Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

undecafluorohexanoic acid (PFHxA), its salts and related substances

ECHA/RAC/RES-O-0000006976-57-01/F

ECHA/SEAC/RES-O-0000007039-72-01/F

8 December 2021

3 June 2021

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8 December 2021

ECHA/SEAC/RES-O-0000007039-72-01/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s): **undecafluorohexanoic acid (PFHxA), its salts and related substances**

EC No.: **-**

CAS No.: **-**

This document presents the opinion adopted 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 consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

Germany has 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 https://echa.europa.eu/restrictions-under-consideration/-/substance-

rev/25419/term on **25 March 2020**. Interested parties were invited to submit comments and contributions by **25 September 2020**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Daniel BORG

Co-rapporteur, appointed by RAC: Betty HAKKERT

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 **3 June 2021.**

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: Johanna KIISKI

Co-rapporteur, appointed by SEAC: Simone FANKHAUSER

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 **9 June 2021.**

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 https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/25419/term on **7 July 2021**. Interested parties were invited to submit comments on the draft opinion by **7 September 2021**.

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 **8 December 2021**. The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **90 days** by the ECHA decision I(2021)0105 dated 5 July 2021.

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

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

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1. OPINION OF RAC AND SEAC

The restriction proposed by the **Dossier Submitter** is:

1. Undecafluorohexanoic acid (PFHxA), its salts and related substances (including polymers) (a) having a linear or branched perfluoropentyl group with the formula C_5F_{11}- directly attached to another carbon atom as one of the structural elements; (b) having a linear or branched perfluorohexyl group with the formula C_6F_{13}-. 2. The following substances shall be derogated from this designation: (a) C_6F_{14}; (b) C_6F_{13}-C(=O)OH, C_6F_{13}-C(=O)O-X' or C_6F_{13}-CF_2-X' (where X' = any group, including salts). (c) Any substance having a perfluoroalkyl group C_6F_{13}- directly attached to a sulphur atom.	1. Shall not be manufactured, used 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 or used in: (a) another substance, as a constituent, (b) a mixture, (c) an article in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances. 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction. 4. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3. 5. Paragraphs 1 and 2 shall not apply until XX XX XXXX [five years after the entry into force] to: (a) hard chrome plating; (b) photographic coatings applied to films, papers, printing plates and inkjet photo media coatings; (c) concentrated fire-fighting foam mixtures that were placed on the market before [date – 18 months after the entry into force of this Regulation] and are used or are to be used in the production of other fire-fighting foam mixtures for cases of class B fires; this shall not apply to: (i) use of fire-fighting foam for training; and (ii) use of fire-fighting for testing unless all emissions to the environment are minimised and effluents collected are safely disposed of. 6. Paragraph 1 and 2 shall not apply to concentrated fire-fighting foam mixtures for defence applications – as long as no

	successful transition to military operable fluorine free foams can be achieved: (a) for seagoing units, air traffic facilities and storage of fuel; (b) for training purposes provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely. 7. Paragraphs 1 and 2 shall not apply to latex printing inks until XX XX XXXX [seven years after the entry into force] 8. Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to: (a) concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500 $m^{2;}$ (b) semiconductors and semiconductor related equipment. 9. Paragraphs 1 and 2 shall not apply to any of the following: (a) 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; (b) personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); (c) High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3 (d) impregnation agents for re-impregnating of articles referred to in paragraph 9(b), (c), (g); (e) textiles for the use in engine bays in the following usage groups: Automotive and aerospace industry (f) epilames used in watches (g) medical devices as specified in Regulation 2017/745 of the European Parliament and of the Council; (h) filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency;

	10. From (entry into force + 12 months), a natural or legal person placing a mixture or an article specified in paragraph 9(b)-9(h) on the market for the first time and benefitting from the derogation therein shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing: (a) the identity of the substance(s) used in the previous year; (b) the quantity of PFHxA, its salts and PFHxA-related substances used in the previous year. The European Chemicals Agency shall forward the data to the Commission by 31 March every year. 11. The concentration limit referred to in paragraph 2 shall be (a) 2000 ppb for the sum of PFHxA and its salts in fluoropolymers; (b) 150 ppm for the sum of PFHxA and its salts in fluoropolymers used in the following usage groups: Engine parts in automotive, aerospace and shipping industry. (c) 10 ppm for the sum of PFHxA and its salts in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force] (d) 100 ppm for the sum of PFHxA related low molecular[1] substances in fluoropolymers. (e) 2500 ppm for the sum of PFHxA related low molecular substances in fluoropolymers used in the following groups: Engine parts in automotive, aerospace and shipping industry. (f) 500 ppm for the sum of PFHxA related substances in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force]. 12. From (entry into force + 12 months), a natural or legal person benefitting from the derogation in paragraph 6 or paragraph 8(a) shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing:

[1] Related substances in the scope of the proposal which are not C6-sidechain fluorinated polymers.

	(a) A description of their efforts on substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances; (b) quantities they used in the previous year of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances per sector specifying: (i) share in training and in operation (ii) whether emission was contained, collected and disposed safely or emitted into the environment. The European Chemicals Agency shall consolidate and forward the data to the Commission by 31 March each year. 13. By (entry into force + 6 years), the Commission shall carry out a review of paragraph 6 and paragraph 8(a) in the light of new scientific information, including the availability of alternatives for articles referred to in paragraph 6 and paragraph 8(a), and proposing amendments if indicated by the outcome of the review. As long as the Commission concludes that there is still need for these derogations this review shall be carried out every three years.

Explanatory notes:

Column 1:

Paragraph 2(a): This paragraph refers to any linear and/or branched perfluorinated hydrocarbon with a total carbon number of C6. It is not degraded to the corresponding PFCA given the stability of the carbon fluorine bond.

Paragraph 2(c): This paragraph refers to any substance having a perfluoroalkylgroup C6F13- directly attached to a sulfur atom. These substances are already covered by the restriction with the arrowhead substance perfluorohexane-1-sulfonic (PFHxS) acid including its salts and related substances. The Dossier Submitter notes that the derogation could also be placed in the right column of the table above. It would be up to the Commission to ultimately decide whether the left or the right side of the entry is the most appropriate to address the derogation of PFHxS, its salts and related substances.

Column 2:

Paragraph 5(c): For fire-fighting foam mixtures for cases of class B fires for a period of time of five years after entry into force of the restriction paragraph 2 shall not apply. After this period of time use, production and placing on the market of fire-fighting foam mixtures shall not be allowed. The specification in 5 (c) (i) and (ii) derogates fire-fighting foam mixtures that contain or may contain PFHxA, its salts and PFHxA-related compounds that are used for training and for testing unless emissions to the environment are minimised and effluents

collected are safely disposed of. Thereby only allowing use of fire-fighting foams in cases of emergency and under specific conditions use in testing. If all releases are contained when testing, paragraph 2 shall not apply to fire-fighting foam mixtures used in testing for a period of time of five years after entry into force of the restriction. Class B fires are fires of liquid substances or substances becoming liquid as specified in the European standard EN2 Classification of Fires.

Paragraph 6: While some armed forces (e.g. Denmark cf. Annex E2.3.4 Table 31) already reported transitions to fluorine free foams (FFF) and positive experiences with these foams, other armed forces reported challenges regarding a complete transition due to missing appropriate aqueous film forming foam (AFFF) alternatives in the defence sector. One of the challenges reported is, that the available FFF do not fulfil the requirements of some defence-specific applications for firefighting foams. Due to some exceptionally high risks of defence-specific fire-scenarios (e.g. firefighting on seagoing units) a switch to FFF is currently not possible. Generally, the use of FFF for defence applications is desired and new alternatives are being investigated regularly. However, at the moment a restriction of the use of AFFF for defence-applications would lead to unacceptable constraints for fire-fighting in some defence-specific scenarios (information received by the Federal Ministry of Defence (Germany) and confirmed by another national authority in the public consultation).

For defence applications a derogation applies as long as a transition due to missing alternatives is not possible for the use in fire-fighting foam mixtures for seagoing units, air traffic facilities and storage of fuel, furthermore, for training purposes provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely (i.e. incinerated at temperatures > 1400 °C).

Paragraph 8: Furthermore, a derogation applies for twelve years after entry into force of the restriction for the use in fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500 m^2.

The Dossier Submitter is aware of the project by ECHA and the European Commission, which studies the use of PFASs in fire-fighting foams, analyses the alternatives and the impact assessment to provide a basis for the decision on an appropriate regulatory measure and gains information for a possible restriction proposal. The restriction of PFHxA, its salts and PFHxA-related substances and respective derogations for fire-fighting foam mixtures are based on an extensive literature research and stakeholder consultation. However, the respective project might lead to further information that were not taken into account in the present dossier and might lead to different conclusions.

Paragraph 10: Annual reporting on the use of PFHxA, its salts and PFHxA-related substances in the production of articles or mixtures covered by Paragraph 9 (b) to 9(h): This will help the European Commission to gather data on the use of these substances in these sectors and to monitor any changes in response to the restriction over time. In the event that the data reveals any concerns for the sector, further actions under REACH can be initiated. The reporting requirement will help to monitor whether there are any changes to uses and quantities which may be an indication to changes in the emissions. The proposed action sends a signal that substitution of PFHxA, its salts and PFHxA-related substances is desirable.

Paragraph 12: The market of fluorine free foams is rapidly developing and testing requirements for fire-fighting foams are already being reviewed, regarding changing requirements when assessing fluorine free foams. Therefore, the feasibility of a transition to fluorine free foams in the defence sector shall be possible for all armed forces in the future. That is why the efforts on substitution will be closely monitored. In the case of fire-fighting foams emissions to the environment occur mainly in the use phase. For this reason, the

reporting requirement is linked to the actual application of FFF (i.e. the applicants benefitting from the derogation) and not the placing on the market. This is further supported by the fact, that FFF have a long shelf life of up to 30 years (see B.9.7).

Annual reporting on the quantities and efforts of substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances will allow the European Commission to also gather data on the used quantities of these substances and to monitor the developments of alternatives for fire-fighting foams. The reporting requirement will not only help to monitor whether there are any changes to uses and quantities which may be an indication to changes in the emissions, but it will also allow a facilitated re-evaluation of paragraph 6 by the European Commission. The proposed action sends the signal that substitution of PFHxA, its salts and PFHxA-related substances is desirable in the field of fire-fighting foams as well.

It is noted that the restriction proposal distinguishes "related substances" as provided in column 1 of the proposal as follows: (1) "side-chain C6 -fluorinated polymers" or "C6-SFPs" and (2) "PFHxA related low molecular substances" or "low molecular weight PFHxA-related substances". For further explanation, see Background Document.

1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that it has not been demonstrated that the restriction on **undecafluorohexanoic acid (PFHxA), its salts and related substances** as initially proposed by the Dossier Submitter is the most appropriate Union wide measure to address the identified risk. Nevertheless, RAC considers that a broad restriction on undecafluorohexanoic acid (PFHxA), its salts and related substances is an appropriate Union wide measure to address the identified risk in terms of its effectiveness, practicality and monitorability, provided that the scope and conditions are modified, as proposed by RAC. For comparison of the Dossier Submitter's proposal and RAC proposal, see Appendix A.

The conditions of the restriction proposed by **RAC** are:

1. Undecafluorohexanoic acid (PFHxA), its salts and related substances (a) having a linear or branched perfluoropentyl group with the formula C_5F_{11}- directly attached to another carbon atom as one of the structural elements; (b) having a linear or branched perfluorohexyl group with the formula C_6F_{13}-. 2. The following substances shall be derogated: (a) C_6F_{14}; (b) C_6F_{13}-C(=O)OH, C_6F_{13}-C(=O)O-X' or C_6F_{13}-CF_2-X' (where X' = any group, including salts).	1) Shall not be manufactured, used 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 or used in: (a) another substance, as a constituent, (b) a mixture, (c) an article in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances. 3) Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.

(c) Any substance having a perfluoroalkyl group C_6F_{13}- directly attached to a sulphur atom. (d) Any substance having a perfluoroalkyl group C_6F_{13} -directly attached to an oxygen atom at one of the non-terminal carbons.	4) Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3. 5) Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to: (a) semiconductors and semiconductor-related equipment. 6) Paragraphs 1 and 2 shall not apply until XX XX XXXX [10 years after the entry into force] to: (a) Coating for hearing aid devices. 7) Paragraphs 1 and 2 shall not apply to any of the following: (a) 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; (b) implantable medical devices; (c) epilames used in watches. [*] *See explanatory notes*. 8) From (entry into force + 12 months), a natural or legal person placing a mixture or an article specified in paragraphs 7 (b) and (c) on the market for the first time and benefitting from the derogation therein shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing: (a) the identity of the substance(s) used in the previous year; (b) the quantity of PFHxA, its salts and PFHxA-related substances used in the previous year. The European Chemicals Agency shall forward the data to the Commission by 31 March every year.

Explanatory notes:

Column 1:

Paragraph 1: Includes polymers where:

- the polymer itself contains a structure listed in this paragraph; examples of such polymers are C6-side-chain fluorinated polymers (C6-SFPs), as detailed later in this document, and/or
- a polymer contains constituents or impurities that have a structure listed in paragraph

1. As discussed later in this document, this may include fluoropolymers.

Paragraph 2(a): This paragraph refers to any linear and/or branched perfluorinated hydrocarbon with a total carbon number of C6. It is not degraded to the corresponding PFCA given the stability of the carbon fluorine bond.

Paragraph 2(b): These substances are considered to belong to the group of perfluoroheptanoic acid (PFHpA), its salts and related substances or longer chain PFASs. The Background Document does not include an assessment of the properties and risks of this group. However, due to close structural similarity, some properties may be read across between, e.g., PFHpA and PFHxA.

Paragraph 2(c): This paragraph refers to any substance having a perfluoroalkylgroup C_6F_{13}- directly attached to a sulfur atom. These substances are already covered by the proposed restriction of perfluorohexane-1-sulfonic (PFHxS) acid including its salts and related substances.

Paragraph 2(d): These substances are not able to be transformed to undecafluorohexanoic acid. Their chemical structure is such that a degradation to a carboxylic acid or to a carboxylate would form two separate shorter fluoroalkyl chains, whose hazards and risks were not assessed in the restriction proposal.

Column 2:

Paragraph 7(a): transported isolated intermediates are derogated from the restriction in alignment with the previous restrictions of PFASs if they are transported and used under strictly controlled conditions and rigorously contained, as defined in Article 18(4) of REACH-Regulation. The term "transported isolated intermediate" is defined under Article 4 of REACH.

Paragraph 8: RAC supports reporting requirements for derogated uses that are not time-limited. If additional derogations without time limits are added at the decision-making stage, RAC proposes to include these in the reporting requirements. Such reporting would help the European Commission to gather data on the use of these substances in these sectors and to monitor any changes. In the event that, the data reveals any concerns for the sector, further actions under REACH can be initiated. The reporting requirement will help to monitor whether there are any changes to uses and quantities which in turn, may indicate changes in the emissions.

[*] Derogations for uses where RAC could not conclude on the effectiveness of a ban

The derogations listed below are for uses where RAC concluded that there are significant uncertainties on the appropriateness and effectiveness of implemented risk management measures to minimise releases of PFHxA, its salts to related substances. Whilst risks should be minimised and releases may currently occur from these uses, it cannot currently be concluded that a ban on placing on the market is the most appropriate restriction option (e.g. should sufficient information become available, then specifying conditions of use and implementing minimum risk management measures via REACH restriction could be more appropriate).

- Concentrated firefighting foam mixtures for cases of class B fires at industrial installations with containment (12-year derogation proposed by the Dossier Submitter).
- Hard chrome plating (5-year derogation proposed by the Dossier Submitter).
- Cladding for optical fibres (derogation requested during the consultation on Annex

XV report).

2. Summary of the RAC opinion

The Committee for Risk Assessment (RAC) supports a restriction on undecafluorohexanoic acid (PFHxA), its salts and related substances.

RAC agrees with the scope of the substance identity proposed by the Dossier Submitter, covering PFHxA, its salts and related substances but with minor modifications. The Committee agrees with the Dossier Submitter that the properties of PFHxA (e.g. its extreme persistence and mobility in the environment, and potential adverse effects on human health and the environment) are of concern and that uses that result in releases to the environment are not adequately controlled and should therefore be minimised.

Releases and ongoing exposures in the environment and to humans have been confirmed by a large set of environmental and human monitoring data.

RAC concludes that the continued use of PFHxA, its salts and related substances in wide-dispersive uses will lead to an increasing environmental stock and further environmental and human exposure. This exposure will not be possible to reverse. Although the database of effects on the environment and human health is limited, the available information points towards comparable adverse effects as seen for closely related PFCAs (to which co-exposure is noted to occur). Consequently, RAC is of the opinion that long term exposure may lead to adverse effects on the environment and human health, and in the event of such effects, they cannot be reversed. RAC notes that the potential for human exposure through the food and drinking water is also clear.

PFHxA, its salts and related substances are widely used in many sectors, with large quantities used in paper and cardboard (food contact materials), textiles and firefighting foams. Due to large uncertainties in the quantitative assessment presented by the Dossier Submitter, RAC evaluated the potential for releases from different uses, and the effectiveness of the proposed restriction to prevent them, qualitatively. RAC concludes that a broad EU-wide restriction with carefully considered targeted derogations and transition periods is the most appropriate measure to reduce the risks of PFHxA, its salts and related substances.

RAC supports the proposed restriction for uses[2] **where it is not possible to implement risk management measures to minimise emissions**, especially wide-dispersive consumer uses in food contact materials, textiles as well as in firefighting foams used for municipal firefighting, which comprise three major emission sources. However, based on limited information available on the conditions of use and the effectiveness of risk management measures, RAC could not conclude on whether certain other uses[3] contribute to the identified risk. This was on the basis that the uncertainties around the current conditions of use and effectiveness of RMMs are too large to conclude that the proposed restriction (a ban on use) was the most effective risk management option. Furthermore, RAC does not support the justification for most of the derogations proposed by the Dossier Submitter as

[2] Textiles (all categories), paper and cardboard, municipal firefighting foams, firefighting foams for defence applications, printing inks, photographic applications, building materials, impurities/constituents in fluoropolymers (incl. fluoroelastomers), medical devices (with the exception of coating for hearing devices and implantable medical devices), cosmetic products, and mixtures for consumer uses.

[3] Chrome plating, firefighting foams used at industrial installations/sites with containment, optical fibres.

there was insufficient information available to conclude that releases from the uses were minimised. However, in the event that a restriction would be implemented, **RAC supports derogations** for the following uses as credible information on the minimisation of releases was available:

- Semiconductors and semiconductor related equipment (12-year transition period);
- Epilame in watches (derogation without a time limit);
- Coating for hearing devices (10-year transition period);
- Implantable medical devices (derogation without a time limit);
- Transported isolated intermediates (derogation without a time limit).

RAC considers that a broad restriction would effectively reduce emissions of PFHxA, its salts and related substances and the related risks. By prohibiting the use of the substances in wide-dispersive uses where risk management measures cannot be used to prevent releases (including the three major emissions sources noted above), future emissions to the environment are anticipated to be significantly reduced. RAC notes that the indicative list of substances published as part of the consultation on the Annex XV report may not include all substances that would be within the scope of the proposed restriction. Consequently, some uses may have not been identified and assessed. RAC also notes that standard analytical methods for the substances and matrices within the scope of the proposed restriction need to be developed. However, RAC concludes that, in general, **analytical methods are commercially available to monitor exposures and the implementation of the restriction**. In summary, although there are uncertainties, RAC is of the opinion they do not change the overall conclusion that there is a risk from PFHxA, its salts and related substances that is not adequately controlled and that the need for a restriction in certain uses has been justified.

2.1. 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. Taking into account the available information on the proportionality of its socio-economic benefits to its socio-economic costs, SEAC considers that it has not been demonstrated that the restriction on **undecafluorohexanoic acid (PFHxA), its salts and related substances** as initially proposed by the Dossier Submitter is the most appropriate Union wide measure to address the identified risks.

SEAC considers that a restriction on **undecafluorohexanoic acid (PFHxA), its salts and related substances** is, in general, an appropriate measure to address the identified risks. However, based on the limited available information on socio-economic impacts and emission estimates, it is not possible to conclude whether the conditions of the proposed restriction, as modified by SEAC, are the most appropriate measure to address the identified risks. Nevertheless, SEAC concluded on the proportionality of a restriction for certain uses, where information on socio-economic impacts was less uncertain. Based on the currently available information, SEAC proposes the following conditions, as discussed in the justification supporting this opinion. For comparison of the Dossier Submitter's proposal and RAC's proposal, see Appendix A.

The **conditions of the restriction proposed by SEAC** are:

Substance Identity (or group identity)	Conditions of the restriction
1. Undecafluorohexanoic acid (PFHxA), its salts and related substances: (a) having a linear or branched perfluoropentyl group with the formula C_5F_{11}- directly attached to another carbon atom as one of the structural elements; (b) having a linear or branched perfluorohexyl group with the formula C_6F_{13}-. 2. The following substances shall be derogated from this designation: (a) C_6F_{14}; (b) C_6F_{13}-C(=O)OH, C_6F_{13}-C(=O)O-X' or C_6F_{13}-CF2-X' (where X' = any group, including salts). (c) Any substance having a perfluoroalkyl group C_6F_{13}- directly attached to a sulphur atom. (d) Any substance having a perfluoroalkyl group C_6F_{13} -directly attached to an oxygen atom at one of the non-terminal carbons.	1. Shall not be manufactured, used 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 or used in: (a) another substance, as a constituent, (b) a mixture, (c) an article in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances. 3. Paragraphs 1 and 2 shall apply 36 months from entry into force of the restriction. 4. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3. 5. Paragraphs 1 and 2 shall not apply until XX XX XXXX [five years after the entry into force] to: (a) hard chrome plating; (b) photographic coatings applied to films and in printing plates;

	(c) concentrated firefighting foam mixtures that are used or are to be used in the production of other firefighting foam mixtures for cases of class B fires; this shall not apply to: (i) use of firefighting foam for training; and (ii) use of firefighting for testing unless all emissions to the environment are minimised and effluents collected are safely disposed of. 6. Paragraphs 1 and 2 shall not apply to latex printing inks until XX XX XXXX [seven years after the entry into force]. 7. Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to: (a) concentrated firefighting foam mixtures for cases of class B fires in tanks with a surface area above 400 m^2 and the bunded areas they are in; (b) semiconductors and semiconductor related equipment. 8. Paragraphs 1 and 2 shall not apply to any of the following: (a) 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; (b) personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (h), (l); (c) personal protective equipment specifically designed for armed forces and in the maintenance of law and order against the risk categories listed in paragraph 8(b) and protective clothing specifically designed for armed forces and in the maintenance of law and order or other emergency response workers; (d) high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3;

	(e) impregnation agents for re-impregnating of articles referred to in paragraph 8(b), (c), (d), (h); (f) textiles for the use in engine bays in the following usage groups: transport and non-road mobile machinery; (g) epilames used in watches; (h) medical devices as specified in Regulation (EU) 2017/745 of the European Parliament and of the Council; woven, knitted and nonwoven medical textiles as specified in Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795; in vitro diagnostic medical devices as specified in Regulation (EU) 2017/746 of the European Parliament and of the Council as well as parts thereof; (i) filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency for filters used in industrial settings or by professionals. 9. From (entry into force + 36 months), a natural or legal person placing a mixture or an article specified in paragraph 8(b)- 8(i) on the market for the first time and benefitting from the derogation therein shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing: (a) the identity of the substance(s) used in the previous year; (b) the quantity of PFHxA, its salts and PFHxA-related substances used in the previous year. The European Chemicals Agency shall forward the data to the Commission by 31 March every year. 10. The concentration limits referred to in paragraph 2 shall be: (a) XXX [*information on concentration limits requested in SEAC consultation*] for the sum of PFHxA and its salts in fluoropolymers;

	(b) XXX [*information on concentration limits requested in SEAC consultation*] for PFHxA related low molecular substances in fluoropolymers. 11. From (entry into force + 36 months), a natural or legal person benefitting from the derogation in paragraph 7(a) shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing: (a) a description of their efforts on substitution of firefighting foams that contain PFHxA, its salts and PFHxA-related substances; (b) quantities they used in the previous year of firefighting foams that contain PFHxA, its salts and PFHxA-related substances per sector specifying: (i) share in training and in operation (ii) whether emission was contained, collected and disposed safely or emitted into the environment. The European Chemicals Agency shall consolidate and forward the data to the Commission by 31 March every year. 12. Paragraphs 1 and 2 shall not apply to flat panel displays used in electrical and electronic equipment until XX XX XXXX [7 years after entry into force]. 13. Paragraphs 1 and 2 shall not apply to functional coating used in electrical and electronic equipment until XX XX XXXX [7 years after entry into force].

Explanatory notes for changes and clarifications proposed by SEAC

Left column:

SEAC agrees with RAC's proposal concerning the identity of substances in the scope of the restriction. SEAC notes that RAC proposes to add paragraph 2(d) because the substances referred to in point (d) are not able to be transformed to undecafluorohexanoic acid. Their chemical structure is such that a degradation to a carboxylic acid or to a carboxylate would necessarily form two separate shorter fluoroalkyl chains which have not been assessed in the restriction proposal.

Right column:

Paragraph 3

SEAC considers that, on the one hand, the transition period should be **long enough** to ensure that producers, importers and users of substances, mixtures and articles are able to comply with the restriction, e.g., in order to allow for required substitution activities and respective adaptations within supply chains. Several respondents to the consultation on the Annex XV report stated that substitution would only be possible for certain specific uses in 2-3 years. High costs or special transition arrangements for these uses could be avoided with a transition period of 36 months. On the other hand, SEAC considers that the transition period should be **sufficiently short** to avoid future manufacture, import or use of the concerned substances in the EU such that emission reduction can be achieved without unnecessary delay. A short transition period would also speed up the transition to alternatives in uses where suitable alternatives are already available and add an incentive to develop alternatives in the rest of the uses. Balancing these considerations, SEAC proposes a **general transition period of 36 months rather than the 18 months proposed by the Dossier Submitter**.

Paragraph 5(b)

SEAC does not support a derogation for photographic coatings applied **on paper** and coatings applied to **inkjet photo media**. SEAC notes that the Dossier Submitter highlights that impacts for this use are poorly understood and considers that more information is needed to conclude whether a derogation is necessary to avoid disproportionate impacts. In particular, information would have been needed on the product types to be covered, the potential emissions, costs of restriction and availability of alternatives (specifically why alternatives are not considered suitable, information on the timeframe of developing alternatives and on the main impediments of developing a suitable alternative).

Paragraph 5(c)

SEAC proposes that the derogation applies to firefighting foam mixtures for class B fires placed on the market before the entry into force of the restriction plus 36 months, instead of 18 months as in the Dossier Submitter's proposal. This is to align the derogation with the general transition period proposed.

In the consultation on the SEAC draft opinion, stakeholders requested that the text of the proposed derogation be made more explicit i.e. to state that it covers the manufacture, use and placing on the market of C6 fluorosurfactants for use in production of foam concentrates (comments #896, 947). SEAC agrees that it is the intention of the derogation to allow all these activities (otherwise the derogation could not be benefitted from in practice) but considers that the entry text is sufficiently clear as it is. SEAC notes that the final wording of the entry text will be proposed by the Commission.

SEAC suggests removing the separate time limit for placing on the market to avoid related practical difficulties (explained in the use-specific discussion in Annex E.6 of the Background Document).

Deleted: paragraph 6 from Dossier Submitter's proposal

SEAC considers that it has not been sufficiently demonstrated in the Background Document that alternatives to fluorinated firefighting foams considered suitable for civilian uses are not

also applicable for military uses over the transition period of 5 years proposed for firefighting foams for class B fires in general. Therefore, SEAC does not support a separate derogation for defence purposes. SEAC recalls that according to REACH Article 2(3), Member States may allow for exemptions from the REACH Regulation in the interests of defence. This option could be taken advantage of where necessary.

Paragraph 7(a)

During the consultation on the Annex XV report, industry stakeholders requested that the minimum tank size of 500 m^2 was reduced to 400 m^2 or that the tank size limit was removed altogether. The choice of 500 m^2 as minimum surface area of the tank for the derogation was not justified in the Annex XV report. The limit of 400 m^2 proposed in the consultation on the Annex XV report was not justified in detail either. However, it was confirmed that experience shows that fluorine free firefighting foams can extinguish fires up to 400 m^2. Moreover, industry stakeholders argued that a derogation is also needed for fires in secondary containment areas, or so called bunded areas. It was highlighted that a fire may burn outside a storage tank within the bund walls, where the surface area exposed to the fire reaches a multitude of the tank surface area itself. It was argued that the harm caused by a large fire, including environmental impacts, are immense. The Dossier Submitter considered that including the bunded area in the derogation would widen the coverage of the derogation too much; they estimated that such secondary containment areas usually have an area ten times larger than the surface area of the enclosed tanks. The Dossier Submitter, however, considered that a fire in the secondary containment area would be covered by the derogation in case the incident started as a tank fire.

