**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restriction on

**PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTDA; their salts and precursors**

**Non-confidential**

**ECHA/RAC/RES-O-0000001412-86-219/F**

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

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| **Substance name** | **EC number** | **CAS number** |
| PFNA; PFDA; PFUnDA; PFDoDA; PFTrDA; PFTDA; their salts and precursors | 206-801-3, 206-400-3, 218-165-4, 206-203-2, 276-745-2, 206-803-4 | 375-95-1, 335-76-2, 2058-94-8, 307-55-1, 72629-94-8, 376-06-7 |

14 September 2018

**General Comments and answers to specific information requests**

## Specific information requests:

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

Are you aware of any other present or future intentional uses either in the EU, or outside the EU for articles imported to the EU? If such uses exist, please provide the following:

* Description of the use
* Quantities used and information regarding the potential risks to the environment (e.g. quantified release estimates)
* Technical and economic information on those applications or uses, for which alternatives are not available and/or the performance of alternatives is not considered adequate. This should include information on potential alternative substances or technologies and justification of why they are not feasible.

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

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

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

* Description of the use
* Quantities present as impurities and related concentrations, and information regarding the potential risks to the environment (e.g. quantified release estimates)
* Technical and economic information on those applications or uses, for which alternatives are not available and/or the performance of alternatives is not considered adequate. This should include information on potential alternative substances or technologies and justification of why they are not feasible.

1. The restriction report foresees a derogation for the manufacture of C9-C14 PFCAs, their salts or related substances where these occur as an unintended by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 8 atoms. Please describe technical or economic reasons why this by-product fraction cannot be avoided.
2. Are C9-C14 PFCAs, their salts or related substances found in recycled materials and at what concentrations? How would the recycling sector be impacted by the proposed restriction?

