeopardize the manufacturing and use of C6 PFC alternatives. Furthermore, we appreciate the acknowledgment by SEAC that challenges exist for economic operators due to the lack of reliable and standardized analytical and extraction methods.  In the light of the above we would like to focus on a few points where additional input is critical to help ensure a workable legal framework while minimizing unnecessary socio-economic impacts.  - TLV of 25 ppb for PFOA or its salts is still too low  While this proposed modification to the original 2 ppb limit provides relief from an unrealistic requirement – necessary to preserve market access to C6 alternatives – a 25 ppb limit is still too low for a complex and highly fragmented international supply chain to consistently comply within the timeframe proposed due to cross-contamination in manufacturing facilities.  The reason is that key Asian manufacturing nations such as China and India are unlikely to adopt similar legislative initiatives for PFOA and related substances, and will likely promote the increasing use of cheap, high performing products incorporating these substances for their growing economies and populations. Additionally, with decreased demand for products treated with long-chain fluorinated substances from EU and US apparel and footwear brands, the cost of these substances in finishing formulations has seen downward pressure and therefore greater availability for Asian manufacturers serving cheaper, domestic brands.  These realities create substantial risk of unintentional cross-contamination, either from natural resources (water) or production facilities serving simultaneous demands of EU, US and Asian brand clients. This risk is especially concerning given the broad and far-reaching scope of the regulation, which covers products, components, preparations, substances, etc. across all industry sectors and multiple, diverse, upstream applications.  Considering this risk and SEAC’s acknowledgement in its draft opinion that “PFOA-related substances are more important than the direct use of PFOA as potential sources of environmental releases of PFOA,” we reiterate our original suggestion of an initial TLV of 500 ppb in apparel and footwear products, with an incremental decrease to 100 ppb within 5 years if supported by the scientific information gathered. This greater limit and extended timeframe further supports one of the cited merits of a longer transition time in SEAC’s draft opinion: “allow progress in various monitoring related challenges (definition of reference chemicals, standardization of analytical methods, definition and standardization of extraction methods and associated reference matrices).”  - Professional Textiles vs Outdoor Textiles creates uncertainties  The draft opinion’s examples and suggested 6 year transitional period for Professional Textiles (e.g. firefighters and military) is appreciated but raises scope of restriction concerns. Per definition any alpine rescue service, disaster control or coastguard member could be considered a professional, even though some serve on a reserve or volunteer basis. The equipment they use provides high attention for the desire of ambitious leisure users, and a huge overlap of both categories exists. Legal uncertainties are therefore created in how to apply the different transitional periods for professional vs. non-professional “outdoor” textiles, i.e., 3 vs. 6 years.  We have noted and support SEAC’s intention to ask for a review of the regulation after 5 years, which would then allow for the integration of scientific results created with a validated test method.  As stated in our 28th February 2015 comments, opportunities among AFIRM members for the most rapid reduction of PFOA and its salts in the supply chain occurred when these substances were restricted by brands 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 in particular the control of cross-contamination sources.  We therefore request ECHA/SEAC to focus on restricting intentional use of PFOA and its salts, and to align on one clear and sufficient implementation timeline for similar product categories of five years. To create a legally sound business environment for economic operators importing any kind of product in scope of the regulation, a scientific and analytically robust TLV for PFOA and its salts should be 500 ppb initially, with a guided incremental decrease possible down to 100 ppb over 5 years. This would allow industry to perform due diligence with their global business partners and support further innovation and research needed to achieve lower concentrations over time. Careful consideration of new data available after the introduction of validated analytical and extraction-methods is a key factor for supporting such an approach. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We believe it should be feasible to reduce the contamination level in facilities to comply with the proposed limit values (25 ppb for PFOA and its salts, 1000 ppb for PFOA-related substances) within the transitional period, also based on comments received from many textile industry stakeholders.  We have reformulated the wording on different kinds of technical textiles to clarify the different transitional periods proposed.  Textiles have been recognised to be one of the biggest emission sources, and therefore we support a longer transitional period for some technical textiles only. | | |
| 223 | **Date/Time:** 2015/11/06 11:38  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  Belgium  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  Items for personal protection to be completed with:  Personal protective equipment, especially for the protection against liquid chemicals for industry (EN 13034) and firefighters (EN 469)  It’s important to know that when there is a health-risk when the user is exposed to PFOA, not using C8-technology for protective clothing is an even bigger risk for the user as the protection against very acute and dangerous risks for which the garments are designed, can’t be guaranteed anymore. | | |
| **SEAC Rapporteurs response:**  Thank you for your comment.  We have modified the list of textile types for which an extended transitional period is proposed however, we have not seen it necessary to include a list of related standards. | | |
| 224 | **Date/Time:** 2015/11/09 14:34  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Fedustria  **Org. country:**  Belgium  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  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 welcomes the opinion of SEAC (supported by RAC), that the threshold values proposed by the Dossier Submitter (2 ppb) should be raised significantly. In the reaction to the public consultation concerning the annex XV dossier, Fedustria raised the problem that the original threshold value of 2 ppb would mean a de facto ban of fluorinated alternatives, which are essential for reaching the high standards for protective clothing. Fedustria agrees with the opinion of SEAC to make a distinction between PFOA including the salts on the one hand and the PFOA related substances on the other hand. However as there are still no validated analytical methods for all PFOA-related substances, it is impossible to give a well-founded comment whether the threshold values proposed by SEAC/RAC are feasible are not. Therefore, it is of utmost importance that the thresholds value of the proposed restriction are being set at a reasonable level that guarantees the further use of the C6-alternatives.  During the public consultation Fedustria stressed that essential characteristic for protective clothing such as a strong and durable oil and chemical repellence, can so far only be met by using C8 chemicals. In that respect Fedustria welcomes the opinion of SEAC proposing an extended transitional period of 6 years after entry into force for companies producing professional protective textiles. An extended transitional period of at least 6 years will certainly be needed as alternatives will not be a “one fits all” solution or a “drop-in” replacement. Alternatives will require reformulation of recipes and a lot of testing by the textile companies will be needed to ensure the protective clothing can still meet the end-use performance characteristics as laid down in several standards.  Using other chemistry for oil- and water repellence for instance might have a detrimental effect on e.g. the flame retardant properties 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. Therefor for textile companies the substitution of a chemical by an alternative is in most cases a complex process with a lot of trial and error, especially when high standards are involved. An extended transitional period of at least 6 years is in these cases crucial for the producers of protective clothing. | | |
| **SEAC Rapporteurs response:**  Thank you for your comment.  We have retained the extension of the transitional period for protective textiles in the opinion and we have also suggested extending it to cover some other types of technical textiles.  Analytical methods are under development and a rapid progress in availability for different applications is expected. | | |
| 225 | **Date/Time:** 2015/11/10 04:00  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Nippon Electric Control Equipment Industries Association  **Org. country:**  Japan  **Company name confidential: No**  **Attachments:**    **<removed>**  **Privacy comment:**  There might be a difference in perception of the exposure between you, SEAC and us.  So, it might disrupt the authorities and the general public.  But we think this is a reasonable and common. | **Comments on the SEAC draft opinion:**  1.We would like to request the evidence that shows the basis of the current regulation value proposal (25 ppb).  We have never experienced this level of severe value in electrical and electronic equipment industry.  Presentation of legitimate evidence is necessary in this industrial sector to understand necessity of work.  2.There is a need to develop the estimation tools for exposure assessment of the article, especially direct human exposure (DHE).  (Some of them might be currently under development in JRC and OECD countries.)  In the medium to long term, it would be necessary to set the regulation and regulation value based on the result of estimation by these tools. | | |
| **Specific information 1:**  1.Nippon Electric Control Equipment Industries Association (NECA) would like to request that the transit period for the products in category 9, EU RoHS Directive would be 15 years, same as medical equipment, category 8.  The definition of category 9 in EU RoHS Directive 2011/65/EU is monitoring and control instruments, including industrial monitoring and control instruments.  Reason a)  Since which parts contain PFOA, more that 25 ppb and less than 1000 ppm in our products, are unknown, an appropriate period of time is needed to investigate it with numerous number of suppliers across various industry sectors.  Reason b)  Category 9 products, especially products like control instruments, might have the variety of specification with millions of the subject parts inside, and the inventory period of parts extends to a long period of time.  For the reason mentioned above, investigation of the parts'compliance and availability, evaluation of the alternative solution and re-authentication of CE conformity would require years of work easily.  2.In case of the industrial monitoring and control instruments, as the distribution is limited to B2B, it might be extremely low that the general public would be exposed by the products.  For the reason mentioned above, it might be reasonable to exclude the application of the restrictions. | | |
| **SEAC Rapporteurs response:**  Thank you for your comment  We note the concern expressed and the complexity of your supply chains, but the reasons why some parts could contain PFOA or PFOA related substances above the thresholds are not explained. It is not clear which type of instruments and which parts might be a potential concern. We did not receive any other specific comments for the products in category 9, EU RoHS Directive. We therefore consider that we do not have enough evidence to propose 15 years derogation.    Your comment refers to the similarity of the situation of the medical equipment industry. However this industry sector has made past efforts to identify PFOA/PFOA-related substances in their supply chains, and has provided detailed evidence that, despite significant effort to find alternatives time was needed to find and implement them. | | |
| 227 | **Date/Time:** 2015/11/10 17:44  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:**  **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 | **Comments on the SEAC draft opinion:**  see attachement | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Please see reply to Comment 245. | | |
| 228 | **Date/Time:** 2015/11/11 12:46  **Type:** Company-Downstream user  **Org. type:**  Company-Downstream user  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  The European textile producing industry already limited PFOA/PFOA-salts-emissions to approx. 5-10 Kg/a, close to zero!  This could be achieved mainly by using fluoropolymers like PTFE produced without APFO, and by shifting standard apparel, carpet textiles etc. to short-chain and fluorine free products as much as technically and economically possible. Also best environmental practices in production are a major key to avoid emissions and to bring them down to this low level.  To reduce PFOA-/PFOA-salts-emissions to the target „zero-emission“, in the past 10 years the European textile industry was spending millions of Euro in R&D, testing and production trials etc. to convert the textile production in technical textile from C8-chemistry almost to C6/short-chain technology as much as possible because short-chain technology was claimed to be PFOA-free and an alternative to generate durable water-, oil-, soil- and chemical repellent finish.  We all now have to recognize that especially short-chain-C6-technology is containing also traces of PFOA and more traces of related substances. These are the state of the art ecological limits of the C6-technology and there is no other alternative-technology we can technically rely on to replace the effects of the C8-products in the majority of textiles. Even with C6-technology we face technical performance limits, and in wide fields of applications - especially in „technical textiles“ - the use of FC-free products is not suitable due to an overall lack of performance. Still there are applications, where C6-systems don’t fulfil the requirements established with C8-chemistry  Technical textiles produced in the EU are delivered as crosssectional B2B-products to other high-technology industry-sectors in the EU to produce a variety of high value products. Many EU companies are highly specialized in the field of technical textiles and produce world-marketable products with the specific high performance level of C8 chemistry. Without this performance companies and complete EU-value added chains will be shifted to non EU-production sites.  In general in our main competitor-markets (Asia, approx. 70 % of world textile production) C8-Chemistry will be used in future in full width. The specialized EU technical textile companies and also EU-Textile trade marks will technically not be able to compete with technical textiles from mainly asian, south- and middle-american markets, which are not controlled by such restrictions, with products with lower performance and at significantly higher prices.  The technical textiles are produced in the EU respecting best environmental -conditions in production with no emission of PFOA/PFOA salts. This also includes emission paths after production like domestic washing, etc. Within their life-cycle Technical Textiles are rarely washed nor are they in environmental contact under conditions that elute PFOA or related substances into the environment, having in mind that the treatment with fluorinated products has the aim to minimize the influence of the environment by durable oil- and water repellency.  Furthermore the finish with fluorinated products generates a significantly higher durability and therefore contributes to a higher product-sustainability. | | |
| **Specific information 1:**  In addition short chain technology, especially C6-chemistry, is 4-6 times more expensive. (The amounts of C6-products, which are necessary to obtain similar effects, are almost 2-4 times higher, and they are up to 50 % more expensive. In addition to increase C6-performance, it is necessary to use additional, expensive products, like special modified crosslinker/booster-systems.  Also the now starting examination on toxicological and environmental aspects of also expensive fluorine-free/booster system products poses in general the question on which alternatives EU-textile industry could rely on in the future. Further restrictions or CLP-classification could also restrict these alternatives.  The basic key element of the restriction is that the industry/down-stream-users have to be able to demonstrate the evidence of compliance with the finally set limits. But how to be compliant without defined testing methods?  This yet non existing testing method has also to consider the connection between PFOA/PFOA-salts claimed in the dossier and the related substances, and also the specific conditions (e.g. storage, UV-radiation, humidity of an treated article etc.) The testing-method should be proofed and set in a collaborative trial for PFOA/PFOA-Salts and related substances within selected approved testing laboratories, before the final draft of the dossier could be handed over to the EU-commission.  Therefore we ask for a well-defined, robust DIN-EN-ISO testing method (eg. DIN EN ISO 17075 for Chrom VI) at affordable costs for down-stream user mass testing, before the final draft is handed over to the EU-commission | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. Please see response to Comment 245. | | |
| 229 | **Date/Time:** 2015/11/11 16:54  **Type:** Company-Downstream user  **Org. type:**  Company-Downstream user  **Org. name:**  **<removed>**  **Org. country:**  United Kingdom  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  your document refers to treatment of textiles using 'pfoa related'(fluorocarbon) products which is confusing as both C6 and C8 contain PFOA as impurity and are therefore both considered a direct route of PFOA to the environment.  C6 fluorocarbon products used to treat textiles contain less than 5 ppb PFOA as impurity.  C8 fluorocarbon products used to treat textiles contain less than 0.5 ppm PFOA as impurity.  please clarify whether these products are defined as 'pfoa related' or not.  in your proposed threshold limits on page 166 / 167 under which column would C6 and C8 fluorocarbon be - pfoa or pfoa related ? | | |
| **SEAC Rapporteurs response:**  Thank you for your comment.  To clarify, a substance or a mixture is under the scope of the restriction if it contains substances included in the left-hand side paragraph of the Annex XVII entry proposal in a concentration exceeding the threshold concentration (unless exempted). The abbreviation PFOA refers to perfluorooctanoic acid itself, whereas "PFOA-related substances" refers to substances that can release PFOA through their degradation.  (C6 substances are under the scope when contain C8 restricted fractions in a concentration exceeding the given threshold level.) | | |
| 230 | **Date/Time:** 2015/11/11 17:18  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:** | **Comments on the SEAC draft opinion:**  We would like to comment via attachment. This is a summary of what we would suggest:  To preserve the possibility of a production in an international value added chain of highly specialized products the EU textile industry needs  • Additional derogations for example in paragraph 3 d) for technical textiles (ref.: Draft SEAC restriction proposal, Sept. 10th 2015)  • Reasonable thresholds that include the ability to use the C6 chemistry in the future  • Affordable, well designed and resilient testing method | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. Please see response to Comment 245. | | |
