# 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/RES-O-0000001412-86-236/F**

**Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 14 September 2018) and SEAC's opinion (adopted 29 November 2018)**

**14 September 2018**

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

**29 November 2018**

**ECHA/SEAC/RES-O-0000001412-86-236/F**

# 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

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

This document presents the opinions adopted by RAC and SEAC and the Committees' 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 **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 **29 November 2018.**

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

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

# Contents

# OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter:

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| Perfluoroalkyl carboxylic acids (branched and/or linear) with the formula:<br>$CF3-(CF2)_n-C$, n=7 or 8 or 9 or 10 or 11 or 12 as structural elements including their salts and including all combinations thereof<br>Perfluoroalkyl carboxylic acids (branched and/or linear) with the formula:<br>$CF_3-(CF_2)_n-$, n=8-13 as a structural element, including their salts<br>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<br>The following substances are excluded from this designation:<br>• $CF_3-(CF_2)_n-X$, n > 7, where X= F, Cl, Br including any substance with linear and/or branched perfluoroalkyl elements and all mixtures thereof<br>• $CF_3-(CF_2)_n-SO2X'$, n > 7 where X'=any group, including salts<br>• $CF_3-(CF_2)_n-C(=O)OH$, n > 12 including salts | 1. Shall not be<br>(a) manufactured, or placed on the market as substances on their own;<br>(b) used in the production of, or placed on the market in:<br>(i) another substances, as a constituent,<br>(ii) a mixture,<br>(iii) an article or any parts thereof,<br>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<br>2. Paragraph 1 shall apply 18 month from entry into force of the restriction<br>3. Paragraph 1 shall not apply to<br>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;<br>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;<br>4. Paragraph 1(b-iii) shall not apply to<br>a) Articles placed on the market before the restriction becomes effective. |

## 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; PFTrDA; 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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| 1. Perfluorocarboxylic acids (linear and/or branched), their salts and PFCA-related substances[1]:<br>(a) Perfluorocarboxylic acids with the formula: $C_nF_{2n+1}$-C(=O)OH n= 8, 9, 10, 11, 12 or 13 including their salts and any combinations thereof;<br>(b) Any PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}$- directly attached to another carbon atom, where n=8, 9, 10, 11, 12 or 13, including any combinations thereof;<br>(c) Any PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}$- that is not directly attached to another carbon atom, where n= 9, 10, 11, 12, 13 or 14 as one of the structural elements, including any combinations thereof.<br>2. The following substances are excluded from this designation:<br>(a) $C_nF_{2n+1}$-X, where X= F, Cl or Br where n= 9, 10, 11, 12, 13 or 14, including any combinations thereof; | 1. Shall not be manufactured, or placed on the market as substances on their own;<br>2. Shall not be used in the production of, or placed on the market in:<br>(a) Another substance, as a constituent[2],<br>(b) A mixture,<br>(c) An article or any parts thereof,<br>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.<br>3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction<br>4. Paragraphs 1 and 2 shall not apply to:<br>(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;<br>(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 |

[1] 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).
[2] Constituent includes impurities i.e. both unintended and intended constituents.

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| (b) $C_nF_{2n+1}$-C(=O)OX', where n>13 and X' = any group, including salts. | Article 18(4) of this Regulation are met;<br>5. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.<br>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.<br>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.<br>8. Paragraph 2(c) shall apply from 31 December 2023 to:<br>(a) Semiconductors; and<br>(b) Semi-finished and finished electronic equipment for use in semiconductors.<br>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. |

## THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on **perfluorocarboxylic acids (linear and/or branched), their salts and PFCA-related substances** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope or conditions are modified as stated in the RAC opinion as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

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| 1. Perfluorocarboxylic acids (linear and/or branched), their salts and PFCA-related substances[3]:<br>(a) Perfluorocarboxylic acids with the formula: $C_nF_{2n+1}$-C(=O)OH n= 8, 9, 10, 11, 12 or 13 including their salts and any combinations thereof;<br>(b) Any PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}$- directly attached to another carbon atom, where n=8, 9, 10, 11, 12 or 13, including any combinations thereof;<br>(c) Any PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}$- that is not directly attached to another carbon atom, where n= 9, 10, 11, 12, 13 or 14 as one of the structural elements, including any combinations thereof.<br>2. The following substances are excluded from this designation:<br>(a) $C_nF_{2n+1}$-X, where X= F, Cl or Br where n= 9, 10, 11, 12, 13 or 14, including any combinations thereof;<br>(b) $C_nF_{2n+1}$-C(=O)OX', where n>13 and X' = any group, including salts. | 1. Shall not be manufactured, or placed on the market as substances on their own;<br>2. Shall not be used in the production of, or placed on the market in:<br>(a) Another substance, as a constituent[4],<br>(b) A mixture,<br>(c) An article<br>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.<br>3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction<br>4. Paragraphs 1 and 2 shall not apply to:<br>(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;<br>(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;<br>5. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.<br>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 |

[3] 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).

[4] In this entry, constituent includes impurities i.e. both unintended and intended constituents.

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| | referred to in column 1, paragraph 1 of this restriction.<br>7. Paragraph 2 shall not apply to materials used for the can coating for pressurised metered-dose inhalers until seven years after the entry into force of the restriction.<br>8. Paragraph 2(c) shall apply from 31 December 2023 to semiconductors either on their own, or in semi-finished and finished equipment.<br>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.<br>10. The concentration limit referred to in paragraph 2 shall be 2000 ppb for the sum of C9-14 PFCAs in fluoropolymers that contain perfluoropropoxy-groups or perfluoromethoxy-groups and are used in the following product groups: PTFE fine powders, fluoroelastomers and aqueous dispersions until 36 months after the entry into force of the restriction. From 36 months after the entry into force of the restriction, the concentration limit shall be 400 ppb for the sum of C9-14 PFCAs. This derogation shall not apply to articles referred to in paragraph 2(c). |

## Explanatory text[5]

**Column 1**

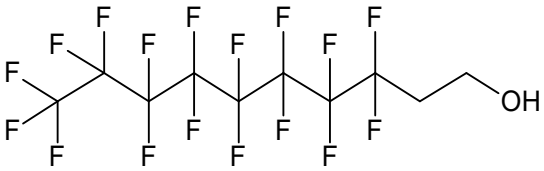
***Paragraph 1 – included substances***

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

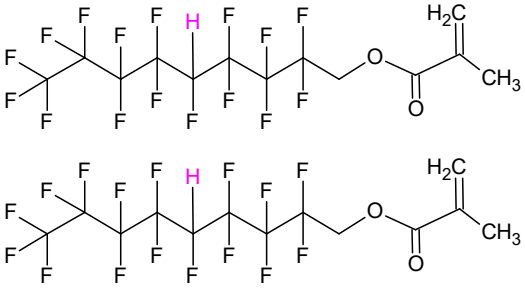
[5] This text is intended to provide clarification of the text in columns 1 and 2 but is not part of the opinion itself.

proposal. Terminology is amended from perfluoalkyl- 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:




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.




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

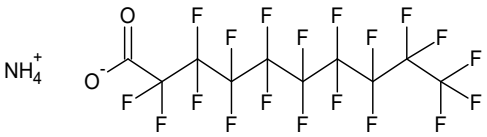
**Paragraph 1(a)** (original proposal: column 1, paragraph 1)

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

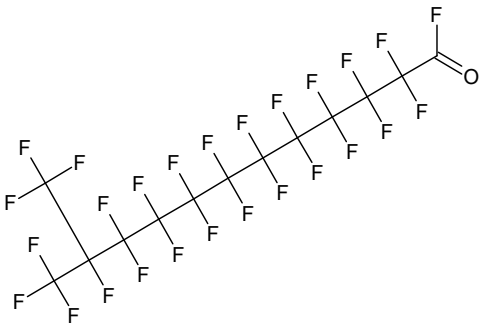
**Paragraphs 1(b) & (c)** (original proposal: column 1, paragraphs 2 & 3)

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:



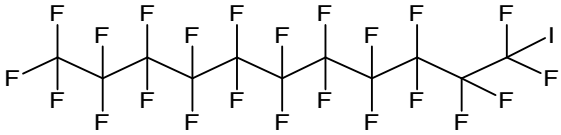

Ammonium nonadecafluorodecanoate and the substance



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

To note however, the substance methyl nonacosafluoropentadecanoate 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-tricosafluoro-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)** (original proposal: column 1, paragraph 4, first bullet)

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)** (original proposal: column 1, paragraph 4, third bullet)

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 (polymer) 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

**Paragraph 4(a)** (original proposal: column 2, paragraph 3(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 for transparency and to highlight that it is not the intention of this restriction to prevent C6 PFCA manufacture.

**Paragraph 4(b)** (original proposal: column 2, paragraph 3(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 for transparency and to highlight that it is not the intention of this restriction to prevent C6 PFCA manufacture.

**Paragraph 5** (original proposal: column 2, paragraph 4(a))

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 of pressurised metered-dose inhalers (pMDIs). Fluorinated polymers 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 and 10**

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.