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| **Ref.** | **Date/type/Org.** | **Comments** |
| **1884** | **Date:** 2018/01/19 18:22  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** Disclosure of the confidential attachment would undermine the protection of our client's commercial interests, including intellectual property | **Comment:**  We are writing to you today with respect to the upcoming ECHA rapporteur meeting to discuss the Restriction Proposal.  We would be grateful if the Rapporteur meeting could address two questions provided in the confidential  attachment in order for our client to submit a complete future potential submission in the ongoing public consultation.  We thank very much you for your attention to our clarification request. |
| **Dossier submitter response:**  The Dossier Submitter thanks for the information provided. Based on the fact that a phase out of the substances is planned in the near future and only a very small amount of the substances is used, the Dossier Submitter agrees with a transition period until 31.12.2023 for semiconductors and semi-finished and finished electronic equipment and an exemption for semiconductors in replacement parts intended for finished electronic equipment placed on the market before 31.12.2023.  In case the substitute is a per- or polyfluorinated substance (PFAS), too, we recommend to minimize emissions as far as possible, since regulatory actions on other PFASs will follow in the near future. |
| **RAC Rapporteurs comments:**  According to the Dossier Submitter, taking into account the very limited quantities made available in the EU market, RAC agrees with a transition period until 31.12.2023 for semiconductors and semi-finished and finished electronic equipment and an exemption for semiconductors in replacement parts intended for finished electronic equipment placed on the market before 31.12.2023.  If the substitute being considered is a per- or polyfluorinated substance (PFAS), RAC recommends to minimise emissions as far as possible or seek a non-fluorinated substance, since regulatory actions on other PFASs will follow in the near future. |
| **SEAC Rapporteurs comments:**  SEAC notes that this comment is linked to comment 1895.  SEAC finds the request related to speciality semiconductors that contain low levels of C9-14 PFCAs is justified by the need of longer time to phase out the use of PFDAs based on substantial substitution activities since 2005. Furthermore, the importer indicates that from 31.12.2019 new semiconductors will comply with the restriction, and therefore, in practice, only the content in already produced articles will be covered by the derogation. Therefore, the requested time limited exemption for semiconductors and articles containing semiconductors seems reasonable, taking into account that also the PFOA restriction exempts semiconductors for photo-lithography processes and compound semiconductors for etching processes.  Therefore, SEAC supports the view of the Dossier Submitter to allow speciality semiconductors that contain low levels of C9-14 PFCAs to be made available (sell-through) until 31 December 2023 and avoid supply chain disruption. In addition, to allow semi-finished and finished electronic equipment containing speciality semiconductors to be used as replacement parts for finished electronic equipment. |
| **1885** | **Date:** 2018/01/29 09:08  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Mineralölwirtschaftsverband  **Org. country:** Germany  **Attachment:** | **Comment:**  Mineral oil industry is obliged by law to mix biofuels (i.e.) ethanol into fuels. Especially ethanol very effectively destroys fire fighting foam. Since that time, AFFF fire fighting foams containing PFCA's are required in refineries an depots to ensure effective fire fighting.  C9-C14 PFCAs do occur as impurities in AFFF fire fighting foams. While this fact is mirrored in the information document, the document states "concentrations in fire fightinmg foams are not known". We therefore offer attached analyses of fire fighting formas used in mineral oil refineries. (This information was already forwarded as comment to restriction of PFOA.) |
| **Answer to specific info request 3:**  Mineral oil industry is obliged by law to mix biofuels (i.e.) ethanol into fuels. Especially ethanol very effectively destroys fire fighting foam. Since that time, AFFF fire fighting foams containing PFCA's are required in refineries an depots to ensure effective fire fighting.  C9-C14 PFCAs do occur as impurities in AFFF fire fighting foams. While this fact is mirrored in the information document, the document states "concentrations in fire fightinmg foams are not known". We therefore offer attached analyses of fire fighting formas used in mineral oil refineries. (This information was already forwarded as comment to restriction of PFOA.) |
| **Dossier submitter response:**  The Dossier Submitter thanks for the comment and the data provided. Derogations that are included in entry 68 to Annex XVII of REACH (PFOA), will also apply to C9-C14 PFCAs. Hence, the use of aqueous firefighting foams (AFFF) will not be affected by this restriction proposal. |
| **RAC Rapporteurs comments:**  RAC notes further information is submitted in 1906 and that a similar comment is submitted in 1888.  RAC notes that the PFOA restriction derogates fire-fighting foam mixtures placed on the market before 4 July 2020. The mineral oil industry has confirmed that derogation as included in the restriction of PFOA will suffice also for C9-C14 PFCAs. This is part of the proposed restriction. |
| **SEAC Rapporteurs comments:**  SEAC notes further information is submitted in 1906 and that a similar comment is submitted in 1888.  SEAC notes that the PFOA restriction derogates fire-fighting foam mixtures placed on the market before 4 July 2020. The mineral oil industry has confirmed that derogation as included in the restriction of PFOA will suffice also for C9-C14 PFCAs. This is part of the proposed restriction. |
| **1886** | **Date:** 2018/02/09 12:42  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** ChemSec  **Org. country:** Sweden | **Comment:**  ChemSec welcomes this important restriction proposal. It is of greatest importance to limit the release of PFAS substances into the environment. The description of the substances covered will include around 200 chemicals. There are good reasons for using this group wise approach. With about 3000 known PFAS substances, it would be highly inefficient to tackle these one-by-one. Also, as is well described, this approach is meant to prevent regrettable substitution as the more well-used C8 PFAS are being increasingly phased out. While it is stated in the dossier that the aim is not to hinder the use of short chained PFAS (C6), who are the natural substitute for the longer chained ones, ChemSec would much welcome a further restriction proposal also of these, as mounting evidence suggest these to share problematic properties with the longer-chained ones. |
| **Dossier submitter response:**  Thank you for your support of this restriction proposal.  The EU Member States are aware of the hazards of short chain PFAS. Therefore, a strategy to reduce the emissions of all PFASs is being developed.  Based on the risk management option analysis (RMOA) of undecafluorohexanoic acid (PFHxA, C6-PFCA) including its salts and precursors the most appropriate way to limit the risks for the environment on an EU level is a restriction of manufacturing and use (<https://echa.europa.eu/documents/10162/82006501-72b4-81bc-ec93-980b76cb1574>). Therefore, a restriction on these substances will be proposed in the near future. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC thanks for the comment which is of more general nature and not specifically related to the proposed restriction. |
| **1887** | **Date:** 2018/02/13 11:11  **Content:**  Scope or restriction option analysis;  Environmental emissions  **Type:** MemberState  **Country:**  Norway  **Attachment:** | **Comment:**  (These comments are also given in the attached Word file)Norway welcomes the restriction proposal on C9-C14 Perfluorinated Carboxylic Acids (PFCAs) including their salts and precursors and acknowledge the efforts by the German and Swedish authorities on preparing the proposal. We agree that there is a need for action at the EU level to prevent emissions and reduce risks from PFCAs.  Suggestions for amendments of the entry  We propose that the chemical description in the regulatory text is revised in accordance with the PFOA-restriction in order to make it more precise. A proposal for amendments in column 1 is given below:    Perfluoroalkyl carboxylic acids (branched or linear) with the formula:  CF3-(CF2)n-CO2H, n=7-12  Any related substance (including its salts and polymers) having a linear or branched perfluoroalkyl group with the formula CF3-(CF2)n-, n = 7 – 12, directly attached to another carbon atom, as one of the structural elements.  Any related substance (including its salts and polymers) having a linear or branched perfluoroalkyl group with the formula CF3-(CF2)n-, n = 8 – 13, as one of the structural elements.  The following linear or branched substances are excluded from this designation:  • CF3-(CF2)n-X, n = > 7, where X= F, Cl, Br  • CF3-(CF2)n-SO3H, CF3-(CF2)n-SO2X', n > 7 where X'=any group, including salts  • CF3-(CF2)n-CO2H , CF3-(CF2)n-CO2X' or CF3-(CF2)n-CF2-X', where n > 12 and X' =any group, including salts  Explanation: A substance may be linear or branched – not both. Chemical formulas should have numbers in subscript (see Attached Word file).  Additional comments to the proposed entry:  • In accordance with our proposals above, we also suggest that the wording of paragraph 3a of the entry is amended. The reference to the number of C-atoms in the carbon chain in fluorochemicals as proposed is unprecise in certain cases (e.g. FTOH's). Hence we propose to change the reference to the number of C-atoms in a perfluoroalkyl chain as follows:  a) the manufacture of a substance where this occurs as an unintended by-product of the manufacture of fluorochemicals with a perfluoroalkyl chain equal to or shorter than 7 C-atoms (see also Attached Word file);  • Furthermore, we also propose to replace the word "unintended" with "unavoidable" in paragraph 3a. The intention of having a substance or not is difficult to enforce.  • The proposed derogation in paragraph 3a only refers to "the manufacture of a substance where this occurs as (…)", it should only refer to paragraph 1a and not to 1b. Paragraph 1b is not relevant for the manufacture of a substance. The proposal as it stands now may be misinterpreted by stakeholders so that they understand that UVCBs, mixtures or articles are derogated from the restriction. Our experience is that stakeholders misinterpret identical wording in the REACH PFOA restriction.  