SEAC considers that **the derogation should cover tanks with a surface area of >400 m^2 and the bunded areas that they are located in**. SEAC notes the concern of the Dossier Submitter about the derogation becoming wider by including the bunded area. However, considering the significant practical problems highlighted by stakeholders, SEAC considers that indeed the respective bunded area should be covered by the derogation, including any other smaller tanks located in the same bunded area, such that the same existing fixed system using one foam agent stock and the same pump room can be used and a scenario of the fire expanding to other places within the bunded area can be avoided. Although it is uncertain how many additional installations would be covered by the derogation after this modification, based on the information available, SEAC considers this is appropriate to ensure successful firefighting in those installations.

SEAC notes that a similar derogation might also be justified for types of installations other than tank farms. SEAC however considers that inclusion of further types of installations would make the derogation a lot wider and the information available does not allow to estimate the related impacts.

During the consultation on SEAC's draft opinion, several stakeholders (e.g. comments #889 and 935) proposed that instead of defining the derogation based on the tank size and the bunded area, a definition based on provisions laid down in Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (SEVESO-II-Directive) could be a better way to phrase this derogation. SEAC does not have the information to rephrase the derogation, but highlights that a restriction on the use of PFASs in firefighting foams is currently being prepared by ECHA (to be submitted in January 2022), which SEAC expects to contain clarifying information on this issue, as it is specifically targeted to the firefighting sector.

Paragraph 7(b)

SEAC highlights that it was reported by industry stakeholders that they consider the wording unclear in terms of coverage. They stated that it would be necessary to clearly cover both semiconductor manufacturing equipment and semiconductor manufacturing processes in the entry text.

A specific wording proposal was made in comment #853: "Semiconductor manufacturing process, semiconductor product (or semiconductor itself), semiconductor manufacturing equipment, and semiconductor incorporated in semi-finished and finished electronic equipment".

SEAC agrees that it is the intention of the proposed restriction to cover all this by the derogation.

SEAC agrees that entries should be made as clear as possible. SEAC considers that the term "semiconductor related equipment" is not completely unequivocal, and this could cause problems for enforcement authorities and some industry actors, and therefore the proposed text not containing this term might be more appropriate.

However, SEAC suspects that if the proposed change to the entry text was made, it might also prevent some applications now covered by the derogation. Specifically, it is not clear to SEAC if anti-adhesive coatings for semiconductor microelectromechanical systems (MEMS, micromachines; discussed in comments #860 and 893) would be covered. In case that would not be the case, a separate derogation of those should be considered, as SEAC supports a 12-year derogation also for MEMS. A wording proposal was included in comment #860, reading: "Paragraphs 1 and 2 shall not apply to anti-adhesive coatings for semiconductor microelectromechanical systems (MEMS, micromachines), including raw materials for the synthesis of the coating precursors". SEAC notes that the wording of the entry text will be proposed by the Commission.

Paragraph 8(b)

Derogations are proposed for personal protective equipment against "risks that may cause very serious consequences such as death or irreversible damage to health" (category III of risk as per Annex I of Regulation (EU) 2016/425 of the European Parliament and of the Council). In particular, the derogation applies to personal protective equipment against category III of risks that are related to the following:

- substances and mixtures which are hazardous to health (a);
- harmful biological agents (c);
- ionising radiation (d);
- high-temperature environments (e);
- low-temperature environments (f);
- falling from a height (g) (not supported by SEAC after the consultation on the SEAC draft opinion);
- electric shock and live working (h);
- bullet wounds or knife stabs (l).

Paragraph 8(c)

During the consultation on the Annex XV report, industry stakeholders reported that Regulation (EU) 2016/425 does not apply to PPE specifically designed for use by **the armed forces or in the maintenance of law and order** and that these uses might need a dedicated derogation. SEAC agreed that continued use for such items appears necessary and notes that there are uncertainties as to whether the derogation in paragraph 8(b) would also cover PPE for risk category III (l) such as bullet-proof clothing or jackets for the military and police. SEAC considers that the availability of such articles should not be affected by the proposed restriction. In relation to equipment used by armed forces, SEAC notes that where necessary in the interests of defence, Member States could make use of the possibility to allow exemptions according to REACH Article 2(3). However, this would not cover similar articles used by law enforcement. Therefore, SEAC proposes a specific derogation for PPE for armed forces and in the maintenance of law and order.

SEAC considers that the wording of 8(c) should be chosen in a way that ensures that the relevant uniforms/ protective clothing would be covered, but other clothing and textile, not requiring specific high-quality liquid (oil) repellence, would not.

It was suggested in the consultation on the SEAC draft opinion that as the military does not refer to their personal clothing and equipment provided for training and operational use as "personal protective equipment", this term should not be used for the derogation concerning armed forces but instead the term "personal equipment" (comment #957) should be used. SEAC acknowledges that it may be difficult for military personnel to select the correct equipment in advance, considering potential unknown scenarios. However, SEAC does not have information on the types of articles that would be covered and, overall, how wide the derogation might become with such change and therefore cannot support such a proposal.

It was also proposed that the derogation would cover "Personal protective equipment **and articles** specifically designed for armed forces and in the maintenance of law and order" (comment #927). SEAC does not have sufficient information to understand how many and what kind of article types would be affected by such a wording and, therefore, cannot support this addition.

There are diverging views among stakeholders on whether protective clothing for firefighters, police and other emergency services are covered by the proposed derogations (comments #875, 864, 814). SEAC therefore suggests them to be explicitly added but recalls that it is the competence of the Commission to propose the wording of any restriction added to Annex XVII. SEAC notes that providing a definition of emergency services might be necessary but cannot make a specific proposal to that end.

Paragraph 8(f)

In the consultation on the SEAC draft opinion industry stakeholders requested that the derogation for engine bays should be widened to also include other parts of vehicles (comments #875, 857, 838, 847, 964). A specific drafting proposal was included in comment #964, reading:

> "Paragraphs 1 and 2 shall not apply to high performance technical textiles used for NVH (noise, vibration, harshness) insulation and engine ignition protection in means of transport, non-road mobile machinery as defined in Regulation 2016/1628, as well as large scale industrial tools and large-scale fixed

installations as defined in Directive 2011/65/EU."

However, this proposal was not accompanied with sufficient supporting information and therefore SEAC does not have sufficient information on the types of articles that would be covered by the proposed wording, the related volumes, the potential related emissions and the level of the expected socio-economic impacts. Therefore, SEAC does not suggest such a reformulation.

Paragraph 8(h)

The Dossier Submitter suggests a broad derogation for medical devices as specified in the Medical Device Regulation (MDR), incl. medical textiles, whilst noting that alternatives might be readily available or already in use for ***some*** of the medical devices that would be derogated (confirmed also by comments #849, 898 provided in the consultation on the SEAC draft opinion). The reasons for still suggesting a broad derogation are the following:

- no product-specific assessment could be provided by the Dossier Submitter, i.e. it could not be clarified by the Dossier Submitter or in the consultations ***which*** products can feasibly use alternatives and for which products a derogation is needed to ensure sufficient performance; and,
- most importantly, the Dossier Submitter and SEAC note that products used within this sector provide health- and life-protecting functions and restricting PFHxA, its salts and related substances might induce negative health and socio-economic impacts to society where use of alternatives does not currently achieve required performance levels.

SEAC notes that several issues associated with this derogation were not clarified by the Dossier Submitter, e.g.

- what exactly falls under the term "medical device";
- are medical textiles indeed covered by the term medical device as specified in the Medical Device Regulation 2017/745 (MDR) and, if yes, which ones;
- for which products are alternatives already on the market and for which products are derogations still necessary;
- the exact timeframe for the development and implementation of alternatives.

During the consultation on the SEAC draft opinion, stakeholders stressed the need to also derogate *in vitro* diagnostic medical devices, falling under the *In Vitro* Diagnostic Medical Device Regulation 2017/746. Whilst SEAC notes the high uncertainties connected to this broad derogation and the possible high emissions related to some of the products affected (e.g. some medical textiles), it concludes from the Dossier Submitter's assessment and the information provided by several stakeholders during the consultations that a derogation is needed, which can, based on the information currently available, not be better targeted (e.g. to specific products, product groups or similar). In other words, a broad derogation is supported by SEAC.

Therefore, SEAC concludes that the derogation should comprise medical devices (as suggested by the Dossier Submitter), medical textiles (which the Dossier Submitter concluded were covered by the MDR) as well as *in vitro* diagnostic medical devices defined under Regulation 2017/746 (not explicitly mentioned by the Dossier Submitter in their initial restriction proposal).

For medical textiles, SEAC recommends following the specification brought forward by EURATEX (comment #940) and supported by several stakeholders, requesting a derogation

for "*woven, knitted and nonwoven medical textiles as specified in Medical Device Regulation (EU) 2017/745 with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795".* SEAC, however, notes that the term "medical textile" itself is not specified or defined in the MDR. However, Art. 2 of the MDR contains definitions for medical devices and products that should be deemed to be a medical device. SEAC understands that the intention of this suggestion therefore is to refer to the product types that are specified in the MDR. In that way these definitions could be used to enable a specification of which medical textiles should indeed be covered by the derogation.[4]

SEAC notes that imposing the proposed condition for reporting (see paragraphs 9 and 11 in the entry) could help to refine this broad derogation in future.

Paragraph 8(i)

SEAC suspects that the absence of a definition for the term "**high-performance**" might cause problems in terms of understanding the coverage of the derogation and for enforcement. In the consultation on the SEAC draft opinion some stakeholders confirmed that they also consider the term problematic (comments #920, 855 , 868, 929). It was stated that "high performance" media would actually mean the same as media "that require a combination of water and oil repellency" and that the term could be deleted as redundant (comment #920). On the other hand, another stakeholder stated that they consider that including the term "high-performance" narrows the scope of the derogation (comment #840). They considered that the term indicates that a 'grade 8' repellent is required. SEAC concludes that it would not be appropriate to delete the term 'high-performance' but rather to define it. It is not clear to SEAC what the exact coverage of the derogation in terms of applications would be if confined to repellent 'grade 8', and since there is no possibility to test this term in another consultation, SEAC cannot make a suggestion to use this as a basis of a definition.

SEAC suggests to apply the derogation only to filters **used in industrial settings or by professionals** because it was reported in the consultation on the SEAC draft opinion that alternatives for consumer uses are available.

Paragraphs 9 and 11

SEAC reviewed the reporting requirements in line with the other conditions proposed. SEAC suggests that the reporting requirements would come into effect at the same time as the restriction, i.e. entry into force + 36 months. Whilst SEAC notes that the sooner the reporting obligation starts, the better from the point of view of collecting information, SEAC considers that it would improve the practicality and enforceability of the reporting requirements if the

[4] During SEAC-53 (discussion and adoption of the SEAC final opinion), a stakeholder from EURATEX clarified that the suggested definition for medical textiles brought forward during the consultation on the SEAC draft opinion by EURATEX and supported by several stakeholders does not sufficiently cover the range of products that should benefit from the derogation, e.g. plasters, as these products are not covered by the MDR. In other words, they would not benefit from the derogation, but in EURATEX's view (based on recent findings) they should. Furthermore, the stakeholder emphasised that derogations should focus on arguments around technical performance rather than being bound to legislative tools such as the MDR. SEAC notes the high uncertainties for this sector and the importance of the availability of sufficiently well-performing products providing health- and life-saving functions. As the specification for medical textiles provided initially by EURATEX was supported by several stakeholders during the consultation on the SEAC draft opinion and as SEAC has no information at hand on impacts of further amending this suggestion (provided as an oral intervention during SEAC-53 without any back-up information), SEAC cannot deviate from its proposal.

start date coincides with the date of implementation of the restriction. SEAC concludes that prescribing a communication requirement to actors in supply chains where a reporting requirement applies could be useful to avoid practical problems. This is further discussed in the Practicality section.

Paragraph 10, replacing paragraph 11 from the Dossier Submitter's proposal

SEAC would first like to clarify that the committee considers the term "fluoropolymer" to only cover polymers where the fluorine atoms are directly bound to the polymer backbone. Fluoroplastics and fluoroelastomers would be fluoropolymers, but side-chain fluorinated polymers would not.

SEAC cannot support the proposals for concentration limit values for fluoropolymers by either the Dossier Submitter or stakeholders (provided in the consultations), as none of these values was justified by sufficient supporting evidence. However, SEAC acknowledges that some special arrangement is needed.

SEAC agrees in principle that setting higher concentration limit values for fluoropolymers within the scope of the proposed restriction is appropriate. However, more information would be needed to give an opinion on the suitable level of the concentration limits. SEAC has listed the pros and cons of the proposed sets of limit values in Annex E.7 of the Background Document.

SEAC also concludes that any derogation should be formulated to ensure that both the manufacture of fluoropolymers (which would also necessitate the manufacture/import and use of the necessary processing aids) and their use in articles are covered. In the consultation on the SEAC draft opinion it was further specified that the legal text should make clear that not only pure fluoropolymers but also mixtures and articles containing them should benefit from the higher concentration limit (comments #946, 947). SEAC agrees that both mixtures and articles should also be covered and also agrees that the wording must be clear but defers the choice of any final wording to the Commission.

SEAC concludes that a reporting requirement alongside any derogation for fluoropolymers could be useful to collect information (on uses and concentrations in substances, mixtures and articles) to inform a review to be carried out at a later point. However, SEAC notes that this option was not assessed by the Dossier Submitter and that stakeholders have not been consulted on it.

Deleted: review clause from Dossier Submitter's proposal

Based on typical practice in restrictions, SEAC suggests deleting the review clause proposed by the Dossier Submitter. SEAC recalls that the European Commission can initiate a review of a restriction at any time and considers this could also be done in the context of future regulatory action on PFAS substances. However, **SEAC considers that several aspects of the proposed restriction should be subject to a review in due course, especially the derogations proposed under paragraphs 5(c), 7(a) and 8(b) to 8(h)**, as large uncertainties are associated with these derogations and with this restriction proposal in general. SEAC notes that some of these derogations could result in relatively large releases and are not time-limited. Furthermore, SEAC notes the potential need to also consider any new information, for example on analytical methods, and if appropriate modify the restriction conditions (e.g. concentration limits) accordingly. SEAC notes the Dossier Submitter's suggestion to carry out a first review six years after the entry into force of the restriction and

a subsequent review every three years if the above derogations are still considered necessary. **Based on the information available, SEAC cannot recommend any concrete timeframe for performing a review** but notes that this should be aligned with the timeframes of reporting in order to allow for the collation and evaluation of the information received.

3. Summary of the SEAC opinion

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, the opinion of RAC, as well as other available information as recorded in the Background Document. SEAC agrees that action is needed on an EU-wide basis, and that a restriction is, in general, an appropriate measure to address the identified risks.

SEAC considers, however, that it has not been demonstrated that the restriction as initially proposed by the Dossier Submitter is the most appropriate Union wide measure to address the identified risks. Even if SEAC cannot conclude whether the conditions of the proposed restriction, as modified by SEAC, are the most appropriate measure to address the identified risks either, SEAC proposes conditions based on the currently available information.

PFHxA, its salts and related substances are widely used in many sectors. Due to large uncertainties in the quantitative emission reduction estimates and cost assessment presented by the Dossier Submitter, SEAC had to base its evaluation of the potential impacts mainly on qualitative information. These uncertainties do not allow use of emission reduction estimates as starting point for SEAC's evaluation of benefits as has been the practice in restriction proposals for similar substances.

SEAC provides its views on derogations considering RAC's conclusions on conditions of use and the effectiveness of risk management measures, availability and costs of alternatives as well as functional losses and reduced product quality and their consequences in terms of socio-economic impacts. SEAC conclusions on each sector and the related uncertainties are discussed in the opinion justification sector by sector. The main uncertainties relate to lack of information on releases and economic impacts. Table 7 of the opinion justification provides an overview on cost estimates, alternatives, RAC's conclusion on uses, releases and emission minimisation as well as proportionality aspects and derogations per sector.

SEAC considers that the proposed restriction is in general practicable, enforceable and monitorable. However, SEAC notes Forum's opinion that the restriction can be regarded as enforceable, as long as it is clear which substances are in the scope of the restriction and that reliable normative test methods are defined covering all types of regulated substances. SEAC agrees that these are relevant points to clarify to improve the enforceability.

4. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

4.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

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

Since the restriction of perfluorooctanoic acid (PFOA; C8), the use of perfluorohexanoic acid (PFHxA) -related C6-chemistry has become widespread. The purpose of the proposed restriction is to reduce current environmental emissions of PFHxA, its salts and related substances from all industrial, professional and consumer uses, including imported articles.

Structural relationships of PFHxA to other perfluorinated carboxylic acids (PFCAs)

Undecafluorohexanoic acid, commonly known as perfluorohexanoic acid (PFHxA), is a per- and polyfluoroalkyl substance (PFASs) and part of the group of perfluorinated carboxylic acids (PFCAs). Other PFCAs include perfluorooctanoic acid (PFOA), restricted under Regulation (EU) No 2020/784, as well as perfluorononanoic acid (PFNA) and perfluorodecanoic acid (PFDA), part of the C9-C14 PFCAs group that have been proposed for restriction under REACH[5]. All PFCAs share the same functional group (CO_2^-), differing only in their perfluorinated carbon chain lengths. Figure 1 shows the structural relationships of the ionised forms of the salts and acids of PFHxA, PFOA, PFNA and PFDA.

PFASs are characterised by the extremely strong and stable C–F bond. The perfluoroalkyl moiety has high chemical and thermal stability, together with both hydrophobicity and lipophilicity, which provides favourable technical properties for use in surfactants and polymers. PFAS applications include surface treatments such as textile impregnation and greaseproof food-contact materials as well as use as processing aids for fluoropolymer manufacture and in aqueous film–forming foams to extinguish flammable liquid fires.

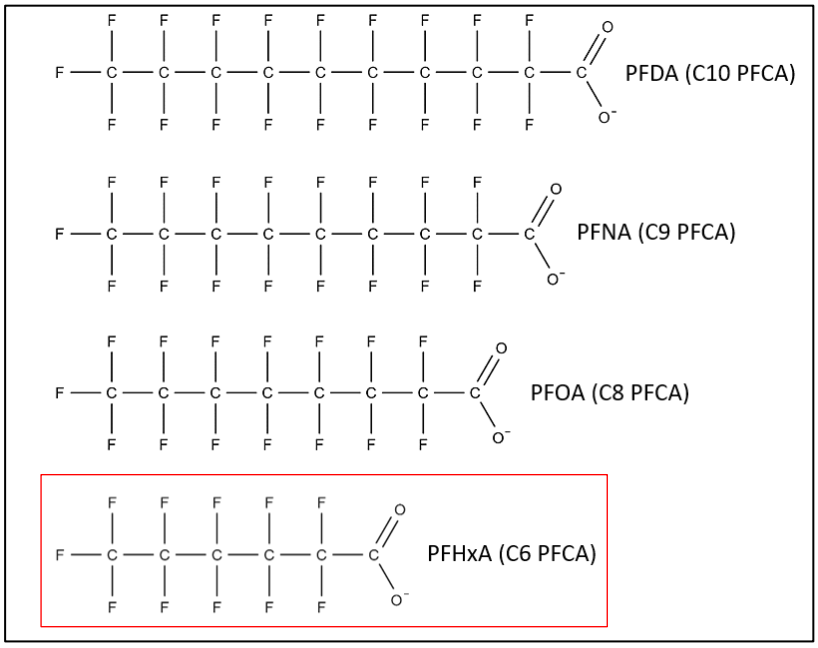

Figure 1. Structural relationship of perfluorohexanoic acid (PFHxA) to the other

[5] https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e18195edb3

perfluorinated carboxylic acids perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA) and perfluorodecanoic acid (PFDA).
PFHxA-related substances, side-chain fluorinated polymers and fluoropolymers

PFHxA-related substances, i.e. substances that can degrade to PFHxA, are included in the scope of the proposed restriction. These include low-molecular weight substances such as 6:2 fluorotelomer acrylate. PFHxA-related substances also include polymers with perfluorinated side-chains that can degrade to PFHxA, so called C6 side-chain fluorinated polymers (C6-SFPs). Fully fluorinated polymers (fluoropolymers), such as polytetrafluoroethylene (PTFE), cannot degrade to PFHxA and are therefore outside the scope of the proposed restriction, unless their composition contains one or more of the substances within the scope of the proposal as a constituent or impurity. Examples are shown in Figure 2.

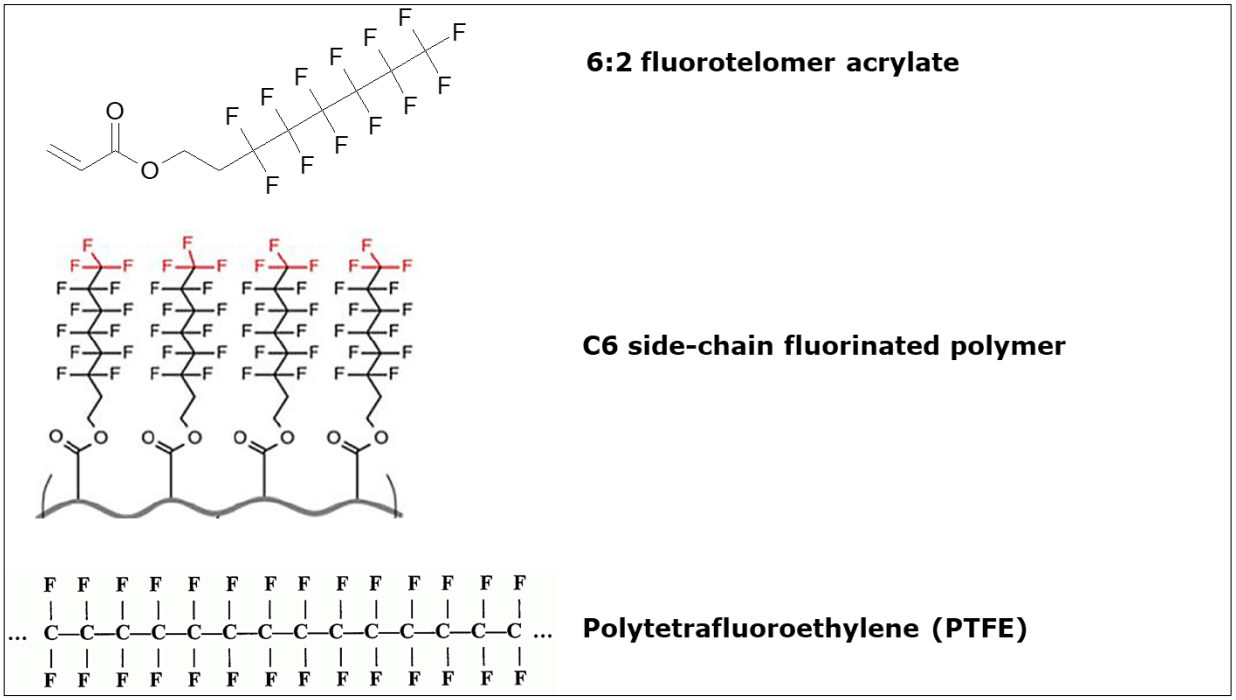

Figure 2. Examples of PFHxA-related substance: 6:2-fluorotelomer acrylate, a C6 side-chain fluorinated polymer (C6-SFP), i.e. a polymer with a side-chain containing 6 perfluorinated carbons that can degrade to PFHxA. Polytetrafluoroethylene, on the other hand, cannot degrade to PFHxA and is therefore not a PFHxA-related substance.
Summary of the Dossier Submitter's proposal:

The proposal aims to restrict PFHxA (in either linear or branched form), its salts and related substances. The risk assessment applies the 'case-by-case' approach described in paragraph 0.10 of Annex I to REACH6, i.e. where a standard quantitative risk characterisation or PBT/vPvB assessment is not considered to be practicable. The overall assessment is qualitative, but it contains quantitative elements, i.e. an assessment of data on physical and chemical properties, conclusions on hazards and related concerns and an exposure

[6] Para 0.10 of Annex I to REACH: In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and shall be summarised in the safety data sheet.

assessment.

In addition to PFHxA, the restriction also covers its salts and related substances which are known or expected to transform (salts) or degrade (related substances) into PFHxA. PFHxA related substances are defined as those with linear or branched perfluoropentyl- or perfluorohexyl chains. This terminal degradation approach, sometimes referred to as the "arrowhead" approach, where the arrowhead is the final product -PFHxA - has been used in this case and is consistent with previous restriction proposals under REACH for:

- PFOA (perfluorooctanoic acid), its salts and related substances (ECHA, 2015a),
- C9-C14 PFCAs (perfluorocarboxylic acids), their salts and related substances (ECHA, 2018) and
- PFHxS (perfluorohexane sulfonate), its salts and related substances (ECHA, 2019a).

Consequently, substances covered by the restriction proposals for PFOA and PFHxS, and their salts and related substances are excluded from the scope of the proposed restriction as well as a single fully fluorinated C6 substance, which is not expected to degrade to PFHxA. Also excluded are other longer-chain PFCAs, including perfluoroheptanoic acid (PFHpA) and its related substances.

Biotic and abiotic degradation of PFHxA-related substances is expected to form PFHxA via the same degradation pathways as demonstrated for PFOA-related substances and for C9-C14 PFCA-related substances. The rate of degradation varies for different PFHxA-related substances and the process may in some cases take years, decades or even longer. Although limited information on the rate of formation of PFHxA from PFHxA-related substances has been published, some PFHxA will, nevertheless, eventually be formed and inclusion of PFHxA-related substances in the scope is thus warranted.

Forty-five substances within the scope of the proposed restriction are currently registered under REACH, while a CLP notification has been submitted for a further 73 substances. It is expected that even a larger number of substances that would be within the scope of the proposed restriction are currently imported in articles and in formulations.

RAC conclusion(s):

RAC agrees with the substance scope proposed by the Dossier Submitter, covering PFHxA, its salts and related substances. RAC identified a specific group of substances within the Dossier Submitter's scope that are unable to degrade to PFHxA, and are thus not PFHxA related substances, and recommends that a further derogation is added to ensure that the scope is focussed on PFHxA related substances. The use of read-across to the closely related homologues PFOA and perfluorobutanoic acid (PFBA) and their related substances is supported and there are no indications that these longer and shorter chain 'close' homologues are different in terms of their degradation and persistence. The scope follows the same terminal degradation ('arrowhead') approach that was used in the previous EU restriction processes for other PFCAs: PFOA, C9-C14 PFCAs and PFHxS. The scope definition includes substances that can degrade to PFHxA and excludes substances that are considered not to degrade to PFHxA (e.g. a fully fluorinated C6 carbon chain) as well as PFASs covered by previous restriction opinions, e.g., PFOA and PFHxS (incl. their salts and related substances).

Key elements underpinning the RAC conclusion:

The substance scope of the proposed restriction, i.e. PFHxA, its salts and related substances follows the same approach that was supported by RAC in the previous restriction proposals for the perfluorinated carboxylic acid homologues: PFOA, C9-C14 PFCAs, and PFHxS. However, RAC notes that unlike the previous restrictions the proposed scope does not exclude

Cl and Br atoms bonded to the perfluorinated carbon chain (i.e. the C_6F_{13}- moiety in the proposed restriction). Only a fluorine atom bonded to the C_6F_{13}- moiety is considered sufficiently stable to be excluded from the scope, i.e. not having the potential to degrade to PFHxA. The Dossier Submitter motivates this difference in scope based on the lack of any data on the degradation of Cl or Br connected to the C_6F_{13}- moiety. RAC supports this broader scope, noting that no data which might demonstrate the lack of formation of PFHxA of Cl and Br bonded to the C_6F_{13}- moiety became available during the consultation on the Annex XV report.

Information on a substance having the same number of fluorine-carbon bonds as PFHxA, and therefore within the Dossier Submitter's scope, was submitted during the consultation on the Annex XV report. Due to an oxygen attached to one of the non-terminal fluorinated carbons, RAC acknowledges that this substance cannot form PFHxA when/if it degrades and should be excluded from the scope of the proposed restriction. RAC notes that there may be additional substances having an oxygen entity attached in the same way to the fluorinated carbon backbone and therefore recommends that substances with this structure are excluded from the scope of the restriction. RAC has proposed suitable wording to this effect for the entry.

RAC considers that the Dossier Submitter presented sufficient evidence on the formation of PFHxA from PFHxA-related substances to support the inclusion of PFHxA-related substances (as defined in the entry) in the scope noting that the rate of formation may vary.