| 231 | **Date/Time:** 2015/11/12 03:42  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Japan Electronics & Information Technology Industries Association(JEITA)  **Org. country:**  Japan  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  (1) Need for reasonable and feasible measures:  We believe that covered substances should be identifiable by identifiers and be manageable, and that thresholds for them should be justifiable via appropriate risk assessment, reasonable and feasible both for authorities and for industry.  Covered substances should be specified by identifiers such as EC number or CAS number 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) And considering the risk analysis and practices in which the whole supply-chain could control substances, we consider that the level on which would be the same as threshold of PFOS under EU POPs Regulation:  - in substances and mixtures：equal to or below 10mg/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.  (2) About appropriateness of proposed thresholds:  Neither RAC Opinion nor draft SEAC Opinion has described risk-based discussion or proper socio-economic impact assessment about rationale and appropriateness of a still very low threshold, 25ppb. Transparency seems to lack in setting the thresholds. The legislators should clearly show the reason for necessity of managing impurity at such a low threshold, as well as the scientific ground and rationality of the threshold of 25ppb for management.  (a) Incomplete risk-based assessment and socio-economic analysis:  For the risk-based discussion and appropriate socio-economic consideration, we would like to propose that the following viewpoints should be considered in socio-economic impact assessment:  (i) Evaluation of cost/benefit of managing impurity:  There is NO cost estimation for controlling PFOA-related impurity along long and complex supply-chain, though proposed restriction in draft SEAC Opinion requires controlling impurity of PFOA for wide variety of final products. SEAC should evaluate the necessity to manage unintended impurities at such a very low threshold, as a part of its socio-economic impact assessment.  (ii) Evaluation of cost for testing/measurement:  There is no cost evaluation/estimation for chemical analysis to detect 25ppb and higher concentration. We should know the differences of these analyses cost based on 25ppb and higher threshold for overall cost/benefit analysis, and such cost/benefit analysis should be a part of socio-economic analysis to determine if proposed restriction will be appropriate measure to control risk of PFOA. 25ppb is far beyond current analytical technology available for these products which are not water, chemicals or mixtures, 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, and total cost for controlling PFOA at 25ppb will not be affordable for the society.  (b) Inconsistency to EU Food contaminant control policy:  EFSA already evaluated the risk of PFOA as food contaminant in 2008. Based on the EFSA study on risk assessment of PFOS and PFOA, tolerable daily intake (TDI) of PFOA is ten times of that of PFOS, and indicative exposure level from food intake of PFOA is less than one-tenth of that of PFOS. Food contamination is good indicator of environmental exposure, so we can estimate that PFOA exposure to environment is less than that of PFOS. Therefore, we strongly insist that 25ppb limit value of contamination of PFOA is not rational, and residual limits of PFOA should be at least the same as that of PFOS, 1000ppm.  Furthermore, TDI is not content of the substance in the subject but standard value for intake, so we should convert TDI to content of the substance in the subject for the comparison. We see there is no rational for the restriction such extreme low level of PFOA in article, comparable to that of foods or drinking water. Much higher limit value for article will be sufficient for controlling risk of PFOA, because exposure from article will be much lower than that of food and drinking water. Considering these issues, we provisionally converted TDI to concentration in the food substance 52.5 ppt, given adult human with body weight of 70 kg consumes 2 kg of foods daily for the consideration of rationality of 25ppb limit value.  (c) Assessment of necessity to manage impurities:  Both of the U.S. and Canadian proposals to restrict PFOA do not require managing impurity in the article. We consider that the necessity to manage impurity should be evaluated by socio-economic impact assessment proposed in (a)(i).  (d) Issues on management of impurity under current proposed restriction from the point of view of practice:  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 presence must be checked, huge number of possible materials and parts would have to be investigated in detail. It should be considered that strict threshold of PFOA than that of PFOS may significantly increase burden for industry.  (e) Residual PFOA in the fluorinated polymers:  According to the annual report on 2010/2015 PFOA Stewardship Program conducted by U.S. EPA and major fluorochemical manufacturers, residual PFOA in the fluorinated polymers varies widely among manufacturers, and the report suggest that some ppm PFOA will be remains in the fluoropolymers. For reality, proposed restriction value of 25ppb should be carefully reexamined. See Table 1 and 2 in PFOA and Fluorinated Telomers 2014 Annual Progress Reports:  http://www.epa.gov/oppt/pfoa/pubs/stewardship/preports8.html | | |
| **Specific information 1:**  (1) Derogation for semiconductor-related process and products  We welcome the derogation for the production, placing on the market and use of substances and mixtures containing one or more substances identified in column 1 for mixtures used in semiconductor photolithography processes (5.b)). However, current scope of derogation is not sufficient, and we would like to propose it as follows (text shown in “ “ is newly added):  Our proposal :  5. b) the production, placing on the market and use of substances and mixtures containing one or more substances identified in column 1 for mixtures used in semiconductor photolithography processes “and etching process of compound semiconductor”.  6. By way of derogation, paragraph 2 shall not apply to:  “f) the placing on the market of semiconductor products.”  Justification:  (a) PFOA is commonly used as substitute of PFOS in semiconductor manufacture. Under the POPs Convention, the use of PFOS for acceptable purposes is permitted, so the use of PFOA should be also permitted for acceptable purposes listed below. The description on this issue in POPs Convention is as follows:  “List of acceptable purposes and specific exemptions for production and use of PFOS, its salts and PFOS-F  Acceptable purposes:  Photo-imaging, photo-resist and anti-reflective coatings for semi-conductor, etching agent for compound semi-conductor and ceramic filter, aviation hydraulic fluids, metal plating (hard metal plating) only in closed-loop systems, certain medical devices (such as ethylene tetrafluoroethylene copolymer (ETFE) layers and radio-opaque ETFE production, in-vitro diagnostic medical devices, and CCD colour filters), fire-fighting foam, insect baits for control of leaf-cutting ants from Atta spp. and Acromyrmex spp.”  http://chm.pops.int/DNNADMIN/HiddenModulesforMandeepsPublications/POPsChemicalsMandeepshiddenmodule/tabid/754/Default.aspx  (b) After semiconductor photolithography processes and/or etching processes of compound semiconductor, mixtures of PFOA are removed from elements which compose a semiconductor. However, such the small threshold and the facts of using above processes would make downstream of supply chain require analysis data of all semiconductors, even of semiconductor manufactured without above processes. Submitting such analysis data is impossible because the ppb level PFOA analytical method does not exist as mentioned in IV(a) of attached comment. After all, without exemption of semiconductor, semiconductor industry could not use above processes.　So we request the exemption of "the placing on the market of semiconductor products."  Please see also our proposal in II. a) (ii) of attached comment.  (2) Derogation for spare/repair parts not only for automobiles but also all the products which have been placed on the market before the date of entry into force  We also welcome the derogation for spare parts of automobiles (6.d)), applying the “repaired as produced principle”. We however question why the scope of the derogation is limited to cars, and believe it should be for all the products which need repair and maintenance. Therefore, we would like to propose it as follows (text shown in “ “ is newly added or changed):  Our proposal :  6. By way of derogation, paragraph 2 shall not apply to:  d) the placing on the market of spare parts “and repair parts for products which have already been placed on the market before” the date of entry into force.  Justification:  Spare parts are basically specified for certain product model(s) and designed at the time of designing the whole product. Usually, they would not be redesigned after the model is discontinued. On the other hand, they serve for products once placed on the market and need to be available to users in order to extend products’ life-time via upgrading or repairing operations. Furthermore, the possible measures for longer life-time of products are recently discussed in the course of “circular economy” and “product durability” in the EU.  In such situation, we believe that a derogation for spare parts for all industries and sectors should be provided. In case the “repaired as produced principle” is not properly accounted for, we anticipate the following negative impacts for both economic operators and consumers within the European market:  (a) Increasing costs for manufacturers: As we said in the above, in most cases spare parts for EEE are specifically made for a specific product model. As such, spare parts are manufactured at the same timing of manufacturing parent products and kept in stock considering service parts retention period (generally much longer than 2 years). If there is no derogation for spare parts, manufacturers would need to retroactively confirm for such parts already in stock before legislation entered into force with suppliers (who themselves need to confirm upper stream in the supply chain with the raw materials’ supplier) if the substance is present in relevant parts of the product at the given threshold. This will create extra efforts and costs in the supply chain. If a supplier cannot provide retroactive information on materials/parts manufactured in the past, chemical analysis might have to be done (which will be destructive and create extra costs). Moreover, in some cases, the manufacturers will have to totally redesigning and re-manufacturing the spare parts even for the dead models. It will also create extra costs not only for manufacturers but also for customers.  (b) Increasing costs for customers: If the extra high cost is created by re-checking in supply-chain or by redesigning / re-manufacturing spare parts, manufacturers may have no other choice than shifting the additional costs partly onto spare parts fee or repair fee. As the result, such cost would be partially borne by consumers.  (c) Decreasing products lifetime: In case where costs are too high to be borne by industry and consumers, manufacturers will no longer be able to ensure the service and refurbishment of products beyond the warranty period legally required. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We have proposed the addition of etching processes to the exemptions from the restriction.  We have also proposed that spare parts already manufactured before the date of entry into force should be exempted.  However, the information from the Background Document shows that the additional costs that could be incurred by industry to put on the market articles and spare parts that comply with the thresholds are justified, given the concerns for health and the environment of PFOA and PFOA-related emissions.  The information you submitted in the Public consultation is general and does not provide evidence for an opposite conclusion. Therefore SEAC rapporteurs do not support derogation for spare parts after the date of entry into force.  Regarding your other comments, we can clarify that :   * The proposed restriction is justified not only by quantitative risk assessment but also by the requirement under REACH to minimise the emissions of PBT/vPvB substances. * Analytical possibilities have been taken into account, and also the extension of the transitional period proposed by SEAC will provide more time for the analytical developments. * We received many comments in the public consultation from industry supporting the new thresholds. * Identifying explicitly all chemicals under the scope is not possible, given their high number. | | |
| 232 | **Date/Time:** 2015/11/12 07:39  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Taiwan Semiconductor Industry Association  **Org. country:**  Taiwan  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  Taiwan Semiconductor Industry Association appreciates the opportunity to provide these comments as part of the public consultation on the draft opinion of the Committee of Socio-economic Analysis (SEAC) for Perfluorooctanoic acid (PFOA).  Taiwan Semiconductor Industry Association welcomes and acknowledges the work of the ECHA committees in proposing in their opinion reports an exemption for semiconductor manufacturing industry photolithography processes.  1. Derogation for Photolithography Uses in the Semiconductor Industry  Taiwan Semiconductor Industry Association welcomes and would like to acknowledge the constructive consideration given by the Committee for Socio-economic Analysis (SEAC) (See Committee for Socio-economic Analysis (SEAC), (Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (Draft 10 September 2015)) and Committee for Risk Assessment (RAC) (Committee for Risk Assessment (RAC), Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (ECHA/RAC/RES-O-0000006229-70-02/F) (Adopted 8 September 2015)) in response to the request of the European Semiconductor Industry Association made in the ECHA June 2015 consultation for a derogation for semiconductor photolithography process.  2. Derogation for Manufacturing Equipment and Parts in the Semiconductor  Industry  Semiconductor manufacturing equipment and production installations (e.g., piping) used in the semiconductor factories to make the semiconductor device (microchip) 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. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Regarding point 2, the information available indicates that it is generally possible for industry to manufacture fluorinated materials that comply with the conditions of the proposed restriction. However we recognise the high complexity of the semiconductor manufacturing equipment and processes, and therefore we have proposed a longer transitional period (5 years instead of 3) for manufacturing equipment.  SEAC rapporteurs support derogation for spare parts manufactured before entry to force, but not after this date (see response to Comment no 231). | | |
| 233 | **Date/Time:** 2015/11/12 11:16  **MS name:**  Germany  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  IV. Non-confidential attachment | | |
| **SEAC Rapporteurs response:**  Thank you for your comment.  We have carefully considered lowering the suggested limit values especially as regards textiles. We share the concern that a too high concentration limit might allow intentional use in the manufacture of imported articles, allowing higher emissions and resulting in competitive disadvantage for EU companies. We have however decided to not make any changes. The limit value must be practicable to allow reliable analytics, and to account for background concentrations and contamination of machinery deriving from earlier use for example.  More generally we note that although exist standardised analytical methods for the determination of the concentrations of given substances at sufficiently low levels, time is needed for the validation of the methods for different matrices.  Relating to concentrations lower than the threshold having been detected in articles on the market, we note that there is usually no information on whether or not there has been intentional use of PFOA, its salts or PFOA-related substances.  It is evident that a longer transitional period than 18 months is needed in many different sectors for a high number of different applications. A longer transitional time allows better communication in long and complex supply chains, and also background concentration and contamination issues are expected to be mitigated. A development of analytical methods is also expected. We also find it more practicable to allow a longer transitional period than writing a longer list of specific exemptions.  As regards the proposed derogation of newly made firefighting foams, there is a general concern among stakeholders (manufacturers and users) that lower concentration limits could limit the firefighting services capabilities.  Overall regarding the concentration limits, SEAC rapporteurs consider that lowering them is an objective for the future and call in the opinion for a review after 5 years in order to lower the concentration limits in light of new additional information. | | |
| 235 | **Date/Time:** 2015/11/12 17:58  **Type:** Company-Downstream user  **Org. type:**  Company-Downstream user  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:** | **Comments on the SEAC draft opinion:**  **<removed>** asks for an exemption of PFOA use in fire-fighting foams: **<removed>** 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. | | |
| **SEAC Rapporteurs response:**  Thank you for your comment.  Your comment seems to have been intended for the public consultation of the Annex XV dossier. A new proposal with a higher concentration limit was included in the SEAC draft opinion that was the object of this second round of public consultation. We believe that this new proposal is taking care of your concerns. | | |
| 236 | **Date/Time:** 2015/11/12 18:06  **Type:** Company-Downstream user  **Org. type:**  Company-Downstream user  **Org. name:**  MGF Gutsche GmbH & CO. KG  **Org. country:**  Germany  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  Comments on the SEAC-Opinion of September 10, 2015  to the Annex XV dossier proposing restrictions on  Perfluorooctanoic acid (PFOA),its salts and PFOA-related substances  To preserve the possibility of a production in an international value added chain of highly specialized products the EU textile industry needs  • Additional derogations for example in paragraph 3 d) for technical textiles (ref.: Draft SEAC restriction proposal, Sept. 10th 2015)  • Reasonable thresholds that include the ability to use the C6 chemistry in the future  • Affordable, well designed and resilient testing methods  Please also see the detailed comment. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. Please see response to Comment 245. | | |
| 237 | **Date/Time:** 2015/11/12 18:15  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  EURATEX  **Org. country:**  Belgium  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  As the European Textile industry is operating in an environment close to zero discharge and to preserve the possibility of a production in an international value added chain of highly specialized products, our industry needs:  • An additional derogation for technical textiles  • Reasonable thresholds that include the ability to use the C6 chemistry in the future  • Affordable, well designed and resilient testing method  • Maintain a long transitional period of at least 6 years as it is needed because alternatives will not be a „one fits all “solution and reformulation of recipes is a long and complex exercise | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. Please see response to Comment 245. | | |
| 238 | **Date/Time:** 2015/11/12 18:21  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **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 | **Comments on the SEAC draft opinion:**  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 | | |
| **Specific information 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 REAChAlternatives 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 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.  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. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. They have been taken into account in our final opinion. Please see reply to Comment 245. | | |
| 239 | **Date/Time:** 2015/11/12 20:05  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  United States  **Company name confidential: Yes**  **Attachment:** | **Comments on the SEAC draft opinion:**  November 12, 2015  Submitted via online form at: https://comments.echa.europa.eu/comments\_cms/SeacDraftOpinionPFOA.aspx  Re: Committee for Socio-economic Analysis (SEAC) draft Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (10 September 2015)  **<removed>** appreciates this opportunity to provide comments to the “Committee for Socio-economic Analysis (SEAC) on the draft Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances” published by the European Chemicals Agency (ECHA). **<removed>** is a manufacturer of firefighting foam agents and is responding accordingly. **<removed>** also appreciates SEAC’s approach of balancing information related to human health, science, the environment, property and industry needs when providing its opinion. This was clearly demonstrated in the firefighting foam discussion on pages 13 and 14 of this draft Opinion.  **<removed>** Supports the Continued Use of Existing Stocks of Firefighting Foams Indefinitely, or, In the Alternative, for At Least 15 Years  **<removed>** supports the proposed derogation 5 (c) to allow for continued use of firefighting foams already placed on the market at the time of entry into force. This derogation took into account the high cost that would be incurred by users of these products if they had to be replaced. Through **<removed>**’s membership in the Firefighting Foam Coalition, we believe that some commenters within the European Union may have proposed a 15-year time limit for this derogation. **<removed>** does not believe such a time limit is necessary, as these products would be expected to be used or replaced within such time periods through normal use or end of life processes. However, if SEAC believes that a time limit is necessary in the final proposal, a 15 year time limit would allow for orderly transition to the new chemistry.  **<removed>** Supports the Proposed Per Substance Limits for PFOA and Related Substances of 1000 ppb, Not An Aggregated Limit  **<removed>** also supports the proposed derogation 5 (d) for firefighting foam to the extent that it means that the proposed concentration limit for PFOA and each of the PFOA related substances is per substance and not an aggregated limit. We believe that each of these substances (outlined in the derogation) should have an individual limit of less than or equal to 1000 ppb (as described on page 14) We recommend that this be clarified in the revised derogation table the way it was described on page 14 of this draft Opinion.  **<removed>** would now like to comment on the discussion for firefighting foams (FFF) contained on pages 13 and 14 of the draft opinion.  We again support SEAC’s proposal “to adopt the higher concentration limit of 1000 ppb per substance, for both PFOA or for each PFOA- related substance, and to reconsider this concentration limit with the aim to lower it in the proposed review of the restriction 5 years after the entry into force.” **<removed>** believes that in 5 years, when this proposed review would be initiated, substantially more information will be available regarding the process capabilities of industry, enabling a more precise balancing of appropriate limits that can be managed by manufacturers of firefighting foam while also providing adequate protection of human health, the environment, and property.  **<removed>** Supports the Proposed 1000 ppb PFOA Limit for FFF Used for Training  We agree with the following from page 14 of the draft opinion; “SEAC proposal (including the higher concentration limit of 1000 ppb for PFOA) will also apply to FFF used for training.” We support this proposal because we believe that most historic contamination attributed to FFF use is the result of past practices that failed to minimize environmental impacts, unlike more recent FFF training practices that are much more environmentally sensitive. The industry currently focuses on containment and treatment of FFF discharges resulting from training events. Alternative fluids are also now used as a surrogate for firefighting foams in training and testing when acceptable. With the transition to newer fluorinated chemistries in FFF, improved knowledge associated with the potential impact of foams and combustion products, and with much improved containment and treatment of the discharges, the industry is able to manage training activities in a much more environmentally sound manner.  Terminology  The terms C6 alternatives and C6 fluorochemicals are used interchangeably in the draft opinion. For clarification purposes, we would like to suggest on page 12 under the Manufacture of C6 alternatives to define each of these terms as C6 fluorotelomer-based alternatives.  On behalf of **<removed>**, I would like to thank you for your consideration of our comments to this draft opinion. If you have any further questions associated with these comments, please contact me.  Respectfully. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments and support.  Regarding the concentration limit, the aim is indeed that the threshold applies to each chemical under scope. The text in the entry has been modified to be consistent with the justification section.  We have also proposed safe and environmental sound handling of foams used for training in the entry of the restriction. | | |