Other comments to the restriction report:  The derogations for the manufacture of substances with the C6 technology is not quantified or reported in table 1-10 ("Estimated annual use volumes and releases …"). We suggest that this is explained in the text.  The results from the Norwegian lakes, as referred on page 124 in the background document, show that the levels of LC PFAS, in particular C-13 PFCA, in fish livers are high and surprisingly are higher in fish from Lake Femunden than from Lake Mjøsa. It should be noted that on the other hand, the levels of other anthropogenic contaminants like e.g. PBDEs and siloxanes in Lake Femunden are low compared to Lake Mjøsa. This does not comply with the assumption that Lake Femunden is insignificantly impacted of discharges from local population, industry and agriculture compared to Lake Mjøsa. Furthermore, reports from these lakes sampled before (M-349 http://www.miljodirektoratet.no/no/Publikasjoner/2015/September-2015/Miljogifter-i-store-norske-innsjoer-2014) and after (M-807 (http://www.miljodirektoratet.no/no/Publikasjoner/2017/September-2017/Miljogifter-i-store-norske-innsjoer-2016/) the report referred in the background document could be referenced as well. In the last mentioned report the levels of C-13 PFCA in particular were high in trout livers both in Femunden and Randsfjorden (nearly identical levels; 35–36 ng/g ww) compared to the levels in Mjøsa (12 ng/g ww). Moreover, the reports find that in general the LC PFAS concentrations in fish liver increase with trophic level in the three main lakes .  Data on the environmental exposure and emissions of C9-C14 PFCAs may also be found in the following reports:  • Report M-856 (http://www.miljodirektoratet.no/Documents/publikasjoner/M856/M856.pdf) "Contaminants in coastal waters of Norway 2016" presents levels, trends and effects of contaminants in biota along the coast of Norway. No upward trends for any PFAS-concentrations were found. Furthermore, a significant downward short-term trend was found for PFNA in the Inner Sørfjord.  • Report M-817 (http://www.miljodirektoratet.no/Documents/publikasjoner/M817/M817.pdf) "Screening of PFAS and Dechlorane compounds in selected Arctic top predators" summarizes the findings of a screening study into the occurrence of selected perfluorinated compounds (PFCs) and dechloranes in Arctic top predators. In Polar bear whole blood samples PFNA and PFUnA were found with the highest mean concentrations of 18 and 12 ng/g ww respectively. In addition, four more long chain carboxylic acids were detected in all samples (PFDcA, PFDoA, PFTriA, and PFTeA). In Ringed seal liver samples, PFNA and PFUnA were found with the highest concentrations at 0.77 and 0.69 ng/g ww respectively. In addition, three more long chained carboxylic acids were detected in all samples (PFDcA, PFDoA, and PFTriA). The sum of the C9 to C14 carboxylic acids is 2.21 ng/g ww and in the same range as the PFOS concentration.  • Report M-812 (http://www.miljodirektoratet.no/Documents/publikasjoner/M812/M812.pdf) on "Environmental Contaminants in an Urban Fjord, 2016" reports that PFCA was detected PFUnDA in sediments, and several PFCAs in water samples, several marine organisms and in eggs and blood of herring gull.  • Report M-757 (http://www.miljodirektoratet.no/Documents/publikasjoner/M757/M757.pdf) "Monitoring of environmental contaminants in air and precipitation" detected several perfluorocarboxylic acids at different occasions.  • Report M - 752 (http://www.miljodirektoratet.no/Documents/publikasjoner/M752/M752.pdf), " Environmental pollutants in the terrestrial and urban environment, 2016" In terms of quantity, PFAS were present in most of the investigated samples. PFTDoA, PFTriA and PFTeA contribute more to sumPFAS higher up in the food-chains (fieldfare, sparrowhawk and tawny owl), but also in rodents. The authors conclude that the reduced relative contribution up from soil and earthworms indicates that alkylated PFASs are more prone to bioaccumulation than PFOS.  • Report, M-862 (http://www.miljodirektoratet.no/Documents/publikasjoner/M862/M862.pdf) "Riverine inputs and direct discharges to Norwegian coastal waters – 2016" detected amongst others, PFNA and PFDA in urban river samples. |
| **Dossier submitter response:**  Thank you for your support. The word "unintended" is replaced by "unavoidable".  We have revised the data on the environmental exposure and emissions in the Background Document. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC thanks for the comment. |
| **1888** | **Date:** 2018/02/15 14:19  **Content:**  Environmental emissions;  Baseline  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Hungary  **Company name confidential:** Yes  **Attachment:**  <redacted> | **Comment:**  - |
| **Dossier submitter response:**  The comment addressed the concern at a possible restriction of the use of aqueous firefighting foams (AFFF).  Derogations that are included in entry 68 to Annex XVII of REACH (PFOA), will also apply to C9-C14 PFCAs. Hence, the use of AFFF firefighting foams will not be affected by this restriction proposal.  However, to our knowledge fluorine free foams are usable for most fire cases. Thus, we recommend using AFFF firefighting foam only for extinguishing burning liquids if no other alternative is available. In case AFFF firefighting foams are used, firewater has to be collected and treated and contaminated soil needs to be excavated and treated as well which may cause high costs.  Thus, the dossier submitters are aware of the potentially very high costs related to remediating PFAS in soil and groundwater. This is one of the reasons fluorine free alternatives are recommended whenever possible. Without a restriction these costs would potentially increase and the costs would still be borne, but by other parts of society than the polluter. Securing safe groundwater access for present and future generations is one reason as to why substitution to fluorine free alternatives are paramount whenever possible. |
| **RAC Rapporteurs comments:**  See response to comment 1885. |
| **SEAC Rapporteurs comments:**  SEAC notes that a similar comment is submitted in 1885.  SEAC notes that the PFOA restriction derogates fire-fighting foam mixtures placed on the market before 4 July 2020. The mineral oil industry has confirmed that derogation as included in the restriction of PFOA will suffice also for C9-C14 PFCAs. This is part of the proposed restriction. |
| **1889** | **Date:** 2018/02/15 15:29  **Content:**  Hazard or exposure;  Environmental emissions;  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Vewin  **Org. country:** Netherlands  **Attachment:** | **Comment:**  C9-C14 PFCA’s are detected in Dutch waters, as the attached document shows. Due to the high mobility of C9-C14 PFCA's in water bodies, purification of these substances is difficult and costly. Additionally, these substances are of concern, as they are possible substitutes for PFOA, which has led to incidents in which PFOA has been detected in drinking water sources, and of which a restriction will become binding in 2020. As such, Vewin supports the restriction of these substances.  Ensuring the protection of the sources of our drinking water from threats caused by chemicals is of great importance. As such, the EU’s drinking water directive has the objective to “protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean” and the water framework directive of the European Union should Ensure that “for surface water, the highest ecological and chemical status possible is achieved, given impacts that could not reasonably have been avoided due to the nature of the human activity or pollution”.  Currently, REACH identifies persistent, bio accumulative and toxic (PBT) substances and very persistent, very bioaccumulative (vPvB) substances as substances of very high concern (SVHC). As a result, a group of pollutants that are important for drinking water production, namely the persistent, mobile and toxic (PMT) substances and very persistent, very mobile (vPvM), are not included in the substance-oriented approach. The drinking water sector has already for a long time signaled that this is a major and current problem, for chemicals to threaten the sources of drinking water are those that are both persistent in the environment and mobile in the aquatic environment. As such, Vewin not only supports the restriction of C9-C14 PFCA’s but also argues – in accordance with ongoing efforts – to develop criteria and an assessment procedure to identify PMT and vPvM substances as substances of very high concern under REACH. |
| **Dossier submitter response:**  Thank you for your support. The data provided has been included in the Background Document. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC thanks for the comment. |
| **1892** | **Date:** 2018/02/16 16:37  **Content:**  Scope or restriction option analysis;  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** National NGO  **Org. name:** Swedish Society for Nature Conservation  **Org. country:** Sweden  **Attachment:**  <redacted>  **Privacy comment:** Confidentiality of this document is requested in order to protect our intellectual property. | **Comment:**  The Swedish Society for Nature Conservation welcomes this restriction proposal. We believe it is essential for this restriction to be in place when the restriction for PFOA, its salts and PFOA-related substances will become effective in 2020. The proposed restriction of C9-C14 PFCAs and related substances will not only prevent a switch by industry using PFOA-based substances to longer chain PFCAs, but it will also reduce the existing emissions of long chain PFCAs from cosmetic products. We believe a restriction is necessary to minimize potentially severe and irreversible adverse effects to the environment and to human health.  We have identified three cosmetics ingredients currently added to top selling cosmetic products on the Swedish market that can be transformed to C9-C14 PFCAs in the environment and would thus fall under the proposed restriction. However, these ingredients do not appear to be essential for the function of cosmetic products, since the same brands offer many alternative products without PFCAs but with seemingly equal properties. The proposed restriction should therefore come at low cost to the cosmetics industry. |