Paragraph 10 is to allow higher limit values for fluoropolymers that contain perfluoropropoxy-groups or perfluoromethoxy-groups and are used in the specific product groups.

# 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 ($CF_2$-) 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), Pentacosafluorotridecanoic acid (PFTrDA) and Heptacosafluorotetradecanoic 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 conclusions:**

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 hazards

**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*

| **Substance** | **CAS-No** | **Intrinsic properties referred to in Article 57 and date of inclusion in Candidate List** | **Reference** |
|---|---|---|---|
| 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<br>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 α2u-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 PFSAs 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 diestrous 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 TiO2, SiO2, Fe2O3, 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 14C-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/m2) 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 $C_x$-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 derivates**

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 atome leading to the formation of the fluorotelomer aldehyde, which will be further degraded (atmospheric lifetime ~4 days) to perfluoroaldehyde. The oxidation of perfluoroaldehyde lead 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 Cx-PFCA (with x= n-1, n, n+1) in individual amounts greater than 0.1 %/a.***

Fluorotelomer stearate monoester/fluorotelomer citrate trimester

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 trimester will be degraded and transformed into Cx-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 $O_3$ (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(CF2)nCH=CH2), 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 be 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 Cx-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 Cx-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)perfluorooctaneamide (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-butyramide (NEtFBA, C3F7C(O)NHCH2CH3) as a more volatile surrogate for

longer chained polyfluorinated amides and identified C3F7C(O)NH2 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, C4F9S(O)2NHCH2CH3) and identified C4F9S(O)2NHC(O)CH3, C4F9S(O)2NHCH2CHOand C4F9S(O)2NHCHO as intermediates, and SO2, COF2 and PFCAs as stable products (Martin et al., 2006). Three PFCAs were detected above the level of the blank: 0.33% C4-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 C8-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 C8-PFCA was observed. Nevertheless, the authors assume that the C8-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 bon 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% C8-PFCA, 0.11 mol% C7-PFCA, 0.07 mol% C6-PFCA and 0.11 mol% 8:2 FTOH were formed after 117 days. In the study with HMU 0.94 mol% C8-PFCA, 0.14 mol% C7-PFCA, 0.06 mol% C6-PFCA, 0.88 mol% 7:2 sFTOH and 0.14 mol% 8:2 FTOH were observed at day 180. The authors estimated (KinKUii) final % C8-PFCA yields from FTU and HMU are 1.5-1.9 % and 3-5.2 %, respectively. In the experiments with forest soil C8-PFCA resulted from transformation of the 8:2 fluorotelomer urethane, since C8-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 Cx-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 Cx-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 perfluoralkyl phosphonic acid (PFPAs) and CnF2n+1H. CnF2n+1H 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 PFPAs 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 µmol C8-PFCA/kg soil. The residual amount of C8-PFCA in the test substance was 0.019 µmol 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 µmol/kg soil (initial concentration of polymer = 77.6 µmol/kg soil; initial concentration of intermediates and C8-PFCA = 0.032 µmol/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 be 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(CF2)n(CH2)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 conclusions:**

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 conclusions:**

**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-PFCA 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 PFCA 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 | | | | | |
| import and use of PTFE mixtures | 15 | 38 | 5.7 | 0.01* | 0 |
| *(volume used outside EU)* | *(9 – 280)* | *(80)* | *(7.2 – 224)* | *(0.01-0.15)** | |
| Manufacture of PFOA-related substances (central estimate) | 30 -300 (165) | 0.05 | 0.015 – 0.15 (0.083) | 0[$] | 0[$] |
| Textiles (uses of C8 based chemicals | | | | | |
| Use in EU | 300 | 2* | 6 | 1.95[§] | 0.2[§] |
| Import in articles (central estimate) | 300 – 3 000 (1 500) | 1* | 3 – 30 (15) | 0.98– 9.8[§] (5,4) [§] | 0.09-0.98[§] (0.54) [§] |
| Fire-fighting foams (central estimate) | 15 – 30 (23) | 4.5** | 0.7 – 1.4 (1) | 0.23 – 0.46 (0.69) | 0.23 – 0.46 (0.69) |
| Paper (central estimate) | 45 – 60 (53) | 2* | 0.9 – 1.2 (1.1) | 0.29 – 0.39 (0.68) | 0 |
| Paints and inks (central estimate) | 15 – 30 (23) | 54.5** | 8.2 – 16.4 (12) | 2,67 – 5,33 (3,9) | 0 |
| Photographic applications | 0.001/0.1 | 0.02/? | 0.0000002/? | 0.000000065 /? | 0.000000065/ ? |

| 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 |
|---|---|---|---|---|---|
| Semiconductors | 0/0.02 | -/3.8 | -/0.000076 | -/0.000025 | -/0.000025 |
| **Total**<br>PFOA/C9-C14 PFCAs<br>PFOA-related substances/C9-C14 PFCA related substances<br>(central estimate) | 18/<br>675 – 3 420***<br>(1 900) | > 32/<br>1.7 -2.8<br>(1.9) | >5.7/<br>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 conclusions:***

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 conclusions:***

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 relapses 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 conclusions:***

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 conclusions:***

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 conclusions:***

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 conclusions:***

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 conclusions:***

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 conclusions:***

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 conclusions:***

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:***

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). A restriction option (RO) covering all emission sources of C9-C14 PFCAs and substances that degrade to C9-C14 PFCAs (C9-C14 PFCAs related substances), including those from imports, is therefore considered an appropriate starting point. 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), Pentacosafluorotridecanoic acid (PFTrDA) and Heptacosafluorotetradecanoic acid (PFTeDA).

The main objective of the proposal is to reduce or prevent future releases of C9-C14 PFCAs and related substances. C9-C14 PFCAs are ubiquitous in the environment and in humans, and they have the potential for environmental long-range transport.

The risks associated with articles and mixtures containing C9-C14 PFCAs including their salts and related substances need to be addressed on a Union-wide basis since releases and exposure takes place in all Member States and the substances have a potential for long range transport.

It is also noted by the Dossier Submitter that an EU-wide restriction would remove any potential distorting effect that national restrictions might have on the free circulation of goods within the Union.

The Dossier Submitter therefore concludes that an EU-wide restriction is necessary to minimise the risks.

**SEAC conclusions:**

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

**Key elements underpinning the SEAC conclusions:**

ECHA's Member State Committee has concluded that C9-C14 PFCAs are PBT/vPvB substances.

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

SEAC agrees with the Dossier Submitter that C9-C14 PFCAs, their salts and related substances may be present as impurities in all articles where other PFCAs containing a carbon chain of less than nine atoms have been used. Examples are provided in A.2.4 in the Background Document.

No manufacturers or intentional users of C9-C14 PFCAs their salts or related substances have been identified in the EEA. The Dossier Submitter has only identified one group of imported articles (semiconductors) containing a C9-C14 PFCA. However, some cosmetics were identified during the Public Consultation as containing C9-C14 PCFAs and more articles containing them might be on the market, as the substances are used worldwide. The Dossier Submitter also reports findings of C9-C14 PFCAs, their salts, and related substances in many products and articles as impurities, and this was confirmed in the public consultation (see discussion on possible derogations below).

Even if current use of the substances is most likely limited, SEAC agrees with the Dossier Submitter that a restriction is justified to avoid potential future substitution of PFOA with the substances covered in this proposal.

# 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 –γ-ω-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 conclusions:**

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:**

The Dossier Submitter discusses various EU measures as possible RMOs. The REACH authorisation process was not considered appropriate because it would not cover C9-C14 PFCAs and related substances in imported articles, which probably contribute to the total EU emissions. Furthermore, it is noted that there are no active registrations under REACH.

A restriction covering all emission sources is considered by the Dossier Submitter to be the most appropriate EU-wide measure to effectively avoid or to reduce possible widespread C9-C14 PFCAs uses and associated emissions.

The Dossier Submitter assesses two different restriction options (ROs) which differ only in terms of derogations (discussed separately below).

RO1 (proposed restriction).

The proposed restriction (RO1) covers the manufacture, placing on the market and use of the substances in all applications. This includes also substances, mixtures and articles where C9-C14 PFCAs are present as impurities.

Restriction option 1 exempts from the restriction C9-C14 PFCAs, their salts and related substances when they occur as unavoidable by-products in the manufacturing of fluorochemicals with a carbon chain equal to or less than 6 atoms and when they are transported isolated intermediates. However, the derogation does not allow the placing on the market of such substances (as such, in mixtures or in articles) because the derogation specifically refers to manufacturing.

The only use identified by the Dossier Submitter during the dossier preparation to be affected by the restriction is imported semiconductors. However, during the opinion development and

Public Consultation on the restriction proposal, additional affected uses were identified. They are discussed below.

Articles placed on the market before the proposed restriction applies[6] (e.g. second-hand articles such as textiles) are excluded from the scope.

Based on the information provided by industry, the following thresholds are proposed for mixtures and articles placed on the market:

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

According to the restriction dossier, industry stated it could comply with similar thresholds as those set for the PFOA restriction, i.e. 25 ppb for the sum of C9-C14 PFCAs and their salts and 1000 ppb for the related substances. The Dossier Submitter, however, received further information suggesting that a threshold for 260 ppb for the sum of C9-C14 PFCA related substance would be feasible for mixtures and articles placed on the EEA market.