| 240 | **Date/Time:** 2015/11/13 05:19  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Semiconductor Industry Association in China  **Org. country:**  China  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  The comments are from Semiconductor Industry Association in China. The detail information is attached in non-confidential attachment. | | |
| **SEAC Rapporteurs response:**  Thank you for your comment.  Please see answers to Comment 231. | | |
| 241 | **Date/Time:** 2015/11/13 09:16  **Type:** Company-Downstream user  **Org. type:**  Company-Downstream user  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  The European textile producing industry already limited PFOA/PFOA-salts-emissions to approx. 5-10 Kg/a, close to zero!  This could be achieved mainly by using fluoropolymers like PTFE produced without APFO, and by shifting standard apparel, carpet textiles etc. to short-chain and fluorine free products as much as technically and economically possible. Also best environmental practices in production are a major key to avoid emissions and to bring them down to this low level.  To reduce PFOA-/PFOA-salts-emissions to the target „zero-emission“, in the past 10 years the European textile industry was spending millions of Euro in R&D, testing and production trials etc. to convert the textile production in technical textile from C8-chemistry almost to C6/short-chain technology as much as possible because short-chain technology was claimed to be PFOA-free and an alternative to generate durable water-, oil-, soil- and chemical repellent finish.  We all now have to recognize that especially short-chain-C6-technology is containing also traces of PFOA and more traces of related substances. These are the state of the art ecological limits of the C6-technology and there is no other alternative-technology we can technically rely on to replace the effects of the C8-products in the majority of textiles. Even with C6-technology we face technical performance limits, and in wide fields of applications - especially in „technical textiles“ - the use of FC-free products is not suitable due to an overall lack of performance. Still there are applications, where C6-systems don’t fulfil the requirements established with C8-chemistry  Technical textiles produced in the EU are delivered as crosssectional B2B-products to other high-technology industry-sectors in the EU to produce a variety of high value products. Many EU companies are highly specialized in the field of technical textiles and produce world-marketable products with the specific high performance level of C8 chemistry. Without this performance companies and complete EU-value added chains will be shifted to non EU-production sites.  In general in our main competitor-markets (Asia, approx. 70 % of world textile production) C8-Chemistry will be used in future in full width. The specialized EU technical textile companies and also EU-Textile trade marks will technically not be able to compete with technical textiles from mainly asian, south- and middle-american markets, which are not controlled by such restrictions, with products with lower performance and at significantly higher prices.  The technical textiles are produced in the EU respecting best environmental -conditions in production with no emission of PFOA/PFOA salts. This also includes emission paths after production like domestic washing, etc. Within their life-cycle Technical Textiles are rarely washed nor are they in environmental contact under conditions that elute PFOA or related substances into the environment, having in mind that the treatment with fluorinated products has the aim to minimize the influence of the environment by durable oil- and water repellency.  Furthermore the finish with fluorinated products generates a significantly higher durability and therefore contributes to a higher product-sustainability. | | |
| **Specific information 1:**  In addition short chain technology, especially C6-chemistry, has not the same efficiency in oil repellency like C8-chemistry. To increase C6-performance, it is necessary to use additional, expensive products, like special modified crosslinker/booster-systems. But at the end they do not reach the same efficiency  Also the now starting examination on toxicological and environmental aspects of also expensive fluorine-free/booster system products poses in general the question on which alternatives EU-textile industry could rely on in the future. Further restrictions or CLP-classification could also restrict these alternatives.  The basic key element of the restriction is that the industry/down-stream-users have to be able to demonstrate the evidence of compliance with the finally set limits. But how to be compliant without defined testing methods?  This yet non existing testing method has also to consider the connection between PFOA/PFOA-salts claimed in the dossier and the related substances, and also the specific conditions (e.g. storage, UV-radiation, humidity of an treated article etc.) The testing-method should be proofed and set in a collaborative trial for PFOA/PFOA-Salts and related substances within selected approved testing laboratories, before the final draft of the dossier could be handed over to the EU-commission.  Therefore we ask for a well-defined, robust DIN-EN-ISO testing method (eg. DIN EN ISO 17075 for Chrom VI) at affordable costs for down-stream user mass testing, before the final draft is handed over to the EU-commission | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. Please see response to Comment 245. | | |
| 243 | **Date/Time:** 2015/11/13 11:01  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:**  **<removed>**  **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 | **Comments on the SEAC draft opinion:**  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 | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. They have been taken into account in our final opinion. Due to the confidential character of the comments we cannot give subject specific replies. | | |
| 244 | **Date/Time:** 2015/11/13 12:17  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  3M Belgium  **Org. country:**  Belgium  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  Please find attached comments by 3M on the Proposed PFOA Annex XV Restriction, Draft SEAC opinion. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments and the information on the development of analytical methods and the possible complications regarding the transitional period. Your feedback as a manufacturer is important.  We have retained our suggestion of extending the transitional period to 36 months, in order to realistically achieve the implementation for manufacturers and downstream industry. | | |
| 245 | **Date/Time:** 2015/11/13 13:50  **Type:** Company-Downstream user  **Org. type:**  Company-Downstream user  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  Comments on the SEAC-Opinion of September 10, 2015  to the  Annex XV dossier proposing restrictions on  Perfluorooctanoic acid (PFOA),  its salts and PFOA-related substances  Close to Zero - reduction of PFOA/PFOA-Salts-Emissions already achieved in the EU-textile producing industry.  The European textile producing industry already limited PFOA/PFOA-salts-emissions to approx. 5-10 Kg/a, close to zero!  This could be achieved mainly by using fluoropolymers like PTFE produced without APFO, and by shifting standard apparel, carpet textiles etc. to short-chain and fluorine free products as much as technically and economically possible. Also best environmental practices in production are a major key to avoid emissions and to bring them down to this low level.  To reduce PFOA-/PFOA-salts-emissions to the target „zero-emission“, in the past 10 years the European textile industry was spending millions of Euro in R&D, testing and production trials etc. to convert the textile production in technical textile from C8-chemistry almost to C6/short-chain technology as much as possible because short-chain technology was claimed to be PFOA-free and an alternative to generate durable water-, oil-, soil- and chemical repellent finish.  We all now have to recognize that especially short-chain-C6-technology is containing also traces of PFOA and more traces of related substances. These are the state of the art ecological limits of the C6-technology and there is no other alternative-technology we can technically rely on to replace the effects of the C8-products in the majority of textiles. Even with C6-technology we face technical performance limits, and in wide fields of applications - especially in „technical textiles“ - the use of FC-free products is not suitable due to an overall lack of performance. Still there are applications, where C6-systems don’t fulfil the requirements established with C8-chemistry  In addition short chain technology, especially C6-chemistry, is 4-6 times more expensive. (The amounts of C6-products, which are necessary to obtain similar effects, are almost 2-4 times higher, and they are up to 50 % more expensive. In addition to increase C6-performance, it is necessary to use additional, expensive products, like special modified crosslinker/booster-systems.  Also the now starting examination on toxicological and environmental aspects of also expensive fluorine-free/booster system products poses in general the question on which alternatives EU-textile industry could rely on in the future. Further restrictions or CLP-classification could also restrict these alternatives.  B2B EU-Industry and Export economic Impact in „Technical Textiles“- further derogation in paragraph 3 of the proposed new text of the restriction  Technical textiles produced in the EU are delivered as crosssectional B2B-products to other high-technology industry-sectors in the EU to produce a variety of high value products. Many EU companies are highly specialized in the field of technical textiles and produce world-marketable products with the specific high performance level of C8 chemistry. Without this performance companies and complete EU-value added chains will be shifted to non EU-production sites.  In general in our main competitor-markets (Asia, approx. 70 % of world textile production) C8-Chemistry will be used in future in full width. The specialized EU technical textile companies and also EU-Textile trade marks will technically not be able to compete with technical textiles from mainly asian, south- and middle-american markets, which are not controlled by such restrictions, with products with lower performance and at significantly higher prices.  The technical textiles are produced in the EU respecting best environmental -conditions in production with no emission of PFOA/PFOA salts. This also includes emission paths after production like domestic washing, etc. Within their life-cycle Technical Textiles are rarely washed nor are they in environmental contact under conditions that elute PFOA or related substances into the environment, having in mind that the treatment with fluorinated products has the aim to minimize the influence of the environment by durable oil- and water repellency.  Furthermore the finish with fluorinated products generates a significantly higher durability and therefore contributes to a higher product-sustainability.  According to the principle of proportionality, and the fact that PFOA/PFOA-salt emissions of the EU textile producing industry are already reduced close to zero we need further derogations.  To maintain production within a value added chain of highly specialized products in unique niche markets, we need further derogations in paragraph 3. of the proposed new text of the restriction exceeding the existing sector of “professional textiles” for the use of C8-chemistry in the field of “technical textiles”, thus adding paragraph 3 d) “technical textiles”.  As Technical Textiles we define for example  • Belts and ropes, e. g. transport conveyor belts for food industry  • Breathable membrane systems  • Special fibers for exhaust air filter / exhaust gas cleaning  • Textile reinforced materials for ultrafiltration e.g. water purification  • Tops of convertible cars, soft-tops, tarpaulins  • Furniture  • Textile sealing, e. g. tapes and gaskets  • Weather-resistant membrane systems for textile constructions/sun protection  • Medical textiles, e. g. Hollow fiber membrane systems for dialysis  In this respect we refer also to the derogation REACH ANNEX 18 for „isolated intermediates“ e.g. fluoroalcohols and fluoro(meth)acrylates for the production of C6-shortchain products for the chemical industry. As no emissions result from these intermediates, the mixtures transported in containers and barrels have no emissions as well. So emission-free handling should be a derogation in general. | | |
| **Specific information 1:**  Limit values  Down-stream-users in the European textile industry do not know, if the proposed limits in the SEAC-Dossier are sufficient to allow the use of short chain FC-chemistry throughout the whole supply chain, especiallyC6-chemistry in the future.  Further downgrading of the limit of 1000 ppb for Related Substances and 25 ppb for PFOA/PFOA-Salts, if at all technically possible, will even more lead to the already existing dramatic cost increase ( e.g. already 4-6 times more chemical cost of C6-chemistry compared to C8-chemisty) and could also have a huge impact on the market structure of the suppliers/telomerproducers which already is an oligopol market. Also the limit of 25 ppm PFOA/PFOA-salts seems to separate the EPA-Stewardship (oligopoly) members from other textile auxilliaries suppliers, to enlarge their marketshare in perfluourinated DWR-products. The market has to be kept open.  Furthermore especially many medium size textile companies, that have built up a market in their niche will lose their business, when necessary products are not marketable due to low limit values.  Therfore we ask to establish reasonable limit values which allow to work with C6/(C4) short-chain technology in the future and we ask to take into consideration that further downgrading the thresholds for related substances could cause an even more dramatic cost increase for down-stream-users and a high risk to shift the market towards a monopoly.  Compliance/Testing method  The basic key element of the restriction is that the industry/down-stream-users have to be able to demonstrate the evidence of compliance with the finally set limits. But how to be compliant without defined testing methods?  This yet non existing testing method has also to consider the connection between PFOA/PFOA-salts claimed in the dossier and the related substances, and also the specific conditions (e.g. storage, UV-radiation, humidity of an treated article etc.) The testing-method should be proofed and set in a collaborative trial for PFOA/PFOA-Salts and related substances within selected approved testing laboratories, before the final draft of the dossier could be handed over to the EU-commission.  Therefore we ask for a well-defined, robust DIN-EN-ISO testing method (eg. DIN EN ISO 17075 for Chrom VI) at affordable costs for down-stream user mass testing, before the final draft is handed over to the EU-commission    Conclusion  To preserve the possibility of a production in an international value added chain of highly specialized products the EU textile industry needs  • Additional derogations for example in paragraph 3 d) for technical textiles (ref.: Draft SEAC restriction proposal, Sept. 10th 2015)  • Reasonable thresholds that include the ability to use the C6 chemistry in the future  • Affordable, well designed and resilient testing methods | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We appreciate that the textile producing industry has already made good progress in limiting emissions from production facilities.  However, we note that of concern are also emissions of PFOA/its salts and PFOA-related substances from articles throughout and after their service life.  The thresholds suggested by RAC and SEAC are intended to allow continued use of C6 chemistry.  Textiles have been identified as a major source of emissions, and volumes of PFOA-related substances seem to be still high. It seems that many stakeholders consider the proposal of 36 months long enough. We note that an EU-wide restriction would not directly affect the use of C8 chemistry outside the EU. One reason for bringing the threshold limit values down is to avoid imports of articles produced using C8 chemistry intentionally.  We have retained the extension of the transitional period for protective textiles in the opinion and we have also suggested extending it to cover some other types of technical textiles. | | |
| 246 | **Date/Time:** 2015/11/13 14:21  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Fire Fighting Foam Coalition  **Org. country:**  United States  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  The Fire Fighting Foam Coalition (FFFC) appreciates this opportunity to provide comments on the “Committee for Socio-economic Analysis (SEAC) draft Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances” published by the European Chemicals Agency. FFFC is a non-profit trade association whose members are manufacturers of fire fighting foam agents and their chemical components, and include the following companies: Angus International (Angus, National Foam, Eau & Feu, Kerr Fire), Chemours, Dr. Sthamer, Dynax, Fire Service Plus, Fire Safety Devices, Dafo Fomtec, ICL (Auxquimia), Kidron, KV Fire, Oil Technics, Profoam, and Tyco (Ansul, Chemguard, Sabo, Williams). Together these companies provide a significant majority of the fire fighting foam used in Europe and worldwide.  FFFC strongly supports the SEAC proposal as outlined on page 14 of the draft opinion for a 1000 ppb concentration limit “per substance, for both PFOA or for each PFOA-related substance” for firefighting foams. FFFC believes this level is low enough to ensure the elimination of long-chain fluorochemicals in foam without restricting the use of short-chain alternatives. As noted on page 13 and 14 of the draft opinion, AFFF agents containing short-chain fluorochemicals are essential for many life-safety and high-value applications such as aircraft rescue and fire fighting at airports and large hydrocarbon/chemical tank fires.  The proposed derogation 5d) on page 6 does not make clear that the concentration limit is per substance for both PFOA and each PFOA-related substance. It is our understanding that ECHA staff have acknowledged the need to revise this derogation to clarify that the 1000 ppb concentration limit is intended to be per substance for firefighting foams.  FFFC supports the proposed derogation 5c) to allow the continued use of firefighting foams already placed on the market when the restriction enters into force. This derogation will help to minimize the costs to users and ensure a smooth transition to the use of short-chain alternatives.  We understand that an additional derogation has been proposed by industry in Europe to address the mixing of old and new foam agents during backfill of foam equipment. This proposed derogation includes a 15-year limit on the use of foams already placed on the market when the restriction enters into force. FFFC believes that 15 years is an adequate amount of time for users to make the transition and could support this proposal should it be included in the final restriction.  As noted in our June 17 comments to ECHA, FFFC has developed best practice guidance focused on eliminating where possible the use of fluorinated foams for testing and training. We fully support the RAC and SEAC view that the use of existing stocks of foam with long-chain content for training should be avoided when possible.  We note the discussion on page 14 of the draft opinion of the potential for groundwater contamination from the use of existing stocks of firefighting foam. Contamination from foam use is usually the result of past practices before the potential environmental impact of foam discharge was known to most users. Over the past decade there has been an increased focus on minimizing discharges of firefighting foams to the environment. Current best practice calls for the containment and treatment of foam discharges, and the use of alternative fluids and methods for testing and training. As such the ongoing and future use of fluorinated foams would not be expected to result in the levels of contamination currently being measured at legacy training sites.  The terms “C6 alternatives” and “C6 fluorochemicals” are used interchangeably in the draft opinion. It might be useful on page 12 under the “Manufacture of C6 alternatives” to clarify that both of those terms are referring to C6 fluorotelomer-based alternatives.  Thank you for your consideration of these comments. Please let us know if you have any questions. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Please refer to our answer to Comments 221 and 239 and to the text of the opinion to see the proposed changes.  We acknowledge the progress made for the minimisation of discharges from using firefighting foams. | | |
