

**Committee for Risk Assessment (RAC)**  
**Committee for Socio-economic Analysis (SEAC)**

Opinion

on an Annex XV dossier proposing restrictions on

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

**ECHA/RAC/RES-O-0000001412-86-219/F**  
**ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]**

**Adopted**

14 September 2018

**14 September 2018**

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

**13 September 2018**

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

**Opinion of the Committee for Risk Assessment**

**and**

**Opinion of the Committee for Socio-economic Analysis**

**on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU**

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

|                          |  |
|--------------------------|--|
| <b>Chemical name(s):</b> | <b>PFNA; PFDA; PFUnDA; PFDoDA; PFTrDA; PFTDA; their salts and precursors</b> |
| <b>EC No.:</b>           | <b>206-801-3, 206-400-3, 218-165-4, 206-203-2, 276-745-2, 206-803-4</b>      |
| <b>CAS No.:</b>          | <b>375-95-1, 335-76-2, 2058-94-8, 307-55-1, 72629-94-8, 376-06-7</b>         |

This document presents the opinion adopted by RAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the public consultation and other relevant information resulting from the opinion making process.

## **PROCESS FOR ADOPTION OF THE OPINIONS**

**Germany** and **Sweden** have submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <http://echa.europa.eu/web/guest/restrictions-under-consideration> on **20 December 2017**. Interested parties were invited to submit comments and contributions by **20 June 2018**.

### **ADOPTION OF THE OPINION**

#### ADOPTION OF THE OPINION OF RAC:

**Rapporteur, appointed by RAC: *Pietro PARIS***

**Co-rapporteur, appointed by RAC: *Normunds KADIKIS***

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **[date of adoption of the opinion]**.

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **14 September 2018**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

#### ADOPTION OF THE OPINION OF SEAC

**Rapporteur, appointed by SEAC: *Lars FOCK***

**Co-rapporteur, appointed by SEAC: *Luisa CAVALIERI***

#### The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **13 September 2018**.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at <http://echa.europa.eu/web/guest/restrictions-under-consideration> on **19 September 2018**. Interested parties were invited to submit comments on the draft opinion by **19 November 2018**.

### The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. [The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]**]<sup>1</sup>.

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and]<sup>5</sup> 71(1) of the REACH Regulation.] [No comments were received from interested parties during the public consultation in accordance with Article[s 69(6) and]<sup>3</sup> 71(1)]<sup>6</sup>.

The opinion of SEAC was adopted **by [consensus.][a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion.]<sup>6</sup>.

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<sup>1</sup> Delete the unnecessary part(s)

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## OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter:

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| <p>Perfluoroalkyl carboxylic acids (branched and/or linear) with the formula:<br/> <math>CF_3-(CF_2)_n-C</math>, <math>n=7</math> or <math>8</math> or <math>9</math> or <math>10</math> or <math>11</math> or <math>12</math> as structural elements including their salts and including all combinations thereof</p> <p>Perfluoroalkyl carboxylic acids (branched and/or linear) with the formula:<br/> <math>CF_3-(CF_2)_n-</math>, <math>n=8-13</math> as a structural element, including their salts</p> <p>Any related substance (including its salts and polymers) with the above defined linear and/or branched perfluoroalkyl structural elements that can degrade to C9-C14 PFCA</p> <p>The following substances are excluded from this designation:</p> <ul style="list-style-type: none"> <li>• <math>CF_3-(CF_2)_n-X</math>, <math>n &gt; 7</math>, where <math>X = F, Cl, Br</math> including any substance with linear and/or branched perfluoroalkyl elements and all mixtures thereof</li> <li>• <math>CF_3-(CF_2)_n-SO_2X'</math>, <math>n &gt; 7</math> where <math>X' =</math> any group, including salts</li> <li>• <math>CF_3-(CF_2)_n-C(=O)OH</math>, <math>n &gt; 12</math> including salts</li> </ul> | <ol style="list-style-type: none"> <li>1. Shall not be       <ol style="list-style-type: none"> <li>(a) manufactured, or placed on the market as substances on their own;</li> <li>(b) used in the production of, or placed on the market in:           <ol style="list-style-type: none"> <li>(i) another substances, as a constituent,</li> <li>(ii) a mixture,</li> <li>(iii) an article or any parts thereof,</li> </ol> </li> </ol> <p>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</p> </li> <li>2. Paragraph 1 shall apply 18 month from entry into force of the restriction</li> <li>3. Paragraph 1 shall not apply to       <ol style="list-style-type: none"> <li>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 8 atoms;</li> <li>b) a substance that is to be used, or is used as a transported isolated intermediate, provided that the conditions in Article 18(4) lit. a) to f) of this Regulation are met;</li> </ol> </li> <li>4. Paragraph 1(b-iii) shall not apply to       <ol style="list-style-type: none"> <li>a) Articles placed on the market before the restriction becomes effective.</li> </ol> </li> </ol> |
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## THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other



available information as recorded in the Background Document. RAC considers that the proposed restriction on **PFNA; PFDA; PFUnDA; PFDoDA; PFTTrDA; PFTDA; their salts and precursors** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the scope and/or conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are:

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| <p>1. Perfluorocarboxylic acids (linear and/or branched), their salts and PFCA-related substances<sup>2</sup>:</p> <p>(a) Perfluorocarboxylic acids with the formula: <math>C_nF_{2n+1}-C(=O)OH</math> <math>n= 8, 9, 10, 11, 12</math> or <math>13</math> including their salts and any combinations thereof;</p> <p>(b) Any PFCA-related substance having a perfluoro group with the formula <math>C_nF_{2n+1}-</math> directly attached to another carbon atom, where <math>n=8, 9, 10, 11, 12</math> or <math>13</math>, including any combinations thereof;</p> <p>(c) Any PFCA-related substance having a perfluoro group with the formula <math>C_nF_{2n+1}-</math> that is not directly attached to another carbon atom, where <math>n= 9, 10, 11, 12, 13</math> or <math>14</math> as one of the structural elements, including any combinations thereof.</p> <p>2. The following substances are excluded from this designation:</p> <p>(a) <math>C_nF_{2n+1}-X</math>, where <math>X= F, Cl</math> or <math>Br</math> where <math>n= 9, 10, 11, 12, 13</math> or <math>14</math>, including any combinations thereof;</p> <p>(b) <math>C_nF_{2n+1}-C(=O)OX'</math>, where <math>n&gt;13</math> and <math>X' =</math> any group, including salts.</p> | <p>1. Shall not be manufactured, or placed on the market as substances on their own;</p> <p>2. Shall not be used in the production of, or placed on the market in:</p> <p>(a) Another substance, as a constituent<sup>3</sup>,</p> <p>(b) A mixture,</p> <p>(c) An article or any parts thereof, 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.</p> <p>3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction</p> <p>4. Paragraphs 1 and 2 shall not apply to:</p> <p>(a) The manufacture of a substance where this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a perfluoro carbon chain equal to or shorter than 6 atoms;</p> <p>(b) A substance that is to be used, or is used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met;</p> <p>5. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.</p> |
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<sup>2</sup> PFCA-related substances are substances that, based upon their structural formulae, are considered to have the potential to degrade or be transformed to C9-14 perfluorocarboxylic acids (linear and/or branched).

<sup>3</sup> Constituent includes impurities i.e. both unintended and intended constituents.

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|  | <p>6. The derogations referred to in paragraphs 3, 4(a),(d),(e), 5 and 6 of Regulation (EC) No 1907/2006, Annex XVII, entry 68 are applicable with the same conditions to the substances referred to in column 1, paragraph 1 of this restriction.</p> <p>7. Paragraph 2 shall not apply to the can coating for pressurised metered-dose inhalers until seven years after the entry into force of the restriction.</p> <p>8. Paragraph 2(c) shall apply from 31 December 2023 to:</p> <ul style="list-style-type: none"> <li>(a) Semiconductors; and</li> <li>(b) Semi-finished and finished electronic equipment for use in semiconductors.</li> </ul> <p>9. Paragraph 2(c) shall apply from 31 December 2030 to semiconductors used in spare or replacement parts for finished electronic equipment placed on the market before 31 December 2023.</p> |
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## Explanatory text<sup>4</sup>

### Column 1

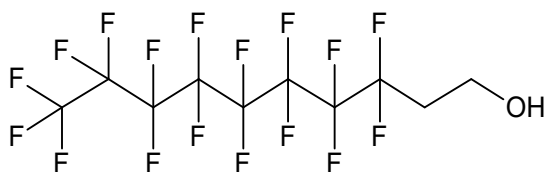
#### Paragraph 1 – included substances

Both linear and branched chained substances are included in the scope. The nomenclature has been amended to cover also branched substances which was not the case in the original proposal. Terminology is amended from perfluoroalkyl- to perfluoro- to avoid possible confusion resulting from the use of both terminologies. The term perfluoro- has been chosen for simplicity.

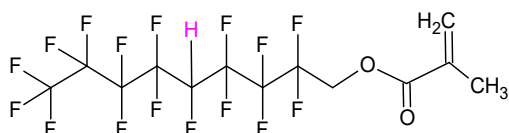
Polyfluorinated (i.e. partially fluorinated) substances containing a structural element with a sufficiently long perfluorinated moiety are included within the scope of the restriction because they degrade to perfluorinated (fully fluorinated) C9-C14 PFCAs e.g. 8:2 FTOH:

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<sup>4</sup> This text is intended to provide clarification of the text in columns 1 and 2 of the conditions proposed by RAC but is not part of the opinion itself.



Polyfluorinated substances containing other partially fluorinated structural elements such as the substance below are not included within the scope of the restriction because they do not contain a structural element with a sufficiently long perfluorinated moiety.



2,2,3,3,4,4,5,6,6,7,7,8,8,9,9-hexadecafluorononyl methacrylate

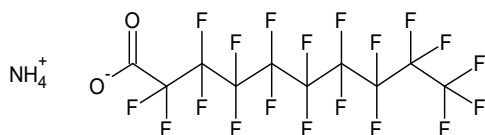
### Paragraph 1(a)

These are the six C9-C14 PFCAs and their salts.

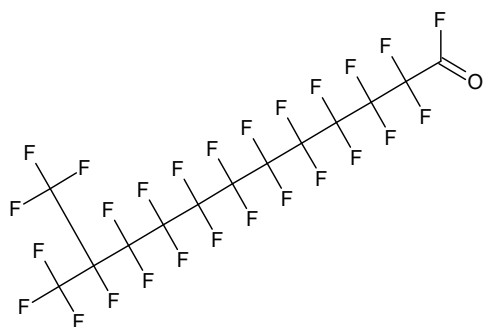
### Paragraphs 1(b) & (c)

These are the related substances which can degrade or be transformed to the C9-14 acids. A definition of 'related substances' is provided as a footnote using wording based upon the definition in entry 68 to Annex XVII.

**Examples of 1(b) substances** include the substance:



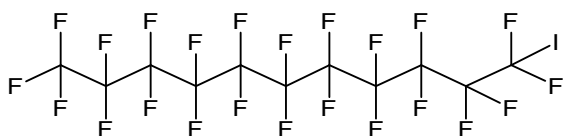
ammonium nonadecafluorodecanoate and the substance



2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,12,12,12-docosafuoro-11-(trifluoromethyl)-dodecanoyl fluoride.

To note however, the substance methyl nonacosafuoropentadecanoate has a perfluoro group  $C_nF_{2n+1}$  directly attached to another carbon atom however the perfluorinated chain ( $C_{14}F_{29}$ ) does not fall within the range  $n=8, 9, 10, 11, 12$  or  $13$  and is outside the scope of the restriction.

**Examples of 1(c) substances include the substance:**



1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11-tricosafuoro-11-iodo-undecane.

In the original entry for related substances proposed by the Dossier Submitter, a substance such as  $C_8F_{17}(CH_2)_2OH$  would not be included, however, this substance has the possibility to degrade to perfluorononanoic acid and so should be included. A clarification has been added to paragraph 1(c) that if  $C_nF_{2n+1}-$  is directly attached to another carbon atom it is out of scope. Without this clarification a substance such as  $C_{14}F_{29}COOH$  would also be included in the restriction by this formulation; it is outside of the scope of the proposed restriction (because it is C15).

The new paragraphs 1(b) & (c) are equivalent in structure to those in entry 68 of Annex XVII for PFOA.

The nomenclature  $C_nF_{2n+1}-$  means any branched or linear perfluorinated alkyl moiety containing carbon atoms on which all the H substituents have been replaced by F atoms. The '-' represents 'bonded to' and any group can be bonded to the  $C_nF_{2n+1}-$  moiety, including for example iodine.

## Paragraph 2 - excluded substances

### Paragraph 2(a)

These are perfluorinated substances with a halogen attached and as such are a different group of substances that are not degraded to PFCAs as confirmed by Nielsen 2014. The Dossier Submitter reports iodine is not excluded by paragraph 2(a) (i.e. it is covered by the restriction) because it is the starting point for the telomerisation process. Current discussions on persistent organic pollutants are considering whether it is acceptable to exclude Br.

### Paragraph 2(b)

This exclusion is for substances that contain perfluoro groups having higher carbon numbers than those mentioned under paragraph 1 and are as such not covered by the restriction because only C9-C14 PFCAs have been identified as PBT or vPvB substances.

It should be noted that if a substance contains structural elements both inside and out of scope, then the substance is still within the scope.

This paragraph is included for transparency reasons as these substances are not in fact covered by the paragraph 1.

The nomenclature X' means any possible functional group.

## Column 2

The revised entry follows the format of existing Annex XVII entries.

**Paragraph 2(a)** to note the term constituent includes impurities i.e. both unintended and intended constituents see ECHA guidance for identification and naming of substances under

REACH and CLP:

[https://echa.europa.eu/documents/10162/23036412/substance\\_id\\_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d](https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d)

#### **Paragraph 4(a)**

This derogation is intended to allow the manufacturing of the C6-based or lower chain length perfluorochemicals. According to the information provided by industry C9-C14 PFCAs and related substances are unintentionally manufactured during C6 manufacturing as a by-product. This so-called 'C8-fraction' by-product can contain up to 30% C9-C14 PFCAs and related substances. It is subsequently separated and reworked and not placed on the market as such.

This derogation applies only to the manufacture of a fluorochemical substance with a carbon chain equal to or shorter than 6 atoms where PFOA occurs as an unavoidable by-product. The derogation does not apply to the substances, mixtures or articles placed on the market.

An identical derogation is included in entry 68 to Annex XVII and hence this could be included in the proposed wording for column 2, paragraph 6 for this restriction. It is nevertheless included here for transparency and to highlight that it is not the intention of this restriction to prevent C6 PFCA manufacture.

#### **Paragraph 4(b)**

This derogation is also intended to allow manufacturing of C6-based or lower chain length perfluorochemicals. The derogation for transported isolated intermediates is needed to allow the rework and further processing of the C6 and C8 fractions off site. This processing is needed for the C6 fraction placed on the market to comply with the proposed thresholds. On-site intermediates are exempted from the restriction provisions described in Article 68(1) of REACH.