| **Answer to specific info request 1:**  Precursors to C9-C14 PFCAs are currently used as ingredients in cosmetic products in Sweden. We have found three such ingredients in products on the Swedish market during 2016 and 2017. These are C9-15 Fluoroalcohol phosphate (CAS 223239-92-7), Perfluorononyl dimethicone (CAS 259725-95-6) and Perfluorononyl dimethicone (CAS 259725-95-6). According to the cosmetic ingredients database (CosIng) these PFCAs have two functions: SKIN CONDITIONING and EMULSIFYING.  These ingredients are used by major international cosmetic brands and in top selling products (Please see attached document for details) which could make the emissions from these products environmentally relevant. However, since quantities are not reported on the ingredient lists it is not possible for us to accurately estimate quantity. We have performed a laboratory analysis of randomly selected cosmetics products that state at least one of these c9-c14 precursor PFCAs on the ingredient list. The results from this analysis are currently being summarized in a scientific report, but have not yet been published. A short summary of our results from the EOF analysis (Extractable organic fluorine) are reported in the attached file, and could to some degree be indicative of the quantities of the c9-c14 precursors in cosmetic products. |
| **Dossier submitter response:**  Thank you for your support and for your information on cosmetic ingredients falling within the scope of this restriction proposal as well as on levels of C9-C14 PFCA in selected cosmetic products. This information is valuable since it demonstrates one of few intended uses of these substances. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC thanks for the comment. |
| **1895** | **Date:** 2018/02/16 19:39  **Content:**  Information on alternatives;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Jones Day  **Org. country:** Belgium  **Attachment:**    <redacted>  **Privacy comment:** Disclosure of the confidential attachment would undermine the protection of our client's commercial interests, including intellectual property | **Comment:**  Please see attached document 'PFDA\_public comments\_Jones Day' |
| **Answer to specific info request 1:**  Please see attached document 'PFDA\_public comments\_Jones Day' |
| **Dossier submitter response:**  Please see our response to comment 1884. |
| **RAC Rapporteurs comments:**  Please see the response to comment 1884. |
| **SEAC Rapporteurs comments:**  Please see the response to comment 1884. |
| **1896** | **Date:** 2018/03/09 21:12  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Jones Day  **Org. country:** Belgium  **Attachment:**  <redacted>  **Privacy comment:** Disclosure of the confidential attachment would undermine the protection of our client's commercial interests, including intellectual property | **Comment:**  The confidential Annex includes consolidated and updated volume data on PFDA in semiconductors, amending the table submitted in February 2018 |
| **Answer to specific info request 1:**  please see confidential annex |
| **Dossier submitter response:**  Please see our response to comment 1884. |
| **RAC Rapporteurs comments:**  Please see the response to comment 1884. |
| **SEAC Rapporteurs comments:**  Please see the response to comment 1884. |
| **1897** | **Date:** 2018/03/13 09:40  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** 3M Belgium  **Org. country:** Belgium  **Attachment:** | **Answer to specific info request 2:**  3M offers the following as its preliminary comments for the public consultation to the ECHA proposal to restrict the manufacturing, use, placing on the market and import of C9-C14 perfluoroalkyl carboxylic acids (PFCAs), their salts and related substances, published on Oct. 6th, 2017 on the ECHA website.  Introduction  As a result of its decision in May 2000 to phase out of the production and use of C-8 compounds, 3M no longer manufactures perfluorooctanyl compounds. The company ceased the manufacture and use of the vast majority of these compounds within approximately two years of the phase-out announcement, and ceased all manufacturing and the last significant use of this chemistry by the end of 2008. In addition, 3M does not intentionally use any C9-C14 PFCAs - including their salts and precursors. However, even when C9-C14 PFCAs and related substances are not intentionally manufactured, processed or used in the production of fluoropolymers, they may still be present as low-level impurities. Fluoropolymers have a high socioeconomic value and life as we experience today would not be possible without them: http://www.plasticseurope.org/en/resources/publications/socio-economic-analysis-european-fluoropolymer-industry-executive-summary  3M supports reasonable measures to restrict the presence of these longer chain C9-C14 PFCAs and believes that every regulation should be practical, consistent, measurable, and enforceable. 3M has concerns regarding the proposed 25 ppb limit for the sum of C9-C14 PFCAs and their salts as the most effective way to achieve that objective.  Process and Measurement Capability    The attached product data table (Table 1) illustrates the range of C9-C14 PFCAs in a cross-section of existing 3M fluoropolymer products and the expected levels after implementation of new technology alternatives for reducing C9-C14 PFCAs: The data show that the current manufacturing process capability for typical fluoropolymers would be unable to meet the 25 ppb cumulative C9-C14 PFCA limit. The data also show that most 3M fluoropolymer products would be able to meet a cumulative C9-C14 PFCA limit of approximately 400 ppb after implementation of new technology.  3M has recently conducted a round-robin test on Perfluorooctanyl carboxylic acid (PFOA) with four external analytical laboratories. The results showed inter-lab variation of approximately +/- 40 % of the average value for ppb-level measurements. We expect similar or higher interlaboratory variation for C9 – C14 PFCAs because the same basic analytical method would be applied to all six homologs.  Proposed Limit  3M proposes that the C9-C14 limit be set to a more realistic 400 ppb total, for the sum of the six homologs and their salts. A limit at this level would account for process capability and measurement uncertainty and avoid impacting products that are not intentionally made with C9-C14 PFCA’s. 3M believes that this may be necessary for others in the industry as well.  Despite very successful voluntary stewardship efforts around the elimination of PFCAs, the possible unintentional presence of very low levels of C9-C14 PFCA’s as impurities in products still exists. There is an analytical method now available which was developed for the recently adopted PFOA restriction and its 25 ppb limit. It seems reasonable for the current proposed restriction to build upon the previously enacted PFOA restriction in a consistent way. Current process capability, in spite of no intentional usage of C9-C14, is unable to meet the proposed cumulative 25 ppb limit. 3M believes that by setting the limit for the sum at 400 ppb, this approach does not undermine ECHA’s overall objective of real reductions in C9-C14 PFCA’s and related substances, but enhances it by making it more workable and enforceable.  Proposed Implementation Time Frame  3M expects it will be challenging to make the technology changes necessary to reduce the levels of these chemicals present as impurities in products further down to a 400 ppb level to address the proposed C9-C14 restriction requirements. Additionally, 3M customers will require time to qualify product changes. Therefore, 3M requests an implementation period of 36 months, similar to the PFOA restriction.  3M appreciates the opportunity to comment on the ECHA proposal to restrict the manufacturing, use, placing on the market and import of C9-C14 PFCAs, their salts and related substances.  Sincerely,  <redacted> |
| **Dossier submitter response:**  Please see our response to comment 1914. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  Please see the response to comment 1914. |
| **1899** | **Date:** 2018/03/27 09:12  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** -the additive is very specific for our products , and design was elaborated based on experience of our company  - position of our products on the EU market is under pressure even if we conducted tests in the past to demonstrate no very high concern  -negative publicity versus our customers can cost us a lot of money and jobs | **Comment:**  scope is defined but interpretation is questionable  hazardous properties of some PFAS differ from those accepted in annex XV |
| **Dossier submitter response:**  In the comment it was asked whether a specified substance falls within the scope. Furthermore it was asked for an exemption for the semiconductor industry.  During further conversation (comment 1909 and 1917) it was clarified that the substance falls under the scope of the proposed restriction. Nevertheless, during ongoing discussion on the C9-14 PFCAs restriction between dossier submitter, ECHA and rapporteurs, it has been proposed that the derogations that are included in entry 68 to Annex XVII of REACH (PFOA), will also apply to C9-C14 PFCAs, as identical derogations. The company has confirmed that the use of the substance is covered by the derogation of entry 68, column 2, paragraph 4 (d) (iii). |
| **RAC Rapporteurs comments:**  RAC agrees with the Dossier Submitter. |
| **SEAC Rapporteurs comments:**  SEAC agrees with the Dossier Submitter. |
| **1900** | **Date:** 2018/04/26 16:54  **Content:**  Scope or restriction option analysis  **Type:** MemberState  **Country:**  Sweden | **Comment:**  In a study by the Commission for Environmental Cooperation (CEC), 31 PFASs were analyzed in 137 articles of clothing and performance apparel (including children’s items) collected across North America between May and September 2017. The articles originated from e.g. China (> 50%), Mexico, Vietnam and Canada. C9-C14 PFCA were detected among the samples (C9: 36/137, C10: 41/137, C11: 11/137, C12: 23/137, C13: 4/137, C14: 19/137) up to levels that would exceed the proposed threshold. This study show that imported articles may contain C9-C14 PFCA and/or their related substances at levels that exceed the proposed threshold in the restriction proposal. The report is available at http://www3.cec.org/islandora/en/item/11777-furthering-understanding-migration-chemicals-from-consumer-products-en.pdf. |
| **Dossier submitter response:**  Thank you for your comment and for your information on the presence of C9-C14 PFCAs in imported articles like textiles. This information is valuable since it demonstrates a need of regulation of imported articles containing C9-C14 PFCAs. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC thanks for the information. |
