Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

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

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

Agreed

13 September 2018

14 September 2018

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

13 September 2018

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

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

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

PROCESS FOR ADOPTION OF THE OPINIONS

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

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: *Pietro PARIS*

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

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

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

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

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: *Lars FOCK*

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

The draft opinion of SEAC

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

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

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

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

The opinion of SEAC

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

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

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

1 Delete the unnecessary part(s)

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter:

Perfluoroalkyl carboxylic acids (branched and/or linear) with the formula: $CF3-(CF2)_n-C$, n=7 or 8 or 9 or 10 or 11 or 12 as structural elements including their salts and including all combinations thereof Perfluoroalkyl carboxylic acids (branched and/or linear) with the formula: $CF_3-(CF_2)_n-$, n=8-13 as a structural element, including their salts 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 The following substances are excluded from this designation: • $CF_3-(CF_2)_n-X$, n > 7, where X= F, Cl, Br including any substance with linear and/or branched perfluoroalkyl elements and all mixtures thereof • $CF_3-(CF_2)_n-SO2X'$, n > 7 where X'=any group, including salts • $CF_3-(CF_2)_n-C(=O)OH$, n > 12 including salts	1. Shall not be a) manufactured, or placed on the market as substances on their own; b) used in the production of, or placed on the market in: i. another substances, as a constituent, ii. a mixture, iii. an article or any parts thereof, in a concentration equal to or above 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related substances 2. Paragraph 1 shall apply 18 month from entry into force of the restriction 3. Paragraph 1 shall not apply to 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; 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; 4. Paragraph 1(b-iii) shall not apply to a) Articles placed on the market before the restriction becomes effective

THE OPINION OF RAC

See the opinion of RAC.

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:

1. Perfluorocarboxylic acids (linear and/or branched), their salts and PFCA-related substances[2]: (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; (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; (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.	1. Shall not be manufactured, or placed on the market as substances on their own; 2. Shall not be used in the production of, or placed on the market in: (a) Another substance, as a constituent[3], (b) A mixture, (c) An article or any parts thereof, in a concentration equal to or above 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related substances. 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction 4. Paragraphs 1 and 2 shall not apply to: (a) The manufacture of a substance where this occurs as an unavoidable by-product of the manufacture of fluorochemicals

[2] 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).

[3] Constituent includes impurities i.e. both unintended and intended constituents.

2. The following substances are excluded from this designation: (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; (b) C_nF_{2n+1}-C(=O)OX', where n>13 and X' = any group, including salts.	with a perfluoro carbon chain equal to or shorter than 6 atoms; (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; 5. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3. 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. 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. 8. Paragraph 2(c) shall apply from 31 December 2023 to: (a) Semiconductors; and (b) Semi-finished and finished electronic equipment for use in semiconductors. 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.

Explanatory text[4]

Column 1

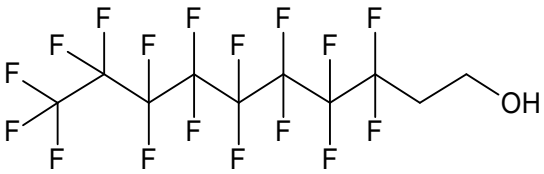
Paragraph 1 – included substances

Both linear and branched chained substances are included in the scope. The nomenclature

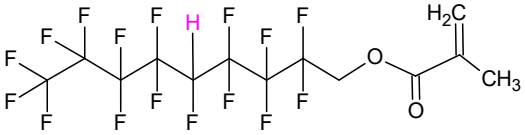
[4] This text is intended to provide clarification of the text in columns 1 and 2 but is not part of the opinion itself.

has been amended to cover also branched substances which was not the case in the original 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

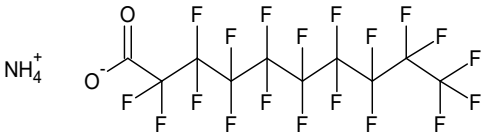
Paragraph 1(a) (original proposal: column 1, paragraph 1)

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

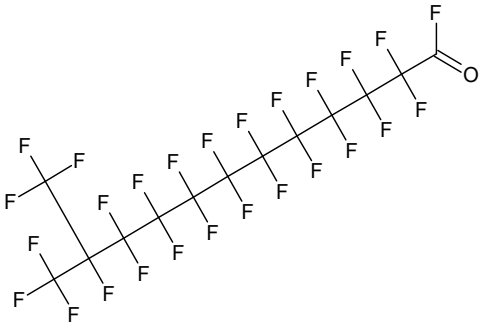
Paragraphs 1(b) & (c) (original proposal: column 1, paragraphs 2 & 3)

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:



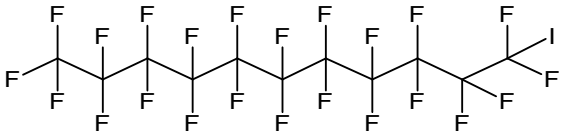
Ammonium nonadecafluorodecanoate and the substance



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

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.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

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

Information on hazard(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Information on emissions and exposures

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Characterisation of risk(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Uncertainties in the risk characterisation:

See the opinion of RAC.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Justification for the opinion of SEAC

Summary of the 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

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Justification for the opinion of SEAC

Summary of the 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, additional affected uses were identified. They are discussed below.

Articles placed on the market before the proposed restriction applies[5] (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

[5] 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).