An identical derogation is included in entry 68 to Annex XVII and hence this could be included in the proposed wording for column 2, paragraph 6 for this restriction. It is nevertheless included here for transparency and to highlight that it is not the intention of this restriction to prevent C6 PFCA manufacture.

#### **Paragraph 5**

This is a standard approach to avoid retroactive application of the rules to articles already placed on the market. It covers both second-hand articles and articles in the stocks if placed on the market by the date referred to in paragraph 2.

The proposed date is 'entry into force' + transitional period. Later on in the process, these will be amended by the Commission with actual dates.

#### **Paragraph 6**

PFOA, its salts and related substances may contain impurities of C9-14 PFCAs, their salts and related substances above the thresholds in the proposed restriction.

This paragraph is intended to ensure that the derogations, which apply for PFOA, its salts and related substances in entry 68 to Annex XVII of REACH, will also apply for C9-14 PFCAs and

their related substances (with the same conditions as in the PFOA restriction). This implies that the proposed restriction will not apply to PFOA, its salts and related substances (or other fluorinated chemicals) which contain impurities (above the thresholds) of C9-14 PFCAs, their salts and related substances and where a derogation exists in the PFOA restriction.

This paragraph will also allow a manufacturer or user of PFOA or related substance to switch to using C9-C14 PFCAs for these derogated uses.

### **Paragraph 7**

This paragraph is to provide a seven year derogation for the production of the internal can coating for pressurised metered-dose inhalers (pMDIs). Fluoropolymers with levels of C9-14 PFCAs exceeding the limit value of 25 ppb are used to produce the internal coating to improve the stability and storage life of the medicines inside. After production of pMDIs levels of C9-14 PFCAs are below the limit value.

### **Paragraphs 8 & 9**

Paragraph 8 is 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. Paragraph 9 is to allow semi-finished and finished electronic equipment containing speciality semiconductors to be used as replacement parts for finished electronic equipment.

## **THE OPINION OF SEAC**

See the opinion of SEAC.

## JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

### Identified Hazard, Exposure/Emissions and risk

#### Justification for the opinion of RAC

##### **Description of and justification for targeting of the information on hazard(s) and exposure/emissions (scope)**

##### ***Summary of proposal:***

Perfluorinated carboxylic acids (PFCAs) are synthetic substances that contain a common structural feature: a perfluorinated carbon chain combined with a carboxylic group (i.e. an acid) and they differ only in the number of (CF<sub>2</sub>-) groups. Because of the highly similar chemical structure and behaviour, C9-C14 PFCAs are considered as a group for this restriction proposal.

In the EU, C9-C14 PFCAs, their salts and related substances mainly occur as unavoidable by-products during the manufacture of per- (fully) and polyfluorinated (partially fluorinated) substances containing a carbon chain of less than nine carbon atoms such as perfluorooctanoic acid (PFOA, C8-PFCA).

In the restriction proposal the longer chains (>C14) PFCAs are not included since only C9-C14 PFCAs were identified as SVHCs and included into the Candidate List. Moreover there is very limited information available for this group. According to the Dossier Submitter, for PFCAs longer than C14, insufficient information is currently available to be able to conclude if they are taken up by organisms and to conclude on their PBT/vPvB properties.

The term 'C9-C14 PFCAs' is used hereafter in this opinion as an abbreviation for: Perfluorononan-1-oic acid (PFNA), Nonadecafluorodecanoic acid (PFDA), Henicosafluoroundecanoic acid (PFUnDA), Tricosafluorododecanoic acid (PFDoDA), Pentacosafuorotridecanoic acid (PFTrDA) and Heptacosafuorotetradecanoic acid (PFTeDA). C9-14 PFCA-related substances are substances that, based upon their structural formulae, are considered to have the potential to degrade or be transformed to C9-14 perfluorocarboxylic acids (linear, branched or both).

The main objective of the proposal is to reduce or prevent exposure of consumers and the environment to C9-C14 PFCAs. No EU manufacturers or users intentionally using C9-C14 PFCAs and only one importer have been identified by the Dossier Submitter. This proposal aims to prevent C9-14 PFCAs, their salts and related substances being used as an alternative to perfluorooctanoic acid (PFOA) (regrettable substitution) after the restriction for PFOA becomes effective in 2020. C9-C14 PFCAs are PBT/vPvB substances, for which it is not possible to establish a safe level of exposure. Therefore, their emissions are to be minimised (REACH recital 70/ Annex I, para 6.5). C9 and C10 PFCAs and their ammonium and sodium salts are listed in Annex VI of the CLP Regulation as Carc. 2 and Repr. 1B. A restriction covering all emission sources of C9-C14 PFCAs, their salts and C9-C14 PFCAs-related substances, including those from imports, has been assessed and is considered the most appropriate restriction option by the Dossier Submitter.

The Dossier Submitter discussed various EU measures as possible risk management options

(RMOs). The REACH authorisation process was not considered to be appropriate by the Dossier Submitter because it would not cover C9-C14 PFCAs, their salts or C9-C14 PFCA-related substances in imported articles, which probably contribute significantly to total EU emissions.

It is also highlighted in the Annex XV dossier that C9-C14 PFCAs are ubiquitous in the environment and in humans, and that C9-C14 PFCAs have the potential for environmental long-range transport.

The Dossier Submitter has confirmed that the proposed restriction covers both linear and branched chain substances. The substances listed in the candidate list as well as the substances with a harmonised classification (see table 1-7) cover linear chain PFCAs, whereas branched PFCAs are not explicitly included. However, due to the challenges in the past of differentiating branched and linear PFCAs by analytical methods and the way analytical methods are carried out, a relevant part of the data provided in the Support Documents of the ECHA Decisions (Candidate Listing) and RAC opinions (CLH) can be assumed to have most likely contained both branched and linear isomers in the test item/analyte. In addition, for the properties of persistence and bioaccumulation the variation between linear and branched isomers can be expected to be sufficiently similar to assume same properties for the branched isomers as for their linear counterparts.

***RAC conclusions:***

The restriction on C9-C14 PFCAs, their salts and related substances will prevent switching to C9-C14 PFCAs as an alternative to PFOA and thus avoid the potential for increased emissions.

RAC agrees that the branched isomers can be expected to be sufficiently similar to their linear counterparts to be covered by the restriction for the reasons outlined in the summary section above. RAC notes the explanation of the Dossier Submitter concerning PFCAs longer than C14 and recognises that insufficient information is currently available to be able to conclude if they are taken up by organisms and conclude on their PBT/vPvB properties.

***Key elements underpinning the RAC conclusion:***

It is important to minimise the emissions of these substances. C9-C14 PFCAs are PBT/vPvB substances. Also sodium and ammonium salts of C9-C10 PFCAs are already in the candidate list as PBT substances. Salts of PFCAs will be in equilibrium with the corresponding acid in the aqueous phase. C9 and C10 PFCAs and their ammonium and sodium salts are listed in Annex VI of the CLP Regulation as Carc. 2 and Repr. 1B.

C9-C14 PFCAs belong to the group of the most persistent chemical substances known. They do not undergo any further abiotic or biotic degradation under environmentally relevant conditions. In C9-C14 PFCAs the carbon chain is perfluorinated. Any hydrogen atoms are substituted with fluorine atoms. The fluorine atoms shield the carbon backbone from any physical or chemical attack making C9-C14 PFCAs very stable organic compounds.

No intentional manufacturing or use of C9-C14 PFCAs, their salts or precursors has been identified in the EU. The Dossier Submitter has only identified one article (semiconductors) containing a C9-C14 PFCA which is imported, but more articles might be on the market, as the substances have been manufactured and used worldwide. The Dossier Submitter also refers to other findings of C9-C14 PFCAs, their salts, and related substances in many articles



as impurities.

After 2016 the global manufacturing volumes of C9-PFCA were expected to fall to zero, although there is no recent information available. C9-C14 PFCAs, their salts and related substances are mainly unavoidable by-products occurring during the manufacturing of per- and polyfluorinated substances containing a carbon chain of less than nine carbon atoms, such as PFOA- (C8-PFCA) based substances and perfluorohexanoic acid- (C6-PFCA) based substances. The C6-PFCA-based substances are alternatives of the C8-based chemistry. During the manufacturing of the C6-PFCA based substances, the fraction mainly containing long-chain PFCAs, the so called C8-fraction can contain up to 30% C9-C14 PFCAs and related substances. In Europe, this C8-fraction is separated and reworked. The remaining C6-fraction is also further processed.

RAC recognises that action is required to avoid the risks for the general public and the environment identified by the Dossier Submitter, and that there is a high potential that possible releases into the environment will result in long-term human and environmental exposure to C9-C14 PFCAs.

## **Description of the risk(s) addressed by the proposed restriction**

### ***Information on hazard(s)***

#### ***Summary of proposal:***

The hazard profile of C9-C14 PFCAs is well known (see Table 1). C9-PFCA and C10-PFCA as well as their sodium and ammonium salts are listed in Annex VI of the CLP Regulation as Carc. 2 and Repr. 1B. In addition, C9-C14 PFCAs are bioaccumulative and extremely persistent. Thus, the substances were added to the REACH Candidate List as substances of very high concern (SVHC) under REACH by unanimous agreement between EU Member States:

- C9- and C10-PFCAs as CMR and PBT (persistent, bioaccumulative and toxic) substances and
- C11-C14 PFCAs as vPvB (very persistent and very bioaccumulative) substances.

C9-C14 PFCAs belong to the most persistent chemical substances known. They do not undergo any further abiotic or biotic degradation under environmentally relevant conditions. In C9-C14 PFCAs the carbon chain is perfluorinated. All the hydrogen atoms are substituted with fluorine atoms. The fluorine atoms shield the carbon backbone from any physical or chemical attack making C9-C14 PFCAs very stable organic compounds.

Due to these properties they have a high potential to cause irreversible adverse effects on the environment and to human health if their releases are not minimised. According to REACH Annex I para 6.5 the risk to the environment cannot be adequately controlled for PBT/vPvB substances. No safe concentration, thus no threshold (PNEC), can be determined for PBT/vPvB substances.

Detailed information on the PBT/vPvB assessment are provided in chapter B.8. of the Annex to the background document.

*Table 1: C9-C14 PFCAs (and salts) were added to the Candidate List based on PBT and vPvB-properties*

| <b>Substance</b>                           | <b>CAS-No</b>                         | <b>Intrinsic properties referred to in Article 57 and date of inclusion in Candidate List</b>            | <b>Reference</b>                   |
|--|---------------------------------------|--|------------------------------------|
| C9-PFCA and its sodium and ammonium salts  | 375-95-1,<br>21049-39-8,<br>4149-60-4 | Toxic for reproduction (Article 57c)<br>PBT (Article 57d)<br>Included on Candidate List 17 December 2015 | (European Chemicals Agency, 2015b) |
| C10-PFCA and its sodium and ammonium salts | 335-76-2,<br>3830-45-3,<br>3108-42-7  | Toxic for reproduction (Article 57c)<br>PBT (Article 57d)<br>Included in Candidate List 12 January 2017  | (European Chemicals Agency, 2017b) |
| C11-PFCA                                   | 2058-94-8                             | vPvB (Article 57e)<br>Included in Candidate List 19 December 2012  | (European Chemicals Agency, 2012a) |
| C12-PFCA                                   | 307-55-1                              | vPvB (Article 57e)<br>Included in Candidate List 19 December 2012  | (European Chemicals Agency, 2012a) |
| C13-PFCA                                   | 72629-94-8                            | vPvB (Article 57e)<br>Included in Candidate List 19 December 2012  | (European Chemicals Agency, 2012a) |
| C14-PFCA                                   | 376-06-7                              | vPvB (Article 57e)<br>Included in Candidate List 19 December 2012  | (European Chemicals Agency, 2012a) |

No human absorption data are available for per- and poly fluoroalkyl substances (PFASs). With respect to animal studies, the studied C9-14 PFCAs have shown to be readily absorbed (> 90%) in rodents following oral exposure (Kudo, 2015). Quantitative studies in vivo on C9-C14 PFCAs for other exposure routes, i.e. inhalation or dermal absorption, are lacking. Nevertheless, toxicity studies on PFOA using these exposure routes demonstrate absorption based on the observed toxicity (Kennedy et al., 2004). Following absorption, PFAS including PFCA such as C9-PFCA, C10-PFCA and C12-PFCA, are distributed primarily to blood and blood rich-tissues such as the liver, kidneys and lungs (Dewitt, 2015). A large number of PFASs, including PFCAs such as PFOA and C10-PFCA have been shown to be highly bound to rat, human and bovine albumin in serum and intracellularly to liver fatty acid-binding protein in the liver and  $\alpha$ 2u-globulins in the liver and kidney (Dewitt, 2015).

In both humans and animals, PFASs are transferred to the fetus via the placenta and to the offspring via breast milk (Dewitt, 2015). Studies in humans have shown varying rates of placental and breast milk transfer between different C9-C14 PFCAs, with levels in fetal serum ranging from approximately 40 % (C10-PFCA) to 180 % (C13-PFCA) of that in maternal serum (Liu et al., 2011b). Levels of C9-C14 PFCAs in breast milk were in the range 3-4 % of that in maternal serum (Liu et al., 2011b).

PFCAs are not metabolised in animals (Kudo, 2015). Studies on PFOA as well as PFSAAs such as PFOS (C8-PFSA) and C10-PFSA in rats have shown that they are excreted untransformed, i.e., without forming any metabolites or conjugates. Thus, PFCAs are believed to represent metabolically inert and stable end-stage products. However, certain precursors have in rodents been shown to transform, to various extents, into e.g. their perfluorinated carboxylate 'backbone structures' (Henderson and Smith, 2007b).

The major route of excretion for PFCAs is renal elimination and to a smaller extent biliary and fecal excretion (Kudo, 2015). In general, the rate of elimination from serum decreases with increasing carbon chain length. The elimination speed is demonstrated to occur in the following order: rats > mice > non-human primates > humans (Borg, 2013). In general, the elimination half-lives are in the magnitude of hours and days for rodents and non-human primates and in the order of years for humans. Also, the elimination half-lives show pronounced gender differences within certain species (e.g., faster elimination in female rodents). The reason for the species and gender differences in elimination rates are believed to be due to active renal reabsorption via renal organic anion transporters.

For PFASs in general, repeated-dose toxicity studies in rodents and monkeys show that liver is the main target organ (Borg and Håkansson, 2012; ATSDR, 2015). The hepatotoxicity is manifested as hepatocellular hypertrophy, increased liver weight, hepatocellular, vacuolation, pigmentation and necrosis, with the adversity being proportional with increasing dose.

Other common toxic effects observed following repeated dosing by PFASs are:

- Decreased body weight.
- Effects on lipid metabolism: decreased serum cholesterol and serum triglycerides.
- Effects on thyroid hormone levels: decreased triiodothyronine (T3) and thyroxine (T4).
- Immunotoxicity (atrophy of thymus and spleen, suppressed antibody responses).
- Developmental toxicity.