| **1901** | **Date:** 2018/04/30 12:45  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** National NGO  **Org. name:** Framtiden i våre hender  **Org. country:** Norway  **Attachment:** | **Comment:**  We strongly support the restriction proposal for all the substances based on the known hazards for these chemicals. We are indeed deeply worried about the extensive use of PFAS in regular consumer products. Our general stance on all PFAS is that they should not be used in any products where they are not absolutely necessary (e.g. matter of life and death), based on a precautionary principle.  We have performed some product tests in different accredited laboratories, on food packaging, skiwaxes, cosmetics and baby/children products. We found (not surprisingly) PFAS in several products in all the tests, and C9-C14 PFCA were detected in both cosmetics and skiwaxes in levels above the restriction proposal.  The test results will be provided in the attachments.  Short sum-up of the results from cosmetics.  • 5 of 15 products (Bodyshop 2 products, Clinique, H&M and KICKS) contained all six PFASs that Sweden and Germany recently proposed to be banned in the EU (C9-C14 PFCA). Additional 4 products contain one or more of these.  • 4 of 15 products contain higher total levels of C9-C14 in sum than the proposed limit of 25 ppb  Short sum up of skiwax results.  • 5 of 8 analysed products contained total levels of C9-C14 that in sum exceeded the proposed limit of 25 ppb. These were from the following brands: Swix, Rode, Toko and Start.  Unfortunately, we don’t know if these substances are intentionally added or not. We have asked the skiwax producers what specific substances they use in their products, but they refused to answer these questions due to competition concerns.  In cosmetics, none of these specific substances are listed in the table of contents. We find it most likely that they are a result of degradation from the other PFASs being used, or contamination from the production process of the employed substances. We think that the proposed limit of 25 ppb is good, and that it should be as strict as this in order to phase out these substances from cosmetics and other consumer goods. |
| **Answer to specific info request 1:**  see the attached test results on skiwax. I can't be sure whether the C9-C14 are intentionally used or not,as the producers dont want to disclose to us what kind of substances are being used, but I think the levels of C9-C14 in Toko fluorine powder, and Start glider is quite high, so it would be interesting for somebody with the right authority to check more into whether these substances are intentionally added or not. |
| **Dossier submitter response:**  Thank you for your support and for your information on cosmetic ingredients falling within the scope of this restriction proposal, levels of C9-C14 PFCAs in selected cosmetic products as well as information on the presence of C9-C14 PFCAs in ski waxes. This information is valuable since it demonstrates a few of the identified intended uses of C9-C14 PFCAs. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC thanks for the information. |
| **1902** | **Date:** 2018/04/30 14:12  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** National NGO  **Org. name:** Framtiden i våre hender  **Org. country:** Norway  **Attachment:** | **Answer to specific info request 2:**  We detected C9-C14 above the proposed limit in one cosmetic product from Body Shop, and one from Clinique. However, we don't know exactly which substance is being responsible for this, as the only thing declared in their table of contents is Ammonium C6-16 Perfluoroalkylethyl  Phosphate (Body shop), and C9-15 Fluoroalcohol Phosphate (Clinique) Therefore, we cannot be sure whether C9-C14 are detected as an impurity from substances with shorter or longer carbon chains. For total levels detected, please se the attached report. |
| **Dossier submitter response:**  Thank you for this information levels of C9-C14 PFCA in selected cosmetic products. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC thanks for the information. |
| **1906** | | **Date:** 2018/06/01 15:45  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Mineraloelwirtschaftsverband  **Org. country:** Germany | **Comment:**  Adding to our comments originally given - pointing out non-avoidable PFCA contamination in firefighting foams- we want to inform about our judgement that a derogation as enshrined in the restriction of PFOA will suffice. |
| **Dossier submitter response:**  See our response to comment 1885. |
| **RAC Rapporteurs comments:**  Thank you for the response. |
| **SEAC Rapporteurs comments:**  Thank you for the response. |
| **1907** | | **Date:** 2018/06/04 10:20  **Content:**  Scope or restriction option analysis;#Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** European Automobile Manufacturers Association (ACEA)  **Org. country:** Belgium  **Attachment:** | **Comment:**  Please note the letter attached. |
| **Dossier submitter response:**  The Dossier Submitter thanks for the information provided.  The Dossier submitter proposed a structural formula to include all possible substances which can degrade to C9-C14 PFCAs. This is in line with the restriction on PFOS and PFOA and the stewardship program of the US-EPA on long chain PFASs. In our view there is no reason to alter the scope of the proposed restriction.  The Dossier Submitter is aware that it may be challenging to receive data on used substances in large supply chains, but the producers have a responsibility to know what kind of substances their products contain. We would like ACEA to work together with ECHA in order to come up with a plan and a timeframe to get the data needed in order to clarify what substances are in the supply chain (with relevance for this restriction, but also in general). If total knowledge cannot be gained soon, then the uncertainty about what substances are in the supply chain need to be minimised at least. In the end no supply chain can be a black box where the producers do not have knowledge about the substances used within the supply chain and contained in the end product. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  Your concern that legal compliance is challenging, especially in industries with global and complex supply chains, and that a global regulation would ease the work for importers. SEAC notes that this might be challenging but that no cost estimate is provided. |
| **1908** | | **Date:** 2018/06/05 18:07  **Content:**  Information on alternatives;#Other socio economic analysis (SEA) issues;#Transitional period;#Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  <redacted>  **Org. country:** United Kingdom  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** The reason for not disclosing this information is to protect the company's and our supplier's intellectual property with respect to the use, materials and processing. | **Comment:**  The restriction if implemented as per the current proposal has the potential to unintentionally interrupt the supply of inhaled medicines for the treatment of lung diseases such as chronic obstructive pulmonary disease and asthma. |
| **Answer to specific info request 2:**  See attached comments document for description of use, environmental impact and socio-economic reasons for continued use until the availability and performance of alternatives is proven. |
| **Answer to specific info request 3:**  See attached comments document for technical and socio-economic reasons why this by-product fraction cannot currently be avoided. |
| **Dossier submitter response:**  The comment (as well as comments 1920 and 1932) addressed a proposed derogation for a medicinal product use covered by directive 2001/83/EC or a time-limited exemption of at least seven years (for development, testing, registration and implementation of an alternative).  According to the PFOA restriction, a request for an exemption of using this medicinal product is currently under discussion. Derogations that are included in entry 68 to Annex XVII of REACH (PFOA), will also apply to C9-C14 PFCAs. Hence, the use of this medicinal product will not be restricted by this restriction proposal if the derogation is agreed for the PFOA restriction. |
| **RAC Rapporteurs comments:**  RAC agrees to accept the proposed derogation because of the low volumes in the order of few grams involved and the important medical use for which these articles are used. RAC takes into account that, as stated by the Company, after application, there is no detectable C9 - C14 PFCA content in the finished product. Therefore, there is no risk to patients from PFCA substances in the marketed pMDI products. |
| **SEAC Rapporteurs comments:**  SEAC notes the small quantity involved and RAC’s support for the derogation, and agrees that taking into consideration the high benefits in terms of human health, the time limited derogation of seven years is justified.  SEAC notes that a similar request for an exemption is currently under discussion under the PFOA restriction (entry 68 to Annex XVII of REACH).  However, the request under the PFOA restriction concerns the use of PFOB containing impurities of PFOI, which are present as impurities in the medicinal product. This request is related to the production of the lining of inhalers and is not detected in the final product. |
| **1909** | | **Date:** 2018/06/07 20:17  **Content:**  Scope or restriction option analysis;#Transitional period;#Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:**  the information in the file contains confidential information with structure and test reports | **Dossier submitter response:**  See our response to comment 1899. |
| **RAC Rapporteurs comments:**  See our response to comment 1899. |
| **SEAC Rapporteurs comments:**  Agree with the Dossier Submitter. |