| 247 | **Date/Time:** 2015/11/13 17:00  **Company name confidential: No**  **Attachment:**  **<removed>** | **Comments on the SEAC draft opinion:**  ECHA  Annankatu 18,  P.O. Box 400,  FI-00121 Helsinki,  FINLAND 13.11.2015  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  We hereby claim a proposal for 1000 ppb limit for PFOA and each single related substance. | | |
| **Specific information 1:**  Film forming foam types, based on mainly C6 chemistry with only smallest parts of C8 and impurities of PFOA, were purchased in the past years instead of PFOS containing foam types. 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 AFFF-foam types based on currently available C6-fluoro telomeric raw materials in our production plant, fulfilling the proposed threshold, is not possible.  Extinguishing systems in fixed installations, monitor applications for mobile emergency response e.g. in refineries, storage tank farms and large industrial plants are based on special technical framework until now will only meet by the properties of film-forming foam concentrate types. These products protect non polar liquid fires even with poor foaming properties. A drop in alternative for these technical frameworks does not exist at the moment. | | |
| **SEAC Rapporteurs response:**  Thank you for the comments and the information that you have provided.  We underline that the new version of the SEAC draft opinion proposes higher concentration limits, that we believe will address your concerns that are related to the original proposal.  The information you submitted tends to confirm the suitability of the new concentration limits. | | |
| 249 | **Date/Time:** 2015/11/13 18:38  **Type:** Academic institution  **Org. type:**  Academic institution  **Org. name:**  **<removed>**  **Org. country:**  Switzerland  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  To whom it may concern:  We welcome the efforts by the original submitters, ECHA and the Committees, in opinion development regarding the restriction proposal for PFOA and PFOA-related substances. To support the development of most effective measures to restrict the production and use of these harmful substances, we would like to submit the following comments on the SEAC draft opinion.  In particular, we are concerned that the transition period of 36 months seems to be too long. It should be noted that all major producers of fluorotelomer-based products in the US and EU joined the US EPA PFOA 2010/15 Stewardship Program in 2006 and have worked effectively to eliminate PFOA, precursor chemicals that can break down to PFOA, and related higher homologue chemicals from emissions and products in the past ten years. In January 2015, EPA released the most recent reports, for years 2013 and 2014, from the participating companies on the progress they have made in reaching the program’s phase-out goals. Results show that the companies are on track to reach the program’s goal of phasing out these chemicals by the end of 2015 (see the report: http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca/20102015-pfoa-stewardship-program-2014-annual-progress).  In addition, considerable efforts have been made to support transition from perfluorooctane sulfonate (PFOS) and related chemicals to alternatives under the Stockholm Convention on Persistent Organic Pollutants. In brief, multiple alternatives on the market including non-fluorinated ones have been identified, and have been or are being assessed including socio-economic analyses. Considering the fact that PFOA-related chemicals (in particular substances based on fluorotelomer raw materials) share almost identical uses with PFOS-related chemicals (i.e. perfluorooctane sulfonyl fluoride (POSF)-based substances), it is recommended that information on alternatives to PFOS and related chemicals under the Stockholm Convention on Persistent Organic Pollutants, in particular availability of alternatives on the market, should be taken into account in the development of the SEAC opinion. For example, in 2012 after POPRC 7, information on alternatives to PFOS and related chemicals was collected (http://chm.pops.int/Convention/POPsReviewCommittee/POPRCMeetings/POPRC7/POPRC7Followup/Requestsforinformation/RequestsforcommentsbyPOPRC7IWGs/CommentsonPFOSinopenapplications/tabid/2746/Default.aspx). Dr. Roger A Klein commented, “Note that there are considerable formulation difficulties with pure C6 fluorotelomers satisfactorily solved by very few companies so far (latest available information: one in the USA, a couple in Europe)”, which shows that as successful phase-out of C8 substances was possible already several years ago. Dr. Klein’s comment was further supported by that the Fire Fighting Foam Coalition (FFFC), “As such some manufacturers have already completed this transition and have a full line of AFFF products available containing pure short-chain C6 fluorosurfactants, while other manufactures are still in the process of reformulation and requalification. This transition is expected to be completed by 2015.” Therefore, it is not only theoretically possible, but also practically feasible to develop pure short-chain PFASs-based fire-fighting foams.  Furthermore, it is noted that there have been many break-throughs in developing non-fluorinated alternatives in applications such as fire-fighting foams (http://www2.epa.gov/greenchemistry/2014-designing-greener-chemicals-award) and durable water-repellent textile finishes (http://www.huntsman.com/textile\_effects/Applications/itemrenderer?p\_rendertitle=no&p\_renderdate=yes&p\_renderteaser=no&p\_item\_id=990135572&p\_item\_caid=1163).  Hence, based on progresses currently being made worldwide, the originally proposed transition time of 18 months may well be enough for industry to act after a preparation time started 10 years ago. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  According to the information received in both public consultations, a longer transitional period than 18 months is needed inmany industrial sectors due to the high number of different applications involved. Please consider that it has also been required by some manufacturers, as you can see from comment 244, for example.  It is important to note, as confirmed by other manufacturers, that the alternatives are not “drop-in” replacements, but they require formulation work to ensure the specific end-use performance needs (including the requirements of technical standards) are met.  A longer transitional time can also take into account the problems related to complex and global supply chains, as described by many stakeholders. The background concentration and contamination issues are also expected to be mitigated during this time. A further development of the analytical methods can be expected too. We also find it more practicable to allow a longer transitional period than writing a much longer list of specific exemptions.  As regards the proposed derogation of newly made firefighting foams, at the present time, there is a general concern among stakeholders (manufacturers and users) that lower concentration limits could limit the firefighting services capabilities. We are aware that alternatives are being increasingly available for many uses concerned and we consider it important that the concentration limits may be reviewed in 5 years' time after the entry into force, with the aim to lower them. Please refer to the opinion for more details, including information on the non-fluorinated alternatives for fire-fighting foams. | | |
| 250 | **Date/Time:** 2015/11/13 18:39  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Industrial Fire Protection Association - Bundesverband Betrieblicher Brandschutz - Werkfeuerwehrverband Deutschland (WFVD  **Org. country:**  Germany  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  On behalf of the Industrial Fire Protection Association - Bundesverband Betrieblicher Brandschutz - Werkfeuerwehrverband Deutschland (WFVD)  we referring to  • the draft of SEAC - Opinion of the Committee for Socio-economic Analysis -10.09.2015;  • the draft of RAC Restriction proposal on PFOA and PFOA-related substances – 15.09.2015  Restrictions – Draft  Thresholds  The conditions of the restriction proposed by SEAC are in line with the requirements for industrial and aviation firefighting purposes. RAC claims and support a higher concentration limit providing the opinion of SEAC.  We agree by way of derogation from § 1.  § 1 shall not apply to:  • the use of firefighting foams already placed on the market on (date of entry into force) and  • placing on the market and use of firefighting foams containing PFOA or its salts or one or a combination of PFOA-related substances identified in column 1, as constituents of other substances or components of a mixture in concentrations less than or equal to 1000ppb.  Period of use  At all events, during the implementation of a “PFOA and related substances” restriction, we propose a threshold value which guarantees the continued used of all foam agents currently stocked by fire departments until 27.06.2031. This permits continued use for 20 years after the prohibition date for PFOS of 27.06.2011, including foam extinguishing agents newly stocked after that date. Should an extinguishing agent which demonstrably has the “same” extinguishing effects/properties as the current AFFF foam extinguishing agents become available before 2031, then this time period can be shortened. | | |
| **SEAC Rapporteurs response:**  Thank you for your comment.  SEAC proposes a transitional period of 20 years to allow the transition to safer alternatives. Details are available in the text of the opinion. | | |
| 251 | **Date/Time:** 2015/11/13 20:02  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  France  **Company name confidential: Yes**  **Attachment:**  **<removed>** | **Comments on the SEAC draft opinion:**  The use of Fluorine Free Foam is not recent as mentioned in the draft and their performances on fire improve for several years. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. They have been taken into account in our final opinion. Due to the confidential character of the comments we cannot give subject specific replies. | | |
| 252 | **Date/Time:** 2015/11/13 21:52  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Semiconductor Industry Association  **Org. country:**  United States  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  Please see the attached comments of SIA. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Please refer to our response to Comment no 232. | | |
| 253 | **Date/Time:** 2015/11/13 22:17  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  United Kingdom  **Company name confidential: Yes**  **Attachment:**  **<removed>**  **Privacy comment:**  Our clients plasma coating technology is highly sensitive and their intellectual property and it would put them at a competitive disadvantage if their name were to be associated with the technology as well as their competitors having access to information relating to their research into alternative technologies and materials. This also contains some sensitive market information on application and volumes. | **Comments on the SEAC draft opinion:**  This response has been prepared by Environmental Resources Management Limited (ERM) on behalf of our client, as a response to the European Chemical Agency’s (ECHA) draft Opinion on the Restriction of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances issued by SEAC as of 10th September 2015.  As part of the previous consultation, we presented the socio-economic impact, chemicals risk, and environmental case for the continued use of our client’s nano-coating process which is used in smart phones and other electronic devices. This process involves polymerising a C8F17-X monomer, which is a perfluorooctanoic acid (PFOA)-related substance, into a covalently-bonded highly water- and oil-repellent coating. This monomer and its resulting polymerised coating (as well as any other alternatives with C8F17-X side chains) fall within the scope of the proposed restriction and is listed in column 1 of the original text of the restriction proposed by the Dossier Submitter on 17 October 2014. In SEAC draft Opinion it was noted that:    “Nano-coatings  Regarding nano-coatings, a company applying coating for smartphone manufacturers, requested during the Public Consultation a derogation for 3 years in order to be able to move to an alternative C6 chemical. SEAC considers that the annual emissions related to this use are probably low compared to other uses, and agrees that 3 years is an acceptable length for the transition to alternatives. Since SEAC is proposing a general transitional period of 36 months for the proposed restriction (see section on Practicality), there is no need for a specific derogation. SEAC considers that the difficulties expected with complying with the concentration limit due to presence of C8 impurities will be avoided with the concentration limits suggested by RAC.”  Since compiling our client’s response to the February 2015 consultation, our client has carried out a series of studies which:  • Puts in doubt their ability to move to a high performance alternative C6 chemistry within the 36 month transitional period.  • Questions the reliability of commercially available analytical detection techniques to accurately detect levels of C8 PFOA-related polymer chemistries that are present in articles.  Both of these studies mean that our client, and their customers in the EU who use their coating technology, will be put at a competitive disadvantage when compared with their non-European manufacturers; if the level of C8 PFOA-related polymer chemistries cannot reliably be measured then it will be impossible to enforce a ban on their import when contained in articles. However, unlike their non-EU competitors, our client, and their customers, will be unable to use the starting C8F17-X monomer to initiate their nano-coating when the ban comes into force, and so, by default, will be unable to produce nano-coated electronics and smart phones using the C8 technology. Their only option will instead be to use a technology that is inferior to that used outside of the EU until a comparable alternative technology is proven (if that is indeed possible) and lose market share as a consequence.  • We therefore request that the transitional period be extended to 6 years for nano-coatings in line with what has been proposed for protective professional textiles which face a similar alternative technology challenge.  • During an extended transitional period our client will continue to use C8F17-X monomer under strictly controlled conditions and create the nano-polymer coating in situ under strictly controlled conditions. Our client will advocate that incineration at the end of life is the safest route for disposal for electronic and smart phone articles that are that are coated using the C8F17-X technology, in line with how the electronics and smart phones would be treated as they are subject to WEEE and RoHS.  We propose that that a new paragraph, 3 d), be inserted into the restriction proposed by SEAC in the draft Opinion:  d) Pulsed plasma nano-coating, for which the transitional period is 6 years after entry into force; | | |
| **Specific information 1:**  A full socio-economic analysis of the consequences of our client not being able to use C8 technology until a move to a high performance alternative is proven was described in detail in our response to the consultation on the Dossier Submitters 17 October 2014 report. This is why we ask that a new exception 3 d) be added extending the transitional period for Pulsed plasma nano-coating to 6 years after entry into force | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. We have considered them carefully. The SEAC final opinion suggests a transitional period of 6 years for pulsed plasma nano coating produced using conditions that minimise emissions to the environment. | | |
| 254 | **Date/Time:** 2015/11/14 12:34  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  DIGITALEUROPE  **Org. country:**  Belgium  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  DIGITALEUROPE, the association representing the digital technology industry in Europe, welcomes the opportunity to comment on the SEAC opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), PFO salts and PFO-­‐related substances, published on the 10th September 2015.  While PFOA is usually not directly contained in electronic products, Fluoropolymers are base plastic materials used in a wide variety of electronic applications. For these Fluoropolymer applications there are neither alternatives nor substitutes. The original proposal to restrict PFOA and PFOA-­‐related substances at 2 ppb for articles therefore presents a serious concern for our industry. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Regarding the consistency with other regulation, we underline that the proposed restriction is intended to minimise the emissions of PFOA and related substances, given the PBT/vPvB properties of these chemicals.  Regarding substance identification, test methods, and your request of derogation for spare parts, please refer to our answer to Comments 231 and 232.  As noted in the Annex XV dossier, the major fluoropolymer manufacturers in the US, Japan and Europe, have joined the US EPA Stewardship Programme. The companies have worked for several years to eliminate PFOA from fluoropolymer production. To our knowledge (according to the information received in the public consultation) there should be fluoropolymers manufactured without PFOA available by the end of the 36 months transitional period, with a concentration not higher than 25 ppb. Please see the opinion for more details. | | |