Since the restriction of PFOA will apply from 2020 and taking into account that the Dossier Submitter had not identified intentional uses of C9-C14 PFCAs, their salts and related substances exist (other than in semiconductors), the Dossier Submitter proposes a transitional period of 18 months after entry into force. This would mean that the two restrictions (PFOA restriction and this restriction of C9-C14 if approved) would apply at approximately the same time.

RO2

The second restriction option (RO2) is similar to RO1 but without a derogation for second-hand articles. This restriction option was discarded by the Dossier Submitter because enforcement would be very difficult for articles already placed on the market and because the restriction would not be proportionate.

Requests for derogation raised in the public consultation on the restriction proposal

The following requests for derogation have been raised:

- Ensure derogations in the PFOA restriction are not undermined
- Exemptions for fire-fighting foams
- Exemption for semiconductors
- Pressurised metered-dose inhalers (pMDIs)

In addition, a request for higher concentration limit and a longer transition period for some fluoropolymers was submitted.

**SEAC conclusions:**

SEAC agrees with the Dossier Submitter that a restriction is the most appropriate EU-wide measure to address the concern caused by releases of C9-C14 PFCAs, their salts and related

[6] The date when the restriction becomes effective is the date when restriction enters into force + transitional period (in this case it is proposed to be 18 months).

substances in the environment and that the choice of the proposed restriction option is justified provided that the scope and the conditions of the restriction are amended as proposed by RAC and SEAC.

SEAC also agrees to the proposed derogations for:

- Articles placed on the market before the end of the transition period
- Manufacture of alternatives with a perfluoro carbon chain length equal to or shorter than 6 perfluoro atoms, including use as a transported isolated intermediate.

In addition, SEAC agrees to the following derogations proposed by the Dossier Submitter during the evaluation of the restriction report:

- Derogations in the PFOA restriction
- Fire-fighting foams
- Semiconductors on their own and for semiconductors incorporated into finished and semi-finished electronic equipment
- Pressurised metered-dose inhalers (pMDI)
- Fluoropolymers

SEAC also agrees with the Dossier Submitter on the proposed concentration limits and transitional period. However, SEAC notes the issue raised by one company on the possibility to produce fluoropolymers with C9-C14 PFCAs in concentrations below 400 ppb, and the corresponding request for a longer transition period. Derogations, the proposed concentration limits and the transitional period are further discussed below.

**Key elements underpinning the SEAC conclusions:**

According to the stakeholder consultation, only one minor use is known for companies located in the EEA. In the Public Consultation on the restriction proposal findings of C9-14 PFCAs in some cosmetics were reported. However, Cosmetics Europe indicated that the use of these ingredients in their industry is minor.

Nevertheless C9-14 PFCAs occur as unavoidable impurities in articles and mixtures as a result of the manufacture of per- (fully) and polyfluorinated (partially fluorinated) substances containing a carbon chain of less than 9 atoms.

During manufacturing of C6 PFCA-based substances in the EEA, the fraction containing longer chain PFCA-based substances (including C9-C14 PFCAs) is separated and reworked, resulting in lower concentrations of C9-C14 PFCAs and related substances in the final products. It is not known if this technology is applied outside the EEA as well. Thus, SEAC considers it likely that imported articles and mixtures may contain impurities of C9-C14 PFCAs, their salts and PFCA-related substances in C6-based products.

The Dossier Submitter underlines that for tested samples, the concentrations that are higher than the proposed thresholds come from articles which are not placed on the market anymore. The information received by the Dossier Submitter from companies is that, for new articles placed on the market today, the proposed thresholds will not be exceeded.

According to the information gathered from the companies contacted by the Dossier Submitter

using questionnaires and interviews, none of these companies have raised any concern with regard to C9-C14 PFCAs as unavoidable impurities. In the Public Consultation on the restriction proposal one large producer of fluoropolymers submitted information that 3 of its product groups currently contained impurities up to approximately 2000 ppb of C9-C14 PFCAs. There is no indication that such substances are intentionally produced or used (other than in semiconductors and possibly in cosmetics). However, SEAC agrees with the Dossier Submitter that missed users are a potential source of uncertainty.

Possible derogations:

**Manufacture of C6 and C4 fluorochemicals**

In the C6-technology impurities of C9-C14 PFCAs are produced during the process of manufacturing of C6. Manufacturers of C6 fluorochemicals requested a derogation for manufacturing short-chain per- and polyfluorinated substances and for transported isolated intermediates.

The Dossier Submitter has informed SEAC that although no information is available it seems possible that also during the manufacturing of C4-chemistries C9-C14 PFCAs their salts and related substances may occur as unavoidable by-products.

SEAC finds the proposed derogation for C6 and lower chain substances appropriate as the intention of this restriction is not to affect the manufacturing of C6 or lower length substances and emissions of C9-C14 PFCAs are not expected from this manufacturing process because this longer chain fraction (C9-C14 PFCAs) is separated and reworked.

**Exempted uses of PFOA**

The PFOA restriction contains a number of derogations for manufacturing, placing on the market or the use of PFOA. In addition to similar derogations which the Dossier Submitter has proposed also for the C9-14 PFCAs, the PFOA restriction includes longer deferrals of the restriction for latex printing inks (2022), textiles for the protection of workers (2023), membranes intended for medical textiles (2023), filtration in water treatment (2023), production processes, and effluent treatment, certain plasma nano-coatings (2023) and non-implantable medical devices (2032), a permanent derogation for fire-fighting foams already placed on the market before the date of application of the restriction, and semiconductor manufacturing equipment.

According to the Dossier Submitter the proposed restriction on C9-C14 PFCAs is not intended to affect the derogations for PFOA in the PFOA restriction. This is reflected in the new entry agreed with the Dossier Submitter. SEAC agrees to include these derogations as the Commission already concluded that the derogations under the PFOA restriction are justified and there is no information available on possibilities for purifying C9-C14 impurities from PFOA. Furthermore, it would make no sense to purify PFOA for C9-C14 impurities as PFOA itself is not less problematic for the environment. The Dossier Submitter proposed to exempt all the uses already exempted under the PFOA restriction, regardless of whether the PFOA or related substances are present or not.

To avoid that the proposed C9-C14 PFCA restriction undermines the uses exempted under the PFOA restriction, SEAC agrees that the proposed restriction would include for these uses the same exemptions already agreed by the PFOA restriction. According to Dossier Submitter

and supported by RAC there is no indication that the negative environmental impact of using C9-C14 PFCA should be considered larger than the negative impact of using PFOA.

**Pressurised metered-dose inhalers (pMDI)**

In the Public Consultation on the restriction proposal, one company producing linings for pressurised metered-dose inhalers requested a time limited derogation of seven years (Public Consultation comments #1908, #1920 and #1932). In the comments the company states that there is no detectable C9-C14 substances in the final product. No detailed analysis of alternatives has been carried out. However, the company states that currently there is no alternative grade of material that meets the limits of the proposed restriction and if an alternative material becomes available, it will take several years to carry out performance/safety testing, validation and registration in all the present markets due to the requirement for long-term drug product stability studies and subsequent regulatory approvals.

The company has provided a socio-economic analysis showing that the annual estimated mass to be managed is in the order of few grams, while the number of patients with respiratory problems who would be affected by the restriction would be around two million in case the time limited derogation would not be granted.

SEAC notes the small quantity involved and RAC's support for the derogation, and agrees that, taking into consideration the high benefits in terms of human health, the time limited derogation of seven years is justified.

SEAC notes that a request for an exemption for the same type of products (pMDIs) is currently under discussion under the PFOA restriction (entry 68 to Annex XVII of REACH). However, the request under the PFOA restriction concerns the use of PFOB containing impurities of PFOI, which are present as impurities in the medicinal product, while this this request is related to the production of the inhalators.

**Semiconductors**

One company (#1895 and #387), already identified by the Dossier Submitter in the restriction dossier, imports C9-C14 PFCAs in a small number of imported semiconductors and semi-finished electronic equipment containing semiconductors. This company requested a longer transitional period until end of 2023 for semiconductors on their own and for semiconductors incorporated into finished and semi-finished electronic equipment. Furthermore, the company requested an exemption for semiconductors used in spare parts or replacement parts until 2030 for finished electronic equipment placed on the market before 31 December 2023. SEAC notes that the total C9-C14 PFCA content in the articles is below 100. The request is justified by the need of longer time to phase out the use of PFDAs based on substantial substitution activities since 2005. Furthermore, the importer indicates that from 31.12.2019 new semiconductors will comply with the restriction, and therefore, in practice, only the content in already produced articles (i.e. semiconductors) will be covered by the derogation. Therefore, the requested time limited exemption for semiconductors and electronic equipment containing semiconductors seems justified and consistent with the PFOA restriction, which also exempts semiconductors for photo-lithography processes and compound semiconductors for etching processes.

On this basis, SEAC supports these time limited derogations.