In addition, a number of perfluoroalkyl acids (PFAAs) have shown reproductive and developmental toxic properties in laboratory animals following exposure in utero. The toxicity is manifested as reduced fetal, perinatal and/or neonatal body weight and viability as well as reduced pup body-weight gain and litter loss in the dams (Borg, 2013). The most adverse of these toxic effects is a dose-dependent marked increase in neonatal mortality that has been observed for several PFAAs.

C9-PFCA has a harmonised classification as STOT RE 1 (H372) (liver, thymus, spleen), Repr 1B (H360Df) and Lact (H362).

C10-PFCA has a harmonised classification as Repr 1B (H360Df) and Lact (H362), as well. Besides, in a study on wistar rats that were exposed to C10-PFCA via the diet at doses corresponding 0, 1.2, 2.4, 4.8, or 9.5 mg/kg/day for 7 days (Kawashima et al., 1995) increased absolute liver weight was observed at 2.4 mg/kg/day. At 9.5 mg/kg/day increased the number of lipid droplets containing amorphous material was observed, indicating marked toxicity to hepatocytes. C10-PFCA was considerably more potent than PFOA in causing increased liver weight.

A combined repeated dose and reproductive/developmental toxicity screening study (OECD

guideline 422) where male and female rats were administered C11-PFCA via gavage at 0.1, 0.3, or 1.0 mg/kg/day was performed (Takahashi et al., 2014). Liver weight was increased in males at 0.3 mg/kg/day and above and in females at 1.0 mg/kg/day, and this change was observed also after a recovery period. In both sexes, centrilobular hypertrophy of hepatocytes was observed at 0.3 mg/kg/day and above and focal necrosis was observed at 1.0 mg/kg/day. In addition, at 1.0 mg/kg/day, body weight gain was decreased in both sexes and changes in various clinical blood parameters. No direct reproductive and developmental toxicity effects were observed. The indication of decreased birth weight of the pups at 1.0 mg/kg/day as well as decreased body weight gain in 4 days after birth can be attributed to maternal toxicity.

A combined repeated dose and reproductive/developmental toxicity screening study (OECD guideline 422) where male and female rats were administered C12-PFCA by gavage at 0.1, 0.5, or 2.5 mg/kg/day was performed (Kato et al., 2015). Dosing at 0.5 and 2.5 mg/kg/day affected the liver, in which hypertrophy, necrosis, and inflammatory cholestasis were noted. Body weight gain was markedly inhibited in the 2.5 mg/kg/day group, and a decrease in hematopoiesis in the bone marrow and atrophic changes in the spleen, thymus, and adrenal gland were observed. No direct reproductive and developmental toxicity effects were observed. The indication of various histopathological changes in the male reproductive organs, including decreased spermatid and spermatozoa counts at 2.5 mg/kg/day as well as continuous diestrus in the females and the fact that 7 out of 12 females receiving 2.5 mg/kg/day died during late pregnancy while 4 other females in this group did not deliver live pups are attributed to general or maternal toxicity.

A combined repeated dose and reproductive/developmental toxicity screening study (OECD guideline 422) where male and female rats were administered C14-PFCA by gavage at 1, 3, or 10 mg/kg/day was performed (Hirata-Koizumi et al., 2015). At 3 and 10 mg/kg/day C14-PFCA caused hepatocellular hypertrophy and/or fatty changes in the liver and follicular cell hypertrophy in the thyroid. No direct reproductive and developmental toxicity effects were observed. The indication of decreased postnatal body weight gain in pups at 10 mg/kg/day can be attributed to maternal toxicity.

No information on C13-PFCA toxicity is available.

### **Degradation of C9-C14 PFCA-related substances**

C9-C14 PFCA-related substances share structural elements with C9-C14 PFCAs, specifically the perfluorinated carbon chain. C9-C14 PFCA-related substances additionally contain a non-fluorinated moiety. C9-C14 PFCA related substances degrade to C9-C14 PFCAs in the environment. Therefore, the hazard profiles of C9-C14 PFCAs apply to these substances as well. According to REACH, if transformation/degradation products with PBT/vPvB properties are being generated, the substances themselves must be regarded as PBT substances.

Only limited degradation studies of C9-C14 PFCA-related substances are available. Therefore, read-across to C8, C6 and C4 PFCA-related substances was used. In general, the polyfluorinated substances are degraded to perfluorinated acids. It can be assumed that the degradation mechanism for C9-C14 PFCA-related substances is similar to the homologues containing a carbon chain of less than nine carbon atoms. Using the weight of evidence approach the Dossier Submitter considers it very likely that similar substances also may degrade in an analogous way in the environment. At the end of a number of degradation

steps, C9-C14 PFCAs are most probably the end product.

In the following sub-chapters the degradation pathways of polyfluorinated substances (PFCA related substances) are described.

### **Fluorotelomer alcohols (FTOHs)**

#### 6:2 FTOH

The photooxidation of 6:2 FTOH was investigated at the surface of TiO<sub>2</sub>, SiO<sub>2</sub>, Fe<sub>2</sub>O<sub>3</sub>, Mauritanian sand, and Icelandic volcanic ash (Styler et al., 2013). At all surfaces the photooxidation resulted in the production of surface-sorbed PFCAs (C7-PFCA, C6-PFCA, and C5-PFCA).

The aerobic biodegradation of 6:2 FTOH was performed in a flow through soil incubation system (Liu et al., 2010a). After 1.3 days, 50% of radio-labelled 6:2 FTOH disappeared from soil, because of microbial degradation and volatilisation. In soil the following stable transformation products were detected after 84 days: 5:3 acid (12%), C6-PFCA (4.5%), C5-PFCA (4.2%), and C4-PFCA (0.8%). In a further study, the authors investigated the aerobic biodegradation of 6:2 FTOH (without <sup>14</sup>C-labelling) in soil (closed system) (Liu et al., 2010b). 6:2 FTOH primary degradation half-life was 1.6 days. After 180 days the following substances were accounted: 30% C5-PFCA, 8.1% C6-PFCA, 1.8% C4-PFCA, 15% 5:3 acid, 1% 4:3 acid, 3% 6:2 FTOH, and 7.1% 5:2 sFTOH. Liu et al. also investigated the biodegradation of 6:2 FTOH in mixed bacterial culture (Liu et al., 2010b). Activated sludge was collected from an industrial wastewater treatment plant and was mixed with a nutrient medium. The sludge was pre-exposed to fluorinated chemicals. The bacterial culture itself was not pre-exposed to fluorinated chemicals. The primary degradation of 6:2 FTOH was rapid with an estimated half-life of 1.3 days. At the end of the study (90 days) C6-PFCA (5%), 6:2 FTCA (6%), 6:2 FTUCA (23%), 5:2 sFTOH (16%) and 5-3 acid (6%) were observed.

Zhao et al. investigated the aerobic biotransformation of 6:2 FTOH in activated sludge of two domestic WWTP (Zhao et al., 2013b). Primary biotransformation was rapid. More than 97 mol% converted within 3 days to at least nine transformation products. The most abundant transformation product was the volatile 5:2 sFTOH. Further major biotransformation products were 5:3 acid (14 mol%), C6-PFCA (11 mol%), and C5-PFCA (4.4 mol%). C4-PFCA and C7-PFCA were not observed within two months.

In an aerobic river sediment system similar biotransformation products as in soil and activated sludge were detected (Zhao et al., 2013a). After 100 days 22.4 mol% 5:3 acid, 10.4 mol% C5-PFCA, 8.4 mol% C6-PFCA, and 1.5 mol% C4-PFCA were detected. C7-PFCA was not observed. Anaerobic degradation of 6:2 FTOH under methanogenic conditions has been analysed by Zhang et al., (Zhang et al., 2013b). The half-life of 6:2 FTOH (primary degradation) was about 30 days. C6-PFCA formation was much lower compared with the results of the aerobic sludge and soil studies (0.2 mol% in the 90d-study, 0.4 mol% in the 176d-study).

#### 8:2 FTOH

8:2 FTOH metabolism universally show the formation of C8-PFCA and, to a smaller fraction, C9-PFCA and lower-chain-length PFCAs (Butt et al., 2014). The degradation of 8:2 FTOH has

been extensively studied in many different matrices. Dinglasan et al. (2004) showed that at least 3% of 8:2 FTOH had been transformed into C8-PFCA in 81 days during an experiment using mixed microbial system obtained from sediment and groundwater. 8:2 FTUCA was identified as major metabolite (~50% of the total mass). Wang et al. (2009) showed that on average 25% of the radiolabelled 8:2 FTOH had been transformed into C8-PFCA (range 10-40%) in aerobic soil after 197 days. When incubating radiolabelled 8:2 FTOH in aerobic activated sewage sludge, Wang et al (2005a) recovered 2.1% as C8-PFCA after 28 days, and when using a combination of sludge and a mixed bacterial culture 6% of the radiolabel was recovered as C8-PFCA after 90 days (Wang et al, 2005b). In anaerobic sludge, less C8-PFCA is formed (0.3 mol% in 181 days) (Zhang et al, 2013). Aqueous photolysis (at 765 W/m<sup>2</sup>) has also been studied, with dependence on water chemistry indicated. Using Lake Ontario water, 18% of the 8:2 FTOH was transformed into C8-PFCA after 6 days (Gauthier et al, 2005). Atmospheric degradation of 8:2 FTOH was studied in a smog chamber (Ellis et al 2004). It was shown that 8:2 FTOH is oxidized, initiated by Cl atoms which represent OH radicals, and forms C9-PFCA (1.6% C mass balance of 8:2 FTOH), C8-PFCA (1.5% C mass balance of 8:2 FTOH) and PFCAs containing a carbon chain of less than eight carbon atoms.

#### 10:2 FTOH

Zhao and Zhu investigated the behaviour of 10:2 FTOH in the systems of soil-earthworm (*Eisenia fetida*), soil-wheat (*Triticum aestivum* L.) and soil-earthworm-wheat, including degradation in soil, uptake and metabolism in wheat and earthworms (Zhao and Zhu, 2017). 10:2 FTOH was biodegraded by microorganisms to C8-PFCA, C9-PFCA and C10-PFCA. C10-PFCA was the primary degradation product in soil and the presence of earthworms and/or wheat stimulated the microbial degradation of 10:2 FTOH in soils.

C11-PFCA was only detected in shoot but not in roots and in soil, implying foliar uptake from the air with transformation of 10:2 FTOH.

***In conclusion, based on the available data it can be expected that n:2 FTOH will be degraded and transformed into C<sub>x</sub>-PFCA (with x= n-2, n-1, n, n+1) in individual amounts greater than 0.1 %/a. It can be assumed that the degradation mechanisms are independent from the chain length.***

#### **Fluorotelomer derivatives**

##### Fluorotelomer iodide (FTI)

The atmospheric fate of 4:2 fluorotelomer iodides was investigated in a smog chamber experiment by Young et al. (Young et al., 2008; Young and Mabury, 2010). Photolysis of fluorotelomer iodides occurs via elimination of the iodine atoms leading to the formation of the fluorotelomer aldehyde, which will be further degraded (atmospheric lifetime ~4 days) to perfluoroaldehyde. The oxidation of perfluoroaldehyde leads to the formation of PFCA (e.g. for 4:2 FTI C3-C5 PFCAs). Because of their long-range potential fluorotelomer iodides contribute to the occurrence of PFCAs in remote areas.

Ruan et al. investigated the aerobic biotransformation of 6:2 FTI in soil (Ruan et al., 2013). The study showed that 6:2 FTI underwent biotransformation processes via 6:2 FTOH pathway to form C5-PFCA (20 mol%), C6-PFCA (3.8 mol%), 5:3 acid (16 mol%), and 4:3 acid (3 mol%). Furthermore, a significant level of C7-PFCA (16 mol%) was formed.



The hydrolysis of fluorotelomer iodides was modelled with HYDROWIN module of EPI Suite software program (Nielsen, 2014; Rayne and Forest, 2010). At 20 °C the hydrolytic half-life is expected to remain constant at 126 days between pH 0 and 9 and then decrease to < 7 hours at pH 14. The hydrolysis of fluorotelomer iodides may be contributing to substantial FTOH and PFCA inputs in aquatic systems.

***In conclusion, based on the available data it can be expected that n:2 FTI will be degraded and transformed into C<sub>x</sub>-PFCA (with x= n-1, n, n+1) in individual amounts greater than 0.1 %/a.***

#### Fluorotelomer stearate monoester/fluorotelomer citrate trimer

The biodegradation of 8:2 fluorotelomer stearate monoester was studied by Dasu et al., in agricultural loam soil using laboratory microcosms within 80 days (Dasu et al., 2012). At the end of the experiment 22% of the initial 8:2 fluorotelomer stearate monoester was detected. The ester bond was hydrolysed and 8:2 FTOH was rapidly formed with a half-life of 2 days. C8-PFCA, which was the major terminal product, consistently increased over time reaching 1.7 mol% by day 80. C8-PFCA concentration has not reached plateau until day 80. Furthermore, C7-PFCA (0.38 mol%) and C6-PFCA (0.16 mol%) were detected as terminal product. C9-PFCA was also observed and increased over time (0.009 mol% on day 80). C9-PFCA is suspected to be from low residuals of 10:2 FTOH in the fluorotelomer stearate monoester. Approximately 14 mol% of intermediate transformation products (sum of 8:2 FTCA, 8:2 FTUCA and 7:2s FTOH) were detected at day 80. Therefore, further increase of C8-PFCA concentration with time is possible. A similar study was performed with forest soil (Dasu et al., 2013). 8:2 fluorotelomer stearate primary degradation was slower than in the previous experiment based on agricultural soil. The major terminal metabolite was C8-PFCA (4 mol% at 94 days). Further terminal metabolites were C7-PFCA (0.9 mol%) and C6-PFCA (0.2 mol%). Dasu and co-workers also studied the biodegradation of 8:2 fluorotelomer citrate in a similar experimental setup (Dasu et al., 2013). The citrate was degraded slower. 4 mol% C8-PFCA, 0.2 mol% C6-PFCA, and 0.8 mol% C7-PFCA were detected at day 218.

***In conclusion, based on the available data it can be expected that n:2 fluorotelomer stearate monoester/fluorotelomer citrate trimer will be degraded and transformed into C<sub>x</sub>-PFCA (with x= n-2, n-1, n) in individual amounts greater than 0.1 %/a.***

#### Polyfluorinated olefins

The atmospheric lifetimes of polyfluorinated olefins are around 8 days with 90% removal via reaction with OH radicals and 10% removal via reaction with O<sub>3</sub> (smog chamber experiment) (Sulbaek Andersen et al., 2005). The major product (~ 90%) in the atmospheric photo-oxidation is the corresponding perfluoroalkyl aldehyde (PFAL). It is therefore likely that PFALs in part will partition to the atmospheric aqueous phase and undergo photo-oxidation there to form the corresponding PFCA (Nielsen, 2014).