| **1914** | | **Date:** 2018/06/14 16:07  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** 3M Belgium  **Org. country:** Belgium | **Comment:**  3M Company response to questions on its derogation request for the proposed C9-C14 PFCAs restriction  3M appreciates the opportunity to respond to the dossier submitters (Germany and Sweden) and the Committees for Risk Assessment and Socio-economic Analysis request for further clarifications regarding 3M’s request for a 36 month introduction period as well as a C9-C14 PFCA concentration limit of 400 ppb (reference number 1897).  3M also offers to further discuss these responses in a meeting.  Questions:  Higher concentration limit  1. Are you producing these polymers inside the EU or are you importing them? 3M produces fluoropolymers in Europe. 3M manufactures fluoropolymers in Europe both itself and via its wholly owned subsidiary: “Dyneon GmbH”.  What kind of applications and products are you referring to in product group A, B & C? A,B,& C refer to sub segments of PTFE fine powder, fluoroelastomer and aqueous dispersion product groups. Detailed descriptions of these product groups are confidential. To what uses/industrial sectors are being supplied with product groups A, B and C? A, B and C represent groups of fluoropolymers that are sold broadly. A good overview is provided by the socio-economic study referenced below: http://www.plasticseurope.org/en/resources/publications/socio-economic-analysis-european-fluoropolymer-industry-executive-summary  2. What is your market share on in these sectors? Market share is hard to define. 3M is one of the top three manufacturers in Europe depending on a specific product category. There are commercial market reports available for fluoropolymers. 3M’s own market analysis might not be complete and it is confidential. Are the products used for purposes that will result in C9-C14 PFCAs in articles or other mixtures above the 25 ppb limit. The processing of fluoropolymers into articles is known to reduce traces of perfluorocarboxylic acids. The levels of residuals in specific articles might be above or below the proposed limit. 3M has limited information on C9-C14 PFCA concentrations in end use articles.  3. Please provide volumes of C9-C14 PFCAs placed on the EU-market and exported from the EU in product groups A, B & C. It is difficult due to market information uncertainties to answer precisely. However, conservatively assuming 1000t/a of these products on the market, 3M estimates less than 2kg of C9-C14 PFCAs placed on the market or exported. Most of the 3M products in A, B & C stay in the EU. Can you quantify the emissions of C9-C14 PFCAs during manufacturing and use of product groups A, B & C? Based on the previous answer, this is estimated to be less than 2 kg per year of emission.  4. What technology are you using today? 3M does not intentionally use C9-C14 PFCA. It uses different containment technologies for fluorosurfactants today. The 3M containment strategy is described by K. Hintzer and W. Schwertfeger in Chapter 21 of “Handbook of Fluoropolymer Science and Technology”, pg 495ff.; Eds. D.W. Smith, S.T. Iacono and s. Iyer, Wiley, Hoboken NJ 2014. What is the new technology you plan to implement to reduce the sum of C9-C14 PFCAs to 400 ppb? 3M plans to develop and implement new technologies from post polymerization processing to the introduction of alternate chemistries to reduce C9-C14 PFCA trace levels. Details are 3M confidential due to ongoing intellectual property activities. Where in the manufacturing process are C9-C14 PFCAs arising and what is the origin of the C9-C14 PFCAs? Trace amounts are generated during polymerization. A chemical side reaction was described by D.P. Carlson (US 3,642,742) for non- aqueous systems and referenced by K. Hintzer and G. Loehr in “Modern Fluoropolymers”, pg. 225 Ed. J Scheirs, John Wiley, Chichester 1997, but only recent advances in analytical technology allowed them to be detected in aqueous based products. Are they degradation products, the result of incomplete polymerisation or another pathway? They are neither degradation products of the polymer nor the result of incomplete polymerization. Please see also the previous answer. Why can these polymers not be purified to remove the C9-C14 PFCAS using best available technology? For the product groups in question there is currently no technology available. The physicochemical properties of C9-C14 PFCA are different enough from C8 (PFOA) to require different solutions. 3M is developing new technologies to reduce levels of these chemicals to meet a 400 ppb level. It should be noted that the current low levels of C8-C14 PFCA’s have been achieved through a series of technology improvements over the last 20 years.  5. Are your products meeting the 260 ppb limit for the sum of the C9-C14 PFCA related substances? 3M does not use chemistries containing C9-C14 PFCA-related-substances (long chain fluorotelomers), so already meets the proposed limit.  6. Please explain if there are technical and/or economic reasons as to why you cannot reach concentrations below 400 ppb for the sum of C9-C14 PFCAs and achieve the proposed threshold of 25 ppb for the sum of C9-C14 PFCAs? 3M is answering the question based on its understanding of the question’s intent. If this is misunderstood 3M would appreciate an opportunity for follow-up communication. The threshold of 25 ppb for the sum of C9-C14 PFCA cannot be achieved for all products, but the current levels can be reduced significantly with the intended new technology introduction as outlined in table 1 (of 3M’s initial comments with reference number 1897) for product group A and B to meet the level of 400 ppb. 3M’s intended technology changes are at this point based on research experiments and further dependent on investments and regulatory clearance of new substances (REACH registration). 3M wishes to point out that these technical changes and investments may not be needed for non-EU producers. Downstream processing of fluoropolymers would reduce C9-C14 PFCA levels, so that imported articles may already be compliant. This is expected to provide a competitive advantage to manufacturers outside of Europe. As noted in the response to question #2. Does the 400 ppb take measurement uncertainty and inter-laboratory variation into consideration? Yes, based on 3M’s estimate of the method it developed for low-level analysis of C9-C14. 3M pioneered the analytical method for PFOA analysis in a fluorinated matrix and shared the method with the EU administration. This method is also the basis for our C9-C14 PFCA analysis. Analytical method variability has to be a consideration in setting restriction limits, otherwise the situation with the PFOS REACH restriction and method reliability would be repeated. (Reference; Leeuwen. S.P.J. van, Karrman, A., Bavel, B. van, Boer, J. de & Lindstrom, G. (2006). EnvironmentalScience & Technology, 40, 7854.)  7. What kind of substitution efforts have you made so far? What additional substitution efforts are you planning? As discussed in response #4 above, the presence of C9-C14 is the consequence of a chemical side reaction. It is not present in the raw materials.  8. Do you have any comparative information from other manufacturers of the same polymer type whether they have similar concentrations of C9-C14 PFCAs in their polymers? 3M has limited understanding about the situation and efforts of other companies in the industry, but suspects other companies may have the same or similar issues. (Please see also the response to question #6) The regulation as proposed will disadvantage EU domestic manufacturing and processing.  Longer transitional period  9. Would your customers really require to re-qualify their product if the only change is in the impurity level in the material provided by you? 3M will have to change processes and composition which will trigger customer requalifications. Fluoropolymer consumers in the transportation, chemical processing, cookware, electronics and pharmaceutical device market segments have to qualify supplier changes for regulatory, quality system requirements or their quality management.  10. Would a transitional period that makes the restriction effective at same time as the PFOA restriction be sufficient for your customers? I.e. the restriction would start to apply in July 2020. No, it would not be sufficient. Fluoropolymer manufacturers are early in the value chain. The different end user industries will need to qualify the changes after 3M’s changes are implemented. The technical changes for PFOA and C9-C14 are different for the product categories A, B and C and independent of each other, so there are no synergies. This would be achieved by the current proposal of 18 months transitional period by the dossier submitter. The transition time has to accommodate the customer qualification. Therefore, 3M asks for the at least 36 month transition time. Certain industries, e.g. pharmaceutical industry will require derogations or even longer transition times than 36 months. |
| **Dossier submitter response:**  The Dossier Submitter thanks 3M for the information. As discussed in the Background Document levels of C9-C14 PFCAs are still increasing in some European biota, although the substances are not used within the EU. The substances occur as unavoidable by-products during the manufacturing of C8 based PFAS and short chain PFAS, e.g. based on C6. C9-C14 PFCAs are PBT and vPvB substances which do not degrade in the environment. Thus, the reduction of emissions into the environment to a minimum is necessary to reduce the risks to humans and the environment.  Information provided by industry during our stakeholder consultation before submitting the restriction proposal stated that the threshold of 25 ppb for C9-C14 PFCAs and 260 ppb for C9-C14 PFCA related substances is feasible within the EU.  3M requests a longer transition period and higher thresholds. 3M states that the concentration of the substances could be reduced from ppm-level to approximately 400 ppb for the sum of the substances.  From our point of view it would be necessary to have detailed knowledge on the products and uses affected. We need to understand how the process can be changed to avoid the presence of C9-C14 PFCAs. This is mandatory to evaluate if other manufacturers could be affected as well.  3M did not provide such detailed information on the precise polymers and uses affected. In our opinion a broad derogation should be avoided. Thus, the Dossier Submitter does not agree to grant a longer transition period and higher thresholds based on the provided data.  Having detailed information about the different product groups A, B & C is also important for the socio economic assessment. It is not certain that we make the same assessment for all applications. Knowledge about what the different applications A, B & C are, as well as more detailed emissions data that specifies emissions of C9-C14 PFCAs for each of the different product groups would be necessary. We also need more information about product group A, B & C in order to clarify if other producers within the EU are able to meet the specified thresholds for these three product groups. |
| **RAC Rapporteurs comments:**  RAC shares the Dossier Submitters point of view that it would be necessary to have more detailed knowledge on the products and uses affected. It is not clear if the process could be changed to further avoid the presence of C9-C14 PFCAs. This information would be needed to evaluate if other manufacturers would be affected as well.  Such detailed information on the precise polymers and uses affected was not provided.  The requested derogation could allow all manufacturers and users of fluoropolymers to use materials with higher concentrations of C9-C14 PFCAs than proposed. This could be a broad derogation and would possibly allow much higher releases into the environment. Moreover, to support derogation better information would be needed on the emissions of C9-C14 PFCAS throughout the manufacturing process supported by data on volumes of emitted C9-C14 PFCAs into air and water. |