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

4.1.3. Information on hazard(s)

Summary of the Dossier Submitter's proposal:

The Dossier Submitter discussed the properties of PFHxA in relation to potential concerns for the environment and human health associated with its persistence, mobility, potential for long-range transport, enrichment in plants, effects on human health and the environment as well as bioaccumulation. Altogether, the Dossier Submitter considered that the combination of concerns, with the exception of bioaccumulation, was of sufficient concern to warrant risk management.

Persistence

The half-life of PFHxA is considered to far exceed the vP criteria in Annex XIII to REACH. The carbon-fluorine bonds provide a very high degree of stability to the substances within the scope of the proposed restriction. Considering the similar structural chemistry of the whole PFCA group it seems very likely that PFHxA is as resistant to degradation as PFOA (half-life > 92 years). Thus, because of this extreme persistence, PFHxA will remain in the environment for decades to centuries after its initial release. As long as PFHxA emissions to the environment continue, including from degradation of PFHxA related substances, this will inevitably lead to an increase in environmental concentrations of PFHxA over time.

Mobility

PFHxA predominantly resides in the aquatic compartment due to its low to moderate adsorption potential, high water solubility and low to moderate tendency to volatise from water to air. These properties make PFHxA mobile in the aquatic environment. Once PFHxA has entered the aquatic environment, e.g., surface waters, there are limited fate processes that would prevent it from being distributed to groundwater and to the marine environment.

Potential for long-range transport

Modelling data indicate that the combination of extreme persistence and mobility lead to a high potential for long-range transport in the environment, which takes place via the atmosphere and oceanic currents. This may also apply to PFHxA-related substances to varying degrees. Occurrence of PFHxA in remote regions such as the Canadian Arctic Ocean or snow in the European Alps has been confirmed by measurements. Thus, vulnerable remote ecosystems are currently exposed to PFHxA.

Removal of PFHxA contamination

Due to its physical-chemical properties, PFHxA is difficult if not impossible to remove from water. This is of relevance for the production of drinking water from raw water, for the treatment of wastewater and for the remediation of contaminated sites. End-of-pipe techniques cannot typically be used to minimise contamination and contamination that has already occurred is likely to be irreversible.

Enrichment in plants

Due to its relatively high-water solubility, PFHxA in soil pore water can accumulate in plants, especially in edible parts, e.g., tomatoes, cabbage, zucchini, lettuce and maize. Such accumulation results in indirect exposure to humans and animals via the environment (i.e. as a result of eating those plants).

Effects on human health

PFHxA is reported to cause adverse effects in sub-acute, sub-chronic and chronic animal toxicity studies. In a developmental toxicity study in mice (Hoberman 2011a), at a dose of 500 mg/kg bw/d a significant increase in the number of stillborn pups and pups dying on day 0 postpartum was observed together with a lack of maternal toxicity. There was a significant dose-related reduction in average pup weight per litter on day 0 postpartum observed at 175 mg/kg bw/d and higher doses. The effects on reproductive toxicity were considered to be adverse. Other treatment-related changes include reduction in thyroid hormone (T3 and T4) levels in rats (NTP, 2018), which the Dossier Submitter used as critical effect to derive a DNEL for PFHxA (0.03 mg/kg bw/d for long-term oral exposure).

Other concerns raised by the Dossier Submitter in relation to effects on human health are the co-exposure to other similar PFASs, potential synergistic effects with other chemicals due to increase of cell membrane permeability, and high systemic exposure via protein binding in blood serum (see section on bioaccumulation below).

Effects on the environment

Standard laboratory studies on aquatic organisms show no effects of PFHxA at environmentally relevant concentrations. However, with regard to the extreme persistence of PFHxA and its expected presence in the environment for decades to centuries, the Dossier Submitter considers the results of standard (eco)toxicity tests to be of limited value as they do not cover e.g., cross-generational effects. In addition, the presence of other PFASs (e.g., PFOA, PFHxA, PFHxS, PFOS, PFBA, PFHpA) in the environment, that are also highly persistent and act in a similar manner, i.e. that could act as a mixture, complicate the assessment of ecotoxicity. The Dossier Submitter further notes that there is a concern that PFHxA is an endocrine disruptor for the environment, although the available data are insufficient to draw a definite conclusion. The same applies to two PFHxA related substances (6:2 FTA and 6:2 FTMA) that are undergoing REACH substance evaluation regarding their endocrine disrupting

properties in the environment.

Bioaccumulation

PFCAs are known to be more bioaccumulative in air-breathing organisms compared to aquatic organisms and elimination half-lives have been shown to be of importance for long-chain PFASs. For PFHxA, considerably lower half-life values are reported in comparison to the half-lives of PFOA and PFHxS. The Dossier Submitter concluded that PFHxA does not fulfil the bioaccumulation criterion of REACH Annex XIII.

However, the Dossier Submitter does consider that the strong protein-binding potential of PFHxA facilitates distribution to plasma, kidney and liver in laboratory mammals.

RAC conclusion(s):

RAC agrees that PFHxA, its salts and related substances possess properties, in particular extreme persistence combined with mobility, that can be considered to constitute an intrinsic hazard. Although only the persistent (and very persistent) criterion of REACH Annex XIII is met, RAC considers that the additional concern for 'mobility' justifies the Dossier Submitter's proposal to apply the 'case-by-case' approach to risk assessment described in paragraph 0.10 of Annex I to REACH[7], i.e. where a standard risk assessment is not considered to be practicable.

In addition to its extreme persistence and mobility in the environment, PFHxA is difficult, if not impossible, to remove from drinking water and contaminated sites. Any PFHxA emitted to the environment or formed *in situ* from the degradation of related substances, will add to an increasing and globally distributed permanent environmental stock. This will result in continuous and increasing exposures of both wildlife and humans exposed via the environment. Although the database on effects on the environment and human health is limited, the information available points towards comparable adverse effects as seen for closely related PFCAs (to which co-exposure is noted to occur). Consequently, RAC is of the opinion that long term exposure may lead to adverse effects on the environment and human health, and in the event of such effects, they cannot be reversed. RAC notes that the potential for human exposure through the food-chain is also clear.

Key elements underpinning the RAC conclusion(s):

Assessment of PFHxA properties of concern

PFHxA has a combination of intrinsic properties that leads to a concern, including its extreme persistence, low adsorption potential, high-water solubility, low volatility and the potential to cause adverse effects. RAC considers the two main properties of concern to be the extreme persistence and mobility in the environment, exacerbated by the fact that once PFHxA has entered the environment, it is very difficult or impossible to remove from drinking water or contaminated sites. RAC notes that the available adsorption and volatilisation data appear to underestimate the mobility of PFHxA as is evident from the available studies on drinking water and environmental monitoring.

Persistence and build-up of PFHxA in the environment

[7] Para 0.10 of Annex I to REACH: In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and shall be summarised in the safety data sheet.

RAC notes that it is well established that PFCAs, including PFHxA, are very stable organic substances whose persistence in the environment greatly exceeds the very persistent (vP) criterion in Annex XIII of REACH (ECHA, 2013a). RAC agrees that emitted PFHxA will remain in the environment for a very long time (decades to centuries), and if emissions do not cease, a permanent environmental stock will continue to build up.

Mobility, long-range transport and removal of PFHxA from drinking water

Low adsorption of a substance to organic carbon (and minerals) in soil, sediment and/or sludge is pivotal to be regarded as mobile. For PFHxA, a number of log K_{OC} values are reported in the Background Document, ranging 1.3 to 3.6, which corresponds to K_{OC} values of around 20 to 4 000 L/kg. Under REACH, substances with log K_{OC} >3 are generally considered as being adsorptive (ECHA, 2016a). The range of reported K_{oc} values thus extends from very low to a substantial adsorption potential. The large range cannot be fully explained, except that the available studies did not follow standardised test guidelines and, as such, there were methodological differences between different studies (e.g. column elution vs. batch adsorption; laboratory vs semi-natural setup) as well as differences in the characteristics of the matrices used (e.g. sludge vs soil; amount of water, organic matter and clay). RAC notes that the higher values indicate substantial adsorption, i.e. log K_{OC} values of 3.0 and 3.6, are obtained from a single study where samples were taken at two depths (40 and 60 cm, resp.) from a water-saturated sediment column that was fed with surface water to simulate riverbank filtration (Vierke et al., 2014). How these values compare to other column studies cannot be determined, as the only other available study for PFHxA that used a similar test setup (although under water-unsaturated conditions), did not calculate distribution coefficients (Gellrich et al., 2012). Both studies did, however, include longer-chain PFCAs and showed that longer chain PFCAs consistently leach more slowly through the column compared to PFHxA (Vierke, 2014; Gellrich et al., 2012). Other studies have reported that PFHxA adsorbs less readily compared to longer chain PFCAs (e.g. Ahrens et al., 2010a; Zhang et al., 2013a; Campos Pereira et al., 2018). This difference in adsorption behaviour can also explain why longer chain PFCAs are more efficiently removed during drinking water during treatment compared to PFHxA (McCleaf et al. 2017; Sun et al., 2016; Rahman et al., 2014; Eschauzier et al., 2012). The low removal efficiency not only affects the production of drinking water but also means that emissions cannot be effectively minimised and that the contamination of the environment that has already occurred is likely to be irreversible. The low adsorption potential of PFHxA is also supported by other available adsorption data presented in the Background Document, with log K_{OC} values reported for PFHxA amounting to 1.3 (average of range 0.2 - 1.8) (Campos Pereira et al., 2018), 1.31 (Guelfo and Higgins, 2013), 1.63 – 2.35 (Sepulvado et al., 2011) and 2.1 (Labadie and Chevreuile, 2011). Considering all above data, RAC is of the opinion that while there are some uncertainties associated with the available adsorption data, **it can be concluded that PFHxA has a low adsorption potential**.

The Dossier Submitter considered PFHxA to have a low to moderate tendency to volatise from water to air based on a Henry's Law Constant (HLC) of 5.3 Pa m³/mol. The HLC was calculated using a molecular weight of 314 g/mol, an experimentally determined water solubility of 15.7 g/L (ambient temperature), and an estimated vapour pressure of 264 Pa at 25 °C (EPI Suite. v4.11.). RAC notes that the Background Document reports an experimental/calculated pK_a of -0.16 for PFHxA (Zhao et al., 2014) from which it can be concluded that at environmentally relevant conditions (ambient temperature, neutral pH) PFHxA will be present in the aquatic environment practically entirely in the anionic form. Basing the HLC on the vapour pressure determined for the acid form, would thus greatly overestimate the volatility from water to air. Therefore, RAC considers it more appropriate to calculate the HLC using the vapour pressure of the dried substance (ionic form), as has been done for another PFASs, the dimer acid of

hexafluoropropylene oxide (HFPO-DA) (ECHA, 2019b). For the ammonium salt of PFHxA, which is solid at 20 °C, the Background Document reports a molecular weight of 331.08 g/mol, an experimentally determined vapour pressure of 0.005 Pa at 25 °C and an experimentally determined water solubility of 57.61 g/L at 20 °C. Using the formula HENRY = VP · MOLW / SOL from ECHA guidance R.16 (ECHA, 2016a), a HLC of 2.87. 10^{-5} Pa m³/mol is obtained. RAC notes that the HLC is far below the trigger of >250 Pa m³/mol, which is given in REACH guidance R.16 for volatile substances, and even far below the 1 to 10 Pa m³/mol that is indicated in the OECD guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD, 2019) as a threshold for substances that can already significantly volatilise under vigorous mixing conditions where the opportunity for water/air exchange is high.

Contrary to PFHxA, the PFHxA-related substance 6:2 FTOH is considered to volatilise readily from water to the atmosphere with HLC values of 317 and 775 to Pa m³/mol. These values were calculated using the above formula and physical chemical data on the ECHA website, i.e. a molecular weight of 331.08 g/mol, vapour pressures of 18 and 44 Pa both determined at 25 °C using gas-phase NMR and the Scott Method, respectively, and an experimentally determined water solubility of 18.8 mg/L at 22.5 °C.

Based on the above, RAC concludes that **PFHxA is highly soluble in water and will not volatilise** to the atmosphere to any substantial extent, while the PFHxA-related substance 6:2 FTOH is expected to volatilise readily to the atmosphere.

Overall, RAC considers that PFHxA has a low adsorption potential, which in combination with a high-water solubility and a low volatility supports a view that **PFHxA is mobile in the aquatic environment**. PFHxA emitted to surface water will remain there and will be distributed to other aqueous compartments, while PFHxA emitted to the soil will leach to ground water. Soil and sediment thus do not act as sinks. These conclusions are supported by monitoring data presented in the Background Document showing that PFHxA leaches from soil to groundwater (e.g. Eschauzier et al., 2013), and can be widely distributed via waterways even reaching the marine environment (e.g. Ahrens et al. (2010); Benskin et al. (2012); Zhao et al. (2012)). The Background Document also reports the presence of PFHxA in snow and air from remote regions (i.e. European Alps and Polar research station) (Benskin et al., 2012; Kirchgeorg et al., 2013). The only feasible route for the findings is long-range transport by atmosphere, most likely due to volatile PFHxA related substances, such as 6:2 FTOH. Overall, RAC considers that PFHxA has the potential to reach remote and pristine areas by long-range aquatic and atmospheric transport.

RAC notes that PFHxA has no known natural sources, and thus when it is detected in the environment far from emission points this is a strong indication of the mobility of PFHxA and/or its related substances. It also demonstrates that PFHxA releases to the environment are of relevance on a global scale even though sources would be geographically limited.

Bioaccumulation and enrichment in plants

PFHxA has the potential to bioaccumulate, as do other PFCAs, primarily via protein binding and not by partitioning into lipids. PFHxA does not bioaccumulate to a significant extent in fish due to its high-water solubility. While PFOA (PBT) and PFHxS (vPvB) have serum elimination half-lives in humans of years, the corresponding half-lives amount to a month for PFHxA in humans and to a few days in other mammals. RAC considers that PFHxA does not have a particularly high bioaccumulation potential.

As PFHxA has high water solubility and is not strongly adsorbed to soil, it remains bioavailable to plants via the soil pore water. Several studies ((Felizeter et al., 2012); (Felizeter et al.,

2014); (Krippner et al., 2014)) have shown that PFHxA is taken up by plants and can enrich, especially in the edible parts (Blaine et al., 2013; 2014). Consumption of these parts by plant-eating wildlife and humans can contribute significantly to the total exposure to PFHxA.

Effects on human health

RAC notes that PFHxA has the potential to cause adverse effects in animal models, e.g. mice, although the database is rather small. The perinatal mortality reported in mice follows the same developmental toxicity pattern as has been observed for PFOA (C8) and PFNA (C9), which have a harmonised classification as Repr. 1B (H360D and H360Df, respectively), as well as for PFHpA (C7) that was regarded as Repr. 1B by RAC (H360D) (ECHA, 2020d). However, PFHxA has not been assessed for harmonised classification.

Other concerns for human health raised by the Dossier Submitter are considered supportive to the overall concern but do not constitute the major basis for the current restriction proposal. Co-exposure to other PFASs may increase the concern for combined exposure resulting in an increased toxicity. The high degree of binding to albumin in blood provides for widespread tissue distribution. However, any toxic effect of the substances is dependent on the degree of unbound substance ("free fraction") allowed to enter tissues and systemic exposure *per se* does not equal toxicity. The possibility for PFHxA to increase uptake of other substances via increased cell membrane permeability needs further exploration before its relevance can be addressed.

Effects on the environment

RAC notes that the aquatic toxicity of PFHxA to algae, aquatic invertebrates and fish is limited, and that while it appears that PFHxA interacts with the hypothalamic–pituitary–thyroid axis (HPT axis), the available *in vitro* and *in vivo* fish data are as yet insufficient to conclude on the endocrine properties of PFHxA in the environment (not evaluated by RAC but subject to Substance Evaluation under REACH).

RAC agrees with the Dossier Submitter that exposure to PFHxA would occur across multiple generations, as PFHxA is extremely persistent and remains bioavailable. Effects resulting from such multi-generational exposure, referred to as inter-generational effects by the Dossier Submitter, are not assessed in standardised OECD test guidelines for environmental toxicity that generally span one life-cycle or less. Ecotoxicological studies that expose test organisms for several consecutive generations are rarely conducted and while they might result in more sensitive endpoints, this remains unclear for PFHxA.

4.1.4. Information on emissions and exposures

Summary of Dossier Submitter's proposal:

Environmental and human monitoring data

Based on monitoring data for PFHxA in surface waters, the Dossier Submitter calculated the **current pollution stock of PFHxA** in European territorial coastal surface waters to be 144 t PFHxA, 16 500 t PFHxA in the North Atlantic Ocean, 700 t in the Mediterranean Sea and 6 t in the Baltic Sea. This estimate is based on the Dossier Submitter's assumption that PFHxA is evenly distributed in the water column.

Monitoring data on the concentration of PFHxA and related substances in house dust, in humans, in consumer textiles, drinking water, surface waters, marine water, soil and biota across Europe are reported in the Background Document (see Appendixes and Annex B.9). These data provide evidence of widespread exposure. PFHxA was detected in various matrices

and environmental compartments including surface water, marine water, drinking water, groundwater, WWTP effluent, sediment, soil, landfill leachate, atmosphere, house dust and biota. The monitoring locations were globally distributed and included remote locations such as the arctic and the deep sea. Concentrations in the Atlantic and Arctic Oceans have been reported on the range of <0.0024 to 0.12 ng/L, while sedimentary particles sampled at a depth of 1 000 m in the north-western Mediterranean Sea (Cap de Creus Canyon) contained 4.57 to 10.66 ng/g. The PFHxA concentrations in European surface water are generally in the lower ng/L range (<LOD/LOQ up to 77 ng/L), but higher concentrations, up to 3 040 ng/L in the industrialised Ruhr area, have also been recorded. Drinking and tap water are reported to contain PFHxA, with one study reporting that PFHxA was detected in 86% of tap water samples from six European countries in the low ng/L range (<0.38 – 5.15 ng/L) (Ullah et al., 2011). Concentrations of PFHxA in tap water sampled from the industrialised Ruhr area of Germany are reported to be higher compared to the rest of Germany (Skutlarek et al., 2006). Regarding groundwater, PFHxA was detected in locations downstream of local sources in the low ng/L range (0.22 – 0.8 ng/L). PFHxA was also reported to be detected in soil and sediment with concentrations being reported in soils from polluted areas of 0.18 up to 2 761 µg/kg. PFHxA was also detected in the air in remote polar regions with a high detection frequency in 2013, whereas in 2016 PFHxA was detected in only ~20% of the samples (NILU, 12014,2016).

Methodology for estimating releases

The Dossier Submitter estimated emissions of PFHxA, its salts and related substances using various approaches. For some uses emissions were calculated using Environmental Release Categories (ERCs) (ECHA, 2016). For some sectors, Specific Environmental Release Categories (SPERCs) were used and in certain cases information provided by industry or from the scientific literature was used. The Dossier Submitter estimated releases using emission factors in combination with the use volumes.

The Dossier Submitter estimated releases to the environment from different life-cycle stages comprising:

i. the manufacture of PFHxA, its salts and related substances, including the manufacture of C6 side-chain fluorinated polymers (C6-SFPs),
ii. use in industrial processes including use as polymerisation processing aids and as a monomer, for the treatment of textiles, manufacture of greaseproof paper and cardboard (food contact materials), use in firefighting foams, use in inks and photographic applications and chrome plating,
iii. article service life,
iv. waste stage through landfilling, based on an assumption that 60% of waste arising is assumed to be landfilled.

Estimates incorporated both direct and indirect releases of PFHxA to the environment. Direct sources comprise releases from EEA-based manufacture of a PFHxA salt and releases resulting from the use of this compound in products and articles. Indirect releases of PFHxA to the environment are a result of the environmental degradation of PFHxA related substances, differentiating between side-chain fluorinated polymers (C6-SFPs) and low-molecular weight PFHxA-related substances.

Emissions of low molecular weight PFHxA-related substances and C6-SFPs were converted to PFHxA equivalents using a conversion factor based on the potential for transformation/degradation into the PFHxA 'arrowhead' by mass. For the conversion of C6 low molecular weight PFHxA-related substances to PFHxA the degradation behaviour of 6:2 FTOH was used as a surrogate.

The Dossier Submitter also addressed releases from semiconductors and semiconductor related equipment, mixtures for consumer uses and building materials/construction products, but no quantitative estimates of emissions were provided for those sectors.

The Background Document also provides a short analysis of the concentration of PFHxA its salts and related substances in cosmetic products, house dust, indirect exposure of humans via the environment via food and possible other sources of PFHxA, such as articles and products (see Annex B.9.17 of the Background Document).

Uses and use quantities

The Dossier Submitter identified the following uses of PFHxA, its salts and related substances:

- PFHxA-related substances are used in **paper and cardboard (food contact materials)** to provide heat resistance, water- and oil-repellence. They are chemically stable and cost-effective (low quantities are sufficient to achieve the desired effect). The Dossier Submitter reported that PFASs might also be used in paper for non-food applications (folding cartons, containers, glossy papers, carbonless forms and masking papers). This was confirmed by a comment received during the consultation on the Annex XV report that reporting the use of a PFHxA-coated paper layer in an iron-based oxygen absorber used in food packaging, pharmaceutical and medical device products.
- Fluorotelomer alcohols (FTOHs) and PFCAs are used in **textiles** mainly for providing durable water repellent finishing that imparts water, oil and stain resistance to the textile. Textiles treated are consumer apparel, professional apparel, including personal protective equipment (PPE), woven and non-woven medical textiles, technical textiles (including for transportation and construction) and home textiles (e.g. upholstery).
- **Fluorinated firefighting foams** are used for class B fires (flammable liquids) and in special cases for class A fires (combustible materials). Fluorinated firefighting foams are used in different sectors: aviation, petrochemical industry (oil and gas platforms, refineries, fuel depots) other industrial uses (e.g. in warehouses, automotive industry), defence (seagoing military units, fuel depots, military aviation, training on ships), and in hand-held fire extinguishers.
- **Manufacture and use of fluoropolymers**: PFHxA, its salts and related substances are used as process media to produce certain fluoropolymers. APFHx (the ammonium salt of PFHxA) is used at industrial sites as a processing aid to manufacture **fluoroelastomers** that are used to produce e.g. seals and tubes for the automotive or aviation sectors. PFHxA can also be found as an impurity in fluoropolymers. **Fluoropolymers** are used in a wide array of industries such as transport, aerospace, energy (e.g. oil and gas, renewable, nuclear), chemical, telecommunications, semiconductor and electronics, pharmaceutical, food, etc.
- **Manufacture of side-chain fluorinated polymers (SFPs):** SFPs are used to impart oil and water repellence in a wide range of sectors (textiles, including leather, hard surfaces or paper fabrics).
- **Semiconductors and semiconductor related equipment**: PFHxA-related substances are used as process agents for the photolithography process, etching process and in cleaning fluids.
- **Chrome plating**: PFHxA-related substances are used as wetting agents for chrome (VI) baths to lower the surface tension of the plating solution, to decrease aerosol emissions and are also added to chromo-sulfuric acid in plastic electroplating to achieve wettability of the hydrophobic plastic surface.

- **Photographic applications**: C6-based fluorinated surfactants are used in photographic equipment or in coatings when manufacturing conventional photographic films. The substances are used as surfactants, as static control agents, as dirt repellents during coating operations and as friction control agents. PFHxA surfactants are also used for photographic coating on paper, inkjet photo media coatings and for photographic coating in printing plates.
- **Printing inks**: C6 based short-chain fluorinated surfactants are used in some water-based inkjet inks and latex inks. The main function is the reduction of water surface tension when applied on nonporous substrates, thereby improving surface wetting during the printing process.
- **Building materials/construction products**: Treatment of hard surfaces like natural stone, ceramics, glass, porous tiles, grout and masonry etc. with either solvent or aqueous based fluoropolymer or side-chain fluorinated polymer solutions or dispersions and paints to provide functional water, oil and dirt repellence, including from biofouling and graffiti. Textiles for civil construction (e.g. flexible textile roofs or ceiling panels); reinforcement fabric for wall plaster. ceiling panels, exterior paints and road marking.
- **Fragrance and flavour**: PFHxA, its salts and related substances are reported to be used for handling fragrance and odour compounds in products and articles. However, only limited data on this use was available to the Dossier Submitter and no additional information was submitted during the consultation on the Annex XV report.
- **Mixtures for consumer uses**: PFASs, in general, are reported to be used in various mixtures intended for end-use by consumers, including impregnating agents, ski or floor wax, cleaning products, car care and polishes. The Dossier Submitter highlights that limited information is available regarding the use of PFHxA-related substances in these products but there is indication that the greatest concentrations are found in ski waxes and in water/dirt proofing products.
- PFASs are used in various **cosmetic products**, serving e.g. as emulsifiers and surfactants or are added to cosmetic products for binding, bulking and skin/hair conditioning purposes.

Stakeholders reported additional uses during the consultation on the Annex XV report, which have been assessed and included in the Background Document:

- **PTFE (polytetrafluoroethylene) and PTFE micro-powders** have desired mechanical, thermic, electrical and chemical characteristics. PTFE may contain PFHxA-related substances as residuals from the manufacturing process, and PFHxA-related substances may also be unintentionally created while producing micro-powders. PTFE micro-powders are used in the medical sector, in electronics and as lubricants.
- **Electronic devices**: Fluorinated polymers are used in **electronic grade coating** to protect electronic devices from water and corrosion damage. Fluorosurfactants are also reported to be used in the production of batteries as plating bath aids, in photoresist strippers as photoresists and in the production of flat panel displays.
- **Filtration and separation media**: PFHxA related substances in filtration and separation media have a very broad range of applications across several market sectors. The products affected are e.g. medical devices; PPE; heating, ventilation and air conditioning (including high-purity applications for hospitals, laboratories etc.); air pollution controls; dust collectors; hydraulic systems; coalescers; gas turbines; fuel systems and many more.

- **Epilame used in watches**: C6 side-chain fluorinated polymers are used in the watchmaking industry in mixtures called epilames. Epilames are applied as coatings to ensure the proper lubrication of moving parts (e.g. wheels, pivots, escapements, stones).
- "C6 fluorinated polymers" are used as a cladding material for **plastic optical fibres**. Low refractive index in the outside keeps the light within the optical fibre, minimises information loss and increases the speed of transmission. Optical fibres are mostly used for in-vehicle data communication.
- **Medical devices**: different applications for PFHxA related substances exist, such as in detergent proof single-use washbowls, non-active medical devices in ophthalmic applications, coatings for hearing aid devices, use in implantable (e.g. catheters, drainage, stents, surgical meshes, etc.) and non-implantable (vascular/delivery catheters, extracorporeal components, wound closures, etc.) medical devices.

During the preparation of the restriction proposal, the Dossier Submitter collected information on uses and production volumes from manufacturers and users of PFASs in several surveys and calls for information. The main survey provided volume information for the years 2016-2018. Information from REACH registrations and CLP-notifications was also used, and on the basis of those, more than one hundred substances within the scope of the proposal were found to be manufactured and/or imported to the EU/EEA. However, the majority of them in quantities below 1 tonne/year (t/a).

According to the Dossier Submitter, no manufacture of PFHxA or its salts takes place in the EU. The main direct use of PFHxA salts and related substances is in the manufacture of C6-SFPs.

Estimated use volumes for the different substance groups under the scope of the proposal are presented in Table 22 (Annex B.9.3.1) of the Background Document. The highest use volumes are indicated for 6:2 fluorotelomer iodides, 6:2 fluorotelomer alcohols and acrylates with C6-perfluorinated sidechains, all in the tonnage band of **1 000 to 10 000 t/a**. Import in the EU/ EEA of PFHxA itself takes place only at low level (six CLP-notifications, no REACH registrations).

The share of the different uses of low molecular weight PFHxA-related substances in total volumes is described in Figure 3 below. Treated paper and cardboard (food contact materials) is the dominant sector of use, with approximately two thirds of the use volume, followed by textiles. For textiles, approximately 75% of clothing that enters the European market is imported.