Fluorotelomer olefins (FTO, F(CF<sub>2</sub>)<sub>n</sub>CH=CH<sub>2</sub>), a sub-class of polyfluorinated olefins, can therefore be considered as a class of substances leading to release of PFCAs.

***In conclusion, based on the available data it can be expected that polyfluorinated olefins will be abiotic degraded and transformed into corresponding PFCAs.***

### Fluorotelomer (meth)acrylates (FT(M)A)

In general, carboxylic acid esters will undergo hydrolysis resulting in the corresponding alcohols and carboxylic acids. It is reported that hydrolysis of perfluorinated telomer acrylates (and methacrylates) may be fast in landfills but that they have half-lives in the range of years in marine systems (using SPARC software program). Hydrolysis of monomeric perfluorinated telomer acrylates may be a significant source to current environmental loadings of FTOHs and the corresponding PFCA. Under some saturated landfill conditions abiotic hydrolytic degradation of fluorotelomer acrylates could occur resulting in significant fluxes of FTOHs and their degradation products into ground water and surface water (Nielsen, 2014; Rayne and Forest, 2010).

Microbial transformation (microbially mediated hydrolysis) of 8:2 fluorotelomer acrylate (8:2 FTA) and 8:2 fluorotelomer methylacrylate (8:2 FTMA) in aerobic soils was investigated by Royer et al. (Royer et al., 2015). 8:2 FTA and 8:2 FTMA were hydrolysed at the ester linkage as evidenced by the formation of 8:2 FTOH, which was further degraded via the known biotransformation pathway. 8 mol% C8-PFCA was formed in FTA-amended soil, and 10.3 mol% C8-PFCA was formed in FTMA-amended soil after 105 days, respectively. Besides the stable metabolites like C8-PFCA, C7-PFCA (1.3-3.4 mol%), C6-PFCA (< 0.4mol%), and 7:3 acid (2.3-3.4 mol%), 38-47 mol% of intermediate metabolites (8:2 FTUCA, 8:2 FTCA, 7:2 sFTOH) were observed at day 105.

***In conclusion, based on the available data it can be expected that n:2 FT(M)A will be degraded and transformed into C<sub>x</sub>-PFCA (with x= n-2, n-1, n) in individual amounts greater than 0.1 %/a.***

### Polyfluoroalkyl phosphoric acid mono-/diesters (monoPAP/diPAP)

Degradation of polyfluoroalkyl phosphates (6:2 monoPAP and diPAP) was studied by Lee and co-workers (2010) using raw wastewater and sewage sludge. It was shown that the ester bonds were cleaved (microbial hydrolysis) leading to the formation of monoPAP and thereafter 6:2 FTOH. In the end, the degradation of 6:2 monoPAP and 6:2 diPAP resulted in C7-PFCA (8.4 mol% and 7.3 mol% expressed as per cent PAP present in the aqueous phase at the start of the experiment), C6-PFCA (2.1 mol% and 6.2 mol%), C5-PFCA (0.7 mol% and 1.5 mol%), and 5:3 acid (0.12-0.38 mol% and 1.5mol%). The authors also performed a chain length study with n:2 monoPAP (n=2,4,6,8). The production of FTOHs in the headspace and the production of FTCAs, FTUCAs and PFCAs in the aqueous phase of the bottles suggest that the monoPAPs were microbially transformed. Although the monoPAP congeners were observed to produce the corresponding FTOHs in relatively similar order (1-2% after 92 days; conservative estimates), the rate of production was observed to decrease significantly as the chain length of the monoPAP increased. The short-chain monoPAPs fully degrade to the corresponding PFCAs, whereas the long-chain monoPAPs only partially degraded to the intermediates (FTCA and FTUCA). This difference may be explained by the steric constraint of the longer chain lengths to microbial attack and that the long-chain monoPAPs maybe preferentially associated with the various surfaces present in the experimental system (Lee et al., 2010).

Biodegradation pathways and plant uptake were elucidated in a greenhouse microcosm supplemented with high concentration of 6:2 diPAP (Lee et al., 2014). The dissipation of the



diPAPs in soil may occur through multiple pathways. The majority of 6:2 diPAP resided in the soil (99%), with minor uptake observed in plants (1%), leaching corresponded to < 0.1 %. The following metabolites were observed after 5.5 months in soil: C6-PFCA > 5:3 acid > C5-PFCA > 6:2 FTUCA = 6:2 FTCA > C4-PFCA > 5:3 Uacid = C7-PFCA. C4-PFCA was the PFCA with the highest concentration in the plants after 5.5 months followed by C6-PFCA, C5-PFCA and C7-PFCA.

The biotransformation of 6:2 and 8:2 diPAPs in aerobic soil was investigated in semidynamics reactors (Liu and Liu, 2016). After 112 days, 6% C6-PFCA, 6.4% C5-PFCA, 0.73% C4-PFCA and 9.3% 5:3 acid were detected as stable transformation products. The biotransformation of 8:2 diPAP in soil proceeded much slower than the biotransformation of 6:2 diPAP. After 112 days, 2.1% C8-PFCA, 0.25% C7-PFCA, 0.34% C6-PFCA and 0.29% 5:3 acid were detected as stable transformation products.

8:2 mono- and diPAPs are reported to undergo slow hydrolysis (lifetime of several years) at environmental conditions. The reaction results in 8:2 FTOH and phosphoric acid (Nielsen, 2014). Mono- and diPAPs of 8:2 FTOHs, including their polymers, can therefore be considered as a class of substances leading to release of C8-PFCA by abiotic degradation process.

***In conclusion, based on the available data it can be expected that n:2 monoPAP and n:2 diPAP will be degraded and transformed into C<sub>x</sub>-PFCA (with x= n-2, n-1, n, n+1) in individual amounts greater than 0.1 %/a.***

#### Polyfluorinated silanes

No relevant information concerning hydrolytic the lifetimes of condensed or polymerised polyfluorinated silanes was found in the open literature.

Silanes have appreciable vapour pressures and may in principle evaporate and undergo photo-oxidation in the atmosphere. It is also conceivable that small siloxanes may partition to the atmosphere and undergo photo-oxidation there. As reaction product PFCA will be formed (Nielsen, 2014).

***In conclusion, based on the available data it can be expected that polyfluorinated silanes will be abiotic degraded and transformed into corresponding PFCAs.***

#### Polyfluorinated amides

Jakson and Mabury (2013) studied the hydrolysis of polyfluorinated amides N-ethyl-N-(2-hydroxyethyl)perfluorooctanamide (NEtFOA) at different pH. Hydrolysis from NEtFOA to C8-PFCA under environmental conditions is negligible. The environmental fate of polyfluorinated amides is suggested to be volatilisation to the atmosphere followed by oxidation by hydroxyl radical with a predicted lifetime of 3 – 20 days.

Jackson et al. studied the atmospheric photo-oxidation (smog chamber experiment) of N-ethyl-perfluoro-butylamide (NEtFBA, C<sub>3</sub>F<sub>7</sub>C(O)NHCH<sub>2</sub>CH<sub>3</sub>) as a more volatile surrogate for longer chained polyfluorinated amides and identified C<sub>3</sub>F<sub>7</sub>C(O)NH<sub>2</sub> as intermediate, and PFCAs and HNCO (isocyanic acid) as products (Jackson et al., 2013). Primary oxidation products reacted further to PFCAs (16% C4-PFCA, 0.3% perfluoropropanoic acid and 0.3% trifluoroacetic acid). The authors predict similar reaction kinetic for N-ethyl-perfluorooctanamide (NEtFOA) and NEtFBA since the length of a perfluorinated chain does not

affect the reaction rate with OH. The primary oxidation products of NETFOA are expected to have much longer lifetimes and could be capable of contaminating Arctic air. The primary oxidation products are expected to react further to form C8-PFCA.

Martin et al. studied the atmospheric photo-oxidation (smog chamber experiment) of N-ethyl perfluorobutanesulfonamide (NETFBSA, C<sub>4</sub>F<sub>9</sub>S(O)<sub>2</sub>NHCH<sub>2</sub>CH<sub>3</sub>) and identified C<sub>4</sub>F<sub>9</sub>S(O)<sub>2</sub>NHC(O)CH<sub>3</sub>, C<sub>4</sub>F<sub>9</sub>S(O)<sub>2</sub>NHCH<sub>2</sub>CHO and C<sub>4</sub>F<sub>9</sub>S(O)<sub>2</sub>NHCHO as intermediates, and SO<sub>2</sub>, COF<sub>2</sub> and PFCAs as stable products (Martin et al., 2006). Three PFCAs were detected above the level of the blank: 0.33% C<sub>4</sub>-PFCA, 0.11% perfluoropropanoic acid, and 0.09 trifluoroacetic acid of the molar balance, respectively. The authors suggest that it is evident that analogous perfluorooctane sulfonamide is a potential source for C<sub>8</sub>-PFCA.

***In conclusion, based on the available data it can be expected that polyfluorinated amides will be abiotic degraded and transformed into corresponding PFCAs in individual amounts greater than 0.1 %/a.***

#### Fluorotelomer urethane (monomers)

Dasu and Lee studied the biodegradation of two 8:2 fluorotelomer urethane monomers in soil (Dasu and Lee, 2016). The biodegradation of toluene-2,4-di(8:2 fluorotelomer urethane) (FTU), containing an aromatic backbone, was investigated in a forest and an agricultural soil. While hexamethylene-1,6-di(8:2 fluorotelomer urethane) (HMU), with an aliphatic backbone, was investigated only in forest soil. In agricultural soil little to no biodegradation of FTU occurred. A production of C<sub>8</sub>-PFCA was observed. Nevertheless, the authors assume that the C<sub>8</sub>-PFCA was produced from residual 8:2 FTOH in FTU (0.56 mol%). In the experiments with forest soil biotransformation of FTU and HMU occurred. The authors mentioned that this activity may be due to fungal enzyme activity which may be more effective in urethane bond cleavage. The addition of toluene-2,4-dicarbamic acid diethyl ester (TDAEE) to the FTU microcosms at day 52, a structurally similar non-fluorinated FTU analog, enhanced the formation of terminal end products from 8:2 FTOH degradation. Based on the enhancements in the FTU microcosm 0.84 mol% C<sub>8</sub>-PFCA, 0.11 mol% C<sub>7</sub>-PFCA, 0.07 mol% C<sub>6</sub>-PFCA and 0.11 mol% 8:2 FTOH were formed after 117 days. In the study with HMU 0.94 mol% C<sub>8</sub>-PFCA, 0.14 mol% C<sub>7</sub>-PFCA, 0.06 mol% C<sub>6</sub>-PFCA, 0.88 mol% 7:2 sFTOH and 0.14 mol% 8:2 FTOH were observed at day 180. The authors estimated (KinKUII) final % C<sub>8</sub>-PFCA yields from FTU and HMU are 1.5-1.9 % and 3-5.2 %, respectively. In the experiments with forest soil C<sub>8</sub>-PFCA resulted from transformation of the 8:2 fluorotelomer urethane, since C<sub>8</sub>-PFCA concentrations were well above what could result from residual 8:2 FTOH.

***In conclusion, based on the available data it can be expected that n:2 fluorotelomer urethane (monomers) will be degraded and transformed into C<sub>x</sub>-PFCA (with x= n-2, n-1, n) in individual amounts greater than 0.1 %/a.***

#### Fluorotelomer ethoxylates (FTEO)

Biotransformation of fluorotelomer ethoxylates was reported by Frömel & Knepper (Frömel and Knepper, 2010). WWTP effluent was used under aerobic conditions. Zonyl FSH, a commercial mixture which contains fluorotelomer ethoxylates (8:2 FTOH residues = 0.29%; 6:2 FTOH residues = 0.54%) with perfluorinated chain lengths between four and 12 and a degree of ethoxylation between 0 and 18 was analysed. Fluorotelomer ethoxylates were

rapidly degraded (half-life (primary degradation) = 1d). The formation of 0.3 mol% C8-PFCA and 2.5 mol% C6-PFCA was observed, but these PFCAs could have been formed from the FTOH-residuals. It can be assumed that studies with a longer time frame will result in higher PFCA concentrations.

#### Fluorotelomer sulfonate (FTS):

The aerobic biotransformation of 6:2 Fluorotelomer sulfonate (6:2 FTS) was investigated in closed bottles in diluted activated sludge from three WWTPs (Wang et al., 2011a). At day 90, 1.5% C5-PFCA, 1.1% C6-PFCA, 0.14% C4-PFCA and 0.12% 5:3 acid were observed as stable transformation products. In addition, 2.6% 5:2s FTOH and 0.8% 5:2 ketone were detected.

Zhang et al investigated the biotransformation potential of 6:2 FTS in aerobic sediment and the biotransformation potential of 6:2 FTS and 6:2 FTOH in anaerobic sediment (Zhang et al., 2016). After 90 days 20 mol% C6-PFCA, 21 mol% C5-PFCA, 0.55 mol% C7-PFCA, and 16 mol% 5:3 acid were detected as stable transformation products.

In the test with anaerobic sediment, no biotransformation of 6:2 FTS was observed over 100 days.

***In conclusion, based on the available data it can be expected that n:2 FTS will be degraded and transformed into C<sub>x</sub>-PFCA (with x= n-2, n-1, n, n+1) in individual amounts greater than 0.1 %/a.***

#### Fluorotelomer thioether amido sulfonate (FTTAoS)

Harding-Marjanovic et al. investigated the aerobic biotransformation of Fluorotelomer thioether amido sulfonate (FTTAoS,) in soil (Harding-Marjanovic et al., 2015). FTTAoS is a PFAS present in several widely used aqueous film-forming foam (AFFF) formulations. Beside 6:2 FTTAoS, which is the most abundant FTTAoS homologue, 4:2, 8:2, 10:2, 12:2, and 14:2 FTTAoS have also been detected in some AFFFs. In this study, the aerobic biotransformation of 4:2, 6:2, and 8:2 FTTAoS was investigated in soil slurries constructed with AFFF-impacted topsoil from a U.S. military base and enriched with an FTTAoS-containing AFFF formulation. The biotransformation of FTTAoS occurred in live microcosms over approximately 60 days and produced 4:2, 6:2, and 8:2 FTS, 6:2 FTUCA, 5:3 acid, and C4 to C8 PFCAs (1.5%).

***In conclusion, based on the available data it can be expected that FTTAoS will be degraded and transformed into corresponding PFCAs.***

#### Perfluoroalkyl phosphinic acids (PFPIAs)

In a review of Wang et al. available information on degradation of perfluoroalkyl phosphinic acids (PFPIAs) were collected and evaluated (Wang et al., 2016).

PFPIAs hydrolyse to yield perfluoroalkyl phosphonic acid (PFPA) and C<sub>n</sub>F<sub>2n+1</sub>H. C<sub>n</sub>F<sub>2n+1</sub>H can be oxidized to form corresponding PFCAs (e.g. via reaction with OH radicals at high temperature or with alkaline conditions).