**Fluoropolymers**

A fluoropolymers producing company (comments #1914 and #390 of the PC) requested a broad derogation covering all the life stages of fluoropolymers including final articles. The company indicated that the C9-C14 PFCAs are developed during the polymerisation and not a result of intended use of C9-C14 PFCAs. The company requested a threshold of 400 ppb for C9-C14 PFCAs and a transitional period of 36 months, as in the PFOA restriction.

On SEAC's request, the company submitted further information in the public consultation on the SEAC draft opinion regarding application of and emissions from each of their three product groups containing C9-C14 PFCAs as impurities; PTFE fine powder, fluoroelastomer and aqueous dispersion. According to the company the three product groups are used at an early stage in the production chain in order to produce a wide range of products. The total volumes of the C9-C14 PFCAs as impurities in fluoropolymers are in the order of kg/year.

The company states that the requested limit value of 400 ppb to be achievable only after implementing technology changes. Through an heat treatment and curing the fluoropolymer mixtures are processed into articles and all impurities, traces and related releases of perfluorocarboxylic acids are minimised and reduced below the limit of detection (almost to 0 grams).

Several companies (Public Consultation on draft opinion, comment #391, #393, #395, #397, #398), #401, #402) producing PTFE flexible hoses used in pharmaceutical, food and beverage and automotive industries, supported in the public consultation on the SEAC draft opinion the request for a higher limit values and a 3 years transitional period in order to be able to produce specific products with high technical properties produced from "modified" PTFE fine powder grades. PTFE modification is essential to provide the necessary flexibility to hoses without introducing the chance of mechanical stresses and cracks. None of those companies declared the concentrations of C9-C14 PFCAs or related substances in their articles.

Based on the above considerations, SEAC considers that a derogation for a higher limit value is justified. However, according to the evidence provided by the company, SEAC finds justified only a derogation limited to relevant product groups (sub-segments of PTFE fine powder, fluoroelastomer and aqueous dispersion) containing perfluoropropoxy-groups or perfluoromethoxy-groups. Therefore, SEAC recommends a threshold of 400 ppb after a period of 36 months as this level can be achieved by the industry. During the 36 months period, SEAC recommends a threshold of 2000 ppb.

SEAC considers that the generic threshold of 25 ppb should be applied to articles manufactured from these materials, as according to the provided information, the final articles already comply with that threshold.

It is not known whether similar fluoropolymers produced by other companies contain C9-C14 PFCAs above the proposed threshold are produced or imported by other companies.

**Fire-fighting foams**

During the Public Consultation on the restriction proposal, the mineral oil industry (Public Consultation comment #1885) stated that, due to legal requirements, aqueous film-forming foams (AFFF) that may contain C9-C14 PFCAs as impurities are required to ensure effective fire-fighting in mineral oil refineries. The information submitted by industry shows that all fire-fighting foams containing impurities of C9-C14 PFCAs also contained PFOA.

SEAC notes that the PFOA restriction derogates fire-fighting foam mixtures placed on the market before 4 July 2020. The mineral oil industry has confirmed that derogation as included in the restriction of PFOA will suffice also for C9-C14 PFCAs.

In order to be consistent with PFOA restriction and noting that C9-C14 PFCAs and PFOA have quite similar properties, SEAC finds that the derogation concerning fire-fighting foams in the PFOA restriction is justified in a restriction on C9-C14 PFCAs. SEAC notes that the Dossier Submitter has not estimated the costs of replacing existing fire-fighting foams neither in the PFOA restriction, nor in this proposal.

SEAC notes that during the last POP Review Committee meeting held in Rome in September 2018 no derogation for training and testing was recommended for fire-fighting foams containing PFOA due to the existence of fire-fighting foams containing alternative substances. SEAC also notes the additional information gathered on quantities of PFOA, its salts and related substances in fire-fighting foams and fluorine-free fire-fighting foams supporting their technical feasibility. However, uncertainties seem to remain on the costs and impacts of substituting foams that have been already placed on the market.

**Articles already placed on the market**

The restriction report prepared by the Dossier Submitter proposes to exempt second-hand and other articles already placed on the market from this restriction.

Justifications for this derogation relate to practicalities and enforcement. Firstly, it would be extremely difficult for the seller to know whether or not a used article contains C9-C14 PFCAs. If second-hand articles were included in the scope of the restriction, a second-hand store may choose not to sell some textile articles in order not to violate the restriction. Secondly, enforcement would only have very limited effect as only the controlled article containing C9-C14 PFCAs would be removed from the market and it is almost impossible to control second-hand articles that are sold or donated between individuals.

For new articles placed on the market before the entry into force of the restriction, but still in the supply chain, enforcement and compliance control would be easier. However, if such articles would not be covered by a derogation, the proposed 18 months transition period would result in further costs. Furthermore, a ban would only result in an earlier treatment in the waste system and hence no added benefit for the environment can be envisaged. However, some relevant releases from washing textiles can be expected also before the waste

stage (although the lower amount for textiles which have already been washed a number of times). Lastly, a longer use of a second-hand article represents a sustainable management of resources.

SEAC agrees with the argument of the Dossier Submitter for including in the proposed restriction the same derogation than as in the PFOA restriction covering also other than second-hand articles.

During the Public Consultation on the SEAC draft opinion, a global industry association serving the manufacturing supply chain for the electronics industry (comment #393), stressed how industrial equipment, and many other products may contain articles made from fluoromaterials such as PTFE and PVDF, which could contain C9-C14 PFCAs and related substances. The association stresses that this equipment might have a long lifetime and they might be sold as used equipment. The association states that to ensure compliance with the proposed restriction used equipment that might contain solid matrix fluoromaterial would have to be disassembled in order to identify all the components, track down all the information and then they would need to be reassembled to be exported to the EU market. SEAC notes that articles already placed in the market including used industrial machinery are already covered by the generic derogation of second hand market, but note that import of used equipment would be restricted.

**Recycled materials**

The Dossier Submitter proposes to include in the scope of the C9-C14 PFCA restriction recycled material and articles made from recycled materials, due to the fact that risks exist also for such products. This is in line with the PFOA restriction.

During the stakeholder consultation carried out by the Dossier Submitter, no indications were received that C9-C14 PFCAs are found in recycled materials. The Dossier Submitter believes that if at all there would be a problem with recycled materials, the main potential sectors where C9-C14 PFCAs could be present, would be paper, food package and textiles. It has, however, not been indicated if C9-C14 PFCAs are present in these applications, neither for recycled materials, nor for new materials, placed on the market today. As the timeframe for recycling paper and food packages is quite fast, the Dossier Submitter suggests that, due to economic and technical reasons, any stock would only last for a short period of time and in practice, it would not be a problem after 18 months transition period when the restriction would apply.

Recycling of textiles might have a longer timeframe, but the market for recycling of textiles in Europe is still immature. Only recycling of treated work clothes might be a problem, but the Dossier Submitter is of the opinion that such articles should not be recycled but they should be incinerated since they can be dangerous due to the potential presence of other dangerous substances as well. Therefore, no derogation is needed for recycling of textiles.

SEAC concludes that an exemption is not needed as most probably the proposed restriction

will not affect recycled materials at all. SEAC notes that no comments from the recycling sector during the two following Public Consultations were received.

Thresholds

The Dossier Submitter proposes thresholds based on information from industry related to the content of the substances covered in this proposal as impurities in alternative substances, mixtures and articles placed on the market.

In the Public Consultation on the restriction proposal, the question if the substances, mixtures and articles currently placed on the market comply with these thresholds was specifically raised. One company (3M) (comment #1914) replied requesting a threshold for PFCAs of 400 ppb for C9-C14 PFCAs for fluoropolymers. This limit value was stated to be achievable only after implementation of new technology and 3M requested an implementation period of 36 months, similar to the PFOA restriction. The company submitted information on quantities in three generic product groups (sub-segments of PTFE fine powder, fluoroelastomer and aqueous dispersion). They estimate that in total 1000 tonnes of these products are placed on the market or exported annually containing less than 2 kg C9-C14 PFCAs. According to 3M the three product groups are used at an early stage in the production chain in order to produce a wide range of products. The company states that the processing of fluoropolymers into articles is known to reduce traces of perfluorocarboxylic acids. It is not known, if similar fluoropolymers are produced by other companies and if they contain C9-C14 PFCA above the proposed threshold. In conclusion, SEAC considers that a derogation for a higher limit value is justified for specific fluoropolymers, but a general higher limit value is not justified.

Transitional period

SEAC agrees with the Dossier Submitter's recommendation of 18 months transitional period. Since no intentional uses of C9-C14 PFCAs and related substances have been identified (other than in semiconductors and possibly in cosmetics), no substitution activities have to be performed and hence an 18 months transition period would not have negative impacts. A timeframe of 18 months should also be sufficient for ensuring that only articles which comply with this restriction proposal are imported. Furthermore, SEAC notes that the proposed exemption for articles placed on the market would also cover articles still in the supply chain.

For cosmetic products there seem to be suitable alternatives available for the industry. The manufacture of the few cosmetic products already identified by the Swedish NGO and by the Danish study containing concentrations above the proposed limits should stop before the proposed restriction is suggested to apply.