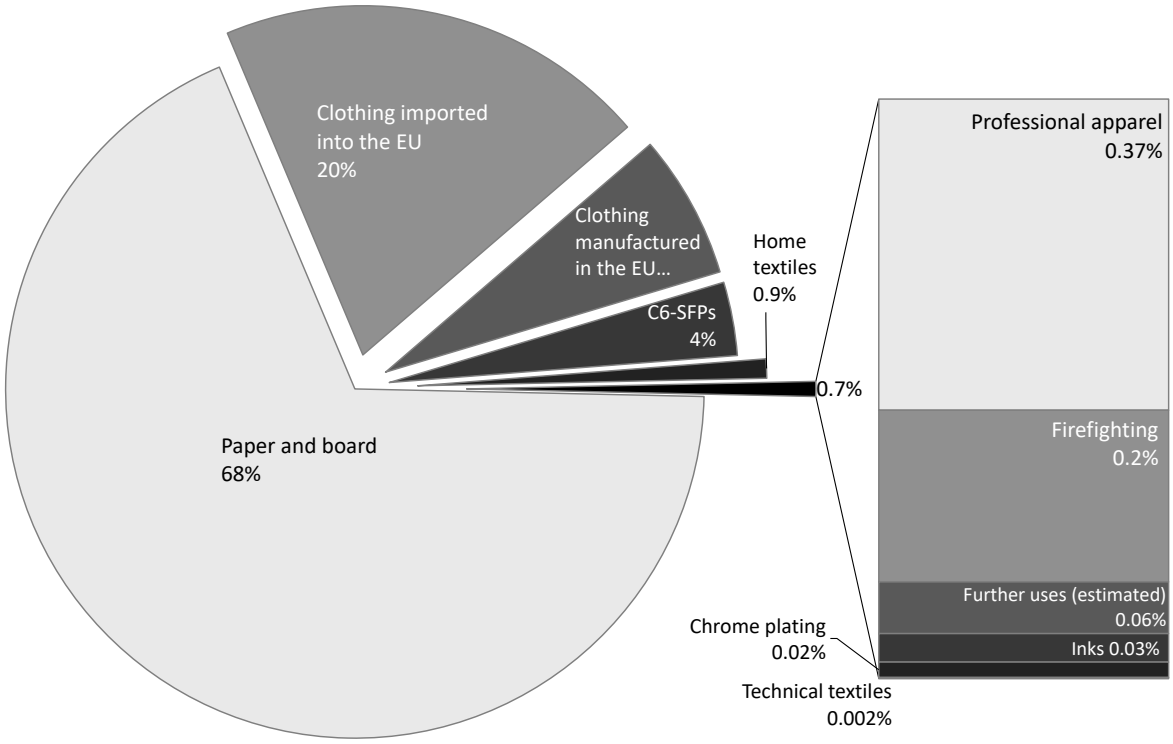

Figure 3. Current use of low molecular weight PFHxA-related substances in the European Union (Figure 1 in the Background Document. Updated after the consultation on the Annex XV dossier).

Emissions

Sector-wise estimates of use volumes and releases for C6-SFPs and low molecular weight related substances as well as the total release (expressed as PFHxA) are provided in Table 25b-d in Annex B.9.18 of the Background Document and summarised in Table 1 of this opinion. For the six main sectors of use, RAC prepared summary tables in order to clarify the assumptions and calculations behind the emission estimates presented in the Background Document (See Background Document Annex B.9.20, RAC's evaluation of exposure assessment) the summary tables are informed by the descriptions of underlying calculations provided in the Background Document, as well as supplementary Microsoft Excel files provided by the Dossier Submitter during opinion development.

Overall releases

The main use sectors, estimated use quantities, release quantities and environmental pollution stock by the year 2040 are provided in Table 25 in Annex B.9.18 of the Background Document and summarised in Table 1.

Overall releases (as provided in section B.9.18 of the Background Document) are estimated to be between 313 and 2 050 t/a for C6-SFPs, between 1 349 and 14 435 t/a for low molecular weight C6-substances and between 113 and 1 200 t/a for PFHxA. About **80% of the releases of PFHxA, its salts and related substances are estimated to occur from products and articles**. **The sectors with the greatest contribution to releases are textiles, paper and cardboard (food contact materials) and firefighting foams.**

A straightforward conversion of current releases of PFHxA related substances to quantities of PFHxA in the environment is not possible. However, the Dossier Submitter assumed the following conversion factors, which were refined during opinion-making after feedback from RAC:

- Low molecular weight related substances - yield of 7 % (w/w) based on experimental data for 6:2 FTOH.
- For C6-SFPs, yield of 1 % (w/w), based on the RAC opinion on the proposed restriction of PFOA restriction (ECHA, 2015).

Applying the above assumptions, **a total release of 113 to 1 200 t PFHxA/a** to the environment was estimated by the Dossier Submitter (Background Document, Annex B.9.18). This corresponds to **a cumulative release of approximately 2 000 to 24 000 t PFHxA** t between the present day and 2040 in the absence of a restriction.

Table 1. Estimated environmental releases of PFHxA and its salts by current uses from quantifiable sources [t/a]

Sector of use	Subsector	Current release of PFHxA its and salts [t/a]	
		Min	*Max*
1. Polymers	1.1. Manufacture of (acrylic-) polymers with C6 side chains	0.6	6
	1.2. Manufacture and use of fluoroelastomers with APFHx	0.10	1
2. Textiles and leather	2.1. Clothing manufactured in the EU*	22	67
	2.2. Clothing imported into the EU*	50	282
	2.3. Clothing used in the EU	82	285
	2.4. Professional apparel, incl. personal protective equipment (PPE)	2	4
	2.5 Home textiles	3	9
	2.6. Technical textiles	0.14	0.26
	2.7. Medical applications*	0.027	0.053
3. Paper and cardboard (food contact materials)	3.1. Grease proof papers	18	849
4. Extinguishing agents	4.1 Formulation and use for professional firefighting	7	39
5. Chrome plating	5.1 Hard chrome plating	0.01	0.3
	5.2 Decorative chrome plating	0.01	0.5
	5.3 Plastics chrome plating	0.02	0.05
6. Inks	6. Inks	0.6	6
	Summary:	**113**	**1200**

** These values are not included in the overall release estimate because they are already included in other (sub-)categories*

RAC conclusion(s):

The available monitoring data from various environmental matrices convincingly demonstrate that emissions to the environment of PFHxA, its salts and related substances occur.

The conversion factors (from PFHxA-related substances to PFHxA) for low molecular weight PFHxA related substances and C6-side chain fluoropolymers are appropriate. However, overall, the methodology used to calculate quantitative releases of PFHxA, its salts and related substances is concluded to be unreliable due to:

- insufficient justification provided for the choice of assumptions made when constructing the exposure scenarios (including unsubstantiated deviations from the applicable ECHA Guidance and concerns relating to the representativeness of data) and over reliance on worst-case (rather than reasonable worst-case) assumptions;

- significant gaps in the reporting of the underlying data and calculation methodology; and
- numerous inconsistencies in reporting between different sections of the Background Document[8].

Therefore, RAC considers that it is not possible to conclude quantitatively on the magnitude (or likely range) of emissions of PFHxA, its salts and related substances from the different uses within the scope of the proposed restriction (with the exception of some sectors[9]). In addition, for several uses, there is insufficient information to conclude on the effectiveness of operational conditions and risk management measures to control releases.

Nevertheless, based on a qualitative evaluation of the available information[10], **RAC concludes that releases to the environment from wide-dispersive uses[11] within the scope of the proposed restriction are inevitable (i.e. the conditions of use mean that releases cannot be controlled by specifying operational conditions and risk management measures) and that the largest emission sources are from textiles, paper and cardboard (food contact materials) and municipal firefighting foams. Other wide-dispersive uses also contribute to releases.**

Further details of RAC's qualitative evaluation are reported in the section "effectiveness in reducing the identified risks".

Key elements underpinning the RAC conclusion(s):

Measured data on environmental and human exposures

RAC notes that all monitoring studies that reported on PFHxA also measured other PFASs. Shiwaku et al. (2016) reported that in the Ai river (Osaka, Japan) in the close vicinity of a fluoropolymer plant the levels of PFOA greatly decreased in the period 2003-2015, whereas in the same period the PFHxA levels increased (26.2 – 1130 ng/L), clearly indicating a shift from longer chained PFASs to shorter chained PFASs.

For the estimations of environmental stocks of PFHxA in European waters, based on the concentrations measured in surface waters, RAC considers the numbers to be overestimated. A vertical gradient is commonly observed for PFASs (including PFHxA) in the water column with the highest concentrations in surface water decreasing with increasing depth (Yeung et al., 2017; Gonzales-Gaya et al., 2019). However, RAC still considers that the environmental monitoring data are sufficient to conclude that PFHxA occurrence in the environment is widespread, and that the levels of PFHxA can be expected to increase due to the restrictions

[8] For example, RAC notes that different values for the same release estimates are presented in different parts of the Background Document, leading to uncertainty as to which is the correct value to take forward (Tables 39 and 25 in Annex E.2.11 and B.9.18, respectively).

[9] Epilames used in watches, semiconductors and semiconductor-related equipment, coating for hearing aid devices, transported isolated intermediates. See section of the opinion on "scope including derogations".

[10] RAC's qualitative evaluation comprised an assessment of (i) whether the use would be likely to result in releases to the environment and (ii) whether releases could be effectively controlled (i.e. minimised) by means other than a restriction on use/placing on the market i.e. by the use of risk management measures. Further details of the qualitative evaluation are provided in section of the opinion on "Effectiveness in reducing the identified risks".

[11] The term 'wide-dispersive' is described in ECHA Guidance on information requirements and Chemical Safety Assessment Chapter R.12 (Appendix R.12.1): Use Description. The term is also referred to in ECHA Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment and ECHA's General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation. For the purposes of this opinion the term means *a use of a substance at many sites and/or by many users (a widespread use) associated with releases to the environment or exposure to humans, including from the waste life-cycle stage*.

of PFOA and other PFAS substances.

The Background Document reports that the amount of monitoring data available for PFHxA in biota compared to long-chain PFASs are limited. The presented monitoring data generally range from below LOD to low ng/kg ww (< 0.04 - 2.22 ng/kg ww) in several organisms including zooplankton, different fish species, seals, mink, polar bears, and several bird species with the sampling locations being populated as well as pristine locations (e.g. Arctic; Antarctic). The exception being a study by Llorca et al. (2012b) that reports levels up to 240 ng/kg ww in algae and 232 ng/kg ww in fish liver. In humans, PFHxA has been shown to occur in several tissues, including lung, brain, liver, kidney and bone (Perez et al., 2013) in ng/g ww levels, but also in human milk (Kang et al., 2016; Nyberg et al., 2018).

PFHxA has been shown to enrich in plants, especially in edible parts (roots, fruits and leaves). As discussed in the hazard section, this is due to its high water solubility and low adsorption potential, resulting in bioavailability to plants via the soil pore water. It has been shown that PFHxA has a concentration factor of e.g., ~ 3.6 in cabbage head and ~ 4.4 in tomatoes but it can be higher or lower in other plants and varies for different parts of the plant.

Human exposure to PFHxA has been demonstrated via e.g. European raw water and drinking water measurements (low ng/L range), cosmetic products (low ng/g to low µg/g range) and house dust (ng/g range). RAC acknowledges that the measured exposure levels of only PFHxA itself likely underestimates the total exposure, since in e.g. house dust the levels of the precursors such as mono- and diPAPs were higher than the levels of PFHxA. Human blood and serum measurements in the Background Document demonstrated low levels of PFHxA in the range of pg/ml to ng/ml.

In summary, **RAC agrees with the Dossier Submitter that there is a large set of measured data available which provide consistent evidence of exposure of the environment and humans**.

Underlying assumptions for emission calculations

The Dossier Submitter had originally reported a realistic worst-case conversion factor (from low molecular weight[12] PFHxA-related substances to PFHxA) of 3.9%. During the development of the RAC opinion the Dossier Submitter revised the factor for low molecular weight PFHxA-related substances to 7% based on a re-evaluation of the available scientific literature. The factor of 7% for **all** low molecular weight precursors is based on degradation studies of 6:2 FTOH and primarily from the results of Liu et al. (2010b).

RAC acknowledges that degradation studies for PFHxA-related substances are limited and that there is quite some uncertainty associated with experimental results as well as variability reported between environmental matrices. In the Background Document, degradation factors for different PFHxA precursors ranging from 0.2 to 20 mol% are presented (Tables 9 and 10), albeit with different matrices, study durations and experimental conditions. The use of the Liu et al. (2010b) study, and the use of 6:2 FTOH as a surrogate, is considered to be a reasonable and balanced approach for estimating the conversion of PFHxA precursors to PFHxA, particularly considering that 6:2 FTOH and 6:2 FT iodide-based products represent the vast majority of the global manufacture and use of fluorotelomer-based products. Furthermore, the results of Liu et al. (2010b) are considered more representative (closed system and longer duration) than those from Liu et al.(2010a) and more in line with the factors obtained in later studies (Zhao et al., 2013a and 2013b and Zhang et al., 2017 (not reported in the Background Document)).

[12] i.e. non-polymeric

In the RAC opinion for the restriction of PFOA, its salts and related substances (ECHA, 2015), factors ranging between 1-10% per year were derived for different classes of PFOA precursors, which is a more representative approach then using a single surrogate for all precursors. However, more data were available for different classes of precursors to PFOA than for PFHxA, thus the use of one factor for PFHxA, selected from the middle of the reported range of degradation factors, is considered to be reasonable. Nevertheless, RAC notes that specific factors for different groups of PFHxA-related substances, based on experimental studies of different PFHxA-related substances, would have provided more representative estimations of conversion between PFHxA-related substances and PFHxA.

RAC notes that read-across from the degradation behaviour of PFOA-related substances to the degradation of PFHxA-related substances is not straightforward and should be attempted with care since the degradation patterns and ratios of the terminal degradation products have been shown to differ between the groups of substances, with more PFOA being formed from PFOA-related substances than PFHxA being formed from PFHxA-related substances (Liu et al., 2010b).

In addition to low molecular weight PFHxA related substances, C6-SFPs can also degrade to form PFHxA. Initially the Dossier Submitter had used a factor of 425 mg PFHxA released per tonne of C6-SFP. RAC had not supported this factor because of the lack of information on the content of C6-SFPs in the treated articles used to derive the factor. A revised factor of 1%, subsequently adopted by the Dossier Submitter, was proposed by RAC based on the same factor that was used in the RAC opinion on the proposed restriction of PFOA, its salts and related substances (ECHA, 2015)[13], where it was considered as an overall (not time delimited) environmental degradation factor for C8-SFPs, based on reported degradation rates of 0.1–5% per year.

No further data on the degradation of C6-SFPs were presented in the Background Document or have been submitted in the consultation on the Annex XV report. Thus, in the absence of more representative data, RAC supports the use of the same degradation factor for C6-SFPs as was used in the restriction of PFOA, its salts and related substances.

C6-SFPs are considered to be less resistant to degradation than C8-SFPs (Menezes, 2020) and thus are likely to have a greater degradation rate compared to PFOA. Nevertheless, it is still considered to be a reasonable estimate based on the range of 0.1-5% degradation per year for C8-SFPs.

RAC notes that the only study in the Background Document specifically addressing the degradation of C6-SFPs (Lang et al., 2016) is not considered to be representative of PFHxA for several reasons. The content and types of perfluorinated substances in the testing material were not analysed meaning that the source of the PFHxA is unclear. In addition, because the study was performed in a period where PFHxA related substances were not yet commonly used in textile treatment it seems unlikely that PFHxA related substances are the major source. Equally, the content of perfluorinated chemicals in the textile material, needed to derive the emission rate, was taken from another study. Therefore, the representativeness of these figures to the tested materials is unclear.

Emission estimates and exposure scenarios

Details of the evaluation of the Dossier Submitter's quantitative assessment of emissions is

[13] In the PFOA restriction RAC assessed the 1% typical degradation rate for polymers on the total amount of polymer released resulting in a 1% PFOA release which is not time delimited as polymers may degrade over a long timeframe.

provided in Background Document Annex B.9.20, RAC's evaluation of exposure assessment). Further details of RAC's qualitative evaluation of released are reported in "effectiveness in reducing the identified risks".

4.1.5. Characterisation of risk(s)

Summary of the Dossier Submitter's proposal:

The Dossier Submitter considered the risk assessment of PFHxA from a threshold, non-threshold and 'case-by-case' approach point of view.

Threshold approaches (PEC/PNEC; RCR)

The Dossier Submitter concludes that for the environmental risk assessment it is not possible to reliably predict current and future environmental concentrations (PEC) and indirect human exposure. Emissions are irreversible and there is a lack of appropriate tools for estimating future concentrations, and insufficient information on fate properties of all PFHxA-related substances, which would need to be taken into account in the exposure assessment in order to estimate the formation rate of PFHxA in the environment. Furthermore, derivation of robust predicted no effect concentration (PNEC) is complicated as there is insufficient information on inter-generational ecotoxicological effects. Thus, a PEC/PNEC approach is not applicable to underpin a conclusion that environmental risks are adequately controlled, either now or in the future.

Regarding human health risk assessment, the Dossier Submitter concludes that standardised risk assessments can be carried out, and that they suggest that the current exposure does not pose a risk for human health. However, the extreme persistence of PFHxA and the increasing environmental stock over time imply uncertainties regarding risks to human health, similar to the long-term risks for the environment. The Dossier Submitter notes that the point of time at which the effects are triggered cannot reliably be estimated, while reversing the effects will be very difficult due to the irreversibility of the exposure.

Non-threshold (PBT/vPvB) approach

The Dossier Submitter concludes that PFHxA by far exceeds the vP criterion, while the data on bioaccumulation and ecotoxicity are not sufficient to identify PFHxA as a PBT or vPvB substance. However, the mobility of PFHxA combined with its extreme persistence adds substantially to the overall concern. Additionally, the Dossier Submitter notes that PFHxA is neither classified as carcinogenic, mutagenic, or toxic for reproduction. Overall, PFHxA is not considered a PBT/vPvB substance, but as its concerns are similar to PBT/vPvB substances the Dossier Submitter further investigated a case-by-case approach.

Case-by-case approach according to paragraph 0.10 of Annex I of REACH

Using the case-by-case approach, the Dossier Submitter concludes that although PFHxA does not meet the criteria for a PBT/vPvB substance, the concerns due to the extreme persistence, the mobility, the long-range transport potential and the difficulty to remove PFHxA from water are in combination comparable to the concerns of PBT/vPvB substances.

Altogether, based on the above considerations, the Dossier Submitter concludes that PFHxA should be treated as a non-threshold substance for the purpose of risk assessment in a similar manner to PBT/vPvB substances. It is not possible to quantitatively derive safe concentrations or to determine the risk of the substances to the environment or human health with sufficient certainty and any releases should therefore be regarded as a proxy for a risk to the environment and human health.

The Dossier Submitter has provided information on the releases of PFHxA, its salts and related substances to the environment. Furthermore, the proposal provides monitoring data to confirm ubiquitous environmental and human exposure. The Dossier Submitter concludes that releases and exposures need to be minimised for PFHxA, its salts and related substances.

RAC conclusion(s):

RAC agrees that threshold approaches may underestimate the risk of PFHxA to the environment and human health due to the continuous increase in environmental stocks and, subsequently, increases in environmental and human exposure. While PFHxA does not seem to have high bioaccumulation potential, and therefore does not meet the criteria for a PBT/vPvB substance, RAC agrees that the properties of PFHxA warrant a case-by-case risk assessment approach where, in analogy to PBT/vPvB substances, any releases and exposures should be regarded as a proxy for a risk to the environment and human health. Therefore, RAC also agrees that releases of PFHxA, its salts and related substances are associated with a risk that is not adequately controlled and should be minimised. The Dossier Submitter has demonstrated that widespread environmental and human exposure to PFHxA and/or its salts and related substances occur.

Key elements underpinning the RAC conclusion(s):

RAC notes, as discussed in the hazards section of this opinion, that the combined properties of concern of PFHxA (particularly the extreme persistence and mobility) result in an intrinsic hazard. The continuous and irreversible exposure of wildlife and humans exposed via the environment may lead to unpredictable long-term adverse effects on the environment and human health. The PFHxA-related substances contribute over a shorter or longer term to the exposure of PFHxA as they degrade into PFHxA, at varying rates. The uncertainty on the effect side in combination with the uncertainties on the exposure side, i.e.:

- the lack of models that take into account the very persistent and mobile nature of PFHxA;
- the lack of fate information on PFHxA related substances; and
- the uncertainties in the rate of PFHxA formation over time;

make threshold approaches inadequate to determine the risks that PFHxA poses to the environment now as well as in the future, but also to human health. RAC notes that the Dossier Submitter considers that a conventional quantitative risk assessment can be carried out for human health, but not for the environment due to lack of intergenerational environmental toxicity studies, while also describing that the same uncertainties apply to human health as to the environment. This is inconsistent. Overall, RAC considers that threshold approaches are not suitable for environmental or human health risk assessments of PFHxA.

Overall, the properties of PFHxA lead to a concern very similar to that of PBT/vPvB substances, even though PFHxA does not seem to have a high bioaccumulation potential. Therefore, RAC supports the use of a case-by-case approach to risk assessment and a risk characterisation where any releases (and exposures) are regarded as a proxy for a risk to the environment and human health that is not adequately controlled. On this basis, releases of PFHxA, its salts and related substances should be minimised to reduce the likelihood of adverse effects. The case-by-case approach to risk assessment was also applied by ECHA in the proposed restriction of intentionally added microplastics (ECHA, 2019e), where the extreme persistence of microplastics in the environment was associated with a continuously increasing

environmental stock that would eventually exceed any 'safe' threshold. This rationale was supported by RAC (ECHA, 2020a).

The Dossier Submitter contends that global environmental and human exposure to PFHxA and/or its salts and related substances has been demonstrated by monitoring data from a range of different matrices, such as WWTPs (influent/effluent, sludge), landfill leachates, river and oceanic waters, groundwater, drinking water, soil, and plants. RAC agrees with this contention.

4.1.6. Uncertainties in the risk characterisation

While RAC considered the data on persistence and mobility, i.e. the main drivers of the hazard/risk associated with PFHxA, some uncertainties were encountered related to adsorption of PFHxA (mobility), and adverse effects in humans and the environment (e.g. current lack of harmonised classification as well as ongoing Substance Evaluation for potential environmental endocrine effects under REACH). However, RAC does not consider these uncertainties to have a major impact on the overall conclusions of the risk characterisation of PFHxA, its salts and related substances.

In relation to adsorption, RAC notes that the available data on adsorption are variable. Most of the data indicate low to very low adsorption, while one study suggests moderate to substantial adsorption. The low adsorption potential is also supported by the low removal efficiency during drinking water preparation using activated carbon. Therefore, RAC considers PFHxA to have a low adsorption potential.

In relation to ecotoxicity, RAC agrees that exposure to PFHxA is likely to occur across generations, due to its extreme persistence. Potential adverse effects resulting from such multi-generational exposure are hardly ever assessed.[14] Also, direct effects related to exposure of PFHxA-related substances remain to a large extent unassessed. Potential effects of related substances, such as endocrine effects, cannot currently be excluded or confirmed. Testing is currently being performed for environmental endocrine effects under the REACH Substance Evaluation process and therefore this point is not used in support of RAC's opinion.

In relation to human health, RAC notes that there are, amongst others, signs of potential reproductive toxicity of PFHxA. Although the main arguments for the restriction are based on the extreme persistence, mobility and long-range transport, the potential adverse effects on human health and the environment further contribute to the concern. In addition, the impact of co-exposure to other (e.g. structurally similar) PFASs and potential cumulative toxicity exerted by PFHxA and e.g. its longer PFCA homologues cannot be excluded. This could result in an underestimation of the risks. Any possibility for PFHxA to increase uptake of other substances via increased cell membrane permeability as expressed in the Background Document needs further exploration before its relevance can be addressed.

Based on its mobility, PFHxA is very difficult to remove during drinking water preparation by commonly used techniques such as granulated active carbon, anion exchange and powdered activated carbon (McCleaf et al., 2017; Sun et al., 2016; Rahman et al., 2014; Eschauzier et al., 2012). More efficient techniques, such as reverse osmosis and nanofiltration, are investigated (Ross et al, 2018), but not yet widely applied. It cannot be excluded that functioning methods for remediation of PFHxA-contaminated sites and drinking water will be available in the future.

Due to the increasing environmental stock and, as a result of that, increasing environmental

[14] Standard ecotoxicity -tests do not cover sufficiently the very long exposure times to PFHxA.

and human exposure, concentrations causing adverse effects may be reached if the uses of PFHxA, its salts and related substances are not restricted. However, it is not certain at what time point in the future this may occur. In addition, any estimations are based on the current available data, and yet unknown more sensitive endpoints may exist. The European Food Safety Agency (EFSA) has, as more information has become available, revised their tolerable intake values for the PFOS and PFOA, leading to much lower limit values than before (EFSA 2020). RAC notes that the newly assessed endpoint (immune toxicity), and the driver for the new limit value, have not been extensively studied for PFHxA, but cannot be excluded.

Uncertainties related to emissions and exposure

As RAC has agreed with the Dossier Submitter on a non-threshold approach to risk assessment and to the use of the case-by-case approach, focussing on persistence and mobility, emissions are therefore used as a surrogate for risk.

The RAC evaluation of the proposed restriction of PFHxA has pointed out significant limitations and uncertainties in the Dossier Submitter's assessment of uses and associated releases. These uncertainties relate to the identified uses (either as such or as an impurity in another substance), use volumes, conditions of use (including risk management measures and their effectiveness), relevant release pathways and release factors. Therefore, the emission estimations by the Dossier Submitter are considered uncertain and resulted in a qualitative approach to estimating emissions rather than a quantitative assessment.

However, RAC considers that the emission information as a whole still points towards substantial releases of PFHxA, its salts and related substances. This is supported by measured data on concentrations in the environment and by modelling.

4.1.7. Evidence that the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are sufficient to control the risk conditions implemented and recommended by the manufactures and/or importers are sufficient to control the risk

Summary of the Dossier Submitter's proposal:

No detailed assessment of implemented operational conditions and risk management measures was presented in the Background Document. However, Section 2.3 and Annex E.1.2 of the Background Document consider, in general terms, that measures such as improved containment during manufacture and use and increased use efficiency are mostly associated with some level of discharge and do not influence contamination outside manufacturing or processing sites. More importantly, relevant emission sources are not addressed by this measure.

RAC conclusion(s):

RAC concludes that there is insufficient scientific data to completely evaluate whether implemented operational conditions and risk management measures are sufficient to address the risks, specifically for hard (functional) chrome plating and for firefighting at industrial installations. Nevertheless, for widespread uses, such as in paper and cardboard, textiles and municipal firefighting foams, operational conditions and risk management measures are clearly not appropriate and effective to control the identified risk. This conclusion is elaborated in the section of the opinion on the "Effectiveness to address the identified risk".

Key elements underpinning the RAC conclusion(s):

RAC is not aware of any risk management measures and operational conditions implemented and recommended by manufacturers and/or importers, except for certain wastewater treatment measures at industrial sites. However, the information presented in the Background Document on releases, environmental monitoring, and human biomonitoring of PFHxA and related substances, indicating widespread presence of the substances in the environment, demonstrate that current risk management measures and operational conditions do not sufficiently minimise the releases of PFHxA, its salts and related substances.

4.1.8. Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

No assessment of existing regulatory risk management measures in the EU was presented in the Background Document.

RAC conclusion(s):

RAC considers the data in the Background Document on emissions and monitoring to demonstrate that existing regulatory risk management instruments are not sufficient to address the risk.

Key elements underpinning the RAC conclusion(s):

The only regulatory risk management on the EU-level that RAC is aware of for PFHxA, its salts and related substances, as opposed to national legislation related to PFASs, is the inclusion of PFASs in the revised Drinking Water Directive (European Council, 2020) where PFHxA is included in a threshold for "sum of PFASs" in EU drinking water. However, this risk management measure regulates PFHxA in drinking water only and does not prevent emissions.

The available data on emissions as well as data from environmental monitoring and human biomonitoring show that current regulatory risk management instruments, or rather the lack thereof, are not sufficient to minimise releases, exposures, and hence, the risk of PFHxA, its salts and related substances.

4.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter has concluded that action is required on a Union-wide basis. PFHxA, its salts and related substances are used for manufacturing of materials, articles and mixtures in large quantities throughout the EU/EEA and a considerable share of articles containing PFHxA or related substances are imported from outside the EU. Due to the properties of these substances, releases and exposures are considered as a proxy for risk to the environment and human health and should be minimised.

The manufacturing, placing on the market and use of PFOA, its salts and related substances (C8-chemistry) is prohibited (with some exceptions) since 2020 under Regulation (EU) 2019/1021 on persistent organic pollutants[15]. A large part of industry has substituted C8-

[15] See Commission Delegated Regulation (EU) 2020/784, OJ L 188, 15.6.2020

based chemicals towards C6-chemistry (e.g. PFHxA and PFHxA-related substances) or fluorine free alternatives. It can be assumed that the vast majority of the remaining companies using C8-chemistry will substitute to C6 chemistry or fluorine-free alternatives. Thus, the use of C6 chemistry is expected to have increased since the restriction on PFOA, its salts and PFOA-related substances entered into force.