Formation of C6 and C8 PFPA was also observed in rainbow trout after daily dietary exposure to C6/C6, C6/C8 and C8/C8 PFPIAs. No degradation of C4/C4 PFPIA was observed in a 28-day OECD 301-F test on ready biodegradability. Thus, degradation of PFPIAs in a specific environment and biota, depends on actual conditions.

***In conclusion, based on the available data it can be expected that PFPiAs will be abiotic degraded and transformed into corresponding PFCAs.***

#### Side-chain fluorinated polymers

Side-chain fluorinated polymers are generally rather persistent, but they may over time release perfluorinated side-chains via breakage of the ester bonds.

Four studies have investigated the degradation of fluorotelomer-based acrylate polymers in soil over two years (Russell et al., 2008). It was assessed whether the FTOH side chain covalently bonded to the polymer backbone may be transformed to PFCAs. The fluoroacrylate polymers contain the polymer itself and also residual raw materials and impurities ('residuals'). Based on the rate of formation of C8-PFCA in soil estimated half-lives of the polymer ranged from 95 to >2000 years. The maximum C8-PFCA concentration ranged from 1.8 to 2.1  $\mu\text{mol}$  C8-PFCA/kg soil. The residual amount of C8-PFCA in the test substance was 0.019  $\mu\text{mol}$  C8-PFCA/kg soil. Hence, C8-PFCA is formed from degradation of residuals and possibly also from degradation of the side chains in the polymer.

Via an analogous degradation pathway to that for 8:2 FTOH, polymer side chains and residuals from FTOH with longer chains (e.g. 10:2 FTOH and 12:2 FTOH) are assumed to degrade to form PFCA with longer chains. Similar to C8-PFCA the concentrations of C9-C11-PFCAs rise with time.

In a further study Russell et al. evaluated the formation of C8-PFCA from the biodegradation of a fluorotelomer-based urethane polymer product in four aerobic soils (Russell et al., 2010). The fluorotelomer alcohol raw material in the polymer synthesis was composed of 34% 6:2 FTOH, 31% 8:2 FTOH, 18% 10:2 FTOH, 9% 12:2 FTOH and 8% 14:2 FTOH and larger. The maximum concentrations of C8-PFCA (modelled; first-order reaction) formed after two years ranged between 0.5 and 1.3  $\mu\text{mol}/\text{kg}$  soil (initial concentration of polymer = 77.6  $\mu\text{mol}/\text{kg}$  soil; initial concentration of intermediates and C8-PFCA = 0.032  $\mu\text{mol}/\text{kg}$  soil. In contrast to Russell et al. 2008 the C8-PFCA formation from residuals was negligible in this study. Hence, the C8-PFCA formation resulted from biodegradation of the fluorotelomer-based urethane polymer. C9-C11-PFCAs were also formed during the experiment, but modelling of the polymer degradation only considered C8-PFCA formation.

Washington et al. also investigated the degradability of an acrylate-linked fluorotelomer polymer in soil and calculated a half-life of 870-1400 years for a coarse-grained test polymer (Washington et al., 2009). The modelled half-life of finely grained polymers was 10-17 years. The polymer can be degraded in soil through attack on the carbon backbone and/or the ester linkage connecting the backbone to the fluoroalkyl side chains resulting in C8-PFCA via the intermediate 8:2 FTOH.

Washington et al. (2015) studied the degradation of two commercial acrylate-linked fluorotelomer-based polymers in four types of soil and found formation of many transformation products including 8:2 FTOH and C8-C14 PFCAs. The estimated half-lives ranged from 33 to 112 years for the polymer.

Washington and Jenkins (2015) also studied hydrolysis in water of a fluorotelomer-based polymer at different pH levels. Compared to day 0, up to 34-fold concentration of 8:2 FTOH

and 190-fold concentration of 10:2 FTOH were measured at day 77. Considering the large production volume of fluorotelomer-based polymers and the poor efficacy of conventional treatments for recovery PFCAs from waste streams, these results suggested that fluorotelomer-based polymers manufactured to date potentially could increase PFCAs fourfold to eightfold over current oceanic loads, largely depending on the integrity of disposal units to contain PFCAs upon hydrolytic generation from fluorotelomer-based polymers.

Rankin et al. investigated the biodegradability of a fluorotelomer-based acrylate polymer in soil-plant microcosm over 5.5 months with or without addition of wastewater treatment plant biosolids (Rankin et al., 2014). Incubation of the fluorotelomer-based acrylate polymer results in the accumulation of C6-PFCA, C7-PFCA, and C8-PFCA concurrently with the reduction of 8:2 FTCA and 8:2 FTUCA. C8-PFCA was the dominant product, constituting 57, 70, and 80% in all microcosm compartments in fluorotelomer-based acrylate polymer/soil, fluorotelomer-based acrylate polymer/plant, and fluorotelomer-based acrylate polymer/plant/biosolids, respectively.

Hydrolytic half-lives of 8:2 fluorotelomer acrylate polymer segments was estimated using SPARC software program (Rayne and Forest, 2010). Under some saturated landfill conditions abiotic hydrolytic degradation of fluorotelomer acrylates could occur resulting in significant fluxes of FTOHs and their degradation products (e.g. C8-PFCA) into ground water and surface water.

Waste incineration of fluorotelomer-based polymers as a potential source of C8-PFCA in the environment was investigated in a comprehensive laboratory-scale by Taylor et al. (Taylor et al., 2014). No detectable levels of C8-PFCA were produced from the combustion of the fluorotelomer-based polymer composites. Hence, the authors concluded that waste incineration of these polymers is not expected to be a source of C8-PFCA in the environment.

***In conclusion, based on the available data it can be expected that side-chain fluorinated polymers will be transformed via n:2 FTOH into corresponding PFCAs.***

#### Other potential C9-C14 PFCA precursors and UVCBs:

Other potential C9-C14 PFCA precursors and UVCBs cannot in general be classified as classes of substances leading to release of C9-C14 PFCAs. However, substances containing  $F(CF_2)_n(CH_2)_2$ -groups will most probably result in release of n:2 FTOHs in the environment. Thus, using the weight of evidence approach they can be considered as a class of substances leading to release of C9-C14 PFCAs.

#### ***RAC conclusion(s):***

RAC notes that the C9-C14 PFCAs are PBT or vPvB substances formally identified as SVHCs. The DNEL/PNEC derivation is therefore considered to be not relevant for these substances (REACH, Annex I para 6.5). In the light of this, risk assessment either for human health and environment can be done only qualitatively. RAC also takes note of the further human health hazard information which is presented by the Dossier Submitter as supporting evidence.

RAC agrees that all the presented C9-C14 PFCA-related substances are degraded to C9-C14 PFCAs by abiotic and/or biotic processes in the environment. For those substances where no

degradation studies are available it can be assumed that based on the chemical similarity the substances will most probably be degraded in a similar way. Thus, based on the weight of evidence approach C9-C14 PFCAs will most probably be formed in the environment from the related substances. Hence, these substances need to be considered as important sources of C9-C14 PFCA in the environment. Furthermore, they need, according to REACH, be considered as PBT-substances as well.

***Key elements underpinning the RAC conclusion(s):***

**C9-14 PFCAs and their salts**

The PBT properties of C9-C14 PFCAs are not discussed further in this opinion because C9-C14 PFCAs are included in the Candidate List on account they fulfil the PBT/vPvB criteria. There is no indication of new data challenging the 2013 opinion from ECHA's Member State Committee (MSC).

Whilst the MSC's opinion focused on C9-14 PFCAs, RAC considers that it is scientifically consistent to apply the logic underpinning the restriction entry for PFOA and PFOA-related substances to this opinion in relation to C9-C14 PFCAs -related substances. Therefore RAC is of the opinion that the above information on the degradation of C9-C14 PFCA-related substances is sufficient to cover these substances in the restriction based on a weight of evidence approach.

**Information on emissions and exposures**

***Summary of proposal:***

**Exposure assessment**

Emission sources

C9-C14 PFCAs, their salts and related substances have been used for several decades resulting in an existing stock in the techno sphere and the environment. Worldwide total manufacturing volumes of ammoniumperfluorononanoate (APFN), the ammonium salt of C9-PFCA for the years 1975 to 2004 were estimated to range between 800 – 2300 t. For a more recent period (2011 – 2015) APFN volumes have been estimated to 17- 107 t. Further manufacturing volumes are not available.

Additionally, the substances are an impurity produced during the manufacturing of PFOA (up to 0.21% C9-C14 PFCAs) and PFOA related substances (20 to 45% C9-C14 PFCA related substances) leading to releases into the environment. In Europe, the manufacturing of PFOA and PFOA-related substances ceased in 2015, thus releases of C9-C14 PFCAs and related substances from those uses are expected to decline.

According to the stakeholders consulted by the Dossier Submitter, currently C9-C14 PFCAs, their salts and related substances are mainly unavoidable by-products during the manufacturing of short-chain alternatives such as C6-based chemistries. The fraction mainly containing long-chain PFCAs, the so called C8-fraction, which can contain up to 30% C9-C14 PFCAs and related substances, is separated and reworked. The remaining C6-fraction is further processed.



Mixtures sold to industry contain C9-C14 PFCAs and related substances in trace levels up to 25 ppb and 260 ppb respectively.

The intentionally used short-chain substances provide special properties, such as high friction resistance, dielectric properties, resistance to heat and chemical agents, low surface energy, as well as water, grease, oil, and dirt repellence. These substances are therefore used for various articles, mixtures and applications such as textiles, paper, and fire-fighting foam today. The substances are released into the environment during different life cycle steps and via various exposure pathways (such as manufacturing of the substances, processing, use and at the waste stage).

Thus, releases will continue because the substances are present as impurities in short-chain alternatives (even if in low concentrations) as well as in some remaining uses of C8-based chemistries (derogated uses, such as articles and firefighting foams already placed on the market).

In the European Commission's public database on cosmetics CosIng, a number of substances containing C9-C14-PFCAs and related substances were found. Although no volumes used in cosmetics are given in the database, the number of entries seems to point to a reasonably common use of the substances in cosmetics.

From the information provided in the public consultation, C9-C14 PFCAs and some C9-14 PFCA-related substances are found in cosmetic products in Sweden and Norway. These substances do not appear to be essential for the function of cosmetic products and alternatives without PFCAs seem to be available. They are found in major international cosmetic brands and in top selling products which could make the emissions from these products environmentally relevant. Cosmetics Europe has confirmed the use of these ingredients in the cosmetics industry is minor. Since quantities of these ingredients are not available it is not possible to accurately estimate quantity.

### Release estimates

Applying the release factors presented in Table 2 approximately 12 tonnes of C9-C14 PFCA related substances are emitted per year within the EU from those uses until the PFOA restriction enters into force in 2020. After the PFOA restriction becomes binding it is estimated that the release of C9-C14-PFCA related substances from the remaining uses will be reduced to 1.4 tonnes per year in the EU. These estimations are however highly uncertain.

PFOA-alternatives, the C6-based fluorochemicals, also contain C9-C14 PFCAs as an impurity:

- C6-related substances (transported isolated intermediates): low ppm range of C9-C14 PFCA related substances.
- C6-related substances (mixtures sold to industry): up to 260 ppb C9-C14 PFCA related substances.

Releases from these uses have not been estimated by the Dossier Submitter, because the estimation of manufacturing and import volumes of C6 based fluorochemicals was not in the scope of this dossier.

Additionally, import of fluoropolymers such as PVDF, which may be manufactured by using

the ammonium salt of C9-PFOA may be a further emission source for C9-C14 PFCAs. Furthermore, it is estimated that about 116 kg of C9-C14 PFCAs are emitted in Europe into the environment by WWTPs until the year 2022, and by using (composted) sludge as fertiliser, about 35 – 70 kg of C9-C14 PFCAs could be directly applied to soil.

*Table 2: Estimated annual use volumes and releases of PFOA (red) and PFOA-related substances (blue), C9-C14-PFCAs (brown) and C9-C14 PFOA related substances (green) subject to the proposed restriction based on current use (worst case scenario) and post 2015 (more realistic scenario) based on the background document for the PFOA restriction (European Chemicals Agency, 2015a)*

| PFOA and PFOA-related substances in...  | Volume used/imported tonnes/year 'post 2015' | Release factor % | Emission estimate tonnes/year 'post 2015' | Releases of C9-C14 PFCAs and related substances 'post 2015' tonnes/year | Releases of C9-C14 PFCAs and related substances 'post 2020' tonnes/year |
|---|--|------------------|---|---|---|
| Import of PFOA  | 0  | 0.35 (70 x 0.5)  | 0   | 0   | 0   |
| in articles   | 3  | ?                | ?   | ?   | ?   |
| Fluoropolymers<br>import and use of PTFE mixtures<br>(volume used outside EU) | 15<br>(9 – 280)                              | 38<br>(80)       | 5.7<br>(7.2 – 224)                        | 0.01*<br>(0.01-0.15)*   | 0   |
| Manufacture of PFOA-related substances (central estimate)                     | 30 -300<br>(165)                             | 0.05             | 0.015 – 0.15<br>(0.083)                   | 0 <sup>§</sup>  | 0 <sup>§</sup>  |
| Textiles (uses of C8 based chemicals)   |  |                  |   |   |   |
| Use in EU   | 300  | 2*               | 6   | 1.95 <sup>§</sup>   | 0.2 <sup>§</sup>  |
| Import in articles (central estimate)   | 300 – 3 000<br>(1 500)                       | 1*               | 3 – 30<br>(15)                            | 0.98– 9.8 <sup>§</sup><br>(5,4) <sup>§</sup>                            | 0.09-0.98 <sup>§</sup><br>(0.54) <sup>§</sup>                           |
| Fire-fighting foams (central estimate)  | 15 – 30<br>(23)                              | 4.5**            | 0.7 – 1.4<br>(1)                          | 0.23 – 0.46<br>(0.69)   | 0.23 – 0.46<br>(0.69)   |
| Paper (central estimate)  | 45 – 60<br>(53)                              | 2*               | 0.9 – 1.2<br>(1.1)                        | 0.29 – 0.39<br>(0.68)   | 0   |
| Paints and inks (central estimate)  | 15 – 30<br>(23)                              | 54.5**           | 8.2 – 16.4<br>(12)                        | 2,67 – 5,33<br>(3,9)  | 0   |
| Photographic applications   | 0.001/0.1                                    | 0.02/?           | 0.0000002/?                               | 0.000000065<br>/?   | 0.000000065/<br>?   |
| Semiconductors  | 0/0.02                                       | -/3.8            | -/0.000076                                | -/0.000025  | -/0.000025  |
| <b>Total</b>  | <b>18/</b>                                   | <b>&gt; 32/</b>  | <b>&gt;5.7/</b>                           |   |   |



| PFOA and PFOA-related substances in...  | Volume used/imported tonnes/year 'post 2015' | Release factor %  | Emission estimate tonnes/year 'post 2015' | Releases of C9-C14 PFCAs and related substances 'post 2015' tonnes/year | Releases of C9-C14 PFCAs and related substances 'post 2020' tonnes/year |
|---|--|-------------------|---|---|---|
| PFOA/C9-C14 PFCAs<br>PFOA-related substances/C9-C14 PFCA related substances<br>(central estimate) | 675 – 3420***<br>(1 900)                     | 1.7 -2.8<br>(1.9) | 18.8 – 55.2***<br>(35.2)                  | 0.01/<br>6.12 – 17.9***<br>(12.62)                                      | 0/<br>0.52 – 1.64***<br>(1.43)  |

\* Assuming that 0.1% of C9-PFCA and 0.01% of C10-C14 PFCA are unintentionally present (based on van der Putte et al 2010); \$ manufacture ceased in 2015; § Estimate: 10% are still treated with C8; \*\* Fire fighting foam: Formulation only, if used, emission factor is up to 100 %; Paints and inks: includes formulation and use of paints and inks; \*\*\* Please note that total use volumes do not include manufacture of PFOA-related substances to avoid double-counting. The emissions from manufacture are included in total emissions.