During the Public Consultation on the restriction proposal, 3M also requested a longer transitional period of 3 years for their customers to implement new technology and to have sufficient time to qualify product changes. The company indicated that due to a change of processes and composition, fluoropolymer consumers in the transportation, chemical processing, cookware, electronics and pharmaceutical device market segments have to qualify supplier changes for their regulatory, or quality system requirements or their quality management. SEAC finds the request justified as described above in the section on

fluoropolymers.

The use of PFOA, its salts and related substances causes unintentional use of C9-C14 PFCAs, their salts and related substances as an impurity. As the restriction of PFOA enters into force in 2020, SEAC finds the Dossier Submitter's suggestion for a transitional period of 18 month to be reasonable. This would avoid any substitution towards C9-C14 PFCAs once the PFOA restriction will become binding.

## 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 where considered, it would be a complement to this restriction and not dual control.

***RAC conclusions:***

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 conclusions:***

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:***

Industry in the EEA is already shifting from the use of long-chain per fluorinated substances to either short chain homologues (such as C6-based chemistries) or fluorine-free alternatives. The C6-based alternatives are reported to comply with the proposed thresholds. Thus,

according to the Dossier Submitter, there are no major economic costs to be incurred by the industry.

Only one user of C9-C14 PFCAs in imported semiconductors was identified in the EEA by the Dossier Submitter. However, there are probably other companies outside Europe using C9-C14 PFCA substances to manufacture articles that are then exported to the EEA. If this is the case, European importers might be affected by the proposed restriction and might have to carry the costs related to ensuring compliance such as administrative costs and costs for testing imported articles. Qualitative considerations are made on possible, but not yet identified, imported articles into EEA.

Substitution and purification costs

The Dossier Submitter assumes that the proposed restriction would not introduce any costs related to substitution of C9-C14 PFCAs as such in the EEA, since only few intentional uses of C9-C14 PFCAs have been identified. In some cosmetic products, PFCAs are minor ingredients but according to The Swedish Society for Nature Conservation many alternative products without PFCAs with seemingly similar properties are currently on the market. In imported semiconductors substitution is already taking place, and for this use a time limited derogation is proposed.

C9-C14-PFCAs are formed unintentionally as impurities during the manufacturing of other fluorinated chemicals. However, based on information provided by the industry, the Dossier Submitter states that the level of impurities of C9-C14 PFCAs in materials and substances produced within the EEA is below the thresholds proposed by this restriction. Hence, there should be no further costs related to introduction of changes in production processes.

The Dossier Submitter considers the possibility that articles containing polyvinylidene fluoride (PVDF) could be produced using C9-PFCA ammonium salt (APFN) as emulsifier and hence they could contain impurities of C9 PFCAs[7]. C9-PFCA has been found in polyvinylidene fluoride (PVDF) used in commercial and industrial products at levels of 100-200 ppm which is 4000-8000 times higher than the proposed limit of 25 ppb. However, since 2005, European industry has not used C9-PFCA APFN as emulsifier for the production of PVDF. Therefore, C9-C14 PCFA impurities should not exist anymore in the EEA. However, outside the EEA, there might still be companies using APFN for that purpose. In 2014, the global production of PVDF ranged from 18,000 to 28,000 tonnes per year, and the demand for thermoplastics (e.g. PVDF) is predicted to increase.

There is no information available on the share of the PVDF manufactured using APFN (and thereby possibly containing C9-C14 PFCAs), neither on the share of imported PVDF into the EU, nor on the exact content of C9-C14 PFCA salts in the final polymer. It should be noted that the use of C9-C14 substances are also regulated or covered by voluntary agreements in

[7] PVDF is used in high-purity semiconductor market (low extractable values), Pulp and paper industry (chemically resistant to halogens and acids), Nuclear waste processing (radiation and hot-acid resistant), General chemical processing industry (extreme chemical and temperature applications), Water treatment membranes (industrial and potable water uses).

other countries, like the US and Canada. The need to comply with these voluntary agreements probably affects the production outside the EEA which, for obvious economic reasons, is likely to be the same also for PVDF for the European market.

Ammonium salt of PFOA (APFO) might unintentionally contain percentages of up to 0.01% C10-C14 PFCAs their salts and PFCA-related substances in articles and mixtures. However, APFO is also covered by the PFOA restriction, and therefore the question on whether impurities of C9-C14 PFCAs would have an impact of the manufacture or use of the APFO is not relevant.

Purification costs might still be relevant e.g. for C4-C6 PFCAs, PVDF and APFO in imported articles, and therefore possible costs might occur for importers, downstream users and consumers if these articles can no longer be imported or would become more expensive. Nevertheless, these costs occurring outside the EEA are not considered significant for the economic impacts in the EEA, since the production of C4 and C6 PFCAs containing high amount of C9-C14 impurities is considered marginal. Anyway, such small costs could partially trickle down to the European consumers who would have to pay a slightly higher price.

The restriction on PFOA will become binding in 2020. Even if the Dossier Submitter is not aware of such intentions, it cannot be excluded that to some extent PFOA might be replaced by C9-C14 PFCAs by some companies. The Dossier Submitter argues that a large part of European industry has already substituted C8-based chemicals (e.g. PFOA) by C6-technology or fluorine free alternatives and believes that the vast majority (if not all) of the remaining companies using C8-chemistry will substitute to C6 or fluorine free alternatives, even if the proposed restriction is not implemented. Among other reasons, the Dossier Submitter argues that the C9-C14 technology production process is more costly than the C4 or C6 process as it needs more elongation cycles and that purification of unintended C8 products is needed. SEAC agrees to the conclusion that substitution from C8 to C9-C14 does not seem to be economically beneficial as performance of C6 or C4 will be similar with less production costs.

Cosmetics

During the Public Consultation on the restriction proposal, information from a Swedish and a Norwegian NGO was submitted showing that precursors to C9-C14 PFCAs are present in cosmetic products in Sweden. One of the tested cosmetic products even contained PFOA in high concentrations and it would therefore also be covered by the PFOA restriction. Similarly, a new Danish report found that 6 out of 17 cosmetic products containing fluorinated substances contained concentrations of C9-C14 PFCAs above the proposed limit values.

More than 11,100 cosmetic products have been screened based on an extract of all scanned products containing fluoroalkyl substances and other fluorinated compounds from an app developed for consumers requesting information on the content of cosmetic products[8].

Those cosmetic companies which submitted information concerning their reactions to the findings of C9-C14 PFCAs and related substances in their cosmetics have indicated that they will withdraw the products from the market. Other cosmetic companies facing the same problems can be assumed to either react the same way withdrawing the products from the market, or substituting with other ingredients. No cost information was submitted by the industry.

Cosmetics Europe, which was invited to take part to the public consultation on the restriction proposal, decided not to contribute to the consultation as the use of these ingredients by the cosmetic industry is minor. This indicates that the negative impact of this restriction would be negligible for the sector.

Compliance costs for importers

For the imported articles (semiconductors) identified to be affected by the restriction, it is proposed to include a time-limited derogation for this use of C9-C14 PFCAs.

Costs for ensuring compliance (testing costs)

To ensure that C9-C14 PFCAs are not unintentionally present in their articles and mixtures some companies might perform testing and they might request information from their suppliers. For instance, companies in the outdoor textile industry have indicated to the Dossier Submitter that they intend to test some of their products once the restriction is implemented.

According to the estimates provided by a large laboratory company Eurofins a cost of €470 is expected for a test that comprises 22 perfluoroalkyl acids (PFAAs), including C9-C14 PFCAs (but excludes the related substances). This package also contains PFOA. This test has a detection limit of 1 ppb. Since this package includes both PFOA and C9-C14 PFCAs, the cost of complying with both restrictions at the same time is identical to the cost of only complying with one of the two restrictions.

During the public consultation on the SEAC draft opinion, a global industry association serving the manufacturing supply chain for the electronics industry (comment #393) outlined that this estimation applies to textiles and not to solid fluoromaterial articles. Tests on fluoropolymers solid matrices are much more complex and are evaluated by the association in the range of $3000-$7000 per item. Such costs are due to the complex treatment of the matrices (freezing in liquid nitrogen and grinding), the necessity to have a large enough

[8] The Danish study was based on products identified using an application from the Danish Consumer Council, a literature survey, information from the labels of cosmetic products and information from the INCI list. The database behind the application contains data on 11 100 cosmetic products which had been entered by consumers scanning the barcodes of cosmetic products using their smartphone. 78 products (0.7 %) had declared contents of fluoroalkyl substances and other fluorinated compounds. Of these 78, 17 products were analysed for their PFAS content. One or more PFAS were found in all these products and in six of the products levels exceeding the proposed sum of C9-14 PFCAs were observed. The number of times an individual product has been scanned by consumers provides an indication of the market for that individual product. Based on this scanning frequency 22 products were initially selected for testing.

sample for analyses, and the necessity to confirm the analysis results on more than one sample batch.

Therefore, SEAC recognises that the costs of measuring the related substances could imply higher costs than those quoted above for certain product groups.