| **SEAC Rapporteurs comments:**  SEAC thanks for your information which has been addressed in the SEAC opinion.  The comment does only give very general information on the costs for the company and the society in general, in case you would have to stop your production of these fluoropolymers, if the limit value would be set to 25 ppb as proposed by the Dossier Submitter.  SEAC notes that the submitted comment did not submit detailed information regarding application of and emissions from each product group and that SEAC therefore does not have sufficient information to conclude on whether a general higher limit value as requested is justified. SEAC notes that in case a higher limit value were justified, the limit value could be 40% lower (240 ppb), as the company included inter-laboratory variation of approximately +/- 40 % in their derivation of the threshold. However, during enforcement activities testing variabilities are already taken into consideration.  In SEAC's draft opinion it is noted that in case the fluoro polymer producer requesting a higher threshold in the public consultation would have to leave the European market this might impact the fluoropolymers’ market in Europe.  SEAC notes your view that downstream processing of fluoropolymers would reduce C9-C14 PFCA levels, so that imported final articles may already be compliant. However SEAC cannot estimate the potential size of a possible competitive advantage to manufacturers outside of Europe.  Due to the general lack of information SEAC does not have sufficient information to support the request for a longer transitional period for the fluoropolymers. |
| **1917** | | **Date:** 2018/06/18 00:58  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes  **Attachment:**  <redacted> | **Dossier submitter response:**  See our response to comment 1899. |
| **RAC Rapporteurs comments:**  See the response to comment 1899. |
| **SEAC Rapporteurs comments:**  SEAC agrees with the Dossier Submitter. |
| **1920** | | **Date:** 2018/06/19 14:11  **Content:**  Scope or restriction option analysis;#Environmental emissions;#Information on alternatives;#Other socio economic analysis (SEA) issues;#Transitional period;#Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United Kingdom  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** The product supply chain related to this submission involves two external companies along with ourselves who have intellectual property related to the material, its processing and end-use. | **Comment:**  Response to request for additional information related to initial comment submission reference ba75d1d1-5a36-4e26-b975-664cdaa8082b dated 5th June 2018 |
| **Dossier submitter response:**  See our response to comment 1908. |
| **RAC Rapporteurs comments:**  See the response to comment 1908. |
| **SEAC Rapporteurs comments:**  As for comment 1908 and 1932, given the small quantity involved, RAC’s support and the high benefits for the society in terms of human health, SEAC supports the time limited derogation of seven years. |
| **1922** | | **Date:** 2018/06/19 15:31  **Content:**  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** Academic institution  **Org. name:** Institute of Environmental Medicine/Karolinska Institutet  **Org. country:** Sweden  **Attachment:** | **Comment:**  IMM supports the measures proposed by Germany and Sweden to restrict the manufacturing, use, placing on the market, and import of C9-C14 PFCAs, their salts and related substances (precursors).  IMM supports the group-wise restriction approach and find the arguments for the proposed actions to be well motivated from scientific, regulatory and practical points of view.  IMM supports the proposed implementation period of 18 months, noting that the compounds under consideration have very limited current uses in the EU, and the aim of the proposal to avoid that the compounds under consideration enter into increasing uses.  IMM notes that the restriction proposal mentions potentially beneficial technical properties of some PFCAs to society. Based on the expertise of IMM, we consider that it is feasible, through dedicated and lasting research/knowledge building, to achieve advanced decision bases allowing for further refined hazard identification/health risk assessment for individual PFCAs and combinations of those. Research and knowledge building on PFCAs should rely on broad international collaboration among regulators, industry and academics in order to sufficiently well capture and take full responsibility of involved scientific and societal complexities in line with the United Nation’s 2030 Agenda for Sustainable Development. The comments are also in line with the Swedish Environment Objective “A Non-Toxic Environment” and with the national memorandum of understanding signed by 17 Swedish authorities and universities, including Karolinska Institutet, regarding increased collaboration to limit the impact of PFAS on health and the environment. |
| **Dossier submitter response:**  Thank you for your support. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC thanks for the comment. |
| **1923** | | **Date:** 2018/06/19 22:31  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** FluoroCouncil  **Org. country:** United States  **Attachment:** | **Comment:** |
| **Answer to specific info request 1:**  The FluoroCouncil would like to highlight that none of these substances has been used by its members, with the exception of the C9 ammonium salt, which was formerly used as a polymerisation aid in the production of certain fluoropolymers. This use has been discontinued by FluoroCouncil members as part of their successful completion of the US EPA Stewardship Programme on PFOA and longer-chain homologues. |
| **Answer to specific info request 3:**  The FluoroCouncil supports an exemption for the unintended production of a limited fraction of long-chain substances, as part of C6 fluorotelomers production, and similarly to what is provided for in the REACH Restriction for PFOA and PFOA-related substances. We note nonetheless that the current paragraph 3a) of the C9-C14 restriction proposal refers to C8 manufacturing. The exemption in paragraph 3a) needs to be amended in order to relate to the manufacture of fluorochemicals with a carbon chain equal to or shorter than 6 atoms (and not 8 atoms). The FluoroCouncil supports furthermore the exemption for transported intermediates set out in paragraph 3b). |
| **Dossier submitter response:**  You mentioned that for the enforceability of the threshold no robust and validated analytical method is available. It is correct that there are currently no standardised analytical methods available to measure the content of C9-C14 PFCAs, their salts and related substances in articles and mixtures. Nevertheless, those methods are being developed already for the restriction of PFOA and related substances. The same methods can be applied for testing C9-C14 PFCAs and related substances.  Response to specific info request 3:  We have changed the paragraph to “… fluorochemicals with a carbon chain equal to or shorter than 6 atoms”. |
| **RAC Rapporteurs comments:**  RAC agrees with the comment provided by the Dossier Submitter. |
| **SEAC Rapporteurs comments:**  SEAC agrees with the comments provided by the Dossier Submitter. |
| **1925** | | **Date:** 2018/06/20 14:46  **Type:** MemberState  **Country:**  Denmark  **Attachment:**  <redacted> | **Answer to specific info request 1:**  C9-C14 PFCAs and C9-C14 PFCA related substances has been identified in cosmetic products (please see attached draft report). C9-C14 PFCA related substances seems to be used intentionally. |
| **Dossier submitter response:**  Thank you for this information on cosmetic ingredients falling within the scope of this restriction proposal as well as on levels of C9-C14 PFCA in selected cosmetic products and the proportion of cosmetic products containing PFASs. This information is valuable since it demonstrates one of few intended uses of these substances. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC notes the valuable information provided on cosmetics and thanks for the support. |
| **1926** | | **Date:** 2018/06/20 14:50  **Content:**  Scope or restriction option analysis;#Hazard or exposure;#Information on costs;#Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** IPEN and European Environmental Bureau (EEB)  **Org. country:** Belgium  **Attachment:** | **Comment:**  EEB and IPEN welcomes the opportunity to comment on this Restriction Report and thank  the German and Swedish authorities for preparing this proposal. We strongly support its  recommendation to restrict the manufacturing, use, placing on the market and import of  C9-C14 PFCAs, their salts and related substances. We would also like to commend the  Dossier Submitters for recommending that the restriction includes recycled material and  articles made from recycled materials.  We are, however, extremely concerned that the restriction is not proposed to include “the  manufacture of a substance where this occurs as an unintended by-product of the  manufacture of fluorochemicals with a carbon chain equal to or shorter than 8 atoms”, as  well as the proposed thresholds of PFCAs for mixtures and articles placed on the market.  In relation to these concerns and some additional issues, we would like to submit the  following information, comments and suggestions.  Compelling evidence of need for strong restriction decision  The dossier provides clear evidence of the long-term, costly and detrimental consequences  of continued released of C9-C14 PFCAs. It acknowledges that they are released into the  environment during every life cycle step and via various exposure pathways, do not  undergo any further abiotic or biotic degradation under environmentally relevant  conditions and that they are very likely to cause severe and irreversible adverse effects on  the environment and human health if their releases are not minimized. It further described  that they are already ubiquitously present in the environment and that remediation of soil  and water is difficult and very costly.  While no user of the C9-C14 PFCAs has been identified in the EU, the dossier also states  that the availability of fluorine free alternatives for many sectors is growing. It is therefore  clear that all evidence and incentives for a strong restriction proposal are there, and that  all other considerations must be made with this in mind.  PFCAs as by-products  It is described in the dossier that C9-C14 PFCAs occur as a byproduct in production of  PFOA as well as the so-called “C6-based chemistries”, and that these unintended by-  products are proposed to not be covered by the restriction.  While PFOA production will decrease once the EU restriction comes into force in 2020 and  the substance is listed in the Stockholm Convention, it will not fully cease due to the  derogations included in the restriction decision. In addition, the restriction dossier further  describes that industry is shifting towards C6 substances, namely perfluorohexanoic acid  1(PFHxA) based substances. It is therefore clear that C9-C14 PFCAs will continue to be  produced if this exemption is allowed in the restriction decision.  