The Dossier Submitter reports in the background document an indicative calculation of potential releases if 5% of PFOA use in textiles will be substituted by C9-C14 substances. A similar argument can be made for all other uses of C8.

#### Environmental exposure

C9-C14 PFCAs are ubiquitously present in the environment. Numerous direct and indirect sources of C9-C14 PFCAs, their salts and C9-C14 PFCA related substances contribute(d) to the overall environmental exposure of C9-C14 PFCAs. C9-C14 PFCAs have been detected mainly in the lower pg/L to low ng/L-range in surface waters and in ground water. This can be partly attributed to accidents, inappropriate disposal, previous use of the area (e.g. former fire-training area), or industrial point sources.

From the information provided in the public consultation, C9-C14 PFCAs were detected up to 0.1 µg/L in about 1600 samples of Dutch water bodies from 2008 to 2016. Due to the high mobility of C9-C14 PFCAs, these substances could contaminate ground water.

In sediments, C9-C14 PFCAs were measured in the pg/g (dw)-range in remote areas to and in the low ng/g range in Europe. In soil measured concentrations vary widely as well (up to 3 ng/g dw) depending among others on factors as sewage sludge application, influence by industrial plants or fire-training activities etc. Temporal trend studies show different pictures: there are some studies showing a decline of the substances in water and biota and others where a decrease of the C9-C14 PFCA levels was not found yet.

#### Human exposure

In contrast to PBT substances that have been identified based on their ecotoxicity, C9- and C10-PFCAs were identified as PBT substances because they are toxic to reproduction in humans. The toxicological properties of C9- and C10-PFCAs also include effects on other human health endpoints. These effects are of particular concern, because the general population is widely exposed to C9-C10 PFCAs via the environment with long elimination half-

lives of up to 12 years from the human serum.

Human exposure occurs via the environment, e.g. consumption of food and drinking water, and via inhalation of contaminated air or indoor dust. No human absorption data via the different media mentioned are available, but human biomonitoring data reflect the presence of general exposure.

Human biomonitoring data from Europe, including remote locations such as Greenland and Faroe Islands, show that C9-C14 PFCA are widely detected in body fluids such as serum and breast milk in human populations at pg/ml to ng/ml levels. Temporal trend studies show increasing levels from 1980s until approximately 2010 where the levels seem to level out or decrease.

The elimination half-lives of PFCAs in humans are in the magnitude of several years and even up to 12 years for males with respect to C10-PFCA and C11-PFCA (Kudo, 2015; Liu et al., 2011b). The long or presumed long half-life of C9-C14 PFCAs in humans is supported by many human biomonitoring studies (Gyllenhammar et al., 2015; Manzano-Salgado et al., 2015; Motas Guzman et al., 2016 and others). Blood/serum concentrations of C9-C14 PFCAs as indicator for exposure characterization of C9-C14 PFCAs represent an integrated measure of exposure to these substances irrespective of the source and specific precursor compound.

In addition, levels of C9-C14 PFCAs in breast milk represent an integrated measure of exposure for infants and toddlers. Human biomonitoring studies in European populations on serum and breast milk levels of C9-C14 PFCAs with samples collected between 2007 – 2017 have been used for the human exposure assessment in this dossier. Besides, the population included consists of population also in remote locations such as Greenland. Temporal trends for all single C9-C14 PFCAs substances in human serum show that the levels of them have been increasing between 1980 and 2010; the levels seem to level out or slightly decrease after that. For the breast milk similar trend is observed in Sweden from 1972 to approximately 2010 and afterwards (Nyberg et al., 2017).

Twenty nine human biomonitoring studies investigating C9-PFCA in human serum and 9 human biomonitoring studies investigating C9-PFCA in human breast milk are reported in this dossier. The serum concentrations of C9-PFCA were ranging from high pg/ml to low ng/ml (most samples). In general, the C9-PFCA has the highest concentrations in comparison to the other PFCAs substances in question. The detection frequency very often was 100 % of samples taken. The concentrations of C9-PFCA in human breast milk samples ranged from < LOD to low pg/ml breast milk. The detection frequency in the studies was low (0-10 % of samples taken).

Twenty five human biomonitoring studies investigating C10-PFCA in human serum and 9 human biomonitoring studies investigating C10-PFCA in human breast milk are reported in this dossier. The serum concentrations of C10-PFCA were ranging from high pg/ml to low ng/ml (most samples). The detection frequency was often > 90 % of samples taken. The concentrations of C10-PFCA in human breast milk samples ranged from < LOD to low pg/ml breast milk. The detection frequency in the studies was low (0-10 % of samples taken).

Nineteen human biomonitoring studies investigating C11-PFCA in human serum and 7 human biomonitoring studies investigating C11-PFCA in human breast milk are reported in this dossier. The serum concentrations of C11-PFCA were ranging from high pg/ml (most samples)

to low ng/ml. The detection frequency was moderate - often > 75 % of samples taken. The concentrations of C11-PFCA in human breast milk samples ranged from < LOD to low pg/ml breast milk. The detection frequency in the studies was low (0-10 % of samples taken).

Ten human biomonitoring studies investigating C12-PFCA in human serum and 5 human biomonitoring studies investigating C12-PFCA in human breast milk are reported in this dossier. The serum concentrations of C12-PFCA were at the level of pg/ml range. The detection frequency was rather low - often 30 - 80 % of samples taken. The concentrations of C12-PFCA in human breast milk samples ranged from < LOD to low pg/ml breast milk. The detection frequency in the studies was very low (0-3 % of samples taken).

Eight human biomonitoring studies investigating C13-PFCA in human serum and 2 human biomonitoring studies investigating C13-PFCA in human breast milk are reported in this dossier. The serum concentrations of C13-PFCA were at the level of pg/ml range. The detection frequency was rather low - often 30 - 80 % of samples taken. The concentrations of C13-PFCA in human breast milk samples ranged from < LOD to low pg/ml breast milk. The detection frequency in the studies was low (0-10 % of samples taken).

Six human biomonitoring studies investigating C14-PFCA in human serum and 1 human biomonitoring studies investigating C14-PFCA in human breast milk are reported in this dossier. The serum concentrations of C14-PFCA were at the level of pg/ml range. The detection frequency was low (0 - 36 % of samples taken). No temporal trend studies on C14-PFCA have been carried out. The concentrations of C14-PFCA in human breast milk samples ranged from < LOD to low pg/ml breast milk. The detection frequency in the studies was very low (0-3 % of samples taken).

Human biomonitoring data from other geographical regions apart from Europe (and Greenland) are not provided within this dossier.

***RAC conclusion(s):***

The properties of the PBT and vPvB substances lead to an increased uncertainty in the estimation of exposure to human health and the environment. The focus is therefore on the assessment of the releases. This approach is in line with the current RAC practice in restrictions.

RAC concludes that even if uncertain, the release estimates provide a sufficient basis to conclude that current and potential future uses of C9-C14 PFCAs and related substances lead to releases. Even if releases are expected to decrease by 2020, due to the PFOA restriction becoming applicable, releases still remain relevant due to impurities in C4 and C6 alternatives and from the manufacturing of those C8 substances that are derogated in the PFOA restriction. Although the estimate of the releases from imported goods and articles are uncertain, there are indications that C9-C14 PFCAs, their salts and their related substances could be present also in them.

RAC notes that the ongoing releases of these substances into the environment will result in long-term human and environmental exposure to C9-C14 PFCAs.

RAC agrees with the Dossier Submitter that the long or presumed long half-life of C9-C14 PFCAs in humans and blood/serum concentrations of C9-C14 PFCAs can be taken as an indicator for exposure, irrespective of the source and specific precursor compound.

***Key elements underpinning the RAC conclusion(s):***

Based on the information provided there are significant amounts of C9-C14 PFCAs and related substances released from a number of emission sources. The main release source are the PFOA and PFOA-related substances.

The annual release estimates are approximately 12 tonnes per year for C9-C14 PFCA related substances until the PFOA restriction becomes effective in 2020. After that it is estimated that releases decrease to 1.4 tonnes per year. Minor releases of C9-C14-PFCAs are from import of fluoropolymers such as PVDF. These estimations are however highly uncertain.

Other releases are from the C6-based fluorochemicals but no estimates are available and this is out of scope of this restriction. Additionally, it is estimated that about 116 kg per year of C9-C14 PFCAs will be emitted into the environment from EU waste water treatment plants until the year 2022.

Moreover, it is possible that after the application date of the PFOA restriction in 2020 and in the absence of this restriction, C9-C14 PFCAs may be used as an alternative for certain uses.

**Characterisation of risk(s)*****Summary of proposal:***

C9-C14-PFCAs were added to the REACH Candidate List as Substances of Very High Concern due to their PBT or vPvB-properties. C9- and C10-PFCA are additionally toxic to reproduction. C9-C14 PFCA-related substances can degrade to the corresponding perfluorinated acids and must therefore be considered as PBT/vPvB substances as well. This is considered by the Dossier Submitter to be in line with the restriction under REACH for PFOA and related substances and the EU Persistent Organic Pollutant (POP) Regulation of PFOS.

Derivation of PNECs is not applicable for substances with these properties (REACH recital 70/ Annex I, para 6.5). Exposure of the environment (and humans) with these substances should be reduced to the extent possible.

The Dossier Submitters conclude that the environment, including human population, is exposed to C9-C14 PFCAs, their salts and related substances via various exposure pathways. Due to the PBT/vPvB-properties environmental risks cannot be quantified.

Available emission estimates and environmental monitoring data are thus a proxy for an unacceptable risk.

***RAC conclusion(s):***

RAC agrees with Dossier Submitter that quantitative risk assessment is not needed and the aim of the assessment is therefore to demonstrate that releases have been minimised. All populations and environmental compartments are potentially at risk.

The human biomonitoring studies show that C9-C14 PFCA have been detected in various human body fluids such as serum and breast milk, however, the concentrations are rather low (no more than low ng/ml human serum and much less in breast milk) and the biological significance of those levels is unknown. Nevertheless, RAC agrees with the Dossier Submitter that the long or presumed long half-life of C9-C14 PFCAs in humans and blood/serum

concentrations of C9-C14 PFCAs can be taken as an indicator for exposure.

***Key elements underpinning the RAC conclusion(s):***

The unintentional use of C9-C14 PFCAs, their salts and related substances, their presence in imported articles and goods, and the possibility to use longer chain PFCAs instead of PFOA/PFOA related substances, result in current and future emissions and exposure to the environment and humans. For PBT and vPvB substances a 'safe' concentration in the environment cannot be established using the methods currently available, and the quantification of risks is not foreseen in REACH.

***Uncertainties in the risk characterisation***

For PBT/vPvB substances the aim is not to characterise their risk, but to evaluate releases as a proxy for risk. Uncertainties in release estimates are discussed above.

The Dossier Submitter performed a survey contacting all relevant stakeholders to receive information on uses. On the basis of the rather limited information received it is not possible to exclude that intentional uses may exist of C9-C14 PFCAs and their related substances within the EU. However, it is reasonable to assume that these uses would be rather small scale and for specific applications.

Data retrieved by the Dossier Submitter from the Swedish Product Register is in part made up from the imports of substances to Sweden. These data show a sharp downward trend and indicate a total phase out for several applications such as textile and paper treatment. Most applications for which a use was reported in 2015 also contain PFOA. It is believed that most of these uses will be affected and disappear once the PFOA restriction becomes applicable. It has not been possible to verify how well this data from the Swedish Product Register represents the trend for the rest of EU.

RAC also regards imports as a source of uncertainty, since we do not know with certainty to what degree C9-C14 PFCAs are included in imported articles.

As the biological relevance of PFCAs concentrations detected in human blood serum and breast milk is unknown, the human health risk characterisation is subject to large uncertainties, especially taking into account the pronounced gender difference of half-life for some of PFCAs substances in question.

RAC consider that the uncertainties described above have no impact on the risk characterisation of these PBT/vPvB substances.

**Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk**

***Summary of proposal:***

The background document does not report risk management measures and operational conditions implemented and recommended by the manufacturers and importers of the substances, as there are no such operators. The processes of manufacturers of C6 mixtures to reduce C9-C14 impurities are briefly discussed.

***RAC conclusion(s):***

RAC concludes that the information provided on the releases as well as the environmental monitoring data demonstrate that current risk management measures and operational conditions are not sufficient to minimise the releases of C9-C14 PFCAs and related substances.

***Key elements underpinning the RAC conclusion(s):***

The RAC conclusion is based on the information discussed under the section on exposure.

**Evidence if the existing regulatory risk management instruments are not sufficient*****Summary of proposal:***

The existing regulatory risk management instruments in place are the harmonised classification of some of these substances and the inclusion in the Candidate List. C9-C14 PFCAs are listed in the Candidate List, which means there is a duty for information flow in the supply chain for articles, which contain above 0.1% of either of these substances (Article 33). This could have an impact on use since an inclusion in the Candidate List clearly establishes that the SVHC substances should be substituted wherever possible. However, when detected in articles the concentration is often below 0.1% that means that the duty to inform in the supply chain is not applicable. In addition, C9-C14 PFCA-related substances are not listed and therefore not covered by information requirements.

Since 2002, the Dossier Submitter reports there is a trend amongst manufacturers in the USA, Canada, Europe and Japan to replace long-chain PFCAs and their potential precursors with chemicals containing shorter perfluoroalkyl chains or with non-perfluoroalkyl products. This decreasing use-trend for C9-C14 PFCAs, their salts and related substances is observed as well considering data obtained from the Swedish Products Register. Moreover, registrants have inactivated REACH registration dossiers for long-chain PFCAs, including C9-C14 PFCAs and related substances in 2017.

According to the results of the stakeholder consultation, no current intentional uses of C9-C14 PFCAs, their salts and related substances for companies located in the EU. The substances mainly arise as unavoidable by-products during the manufacture of PFCAs containing a carbon chain of less than 9 carbon atoms. C9-C14 PFCAs, their salts and related substances, thus, may occur as impurities in articles and mixtures if fluorinated substances containing a carbon chain of less than nine carbon atoms are used. The availability of fluorine-free alternatives for many sectors is growing. However one intentional user has been found for imported semiconductors. The company reported the use of C10-PFCA in a small number of semiconductors imported into the EU. An alternative is available and will be used in the near future. Additionally there are hints that C9-C14 PFCAs are intentionally used outside the EU, such as the use of C9-C14 PFCAs in semiconductors.