Enforcement costs for National Enforcement Authorities

For estimating enforcement costs, the Dossier Submitter refers to the generic value of €55,600 per year for administrative costs for enforcing a restriction. This is not a substance specific estimate and it does not cover testing costs. The Dossier Submitter considers this figure to be a high estimation, as part of the costs related to the PFCA enforcement activities can be shared with the enforcement costs connected with the implementation of the PFOA restriction. Since C9-C14 PFCAs and PFOA can be expected to be found in similar articles, the C9-C14 PFCA restriction would only imply a minor additional burden for national enforcement authorities as, after 2020, they will have to control certain imported articles anyway due to the PFOA restriction.

***SEAC conclusions:***

SEAC agrees with the Dossier Submitter that no major economic impacts are expected from the restriction as there are only few affected uses, and there are no indications that the industry would substitute PFOA by C9-C14 PFCAs.

Only limited quantitative information has been found by the Dossier Submitter after reasonable enquiries to appropriate stakeholders. Therefore, the analysis of costs for this restriction proposal is mainly based on a qualitative assessment undertaken by the Dossier Submitter, whilst using some quantitative information as supporting arguments. Taking the available qualitative and the few quantitative information available in the Dossier and the information submitted in the Public Consultation on the restriction proposal and the SEAC draft opinion into account, SEAC agrees with the use and the conclusions of this qualitative approach.

As mentioned above, 3M reported the content of C9-C14 PFCAs in three product groups. The company indicated that the content is formed during a polymerisation process and that it is not a result of the intended use of C9-C14 PFCAs. The company indicates that if the limit value for C9-C14 is not increased from 25 ppb to 2000 ppb (and to 400 ppb after a 3 years transition period), the company will not be able to continue to produce these three product groups. There is no information on the costs related to such a scenario.

SEAC notes that, reformulation should not be necessary since no intentional use of C9-C14 PFCAs has been identified in the EEA. Therefore, the proposed restriction should not generate reformulation costs or other substitution costs, apart from the costs related to the technical improvements to minimise the impurities of C9-C14 PFCAs in the specific fluoropolymers as described above.

However, it is likely that some cosmetics already on the market would contain C9-C14 PFCA related substances and/or impurities of C9-C14 or other less hazardous mixtures. Therefore, SEAC cannot exclude that for this sector reformulation would be needed implying minor reformulation costs for the industry.

Regarding costs for enforcement, SEAC agrees that the generic value of €55,600 highly overestimates the administrative cost for enforcing the restriction. SEAC notes that enforcement costs also include testing costs done by the authorities. Testing would introduce costs which could otherwise have been used for testing other entries of REACH Annex XVII.

***Key elements underpinning the SEAC conclusions:***

SEAC conclusion on costs is grounded on the following considerations:

- No substitution costs have been provided in the Public Consultations, with the exception of one importer of semiconductors. This import use is time-limited and a derogation is proposed.
- As mentioned above, 3M asked for higher limit value of 400 ppb for C9-C14 PFCAs and a transitional period of 36 month to adapt to new technology reducing impurities of C9-C14 PFCAs below that limit. The new technologies may influence post polymerisation processing and introduce alternative chemistries. Details are kept confidential. It is not clear whether this adaption would be performed anyway even if no restriction is introduced. If not, the cost of introducing this new technology would be part of the costs for the restriction. However, no cost information was submitted by the company. The company notes that the intended technology changes at this point are based on research experiments and further investments and regulatory clearance of new substances (REACH registration).
- In the case where the implementation of PFOA restriction would result in substitution to C9-C14 PFCAs, a restriction on C9-C14 PFCAs will imply costs. However, these costs per kg are lower than those identified in the PFOA restriction background document for substituting from PFOA to C6. It seems reasonable to take this approach as, during the evaluation and Public Consultation of the PFOA restriction, substitution to C6-based chemistries or to non-fluorinated alternatives was considered to be the way to substitute PFOA. These substitution costs have already been taken into account in the evaluation of the PFOA restriction. SEAC notes that another incentive for industry not to switch to C9-C14 PFCAs is that these substances will probably be covered by the Stockholm Convention, and therefore a switch would be seen a short-sighted response to the PFOA restriction.
- As for many previous restrictions, importers are likely to require documentation about the compliance of the imported products. It is not clear to SEAC if the extra-EU producers or the EEA consumers will in the end carry the costs for documenting compliance for imported products. However, probably the administrative costs for importers to collect and verify the documentation which would finally trickle down to consumers are considered negligible.
- In the Public Consultation on the restriction proposal [#1907) the European Automobile Manufacturers Association (ACEA) mentioned that materials or components purchased from China could potentially contain concentrations above the proposed thresholds for these long chain perfluorinated substances due to the usual global parts sourcing. ACEA therefore finds that without an exhaustive global regulation, legal compliance is challenging, especially in industries with global and

complex supply chains. SEAC recognises that this might be challenging but notes that no cost estimate is provided.

- Testing would likely take place only on imported articles and in combination with the testing for the content of PFOA. The additional cost to cover testing of textiles for C9-C14 substances is today around €150. However, the additional costs for also testing for C9-C14 PFCAs when looking for e.g. PFOA are expected to be lower than the costs indicated in the BD. Commercial laboratories usually propose packages for testing a number of PFAAs. A company sells a package with 22 PFAAs including PFOA and C9-C14 PFCA. Leaving out/including any of the PFAAs in the test, will not change the price significantly (tested by LC-MS/MS). For fluoropolymers testing costs can be rather high.
- The administrative enforcement cost estimate based on an average cost per restriction is seen only as an indicative value, as there is no basis for stating that the enforcement activities would be relevant for this restriction entry. SEAC agrees with the Dossier Submitter that the enforcement activities for the proposed restriction would be combined with parts of the enforcement activities related to the PFOA restriction.
- Regarding the need for reformulation of cosmetic products, several studies found C9-C14 PFCAs in cosmetics (Sweden, Norway and Denmark). Out of 11 100 cosmetic products reviewed in the Danish study 78 products (0.7 %) had declared the contents of fluoroalkyl substances and other fluorinated compounds. Of these 78, 17 products were analysed for their PFAS content. One or more PFAS were found in all these products and in six of the products levels exceeding the proposed sum of C9-14 PFCAs were observed. SEAC agrees with the Dossier Submitter that, overall, the number of cosmetic products containing C9-C14 PFCAs has to be considered quite low and that substitution or phase out of the products do not seem to be a problem for the cosmetic industry.
- If the cosmetics industry would need to reformulate some of its products, SEAC recognises that there would be some costs attached. An order of magnitude estimate of such costs is available in one of the most comprehensive studies concerning reformulation costs (RTI (2002)) that was also reported in the D4/D5 restriction case. For cosmetics, the study suggests that the average cost of reformulation due to substitution is €52,000 for a non-critical minor ingredient and € 110,000 for a critical minor ingredient with functional effects (2012 price level). The reformulation steps included in these cost estimates are idea generation, product development, sensory evaluation, consumer sampling, shelf life studies, packaging, production and manufacturing, and market testing and commercialisation.

**Benefits**

***Summary of proposal:***

The Dossier Submitter states that even if benefits exist from the proposed restriction, they are not quantifiable.

C9 and C10 PFCA are toxic to reproduction and their level in human blood and serum has increased. No monetary valuation of human health impacts has been possible since clear

cause-effect relationship between C9-C14 PFCA levels and different health impacts have not been established.

The main justification for the need to address the risk is that C9-C14 PFCA, their salts and PFCA-related substances are PBT and vPvB substances and have been detected in environment, food, drinking water and house dust.

Costs avoided for remediation would be an element of the benefits. The Dossier Submitter argues that as for other PBT and vPvB substances, it would be more cost effective to regulate the use of C9-C14 PFCA and their related substances beforehand rather than abating contamination or replacing a contaminated water source afterwards.

The use of chemistries containing C9-C14 PFCAs as an impurity and historical uses of the substances have contributed to the contamination of (drinking) water and soil with corresponding high costs of remediation. Most of this contamination has been caused by the use of PFASs (including long-chain PFASs) in fire-fighting foams in fire events. The remediation costs are mainly related to the treatment of ground/drinking water and the excavation and disposal of contaminated soil.

The Dossier Submitter quotes, as an example of cost effectiveness, cases of PFAS from fire-fighting foams containing PFCA which have been found in drinking water in Sweden (Swedish Chemicals Agency, 2016) where contamination with PFAS has required new supply chains of drinking water or treatment of water has been established for a sum of about €50 million in order to meet the quality standards for drinking water.

In view of the lack of more appropriate tools for evaluation of benefits, the Dossier Submitter states that it is a standard procedure to use reduced emissions of PBT and vPvB substances as a proxy for the risk reduction. However, in this case, according to the Dossier Submitter, the reduction of emissions is not quantifiable.

***SEAC conclusions:***

SEAC notes that RAC has agreed with the Dossier Submitter that the C9-C14 substances represent a risk. As noted by RAC, there are only very limited current releases that would be affected by the restriction. Consequently, the benefits derive from preventing the potential future substitution from PFOA to C9-C14 substances. Furthermore, SEAC agrees with the Dossier Submitter that a quantification of the benefits is not possible in this case, especially due to the general problems of evaluating vPvB and PBT substances, using an impact pathway approach to valuation of benefits.