This conclusion is even clearly stated in the dossier itself on page 18:  “Thus, releases will continue because the substances are unintentional by products during the  manufacturing of short-chain alternatives, such as the C6-based chemistries and some  remaining uses of C8-based chemistries (derogated uses, such as firefighting foams).”  In addition, mounting evidence shows that the C6 fluorinated substances are regrettable  substitutions that are persistent, bioaccumulate and are toxic. Serious concerns about C6  and C4 fluorinated substances include:  •  •  Many are found in the Arctic, including in wildlife and humans.  Many are found in remote areas of the Earth including remote mountain areas, in  the ocean, and in deep sea locations.  There is some data indicating that short-chain perfluorinated compounds are more  efficiently taken up in food crops.  Many are found in wildlife and in humans.  There are many pathways of exposure to these substances including consumer  products, household dust, drinking water, and others.  Those with publicly data indicate transfer from mother to the developing fetus  during pregnancy and excretion during breast feeding.  Those with publicly available data show a variety of serious adverse effects,  including in vitro data indicating endocrine disruption, DNA damage, altered  differentiation, effects on behavior and cognition, and impaired development,  among others. In humans, effects include altering blood lipids, reduced fertility,  immunosuppression, thyroid hormone function, and attention deficit disorder  among others.  Claims of confidential business information have obstructed efforts by regulators  and scientists to adequately assess the characteristics of the proposed fluorinated  alternatives.  Please see Annex 1 for references to peer reviewed scientific studies on these regrettable  substitutes.  It is therefore surprising that the restriction proposal instead of discouraging the increased  use of C6 fluorinated substances, specifically states that it is not intended to prevent the  manufacturing of C6 and other short-chained fluorinated substances. This creates a large  gap in the regulation that will cause further harm and costly clean-up measures.  EEB and IPEN therefore propose to remove this suggested exemption.  Thresholds for PFCAs should be lowered  The restriction proposal suggests restricting the use, placing on the market and import of  C9-C14 PFCAs, their salts and related substances as substances on their own or in a  mixture or in an article or parts therein in a concentration equal to or above 25 ppb for the  sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related  substances. These thresholds are based on the content of PFCAs in mixtures sold to  2industry that contain C9-C14 PFCAs and related substances in trace levels up to 25 ppb  and 260 ppb, respectively.  Since the primary goal of the proposal is to reduce and eliminate releases of C9-C14 PFCAs  and related substances to the environment, these limits should be as low as possible. More  importantly, there is no justification for these proposed limits based on environmental and  health implications. The limits should be based on emerging scientific evidence, not  convenience for industry. For these substances, 25 ppb (25,000 ppt) and 260 ppb (260,000  ppt) are not “trace” amounts and these levels would ensure subsequent soil and water  pollution and possibly contamination in people.  Recent advisories and limits for PFAS in drinking water provide useful guidelines on limits.  US EPA has a health advisory level of 70 ppt for PFOS and PFOA. 1 The US State of  Minnesota has a health advisory limit in drinking water of 35 ppt for PFOA and 27 ppt for  PFOS. 2 The US State of Vermont has a drinking water health advisory combined limit for  PFOS and PFOA of 20 ppt. 3 In drinking water, the US State of New Jersey has established an  enforceable maximum contaminant level for PFOA of 14 ppt and for PFNA, 13 ppt. 4 An  analysis including impacts on immune suppression in children has yielded a proposed  drinking water limit of 1 ppt. 5  EEB and IPEN therefore propose to lower PFCA thresholds significantly, to less than 70  parts-per-trillion to fully achieve the intent of this restriction.  Semiconductor derogation should be rejected  Only one, non-EU company has come forward to request a derogation at a very late stage  for import of (their) semiconductors. Since sufficient evidence was not provided and no  companies in the EU is still using C9-C14 PFCAs intentionally for this or any other purpose,  this derogation should not be approved. Furthermore, it is clear that the semiconductor  industry is moving away from fluorinated substances. In 2017, the World Semiconductor  Council, which includes all major manufacturers in Europe, announced a global phase-out  of PFOS and recommended that, “Governments/Authorities inform their appropriate  environmental regulatory ministries and the UN Stockholm Convention of this successful  action by the global semiconductor industry.” 6  https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-  advisories-pfoa-and-pfos  1  2  http://www.health.state.mn.us/divs/eh/hazardous/topics/pfcs/current.html#Example1  3  https://anrweb.vt.gov/PubDocs/DEC/PFOA/PFOA%20-  %20PFOS%20Health%20Advisories/Vermont/PFOA\_PFOS\_HealthAdvisory\_June\_22\_2016  .pdf  4  http://www.nj.gov/health/ceohs/documents/pfas\_drinking%20water.pdf  5  Grandjean P, Budtz-Jorgensen (2013) Immunotoxicity of perfluorinated alkylates:  calculation of benchmark doses based on serum concentration in children, Environmental  Health 12:35  6  https://www.semiconductors.org/clientuploads/directory/DocumentSIA/International%  20Trade%20and%20IP/21st%20WSC%20Joint%20Statement%20May%202017%20Kyo  to%20(Final).pdf  3Costs for remediation are extremely high  Finally, we would like to provide some further information in relation to the costs of  remediation, which are mentioned in relation to the economic impacts but not quantified.  These costs should be clearly stated to make sure that the burden on country budgets is  taken into account when considering any exemptions to this restriction. As expected,  pollution prevention is far more economical than clean-up. Calculations of the total costs  for cleaning up groundwater polluted by PFAS around firefighting areas in Norway show  that 3.5-5.5 million euros is required per training site. 7 Industrial sludge disposal on  agricultural fields in Germany polluted both surface water and a drinking water reservoir  resulting in PFAS contamination in humans. Approximately 2.5 million euros have been  spent on clean-up annually since 2006 and operating costs of the water purification plant  are approximately 100,000 euros/year. 8 In Sweden, addressing PFAS contamination of  drinking water costs Uppsala 1 million euros/year and developing a new water supply in  Ronne cost 3 million euros. 9 In the US, the Air Force is expected to spend more than USD$2  billion for PFAS clean-up around military bases. 10 A single US state spends USD$2 million  per month responding to PFAS contamination. 11  RAC and SEAC opinions should clearly describe the human and environmental impacts of  the suggested derogations, both in terms of harms and of economic cost, in order to allow  policy decision makers (REACH Committee and Commission) to fully understand the risks  of their decisions. |
| **Dossier submitter response:**  Thanks for your support. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC notes the valuable information provided and thanks for the support. |
| **1932** | | **Date:** 2018/06/20 18:19  **Content:**  Environmental emissions;Information on alternatives;Information on benefits;Other socio economic analysis (SEA) issues;Transitional period;Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United Kingdom  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** The use of the material and its processing is protected by the IP of the companies involved. | **Comment:**  Further comments submitted in response to question/clarifications from the review process. |
| **Answer to specific info request 2:**  Further comments following questions or clarifications requested for comment submissions;  REFERENCE NUMBER: ba75d1d1-5a36-4e26-b975-664cdaa8082b  REFERENCE NUMBER: 50f90ee5-7f62-48c0-9cad-fa85c986d008  See attachment. |
| **Dossier submitter response:**  See our response to comment 1908. |
| **RAC Rapporteurs comments:**  See the RAC response to comment 1908. |
| **SEAC Rapporteurs comments:**  As already commented for comments 1908 and 1920, given the small quantity involved, RAC’s support for the derogation and the high benefits for the society in terms of human health, SEAC supports the time limited derogation of seven years. |
| **1933** | | **Date:** 2018/06/20 19:40  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** ARCHROMA  **Org. country:** Switzerland  **Attachment:** | **Answer to specific info request 1:**  cf. input from the FluoroCouncil |
| **Answer to specific info request 2:**  cf. FluoroCouncil input |
| **Answer to specific info request 3:**  As the only company conducting the entire production of C6 fluorotelomers in the EU, we welcome paragraph 3 a) of the proposed restriction, with the exception that it currently refers to the production of C8 fluorotelomers instead of C6 fluorotelomers. In line with the wording adopted under the Restriction for PFOA and PFOA-related substances, the wording needs to be amended as follows:  a) the manufacture of a substance where this occurs as an unintended by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 6 atoms;  The need for a derogation is due to the fact that the first step of the production of short-chain fluorotelomer alternatives, the so-called “telomerisation process”, leads to the production of an unavoidable fraction of C8 and longer chain substances belonging to the C9-C14 substances to be restricted. Importantly, C9-C14 substances are not “used” in the manufacturing of C6 substances. This long-chain fraction is an unintentional byproduct occurring during production. It is an isolated intermediate, it is not a commercial product. The amount of this residual fraction has been reduced in the course of past years and further steps are being taken to reduce it even further by 2020. This fraction is reprocessed under strictly controlled conditions. |
| **Answer to specific info request 4:**  This requires further assessment. |
| **Dossier submitter response:**  Thank you for your comment. |
| **RAC Rapporteurs comments:**  Noted. |
| **SEAC Rapporteurs comments:**  SEAC thanks for the information. |