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 of the restriction report

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 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 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
- Pressurised metered-dose inhalers (pMDI)

SEAC also agrees with the Dossier Submitter on the proposed concentration limits and transitional period. However, SEAC notes the uncertainty 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 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 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 other 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, 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 in the final product. Based on the comments, no detailed analysis of alternatives has been carried out by this company since they only recently found out they would be affected both by C9-C14 PFCA proposal and the PFOA restriction. However, the company states that currently they are investigating what alternatives may be available and what could be done to mitigate the risk of interrupting patient supply. According to the company, at present, there is no known alternative material that meets the limits of the proposed restriction. The company also claims that if an alternative becomes available, it would 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. This request is related to the production of the lining of inhalers and is not detected in the final product.

Semiconductors

One company (#1895), already identified by the Dossier Submitter in the restriction dossier, imports C9-C14 PFCAs in a small number of imported semiconductors. This company requested a longer transitional period until end of 2023 for semiconductors and semi-finished electronic equipment. Furthermore, the company requested an exemption for semiconductors used in spare parts until 2030 for finished electronic equipment placed on the market before 31 December 2023. SEAC notes that the C9-C14 PFCA content in the articles is in the low kg range (exact amounts are estimated but claimed confidential). 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 will be covered by the derogation. Therefore, the requested time limited exemption for semiconductors and articles containing semiconductors seems reasonable, taking into account that also the PFOA restriction exempts semiconductors for photo-lithography processes and compound semiconductors for etching processes.

On this basis, SEAC supports these time limited derogations.

Fire-fighting foams

During the Public Consultation, the mineral oil industry (Public Consultation comment #1885) stated that, due to legal requirements, aqueous film-forming foam (AFFF) fire-fighting foams 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.

Articles already placed on the market

The Dossier Submitter proposes to exempt second-hand articles 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.

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 Public Consultation 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, the question was raised if the substances, mixtures and articles currently placed on the market comply with these thresholds. One company (comment #1914 by 3M of the PC) 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. However, they did not submit detailed information regarding the application of and emissions from each product group. It is not known either, if similar fluoropolymers are produced by other companies and if they contain C9-C14 PFCA above the proposed threshold. In conclusion, at the current time SEAC does not have sufficient information to conclude on whether a general higher limit value as requested is justified. SEAC notes that if a higher limit value was justified, the limit value could be 40% lower (approximately 290 ppb), as the company included inter-laboratory variation of approximately +/- 40 % in their derivation of the threshold. However, during enforcement activities testing variabilities are already taken into consideration.

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, 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.

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. SEAC does not consider the information provided in the Public Consultation sufficient to support a longer transitional period for the fluoropolymers because the information on alternatives, products and production processes does not allow SEAC to understand why other companies in the same sectors do not face the same challenges.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of the 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[6]. C9-PFCA has been found in 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 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

[6] 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).

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, polyvinylidene fluoride (PVDF), ammonium salt of PFOA (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, 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[7].

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

[7] 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.

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, 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 Eurofins (e-mail to Dossier Submitter from 2018-04-09), 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. SEAC recognises however that the costs of measuring the related substances would imply higher costs than those quoted.

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 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 400 ppb and only 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 use of C9-C14 PFCA has been identified in the EEA. Therefore, the proposed restriction should not generate reformulation costs or - other substitution costs, apart from the specific costs related to the production of 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 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 related to 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 consultation, with the exception of one importer that has been identified. 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 depend on further investments and regulatory clearance of new substances (REACH registration).

  No information on its costs and on costs for the society in general was provided by 3M, in case production of these fluoropolymers would have to stop, if the 25 ppb limit value would be confirmed. The company submitted only very generic information on the socio-economic value of fluoropolymers.

  If the proposed threshold can be met by other producers of fluoropolymer products, the socio-economic impacts might be quite limited. However, this depends on how the fluoropolymers are replaced, e.g. whether production will be replaced by imports in case the final products are able to comply with the limit values.
- If the implementation of the 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 [#1907) the Automobile Manufacturers Association 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 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).
- 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 the 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 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 the 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 only C9-C14 PFCAs only were found in few mixtures where they are easily substituted and in imported semiconductors where an exemption is proposed. As is 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, 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 consultation 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 is one of the main three fluoropolymer producer manufacturers in Europe. In case this company would have to leave the European market this might impact the competition within the fluoropolymers sector. The company's market analysis is kept confidential.

According to this company, downstream processing of fluoropolymers would reduce C9-C14 PFCA levels, so that imported final articles might already be compliant. This is expected to provide a competitive advantage to manufacturers outside the EEA. SEAC cannot estimate the potential size of this impact.

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 1: 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. Un-quantified costs if one producer is not able to continue the production of certain flouropolymers. 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. Enforcement cost: Low as enforcement will likely be combined with enforcement of PFOA

	restriction. Some additional testing might be performed. 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. • Pressurised metered dose inhalers • Manufacture and transport of C6 and C4 fluorochemicals • Articles already placed on the market
Unintended uses, not covered by proposed exemptions	Production of fluoropolymers. One producer might not be able to continue the production of flouropolymers, due to high content of C9-C14 PFCAs. Cosmetics. Some reformulation of cosmetic products might be needed due to change of minor ingredients. Cosmetics Europe has expressed no concern. 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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Justification for the opinion of SEAC

Summary of the 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 levels 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.

Targeting and detection of non-compliance may cause some analytical challenges. In practice, analysis could be problematic as it has not been tested out and could be complicated and expensive.

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 industry's 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 targeted testing methods are developed.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Justification for the opinion of SEAC

Summary of the 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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

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 (missed during both stakeholders and public consultation) 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 process.
- 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 consultation 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, 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 consultation, 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[8]. 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[9] 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.

[8] 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.

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