According to the stakeholder consultation C9-C14 PFCAs, their salts and related substances are not used in the EU for manufacturing fluoropolymers. It is possible that manufacturers outside the EU still use C9-C14 PFCAs, their salts and related substances for manufacturing fluoropolymers. Thus, imported articles may still contain these substances.



The voluntary US-EPA 2010/2015 Stewardship Program and the Canadian restriction on long-chain PFCAs are the only existing measures to reduce the releases of C9-C14 PFCAs. However, indirectly, also the Norwegian ban of PFOA in textiles and the EU-restriction on PFOA have a reducing effect on the unintentional use of C9-C14 PFCAs. However, imported articles and mixtures may still contain higher amounts of C9-C14 PFCAs and their related substances because it is possible that outside the EU, e.g. in Asia, long-chain PFCAs including C9-C14 PFCAs are still used.

***RAC conclusion(s):***

RAC conclude that the available data on releases as well as the environmental and human monitoring data demonstrate that regulatory risk management instruments already in place are not sufficient to reduce releases and exposures of C9-C14 PFCAs, their salts and related substances.

***Key elements underpinning the RAC conclusion(s):***

The background document includes only a brief description of the existing regulatory risk management instruments and their effectiveness. The main regulatory instruments seems to be the inclusion in the candidate list. However the duty to inform in the supply chain on articles does not apply when the concentration of the SVHC is below the 0.1% limit. Moreover, the related substances are not included in the Candidate List. The RAC conclusion is based on the information discussed under the section on exposure.

## **JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS**

### **Justification for the opinion of RAC**

***Summary of proposal:***

The risks associated with articles and mixtures containing intentionally and unintentionally used C9-C14 PFCAs including their salts and precursors need to be addressed on a Union-wide basis because of two main facts:

- Exposure takes place in all Member States, and
- The free movement of goods within the Union.

The Dossier Submitters therefore concludes that an EU- wide restriction is necessary to minimise the risks. It is also noted by the Dossier Submitter that an EU wide restriction would remove any potential distorting effects that national restrictions might have on the free circulation of goods.

A large variety of emission sources contribute to the exposure of humans and the environment to C9-C14 PFCAs. Human biomonitoring shows that the whole EU population is exposed to C9-C14 PFCAs and monitoring studies show the ubiquitous presence of the substances in all environmental media. Thus, exposure to humans and the environment takes place in all EU-Member States. A restriction on C9-C14 PFCAs, their salts and related substances is the most appropriate way to limit the risks (due to further releases into the environment) for human health and the environment on an EU level.

Therefore national regulatory actions will not adequately manage the risks of C9-C14 PFCAs and related substances.

The restriction on PFOA, PFOA-related substances and its salts will become binding in 2020 with certain derogations. This so called C8-chemistry represents the preferred choice of chain length for almost all fluorinated applications due to its superior properties with regard to quality and cost. A large part of the industry has already substituted C8-based chemicals towards C6-technology or fluorine free alternatives. It is believed that the vast majority of the remaining companies using C8-chemistry will substitute to C6 or fluorine-free alternatives. However, it may be possible that companies may consider the use of C9-C14 PFCAs, their salts and related substances in the future, especially after the restriction on PFOA, its salts and related substances becomes binding in 2020. Thus, an EU-wide measure is necessary to prevent possible future manufacturing and use resulting in increasing releases into the environment.

The restriction will complement the decreasing trend in the use of C9-C14 PFCAs, its salts, and related substances triggered by the US-EPA PFOA Stewardship Program (see Annex E.1.1), the Canadian restriction on long-chain PFCAs, the Norwegian ban of PFOA in consumer articles and the EU-restriction of PFOA, its salts and related substances. An EU-wide restriction will prevent and reduce the releases of C9-C14 PFCAs, their salts and related substances within the EU in a harmonised manner. Moreover, a restriction within the EU may be the first step for global action.

***RAC conclusions:***

Based on the key principles of ensuring a consistent level of protection of human health and the environment across the EU, RAC supports the view that action is required on an EU-wide basis to address risks associated with C9-C14 PFCAs including their salts and precursors.

RAC recognises that a restriction on a Union-wide basis is justified to reduce any potential release of these substances into the environment and to prevent any future manufacturing, placing on the market and use. This EU-wide measure may also be the first step for global action.

***Key elements underpinning the RAC conclusion(s):***

A large variety of emission sources contribute to the exposure of humans and the environment to C9-C14 PFCAs. Human biomonitoring shows that the whole EU population is exposed to C9-C14 PFCAs and monitoring studies show the ubiquitous presence of the substances in all environmental media. Thus, exposure to humans and the environment takes place in all EU-Member States. A restriction on C9-C14 PFCAs, their salts and related substances is the most appropriate way to limit the risks (by effectively reducing releases into the environment) for human health and the environment on an EU level.

## **Justification for the opinion of SEAC**

***Summary of proposal:***

See the opinion of SEAC.



***SEAC conclusion(s):***

See the opinion of SEAC.

***Key elements underpinning the SEAC conclusion:***

See the opinion of SEAC.

## **JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE**

### **Justification for the opinion of RAC and SEAC**

Emissions (and therefore risks) of C9-C14 PFCAs, their salts and related substances could potentially arise during all life cycle stages. C9-C14 PFCA-related substances can contribute to human and environmental exposure of C9-C14 PFCAs, since they degrade to C9-C14 PFCAs in the environment.

Imported mixtures and articles constitute relevant emission sources of C9-C14 PFCAs, their salts and related substances during use and at disposal within the EU. Also this release source can be targeted by a restriction.

A restriction covering all emission sources is considered to be the most appropriate EU-wide measure to effectively reduce emissions of C9-C14 PFCAs, their salts and related substances.

RAC cannot assess to what extent non-EU use of C9-C14 PFCAs, their salts and related substances contributes to pollution in the EU, but recognises that global efforts may be required to reduce the long-range transport of C9-C14 PFCAs to Europe.

### **Scope including derogations**

#### **Justification for the opinion of RAC**

##### ***Summary of proposal:***

##### Derogations

Short-chain fluorotelomers are available and are already being used by industry. The C6-PFCA based substances are alternatives of the C8-based chemistry. During the manufacturing of the C6-PFCA based substances, the fraction mainly containing long-chain PFCAs, the so called C8-fraction, can contain up to 30% C9-C14 PFCAs and related substances. In Europe, this C8-fraction is separated and reworked. The remaining C6-fraction is further processed. Mixtures sold to industry contain C9-C14 PFCAs and related substances in trace levels up to 25 ppb and 260 ppb, respectively. It is not the intention of this restriction to prevent the manufacturing of these so called short-chain alternatives. That is why a specific exemption for this manufacturing as well as the use of transported isolated intermediates is included.

*'Second-hand' market and articles placed on the market before the restriction*

The proposed restriction does not cover all articles placed on the market before the restriction becomes effective (e.g. textiles). One reason for this is that the second hand market is difficult to control, in most cases one consumer donates/sells single articles to another consumer (directly or via a second hand store). It would not be practical to remove single articles from the market. Also, to use e.g. a jacket as long as possible before it turns into waste is a sustainable management of resources. Therefore a derogation for the second hand market is assessed as reasonable. This is in line with the PFOA restriction.

### *Semiconductors*

One company reported the use of C9-C14 PFCAs in the low kg range (exact amounts are estimated but claimed confidential) in a small number of semiconductors which are imported into the EU. The company requested a longer transitional period until 2023. A qualitative description of releases during the life cycle of the semiconductors were provided and release levels were generally described as 'trace' or '*de minimis*' amounts'.

### *Fire fighting foams*

Comments received in the public consultation reported that aqueous film forming foams (AFFF) fire fighting foams containing C9-14 PFCAs are required in refineries and depots to ensure effective fire fighting. C9-C14 PFCAs occur as impurities in AFFF fire fighting foams and C9-14 PFCAS were evident from analyses of different fire fighting foams provided.

The current restriction should not undermine derogations that are included in Annex XVII, entry 68 of the REACH Regulation. Information received in the public consultation confirms if the derogations for fire fighting foams in Annex XVII of entry 68 are included in the current restriction, they are sufficient to allow the use of fire fighting foams that were placed on the market before 4 July 2020 (column 2, paragraphs 4(e) and 5). The derogation for fire fighting foams in Annex XVII of entry 68 are included in the current restriction.

The following analysis of fire fighting foam is based upon information provided in the public consultation and the Background document.

PFAS-containing firefighting foams are usually used to extinguish liquid fires (class B), such as large storage tank fires and aircraft crashes.

According to the Nordon report (2013) mixtures of C8-C20  $\gamma$ - $\omega$ -perfluorotelomer thiols with acrylamide (CAS number 70969-47-0) were used in the most common fluorosurfactants in use in firefighting foams since the discontinuation of the PFOS based surfactants. According to the industry most of the manufacturers committed to continuing use of this chemistry until 2016 (Posner et al., 2013).

Recently, Dauchy and co-workers analysed nine different firefighting foam concentrates manufactured after 2002 by four different manufacturers (Dauchy et al., 2017). A number of PFAS were analysed, among them also C9-C13-PFCAs. The substances actually used in firefighting foams are unknown. Many related substances are difficult to analyse. Therefore, to mirror the presence of precursor-substances in firefighting foams, the authors oxidised the samples to transform the related substances into the end-stage products. Main degradation products were found to be short-chain PFAS, but C9-PFCA was found as well. The data indicate that C9-PFCA related substances are present in firefighting foam concentrates, however the

concentrations were lower compared with other substances. Similar results were reported in an earlier study by Houtz et al. (Houtz et al., 2013). Thus, C9-PFCA related substances may not be used as active ingredients, but rather occur as impurities. Most probably, these substances are unintended by-products generated during the manufacture of polyfluorinated substances containing a carbon chain of less than nine carbon atoms as reported during the stakeholder consultation.

In a chemical analysis of PFASs in selected fire-fighting foams on the Swedish market 2014, C9-C14 PFCA were detected in some of the sampled fire-fighting foams (Swedish Chemicals Agency, 2015a). However, the levels were significantly lower than e.g. C6-PFCA (C6-PFCA precursors are intentionally used) and likely represent impurities.

The information provided by the industry during the public consultation indicates that the C9-C14 PFCAs are present in fire fighting foams as unintended impurities and the concentrations in many cases are above the threshold limit set for the restriction.

The release estimates by the Dossier Submitter indicates a range 0.23-0.46 tonnes per year. However, the information provided in the PC, indicates higher concentration than that provided by Dossier Submitter. Therefore releases provided by Dossier Submitter could be underestimated.

#### *Recycling*

The restriction proposal also includes recycled material and articles made from recycled materials. The Dossier Submitter has demonstrated that humans and the environment are exposed to C9-C14 PFCAs, their salts and related substances. Because of the extreme persistence of these substances, each release increases the environmental stock of C9-C14 PFCAs. When recycled materials contain these substances, releases are ongoing in the future.

This is in line with the Commission's regulation (EU) 2017/1000 on PFOA. As the Commission states in its detailed explanation for PFOA, an exemption for recycled materials would potentially lead to higher releases to the environment in comparison with an appropriate waste management. Recycling of contaminated wastes contributes to environmental releases and the contaminants may again circulate through use, disposal and recycling phase of articles. This would also be the case for articles and mixtures containing C9-C14 PFCAs, its salts and related substances. In addition (as the Commission also states for PFOA), substances with POP properties, in line with the objectives of Regulation (EC) No 850/2004, should not be recycled. C9-C14 PFCAs, their salts and related substances have not yet been identified as POPs under the Stockholm Convention, however, their properties are similar to PFOA which is being discussed.

#### *Fluoropolymers*

Fluoropolymers can be manufactured either in the emulsified or in the dry form. For the emulsified form an emulsifier is needed. Based on information from the literature one of the most important polymers manufactured with salts of C9-C14 PFCAs is polyvinylidene fluoride (PVDF). APFN, the ammonium salt of C9-PFCA has been used as an emulsifier for manufacturing PVDF.

During the Dossier Submitter's stakeholder consultation industry stated it does not use C9-C14 PFCAs for fluoropolymer manufacturing within the EU. During the public consultation on

the restriction report one company stated that 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. The company expressed concerns regarding the proposed 25 ppb limit for the sum of C9-C14 PFCAs and their salts and indicated three groups of their products would not current comply with this limit value. The company proposed that the limit be set to a more realistic 400 ppb total, for the sum of the six C9-14 PFCAs and their salts. Additionally, an implementation period of 36 months was proposed to allow technical changes to the three product groups so that they could comply with the higher limit value of 400 ppb and to allow their customers to re-qualify the products.

***RAC conclusions:***

*'Second-hand' market:* RAC agrees with the derogation for articles and mixtures placed on the market before the proposed restriction becomes effective (including second hand articles) due to the difficulty to enforce the restriction.

*Semiconductors:* taking into account the very limited quantities made available in the EU market, RAC agrees to grant a time limited exemption for semiconductors that contain low levels of C9-14 PFCAs and for semi-finished and finished electronic equipment containing speciality semiconductors to be used as replacement parts for finished electronic equipment. However, it should be understood that all other electric or electronic articles are covered by this restriction, unless exempted by paragraph 6 (exemptions in the PFOA restriction) from 18 months after the entry into force of this restriction.

*Fire fighting foams:* RAC is not able to fully evaluate the releases from fire fighting foams containing C9-C14 PFCAs, and notes that the releases are not insignificant and probably higher than estimated by the Dossier Submitter. However, because the current restriction should not undermine derogations provided for fire fighting foams that are included in Annex XVII, entry 68 of the REACH Regulation, RAC agrees to include the same derogations in this restriction.

*Recycling:* RAC agrees that recycling should be covered in the restriction from the evidence presented by the Dossier Submitter, particularly the extreme persistence of the substances and their likelihood of continuing to be present in articles over successive life cycles.

*Fluoropolymers:* RAC considers that a generic broad derogation should be avoided. Thus, RAC does not support the requested higher thresholds and longer transitional period based on the data provided.

*Pressurised metered-dose inhaler (pMDIs):* In the public consultation a company stated that the proposed restriction has the potential to affect the manufacture and supply of pMDI medicines that are critical for the management of lung diseases such as obstructive pulmonary disease and asthma.

RAC agrees to accept the proposed derogation because of the low volumes in the order of few grams (exact estimate is claimed confidential by the company) 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.

***Key elements underpinning the RAC conclusion(s):***

Unless detailed below, RAC supports the analysis and proposals of the Dossier Submitter as described above.

*Fluoropolymers*

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 currently unclear 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 were 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 a derogation, better information would be needed on the emissions of C9-C14 PFCAS throughout the manufacturing process including data on volumes of emitted C9-C14 PFCAs into air and water.