| 255 | **Date/Time:** 2015/11/14 22:56  **Type:** National Authority  **Org. type:**  National Authority  **Org. name:**  Environment Agency Austria  **Org. country:**  Austria  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  Environment Agency Austria:  Comments on SEAC draft opinion PFOA, its salts and PFOA-related substance  13.11.2015  Threshold for PFOA, its salts and PFOA-related substances  The Environment Agency Austria is aware of the fact that the second public consultation on restriction proposals is mainly on the socio-economic aspects of a restriction. Nevertheless we think it is crucial to submit the following information.  1.) SEAC (and also RAC) suggests a threshold of 25 ppb for PFOA and 1000 ppb for PFOA-related substances in articles.  Environment Agency Austria does not agree on the proposed thresholds for PFOA and PFOA-related substances.  - The RAC threshold would allow the intentional use of PFOA and PFOA-related substances in articles, especially articles imported into the EU.  - The higher threshold values would allow higher emissions and reduce the benefits of the restriction; this would result in a less effective measure in terms of risk reduction potential.  - The increasing threshold would bring a competitive disadvantage for companies inside the EU, because PFOA and PFOA-related substances cannot be placed on the market; whereas companies outside the EU can intentionally use the substances and export articles inside the EU.  - The lower threshold mentioned in the restriction dossier is based on confidential data from industry.  - The lower threshold values are measurable for PFOA and some PFOA-related substances (ref. to scientific literature studies cited in the background document of the restriction dossier).  - The lower threshold values allow the use of alternatives (e.g. short-chain fl. alternatives).  - Textiles are the main emission source of PFOA-related substances (ref. to RAC opinion, 2015), measured values (ref. to background document to the Opinion on the Annex XV dossier) are below the RAC proposed threshold and thus cannot be determined if companies used the substances intentionally or not. The proposed restriction with the proposed limit values defined by RAC (´on balance´) might not change the situation from now.  We suggest to use the threshold of 2 ppb for PFOA and 100 ppb for PFOA-related substances in final articles, as originally proposed in the restriction dossier.  2.) SEAC suggests a threshold of 1000 ppb for PFOA in fire-fighting foam.  The Environment Agency Austria does not agree on the proposed thresholds for PFOA in fire-fighting foams.  - The use of aqueous film forming foams AFFFs was investigated by KEMI (2013). PFOA is still present in old and new generation AFFF, further a correlation between the use of AFFFs and PFASs in groundwater and military bases (Filipovic et al., 2015; Moody et al., 2003) or airports (Ahrens et al., 2015, Umweltamt Düsseldorf Landeshauptstadt, 2015) has been proven.    - Drinking water can be contaminated with PFOA as well and the increasing relevance of PFOA as drinking water contaminant was also subject of a review by Post et al., 2012.  - Decontamination of the environment from PFAS in general is difficult and very expansive e.g. Per- and polyfluoroalkyl substances (PFAS) in aqueous film forming foams (AFFF) is one of the largest and potentially most costly environmental problems currently facing the US military (Fresenius Tagung, Idenstein 2014).  - Up to now, little is known about the mixture toxicity of PFASs at environmental relevant conditions. Due to the permanent release and their persistence in nature more than one generation will suffer from their exposure (Ahrens et al., 2014).  - Mixtures of PFOS and PFOA have been shown to exhibit toxic interactions on Danio rerio embryos that could not be explained by concentration addition or independent action (Ding, 2013 cited in Ahrens, 2014). In addition, ecotoxicity increased with increasing molar ratio of PFOS in binary mixture (Liu et al. (2010), cited in Ahrens, 2014).  In addition to the PBT properties of PFOA and the above mentioned concerns about increasing the threshold, mixture toxicity issues need to be considered and the thresholds have to be kept as low as possible.  References:  Ahrens, L. and Bundschuh, M. 2014: Fate and effects of Poly-and Perfluoroalkyl substances in the aquatic environment: a review, Environ. Toxicology and Chemistry, Vol 33. No 9, 1921-1929, 2014  Ahrens, L. et al., 2015. Stockholm Airlanda Aiport as a source of per- and polyfluoroalkyl substances to water, sediment and fish. Chemosphere, Volume 129, pp. 33-38.  Background document to the Opinion on the Annex XV dossier) proposing restrictions on Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances ECHA/RAC/RES-O-0000006229-70-02/F  Filipovic, M. & Berger, U., 2015. Are perfluoroalkyl acids in waste water treatment plant effluents the result of primary emissions from the technosphere or of environmental recirculation?. Chemosphere, Volume 129, pp. 74-80.  Fresenius Tagung: PFAS „Anlysis – Fate – Human Exposure-Regulation“, abstract book, June 15-18, 2014  KEMI, 2013. Report 5/13, Stockholm, Sweden: Swedish Chemicals Agency.  Moody, C. A. & Field, J., 1999. Determination of Perfluorocarboxylates in Groundwater Impacted by Fire-Fighting Activity. Environmental Science Technology, Volume 33, pp. 2800-2806.  Post, G.B., Cohn, P.D., Cooper, K.R. 2012. Perfluorooctanoic acid (PFOA), an emerging drinking water contaminant: a critical review of recent literature. Environ Res. 2012 Jul;116:93-117.  RAC Opinion, 2015: Opinion on an Annex XV dossier proposing restriction on PFOA, ist salts and PFOA-related substances (ECHA/RAC/RES-O-0000006229-70-02/F)  Umweltamt Landeshauptstadt Düsseldorf, 2015b. PFT Grundwasserverunreinigung im Stadtgebiet. [Online] Available at: http://www.duesseldorf.de/umweltamt/altlast/pft\_gerresheim.shtml. | | |
| **SEAC Rapporteurs response:**  Thank you for your comment.  We have carefully considered lowering the suggested limit values especially as regards textiles. We share the concern that a too high concentration limit might allow intentional use in the manufacture of imported articles, allowing higher emissions and resulting in competitive disadvantage for EU companies. We have however decided to not make any changes to our suggestion. The limit value must be practicable to allow reliable analysis, and to account for background concentrations and contamination of machinery deriving from earlier use, for example.  More generally we note that even when analytical methods for the determination of the concentrations of given substances at sufficiently low levels exist, time is needed for the validation of the methods for different matrices.  Regarding the concentrations (lower than the thresholds) detected in several articles on the market, unfortunately it is not clear whether or not there has been intentional use of PFOA, its salts or PFOA-related substances.  As regards the proposed derogation of newly made firefighting foams, at the present time, there is a general concern among stakeholders (manufacturers and users) that lower concentration limits could limit the firefighting services capabilities. We are aware that alternatives are increasingly available for many uses concerned and we consider it important that the concentration limits may be reviewed in 5 years' time, after the entry into force, with the aim to lower them.  We have included in the opinion some information submitted in the public consultation on the remediation costs due to environment contamination. | | |
| 256 | **Date/Time:** 2015/11/15 14:36  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  France  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  We thank SEAC for the opportunity to consult further on the published Opinion on an Annex XV dossier proposing restriction on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (September 2015).  Our Company supports SEAC’s recommendation to adopt the concentration level of 1,000ppb per substance, for both PFOA or for each PFOA-related substance within the firefighting foam derogation as detailed on page 14 of the document. | | |
| **SEAC Rapporteurs response:**  Thank you for the support. | | |
| 257 | **Date/Time:** 2015/11/15 17:09  **Type:** International NGO  **Org. type:**  International NGO  **Org. name:**  Greenpeace  **Org. country:**  Netherlands  **Company name confidential: No**  **Attachment:**  *see comment 261* | **Comments on the SEAC draft opinion:**  Greenpeace agrees with the need for the Restriction of PFOA and PFOA-related substances - An attachment addresses the following areas:  General comments address: 1)Precursor substances that contribute to PFOA exposure; and 2)information on concentration levels found in imported articles.  Specific comments address: 1)the issue of threshold values which should be lower than proposed in order to achieve the primary desired purpose and benefit of EFFECTIVELY reducing exposure to health and environment; 2)the need to re-visit and delete the proposed derogation for recycled materials (proposed derogation 6. b)); and 3)information on the additional need to regulate short-chain PFCs for the benefit of those reviewing the public comments, including all stakeholders to avoid regrettable substitution. | | |
| **SEAC Rapporteurs response:**  Please see the response to comment 261. | | |
| 258 | **Date/Time:** 2015/11/15 19:39  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  United Kingdom  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  We appreciate the opportunity to respond to SEAC’s opinion on an Annex XV dossier proposing restriction on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances as published in September 2015.  The recommendation of SEAC to adopt the higher concentration limit for firefighting foam of 1,000ppb per substance, for both PFOA or for each PFOA-related substance, is supported by our Company. This level will ensure the elimination of long-chain fluorinated products without adversely restricting the use of high performance C6 fluoro-telomer alternatives. | | |
| **SEAC Rapporteurs response:**  Thank you for your support. | | |
| 259 | **Date/Time:** 2015/11/15 19:41  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  United Kingdom  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  Thank you for this further round of consultation to this important issue. We support SEAC’s proposal on page 14 of 1,000ppb per substance, for both PFOA or for each PFOA-related substance. We are an SME, manufacturing firefighting foam and value SEAC’s consultation into our industry’s requirements. C6 fluoro-telomer products are currently a vital part of fire protection in some sectors (as identified in the SEAC Opinion document, published 10th September 2015). | | |
| **SEAC Rapporteurs response:**  Thank you for your support. | | |
| 260 | **Date/Time:** 2015/11/16 08:50  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Fire Industry Association  **Org. country:**  United Kingdom  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  FIA welcomes and fully supports the current SEAC proposal in its draft “Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances” dating September 10th, 2015, on pages 13 and 14 of an individual threshold value of 1000ppb for PFOA and each related substance.  We have however noted that the proposed wording for the restriction text (pages 4-6, particularly paragraph 5d) seems to differ from the corresponding justification on the pages 13 and 14 of the same document:  The derogation proposed in 5d) on page 6 leaves it unclear if the threshold value is to be applied on the content of the entire group of chemicals specified as PFOA and related substances or on each individual representative of that group. The justification speaks of 1000ppb per individual substance. This was addressed to ECHA accordingly for awareness.  Based upon the respective correspondence between ECHA’s Risk Management Implementation Unit and EUROFEU’s FFA as well as with other members of the industry it is our understanding that SEAC has acknowledged the need to revise the derogation proposal accordingly to clarify the intended threshold limit in firefighting foams to be 1000ppb per each individual substance as defined in the restriction.  FIA also welcomes and supports the derogation 5c) allowing the use of those firefighting foams which are already on the market at the time the restriction enters into force. This derogation greatly helps securing a continuous fire protection in high risk areas and a seamless transition towards alternative foam agents. It was however noted that SEAC’s proposal does not clarify how foam agent stocks shall be handled: A significant volume of foam agents is stored on industrial sites to supply mandatorily required fix installed fire protection systems or as an emergency stock in moveable large volume containments (trailers, skids, etc.). In order to keep the corresponding fire protection systems fully operational at any point in time a defined volume of foam agent must be stored on site.  Any consumption of that stored volume must be restored to the required minimum storage volume (in Europe typically defined by EN-Standards). It is hence a critical requirement to backfill a foam storage containments with fresh foam agent in any case of partly consumption of the stored (old) foam agent. This practice leads to backfilling existing stock volumes (which are already on the market hence exempted according to paragraph 5c and 5d of the recent draft of the regulation in SEAC’s recent opinion document) with new foam agents (which have to comply to the restriction). The draft proposal by SEAC does not specify how the resulting mixture will be classified: will the stock volume remain exempted as it was before backfilling or will it be considered new? | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  SEAC rapporteurs have made some proposals in the final opinion. Please see response to Comments 221 and 239. | | |
| 261 | **Date/Time:** 2015/11/15 17:09  **Type:** International NGO  **Org. type:**  International NGO  **Org. name:**  Greenpeace  **Org. country:**  Netherlands  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  Greenpeace agrees with the need for the Restriction of PFOA and PFOA-related substances - An attachment addresses the following areas:  General comments address: 1)Precursor substances that contribute to PFOA exposure; and 2)information on concentration levels found in imported articles.  Specific comments address: 1)the issue of threshold values which should be lower than proposed in order to achieve the primary desired purpose and benefit of EFFECTIVELY reducing exposure to health and environment; 2)the need to re-visit and delete the proposed derogation for recycled materials (proposed derogation 6. b)); and 3)information on the additional need to regulate short-chain PFCs for the benefit of those reviewing the public comments, including all stakeholders to avoid regrettable substitution. | | |
| **SEAC Rapporteurs response:**  Thank you for the information you submitted.  We completely agree that PFOA-related substances must be included in the scope.  We share the concern that a too high concentration limit might allow intentional use in the manufacture of imported articles, allowing higher emissions and resulting in a competitive disadvantage for EU companies. However the limit value that will be adopted has to be practicable to allow reliable analysis and to account for background contamination of machinery deriving from earlier use, for example. Relating to concentrations (lower than the proposed threshold) detected in articles on the market, it is not clear whether the use was intentional or not. Anyhow we think that it would be important to review the concentration limits 5 years after the entry into force.  We share the concern of environmental hazards of short-chained alternatives, however generally speaking they seem to be less bioaccumulative and less toxic (but with comparable persistence) compared to the C8 substances proposed for restriction; therefore at this moment we support this substitution.  We consider it preferable that articles made of recycled materials would not contain PFOA, its salts or PFOA-related substances. The proposed restriction contributes to that by "cutting pollution at the source; the effect in terms of articles made of recycled materials will materialize gradually. There are also other factors we have taken into account. Additional arguments we have considered can be found in the opinion. However, please note that recycling was considered to be derogated in the original proposal from DE/NO and no fully assessed RMOA (risk management option analysis) has been received to justify why recycling should be brought into scope. | | |
| 262 | **Date/Time:** 2015/11/16 10:29  **MS name:**  Sweden  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  1. The Swedish Chemicals Agency opposes the unconditional derogation for firefighting foams (FFF) already placed on the market (paragraph 5c).  Both RAC (p.16 in RAC opinion) and SEAC (p.14 in SEAC draft opinion) suggest that the use of FFFs containing PFOA (and related substances) for training exercises should be avoided. These suggestions are in line with recommendations given by FluoroCouncil.  There are several reported cases in the EU of underground water contamination associated with the use of FFF for training. In Sweden there has been several reported cases of drinking water contamination associated with the use of FFF for training. Two are mentioned below:  • In Uppsala the drinking water supply for nearly 200,000 people has been contaminated. In order to meet drinking water quality standards, the municipal water company has annual costs of approximately 10 million SEK (1.1 million €) for filtration of the contaminated water.  • In Kallinge/Ronneby (population of 5,000), the drinking water plant has shut down after finding high levels of especially PFOS and PFHxS in the drinking water. 20 children from Kallinge were sampled and analysed in the spring of 2013. Compared with a nearby city (reference group with levels comparable with what has been found in children and young adults in other Swedish studies), the concentrations of PFOA were increased 8 times in serum (The concentrations of PFOS, PFHxS and PFBS were increased even higher).  In order to avoid similar episodes in the future, the Swedish Chemicals Agency is of the opinion that:  • the use of FFFs containing PFOA (and related substances) for training exercises should be excluded from the derogation. If considered necessary, this exclusion could be accompanied by a clause providing that individual member states may, within their territory, allow the use of FFFs containing PFOA for training exercises until a set date.  • the derogation for firefighting foams already placed on the market, should either be time limited (e.g. to 2030 as suggested by the DS) or subject to revision in the proposed review of the restriction 5 years after entry into force.  2. On page 14 in the draft opinion, SEAC states that:  ”SEAC also notes that fires have long term and indirect negative consequences, since they cause high emissions to air and the environment of hazardous chemicals, some of them being PBTs, with delayed environmental impacts and indirect human health impacts. Therefore SEAC adopts a cautious and balanced approach in order to have enough confidence that the restriction and concentration limits still ensure the availability of suitable FFF for every situation.”  This is a questionable argument for the use of PFOA-based FFFs, since hazardous substances from fires are created regardless of whether FFFs are used or not. Additionally, since the fluorinated substances in the foam function as very effective surfactants they are also likely to cause the hazardous substances to easier leak into the ground.  The Swedish Chemicals Agency is of the opinion that this text should be deleted, unless it can be supported by a reference.  3. Since fluorine-free FFFs are already available and in use at some airports in the EU (see e.g. the public consultation comment from Swedavia), stricter concentration limits are technically feasible. SEAC notes that the experience of using these products are rather new, and that availability issues could arise in the short term.  The Swedish Chemicals Agency strongly suggests that the limit values should be subject to reconsideration in a review of the restriction 5 years after entry into force.  4. SEAC proposes a longer transitional period (36 months, with some exceptions) than both RAC and the Dossier Submitter (18 months).  The arguments for the longer transitional period are not obvious. The only motivation in the draft opinion is that it would “lower at least the annual investment and certification costs, compared to the 18 months period” (p.20). Whether it would lower the total implementation costs is unclear. A longer transitional period would also increase the quantities – and the associated costs (soil remediation, drinking water purification, potential adverse health effects etc.) – of PFOA (and related substances) released into the environment.  Results from the 2010/2015 PFOA Stewardship Program (initiated by US EPA) have shown that the industry will phase out PFOA and PFOA-related substances by the end of this year. This demonstrates that there are suitable alternatives on the market today. According to FluoroCouncil, which represent approximately 90 percent of the fluoro industry in US and EU, the 36 month transition period would discourage remaining downstream users from further transition efforts.  The Swedish Chemicals Agency supports the shorter transitional period proposed by the DS and RAC.  5. SEAC proposes derogations without a limitation in time for several uses. Industry has requested time limited derogations for 10-15 years for these uses:  • Photolithography processes in the semi-conductor industries  • Photographic coatings applied to films, papers, or printing plates  • Implantable medical devices  The Swedish Chemicals Agency does not support unlimited derogations for these uses. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments and the information.  Point 1.  Regarding firefighting foams used for training, we agree and it is recognised that they have caused significant environmental pollution in the past, but several stakeholders mentioned that the practice has been significantly improved. To take your concerns into accountin the opinion, we have proposed to state in the entry that foams used for training should be used in such a way that emissions to the environment are minimised, and that effluents collected are safely disposed of. However, not applying the derogation to foams used for training has been reported by some stakeholders to create potential problems, since they may need real foams to reproduce what could happen in some specific situations. Leaving it to each country to regulate the foams used for training does not seem compatible with the intention to propose EU-wide RMMs.  Regarding the limitation in time for the derogation on foams, SEAC agrees that no information received during the Public Consultation opposes such a limitation, and therefore SEAC rapporteurs have proposed to SEAC a time limit of 20 years. Please see the opinion for more details.  We have also included in the opinion some information from Italy submitted during the public consultation on the costs relating to the purification of drinking water after the groundwater contamination generated by a plant having produced PFOA for many years.  Point 2.  SEAC rapporteurs still consider that using foams helps extinguishing fires and therefore prevents hazardous chemical emissions from fires (especially from industrial facilities).  Point 3.  SEAC rapporteurs agree and think that the text in the draft opinion already proposes such a review with explicit reference to limit values in firefighting foams.  Point 4.  According to the information received in both public consultations, a longer transitional period than 18 months is needed in many industrial sectors due to the high number of different applications involved.  Please consider that it has also been required by some global manufacturers, as you can see from comment 244.  It is also important to note, as confirmed by other manufacturers, that the alternatives are not “drop-in” replacements, but they require formulation work to ensure the specific end-use performance needs (including the requirements of technical standards) are fully met. Alternatives for all uses under the scope, will not be available by18 months after the entry into force, according to the information received.  A longer transitional time can also take into account the problems related to complex and global supply chains, as described by many stakeholders. The background concentration and contamination issue are also expected to be mitigated during this time. A further development of the analytical methods can be expected too.  We also believe it is more practicable to allow a longer transitional period than writing a much longer list of specific exemptions, considering the wideness of the scope  Point 5  Given the extremely low share of emissions from the semiconductor manufacturing processes (photolithography and etching processes), SEAC rapporteurs do not see the benefit of creating enforcement costs for this sector and public authorities. Anyway, this derogation can be reviewed 5 years after the entry into force. | | |