The Dossier Submitter highlights the existence of spatial distribution following emissions of PFHxA, its salts and related substances. The terminal degradation product PFHxA is mobile in the aquatic environment, can be distributed easily within and between environmental compartments by aqueous media, and has long-range transport potential. Thus, effects will not only occur at the point of release of PFHxA but also far away. Due to the specific properties of PFHxA, its salts and related substances local end-of-pipe technologies are not sufficient to reduce the releases. Furthermore, the proposal describes the wide variety of consumer and professional uses and releases from these uses. Those releases cannot be managed by national regulatory activities. The Dossier Submitter therefore concludes that only action on a Union-wide basis would effectively reduce the environmental exposure to PFHxA in the EU, limit the potential for trans-boundary exposure to PFHxA from EU sources and avoid trade and competition distortions.

SEAC and RAC conclusion(s):

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 within the Union, RAC and SEAC support the view that action is required on an EU-wide basis to address the risks associated with PFHxA, its salts and related substances.

Key elements underpinning the SEAC and RAC conclusion(s):

RAC:

RAC considers that EU-wide measures are needed to reduce the releases of PFHxA, its salts and related substances into the environment from their manufacturing, use and placing on the market.

The uses of PFHxA, its salts and related substances are broad and articles and mixtures containing these substances are placed on the market in all EU member states. Emissions can occur at every stage of the life cycle. Thus, a large variety of emission sources contribute to environmental and human exposure. Due to the very persistent and mobile properties of the substances, including their long-range transport potential, national regulations would not sufficiently limit the risks. Environmental and human monitoring data show ongoing exposure. Thus, risk management action by reducing emissions from PFHxA, its salts and related substances to the environment on an EU level, also covering articles from outside the EU, is needed to limit the risks for human health and the environment.

SEAC:

For the substances covered by the scope of the restriction proposal, SEAC notes that PFHxA itself is not registered under the REACH regulation, i.e. it can be concluded that it is not manufactured in or imported into the EU in volumes greater than 1 tonne per year. By July 2020, 44 notifications on PFHxA have been made to the C&L inventory[16] by manufacturers/importers. PFHxA salts and PFHxA-related substances (precursors), which can degrade to PFHxA (whose properties are in the focus of the hazard assessment), are

[16] https://www.echa.europa.eu/information-on-chemicals/cl-inventory-database

registered in the EU. SEAC notes that PFHxA, its salts and related substances are therefore used and placed on the market as substances, in mixtures and in articles throughout the union and respective releases and exposure take place in all EU Member States. PFHxA is considered very persistent and mobile, it is ubiquitous in the environment and in humans, and has the potential for long-range environmental transport. Removal of PFHxA from wastewater, drinking water and contaminated sites is difficult, if not impossible, and any such remediation activities are known to be extremely costly. The Dossier Submitter concludes that risks to human health and the environment are not adequately controlled.

Since releases and exposure may take place in all Member States and due to the properties of the substances, SEAC agrees that regulatory measures on a national basis would not adequately manage the risks arising from PFHxA and its related substances. Therefore, SEAC agrees that action is required on an EU-wide basis in order to avoid such releases into the environment, resulting in long-term human and environmental exposure in the Member States and, at the same time, to facilitate the free movement of goods in the single market.

Although SEAC agrees that action is needed on an EU-wide basis, it recognises the challenges to estimate the effectiveness and efficiency of an EU-wide measure in case of a long-range transboundary pollutant. In fact, in this case emissions taking place outside the EEA may travel inside the EEA and *vice versa*, which affects the final environmental stock and exposure levels in the EEA. Information on the flows of these substances and on the impact on actual stocks would improve the analysis on the effectiveness of the measure. However, such information is not available, neither to the Dossier Submitter, nor to SEAC.

4.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of the Dossier Submitter's proposal:

A restriction covering **all emission sources** was considered by the Dossier Submitter to be the most appropriate union-wide measure to effectively reduce emissions of PFHxA, its salts and related substances in order to prevent irreversible impacts of PFHxA for environment and human health. The proposal comprises a generic ban on use and placing on the market (set using generic concentration limits) complemented with a series of use specific (time limited and unlimited) derogations.

PFHxA, its salts and related substances have a wide variety of uses in the EU. Over 100 substances within the scope of the proposal are currently manufactured and/or imported into the EU. Of these, approximately forty substances are manufactured and/or imported in volumes from 1 to 1 000 t per year.

The Dossier Submitter considers that emissions of PFHxA, its salts and related substances occur during every lifecycle step of the substances, including manufacture, industrial use, use in mixtures for consumer uses, service life and end of life (disposal of waste). PFHxA-related substances significantly contribute to human and environmental exposure of PFHxA since they will eventually degrade to PFHxA in the environment. Furthermore, imported articles, emitting PFHxA and PFHxA-related substances during their service life and after disposal also constitute relevant emission sources. Imported articles cannot be targeted by risk management measures other than a restriction.

Transition period

A transition period of 18 months was considered appropriate by the Dossier Submitter for most uses to reduce the ongoing releases into the environment as soon as possible. It has been demonstrated that for certain uses alternatives are available. The Dossier Submitter proposes longer transition periods for specific uses where alternatives cannot be immediately implemented but where the uses are considered to be critical.

Concentration limits

The proposed concentration limits for the restriction are the same as those for the restriction of PFOA, its salts and related substances, i.e., 25 ppb for the sum of PFHxA and its salts, and 1 000 ppb for the sum of PFHxA-related substances. This is also similar to the proposed restriction for C9-C14 PFCA, its salts and related substances with the concentration limits 25 ppb for the sum of C9-C14 PFCAs and their salts and 260 ppb for the sum of their related substances. In addition, the Dossier Submitter has proposed higher concentration limits of:

- 1 000 ppb for the sum of PFHxA and its salts and 100 ppm for the sum of PFHxA-related substances in fluoropolymers,
- 150 ppm for the sum of PFHxA and its salts and 2 500 ppm for the sum of PFHxA-related substances in engine parts in automotive, aerospace and shipping industry, and

- 10 ppm for the sum of PFHxA and its salts, and 500 ppm for the sum of PFHxA-related substances in fluoropolymers used in the coating of electronic devices (derogation for 7 years).

Derogations without time-limit

The proposed derogation of the use of fluoropolymers with higher concentration limits as provided in the section above has no time limit. For textiles, derogations are proposed for certain personal protective equipment (PPE), certain high visibility clothing, textiles in engine bays in the automotive and aerospace industry and in filtration and separation media. This is because these uses, if restricted, are considered to have high societal costs by the Dossier Submitter, and alternatives do not meet the properties needed with regard to oil and/or dirt repellence. For these uses, a yearly reporting requirement has been proposed.

Derogations without a time-limit are also proposed for the use of firefighting foams in defence uses in airports, ships, fuel depots and for training purposes in enclosed areas, for medical devices (expected to cover also medical textiles) and for epilames used in watches. This is because alternatives are not currently available, and a restriction would result in high societal costs. For these uses, an annual reporting requirement has also been proposed.

Time-limited derogations

A 5-year transition period is proposed for concentrated firefighting foams that are used in the production of other firefighting foam mixtures. This applies if they were placed on the market within 18 months of the restriction coming into force. However, the derogation does not apply to uses for training and testing, unless all releases are contained. The longer transition period is proposed due to the large stocks held and the magnitude of the emissions when the stocks are used, to ensure capacity for action in case of emergencies.

A 12-year transition period is proposed for fighting class B fires at installations with large tanks (defined as having a surface area above 500m^2). This is because not enough evidence is available that fluorine free firefighting foams perform as well as fluorinated products, and there are high fire-related risks arising from this uncertainty. A 12-year transition period is also proposed for semiconductors and semiconductor related equipment. This is due to alternatives not being available at the moment but considered possible with enough time by the Dossier Submitter.

A 7-year transition period is proposed for fluoropolymers used in coating of electronic devices (higher concentration limit). A 7-year transition period is also proposed for latex printing inks. This takes account of the service life of related printer hardware. A 5-year transition period is proposed for hard chrome plating. This is because alternatives are available but have not been tested sufficiently. A 5-year transition period is proposed for photographic coatings to films, papers, in printing plates and inkjet photo media coatings. This is to provide enough time for phase-out of these uses.

Table 2. Derogations proposed by the Dossier Submitter

Derogation	Time-period
Articles placed in the market before entry into force of the restriction	18 months
Hard chrome plating	5 years
Photographic coatings applied to films, papers and printing plates, inkjet photo media coatings	5 years
Firefighting foams - Mixtures for class B foams (general) - Large tanks - aqueous film forming foams for defence applications	 5 years 12 years Permanent
Latex printing inks	7 years
Semiconductors and semiconductor-related equipment	12 years
Transported isolated intermediates	Permanent
Textiles - PPE in risk category III (a), (c), (d), (e), (f), (g), (h), (l) in Reg. (EU) 2016/425 - High visibility clothing (class 3 in EN ISO 20471) - Impregnating agents for re-impregnation of PPE and high visibility clothing - Textiles in engine bays (automotive and aerospace industry) - Filtration and separation media	 Permanent Permanent Permanent Permanent Permanent
Epilames in watches	Permanent
Medical devices as defined in Regulation 2017/745	Permanent
Fluoropolymers (separate higher concentration limits) - Fluoropolymers in general - Fluoropolymers in engine parts in automotive, aerospace and shipping industry - Fluoropolymers in coating of electronic devices	 Permanent Permanent 7 years

Stocks

The relevance of stocks was considered by the Dossier Submitter when considering whether derogations are needed and in defining the length of the transition period. This is relevant in particular for the use of concentrated firefighting foams (see above).

"Second-hand" market and articles placed on the market before the restriction

In line with many existing restrictions, the proposed restriction does not cover the "second-hand" market (e.g. used textiles and textiles in the supply chain). One reason is the difficulty of enforcement, since in most cases one consumer donates/sells single articles to another consumer (directly or via a second-hand retailer). It would not be practical to remove single articles from the market. Also, to use an article as long as possible before it turns into waste is a sustainable use of resources.

Recycled materials

The restriction proposal includes recycled material and articles made from recycled materials. The Dossier Submitter has demonstrated a concern resulting from the exposure to PFHxA, its salts and related substances. Subsequently, there is a concern if recycled materials contain these substances. An exemption for recycled materials could lead to higher releases to the environment in comparison with appropriate waste management.

RAC conclusion(s):

RAC agrees that a broad EU-wide restriction with targeted and carefully selected derogations and transition periods is the most appropriate measure to reduce the risks of PFHxA, its salts and related substances. However, RAC does not agree that the entire scope of the restriction proposed by the Dossier Submitter has been sufficiently justified, including for some of the proposed derogations.

Key elements underpinning the RAC conclusion(s):

Emissions of PFHxA, its salts and related substances occur at all life cycle stages, with subsequent transformation or degradation to PFHxA from the related substances. Considering the broad use of the substances in many sectors, a broad restriction covering all uses, articles, and mixtures (known and potentially unknown), with carefully selected and justified derogations where emissions are confirmed to be either negligible and/or minimised using appropriate operational conditions and risk management measures to a low level, is from a risk perspective an effective measure. A broad restriction also covers potential future uses. Articles, including imported ones, constitute a major emissions source and cannot be efficiently targeted by a risk management option under REACH other than restriction. However, RAC does not agree that all the proposed restricted uses and derogations have been justified by the Dossier Submitter.

Concentration limits

The concentration limits, 25 ppb for the sum of PFHxA and its salts and 1 000 ppb for the sum of PFHxA-related substances, are aligned with the previous restrictions of PFOA and PFHxS, and similar to the restriction of C9-C14 PFCAs (with thresholds of 25 for PFCAs and salts and 260 ppb for related substances, respectively). RAC considers the proposed thresholds to provide a reasonable balance between prohibiting intentional uses while maintaining the possibility to enforce the restriction (see section of the opinion on the practicality, incl. enforceability, of the proposed restriction). RAC recommends the development of standardised methods for the analysis and enforcement of these concentration limits.

Transition periods

Residual emissions from articles produced or placed on the market during the 18-month transition period were not estimated by the Dossier Submitter. Service lives of articles are variable and depend on the sector, e.g. for paper and cardboard (food contact materials) the Dossier Submitter assumed a service life of ≤ 1 year whereas for home- and technical textiles a service life of ≥ 10 years was assumed, thus emissions of PFHxA or related substances during the service life and at the end-of-life of articles produced or placed on the market during the transition period will occur but vary depending on the sector/use. Based on the large use of PFHxA related substances in textiles and paper and cardboard (food contact materials), where adequate control of risk via risk management measures is not considered feasible, the 18-month transition period will result in considerable emissions. Thus, RAC recommends that the overall transition period to be as short as practically possible.

'Second-hand' market:

RAC agrees with the proposal to derogate articles and mixtures placed on the market before the proposed restriction becomes effective (including second-hand articles) for practical reasons (identification and destruction of these) as well as difficulties related to control/enforcement. This is also in line with previous restrictions on PFASs under REACH.

Recycled materials:

RAC agrees that recycled materials should be included in the scope of the restriction. PFHxA, its salts and related substances are likely to be present in articles over successive life cycles. Recycled materials are included in the restrictions on PFOA its salts and related substances (European Commission, 2020) and was supported by RAC for the proposed restrictions on C9-C14 PFCA (ECHA, 2018d) and PFHxS (ECHA, 2020), including their salts and related substances.

Derogations

A number of uses of PFHxA, its salts and related substances were proposed to be derogated by the Dossier Submitter (see Table 2) or by respondents to the consultation on the Annex XV report, either permanently (i.e., without a time-limit) or temporarily (i.e., with a 'transitional period' before which the conditions of the restriction enter into effect).

For RAC to conclude that a proposed derogation would not affect the effectiveness of the proposed restriction, emissions from the use should be either negligible or the operational conditions and risk management measures must have been justified to be appropriate and effective to minimise residual emissions to a very low level.

Further evaluation of the use/sector-specific derogations (proposed either by the Dossier Submitter or by respondents to the consultation on the Annex XV report) is integrated into the subsequent section of this opinion on the 'Effectiveness in reducing the identified risks'.

Justification for the opinion of SEAC

Summary of proposal:

In addition to the proposed restriction, the Dossier Submitter assessed the following risk management options:

- A **restriction** with **no concentration limit;**
- A **restriction** on **selected products;**
- A **restriction** on **specific sectors;**
- **Labelling;**
- **Voluntary** industry activities;
- The **Stockholm Convention;**
- EU **Drinking Water Directive;**
- **Operational Conditions** implemented and recommended by the manufacturers and/or importers;
- Further **international regulatory** activities.

All risk management options considered have been evaluated against the criteria effectiveness, practicality and monitorability (see Background Document, section 2.3, table 6). Based on these criteria, the proposed restriction was regarded as the most appropriate option.

A transition period of 18 months in general is proposed in the Background Document. Concentration limits of 25 ppb for the sum of PFHxA and its salts and 1000 ppb for the sum of PFHxA-related substances are suggested.

The Dossier Submitter has identified the following uses of PFHxA, its salts and related substances:

- PFHxA-related substances are used in **paper and cardboard (food contact**

materials) for their chemical stability, heat resistance, water- and oil-repellence and their cost-effectiveness (low amounts are enough to achieve the desired effect). The Dossier Submitter reports that PFASs might be used also in paper for non-food applications (folding cartons, containers, glossy papers, carbonless forms and masking papers). This is confirmed by one comment received during the consultation on the Annex XV report reporting the use of a PFHxA-coated paper layer in an iron-based oxygen absorber used in the food packaging industry but also in pharmaceutical and medical device products.

- Fluorotelomer alcohols (FTOHs) and PFCAs are used in **textiles** mainly as durable water repellent finishing that imparts water, oil and stain resistance to the textile. Textiles treated are consumer apparel, professional apparel, including personal protective equipment (PPE), woven and non-woven medical textiles, technical textiles (including in transportation and construction uses) and home textiles (e.g. upholstery).
- **Fluorinated firefighting foams** are used for class B fires (flammable liquids) and in special cases for class A fires (combustible materials). They include fluorinated surfactants to lower the surface tension and allow the formation of an aqueous film between fuel and foam, thereby cooling the surface, acting as a vapor barrier, allowing a fast spreading of the foam on the fuel and preventing re-ignition. Fluorinated firefighting foams are used in different sectors: aviation, petrochemical industry (oil and gas platforms, refineries, fuel depots) other industrial uses (e.g. in warehouses, automotive industry), defence (seagoing military units, fuel depots, military aviation, training on ships), and in hand-held fire extinguishers.
- **Manufacture and use of fluoropolymers**: PFHxA, its salts and related substances are used as process media to produce certain fluoropolymers. APFHx (the ammonium salt of PFHxA) is used at industrial sites as processing aid to manufacture **fluoroelastomers** that are used to produce e.g. seals and tubes for the automotive or aviation sectors. PFHxA can also be found as impurity in fluoropolymers. Fluoropolymers are used in a wide array of industries such as transport, aerospace, energy (e.g. oil and gas, renewable, nuclear), chemical, telecommunications, semiconductor and electronics, pharmaceutical, food, etc.
- **Manufacture of side-chain fluorinated polymers (SFPs):** SFPs are used for several applications as finishing agents or as repellents to impart oil and water repellence in a wide range of sectors (textiles, including leather, hard surfaces or paper fabrics).
- **Semiconductors and semiconductor related equipment**: the substances are used as process agents for the photolithography process, etching process, in cleaning fluids and in fluoroelastomers. Relevant properties for the semiconductor industry are surface activity, purity and stability.
- **Chrome plating**: PFHxA related substances are used as wetting agents for chrome baths to lower the surface tension of the plating solution. The surfactants are used in metal plating with Cr(VI) to decrease aerosol emissions to reduce emissions of the carcinogenic Cr(VI) to the air. PFHxA related substances are also added to chromo-sulfuric acid in plastic electroplating to achieve wettability of the hydrophobic plastic surface.
- **Photographic applications**: C6-based fluorinated surfactants are used in photographic equipment or in coatings when manufacturing conventional photographic

films. The substances are used as surfactants, as static control agents, as dirt repellents during coating operations and as friction control agents.

- **Printing inks**: C6 based short-chain fluorinated surfactants are used in some water-based inkjet inks and latex inks. The main function is the reduction of the water surface tension when applied on nonporous substrates, thereby improving surface wetting during the printing process. In absence of a surfactant the mixture would tend to form large unequal drops that would lead to a non-uniform surface coverage of the inks.
- **Building materials/ construction products**: uses covered by this sector are e.g. treatment of hard surfaces like stone, ceramics, glass, tile ground, etc. with either solvent or aqueous based fluoropolymer or side-chain fluorinated polymer solutions or dispersions and paints to provide functional water and oil/dirt repellence. During the consultation on the Annex XV report, stakeholders submitted information on further uses: coated C6 fabric in reinforcement of roofing membranes; protection of surfaces and facades against water, moulds, mosses, soil, solvents and oil-based stains (e.g. graffiti); non-woven for construction to bring weathering resistance; water- and oil-repellent penetrating sealers for natural stone, porous tile, grout and masonry; textiles for flexible civil construction (e.g. flexible textile roofs or ceiling panels); and reinforcement fabric for wall plaster to ensure water and UV-resistant effects. C6 is used in flexible civil construction, including flexible textile roofs for sport stadiums or houses, ceiling panels, exterior paints and road marking.
- **Fragrance and flavour**: PFHxA, its salts and related substances have properties that are used for handling of fragrance and odour compounds in products and articles, as they are surface-active and inert to different chemicals. However, their use in this sector is unclear to the Dossier Submitter and no additional information was submitted during the consultation on the Annex XV report.
- **Mixtures for consumer use**: PFASs are used in various mixtures intended for end-use by consumers, including impregnating agents, ski or floor wax, cleaning products, car care and polishes. The Dossier Submitter highlights that limited and uncertain information is available regarding the use of PFHxA-related substances in these products but there is indication that the highest concentrations are found in ski waxes and in proofing products.
- PFASs are used in various **cosmetic products**, serving e.g. as emulsifiers and surfactants or are added to cosmetic products for binding, bulking and skin/hair conditioning purposes.

Stakeholders reported additional uses during the consultation on the Annex XV report, which have been assessed and included in the Background Document:

- PTFE (polytetrafluoroethylene) and PTFE micro-powders have desired mechanical, thermic, electrical and chemical characteristics. PTFE may contain PFHxA-related substances as residuals from the manufacturing process, and PFHxA-related substances may also be unintentionally created while producing the micro powder. PTFE micro-powders are used in the medical sector, in electronics, in the field of tribology, mechatronics and serve as an additive to different substances and liquids to enhance their attributes.
- Electronic devices: fluorinated polymers are used in electronic grade coating in order to achieve high levels of water repellence for the protection of electronic devices from water and corrosion damage. Fluorosurfactants are also applied in batteries as plating bath aids, in photoresist strippers as photoresists and in the production of flat panel

displays as coating solutions, due to their anti-corrosion and electrostatic properties.

- Filtration and separation media: PFHxA related substances in filtration and separation media have a very broad range of applications across several market sectors. The products affected are e.g. medical devices; PPE; heating, ventilation and air conditioning (including high-purity applications for hospitals, laboratories etc.); air pollution controls; dust collectors; hydraulic systems; coalescers; gas turbines; fuel systems and many more.
- Epilames used in watches: C6 side-chain fluorinated polymers are used in the watchmaking industry in mixtures called epilames. Epilames are applied as coating on some internal pieces of mechanical watches and electronic quartz watches. They ensure the proper lubrication of moving parts (e.g. wheels, pivots, escapements, stones). The epilame coating is required to obtain a low surface tension for the lubricant (oil) to stay in place and not spread through the movement of the mechanical watch-parts. Furthermore, the epilame coating must be chemically compatible with the respective substrate on which it is deposited and must also not react with the components of the lubricant.
- C6 fluorinated polymers are used as a cladding material for plastic optical fibres. Low refractive index in the outside keeps the light within the optical fibre, minimises information loss and increases the speed of transmission. According to stakeholders, the optical fibres are mostly used for transmission media for in-vehicle data communication. They help to prevent traffic accidents and thereby save lives. In the future the properties provided by the fibres may become more important and the fibres more demanded as self-driving cars may make a rise in the market.
- Medical devices: different applications for PFHxA related substances exist, such as the production of detergent proof one-use washbowls, non-active medical devices in ophthalmic applications, coatings for hearing aid devices, use in implantable (e.g. catheters, drainage, stents, surgical meshes, etc.) and non-implantable (vascular/delivery catheters, extracorporeal components, wound closures, etc.) medical devices.
- Photographic coating on paper and in printing plates: PFHxA surfactants are also used for photographic coating on paper, inkjet photo media coatings and for photographic coating in printing plates.

The Dossier Submitter has considered the availability of suitable alternatives and/or the anticipated resources required to substitute the above-mentioned current uses and proposed derogations for particular uses where considered necessary.

The **derogations** proposed are justified as follows:

- For the **manufacture and use of fluoropolymers**, higher concentration limits for PFHxA, its salts and related substances are proposed for different applications (see paragraph 11 in the restriction proposal entry). This is due to low emissions and high costs expected in a wide variety of sectors (loss of profits to the European manufacturers). Specifically, higher concentration limits for engine parts in automotive, aerospace and shipping industry are suggested because there is some evidence that the automotive and aerospace industries rely on specific fluoroelastomers to comply with international safety standards (and cannot use alternative materials arbitrarily). Higher concentration limits are also proposed for electronic grade coating because information submitted in the consultation on the Annex XV report suggests that there is currently no economically feasible alternative.
- For **textiles**, derogations are proposed for several specific uses, such as personal protective equipment (PPE) against severe risks, high visibility clothing, and impregnation agents for re-impregnating PPE and high visibility clothing (see paragraph 9 in the restriction proposal entry). This is because these are considered by the Dossier Submitter uses which are fulfilling important safety aspects, and alternatives do not meet the properties needed with regard to oil and/or dirt repellence. In addition, a derogation is proposed for technical textiles used in engine bays in the automotive and aerospace industry because the Dossier Submitter considered it likely that PFHxA-related substances function as important part of the risk management in these applications and a restriction might result in very high societal costs. For these uses, a yearly reporting requirement has been proposed.
- For **medical devices** and related impregnation agents, a general derogation is proposed due to the possibility of additional uses that have not been identified so far and to the possible negative human health impacts of restricting such uses. The Dossier Submitter concludes that any such derogation should also cover medical textiles.
- An additional derogation is proposed for the use of **epilames in watches** because of the very low releases expected and potentially high economic costs for this sector.
- A derogation is proposed for **filtration and separation media** used in high performance air and liquid applications that require a combination of water- and oil-repellence due to the important functions fulfilled and to very small releases.
- Derogation for a substance that is to be used or is used as a transported isolated intermediate (no justification provided by the Dossier Submitter).
- **Firefighting foams**:
    - A longer transition period (5 years) is proposed for concentrated firefighting foams that are used in the production of other firefighting foam mixtures. This applies if they were placed on the market before 18 months (or 36 months, if the SEAC suggestion of a 36-month transition period is taken forward) had passed after the restriction coming into force. The derogation applies to testing and training if and only if all emissions to the environment are minimised and effluents collected and safely disposed of. Noting the large stocks held and potentially huge emissions when the stocks are used (to ensure capacity for action in case of emergency cases) the Dossier Submitter suggests this longer transition period (instead of a derogation) in order to avoid early disposal and any related replacement costs but to still create incentives to substitute with fluorine-free foams.

  - A derogation is proposed for defence uses in airports, ships, fuel depots and for training purposes in enclosed areas. This is because currently available alternatives do not fulfil the requirements of some defence-specific applications, which results in unacceptable risks for human health and the environment. For these uses, a yearly reporting requirement has also been proposed.
  - A longer transition period (12 years) is proposed for firefighting foams for class B fires in large tanks (>500m^2). This is because not enough evidence is available that fluorine free firefighting foams perform as well as fluorinated products in these circumstances, and there are high risks arising from this uncertainty.
- A longer transition period (12 years) is proposed for **semiconductors and related equipment**. This is due to alternatives not being available at the moment, but considered possible with enough time by the Dossier Submitter.
- A longer transition period (7 years) is proposed for **latex printing inks**. This takes account of the service life of related printer hardware.
- A longer transition period (5 years) is proposed for **hard metal chrome plating**. This is because alternatives are available but have not been tested sufficiently.
- A longer transition period (5 years) is proposed for **photographic coatings** applied to film, papers, in printing plates and for inkjet photo media coatings. This is to provide enough time for phase-out of these uses. The longer transition period for inkjet photo media coatings is due to the functional losses expected and comparatively low emissions, although the Dossier Submitter considers the impacts to be poorly understood.
- **Articles placed on the market before 18 months** have passed from the entry into force of the restriction have been derogated.

SEAC conclusion(s):

Choice of risk management option

SEAC agrees that a restriction is an appropriate risk management option to be used to address the risks related to PFHxA, its salts and related substances considering the different uses and life cycle stages of substances, mixtures and articles, including imported articles. It also covers potential future uses, including the use as substituents of long-chain PFCAs, avoiding regrettable substitution of already restricted substances, such as e.g. PFOA. Using a restriction as an EU-wide measure to manage the risks posed by these substances is also coherent with the approach taken for other similar substances (specifically PFOA, C9-C14 PFCAs, PFHxS, and their related substances), which overall improves the practicality and monitorability of the restriction.

SEAC agrees that among the options analysed by the Dossier Submitter, a restriction is, in general, the most appropriate EU-wide measure to address the identified risks from PFHxA, its salts and PFHxA-related substances. Even if the conditions of the restriction are modified as proposed by SEAC, large uncertainties remain as regards the overall proportionality of the restriction (see SEAC's evaluation in the 'socio-economic impact' section of this opinion).

Scope of the proposed restriction

SEAC generally agrees with the scope as proposed by the Dossier Submitter for reducing releases of PFHxA, its salts and PFHxA-related substances. However, SEAC considers some changes to the scope presented in the proposal necessary, mainly based on information

provided during the consultation on the Annex XV report.