***Key elements underpinning the SEAC conclusions:***

According to RAC, C9-C14 PFCAs, their salts and precursors are considered as PBT/vPvB substances and all populations and environmental compartments are potentially at risk. SEAC recognises the challenges in impact assessment for PBT and vPvB substances. The current practice to describe the benefits for these cases is based on quantified release estimates and qualitative supportive information (SEAC approach for evaluating cases on PBT/vPvB substances).

There are only limited numbers of uses that are affected by the proposed restriction, and the benefits of the proposed restriction depend on potential future substitution from PFOA to C9-C14 substances.

SEAC takes note of possible high remediation costs for C9-C14 PFCAs contaminated sites and drinking water. This indicates potentially high benefits of reducing emissions of fluorinated substances. Whether C6 or C9-C14 PFCAs are released to the environment may not affect these remediation costs, as the quality standard for drinking water in general is related to the sum of the number of fluorinated substances, independent of which fluorinated substance is found. As a consequence, the remediation cost estimate is more relevant evaluating a switch to non-fluorinated substances.

SEAC notes that if remediation actually reduces the content of PBT and vPvB substances in the environment and no other side effects occur as a consequence of the remediation activity, the impacts on human health and the environment might be similarly reduced. However, in this case double counting of gains for the environment and health is not a problem as avoided effects on the environment and health have not been quantified.

**Other impacts**

***Summary of proposal:***

The other impacts assessed by the Dossier Submitter regard the social impacts and wider economic impacts such as loss of export revenue and distributional impacts. None of these impacts assessed are considered to be significant by the Dossier Submitter.

*Social impacts*

The social impacts of the restriction on C9-C14 PFCAs are assumed to be negligible, since taking the proposed exemptions into account C9-C14 PFCAs were found in few cosmetic products where they will be substituted. As discussed in previous chapters, importers of other articles containing PFCAs can potentially be affected.

*Wider economic impacts*

The Dossier Submitter considers the magnitude of wider economic impact of the proposed restriction to be moderate. As far as imported goods are concerned, if import of C9-C14 PFCAs in articles is identified (aside semiconductors that are derogated), there might be impacts on the importers, on consumer prices and on articles' quality.

In case some other articles containing C9-C14 PFCAs are indeed imported, the Dossier Submitter considers that the proposed restriction on C9-C14 PFCAs will have a small but positive effect on the competitiveness of EEA-companies who have already substituted to PFAS-free substitutes, or short-chain alternatives. Since no EEA companies are using C9-C14 PFCAs, none will lose competitiveness on export markets.

The Dossier Submitter anticipates that the restriction will only have minor distributional effects, since no active use of C9-C14 PFCA has been identified within the EEA and only one use has been identified for imports to the EEA.

***SEAC conclusions:***

SEAC agrees with the Dossier Submitter that the social and wider economic impacts are negligible (if they exist at all).

***Key elements underpinning the SEAC conclusions:***

The Dossier Submitter provided qualitative information and analysis of the social and wider economic impacts. The information provided during the public consultations and by direct consultations with some stakeholders did not provide any further data regarding impacts for SEAC to consider.

**Competition**

3M which requested a higher threshold in the Public Consultation on the restriction proposal is one of the main three fluoropolymer manufacturers in Europe. SEAC notes that without a derogation this company would have to leave the European market and that this might impact the competition of 3M and its downstream users within the fluoropolymers sector, providing a competitive advantage to manufacturers outside the EEA and introducing additional costs for downstream users.

SEAC notes that information concerning the market were kept confidential by 3M. However, even if the size of the impact on the competition in this sector cannot be estimated, SEAC notes that in case a derogation would not be granted, these impacts would not be negligible.

**Overall proportionality**

***Summary of proposal:***

Having small costs (and benefits) due to the fact that only one user of C9-C14 PFCAs has been identified, in imported semiconductors, the Dossier Submitter concludes that the proposed restriction is proportionate.

The Dossier Submitter argues that the benefits associated with the implementation of this restriction outweigh the cost to society. The Dossier Submitter also refers to PFOA (C8 chemistry) which has a similar hazard profile and for which the restriction was found to be proportionate.

***SEAC conclusions:***

SEAC acknowledges that both benefits and costs associated with the implementation of the proposed restriction are expected to be limited. Furthermore, SEAC agrees with the Dossier Submitter that the expected benefits outweigh costs to society.

Considering the similar hazard profiles of the PFOA and C9-C14 PFCA and taking into consideration that both SEAC and the Commission already agreed on the proportionality of the PFOA restriction, SEAC concludes that the proposed C9-C14 PFCA restriction is also to be considered proportional.

SEAC notes the uncertainty concerning costs related to the fact that 3M might not be able to continue producing three product groups of fluoropolymers.

***Key elements underpinning the SEAC conclusions:***

SEAC recognises the challenges in demonstrating the proportionality for PBT/vPvB substances and more specifically for cases, such as this one, with only limited existing uses.

As the major purpose of the proposed restriction is to avoid substitution from PFOA to C9-C14 PFCAs and since in general the effect of PFOA and C9-C14 PFCAs with regard to PBT /VPvB properties is considered to be similar, SEAC agrees with the Dossier Submitter that the cost and benefit information available for the PFOA restriction can be used to justify the proportionality of this C9-C14 PFCA restriction.

SEAC highlights that the cost-effectiveness estimates per se do not give any indication on the proportionality of the proposed restriction. To conclude on proportionality, the cost effectiveness has to be considered in relation to the benefits of the proposed restriction. So far, SEAC has not been able to establish a benchmark (range) of proportionate costs to reduce emissions of PBT/vPvB substances.

If the targeted substances or articles would be placed on the market in the future, the related impacts of such marketing have been identified in the proposal and evaluated in this opinion.

SEAC considers that the conclusion that the proposed restriction is proportionate is supported by the fact that it has potential to reduce high remediation costs to be incurred in the future to decontaminate soils and underground drinking water resources if non fluorinated alternatives are used. SEAC also considers that the proposed restriction has potential to avoid further bioaccumulation of these substances in humans and the environment.

***Table 3:*** *Summary of impacts of the proposed restriction*

| | |
|---|---|
| Benefit for environment | The risk reduction due to reduced emission of vPvB and PBT substances |
| Benefit for human health | Not quantified |
| Costs | Some minor costs related to substitution from PFOA to shorter chain or non-fluorinated alternatives instead of to C9-C14 PFCAs: For textiles such cost would be less than EUR 35/kg used.<br><br>If the exemption related to fluoropolymers considered justified by SEAC is not adopted unquantified costs will occur if the producer is not able to continue the production of certain flouropolymers.<br><br>Testing cost for industry: A cost of €470 is expected for a test that include 22 PFAAs, including C9-C14 PFCAs (but excluding the |

| | |
|---|---|
| | related substances). This package also tests for PFOA.<br><br>Enforcement cost: Low as enforcement will likely be combined with enforcement of PFOA restriction. Some additional testing might be performed.<br><br>Avoiding large costs for abatement or replacement of PFCA-contaminated water sources are also a source of potential benefit from this restriction, especially if fluorine- free alternatives are used. |
| Intended uses | No impacts. Few intentional uses of C9-C14 PFCAs were identified, i.e. in imported semiconductors where an exemption is proposed and possibly in cosmetics where they can be easily substituted. |
| Unintended uses, covered by proposed derogations | Exemptions under the PFOA restriction (entry 68), e.g fire-fighting foams placed on the market before 2020.<br><br>Pressurised metered dose inhalers<br><br>Manufacture and transport of C6 and C4 fluorochemicals<br><br>Articles already placed on the market |
| Unintended uses, not covered by proposed exemptions | Cosmetics. Some reformulation of cosmetic products might be needed due to change of minor ingredients. Cosmetics Europe has expressed no concern.<br><br>Non-identified content in articles. |
| Recycled materials | Covered by the proposed restriction. No impacts have been identified. |

## 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:***

The Dossier Submitter concludes that the restriction is implementable, manageable and enforceable.

**Implementability**

According to the available information, most tested articles are below the proposed limits – hence it should be possible to avoid high level of impurities.

As described in Annex E.2. of the Background Document, it appears that the necessary technology, techniques and alternatives are available and economically feasible. The Dossier Submitter has described alternatives, both C4 and C6 PFCAs, as well as fluorine free alternatives. In general, C6-based chemistry is more expensive than C8 chemistry. According to some stakeholders the quality/performance of C6 based products is still not as good as long-chain based products, e.g. with regard to oil repellence.

For textiles costs of fluorine free options are higher. The Dossier Submitter estimates the production costs to be 2.3 – 3.5 % higher for fluorine-free fabrics than for C6-PFCAs.

The European Automobile Manufacturers Association notes that the lack of exhaustive lists of CAS (Chemical Abstracts Service) numbers it is nearly impossible to collect reliable information from a large, complex, highly tiered und mostly unknown global supply chain. In their response the Dossier Submitter recognises that it may be challenging to receive data on used substances in large supply chains, but notes that the producers have a responsibility to know what kind of substances their products contain.