| 263 | **Date/Time:** 2015/11/16 10:39  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  **<removed>**  **Org. country:**  South Korea  **Company name confidential: Yes**  **Attachment:**  **<removed>** | **Comments on the SEAC draft opinion:**  **<removed>** appreciates the opportunity to provide these comments as part of the public consultation on the draft opinion of the Committee of Socio-economic Analysis (SEAC) for Perfluorooctanoic acid (PFOA).  **<removed>** welcomes and acknowledges the work of the ECHA committees in proposing in their opinion reports an exemption for semiconductor manufacturing industry photolithography processes. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. They have been taken into account in our final opinion. Due to the confidential character of the comments we cannot give subject specific replies. | | |
| 264 | **Date/Time:** 2015/11/16 10:53  **Company name confidential: No**  **Org. country:**  Sweden | **Comments on the SEAC draft opinion:**  We welcome the introduction of a regulatory threshold for PFOA and PFOA-related substances in articles of 2 ppb for PFOA and 100 ppb for PFOA-related substances. We have two comments concerning the practical implantation of the thresholds, namely;  1. Can the proposed limit of 2 ppb PFOA be accurately and reproducibly determined in consumer products with available analytical methods? As far as we know, there are currently no validated analytical methods for compliance testing of articles, although academic researchers have made good progress in method development from some products (e.g. textiles). A good example of an analytical method for analysis of textiles is in the work of van der Veen et al. (2016) [”Development and validation of a method for the quantification of extractable perfluoroalkyl acids (PFAAs) and perfluorooctane sulfonamide (FOSA) in textiles” by Ike van der Veen, Jana M. Weiss, Anne-Charlotte Hanning, Jacob de Boer and Pim E.G. Leonards in Talanta 147 (2016) 8–15], where the authors have overcome some of the reproducibility problems. In the Madrid Statement [”The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)” Arlene Blum, Simona A. Balan, Martin Scheringer, Xenia Trier, Gretta Goldenman, Ian T. Cousins, Miriam Diamond, Tony Fletcher, Christopher Higgins, Avery E. Lindeman, Graham Peaslee, Pim de Voogt, Zhanyun Wang, and Roland Weber in Environmental Health Perspectives, 123 (2015) A-107-A111] it is proposed that chemical and product manufacturers should develop reliable analytical methods for compliance testing. The existence of such a regulatory threshold will certainly be an incentive for manufacturers to do so and therefore we do NOT recommend any further delay in the implementation of the REACH restriction proposals. It is important that we determine if these regulations (e.g. the US EPA Stewardship Program and REACH restriction proposals) have been effective in reducing PFOA levels in articles as soon as possible in order to protect the environment and human health from this harmful chemical. There have been enough delays in product stewardship and regulation despite knowing that PFOA is hazardous for many years.  2. It is possible that the proposed regulatory limits mean that non-fluorinated product manufacturers breach the thresholds in their articles. We are aware of a company (name will not be mentioned) that repeatedly detected PFOA in their non-fluorinated textile products. Repeated analysis demonstrated that PFOA was present at around 1 µg/m2 in some of the company’s non-fluorinated retail textile products. After investigation, it was concluded that the contaminated entered during the manufacturing process, possibly through contaminated supply chains. Recycling of paper and board also means that low levels of per- and polyfluoroalkyl substances (PFASs) are present in some non-fluorinated food contact papers. It is unfortunate if companies who have made environmentally sound decisions are penalized by the regulatory threshold. Product manufacturers therefore need some more experience of how contamination enters products through contamination during manufacturing and through supply chains, both intentionally and unintentional. The Madrid Statement recommends that chemical and product manufacturers work together to better understand how PFASs enter supply chains. Again, the existence of such a regulatory threshold will be a strong incentive for manufacturers to make progress in this task. We do NOT recommend therefore increasing these thresholds to 25 ppb for PFOA and 1000 ppb for PFOA-related substances in articles as proposed by industry groups because this will (i) hinder progress in understanding contamination of supply chains and (ii) allow the continued intentional use of PFOA and PFOA-related substances in articles.  Cousins and Vestergren (Researchers from Department of Environmental Science and Analytical Chemistry (ACES), Stockholm University, Sweden). | | |
| **SEAC Rapporteurs response:**  Thank you for your comment.  We agree that implementation should not be unnecessarily delayed.  However, taking into account the information submitted in the public consultation by many stakeholders, we consider the 2 ppb limit value too low, partly due to the mentioned background concentration and contamination problems. Please see the opinion for more details. | | |
| 265 | **Date/Time:** 2015/11/16 11:04  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Verband TEGEWA e.V.  **Org. country:**  Germany  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  Please see attachment for detailed information. | | |
| **Specific information 1:**  Please see attachment for detailed information. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We note that analytical methods are developing quickly, and when it is foreseen that a new restriction will enter into force there is even more interest for laboratories to further develop the existing and new methods.  We acknowledge that part of the industry has already made the transition. When considering our suggestions for limit values and transitional periods we have considered the pros and cons for all the different parties involved.  We have noted,according to many comments received during this consultation and the previous one on the Annex XV dossier that the performance of the alternatives for several applications, including Personal protective equipment (PPE), is not considered by many stakeholders sufficient and/or adequate to meet the requirements set by currently valid technical standards. Additional details are discussed in the opinion. We support a review in 5 years' time after the entry into force of the restriction. | | |
| 266 | **Date/Time:** 2015/11/16 11:07  **Type:** Company-Downstream user  **Org. type:**  Company-Downstream user  **Org. name:**  **<removed>**  **Org. country:**  Finland  **Company name confidential: Yes**  **Attachment:** | **Comments on the SEAC draft opinion:**  As a user of fire fighting foam as part of our overall Fire Hazard Management policies we are obviously interested in the current proposals to limit environmental effects of foam application. In all our Fire Hazard Management efforts to reduce risk to life safety and our business we take into account possible environmental consequences of the fire itself and of the firefighting actions and take every measure we can to minimise them through, for example, containment on site for appropriate controlled disposal of firewater run off at a later date.  We would express our support of the more realistic limits of the second draft document for a 1000 ppb concentration limit “per substance, for both PFOA or for each PFOA-related substance”, that allows the use of C6 based Film Forming Foams in foreseeing future. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We understand that you support the proposed restriction and the exemptions relating to firefighting foams. | | |
| 267 | **Date/Time:** 2015/11/16 13:03  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  Switzerland  **Company name confidential: Yes**  **Attachment:**  **<removed>** | **Comments on the SEAC draft opinion:**  Our company is one of the member companies of the FluoroCouncil, global trade association of producers of FluoroTechnology. All FluoroCouncil member companies are signatories of the 2010/2015 PFOA Stewardship Program, the global partnership between the U.S. Environmental Protection Agency (EPA) and industry aiming at voluntary goals to globally eliminate PFOA and other long-chain fluorochemicals from facility emissions and product content by the end of 2015. Therefore, all FluoroCouncil members actively advocate for the an effective restriction of PFOA and C8 chemicals which would allow all industry sectors down the supply chain to complete the transition to the alternative short-chain/C6 fluorochemicals which have a significantly enhanced environmental profile while meeting the needs of the customers.  Derogation for the manufacturing of C6 alternatives  As the only company conducting the entire production of C6 alternatives in the EU, we welcome the intention of ECHA’s Risk Assessment and Socio-Economic Committees to exempt the manufacture of the C6 alternatives from the restriction. In SEAC Draft Opinion of 10 September 2015, one can read (p.12): “It is a key prerequisite for the practicality and proportionality of the restriction that the possibility to manufacture and use C6 alternatives to C8 chemistry will not be jeopardised.”  However, we are concerned that the proposed wording of the derogation in paragraph 5 a) may jeopardise the possibility of an “off-site rework” of the unintentionally produced C8 fraction.  We would therefore like to suggest the following alternative wording for the derogation:  5. a) In the context of C6 fluorotelomer manufacturing, the use of C6 mixtures and of the unintentionally produced C8 fraction, as transported isolated intermediates, where the conditions in Article 18(4) are met.  Thresholds and analytical methods  We approve the proposed threshold of 25 ppb for PFOA or its salts in mixtures and articles. We would welcome further clarification of the proposed 1000 ppb threshold for “one or a combination of PFOA-related substances”.  However, such thresholds require the development of an appropriate analytical method. Until such a method is available, an already existing transitional method – the method of “hydrolysis of polymers generating 8:2 FTOH” - could be used. This method is not based on the 25 ppb / 1000 ppb thresholds, but it allows to distinguish C8/long-chain-based intermediates, mixtures and articles from those containing C6/short-chain alternatives (method provided in FluoroCouncil’s contribution). Such a method being already available, it would allow a more rapid entry into force of the restriction.  Transitional period  We support FluoroCouncil’s position advocating for a transitional period of 18 months. Although we cannot comment on individual requests for a longer transitional period, in line with the FluoroCouncil, we do not endorse the statement that there is a general need for industry for a 36-month lead time as short-chain alternatives exist today and are readily available on the market. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments and the information on the development of non-fluorinated alternatives.We have considered the suggestions for the wording of specific exemptions. However, we think that the current wording (together with the justification in the text) includes the relevant manufacturing process sufficiently; the final wording will be defined by the Commission. We have replaced in the entry "one or a combination of PFOA-related substances" by "1000 ppb for any single PFOA-related substance and 1000 ppb for the sum of all PFOA-related substances ", to make it clearer.  As regards the proposed transitional period of 36 months, according to the information submitted by many stakeholders, it is necessary for a large number of applications in several industrial sectors..  It is also important to note, as confirmed by some manufacturers, that the alternatives are not “drop-in” replacements, but they require formulation work to ensure the specific end-use performance needs are fully met.  Alternatives for all uses under the scope, will not be available by18 months after the entry into force, according to the information received.  A longer transitional time can also take into account the problems related to complex and global supply chains, as described by many stakeholders. The background concentration and contamination issue are also expected to be mitigated during this time. A further development of the analytical methods can be expected too. | | |
| 268 | **Date/Time:** 2015/11/16 13:18  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Austrian Economic Chamber  **Org. country:**  Austria  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  Please see our comments attached. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We have retained the extension of the transitional period for protective textiles in the opinion and also suggest extending it to cover some other types of technical textiles.  SEAC rapporteurs think that given the proposed exemptions and new concentration limits, the restriction does not create concerns for foam manufacturers and users. Many comments were received from stakeholders confirming this in this second public consultation. | | |
| 269 | **Date/Time:** 2015/11/16 13:28  **Type:** Company-Downstream user  **Org. type:**  Company-Downstream user  **Org. name:**  Statoil  **Org. country:**  Norway  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  Statoil would like to add some comments to the ongoing public consultation regarding suggested PFOA restrictions in the EU/EEA zone, specifically the draft opinion of the Committee of Socio-economic Analysis (SEAC). The comments are made based on recent acquired experience/knowledge from our operations as an oil and gas producer on the Norwegian Continental Shelf.  Statoil recognize the need and effort to restrict use and spread of hazardous chemicals in general, and support restrictions on PFOA and PFOA related substances. However, as a user/consumer of firefighting foams in our operations, the suggested restrictions on PFOA may add unwanted economic and environmental effects if they are adopted without any exceptions.  Firefighting foams containing PFOA has not been delivered by our main foam supplier after 2002. However, our storage tanks have contained PFOA based foams in a mix with newer formulations until 2005/2006. When replacing foams in 2005/2006, then with a focus to replace PFOS, most of remaining PFOA has been replaced. In a recent survey of perfluorinated compounds (PFC’s) in AFFF based firefighting foam stocks (2015), PFOA has been found to remain in the range of 1.000–22.000 ppb in the surveyed stocks. Remains of PFOA have also been detected in selected tanks containing our new, fluorofree, Re-Healing foam, in the range of 200 – 700 ppb. Quantification limits in the foam analyses has been reported to vary between <50 ppb up to <1.000ppb, depending on matrix effects and dilution factors applied in each analysis. This is well above the proposed restriction limit of 25 ppb PFOA. For all intents and purposes, the exact source of PFOA found in foam stocks is not unambiguous. Levels of PFOA may be remains of what was originally added constituents, impurities in constituents or a degradation product of other PFC’s.  PFC’s are by nature persistent and for some applications also used as tracer chemicals. Ongoing substitution work in our operations aim to replace perfluoro based firefighting foams going forward, but we experience that trace levels of ingredients/impurities in old foam types are likely to be detected for years to come. Risk of detecting trace levels of PFOA above a future regulation limit (or not being able to quantify to a low enough limit), may possibly lead to a future regulative claim to replace large quantities of foam stocks which in reality are based on Best Available Technology (wrt Environmental properties).    To account for trace levels/remains of PFOA in existing firefighting foam stocks placed on the market (and analytical uncertainty), Statoil would like ECHA to consider raising the proposed restriction limits for PFOA from 25ppb to e.g. 1.000-10.000 ppb, alternatively consider a full exception for PFOA in existing stocks of firefighting foams. Statoil is aware of the fact that the adopted opinion of the Committee for Risk Assessment (RAC, 8th September 2015) do not propose an exception for firefighting foams already in stock while the draft opinion of SEAC propose an exception for such products.    Both the persistent nature of PFC’s and the analytical challenges regarding impurities in chemical products call for a special attention when it comes to regulating existing stocks of firefighting foams and associated systems that has contained PFOA based products at some point in time. Statoil is committed to the overall ambition of substituting hazardous chemicals and support the joint effort that is taking place in ECHA. At the same time, our business call for restrictions that take into consideration the economic and practical consequences in a short/medium/long time perspective. The proposal from SEAC, with a way of derogation on firefighting foams, will meet our concerns regarding trace levels/remains of PFOA in firefighting foams. If final restrictions are adopted with a 25 ppb limit on PFOA and no derogation for firefighting foams in stock, there is a risk that large volumes of firefighting foam in stock need to be replaced in the near future, including recently acquired volumes of non-PFC based foams. This is neither economically or environmentally viable from our point of view. If needed, Statoil will try to elaborate on our comments and views submitted during this consultation. | | |
| **Specific information 1:**  The proposal from SEAC, with a way of derogation on firefighting foams, will meet our concerns regarding trace levels/remains of PFOA in firefighting foams. If final restrictions are adopted with a 25 ppb limit on PFOA and no derogation for firefighting foams in stock, there is a risk that large volumes of firefighting foam in stock need to be replaced in the near future, including recently acquired volumes of non-PFC based foams. This is neither economically or environmentally viable from our point of view. | | |
| **SEAC Rapporteurs response:**  Thank you for your comment and the information submitted.  We agree that existing stocks should be exempted.  The final decision regarding this exemption, not proposed by RAC but proposed by SEAC, pertains to the European Commission. | | |