In particular, SEAC concludes that:

- It is appropriate to include substances causing emissions of PFHxA because of degradation (i.e. PFHxA-related substances) under the scope of the restriction. Further information is given in the respective RAC sections of this opinion.
- The proposed concentration limit values provide a balance between the need to prevent intentional use and to minimise emissions, and the availability of analytical methods.
- Whilst SEAC notes that for some sectors and/or uses covered by the restriction, alternatives are expected to be available relatively quickly, a general transition period of **36 months** will be needed for the actors affected to adapt their operations (any respective details are given in the section below).
- SEAC notes that several derogations and sector- or use-specific extended transition periods seem necessary (mainly based on information provided in the consultation on the Annex XV report). As reported in the proportionality section of this opinion, SEAC cannot conclude on the proportionality of the overall restriction proposal due to lack of data and robust analysis and assumptions by the Dossier Submitter, based on the information available. SEAC recognises that the broad scope of the restriction proposal, covering many different sectors, posed challenges in terms of data collection, but SEAC still considers that the sectoral analysis by the Dossier Submitter was not sufficiently developed to allow a credible conclusion on the proportionality of the proposed restriction. However, SEAC has assessed if restricting the separate uses covered is proportionate in cases where sufficient information for such analysis is available. Furthermore, SEAC proposes derogations for uses for which it considers that, based on the available evidence, a restriction would not be proportionate. SEAC underlines that while several proposed derogations have not been assigned with a specific end date, **none of the derogations are intended to be permanent**. The information available, the lack of alternatives providing oil repellent properties and the fact that the timeline for development and implementation of any such alternatives is currently unknown does not allow an appropriate duration for the derogation to be proposed. SEAC's conclusions on the various suggested derogations are presented in detail in Background Document, Annex E.6 (constitutes a part of this opinion).

Key elements underpinning the SEAC conclusion(s):

Choice of risk management option

SEAC notes that PFHxA, its salts and related substances are used widely in many different sectors and for many different uses, and emissions are occurring during every life cycle step, including manufacture, industrial use, use in consumer products, service life and the disposal phase. Furthermore, imported mixtures and articles constitute relevant emission sources (the latter cannot be targeted by any other risk management measure than a restriction). Once released, the substances ultimately form PFHxA, which will stay in the environment and is distributed on a wide scale. Furthermore, its removal is extremely difficult. The Dossier Submitter suggests a number of derogations from the restriction proposal (most of them time-limited, but some also not limited in time). This is regarded as necessary due to several reasons, mainly the lack of sufficiently well performing alternatives (detailed information on a per-sector basis is given in Background Document

Annex E.6, which constitutes a part of this opinion). The Dossier Submitter assumed that the proposed restriction would reduce emissions of the substances under consideration by approximately 50-60 % over 20 years in a comparison to the non-restriction scenario. During RAC/SEAC opinion making the Dossier Submitter further concluded that large quantities of releases occur from disposal at end of life (via landfilling) instead of actual service-life for some articles affected (e.g. for products having a rather short service life, such as grease-proof paper or clothing) i.e. the substances under consideration are emitted from landfills for many years. Therefore, the restriction is expected to be effective even beyond the 20-year timeframe. None of the other risk management measures under consideration would, in the Dossier Submitter's view, perform similarly. More information on the effectiveness of the proposed restriction is given in RAC's section above.

Based on the criteria of effectiveness, practicality and monitorability, SEAC agrees with the Dossier Submitter's conclusion that the suggested restriction can be regarded as the most appropriate amongst those discussed in the restriction proposal, as it is targeted to the concern (through limiting emissions of any potential future uses, including the use as a substituent of long-chain PFCAs), whilst considering specific provisions for particular sectors and/or products and uses affected, e.g. different transition periods, derogations and reporting requirements. More information on these aspects is given below and in the respective sections of the Background Document.

SEAC notes that the proposed restriction is in line with the existing restrictions on other perfluorinated alkyl substances (PFOA and C9-C14 PFCAs) in terms of function of the substances covered, types of uses and conditions of the restrictions. SEAC finds this approach useful in terms of consistency of legislation, clarity of the measure to the affected parties, overall practicality and monitorability.

Scope of the proposed restriction

Coverage of substances:

SEAC notes that the aim of the restriction proposal is to reduce emissions of PFHxA to a level as low as possible. SEAC agrees that including all sources of PFHxA emissions is relevant to that end. Inclusion of PFHxA-related substances is specifically relevant considering that according to the analysis in the Background Document, an overwhelming majority of emissions of PFHxA originates from uses of those substances degrading to PFHxA. By including PFHxA-related substances under the scope also future emissions due to possible substitution of PFOA-related substances by PFHxA-related substances can be avoided. SEAC also considers that a restriction with similar coverage than that previously employed for PFOA, C9-C14 PFCAs and PFHxS can be expected to be clear and understandable for all affected parties.

Concentration limits:

SEAC notes that the concentration limits proposed by the Dossier Submitter are 25 ppb (i.e. 25 µg/kg) for the sum of PFHxA and its salts and 1 000 ppb for the sum of PFHxA- related substances. SEAC understands that these values were chosen in order to balance several different aspects, such as preventing intentional use of the substances (and therefore protecting human health and the environment by avoiding emissions), but allowing usage of alternatives (possibly containing unintentional impurities e.g. due to trace contaminants in production facilities), preventing contradiction with other regulatory measures as well as enabling proper enforcement and guaranteeing the availability and technical capabilities of analytical methods. However, only limited information is available on unintentional impurities

of PFHxA, its salts and related substances.

SEAC recognizes that the emphasis of testing will be on PFHxA-related substances as there is no direct use of PFHxA itself, and that the analysis of the related substances may be more complicated than that of PFHxA. However, the issues with testing for related substances are understood to be related to issues like the availability of isotope -labelled standards, and therefore changing the limit values would not affect the situation.

SEAC recalls that the same limit values are applied in the PFOA restriction. With regard to the limit values for PFOA, SEAC notes that the Commission Regulation[17] to include PFOA in Regulation (EU) 2019/1021 (POP) sets a higher concentration limit of 1 ppm for PFOA and its salts in PTFE micro powders (to be reviewed by the Commission no later than 5 July 2022). This is to allow a company to modify the irradiation process to reduce unintentional production of PFOA and to comply with the limit of 25 ppb.

The feasibility of the proposed concentration limits was contested by some stakeholders during the consultation of the Annex XV report. Specifically, the availability of analytical methods capable of quantifying levels this low in specific matrices was questioned. Availability of analytical methods is further discussed in the practicality and testing cost -sections of this opinion.

Overall, SEAC considers that the proposed concentration limits seem reasonable for PFHxA, its salts and PFHxA-related substances. However, contents in fluoropolymers are considered separately by SEAC.

The higher concentration limits proposed for fluoropolymers are discussed in the use-specific assessment of derogations (Background Document Annex E.6, which constitutes a part of this opinion). Overall, SEAC considers that setting specific higher concentration limits for fluoropolymers is appropriate due to the largely poor availability of alternatives and the wide reliance on high-performance fluoropolymers throughout industry sectors. However, even after the consultation on the SEAC draft opinion SEAC does not have enough information to support any specific limit values. SEAC has listed the pros and cons of the proposed sets of limit values for fluoropolymers (see Annex E.7 of the Background Document).

Transition period: The Dossier Submitter suggests a transition period of 18 months from the entry into force of the proposed restriction, as this is considered a sufficient timeframe for the affected parties to phase out the use of the substances (e.g. due to alternatives being already widely available) whilst being short enough to reduce the ongoing releases into the environment which continuously increase the environmental stock. Different, product-specific, transition periods are suggested where regarded necessary and justified by the Dossier Submitter.

SEAC considers that on the one hand, the transition period should be **long** enough to ensure that the producers, importers and users of substances, mixtures and articles are able to comply with the restriction, e.g. in order to **allow for required substitution activities** and respective **adaptations within supply chains**. Also, while articles already placed on the market are outside the scope of the proposed restriction, some **arrangements with regard to new articles** will be necessary in supply chains (negotiation of contracts etc.). From the comments submitted during the consultations on the Annex XV report and the SEAC draft opinion, SEAC notes that the **time available for industry to prepare** for the proposed restriction has not been perceived as sufficiently long. Unlike for earlier PFAS restriction cases,

[17] Commission Delegated Regulation (EU) 2020/784, OJ L 188, 15.6.2020

there was no classification proposal, SVHC identification[18] or alike to alert affected stakeholders. According to current knowledge, PFHxA does not meet the toxic or bioaccumulative criteria in Annex XIII of REACH, and, whilst identified in the Commission's new chemical strategy for sustainability[19] as a potential new hazard criterion, mobility is not yet a standard hazard criterion. Therefore, phase-out had not been regarded to be necessary by some industry actors. During the consultation process, some stakeholders even highlighted that the justifications of the PFOA restriction proposal had led them to think that transition to C6 substances would be considered a viable solution and reported having carried out **substitution of C8 by C6**. Furthermore, SEAC considers that some transition time is necessary to enable progress in the availability of and access to (preferably standard) **analytical methods**, thereby improving the enforceability and practicality of the restriction. SEAC notes that the Forum[20] highlighted in their advice that the development of standard methods is time-consuming.

SEAC highlights that the **versatility of uses** of PFHxA-related substances is large, and several uses were not covered by the impact analysis in the Annex XV dossier. Based on the outcome of the consultations on the Annex XV report and the SEAC draft opinion it appears that alternatives with similar functionalities are not readily available in numerous applications in many sectors. In many cases substitution may also be more demanding than with the earlier PFAS restrictions since this time other PFAS alternatives may not be applicable (considering that even C4 are under regulatory scrutiny) but a fundamentally different solution is needed. Therefore, SEAC considers that in addition to the longer transition periods suggested for specific applications, a longer general transition period than the 18 months proposed by the Dossier Submitter is necessary in case a restriction is enacted.

Several respondents to the consultation on the Annex XV report reported that they expect substitution to be possible in 2-3 years. High costs or special transition arrangements for these uses could be avoided with a transition period of 36 months. For some uses, the necessity of a transition time of 4 years was stated by industry stakeholders (see Table 3 for an overview).

On the other hand, SEAC considers that the transition period should be **short** enough to avoid future manufacture, import or use of the concerned substances in the EU such that **emission reduction** can be achieved without unnecessary delay. SEAC also points out that a short transition period would speed up the transition to alternatives in uses where suitable alternatives are already available (e.g. paper and cardboard/food contact materials or others) and add **incentive to develop alternatives** in the rest of the uses. Being at the forefront in the development of alternatives is expected to enhance the competitiveness of the EU industry in the longer term. SEAC also highlights that the ambitions to **phase out all PFASs in general have been widely advertised** in the recent years (e.g. see conclusions of the Council of the European Union "Towards a Sustainable Chemicals Policy Strategy of the Union"[21]), and thereby expects most actors to have been aware of the trend. Also, the time from the publication of the restriction intention until the date of application will be several years (~1 year for dossier preparation, ~1 year for opinion making, ~½ year for legislative

[18] The German Competent Authority proposed in 2018 an Annex XV proposal for identification of PFHxA and its ammonium salt as SVHCs under Article 57(f) of REACH (see ECHA website). This proposal was later withdrawn.
[19] European Commission, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM(2020) 667 final, Brussels, 14.10.2020 (https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf)
[20] Forum for Exchange of Information on Enforcement as per REACH Art. 76f
[21] http://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf

processes, plus the proposed 3 years general transition period).

Table 3: Transition time needed, as reported by industry stakeholders in the consultation on the Annex XV report

Length of the general transition period	Applications where high socio-economic impacts could be avoided if a longer (than originally suggested by the Dossier Submitter) transition period is applied as phase-out appears feasible within the period mentioned below (a non-exhaustive list based on the information available)
2-3 years	• Consumer water-proofing sprays (comments #2968, 3033, 3049) • Water-repellents for outdoor, sports apparel (comments #3015, 3028, 3049) • Protective wear (not class 3 PPE) (comment #2962, (3015)) • Water-repellents in construction applications (comment #2968, 3049) • Certain types of surfactants (comment #3030) • Decorative chrome plating
4 years	• (All of the applications in the row above) • Inkjet printing inks (comment #2987, confidential) • Possibly some uses in firefighting foams (comment #3010) • Possibly oxygen absorbers for food and medication packaging (comment #3125)

SEAC also highlights that there are numerous actors in many industry sectors that stated in the consultations on the Annex XV report and SEAC's draft opinion that the performance level of the alternatives available is not sufficient currently, and the quality of their products would deteriorate if the alternatives were introduced now, causing considerable losses. However, several respondents did not give an estimate of the time needed for transition and are not covered by the list in Table 3. It was stated in many comments that the cost of the alternatives is not the issue, but performance is. SEAC notes that a longer general transition period would also allow those companies to progress with substitution, carry out the transition in a more controlled manner and reduce costs, although the exact magnitude of these costs is not known to SEAC.

Unfortunately, no quantitative estimates of the costs avoided per application with the referred transition times are available. Several stakeholders stated in the consultations on the Annex XV report and SEAC's draft opinion that if the transition period was too short, it would be impossible to develop fluorine-free technologies for the technically more advanced and challenging applications, and thereby the markets and the associated jobs would be lost. A short transition period might also prevent carrying out existing long-term contracts, but the welfare implications of this are not known to SEAC. SEAC acknowledges that implementing a substitute to mass production level and requalifying the products with clients will take time even if a substitute is available in general. SEAC agrees that negative socio-economic impacts could be expected in terms of profit losses, reduced product quality, shift of market shares to importers in cases where the substance is not contained in the finished article, etc. Further details on a sector basis are given in the cost section below.

On the other hand, SEAC keeps in mind that the longer the transition period, the larger the emissions before the restriction enters into force. The general transition period will be applied also to all uses of textiles and paper and cardboard (food contact materials), where high emissions have been observed and alternatives are mostly available. However, SEAC assumes that not all stakeholders will make use of the full transition period as substitution is a step-wise approach and some uses might be stopped already earlier anyhow. SEAC considers that four years might be too long considering that RAC recommended to keep the transition period as short as possible.

Taking into account all of the above, SEAC proposes a general transition period of 36 months.

Derogations proposed by the Dossier Submitter: SEAC agrees that derogations are necessary for several uses where technically and/or economically feasible alternatives are not available or are still in the development phase. Applying derogations requires careful consideration with regard to uses considered by the Dossier Submitter to have high societal costs. SEAC's evaluation and conclusions on the various suggested derogations are presented in detail in Background Document Annex E.6, which constitutes a part of this opinion.

SEAC highlights that supporting information for many of the derogation requests is incomplete such that it makes the derivation of scientifically based conclusions challenging. During SEAC opinion-making, stakeholders were encouraged to submit more information on specific points through the consultation. Some further information was received; however, uncertainty remains. This is largely due to the wide variety of uses and users, but also due to the information received not being representative of all the different use situations and not giving a clear picture of the situation over the entire sector.

SEAC notes RAC's conclusion that the largest emission sources seem to be textiles, paper and cardboard (food contact materials) and firefighting foams. The impacts of the emissions from the other sectors on the overall effectiveness of the restriction could be expected to be comparatively low, as far as the emission levels will not increase considerably (noting that emissions as a proxy of the impacts do not reflect the accumulation of stocks to the environment of very persistent substances). Keeping in mind that RAC considers that minimisation of emissions should be sought for PFHxA, its salts and related substances, SEAC still considers that the above suggests that timelines for transition to alternatives in the other sectors should be set to be practical for industry in order to avoid potential failures and related high socio-economic consequences.

Applications for which derogations were requested during the consultation: during the consultation on the Annex XV report, stakeholders requested derogations for several uses. These requests have been reported and evaluated in Background Document Annex E.6, which constitutes a part of this opinion.

Labelling: in the consultations, NGOs stressed repeatedly that articles or mixtures benefitting from a derogation or a transition period should be labelled; this would raise consumer awareness on the presence of the substances in products and give purchasers the possibility to make an informed choice on which products to buy (PFAS-free vs. PFAS-containing). Also proper waste management can be ensured by labelling (comment #3077). SEAC acknowledges that improved flow of information would be beneficial in terms of achieving the aims of the restriction and also notes that in this way the purchasers would be better able to contribute to phase-down if they so wish, since the market would adapt to changes in behaviour. SEAC has no information on the costs associated with a labelling requirement, nor on how purchasers would react to such labels and their effectiveness in promoting awareness and proper waste management. Therefore, SEAC cannot evaluate whether costs and benefits of such requirement would be well balanced.

Recycling and reuse of articles and any related issues:

The scope of the proposed restriction includes recycled material and articles made from recycled materials. According to the Dossier Submitter, there is a concern if recycled materials contain PFHxA, its salts and related substances and a derogation for recycled materials would potentially lead to higher emissions to the environment. SEAC agrees with the Dossier Submitter that the recycling of contaminated waste contributes to environmental releases and the contaminants may again circulate through use, disposal and recycling phase of articles.

SEAC notes that a recent Dutch study by Rijkswaterstaat, Ministry of Infrastructure and Water Management (see also paragraph below) seems to confirm that PFHxA was found in sludge from paper production where recycled paper was used[22]. Hence, excluding recycled material and articles made from recycled materials from the scope of the restriction proposal appears problematic from a chemicals risk-point of view. As to the socio-economic consequences of restricting these uses, there is no information available to SEAC that would allow drawing a conclusion on these aspects. The proposal does not analyse a restriction option where recycled material would be out of scope, and during the consultation on the Annex XV report limited information was provided.

Notwithstanding any general socio-economic benefits of recycling as such, SEAC highlights a few aspects:

- SEAC notes that compost mixed with **sludge from paper production** (containing PFAAs) has been used as a fertiliser product, which is likely to have resulted in contamination of arable land (e.g. in Rastatt, Germany). As a result, the concentration of short-chain PFAAs in some crops exceeded the thresholds derived by authorities, preventing the use as food. Such contamination is expected to have negative impacts e.g. to the concerned farmers as well as to the local community. In the Dutch study mentioned above, effluent from four companies in the paper industry were investigated regarding discharges of PFASs. The investigated companies process wastepaper and produce new paper and cardboard. A significant finding of the study was that a factory that did not use recycled paper in its production of paper barely discharged PFASs in contrary to the other three factories using recycled paper, which discharged relatively high amounts of PFASs in the effluent ranging from a few nanograms per litre to almost 400 ng/l for different PFAS components (including PFHxA). Ink in the recycled paper could be a possible source for PFAS emission. This finding might indicate that recycling is a source for emission of PFHxA.
- Concerning articles containing PFHxA, its salts or PFHxA-related substances, **textiles** (mostly clothing) could be expected to be one of the product types most typically being reused. There is no specific information available on the existence or wideness of recycling and/or reuse of PFAS-containing textiles. As far as clothing is discussed, it can be expected that the articles have been washed several times and have lost some of the PFASs originally contained by the time they are directed to recycling or reuse. Accordingly, the level of concern with regard to PFAS content can be expected to be lower for recycled/reused textiles than for virgin textiles (as far as they are not further introduced during the recycling process). It was reported in the consultation on the Annex XV report that complex methods are needed in the recycling of DWR (durable water repellent) treated laminates; recycling is reported to be at the edge of technical feasibility, but likely not economically viable. It was also highlighted that customers appear to prefer to resell garments via second-hand channels rather than to return them to stores for recycling (comment #3068).
- According to the Background Document, PFASs are used in many different kinds of **building materials,** and fluorinated substances are for example added in paints to improve flow, wetting, and levelling. Based on volume, construction and demolition (C&D) waste is the largest waste stream in the EU, 500 million tonnes per year.[23] The Waste Framework Directive 2008/98/EC aims to have 70% of C&D waste recycled by

[22] A.C .H. Jans & R.P.M. Berbee, Sources of PFAS for Dutch surface waters, Rijkswaterstaat, 14 July 2020.
[23] European Commission, Circular economy, Actions for specific materials and sectors, Construction and demolition: https://ec.europa.eu/growth/industry/sustainability/built-environment_en (30.6.2020)

2020. According to COM (2018) only about 50% of C&D waste is currently being recycled while some EU countries are recycling even up to 90%.[24] Derogation regarding recovery products[25] from C&D waste would help achieving the recycling goal for C&D waste. However, PFAS emissions to the environment would be avoided better without such derogation.

- E-waste recycling was also reported during the consultation on the Annex XV report as a possible source of PFHxA releases into the environment and human exposure to PFHxA, based on studies conducted in Asia (comment #3107). However, SEAC notes that evidence suggesting that these findings hold true for the EU is lacking, but recognises that many electronic articles in the EU originate from Asia.
- SEAC notes that products imported from outside the EU represent a challenge in the context of recycling, since information on their exact composition may be unavailable and this risk should also be covered in the restriction proposal regarding recycling.

SEAC notes that recycling of contaminated materials might contribute to higher emissions to the environment than high-temperature incineration, as contaminants may still circulate through use, disposal and recycling phases of articles. Hence, it would be reasonable to include products, materials and articles originating from recovery processes in the scope of the restriction as well.

Based on the fact that the Dossier Submitter did not assess (per sector and/or use affected) any socio-economic impacts of recycling activities in the light of the proposed restriction and due to the absence of any respective information submitted during the consultation, SEAC cannot conclude on the socio-economic impacts of the restriction on recycling.

Spare parts:

SEAC notes that during the consultation on the SEAC draft opinion, several stakeholders requested an explicit derogation for spare parts. From the information provided, SEAC notes that one stakeholder from the automotive industry requests an indefinite exemption for spare parts of vehicles, as these products are used for long periods of time and over long distances and require regular maintenance and repair (comment #847). The stakeholder requests that the derogation should apply to ***any spare part produced before the restriction enters into force***, in order to avoid any respective disposal of already produced spare parts or costly and time-consuming redesign and re-evaluation of affected products/product parts. Several other stakeholders request an indefinite derogation for spare parts for electrical and electronic equipment (EEE) (comments #853, 872, 907, 912, and others). These stakeholders request that spare parts are derogated ***for EEE products that were already placed on the market before the restriction enters into force***. Some of the stakeholders request that the derogation should be aligned to the situation within the RoHS Directive 2011/65/EU, which e.g. sets uniform exclusions for cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the products placed on the market before the restriction applies. Stakeholders state that a re-design of a spare part often also requires a re-design of the EEE, because otherwise, the original performance (i.e. safety and durability) cannot be guaranteed. This would also avoid any early disposal of products.

SEAC notes that derogations for spare parts could make sense from a circular economy perspective, as these would allow for the repair and maintenance and likely extend the lifetime

[24] European Commission, EU Construction and Demolition Waste Protocol and Guidelines, 18/09/2018: https://ec.europa.eu/growth/content/eu-construction-and-demolition-waste-protocol-0_en (30.6.2020)
[25] The material or articles made from recovered demolition C&D waste may have an end-of-waste status and thus are in the scope of REACH.

of affected articles already on the market. However, in SEAC's view, the requested non-time limited character of any such derogations cannot be justified as the affected products would reach their end-of-life also at one point in time. Furthermore, for EEE, there might be consistency considerations with exemptions applicable under the RoHS Directive. SEAC also notes that overall, RAC does not support a derogation for the above products/sectors, as uses are wide and dispersive and emissions cannot be controlled by means other than a restriction. SEAC concludes that it will be important that these issues are considered, as both the reduction of emissions and the principle of a circular economy are relevant for the decision maker. However, SEAC does not have the information to assess the socio-economic impacts of specific (time-limited) derogations for spare parts for the automotive and EEE industry and notes that this issue is possibly relevant for other sectors as well.

4.3.1. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of the Dossier Submitter's proposal:

Due to the properties and risks of PFHxA, the Dossier Submitter considers as the ultimate aim to minimise the emissions of PFHxA, its salts and related substances in order to minimise environmental and human exposures. The risks cannot be quantified with sufficient certainty for the environment and human health, meaning that the effectiveness cannot be measured with reduced risk quotients or decrease of specific exposure levels. To inform risk management, the assessment of effectiveness needs to encompass, according to the Dossier Submitter, a qualitative assessment of risks by looking into the overall release reduction, release patterns and exposure pathways.

The Background Document identifies a high number and a large variety of uses of PFHxA, its salts and related substances. The Dossier Submitter is confident, that the general information presented on the use of the substances in different sectors is exhaustive. The release estimation contains, on the contrary, several uncertainties but the Dossier Submitter has calculated rough estimates. Increase in pollution stock, expressed as released and formed PFHxA, would without the restriction in 2040 be between approximately 2 400 and 24 000 t.

In section B.9.18 the Dossier Submitter has estimated the current pollution stock of PFHxA using measured data of PFHxA as follows. Using the measured maximum concentration of PFHxA (9.56 ng/L) (Ahrens et al., 2009a) about 7 t PFHxA could be found in the German Bights surface water. Extrapolating this result to European territorial coastal surface waters, considering an average coastline of 68 000 km, about 144 t PFHxA have been accumulated in this water body. The coastal waters are part of a larger system of seas and oceans. There are some publications available which report the PFHxA concentration in open sea surface water (see table 50 in Appendix B.4.2 of the Background Document). Assuming the measured PFHxA-concentration in the open sea surface water is equally distributed over the whole water body from surface to bottom, in the North Atlantic Ocean about 16 500 t PFHxA, in the Mediterranean Sea about 700 t and in the Baltic Sea about 6 t PFHxA are retained. This assumption would only be a narrow regional snapshot considering that a dilution on regional scale takes place and PFHxA is distributed worldwide in water.

After the restriction comes into force, products containing PFHxA, its salts and PFHxA-related substances will not be manufactured in the EU and the substances will not be placed on the EU market, except for uses where exemptions have been granted on socio-economic grounds. The Dossier Submitter expects the releases to substantially decrease and therefore considers the restriction effective. Remaining sources of release will consist of impurities below the proposed threshold(s), products still in use, derogated uses and releases from landfills.

For the estimations of the effectiveness of the proposed restriction, the Dossier Submitter compared the estimated cumulative releases of C6-SFPs, C6 low-molecular weight related substances and PFHxA and its salts after 20 years with and without a restriction, expressed as PFHxA formed. The cumulative releases were based on the current releases (t/a) for relevant life cycle steps, the emissions with/without the proposed restriction, the average service lives of articles (1-15 years) and landfill residence time (10 years). An overview of the life-cycle steps and average service lives (including landfill residence time) used to derive the cumulative releases per sector/subsector with and/or without a restriction over 20 years is provided in Background Document Annex B.9.20 (RAC's evaluation of exposure assessment).

The Dossier Submitter estimated the emissions of PFHxA, its salts and related substances (expressed as PFHxA released and formed in total) **to be reduced by approximately 50 %** over 20 years in comparison to a non-restriction scenario. Current use of articles and products containing PFHxA, its salts and/or related substances and their continued use after entry into force of the restriction (which depend on the length of technical and service life), leaching from landfills and soils, and exempted uses would still cause an increase of the pollution stock. The Dossier Submitter estimates that about 80% of the releases of PFHxA, its salts and related substances occur from deposits of end-of-life products and articles. It is noted that the contribution of releases from landfilled waste is not substantially reduced over this period.

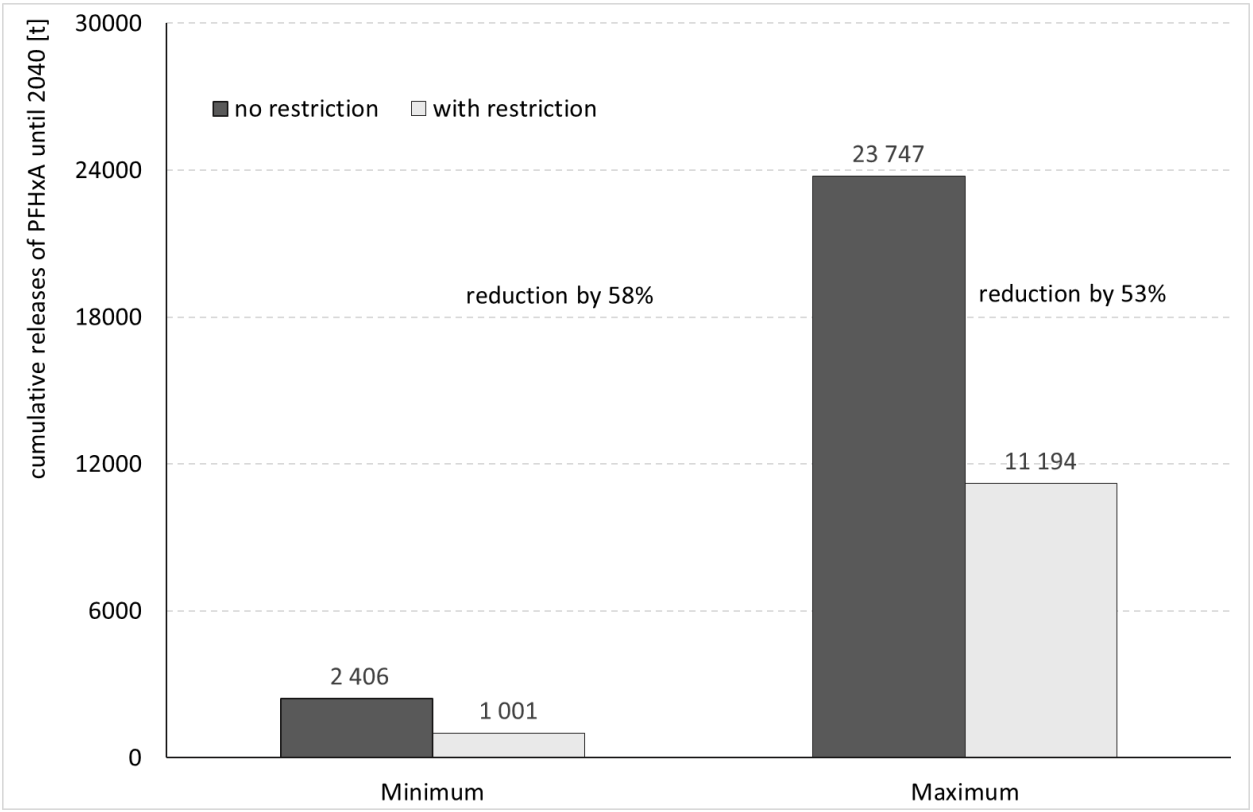

Figure 4. Estimated cumulative releases of PFHxA over 20 years (Figure 2 in the

Background Document).
The Dossier Submitter considers that a restriction with a concentration limit of zero would be most effective, as this would end the exposure of PFHxA, its salts and PFHxA-related substances to the environment. Nevertheless, this threshold is not feasible and enforceable (e.g. due to detection limits). Consequently, according to the Dossier Submitter, to prevent intentional use but allow usage of alternatives and prevent contradiction with other regulatory measures a concentration limit above zero was chosen.