Detection of non-compliance may cause some analytical challenges. In practice, testing could be problematic as new analytical methods have to be developed. Testing of some matrices could be complicated and expensive as indicated in the Forum advice.

As the proposed restriction is in line with the US-EPA Stewardship Program, many industry actors are already getting prepared for using different substances and technologies from 2015 on and the Dossier Submitter concludes that the proposed restriction is an implementable option for the actors involved within the timeframe of 18 months.

**Enforceability**

National Enforcement Authorities (NEAs) can set up efficient supervision mechanisms to monitor compliance with the proposed restriction. For imported articles, the Dossier Submitter thinks that compliance control can be accomplished by border authorities and that notification of any violation of the restriction can be reported in the RAPEX System (Rapid Exchange of Information System).

Standard analytical methods to measure the content of C9-C14 PFCAs, their salts and PFCA-

related substances in articles and mixtures are not yet available. Such standard analytical methods are being developed for the restriction of PFOA and related substances, and the Dossier Submitter argues the same methods can be applied for testing C9-C14 PFCAs and related substances. Therefore, the Dossier Submitter concludes that NEAs will be able to establish combined inspection regimes for PFOA and C9-14 PFACs.

Sweden has already initiated the development of a new CEN standard within the Technical Committee TC248/WG26, 'EC restricted substances in textiles' that specifies a test method for detection and quantification of extractable long-chain perfluorinated and polyfluorinated substances in textile articles that include long-chain per- and polyfluorinated compounds from C7 – C14.

Nevertheless, the Dossier Submitter expects that the establishment of an EU standard method(s) could make the routine implementation of these tests easier, but it would also imply expenditure of time and money. At the same time the economic costs for the development of such a standardised method may be minimised due to the fact that there will be already a standardised method for the restriction of PFOA.

Articles and mixtures to be targeted by sampling for enforcement are listed in Annex A.2.4 of the Background Document.

***SEAC conclusions:***

SEAC finds that the proposed restriction is implementable, manageable and enforceable, although it would be helpful if more testing methods are developed which are targeted to different matrices.

***Key elements underpinning the SEAC conclusions:***

SEAC agrees that the content of C9-C14 PFCAs can be measured and that the restriction can be enforced, noting the challenges in enforcement and that enforcement activities are organised differently in Member States.

Manufacturers of products will need to seek confirmation from their suppliers about the content of C9-C14 PFCAs in the polymers or mixtures they purchase. The retailers of articles containing low chain PFCAs may request a declaration from their suppliers that none of their products contains C9-C14 PFCAs. As the main instrument for enforcement, the NEAs may request information about the product composition from the suppliers of the consumer products.

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, SEAC recognises that the restriction will be challenging to enforce.

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.

According to the Forum, the term 'unintended by-product' may pose practical difficulties when enforcing the restriction because it may be difficult to decide if the by-product was formed intentionally or unintentionally. SEAC notes that the Dossier Submitter has agreed to replace 'unintended' with 'unavoidable', which is also consistent with the PFOA restriction.

## 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-1 in water (0.025 µg L-1 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:***

In the restriction dossier it is suggested that time trend monitoring could be performed with samples from the environment, from animals or from humans.

The Dossier Submitter highlights that 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.

Besides the availability of analytical methods, a sampling strategy is needed to monitor the restriction. This can be done using time trend monitoring and/or by monitoring of emissions.

As C9-C14 PFCAs are persistent substances, they will remain in the environment for a long period 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-EEA-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.

In such a trend monitoring, reductions of releases of C9-C14 PFCAs and PFCA-related substances in the environment should result in decreasing or not increasing C9-C14 PFCAs concentrations. Therefore, it might be sufficient to measure C9-C14 PFCAs, because C9-C14 PFCAs related substances 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, the Dossier Submitter argues that, in some cases, release of C9-C14 PFCAs from environmental sinks, like sediment might bias time trend.

***SEAC conclusions:***

Based on the information provided in the restriction report, SEAC agrees that the restriction is monitorable.

## 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:***

The major uncertainties for the socio-economic assessment identified by the Dossier

Submitter are the following:

- Whether intentional or unintentional uses and users of C9-C14 substances (not identified during both stakeholders' and public consultations) exist within the EEA.
- The amount of C9-C14 produced and used within the EEA and the products in which it is present.
- What alternatives exist to avoid C9-C14 PFCA as unintended byproducts.
- Whether C9-C14 PFCAs are present in imported articles. The Dossier Submitter assumes that import of articles containing C9-C14 PFCA without the knowledge of the importer may take place. Importers may also have missed to report imports in the public consultation processes.
- To what extent the proposed restriction would affect the use of PFCAs and PFCA-related substances with a chain length shorter than eight due to higher levels of impurities than the proposed thresholds.
- To what extent the users of C8 chemistry would substitute to C9-C14 substances after PFOA restriction becomes effective.
- The total amount of costs associated with the restriction including testing costs to ensure compliance.

***SEAC conclusions:***

As the substances are not registered under REACH, SEAC finds it reasonable to expect that C9-C14 substances will be very limited within the EEA (except for the imported semiconductors). No information on intentional uses in the EEA was received in the public consultations either, although it is uncertain whether the PFCAs are used intentionally in cosmetics.

SEAC agrees with the Dossier Submitter that import of articles containing C9-C14 PFCAs cannot be excluded. However, both during the stakeholders consultation carried out by the Dossier Submitter and during the Public Consultation on the restriction proposal and the SEAC draft opinion, only one type of imported articles (semiconductors) has been identified so far. Taking into consideration that no other companies have reacted to this proposal, SEAC concludes that this uncertainty is of little magnitude and does not affect SEAC conclusions.

Based on the information in the restriction report and comments received in the public consultations, SEAC does not consider the possible impurities in the alternatives with chain lengths shorter than 8 a major uncertainty. It seems clear that the proposed thresholds can be met by industry. However, 3M explained that impurities of C9-C14 can occur during the production of fluoropolymers.

SEAC agrees with the Dossier Submitter that, as a consequence of the PFOA restriction, some users of C8 chemistry could decide to shift to C9-C14 substances instead of choosing other alternatives such as for instance C4 or C6 substances. However, SEAC has not been informed of such intentions. Taking into consideration the fact that, in general, before making new investments, companies would check the upcoming regulatory framework, e.g. under the Stockholm Convention, and consumer reactions in order to avoid a regrettable substitution,

SEAC concludes that such shift is very unlikely and does not affect SEAC conclusions.

However, to illustrate the possible economic costs for this restriction proposal, the Dossier Submitter refers to information from the Background Document of the PFOA restriction. In case industry would have substituted the use of PFOA by C9-C14 instead of C6, the possible substitution cost would always be less than the cost for substituting from PFOA to C6. For the textile sector, the worst-case estimate for substitution cost per kilo when substituting from PFOA to C6 chemistry is €35 per kg of PFOA related substance used. Hence the cost of changing from C9-C14 to C6 would be lower than the €35 per kg[9]. Consequently, as the PFOA restriction is already considered proportionate also for textiles, this restriction is also considered to be proportionate.

In the PFOA restriction, the central estimate for the cost of substitution of PFOA (and PFCA-related substances) to C6 (and related substances) was €34.7 million[10] per year. As the industry will substitute to C9-C14, instead of C6, only if it is economically worthy, the cost per kg of substituting PFOA to C9-C14 should be always less than the cost per kilo to substitute PFOA with C6. Hence, the additional costs of not being able to substitute PFOA by C9-C14 PFCAs would be less than €0.35 million per percentage of PFOA substitution. The Dossier submitter has calculated the impact if 5% of the PFOA in textile is substituted by C9-C14 PFCAs but has not substantiated why 5% would be a reasonable estimate.

Concerning cosmetics, some mixtures containing C9-C14 PFCA and C9-C14 related substances have been identified by a Swedish and a Norwegian NGO and by the Danish EPA. Hence, it is very likely that other cosmetic products could be on the market, including those not being covered by the PFOA restriction.

In addition to uncertainties discussed above, both costs and benefits of the substitution away from possible use of C9-C14 PFCAs are highly depending on the extent to which industry would switch to non-fluorinated alternatives. SEAC notes that this restriction is part of wider European and global measures to replace PFASs of concern with safer alternatives, and that the full risk reduction from these activities could only be estimated later on. However, only the costs of alternative that industry will implement as a response to this restriction is relevant when evaluating the proposed restriction. Possible further substitution to non-fluorinated alternatives is not part of the cost estimate for this restriction.

To the extent that the proposal aims at preventing future new uses of C9-C14 PFCAs the uncertainties in relation to the proportionality are of less importance.

SEAC considers that the uncertainties discussed above do not change the overall conclusion on costs, benefits and proportionality of the proposed restriction.

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[9] This calculation is based on the situation where a manufacturer using PFOA ex ante look at different alternatives. If the manufacturer already has changed from PFOA to C9-C14 PFCAs some further costs can be envisaged.

[10] It should be noted that SEAC considered this to be an underestimate.