| 270 | **Date/Time:** 2015/11/16 14:50  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  **<removed>**  **Org. country:**  Belgium  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  The **<removed>** notes with interest the SEAC’s scientifically sound socio-economic analysis of the proposed restriction on Pentadecafluorooctanoic acid (PFOA), its salts and PFOA-related substances. **<removed>** welcomes the opportunity to further contribute to the public consultation process by providing comments on the draft opinion of 10 September 2015.  These comments reference and elaborate on the input provided 28th February 2015, echoing the position developed by the AFIRM group and endorsed by our membership which was submitted during the initial ECHA outreach on the REACH Annex XV dossier submitted by Germany and Norway.  **<removed>** concurs with many of the recommended changes proposed in SEAC’s opinion, in particular the modified concentration limits, extended transitional periods and certain derogations. We also welcome the important clarification that a key prerequisite for this restriction is that it not jeopardize the manufacturing and use of C6 PFC alternatives. Furthermore, we appreciate the acknowledgment by SEAC that challenges exist for economic operators due to the lack of reliable and standardized analytical and extraction methods.  In the light of above we would like to focus on a few points where additional input is critical to help ensure a workable legal framework while minimising unnecessary socio-economic impacts.  - Threshold Limit Value of 25 ppb for PFOA or its salts is still too low  While this proposed modification to the original 2 ppb limit provides relief from an unrealistic requirement – necessary to preserve market access to C6 alternatives – a 25 ppb limit is still too low for a complex and highly fragmented international supply chain to consistently comply with in the timeframe proposed due to cross-contamination in manufacturing facilities.  The reason is that key Asian manufacturing nations such as China and India are unlikely to adopt similar legislative initiatives for PFOA and related substances, and will likely promote the increasing use of cheap, high performing products incorporating these substances for their growing economies and populations. Additionally, with decreased demand for products treated with long-chain fluorinated substances from EU and US apparel and footwear brands, the cost of these substances in finishing formulations has seen downward pressure and therefore greater availability for Asian manufacturers serving cheaper, domestic brands.  These realities create substantial risk of unintentional cross-contamination, either from natural resources (water) or production facilities serving simultaneous demands of EU, US and Asian brand clients. This risk is especially concerning given the broad and far-reaching scope of the regulation, which covers products, components, preparations, substances, etc. across all industry sectors and multiple, diverse, upstream applications.  Considering this risk and SEAC’s acknowledgement in its draft opinion that “PFOA-related substances are more important than the direct use of PFOA as potential sources of environmental releases of PFOA,” we reiterate our original suggestion of an initial TLV of 500 ppb in apparel and footwear products, with an incremental decrease to 100 ppb within 5 years if supported by the scientific information gathered. This greater limit and extended timeframe further supports one of the cited merits of a longer transition time in SEAC’s draft opinion: “allow progress in various monitoring related challenges (definition of reference chemicals, standardization of analytical methods, definition and standardization of extraction methods and associated reference matrices).”  - Professional Textiles vs Outdoor Textiles creates uncertainties  The draft opinion’s examples and suggested 6 year transitional period for Professional Textiles (e.g. firefighters and military) is appreciated but raises scope of restriction concerns. Per definition any alpine rescue service, disaster control or coastguard member could be considered a professional, even though some serve on a reserve or volunteer basis. The equipment they use provides high attention for the desire of ambitious leisure users, and a huge overlap of both categories exists. Legal uncertainties are therefore created in how to apply the different transitional periods for professional vs. non-professional “outdoor” textiles, i.e., 3 vs. 6 years.  We have noted and support SEAC’s intention to ask for a review of the regulation after 5 years, which would then allow for the integration of scientific results created with a validated international test method.  As stated in our 28th February 2015 comments, opportunities among **<removed>** and AFIRM members for the most rapid reduction of PFOA and its salts in the supply chain occurred when these substances were restricted by brands 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 in particular the control of cross-contamination sources.  We therefore request ECHA/SEAC to focus on restricting intentional use of PFOA and its salts, and to align on one clear and sufficient implementation timeline for similar product categories of five years. To create a legally sound business environment for economic operators importing any kind of product in scope of the regulation, a scientific and analytically robust TLV for PFOA and its salts should be 500 ppb initially, with a guided incremental decrease possible down to 100 ppb over 5 years. This would allow industry to perform due diligence with their global business partners and support further innovation and research needed to achieve lower concentrations over time. Careful consideration of new data available after the introduction of validated analytical and extraction-methods are a key factor for supporting such an approach. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We believe it should be feasible to reduce the contamination level in facilities to comply with the proposed limit values (25 ppb for PFOA and its salts, 1000 ppb for PFOA-related substances) within the transitional period proposed, also based on comments received from other textile industry stakeholders.  We have now reformulated the wording on different kinds of technical textiles.  Textiles have been recognised to be one of the biggest emission sources, and therefore we support longer transitional periods for some technical textiles only. | | |
| 272 | **Date/Time:** 2015/11/16 15:48  **Type:** Company-Downstream user  **Org. type:**  Company-Downstream user  **Org. name:**  VdS Schadenverhütung GmbH  **Org. country:**  Germany  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  VdS Schadenverhütung agrees in general with the conditions of the restriction proposed by SEAC. We welcome the proposed derogation (5.) from paragraph 1 regarding:  c) the use of firefighting foams already placed on the market on [date of entry into force].  and  d) placing on the market and use of firefighting foams containing PFOA or its salts or one or a combination of PFOA-related substances, as constituents of other substances or components of a mixture in concentrations less than or equal to 1000 ppb.  This approach should ensure the further availability of suitable FFF for the present concepts for fixed extinguishing systems requiring AFFF for special risks and/or materials in order to ensure efficient firefighting.  We request for the derogation to be applied as long as FFF agents with performance equivalent to today’s fluorinated AFFF are not available on the market. We understand the idea to reconsider this derogation 5 years after entry into force as a chance for the market to develop suitable products or alternative concepts for fixed extinguishing systems without further need of FFF for certain risks or materials.  For further details we refer to our initial statement to the restriction proposal in the attched document.  VdS | | |
| **SEAC Rapporteurs response:**  Thank you for your comment but it seems they refer to an older version of the draft opinion that was submitted for the previous public consultation. In the version submitted for this second public consultation, concentration limits have been raised, and we believe that your concerns have been taken care of in this respect. | | |
| 273 | **Date/Time:** 2015/11/16 16:36  **Type:** Academic institution  **Org. type:**  Academic institution  **Org. name:**  Water Research Institute - National Research Council of Italy  **Org. country:**  Italy  **Company name confidential: No**  **Attachments:**    **<removed>** | **Comments on the SEAC draft opinion:**  COST ANALYSIS FOR THE MITIGATION OF PFOA POLLUTION IN GROUNDWATERS: THE CASE STUDY OF THE PROVINCE OF VICENZA, VENETO REGION  Emission reduction derived by the restriction proposal can result in cost-saving of treatments of potable waters polluted by PFOA and related compounds. Here is presented a case study of PFOA pollution of groundwater used as a source for drinking waters. The studied area is located in the province of Vicenza (Veneto region, Northern Italy). In this geographical area a plant, (name available in the confidential version of the file), for the manufacturing of fluorochemical specialties including PFOA is located. Decennial unrestricted discharges from the plant and the concomitant geological situation led to a continuous and severe pollution of the groundwater (and on the consequence of drinking waters) in an area wider than 150 km2 which furnishes potable waters for 110,000 inhabitants. The time needed to reclaim the aquifer, considering the aquifer dimensions and its hydrodynamic characteristics, can be roughly estimated to many decades. Attached a detailed report of the additional costs of drinking water purification due to the pollution of groundwater by PFOA and other perfluoroalkyl acids (PFAA), sustained by local authorities and water managers for the production of drinking waters, can be found. | | |
| **SEAC Rapporteurs response:**  Thank you for the information submitted. It is indeed useful, and we have integrated the non- confidential information in the final opinion of SEAC, to better depict the avoided drinking water treatment costs, allowed by the proposed restriction. | | |
| 274 | **Date/Time:** 2015/11/16 16:42  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:**  **<removed>**  **Privacy comment:**  This information is supplied confidentialy for competitive reasons and to preserve intellectual property. | **Comments on the SEAC draft opinion:**  This company has submitted comments and an SEA on the draft dossier and takes the opportunity to make additional comments on the draft SEAC opinion. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. They have been taken into account in our final opinion. Due to the confidential character of the comments we cannot give subject specific replies. | | |
| 275 | **Date/Time:** 2015/11/16 17:11  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  European Semiconductor Industry Association  **Org. country:**  Belgium  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  The European Semiconductor Industry Association (ESIA) appreciates the opportunity to provide these comments as part of the public consultation on the draft opinion of the Committee of Socio-economic Analysis (SEAC) for Perfluorooctanoic acid (PFOA).  1. Derogation for Photolithography Uses in the Semiconductor Industry  ESIA welcomes and would like to acknowledge the constructive consideration given by the Committee for Socio-economic Analysis (SEAC) and Committee for Risk Assessment (RAC) in response to the request of the European Semiconductor Industry Association made in the ECHA June 2015 consultation for a derogation for semiconductor photolithography processes. | | |
| **Specific information 1:**  2. Derogation for Manufacturing Equipment in the Semiconductor Industry  ESIA endorses the information submitted to the SEA committee draft opinion consultation by the Industry Association, SEMI which represents the suppliers of semiconductor manufacturing equipment machines.  Semiconductor manufacturing equipment used in semiconductor factories to make semiconductor devices (or microchips) have parts made of fluoropolymer and fluorotelomer material that may contain substances within the scope of this restriction dossier. Such equipment includes articles, instruments and sub-assemblies of semiconductor manufacturing equipment, as well as piping installations which may contain fluoropolymer and fluorotelomer material, (e.g. O-rings, seals, Teflon tubing), used due to their chemical resistance properties. Much of the supply chain for these parts resides outside of the EU.  Despite the raised threshold levels and increased 36 months transitional period, ESIA has serious concerns about the ability to comply with the restriction as proposed due to:  - the very complex nature of the equipment supply chain in the semiconductor sector. Most semiconductor manufacturing equipment contains thousands of components directly specified by the equipment manufacturer and such components are themselves made of subcomponents designed by other manufacturers, and so on, representing several tiers of a global supply chain and thousands of upstream company design choices in that chain.  - the lengthy qualification periods required following substitution within the sector to ensure semiconductor product (i.e. microchips) still function following the change  - the severe impairment that would be caused to the second-hand semiconductor manufacturing equipment market  - the lack of availability of analytical techniques and procedures that can be applied by sector companies to verify compliance  Therefore ESIA echoes SEMI’s requests that:  - a derogation from the restriction on articles be granted for the equipment used in semiconductor manufacturing processes for a period of at least ten years with a possibility of review after 10 years  - a derogation without end date for second-hand semiconductor manufacturing equipment and for articles intended for their repair and maintenance  - a derogation is also granted for chemical containers and infrastructural equipment used in wafer fabrication facilities (semiconductor manufacturing plants).  Articles incorporated into semiconductor manufacturing equipment placed in EEA by the sector remains a marginal source of PFOA, estimated to be much less than 100 kg per year and the cost of compliance is estimated as at least €350 million. Therefore without further derogation, the cost-effectiveness of the proposed restriction can be shown to be disproportionate for the semiconductor manufacturing equipment industry.  The SEMI response to the SEAC draft opinion public consultation provides additional justification on the estimate of PFOA used in semiconductor manufacturing equipment, the costs presented by the proposed restriction and a socio-economic assessment of the impact the restriction would have on the sector. ESIA urges the SEA Committee to consider the details of the SEMI submission. | | |
| **SEAC Rapporteurs response:**  Thank you for the comments and information submitted.  Please refer to Comments 231 and 232 for answers.  In addition, SEAC rapporteurs think that containers and infrastructure would be covered by the exemption proposed on “semiconductor manufacturing equipment”.  However, since we have no clear information about the potential PFOA content and emission from older second-hand equipment and from articles intended for maintenance of such equipment, SEAC rapporteurs are not in favour of derogation in this case. | | |
| 276 | **Date/Time:** 2015/11/16 17:22  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  SEMI Europe  **Org. country:**  Germany  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  SEMI welcomes the opportunity to comment on the draft SEAC opinion. Please find enclosed our submission:  - primary comments summarising SEMI concerns and recommendations  - supplemental document containing SEMI's socio-economic analysis in relation to our recommendations  - SEMI PFOA modeling calculator | | |
| **Specific information 1:**  SEMI requests a derogation from the restriction on articles for the equipment used in the semiconductor manufacturing industry and the articles intended for/contained in such equipment.  The documents in attachment outline SEMI's request and socio-economic analysis. | | |
| **SEAC Rapporteurs response:**  Thank you for the comment and for the socio-economic and technical information submitted.  Please refer to our answers to Comments 231, 232 and 275. | | |
| 279 | **Date/Time:** 2015/11/16 17:56  **Type:** Academic institution  **Org. type:**  Academic institution  **Org. name:**  Water Research Institute - National Research Council of Italy  **Org. country:**  Italy  **Company name confidential: No**  **Attachment:**  **<removed>** | **Comments on the SEAC draft opinion:**  This submission integrates and completes the previous submission . In the present submission a confidential document is added | | |
| **SEAC Rapporteurs response:**  Thank you for the information. Please see response to Comment 273. | | |
| 280 | **Date/Time:** 2015/11/16 18:03  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:**  **<removed>** | **Comments on the SEAC draft opinion:**  We as a company would like to emphasize how important the usage of FC products is in order to meet the currently valid standards for Personal protective equipment (PPE) applications for which 80 percent of our products are used.  Our protective textiles are delivered to essential authorities like Police Departments, Customs, Bundesgrenzschutz (Federal Border Guard) and Fire Departments in various European States.  Here, the respective specifications demand maximum valences regarding the protective function of the textile.  We would like to emphasize that in some fields this maximum protection can only be achieved with the use of C8 products. Even C6 products cannot reach this high level of valences.  Losing the entire fluorocarbons would mean we would no longer be able to deliver in this market.  To sum up we would like to stress the fact that our company is already implementing the currently valid standards and, along with it, among other things, a switch to C6 technology, with great effort. If C6 technology were to be banned now within a very short time, we would be deprived of our working basis. Also the chemical supply industry is currently not offering adequate substitutes for our range of products. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. They have been taken into account in our final opinion. A proposal for an extended transitional period for textiles for the protection of workers from risks to their health and safety is included in the opinion. Please see the text of the opinion for more details. | | |
| 281 | **Date/Time:** 2015/11/16 18:26  **Type:** Company-Manufacturer  **Org. type:**  Company-Manufacturer  **Org. name:**  **<removed>**  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:**  **<removed>**  **Privacy comment:**  This information is provided confidentially for competitive reasons and to preserve intellectual property | **Comments on the SEAC draft opinion:**  This company has received specific questions related to the use of PFOA and related substances for the textiles sector and wishes to contribute its comments | | |
| **SEAC Rapporteurs response:**  Thank you for your comments. They have been taken into account in our final opinion. Due to the confidential character of the comments we cannot give subject specific replies. | | |
| 282 | **Date/Time:** 2015/11/16 18:46  **Type:** National NGO  **Org. type:**  National NGO  **Org. name:**  Breast Cancer UK  **Org. country:**  United Kingdom  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  Breast Cancer UK is dedicated to the prevention of breast cancers by reducing public exposure to the carcinogenic, hazardous and hormone disrupting chemicals which are routinely found in the environment and everyday products.  Our concerns extend to the potential role of PFOA (Perfluorooctanoic acid) in increasing cancer risk, as outlined in the annex XV dossier. PFOA is an endocrine disrupting chemical which interferes with oestrogens(1). A recent study found elevated serum PFOA levels were associated with increased breast cancer risk in genetically susceptible populations(2). Biomonitoring studies have shown it is widespread in human body fluids and tissues, as a result of environmental exposures(3). PFOA is classified as a Substance of Very High Concern (SVHC). It is persistent, bioaccumulative and toxic and may cause severe and irreversible adverse effects on the environment and human health. In October 2015, PFOA was nominated for listing on the UN’s Stockholm Convention on Persistent Organic Pollutants(4).  Breast Cancer UK welcomes the conclusion of the SEAC and the committee for risk assessment (RAC) that action should be taken on the restriction of PFOA, its salts, and PFOA-related substances. As mentioned in the dossier, PFOA is ubiquitous in the environment including air, water, soil, sediment, biota and in humans. We agree that a risk management option covering all emission sources of PFOA and substances that degrade to PFOA, including those from imports, is needed.  We disagree with several proposed changes to the annex XV dossier included in the SEAC opinion. Specifically; we do not agree with the proposal to increase allowable concentrations of PFOA from 2ppb to 25ppb, and in some instances 1000ppb. Furthermore, we disagree with the derogation to some industries, especially on the basis that they “don’t use much” PFOA or PFOA related substances. Our arguments are outlined as follows.  Proposal to increase the maximum allowable concentrations of PFOA as constituents/mixtures/articles from less than 2ppb to less than 25ppb, and of one or a combination of PFOA-related substances from less than 2ppb to 1000ppb  We have significant concerns relating to the proposal to increase maximum allowable concentrations. We accept that a maximum concentration of 2ppb may be unrealistic to achieve, due to lack of reliable analytical methods and other arguments outlined under “Concentration limits applied to PFOA and PFOA-related substances” in the SEAC opinion. However, we do not believe the RAC or SEAC have provided justification as to why this limit has increased so drastically since the original RAC report was published. Allowing such an increase is likely to encourage substitutions with other perfluorinated and polyfluorinated substances (often contaminated with PFOA) which models predict may also be persistent, bioaccumulative and toxic and so result in further environmental contamination(5). A lower level of permissible PFOA and PFOA-related substances may encourage more investment in the use of non-toxic replacements, some of which are already available(6) and consequently reduce environmental pollution.  