Other risk management options considered

The proposal discusses potential Union-wide risk management measures and four restriction options, which alone and in combination with the proposed restriction were explored with regard to their effectiveness, practicality and monitorability: (1) Restriction with no concentration limit was considered effective from the point of view of release cessation but discarded as not proportionate; (2) Restriction on selected products and (3) Restriction on specific sectors were considered not effective for limiting future uses (and hence potential future releases); (4) For product labelling no evidence was available on its effectiveness; (5) Additional operational conditions implemented and recommended by the manufactures and/or importers risk management would not reduce release from all downstream uses and imported articles; (6) Voluntary industry measures would potentially be effective for certain sectors and life-cycle steps but not all (7) EU Drinking water Quality Standards would have different effect, targeted to managing already caused contamination. Dossier Submitter considers it also necessary to trigger regulatory risk management measures internationally.

Suitability of alternatives to PFHxA, its salts and related substances

The Background Document identifies sector-wise potential alternatives where information has been available (see Annex E.2 of the Background Document). The following table (Table 4) provides a summary of the information in the Background Document on alternatives, their availability and information on their hazards and risks.

Table 4. Summary of alternatives as provided in the Background Document.

Use/sector	Alternatives and their availability and hazards/risks
Fluoropolymers and C6-SFPs (use and manufacture) in general	No specific alternative substances, technologies or their hazards/risks are mentioned. The Dossier Submitter generally notes that for certain sub-uses alternatives might be available (e.g. cookware, textiles, food processing).
Fluoroelastomers in automotive, aerospace and shipping applications	The Dossier Submitter inform that fluoroelastomers can be produced using so called soap-free emulsion polymerization, but that the resulting fluoroelastomers do not reach the same performance levels.
Semiconductors (Annex E.2.2.1.4)	In summary, no single `drop in' chemical alternative is available which can substitute PFHxA in all production processes within the semiconductor industry. During the assessment of alternatives for PFOS (UNEP 2018a) the following substances were identified (one company as source): - amyl acetate - anisole - *n*-butyl acetate - ethyl lactate

	- methyl-3-methoxypropionate - propylene glycol methyl ether acetate. IBM and Fujifilm have reported the availability of non-PFAS technologies for certain processes and further development of the semiconductor manufacture is ongoing also elsewhere. Fluoroelastomers fulfil functions in the production of semiconductors that are critical for the functionality of the semiconductor and currently there are no alternatives available. Section E.2.2.1.5 in the Background Document state: "a fluorocarbon surfactant/surface modifier is much preferred to available alternatives because the known alternatives all contain silicon." No hazards/risks of alternative substances are mentioned.
Electronic grade coating (electronic devices) (Annex E.2.2.2.2)	According to one stakeholder (comment no. 3007), for combination of all wanted properties of the coating there are currently no alternatives available, but only for ensuring specific properties. Some information on hazards/risks of alternative substances were mentioned in a confidential comment in the consultation on Annex XV report.
Firefighting foams (Annexes E.2.3.2 and E.2.3.4)	Several use specific non-fluorinated alternatives (trade names) are provided in Table 30 of the Background Document. Those include: • Hydrocarbon based foams, • protein based foams, • foams based on other detergents such as alkylsulfates. In many firefighting uses, e.g. at airports, PFAS based firefighting foams have been replaced by non-fluorinated alternatives (see examples in Table 31 of the Background Document). For large tanks no drop-in alternatives of the current foam generation have been, however, identified based on a study of LASTFIRE (Ramsden, 2018). The Dossier Submitter concludes also that based on EC/ECHA (2020b) study on firefighting foams, it cannot be ruled out that shorter chained PFASs will be used as alternatives in the future. However, a distinct tendency to use fluorine-free alternatives can be observed. No hazards/risks of alternative substances are mentioned.
Printing inks (Annexes E.2.4.2 and E.2.4.4)	Stakeholders expect that a simple "drop in" substitution will not be possible. Some alternative technologies are solvent based or UV-curable mixtures (Stakeholder Consultation, 2018). No specific alternative substances or their hazards/risks are mentioned.
Chrome plating (Annex E.2.5.2)	Fluorinated surfactants are only used in metal plating with chromium (VI) (Blepp et al., 2017; UNEP, 2018a). No surfactants are needed in fully closed plating systems, however, there is no single technological closed system applicable for all specific plating processes. As part of the assessment of alternatives for PFOS in chrome plating processes it was confirmed that non-fluorinated surfactants seem feasible for decorative as well as hard chrome plating (UNEP, 2019). Successfully tested alternative immersion techniques include acidic permanganate solutions, nitric acid and trichloroacetic acid mixtures.

	Further fluorine free alternative substances and technologies are listed in Table 34 of the Background Document. Several of the alternatives are classified as hazardous.
Building materials (Annex E.2.6)	Testing of alternatives in specific building material uses has taken place according to the information from the consultation on the Annex XV report. Based on information from the Stakeholder Consultation (2018), fluorine-free alternatives are possible for water repellency of external glazing and interior decorative glass as well as for the solar sector. Suppliers in the paint industry have provided information that surface-active fluorinated substances are generally significantly more expensive than alternative surface-active substances. They are therefore used only if such a low surface tension is required that this cannot be achieved with a fluorine-free alternative (UNEP, 2013). The alternative substances apparently available have generally not been specified in the Background Document. No hazards/risks of alternatives are mentioned. For water-based paints, silicones have been mentioned as substitutes based on the restriction proposal of long-chain PFCAs.
Photographic applications (Annex E.2.7.4)	Most remaining photographic applications are expected to disappear due to further digitalisation, hence normally no alternatives will be needed. One stakeholder asked for a derogation for inkjet photo media based on the claim to be able to find an alternative at the latest by end of 2027. No further information has been provided. No hazards/risks of alternatives are mentioned in the Background Document.
Fragrance and flavour industries (Annex E.2.8)	The use of PFHxA, its salts and related substances is indicative only in this sector. No information on alternative substances is available. No hazards/risks of alternatives are mentioned.
Mixtures for consumer use (Annex E.2.9.4)	Publicly available information suggests that alternatives are already available. A broad range of fluorine-free impregnating agents, ski and floor waxes and cleaning agents are on the market. There also seem to be manufacturers producing both fluorinated and fluorine-free products. No further specific information on the alternatives is, however, listed. No hazards/risks of alternatives are mentioned.
Cosmetic products (Annex E.2.10.4)	Market research indicates that PFAS-free alternatives are available for all cosmetic products. Some large producers have announced a phase-out of all PFASs from their products. No specific alternative substances or their hazards/risks are mentioned.
Textiles (Annex E.2.11.4)	Several technologies applying alternative substances are available (substances specified in Annex E.2.11.4), one example is paraffin applying technologies. According to a recent report (commissioned by European Commission – DG Environment, 2020, overview in Table 1 of the study) alternative technologies and substances are available and already in use that provide good water repellency. Human health and environmental hazards and risks of most alternatives are

	according to the report not fully understood. However, according to the Commission report the properties of some substance groups (e.g. dendrimers, hydrocarbons) are most likely less hazardous than PFASs. Alternatives to provide equivalent oil and dirt repellence properties are not available.
Paper and board (food contact materials) (Annex E.2.12.4)	Application of several other PFASs is possible in this sector. Several non-fluorinated alternatives have also been identified in other regulatory processes. Those are use of plastics or silicon oils/resins/ elastomers instead of paper and board. Alternatives to the FCM layer include inorganic salts of fatty acids, other PFASs, different paper refinement technologies and natural materials. No hazards/risks of alternatives are mentioned. For discussion on other PFASs, please, see text after the table.
Polytetrafluoroethylene, PTFE (Annex E.2.13.1)	Note: this substance is used also in some of the sectors covered above (e.g., printing inks, paints, coatings, industrial lamination, etc.). The Dossier Submitter mentions that there are alternative substances or alternative manufacturing processes for PTFE that create impurities of PFHxA lower than 25 ppb. No alternative substances are specified. There is no information available on the potential hazards/risks of the substitution.
Filtration and separation media (Annex E.2.13.4)	Note: this use is relevant for medical devices, PPE, HVAC (including EPA/HEPA/ULPA), Air Pollution Controls (APC), dust collectors, hydraulic systems, coalescers, gas turbines, and fuel systems. The Dossier Submitter notes that if the needed technical requirements for filters claimed by stakeholders are valid, there are no current available substitutes. The Dossier Submitter further considers that, yet it might be possible that alternatives are already available for some applications (e.g. when mainly water-repellent properties are needed) or that substitution is available in the near future. The Background Document mentions also that no robust comparative analysis has been submitted on the consequences of using alternatives instead of PFHxA-related substances. No alternative substances are mentioned. No hazards/risks of alternatives are mentioned.
Epilame used in watches (Annex E.2.13.5)	Stakeholders claim that alternatives are not available. The historically used stearic acid does not according to the stakeholders fulfil current industry standards due to its poor oil repellency and wash resistance. The Dossier Submitter concludes that it is not clear what the industry standards are.
Medical devices (Annex E.2.13.6)	According to the Dossier Submitter, there seem to be fluorine-free alternatives which allow the production of detergent-proof washbowls. No alternative substances, hazards/risks are mentioned. For ophthalmic applications water-based alternatives are mentioned to be available, but they are not specified. No hazards/risks of alternatives mentioned. For specialty compounds for polymers applied in medical devices no alternative substances, their hazards/risks are mentioned. For coating of hearing devices, no alternative substances are available

	according to stakeholders. For medical textiles no alternative substances are mentioned.
Optical fibres (Annex E.2.13.7)	No alternative substances have been mentioned.
Other special uses (Annex E.2.13.8)	No discussion on alternative substances for remaining minor uses (except for special glass as provided in building materials (see above).

Generally, in the Dossier Submitter's view, substitution by C4 fluorinated substances may take place due to the proposed restriction, in a similar manner to the previous restrictions of PFASs. This would be a case of regrettable substitution as the hazard profile of these substances is similar to PFHxA, they are extremely persistent and mobile in the environment. However, the Dossier Submitter concludes that stakeholder consultations in the preparatory stage and the consultation on the Annex XV report did not produce any evidence that broad substitution with C4-related substances (or other fluorinated substances) could be expected for the concerned uses.

The Dossier Submitter notes that some short-chain fluorochemicals outside the scope of this restriction proposal are already subject to further regulatory attention under REACH as either SVHC, potential SVHC (PACT listing) or under substance evaluation (listed on the CoRAP).

RAC conclusion(s):

Consistent with, and following from, the RAC conclusion on the quantitative emissions assessments, the (cumulative) release estimates over 20 years with/without the restriction reported in the Background Document (i.e. the basis of the estimated quantitative effectiveness) are not considered to be reliable. Therefore, the **quantitative** assessment of the effectiveness of the proposed restriction reported by the Dossier Submitter cannot be considered to be robust.

Similar to the RAC evaluation of releases, RAC **qualitatively** evaluated the effectiveness of the proposed restriction from the point of view of the overall objective to minimise the releases and exposures.

RAC considers that the proposed restriction would be effective in reducing emissions and the risks of PFHxA, its salts and related substances. By restricting the use of the substances in the three major use/emissions sources - paper and cardboard (food contact materials), textiles, and firefighting foams, the emissions to the environment and increase in the already existing pollution stock are anticipated to be significantly reduced. However, there is insufficient information to conclude that **all of the uses** targeted by the restriction contribute to the identified risk, specifically uses in chrome plating, firefighting at industrial installations with containment and in optical fibres. Equally, RAC considers that some of the proposed derogations would adversely affect the effectiveness of the proposed restriction to an extent that they should not be incorporated into the restriction.

RAC notes that the longer it takes for the restriction to be implemented, the lower its overall effectiveness because of the pollution stock accumulating during implementation periods.

For many uses, alternatives appear not to be available. However, for some uses or sub-uses, alternatives technologies and/or substances may be available. Due to lack of information in the Background Document and the consultation on the Annex XV report, RAC cannot assess the hazards and risks of alternatives other than that alternative substances, except other PFASs, are likely to be less persistent than PFHxA.

Key elements underpinning the RAC conclusion(s):

In RAC's view, reduced emissions and reduced cumulative emissions are the most appropriate measures of the effectiveness of the restriction for PFHxA, its salts and related substances.

Of the different risk management options discussed by the Dossier Submitter, RAC agrees that overall a broad restriction on all uses with specific and targeted derogations is the most effective measure to achieve the minimisation of releases, which was concluded by RAC to be an appropriate objective for risk management of PFHxA, its salts and related substances (see sections "Information on hazard(s)" and "Characterisation of risk(s)"). A similar restriction but with no concentration limit, as opposed to the proposed concentration limits, may marginally increase the effectiveness of a restriction due to lower residual levels of the substances in mixtures/articles but would be more problematic to enforce (and may be unenforceable). A restriction on selected products and/or specific sectors may be effective to address risks from current uses but does not affect potential future uses (in different sectors) and releases.

RAC agrees that although labelling of articles (e.g. "Contains PFAS") may have some effect to reduce releases, it is unlikely to be effective in general, and is also associated with practical difficulties such as ensuring that information on contents passes through the value chain.

Voluntary industry measures might contribute to emission reductions for certain sectors and life-cycle steps but not to the same extent as a broad restriction. Additional operational conditions from manufactures and/or importers is not expected to provide any significant release reductions given the wide variety of (downstream) uses and emissions at different life-cycle stages. Finally, risk management via Environmental Quality Standards (EQS) would not target the emissions as such.

Due to the limitations of the quantitative approach to estimate emissions and cumulative emissions, RAC instead considered the effectiveness of the proposed restriction in a sector-by-sector qualitative evaluation. The qualitative evaluation focussed on identifying **uses where a restriction is the most effective risk management measure (i.e. where emissions are inevitable and cannot be minimised by means other than a restriction).**

Use of PFHxA, it salts and related substances in a wide dispersive use[26], including a use associated with releases to the environment at the waste/recycling life-cycle stage and where there is limited potential for containment using risk management measures, is considered as a qualitative, but strong, indication that releases from a use would be inevitable.

For industrial sites, the level of site-specific risk management is considered, where information is available, to identify whether site-specific measures have been or could be used to minimise the emissions, e.g. the presence/absence, type and effectiveness of site risk management measures, considering the properties of the specific substance in use, level of containment in the process.

RAC based the qualitative evaluation on the information available in the Background Document as well as on additional information submitted during the consultation on the Annex

[26] The term 'wide-dispersive' is described in ECHA Guidance on information requirements and Chemical Safety Assessment Chapter R.12 (Appendix R.12.1): Use Description. The term is also referred to in ECHA Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment and ECHA's General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation. For the purposes of this opinion the term means *a use of a substance at many sites and/or by many users (a widespread use) associated with releases to the environment or exposure to humans, including from the waste life-cycle stage*.

XV report.

As outlined above, RAC also considered the effect of proposed derogations (by the Dossier Submitter or via the consultation on the Annex XV report) on the overall effectiveness of the restriction. These are also discussed in this section on a sector-by-sector basis.

Textiles (non-medical): wide dispersive use, including consumer and professional uses, specific RMMs unlikely to minimise emissions.

Use of PFHxA-related substances in textiles is a high-tonnage, wide dispersive use across the EU, including use by consumers and professionals. According to the Dossier Submitter, the substances are slowly released from textiles during use, at end-use or after landfilling. RAC considers that there is sufficient measured/experimental evidence on the presence of emissions from textile materials. RAC notes that stakeholders provided information during the consultation on the Annex XV report confirming the use of PFHxA related substances in textiles (both C6 SFPs and low molecular weight related substances), but that the percentage of the textiles treated with the substances was overestimated by the Dossier Submitter. RAC also noted several inconsistencies in the Dossier Submitter's approach for the estimation of the emissions, which are likely to result in an overestimation of releases from textiles. RAC notes that there are currently no sector specific EU level regulatory measures in place to ensure recycling of textiles in such a manner that could ensure minimisation of emissions of PFHxA-related substances.

Clothing/ consumer apparel

The article service life for the majority of clothing is, in general, relatively short (assumed to be up to 5 years). According to the Dossier Submitter, the main releases of PFHxA-related substances from textiles occur due to degradation by UV-light, abrasion and washing. Then, according to the Dossier Submitter, the textiles are mainly landfilled or, to a lower extent, incinerated. The implementation of any RMMs is complicated due to the fact that the main uses of textiles are by consumers and professionals and all those are wide dispersive uses. During the consultation on the Annex XV report stakeholders provided information only about RMMs relevant to the production life cycle.

While RAC concludes that emissions from textile manufacturing sites could potentially be minimised, emissions during article service life and the waste life cycle (via landfill or textile recycling) are inevitable. A restriction on the use would be effective in preventing further emissions to the environment. **RAC therefore, supports a restriction for clothing/ consumer apparel**.

Professional apparel, including personal protective equipment (PPE)

The article service life for the majority of professional clothes and PPE in general is relatively short (1-2 years). According to the Dossier Submitter, textiles are mainly landfilled or, to a lower extent, incinerated. During the consultation on the Annex XV report stakeholders provided some information about RMMs relevant to the production life cycle, while the information provided on the use and waste life cycles was very limited, e.g. PPEs are collected after use as waste by an external professional company. The implementation of any RMMs is complicated, but not impossible, due to the fact that the main uses of textiles by professionals are wide dispersive uses.

While RAC concludes that emissions from textile manufacturing sites could potentially be minimised, emissions during article service life and the waste life cycle without specifying additional risk management measures are inevitable. A restriction on the use would be

effective in preventing further emissions to the environment. **RAC therefore supports a restriction for professional apparel, including personal protective equipment (PPE)**.

Home textiles

The article service life in the majority of home textiles is relatively long (up to 15 years). According to the Dossier Submitter, the compounds are released from home textiles service life by degassing, by cleaning and by development of house dust. The implementation of any RMMs is complicated because the main uses of textiles are by consumers and professionals and all those are wide dispersive uses.

Similarly to other textile uses, RAC concludes that emissions from textile manufacturing sites could potentially be minimised. However, emissions during article service life and the waste life cycle stage are inevitable. A restriction on the use would be effective in preventing further emissions to the environment. **RAC therefore supports a restriction for home textiles.**

Technical/ industrial textiles

Technical textiles are mainly used in automotive and aerospace applications, as filtration media and in the construction sector. The Dossier Submitter noted that EU-wide use quantities and therefore potential for releases from end of life are unknown. For some uses, stakeholders proposed to ensure proper disposal of articles via the Directive 2000/53/EC of the European Parliament and of the Council on end-of life vehicles, but the impact of that proposal on the reduction of the emissions is unknown.

While RAC concludes that emissions from textile manufacturing sites could potentially be minimised, emissions during article service life and the waste life cycle without specifying additional risk management measures are inevitable. A restriction on the use would be effective in preventing further emissions to the environment **RAC therefore supports a restriction for technical/ industrial textiles.**

Medical textiles - wide dispersive professional uses, possible RMMs to prevent emissions

Medical textiles have a wide range of uses in health care settings. They are used in different forms in ambulances, consultation couches, intensive care units, laboratories, operating rooms, wards etc. During the consultation on the Annex XV report stakeholders provided some information about RMMs relevant to the production life cycle. The use is widespread, but due to the specialised nature of the use some of the textiles will be disposed as hazardous waste. According to the Dossier Submitter the potential release will be in range of kilograms per year.

RAC is of the opinion that the continued use of PFHxA related substances in medical textiles, without specifying additional risk management measures, would result in emissions to the environment, although a contribution to the identified risk compared to other types of textiles will be relatively limited. **RAC therefore supports a restriction for medical textiles.**

The Dossier Submitter proposed an indefinite derogation for textiles used in engine bays in the automotive and aerospace industry (Paragraph 9e of the Dossier Submitter proposal).

Textiles for use in engine bays in the automotive and aerospace industry are considered by the Dossier Submitter as a subset of technical textiles. According to the assumptions made for technical textiles in general, it is likely that to the uppermost part of these textiles are treated with fluorinated polymers (fluoropolymers and C6-SFPs). The used quantities were not known to the Dossier Submitter, and a quantification of the emissions was therefore not considered possible. The releases of PFHxA its salts and related substances are considered by

the Dossier Submitter low from technical textiles in general and much lower in this particular subset. No information on risk management measures has been provided. Due to unknown quantities used in this wide-dispersive use, where possible emissions cannot be quantified, and lack of information on RMMs, **RAC cannot support the proposed derogation for textiles used in engine bays without further information**.

Further derogations requested/proposed for specialised and technical textile uses

Derogations were requested during the consultation on the Annex XV report for several specific subtypes of textiles, such as outdoor technical textiles (e.g. outdoors upholstery, awnings), home textiles, upholstery for residential, commercial, and automotive settings, high-performance sports equipment and nonwoven textiles used in e.g. transport and construction, including their re-impregnation (e.g. comments #3028, #3040, #3070, #3076, #3109, #3140, #3161).

EURATEX, the European Apparel and Textile Industry Confederation, representing 171 000 companies in this sector in the EU, stated that technical textiles require fluorinated substances to fulfil safety and performance standards (e.g. EU legislation, EU/national standards, ISO standards, Technical Performance Profile, EU industrial standards (VDI-, IMO-, BDLI-, ESA-), company standards and other global legislation and standards). Use of shorter chain fluorinated substances and non-fluorinated alternatives cannot fulfil these requirements. For other uses a minimum transition period of 36 months was requested.

Limited information is available on use volumes and possible PFHxA-emissions from these sub-sectors; however, they are likely to be significant. The Dossier Submitter estimated the emissions to be in the order of a few hundred kilograms/year for technical textiles to tonnes/year for professional and home textiles (Table 25b-d of the Background Document). One company reported in the consultation on the Annex XV report (comment #3040) use quantities of 500 kg/year for aeronautic textiles. Information on the risk management measures applied during the production process of textiles was submitted (comment #3161), resulting in estimated emissions during initial textile treatment to wastewater of < 0.02 kg/year. However, RAC considers the emissions to occur primarily during service life of the textiles (including washing), requiring re-impregnation, and also after end-of-life. Altogether, based on limited sub-sector specific information on use volumes and emissions, but with a probability that use volumes and emissions will be substantial, and likely to most extent directly to the environment during the service life, **RAC does not support a derogation for specialised and technical textiles**.

Paper and cardboard (food contact materials) - wide dispersive use, including consumers and professional use, RMMs unlikely to prevent emissions

Use of PFHxA-related substances in grease-proof paper and cardboard (food contact materials) is a high-tonnage, wide dispersive use across the EU, including consumer and professional use. Although emissions from manufacturing sites could theoretically be minimised and are considered low by the Dossier Submitter due to closed processes, emissions during article service life and the waste life cycle are inevitable and likely to be significant, particularly given the persistent properties of the perfluorohexanoic moiety in the related substances used. For example, whilst emissions during service life could be relatively low (i.e. default release factors articles with low release potential [ERC11a] are 0.05% for air and 0.05% for water) any releases would contribute to environmental stocks. No information challenging the relevance of the default release factors from ECHA Guidance for these articles, specifically information indicating a lower emission potential, was received in the consultation on the Annex XV report. Given the short service life of these articles, the potential for

emissions associated with the waste or re-use life-cycle stages are particularly important to consider. Paper and cardboard are increasingly likely to be recycled at the end of their service life rather than being disposed of via other routes, i.e. landfill or incineration, because of circular economy principles. The pulping of wastepaper fibres during the recycling process will likely result in the emission of PFHxA and/or related substances into wastewater. Any PFHxA formed during the process ending up to wastewater or PFHxA formed from related substances ending up to wastewater from the initially used related substances would unlikely be removed by wastewater treatment (see hazard assessment section on difficulty to remove at end-of-pipe). Furthermore, related substances or PFHxA separated from the used paper and cardboard in the recycling process may be assumed to end up in either other industrial raw material streams, landfill or incineration (see below). It should be noted that operators producing, recycling or incinerating paper or paper pulp are under the scope of the Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control). Similarly, paper or cardboard containing PFHxA or PFHxA-related substances disposed of via home or municipal composting will result in contamination of composts (leading to accumulation of PFHxA and related substances in soils/plants). Burning of paper at home in fireplaces or in the backyard is also likely to occur. Also relevant is that disposal via municipal solid waste (energy from waste) incineration may not result in minimisation if incinerators do not operate at sufficiently high temperatures to destroy all PFHxA and related substances.

In conclusion, use of PFHxA its salts and related substances in paper and cardboard will inevitably result in emissions to the environment, primarily as a result of end-of-life disposal or recycling practices. The presence of these substances in paper/cardboard is not consistent with minimisation of emissions or circular economy principles and, irrespective of more reliable information on the tonnages used and likely emission pathways to the environment, will contribute to the identified risk.

For this use RAC considers that there is no potential for minimisation of releases by other measures. A restriction on the use would be effective in preventing further emissions to the environment. **RAC therefore supports a restriction for paper and cardboard (food contact materials).**

During the consultation on the Annex XV report, stakeholders requested a derogation or a longer transition period of at least five years to develop alternatives to current food contact materials that can provide an equivalent functional performance and that do not contain plastics (Comments #2966, 3064). The volumes of PFHxA-related substances are stated to be in the order of hundreds of metric tons per year. Based on the high volumes of substances used, that may end up in landfills and constitute a major emission source, **RAC does not support a derogation for food contact materials**. Reducing emissions from food contact materials, which is one of the largest emission sources, is key to the effectiveness of this restriction.

Firefighting foams

Firefighting foams containing PFHxA-related substances are used for class B fires (flammable liquids) as well as in special cases for class A fires. About 12 000 – 20 000 t of fluorosurfactants-based firefighting foam concentrates are placed on the market per year in Europe. RAC notes that the upper bound was not challenged by third parties in the consultation on the Annex XV report. According to EUROFEU, about 10% of this amount is used in fire incidents. As an alternative estimate, 6 - 15% of the amount of concentrate in stock is used in fire incidents. Part of that tonnage is used in fixed industrial firefighting systems whilst the remaining part is used by professional fire brigades in mobile systems.

The use of perfluorinated substances in the aqueous film forming foams by volunteer fire brigades is assumed to be phased out and mainly fluorine free foam agents are used as replacements. According to the Dossier Submitter diverse areas of application can be found, e.g. aviation, defence applications, other industrial uses such as plant fire brigades or other uses such as hand-held fire extinguishers.

Municipal/mobile firefighting - wide-dispersive; RMMs unlikely to result in emission containment

As a worst-case estimate it is assumed in the Background Document that 100% of the foam used in fire events is released into the environment. Firefighting foams will not be incinerated during an event of fire. Considering the conditions of use, RAC concurs with the Dossier Submitter's assumptions. The diversity of potential conditions of use makes the implementation of any appropriate risk management measures that could effectively reduce emissions to the environment extremely difficult. On this basis, use in municipal/mobile firefighting will inevitably contribute to the identified risk.

For this use RAC considers that there is no potential for minimisation of releases by measures other than a ban. A ban on use would be effective in preventing further emissions to the environment. **RAC therefore supports a restriction for the use in municipal/mobile firefighting foams.**

The Dosser Submitter proposed a 5-year derogation for 'concentrated firefighting foam mixtures placed on the market before entry into force of the restriction and to be used for the production of other firefighting foam mixtures for class B fires' (Paragraph 5c of the Dossier Submitter proposal).

In recent years, several fluorine-free firefighting foams have met the requirements of Class B firefighting performance certifications resulting in a shift to fluorine-free foams. Therefore, PFHxA-based firefighting foams are no longer considered to be necessary by the Dossier Submitter. However, considering the large stocks held, and that adjustments of equipment may be necessary, the Dossier Submitter propose to derogate the use of PFHxA-related substances in firefighting foams already placed on the market for five years after entry into force of the restriction.