*Pressurised metered-dose inhaler (pMDIs)*

The medicine in pressurised metered-dose inhaler (pMDI) treatments is typically contained in a polymer coated aerosol can to improve the stability and storage life of the medicine inside. The can coating process typically involves applying an aqueous dispersion of polymer and emulsifier, which can contain low levels of PFCAs but above the proposed limits.

The company requested a 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).

**Justification for the opinion of SEAC**

***Summary of proposal:***

See the opinion of SEAC.

***SEAC conclusion(s):***

See the opinion of SEAC.

***Key elements underpinning the SEAC conclusion(s):***

See the opinion of SEAC.

## Effectiveness in reducing the identified risks

### Justification for the opinion of RAC

#### *Summary of proposal:*

The proposed restriction is defined as a ban on the use of C9-C14 PFCAs, their salts and related substances. This includes a restriction on the manufacturing, placing on the market and use of C9-C14 PFCAs, their salts and their related substances in the EU and the import of C9-C14 PFCAs, their salts and their related substances including in articles to the EU.

#### *Suitability of C6-based alternatives*

It can be assumed that short-chain PFCAs are similarly persistent to the long-chain PFCAs and cannot be degraded under biotic or abiotic conditions.

It is expected that the bioaccumulation potential of PFCAs with a perfluoro carbon chain equal to or shorter than 6 atoms is lower compared to the long-chain PFCAs. Nevertheless, there is evidence that short-chain PFCAs are very mobile and have the potential to reach water bodies, which are of special concern regarding human exposure (e.g. groundwater and raw water for drinking water treatment) (Eschauzier et al., 2013; Gellrich et al., 2012). Due to the low adsorption potential short-chain PFCAs can scarcely be removed from the environment (Zhang et al., 2013a).

Short-chain PFCAs are known to accumulate in plants due to their high water solubility and low adsorption potential, especially in the edible part of the plants (Felizeter et al., 2014; Wen et al., 2014).

#### *Risk reduction capacity*

The risk reduction capacity of a restriction for vPvB and PBT substances is in the standard case measured by the volume (tonnes per year) of the substance which is reduced by the restriction. In this case only one intentionally user (imported semiconductors) was reported by consulted stakeholders and they have indicated that only kilograms are used per year.

This restriction aims to remove the uncertainty related to possible substitution to C9-C14 substances which might occur once the PFOA restriction becomes binding. The Dossier Submitter calculated possible releases with an illustrative example. Assuming 5 % of the users of C8-chemistry substituted to C9-C14 substances instead of C6 or fluorine-free alternatives, this restriction results in a risk reduction of 95 tonnes per year in quantities used.

The disregarded restriction option is defined as a ban on the use of C9-C14 PFCAs, their salts and their related substances without any derogations. The difference with respect to the proposed restriction option is that the discarded restriction option lacks a time derogation for articles placed on the market before the restriction becomes effective.

There is a potential need for managing the stock of C9-C14 PFCAs in for example landfills and other parts of the techno sphere. This is however outside the scope of this restriction but if such EU-wide regulatory measures were considered, it would be a complement to this restriction and not dual control.



***RAC conclusion(s):***

RAC agrees with the proposed restriction. RAC notes that the risk reduction capacity of the proposed restriction cannot be accurately estimated, as it is heavily based on the potential substitution from C8 chemistry to C9-C14 and possible unknown current uses in imported articles. RAC agrees with the Dossier Submitter that preventing this possibility is justified based on information on releases and environmental and human exposure discussed above. In addition to this, the restriction has a limited risk reduction capacity related to the imported semiconductors.

RAC notes also the concerns reported by the Dossier Submitter related to the properties of C6 substances. There is evidence of some concern for the short chain PFCAs, but further investigation is needed. The current knowledge gives an indication for possible identification as substances of equivalent level of concern (Art.57(f)), however, a full risk characterisation has not been carried out.

The only other restriction option (i.e. without exemptions) seems not practicable. RAC is aware that there is a potential need for managing the stock of C9-C14 PFCAs substances in, for example, landfills and other parts of the techno sphere, outside the scope of this restriction. But, any such EU-wide regulatory measure should be considered as complementary to this restriction.

***Key elements underpinning the RAC conclusion(s):***

RAC notes that the calculation of the potential risk reduction capacity due to substituting C8 substances with C9-C14 substances is based on the tonnages used. Applying the release factors presented by the Dossier Submitter, these could be converted into releases which would be a more accurate proxy for the risk. However, this is not considered necessary.

**Socio-economic impact****Justification for the opinion of SEAC****Costs*****Summary of proposal:***

See the opinion of SEAC.

***SEAC conclusion(s):***

See the opinion of SEAC.

***Key elements underpinning the SEAC conclusion(s):***

See the opinion of SEAC.

### **Benefits**

#### ***Summary of proposal:***

See the opinion of SEAC.

#### ***SEAC conclusion(s):***

See the opinion of SEAC.

#### ***Key elements underpinning the SEAC conclusion(s):***

See the opinion of SEAC.

### **Other impacts**

#### ***Summary of proposal:***

See the opinion of SEAC.

#### ***SEAC conclusion(s):***

See the opinion of SEAC.

#### ***Key elements underpinning the SEAC conclusion(s):***

See the opinion of SEAC.

### **Overall proportionality**

#### ***Summary of proposal:***

See the opinion of SEAC.

#### ***SEAC conclusion(s):***

See the opinion of SEAC.

#### ***Key elements underpinning the SEAC conclusion(s):***

See the opinion of SEAC.

### **Uncertainties in the proportionality section**

See the opinion of SEAC.

## Practicality, incl. enforceability

### Justification for the opinion of RAC

#### *Summary of proposal:*

##### Practicality

The proposed restriction is considered to represent an implementable option for the actors involved within the timeframe of 18 months. It appears that the necessary technology, techniques and alternatives are available. The RMO is in line with the US-EPA Stewardship Program. Thus, many industry actors already started preparations for using different substances and technologies starting from 2015 onwards.

##### Concentration limits

Based on the information provided by industry, C9-C14 PFCAs, their salts and related substances occur as unavoidable by-products during manufacturing of PFCAS containing a carbon chain of less than nine carbon atoms. With the shift from C8 to short-chain alternatives, such as C6 and C4-based substances the amount of unavoidable manufactured C9-C14 PFCAs is reduced. Industry stated it is able to comply with similar thresholds as set for the PFOA restriction, i.e. 25 ppb for the sum of C9-C14 PFCAs and the salts and 1000 ppb for the related substances.

- The Fluorocouncil suggested a threshold of 25 ppb for any of the acids or 1000 ppb for the sum of all substances related to any one of the individual acids covered by the restriction;
- However, further information was provided that a threshold for 260 ppb (for the sum of C9-C14 PFCA related substance is feasible for mixtures and articles placed on the EU market.

In transported isolated intermediates C9-C14 PFCAs, their salts and related substances are present when using C6-based chemistry. One fraction, the C8 fraction, contains up to 30% C9-14 PFCAs and related substances. This fraction is re-worked. The other fraction, the C6 fraction has a reduced concentration of C9-14 PFCAs, in the low ppm range. To allow the manufacturing and processing of C6-based chemistries, stakeholders asked either for a derogation for transported isolated intermediates or to set a higher threshold. A derogation is included in the entry agreed by RAC for transported isolated intermediates. Thus, based on the information provided, it is concluded that the following thresholds are feasible for mixtures and articles placed on the market:

- 25 ppb for the sum of C9-C14 PFCAs and their salts
- 260 ppb for the sum of C9-C14 PFCA related substances

Articles and mixtures tested for C9-C14 PFCAs, their salts and related substances in the past (see Annex B.2. of the Background Document for details) seem to mainly contain lower concentrations, thus the data presented suggest that the proposed threshold of 25/260 ppb is reasonable.

##### Enforceability

Enforcement authorities can set up efficient supervision mechanisms to monitor industry`s

compliance with the proposed restriction based on standard analytical methods. Although there are no standard analytical methods yet available to measure the content of C9-C14 PFCAs, their salts and related substances in articles and mixtures, methods are being developed to check compliance with the restriction of PFOA and related substances. It is assumed that the same methods can be applied for testing C9-C14 PFCAs and related substances.

***RAC conclusions:***

Standard analytical methods to measure the content of C9-C14 PFCAs, their salts, and the related substances, in articles and mixtures are not yet available. It is necessary to develop a standardised method to allow for a uniform and consistent enforcement of the restriction. The dossier submitter states that the methods developed for the restriction of PFOA can be applied for testing C9-C14 PFCAs and for related substances. Nevertheless, the establishment of an EU standard method for the PFCAs could make the enforcement easier. Until standard analytical methods are developed, RAC recognises that the restriction will be challenging to enforce, particularly for articles for which there are no methods available.

The proposed thresholds generally do not appear to present any problems for the industry to comply with restriction, although one company in the PC has raised this as an issue.

***Key elements underpinning the RAC conclusions:***

A standard method for the preparation, sampling and analysis of the relevant substances is not mentioned in the BD. The Forum points out that it is important that analytical methods are developed that can clearly distinguish between substances that are covered by the restriction and those that are exempted. In addition, the Forum recommends that if possible, the Dossier Submitter assesses whether sampling can influence the results of analysis. A further issue noted by the Forum is, depending upon the standard method that is developed, it may be preferable to remove the limit value for the PFCA-related substances, and retain only the 25 ppb limit value for C9-C14 PFCAs and their salts, expressed as 'free acid' (i.e. after the related substances have been converted to PFCAs in the analytical method). This approach would facilitate enforcement of the restriction.

RAC agrees with the importance of developing standard preparation, sampling and analytical methods that can distinguish substances within the scope of this restriction. Standard methods are usually handled by CEN.

Concerning the single limit value, RAC considers that such an approach would not be preferable because it is important to ensure the PFCA-related substances are measured, as well as the PFCAs themselves. RAC also notes there are analytical methods in development that convert all the PFCA-related substances to PFCAs, but these have not yet been standardised. In addition, a single limit value of 25 ppb for 'free acids' would prohibit the placing on the market of C6 substances.

According to information provided during the Dossier Submitter's stakeholder consultation, C9-C14 PFCA-related substances can occur as impurities up to a concentration of 260 ppb in mixtures sold to industry. In final articles and mixtures used by consumers the concentrations of these impurities should be lower, although some exceptions were identified in the public consultation such as specific cosmetics or fluoropolymers. Therefore the proposed thresholds

generally do not appear to present any problems for the industry to comply with restriction.

### **Justification for the opinion of SEAC**

#### ***Summary of proposal:***

See the opinion of SEAC.

#### ***SEAC conclusion(s):***

See the opinion of SEAC.

#### ***Key elements underpinning the SEAC conclusion:***

See the opinion of SEAC.

## **Monitorability**

### **Justification for the opinion of RAC**

#### ***Summary of proposal:***

There are numerous analytical methods reported in the scientific literature to measure C9-C14 PFCAs and some related substances in almost all environmental media, e.g. water, air, biota, and in humans.

There is a standard in Germany (DIN 38407-42) for analysing C9-C14 PFCAs (and other PFCAs and PFSAs) in water, sewage and sludge (Deutsches Institut für Normung e.V. (DIN), 2011). The method is applicable to concentrations higher than 0.01 µg L<sup>-1</sup> in water (0.025 µg L<sup>-1</sup> in treated sewage). Within that method unfiltered water samples are spiked with mass-labelled internal standards and extracted with solid phase extraction. The instrumental analysis should be performed with liquid-chromatography coupled to a mass-spectrometer.

A possible method to measure C9-C14 PFCA-related substances without knowing every single substance present is to convert these substances by oxidation to their corresponding acids (free acids) and subsequently carry out an analysis of C9-C14 PFCAs, for example in water samples. Oxidation can be performed with hydroxyl radicals (Houtz and Sedlak, 2012). These can be produced in a water sample by thermolysis of persulphate under basic pH conditions.

Besides the availability of analytical methods a sampling strategy is needed to monitor the restriction. There are different possibilities:

- time trend monitoring,
- monitoring of emissions.

For both strategies it has to be kept in mind that C9-C14 PFCAs are persistent substances, which will remain in the environment for long periods even if releases to the environment are stopped immediately. In addition there will be continuing releases from articles in use and from long-range transport from non-EU-countries.

A time trend monitoring can be performed with samples from the environment, from animals

or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring. Reductions of releases of C9-C14 PFCAs and related substances in the environment should result in decreasing C9-C14 PFCAs concentrations in such a trend monitoring. It might be sufficient to measure C9-C14 PFCAs in such a trend monitoring, because C9-C14 PFCAs related substance will be degraded to C9-C14 PFCAs in the environment. Decreasing trends in releases will then not be directly measurable in environmental samples, because time is needed for degradation. Furthermore, it has to be kept in mind that the release of C9-C14 PFCAs from environmental sinks, like sediment, might bias time trend in some cases.

***RAC conclusions:***

RAC notes that methods are available to monitor environmental and human health concentrations and agrees with the Dossier Submitter that the proposed restriction is monitorable.

**Justification for the opinion of SEAC**

***Summary of proposal:***

See the opinion of SEAC.

***SEAC conclusion(s):***

See the opinion of SEAC.

***Key elements underpinning the SEAC conclusion:***

See the opinion of SEAC.

## **UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC**

### **RAC**

***Summary of proposal:***

The data collection process is an area of potential concern.

Only one intentional use (imported semiconductors) was reported by consulted stakeholders and they indicate that only low kilogrammes are imported per year (the actual figures have been claimed as confidential). Cosmetics have however been confirmed as a potential source of C9-C14 PFCAs and their related substances in the public consultation process. Cosmetics Europe in turn has confirmed the use of these ingredients in the cosmetics industry is minor, but actual volumes of C9-14 PFCAs in cosmetics is however not been provided and substitutes with similar technical and economic properties seem to be available. It is therefore not possible to make a complete quantitative assessment of the risk reduction capacity of the restriction. Based on a qualitative assessment we do however argue that this restriction has an important risk reducing capacity in reducing the uncertain volumes which could be

contained in imported goods. It is also considered important to reduce the uncertainty connected to the possible substitution of PFOA with C9-C14 PFCAs.

The restriction on PFOA, PFOA-related substances and its salts will become binding in 2020 with the exception of certain derogations. It is at the moment not possible to assess to what extent the substitution from C8 to C9-C14 might occur once the PFOA restriction becomes binding. Imported articles are also regarded as a potential area of concern and uncertainty.

***RAC conclusions:***

RAC agrees with the Dossier Submitter that main uncertainties of the proposed restriction relates to the possible substitution from C8 to C9-14 substances and the possible unknown uses in the EU and in imported articles. Furthermore, there are some uncertainties in degradation rates and release factors.

RAC considers that these uncertainties affect the magnitude of risk and risk reduction capacity, but do not as such question the conclusion that there is a risk that is not adequately controlled.

**SEAC**

***Summary of proposal:***

See the opinion of SEAC.

***SEAC conclusion(s):***

See the opinion of SEAC.

***Key elements underpinning the SEAC conclusion(s):***

See the opinion of SEAC.