Derogations  We accept the derogation of firefighting foam (FFF) which contains PFOA substances already on the market, based on a potential inability to fight fires due to financial constraints, however we disagree strongly that any new FFF which contains up to 1000ppb should be allowed. FFF containing PFOA has been linked to ground water contamination incidents such as those at RAAF bases in New South Wales, Australia where historically PFOA was used(7). The severity of the contamination caused the Environment Protection Authority to issue warnings to residents advising them to stop eating local seafood, and locally produced eggs and milk. A maximum allowable level below 1000ppb will provide less incentive to find alternative FFF and further environmental pollution. A particular concern noted in the opinion was the ability to fight fires at airports, yet it was stated that alternatives do currently exist and are being used. The argument suggesting a possible lack of availability is weak, especially if the period for changeover is extended from 18 months to 3 years.  We do not accept the derogation for photographic coatings applied to films, papers or printing plates, nor to the manufacture, placing on the market and use of substances and mixtures needed to produce them. We also question the need for derogation for photolithography in semi-conductor industries. Derogations will not help support global elimination of PFOA and decreases incentive for industry to develop non-toxic replacements. The argument that “this sector is responsible for a very low share of total emission of PFOA and PFOA-related substance” is not justifiable, especially for non-essential purposes such as use in one particular brand of printer cartridge.  Finally, we are concerned about derogation for recycling and second-hand articles as this will contribute further to environmental pollution and prevent global elimination.  References  1. Sonthithai et al. (2015) Journal of Applied Toxicology 2015, Aug 3 DOI 10.1002/jat.3210  2. Ghisari et al. (2014) Environmental Health 2014, 13(1):19  3. Vierke et al. (2012) Environmental Sciences Europe 2012, 24:16  4. Global chemical experts take science to action by moving towards phase out of toxic chemicals. http://chm.pops.int/Implementation/PublicAwareness/PressReleases/OutcomesofPOPRC11/tabid/4692/Default.aspx last accessed 14.11.15  5. Gomis et al. (2015). Science of the Total Environment. 505:981-91.  6. Substitution support portfolio  http://www.subsport.eu/case-stories?search=PFOA&sektor=0&Function=0&prozess=0&cslimit=15&type=case\_studies last accessed 14.11.15  7. ABC news sept 16 2015. http://www.abc.net.au/news/2015-09-16/nsw-govt-announces-two-reviews-into-williamtown27s-toxic-raaf-/6780756 last accessed 14.11.15 | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We agree that it is important to set the threshold limit levels as low as possible. Taking the information submitted by many stakeholders into account, it seems that at this stage it is not possible to go lower than 25 ppb for PFOA and its salts and 1000 ppb for PFOA-related substances. We consider it important that these limit values may be reviewed in 5 years with the view to lower them.  We do not consider it likely that these limits would encourage industry to substitute with other long chained perfluorinated substances.  Regarding firefighting foams, the local contamination seems to be mainly linked to past practice. Anyway lower concentration limits (and possible substitution with non-fluorinated alternatives) are an objective for the future. At present, there is a general concern among stakeholders (manufacturers and users) that lower concentration limit could limit the firefighting services capabilities.  Please see the opinion for more details. | | |
| 283 | **Date/Time:** 2015/11/16 18:45  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  European Portable Battery Association  **Org. country:**  Belgium  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  The position of EPBA is attached in section IV, as well as outline here below:  Comments by the European Portable Battery Association to the call for comments on the SEAC Opinion on the proposal to restrict the use of PFOA  Introduction  The European Portable Battery Association (EPBA) is the authoritative voice of the portable power industry. The association supports the common interests of its members regarding portable batteries and battery chargers with European institutions and other leading international bodies to provide consumers with complete power solutions which are sustainable across their life-cycle.  We welcome the opportunity to provide comments on the SEAC Opinion of the proposal Annex XV Restriction Report by Germany and Norway which propose to restrict the use of Perfluorooctanoic Acid (PFOA), its salts and PFOA related substances.  Fluorinated Polymers which are either manufactured with or derived from PFOA are used in Lithium Ion battery technologies. In particular, the proposal will impact the anode and cathode binders of Lithium Ion batteries which are based on Polyvinylidene Fluoride (PVDF). For these applications, there are no viable alternatives available, which make the proposal, in combination with the strict limit of 25ppb, a serious concern four our industry.  Comments  Scope of the proposed restriction  EPBA understands that the restriction report focuses on a limited number of products and sectors for which it assesses the use of PFOA and extrapolates its findings to all sectors and product categories using PFOA. While the EPBA supports measures aiming at a controlled use of substances, we are of the opinion that as a key principle a restriction of a certain substance should only be accepted if it is based on a scientifically sound risk assessment.  The current report however does not include an assessment of the impact a restriction of PFOA would have on the battery industry. We therefore urge once again that a complete impact assessment of a PFOA restriction for Lithium Ion batteries should be carried out taking into account all scientific evidence as well as all three pillars of sustainable development (social, economic and environment) and give consideration to practical opportunities available for the management of identified risks in relation to batteries.  Threshold of 25ppb  The proposal sets the limit for manufacturing, use and placing on the market of PFOA and its related substances at 25ppb which will apply to single substances, constituents of other substances in concentrations, mixtures in concentrations and in articles.  While we acknowledge that the threshold has shifted up following the comments to the original proposal by stakeholders, we would still support a higher threshold, given the fact that the residual amounts of PFOA in fluoropolymers will contain 20ppm of residual PFOA, which is significantly higher than the proposed 25ppb. Moreover, according to the European Food Safety Authority (EFSA), the threshold daily intake for an adult human for PFOA is set at 52.2 ppb. It seems therefore questionable that the limits set for electronic consumer goods should be higher than those of food, given the fact that the exposure of consumer goods would naturally be lower than exposure from food.  As mentioned above, a detailed impact assessment should take into account all scientific evidence on the basis of which the restriction limit has to be quantified.  Transition period  The transition period of 36 months to implement the restriction as foreseen by SEAC and RAC has been increased. While again we acknowledge this change, we would like to reiterate that any substance restriction should take into account the complexity of the manufacturing process and should therefore allow for sufficient time to industry to modify its supply and production processes. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  As noted in the Annex XV dossier, the major fluoropolymer manufacturers in the US, Japan and Europe have joined the US EPA Stewardship Programme. The companies have worked for several years to eliminate PFOA from fluoropolymer production. According to the information received in the public consultation, there should be fluoropolymers manufactured without PFOA available by the end of the 36 months transitional period, with a concentration not higher than 25 ppb.  It is not clear from your comment why alternatives would not be suitable for lithium ion battery technologies.  According to our knowledge the Dossier Submitters (Germany and Norway) have made their best efforts toidentify all relevant sectors and included in the dossier the information available. It is most unfortunate if some stakeholders have not noticed the stakeholder consultation that took place prior to the submission of the Annex XV dossier and have not submitted information; however our understanding is that the representativeness of the study made is very high.  Although more in the RAC remit, we note that since the restriction proposal is primarily based on environmental concerns, the limit values cannot be derived based on human health considerations. | | |
| 286 | **Date/Time:** 2015/11/16 20:09  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  FluoroCouncil  **Org. country:**  United States  **Company name confidential: No**  **Attachments:**    **<removed>** | **Comments on the SEAC draft opinion:**  Detailed comments are provided in the attached document "FluoroCouncil Comments to SEAC Public Consultation on Annex XV PFOA Restriction Proposal" | | |
| **Specific information 1:**  Detailed comments are provided in the attached document "FluoroCouncil Comments to SEAC Public Consultation on Annex XV PFOA Restriction Proposal" | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We agree that putting industry that has already transitioned at a competitive disadvantage is undesirable. However from the information received from your association during both public consultations, we also acknowledge that “It is important to note that the alternatives usually are not “drop-in” replacements, instead requiring formulation work to ensure the end-use performance needs are met. This reformulation can only be achieved through joint collaboration between all segments of the value chain for each application”.  Thank you for the information on investments made in the development of alternatives by the FluoroCouncil member companies and for sharing the position of many companies and trade associations in the “coalition letter” regarding the concentration limit of 2ppb, initially proposed in the restriction proposal.  Thank you for expressing your support to the 25 ppb limit value and also for the discussion on analytical methods. At this stage the lead substances approach is supported by SEAC.  The definition of the scope in the entry has been modified. Furthermore we have replaced in the entry "one or a combination of PFOA-related substances" by "1000 ppb for any single PFOA-related substance and 1000 ppb for the sum of all PFOA-related substances”  Regarding the suggestion for the wording of point 5a,we have considered it.. However, we think that (together with the justification in the text of the opinion) it includes the relevant manufacturing process sufficiently. The final wording will be defined by the Commission. | | |
| 287 | **Date/Time:** 2015/11/16 21:31  **MS name:**  Norway  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  We welcome the efforts by ECHA and the Committees in opinion development regarding the restriction proposal for PFOA and PFOA-related substances. The draft background document includes all currently available relevant information, nevertheless we would like to highlight the following:  \*Transition period  We do not see any reasons to extend the general transition period to 36 months (from 18 months). Major parts of the affected industry have already committed to phase out PFOA and PFOA-related substances by the end of 2015 through the US EPA PFOA stewardship program. The need for a longer transition period indicated by some parts of the industry is covered by the proposed derogations for the sectors and uses concerned.  \*Fire-fighting foam  SEAC proposes derogations for fire-fighting foams. We cannot see that there are any good arguments to support this. As described in the background document and also in the public consultation (i.e. comment no. 1306 and 1336), there are already PFOA-free alternatives available on the market: i) foam containing short chain per- and polyfluoroalkyl substances and ii) fluorine free foam.  We do not support SEACs proposal for a permanent derogation for the use of fire-fighting foams that were placed on the market before the regulation of PFOA and PFOA-related substances enters into force. As described in the background document we suggest that the use of fire-fighting foam in stock should be allowed until 2030 when the manufacturer's guaranteed time frame for the foam expires. There is no reason to allow the use of foam that is not guaranteed by the manufacturers. We are also of the opinion that these stocks should not be used for training purposes because of their pollution potential.  Fire-fighting foams placed on the market after the entry into force of the regulation should meet the general threshold values for mixtures. SEAC proposes to raise the limit value for PFOA as a constituent of other substances in fire-fighting foams to 1000 ppb. The same limit value (1000 ppb) is also proposed for each one of the PFOA-related substances. The draft background document and draft SEAC opinion do not present any new data that support SEAC's proposals for these revised limit values. On the contrary, the societal costs from not regulating PFOA and PFOA-related substances as strictly as possible in fire-fighting foams are considerable.  The use of PFOA and PFOA-related substances are direct sources of emissions. As described in the background document, there are several examples from Europe of drinking water being polluted by PFOA from fire-drill sites. This is of great concern for the affected human populations. Recent calculations of the total costs for cleaning up groundwater polluted by PFAS around fire-fighting areas in Norway show that 3,5-5,5 mill Euro is required per training site. These numbers include investment and operation of groundwater cleaning systems necessary in some Norwegian airports polluted by PFAS from fire-fighting foams. Chemical analysis show that PFOA migrates into the ground water to a higher extent than PFOS. In the draft background document, the central estimate for the substitution costs on European level for PFOA-related substances in fire-fighting is 1,6 mill Euro. This is considerably less than the costs for ground water treatment per fire-fighting drill site, even though we have to take into account that the groundwater is treated for PFASs in general. | | |
| **SEAC Rapporteurs response:**  Thank you for the comments.  We agree that the derogation for FFF already in stock does not need to be unlimited in time and we propose to limit this derogation to 20 years.  SEAC rapporteurs think that stocks could be used for training provided that the emissions to the environment are minimised. Imposing their early replacement would also create costs, and emissions to the environment, depending on the destruction method.  The new concentration limit is based on several contributions made by manufacturers and users during the public consultation. We agree that foams that could comply with lower concentration limits are available on the market, but it is not certain that they cover all requirements of users across the EU.  We recognise the damage costs caused by contamination by foams in the past. However, these costs are also related to past practice, and cannot be fully compared with substitution costs. We also note that substitution costs are only part of the cost of lower concentration limits, and that safety regarding fire protection are critical and need to be considered. | | |
| 288 | **Date/Time:** 2015/11/16 23:10  **Type:** International NGO  **Org. type:**  International NGO  **Org. name:**  Europeam Environmental Bureau (EEB)  **Org. country:**  Belgium  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  The European Environmental Bureau (EEB) did support the restriction of PFOA and PFOA related substances proposed by Norway and Denmark, however, due to the severe changes in the scope proposed by RAC and SEAC, which render it meaningless, we no longer support this restriction as presented in this public consultation. Its approval with the thresholds and derogations proposed in SEAC's opinion will mislead EU citizens who might believe that action is being taken to substantially reduce human and environmental exposure to these substances of high concern, when this is not the case at all. Moreover, we believe that RAC and SEAC are asked to submit their opinion on the restriction proposal, but we question whether the REACH text permits the committees to redefine the scope of the proposal as they have done here.  Thresholds for articles and fluoropolymers  The use of fluoropolymers and the service life of imported articles are considered by the dossier submitter (DS), RAC and SEAC the most important uses when it comes to potential for emissions of PFOA from PFOA related substances. Both the DS report and RAC and SEAC opinions estimate potential emissions from these sources in the range of 2 to 20 tonnes per year for each of them, from a total estimation of 5.7 to 35.2 t/y from all sources. This is, these sectors represent by far the most important sources of these SVHC that the proposed restriction should help reducing.  The DS had initially put forward a threshold of 2 ppb for PFOA and PFOA related substances in order to ensure that these substances were not intentionally applied in these uses.  Although during the public consultation it has been shown that safer fluorinated free alternatives are available to companies and authorities marketing and using these articles and foams, several companies, well behind track, have asked for higher thresholds, claiming that analytical methods are not available and the difficulty to avoid PFOA contamination.  In response to these comments, the DS presented a revised proposal for the thresholds: 2ppb for PFOA and 100 ppb for PFOA related substances in these sectors. These levels would ensure that no PFOA related substances are used intentionally and, at the same time, would avoid the PFOA contamination problem.  RAC opinion recognises that analytical methods to detect these thresholds are available. It also states that a standardised analytical method is available for the determination of PFOS in coated and impregnated solid articles, liquids and firefighting foams (CEN/TS 15968:2010), which most likely could be adjusted to also include PFOA. RAC also states that the lack of a standardised method is not a sufficient reason for decreasing the scope.  However, RAC and SEAC opinions reject the DS revised proposal and put forward a substantially higher threshold for these sectors: 25ppb for PFOA and 1,000 ppb for PFOA related substances. The opinions do not include any calculations on the increased risk for the environment and for human health of this significant decrease of the scope of the restriction.  Analytical results of the presence of PFOA and PFOA related substances in articles and fluoropolymers included in the Annex XV dossier (Appendix B.2.2.5) and also submitted during the public consultation (see references below), show that very few articles present levels of PFOA and PFOA related substances above the thresholds proposed by RAC. This means that the restriction will only eliminate from the market a marginal number of articles, rendering it meaningless.  Moreover, ECHA’s committees’ proposal of 1,000 ppb will allow the intentional use of PFOAs in articles, which will make the restriction meaningless. This is unacceptable to us.  Therefore, we ask SEAC to reconsider the thresholds of the revised proposal from the DS, in order to make the restrictions aim effective in reducing the risks to the environment and the human health posed by these SVHCs. If not, we ask the Member States and the Commission to reject the approval of this restriction. | | |
| **Specific information 1:**  Fire Fighting Foam (FFF) derogation  RAC's opinion clearly states that the use of PFOA and PFOA related substances in FFF is a risk for the environment and for human health. Safer alternatives are available as recognised in SEAC's opinion. The time line until entry into force of the restriction proposed by the DS is long enough to enable the transition to safer alternatives for the firefighting authorities than have still not done so. Therefore, we believe there is no solid justification to allow the continued use of these foams by introducing a derogation. | | |
| **SEAC Rapporteurs response:**  Thank you for your comments.  According to the information submitted in the public consultations, suitable alternatives do not exist for all different applications. Derogations suggested in the final opinion are considered necessary at this time. We find it important that concentration limits and derogations may be reconsidered 5 years after the entry into force in view of new information and technical development.  We share the concern that a too high concentration limit might allow intentional use in the manufacture of imported articles, allowing higher emissions. However the limit value that will be adopted has to be practicable to allow reliable analysis and to account for background concentrations and contamination of machinery deriving from earlier use, for example. Relating to concentrations (lower than the threshold) detected in articles on the market, we note that it is not clear whether the use was intentional or not. As regards the proposed derogation of newly made firefighting foams, currently there is a general concern among stakeholders (manufacturers and users) that lower concentration limits could limit the firefighting services capabilities. We are aware that alternatives are increasingly available for many applications concerned, and for this reason we support a review in 5 years' time after the entry into force. | | |