The Dossier Submitter estimated from the total annual releases of 100 t - 563 t PFHxA-related substances from firefighting foams that a 5-year derogation period would lead to total releases of 500 – 2 815 t PFHxA-related substances, resulting in total emissions of 35 - 197 t PFHxA. RAC considered that these estimates were unreliable. Nevertheless, the emissions arising from this proposed derogation may be significant, in the order of tonnes, and with a high risk of being directly emitted to the environment and with possibilities of substantial local contamination. No risk management measures have been presented for this use and emissions from extinguishing fires outside enclosed areas are acknowledged to be difficult to contain. Based on the relatively high expected localised emissions, with a substantial risk of direct release to the environment, and the lack of risk management measures to prohibit/minimise these releases**, RAC does not support a derogation for concentrated PFHxA-based firefighting foams**. **As no derogation is supported for the use of such foams, RAC sees no need to support a derogation for training.**

Firefighting for defence applications - wide-dispersive; RMMs unlikely to result in emission containment

Similar as for municipal firefighting, the Dossier Submitter assumes that 100% of the foam used in fire events is released into the environment. Firefighting foams will not be incinerated

during an event of fire. RAC concurs with these assumptions. Specifics of the use and not predictable conditions and places of the use make an implementation of any RMMs reducing emission to the environment extremely difficult. Emissions from firefighting for defence applications will contribute to the identified risk.

For this use RAC considers that there is no potential for minimisation of releases by other measures. A ban on the use would be effective in preventing further emissions to the environment **RAC therefore supports a restriction for the use in firefighting foams for defence applications.**

The Dossier Submitter proposed an indefinite (non-time limited) derogation for firefighting foam mixtures for defence applications (seagoing units, air traffic facilities and storage of fuel) for as long as no successful transition to military operable fluorine free foams can be achieved (Paragraph 6 of the Dossier Submitter proposal).

RAC notes that in two European countries, Denmark and Norway, the defence sector has shifted to fluorine free foams. However, other countries have reported that missing alternatives have prevented a complete transition to fluorine-free foams. One of the challenges reported is that available fluorine free foams do not fulfil the standards of certain defence-specific applications. In the consultation on the Annex XV report, it was also stated that NATO technical standards do not currently allow the use of fluorine free foams. RAC notes that Denmark and Norway are members of NATO.

The derogation includes a requirement for annual reporting to ECHA on the quantities used and the efforts of users to substitute firefighting foams that contain PFHxA, its salts and PFHxA-related substances. The objective of this element of the proposed restriction is to assist the European Commission in gathering data on the use of the substances in these sectors and monitor the development of alternatives. Also, the Dossier Submitter proposes that the European Commission shall re-evaluate the need to the derogation in light of new scientific information, including the availability of alternatives.

From the estimated total annual releases of 100 t - 563 t PFHxA-related substances from firefighting foams, the share from defence applications was considered to be 6% and, thereof, approximately 50% from seagoing units, air traffic facilities and fuel storage. Altogether this resulted in estimated annual emissions by the Dossier Submitter of 3 to 17 t PFHxA-related substances, with corresponding annual emissions of 210 kg to 1.2 t PFHxA. Over 20 years this derogation would result in emissions of 4 to 24 t PFHxA (and more in a longer perspective). These estimates are not considered by RAC to be reliable. However, as for the general derogation request for PFHxA-based firefighting foams (above), the estimated emissions from this derogation are in the order of tons emitted to the environment, with the potential for high local contamination. No risk management measures for this use have been presented and are also considered practically difficult for the use on seagoing units and air traffic facilities. Based on the relatively high expected emissions directly to the environment, and the lack of risk management measures to prohibit/minimise these releases, **RAC does not support a derogation for PFHxA-based firefighting foam mixtures for defence applications. As no derogation is supported for the use of such foams, RAC sees no need to support a derogation for training.** RAC notes that Article 2(3) of REACH allows Member States for exemptions from REACH for certain substances in specific cases where necessary in the interests of defence.

Concentrated firefighting foam mixtures for cases of class B fires at industrial installations **-** industrial use, possible RMMs to prevent emissions

Fixed and mobile firefighting systems using C6-based firefighting foams are used at industrial

installations, including SEVESO sites; typically with some form of containment and treatment of firefighting water.

The formulation of firefighting foam concentrates at industrial sites occurs under strictly controlled conditions. According to the Dossier Submitter the emission of PFHxA and its related substances during formulation is below 100-250 kg/year.

RAC notes that the specific conditions of use at industrial installations (including the types of risk management measures and their effectiveness) was not specifically considered by the Dossier Submitter. According to comments from industry received in the consultation on the Annex XV report, less than 10% of aqueous film forming foams are used before the end of its lifetime and in industrial installations firefighting water is collected after fire incidents (or testing). For example, in the oil industry, all facilities for storage, filling, production, handling and usage of flammable and hazardous substances are situated in retention basins (bunds) or on paved surfaces so that any firefighting water can be contained and treated using techniques such as activated carbon, on-site or municipal WWTP or otherwise disposed of according to local legislation.

RAC notes that, according to Maga et al. (2021), activated carbon has a low specific adsorption of fluorosurfactants in the range of approximately 0.01 to 0.1%. Treatment of firefighting waters via incineration could be effective but requires temperatures of above 1 100 °C and the incineration of large volumes of water is energy intensive and impractical. The same publication also identifies that the use of functional precipitation agents for the treatment of PFAS containing fire water could result in effective minimisation of releases. According to comments provided in the consultation on the Annex XV report, some stakeholders are of the opinion that treatment with activated carbon can remove the unwanted fluorinated components before firefighting water is further processed in the wastewater treatment plant. RAC notes that the stakeholders' statements were not accompanied by scientific references or measured data.

RAC is of the opinion that emissions of PFHxA-related substances from use at industrial installations are not likely to be minimised under all circumstances (i.e. carbon filtration or use of municipal wastewater treatment systems). However, there appear to be risk management measures which could be implemented to minimise emissions (i.e. incineration at temperatures >1 100 °C, and potentially functional precipitation), although there is currently insufficient information available to fully assess the effectiveness of these risk management measure and, consequently, to specify them as a condition of continued use (i.e. as a condition for a derogation). Due to these significant uncertainties RAC cannot conclude on the effectiveness of the proposed restriction (i.e. ban on use with derogations for certain types of fires) for this use as it is uncertain if the specific use at industrial sites with containment would contribute to the identified risk in all circumstances.

The continued use of PFHxA related substances in firefighting foams at industrial installations, without specifying additional risk management measures, would result in emissions to the environment, but a lack of information prevents a reliable quantitative estimate on the scale of the emissions per year. RAC notes that in 2020 ECHA was requested by the Commission to investigate the need for a restriction of PFASs in firefighting foams, including in industrial installations. This restriction proposal is planned to be submitted in October 2021. RAC recommends that these uncertainties should be specifically addressed in this ECHA proposal to allow an improved assessment of the effectiveness of a restriction in this use. **RAC therefore, without further information on the effectiveness of potential RMMs, cannot conclude that a ban on the use of PFHxA, its salts and related substances for the use in firefighting at industrial installations with containment is the most**

effective EU wide measure to reduce risks.

The Dossier Submitter proposed a 12-year derogation for concentrated firefighting foam mixtures for cases of class B fires in tanks with a surface area above 500 m^2 (Paragraph 8a of the Dossier Submitter proposal).

Due to the current lack of suitable alternatives for PFHxA-based firefighting foams for fighting class B fires at installations with large (surface area >500 m^2) tank fires, the Dossier Submitter proposed a derogation for this use for 12 years. Similar to the proposed derogation for defence applications (above), the proposed derogation is associated with an annual reporting requirement on the quantities and efforts of substitution as well as a re-evaluation by the Commission in light of new scientific information.

From the annual releases of 100 t to 563 t of PFHxA-related substances from firefighting foams a share of 59% of foam concentrates for class B fires in chemical and petrochemical industries was assumed and, thereof, 20% for use in large tank fires. Altogether, the Dossier Submitter estimated that 12 to 66 t of PFHxA-related substances could be released annually from the use of firefighting foams on large tanks, corresponding to annual emissions of 840 kg to 4.6 t PFHxA (Over 12 years 10 to 56 t PFHxA could be released). RAC considers these estimates as unreliable and notes that some kind of risk management measures will typically be present to reduce/minimise releases to the environment. In the consultation on the Annex XV report, EUROFEU (The European Committee of the Manufacturers of Fire Protection Equipment and Fire Fighting Vehicles) considered the emissions to be approximately 5-10% of the amounts used due to these risk management measures. Nevertheless, potential emissions remain on a magnitude of tons over a 12-year period and with a potential of a high local contamination, and **without further specified additional risk management measures, RAC does not support a derogation for PFHxA-based foams for use in large tanks**. However, to obtain more specific information on risk management measures for this particular use, which would allow a more informed decision, RAC recommends awaiting the restriction proposal on PFASs in firefighting foams to be submitted, which is scheduled for October 2021. Should the Commission choose to derogate this use, RAC underlines the importance of effective risk management measures to retain, treat and dispose used foams and/or fire-water from testing of the systems and/or fires.

Manufacture and use of fluoropolymers – industrial use; professional and consumer wide-dispersive use; RMMs unlikely to result in emission containment

Fully fluorinated polymers (fluoropolymers) are not within the scope of the restriction, as they have not so far been confirmed to degrade to form PFHxA. However, as they may contain PFHxA, its salts or related substances as impurities they are nonetheless potentially affected by the proposed specific concentration limits for polymers proposed by the Dossier Submitter. These specific concentrations limits apply instead of the generic concentration limits:

(g) 2 000 ppb for the sum of PFHxA and its salts and 100 ppm for the sum of PFHxA related low molecular substances in fluoropolymers,
(h) 150 ppm for the sum of PFHxA and its salts and 2500 ppm for the sum of PFHxA related low molecular substances in fluoropolymers used in engine parts in automotive, aerospace and shipping industry,
(i) 10 ppm for the sum of PFHxA and its salts and 500 ppm for the sum of PFHxA related substances in fluoropolymers used in coating of electronic devices (7-year derogation).

In absence of specific information on the behaviour of these impurities the release potential of these impurities may be assumed to be similar to the release potential of any substance from an article. As fluoropolymers are widely used in various forms (see Annexes E.2.1 and

E.2.13 of the Background Document), **RAC concludes that it is unlikely that a measure other than a restriction on the maximum concentration of PFHxA, its salts and related substances in fluoropolymers would be effective in preventing emissions to the environment**.

Concentration limit of 2 000 ppb (2 ppm) for the sum of PFHxA and its salts (Paragraph 11a of the Dossier Submitter proposal) and 100 ppm for the sum of low-molecular weight PFHxA-related substances (Paragraph 11d of the Dossier Submitter proposal) in fluoropolymers in general

Based on the assumption that fluoropolymers on the EU market contain PFHxA, its salts and related substances at the concentration limit for this proposed derogation, the Dossier Submitter estimated emissions to the environment of up to 850 kg PFHxA over a 20-year period (42.5 kg/year). Based on this **RAC does not support a derogation with higher concentration limits for fluoropolymers.**

Concentration limit of 150 ppm for the sum of PFHxA and its salts (Paragraph 11b of the Dossier Submitter proposal) and 2 500 ppm for the sum of low-molecular weight PFHxA-related substances (Paragraph 11e of the Dossier Submitter proposal) in fluoropolymers in engine parts in automotive, aerospace and shipping industry

Based on the assumption that fluoroelastomers on the EU market contain PFHxA, its salts and related substances at the concentration limit for this proposed derogation the Dossier Submitter estimated emissions to the environment of approximately 2.1 t PFHxA over a 20-year period (100 kg/year). **RAC does not support a derogation with a higher concentration limits for fluoropolymers in engine parts in automotive, aerospace and shipping industry.**

Concentration limit of 10 ppm for the sum of PFHxA and its salts (Paragraph 11c of the Dossier Submitter proposal) and 500 ppm for the sum of low-molecular weight PFHxA-related substances (Paragraph 11f of the Dossier Submitter proposal) in fluoropolymers used in coating of electronic devices

The Dossier Submitter could not quantify the amounts of fluoropolymer-coatings in electronic devices and assumed the PFHxA releases to be low due to a small use of such coatings, that the electronic coatings are on the nanometre scale, that only small areas are coated and that the fluoropolymers are mainly additives in the matrix. RAC notes that although specific (confidential) information was provided in the consultation on the Annex XV report (comment #3007) related to this derogation request, the use volumes and RMMs described are company specific and are difficult to extrapolate to this use sector as a whole. RAC also notes that the use volumes provided in the comment are significant. **RAC does not support a derogation with the higher concentration limits in fluoropolymers used in coating of electronic devices[27].**

Fluoroelastomers containing Ammonium Perfluorohexanoate (APFHx)

APFHx is used as processing aid for manufacturing a subset of fluoroelastomers and it could remain as a residual impurity in these elastomers. The APFHx containing rubbery material is used to produce e.g. seals and tubes in the transportation sector such as in automotive or aviation. The Dossier Submitter assumes that despite the fact that the use is wide dispersive,

[27] According to the information provided during the consultation on the SEAC DO, side-chain fluorinated polymers are used in coating of electronic devices. This information did not lead to opening of the RAC opinion because the outcome would not have changed.

and mainly outdoor, the expected release is low. RAC considers that implementation of any RMMs to reduce emissions to the environment throughout the high variety of the fluoroelastomers uses is difficult. Emissions from fluoroelastomers containing ammonium perfluorohexanoate will contribute to the identified risk although emissions are likely to be low compared to the other uses.

For this use RAC considers that there is no potential for minimisation of releases by other measures. A restriction on the use would be effective in preventing further emissions to the environment from the service life and waste life cycle stages. A higher concentration limit, as proposed by the Dossier Submitter, will allow some emissions, but the amounts are not presented. **Therefore, RAC does not support higher separate concentration limits for fluoropolymers (including fluoroelastomers).**

Photographic coatings applied to films, papers, printing plates and inkjet photo media coatings – wide dispersive use, including consumer and professional uses, RMMs unlikely to prevent emissions.

PFHxA-related substances are used in low concentrations as wetting agents in photographic applications to produce photographic or x-ray material, replacing PFOA-related substances. Non-fluorinated alternatives are used for specific photographic applications and a transition to digital imaging is occurring.

According to the Background Document, the exact quantities of PFHxA-related substances used in photographic equipment and the release rates at manufacturing and throughout the life cycle are unknown. However, due to likely low used tonnage in this sector the release of PFHxA and its related substances is considered as very low.

The use in inks has a very wide scope. Perfluorinated substances are added to printing inks for hydrophobisation of surfaces, for example of textiles, paper, glass, building materials/ construction products or adsorbents. To some extent, inks containing perfluorinated substances are used by consumers. Part of the printed articles have short service lives and low levels of recycling.

RAC considers that there is no potential for the minimisation of releases by measures other than a ban on use. A restriction on the use would be effective in preventing further emissions to the environment **RAC therefore supports a restriction for printing inks and photographic applications.**

The Dossier Submitter proposed a 5-year derogation from the conditions of the restriction (Paragraph 5b of the Dossier Submitter proposal) as for some applications, such as inkjet coatings, no suitable non-fluorinated alternatives have been reported, but research is ongoing. Concerning photographic coatings applied to films and in printing plates, remaining products where continued use of PFHxA is requested are by professional or hobby photographers, in medical or defence applications. Digital techniques are estimated to replace traditional photographic film within the coming years substantiating the 5-year derogation.

The exact quantities used in photographic equipment and the release rates at manufacturing and throughout the life cycle are not reported in the Background Document, but the tonnages used were considered to be small and the release of PFHxA and its related substances to be very low. Nevertheless, the Dossier Submitter estimated the emissions from this derogation (jointly with the derogation for latex printing inks (Paragraph 7) over 6 years (median of five and seven years). In total, jointly for these sectors, annual releases of 8 to 80 t of PFHxA-related substances were estimated, resulting in total emissions of 48 to 480 t of related substances and 3.4 to 34 t PFHxA when applying the 7% factor. RAC consider these estimates to be uncertain. RAC also notes that several different specific uses are covered by the

Paragraph 5b derogation request, and that the contributions from the different specific uses to the total estimated emissions will vary.

The use of PFHxA-related substances in the different photographic and printing applications covered in the 5-year derogation proposal (including consumer use) can be considered to be wide-dispersive uses. No RMMs to contain the emissions have been described. Without any appropriate RMMs to minimise the emissions of PFHxA (possibly in the order of tonnes during the derogation period), **RAC does not therefore support a 5-year derogation for photographic coatings applied to films, papers, in printing plates and inkjet photo media coatings**.

Chromium plating

6:2 FTS, a PFHxA related substance, is used as a surfactant in chrome (chromium VI) plating, mainly as a mist suppressant as a substitute for PFOS. Plating solutions have a limited usage lifetime and have to be changed regularly. According to the German national metal plating association (ZVO), 20% of the applied surfactant is lost during the plating processes annually. The Dossier Submitter extrapolated German tonnage data to all EU member states and calculated releases to be below 1 t/a. The chrome plating industry is characterised by heterogeneity and a large share of small and medium enterprises (SMEs). In the Background Document, there is lack of further information concerning the appropriateness and effectiveness of risk management measures i.e. closed-loop systems, wastewater treatment or treatment of the ventilation air to minimise releases of PFHxA related substances from this use. It should be noted that Regulation (EU) 2019/1021 on persistent organic pollutants allows the use of perfluorooctane sulfonic acid (PFOS) and its derivatives as mist suppressant for non-decorative hard chromium (VI) plating in closed loop systems. Under this regulation releases of PFOS to the environment are minimised by applying best available techniques. The Commission shall review the need for a prolongation of the derogation for this use of PFOS for a maximum of five years by 7 September 2025. In the absence of such information RAC considers that the Dossier Submitter has not sufficiently justified a ban on the use of PFHxA related substances in chrome plating as there is a possibility, albeit perhaps for a sub-set of plating activities, that appropriate operational conditions and risk management measures could be effective to address the identified risk.

RAC notes that that to address these uncertainties, information on the effectiveness of implemented or potential RMMs to minimise releases of PFHxA-related substances to the environment should be assessed. Moreover, representative information on tonnage and surfactant lost should be collected in a more representative sample of EU Member States. Nevertheless, RAC is of the opinion that the continued use of 6:2 FTS in chrome plating, without specifying minimum risk management measures, would likely result in continued emissions to the environment but a lack of information prevents specification of appropriate RMMs or a quantitative estimate on the scale of emissions per year. **Therefore, without further information on the effectiveness of potential RMMs, RAC cannot conclude that a ban on the use of PFHxA, its salts and related substances for chrome plating is the most effective EU wide measure to reduce risks.**

In addition, the Dossier Submitter proposed a 5-year derogation for hard (functional) chrome plating *(Paragraph 5a of the Dossier Submitter proposal)*. Industry considers that fluorine-free alternatives to 6:2 FTS as not equally effective and that, as such, they may pose risks with respect to safety and process stability. As part of an assessment under the POPs Convention of alternatives to the use of PFOS in chrome plating processes non-fluorinated surfactants were considered feasible for hard chrome plating and no surfactants were considered necessary in closed coating reactors (UNEP, 2018; 2019). For plastic electroplating

the Dossier Submitter considers non-fluorinated alternatives to be suitable and for decorative plating a shift to Cr(III)-based electrolytes is an alternative to requiring mist suppressants. However, based on limited information on the suitability of alternatives for hard (functional) chrome plating the Dossier Submitter proposed a temporary five-year derogation after the entry into force of the restriction.

From the estimated annual releases of 1.8 t 6:2 FTS (range 0.1 - 3.6 t) a derogation for hard chrome plating for 5 years would be anticipated to lead to releases of 9 t 6:2 FTS (range 0.4 - 18 t) and subsequently 0.6 t PFHxA (range 30 kg - 1.3 t) when applying the default 7% conversion factor. As for other quantitative release estimates, RAC concludes that these estimates cannot be supported. Nevertheless, this derogation is likely to result in (local) emissions of 6:2 FTS and/or its degradation product PFHxA. No description of associated operational conditions and RMMs was presented by the Dossier Submitter, nor submitted by stakeholders in the consultation on the Annex XV report. Therefore, **RAC does not support a 5-year derogation for the use in hard chrome plating**.

Cladding for optical fibres

One company provided information that C6 fluorinated polymers (PFHxA-related substances) are used as cladding material in optical fibres. The low refractive index is an inherent property of the fluorine atoms in the polymers and stakeholders claim that it cannot be achieved with any other polymer. The optical fibre is imported to Europe enclosed in a jacket. After the service life of approximately 10 years, all (100%) of the C6 fluorinated polymer in the cladding of the optical fibres is expected to still be contained in the jacket of the optical fibres and be subject to end-of-life management. RAC acknowledges that with proper waste-management emissions to the environment from this use could be low. **Therefore, without further information on the effectiveness of potential RMMs, RAC cannot conclude that a ban on the use of PFHxA, its salts and related substances for the use in optical fibres is the most effective EU wide measure to reduce risks.**

Building materials/construction products (including laquer) - wide-dispersive uses; RMMs unlikely to result in emission containment

PFHxA, its salts and related substances are used in building materials/ construction products, such as coatings. Due to insufficient data on tonnages of PFHxA and related substances used in building materials/ construction products, and for the release of perfluorinated substances from building and construction, a quantitative assessment of the release to the environment is not possible. However, the amounts are likely to be significant. A direct release of perfluorinated surfactants from the sector building and construction into the environment is considered as very likely and also widespread.

RAC considers that there is no potential for minimisation of releases by other measures. A restriction on the use would be effective in preventing further emissions to the environment. **Therefore, RAC supports a restriction in building materials/ construction products.**

Derogations were requested in the consultation on the Annex XV report for the construction sector in general (Comment #2968), paints (comments #2964, #2969), protection of hard surfaces (Comments #2969, #3049) and for additives for products used by the roofing industry (Comments #2973, #3045). The Dossier Submitter could not estimate emissions for these sectors due to lack of data. One stakeholder (comment #3045) estimated the use of PFHxA, its salts and related substances in roofing membranes to be approximately 40 t/a in the EU. For the use in paints and inks, the Dossier Submitter estimated emissions in the range of 50 - 100 t/a in the EU. Taking into account that outdoor uses are likely in this sector, direct

releases to the environment cannot be excluded. In the absence of information on volumes for this use and specific information on likely emissions to the environment, **RAC does not support any derogations for building/construction materials.**

Cosmetic products – wide dispersive use, including consumer and professional uses, RMMs unlikely to prevent emissions

According to the Dossier Submitter, PFHxA is not an ingredient of cosmetic products. The presence of PFHxA in cosmetics may be as an impurity in and/or a degradation product of intentionally added PFASs. The use by consumers makes by default an implementation of any RMMs reducing emissions to the environment extremely difficult. Additionally, it is likely that PFHxA is dermally absorbed, therefore it has to be considered that cosmetic products may pose an additional relevant source for human exposure. Due to lack of information on tonnage it is not possible to assess the quantity of the emission from this use.

For this use RAC considers that there is no potential for minimisation of releases by other measures. A restriction on the use would be effective in preventing further emissions to the environment. **RAC supports a restriction for cosmetic products.**

Mixtures for consumer uses, fragrance and flavour industries – wide dispersive use, including consumer and professional uses, RMMs unlikely to prevent emissions

Due to limited information available about used tonnages of PFHxA, its salts and related substances in mixtures for consumer uses the Dossier Submitter was not able to quantify the potential releases. The uses and manners of application of the several mixtures for consumer uses (i.e. cleaning products, polishes, ski waxes or impregnating sprays) leads to direct releases of the substances into air, water and soil. Although the substances are used in low concentrations in consumer products, emissions to the environment by mixtures for consumer uses can be significant due to the assumed large quantities and widespread of use of several mixtures for consumer uses in the EU.

In the field of fragrance and flavour industries, the use of PFHxA, its salts and related substances is very similar to above. It is not clear how big the emissions are to the environment from this use and if this use is necessary. It is clear that the use is widespread and in case of consumers any RMMs to reduce the emission to the environment will be difficult to implement.

For these uses RAC considers that there is no potential for minimisation of releases by other measures. A restriction would be effective in preventing further emissions to the environment. **RAC therefore from a risk perspective supports a restriction for mixtures for consumer uses.**

Medical devices - wide dispersive professional uses, possible RMMs to prevent emissions

Concerning the use of PFHxA, its salts and related substances in medical devices (excluding medical textiles) the Dossier Submitter provides only general information that the release of PFHxA to the environment can be in the range of kg/a. In some medical devices it could be possible to implement additional risk management measures i.e. incineration after use of detergent proof, single-use, washbowls and coated medical tubing. In other cases, i.e. in eye drops or coating for hearing aid devices the implementation of risk management measures to reduce emission to the environment will be extremely difficult, if not possible.

The continued use of PFHxA related substances in medical devices, without specifying additional risk management measures, would result in emissions to the environment but the scale of the of the emissions per year seems to be low in comparison to other uses. **Based**

on the lack of presented risk management measures for this sector, RAC supports a restriction for medical devices, with some exceptions (coating for hearing aid devices, implantable medical devices).

The Dossier Submitter proposes an indefinite derogation for medical devices in general (*Paragraph 9g of the Dossier Submitter proposal)*, as defined in Regulation 2017/745. Although medical devices cover a broad and diverse range of articles, the Dossier Submitter assumed from stakeholder information that approximately 90% of medical devices were textiles or textile related materials. From this assumption, emissions were estimated to be in the range of kg/a and with a total cumulative release in the order of up to >1 tonne over 20 years. From this relatively unspecific information on medical devices, with no specific information on RMMs, **from a risk perspective RAC cannot support a general derogation for medical devices**.

One company requested a derogation for C6-fluorinated polymers in **single-use, detergent proof, disposable washbowls** in the medical sector, used to prevent cross infections and hospital acquired infections. Re-usable plastic washbowls have shown to be contaminated with multi-drug resistant human pathogens even after washing and sterilisation, which according to the stakeholder motivates the use of disposable washbowls. No risk management measures were presented for this use and RAC notes that after use the washbowls are described as being macerated and released to the drain. Therefore, without any risk management measures to prevent release of C6-SFPs to the environment (i.e. via wastewater) **RAC does not support a derogation for this use**.

Three companies requested derogations for the use of low molecular weight PFHxA-related substances in **ophthalmic applications** (as non-reactive substances in eye drops, in tamponades following surgical treatment of severe retinal detachment, and in washout solutions), where conventional water-based solutions are not considered to be functional. One company provided (comment #3132) a use amount of <5 tonnes/year and the Dossier Submitter estimates releases in the range of 1-10 tonnes/year, equal to the same amount that is being used. Based in the estimated emissions, in the order of tonnes, of which most is expected to the released to the environment and no descriptions of RMMs to prevent emissions **RAC does not support a derogation for this use.**

Implantable and non-implantable medical devices

One company provided additional information in the consultation on the Annex XV report (comment #3014) on the use of PFHxA-related substances blended with polymers for use in implantable and non-implantable medical devices. Examples of such implantable devices include: vascular catheters, implantable biosensors, surgical meshes, pacemaker leads and vascular grafts. Examples of non-implantable devices are: delivery catheters, extracorporeal therapy components, cardiopulmonary bypass systems, wound dressings and contact lenses.

The PFHxA-related substance is specified to be used in very small quantities in medical devices. Based on information from this respondent the combined use of PFHxA-related substances in current catheter products is estimated to be 20 kg per year and in hemodialyzer applications to be "double-digit tonnes" per year. The medical devices are used in hospitals and clinics and are stated to be collected as medical waste and incinerated. **Due to the estimated low emissions of substances from implants, RAC supports a derogation for implantable medical devices. RAC does not support a derogation for use in non-implantable medical devices.**

The European Hearing Instrument Manufacturers Association requested in the consultation on the Annex XV report (comment #3121) a 10-year derogation for the use of PFHxA-related

substances in **hearing aids**, where the substances are needed to ensure that the device has a hydrophobic and oleophobic coating so that water, sweat and ear wax will not enter the interior of the device and cause corrosion. The stakeholder estimates the use of PFHxA-related substances for this application to be < 1 kg/year and state that the use of PFHxA-related substances for hearing aids is strictly controlled, including manufacturing, life cycle, and disposal, allowing for control of human and environmental exposure, and that the hearing aids are treated as medical/electronic waste under controlled procedures, which do not result in emissions to environment. Based on the low magnitude of potential emissions and the RMMs described, **RAC supports a 10-year derogation for this use.**

Several stakeholders in the consultation on the Annex XV report requested derogations for non-woven and woven medical textiles which are widely used in healthcare and medical application.

Non-woven medical textiles are used in hospitals to avoid cross-contamination and are considered as cost-effective and disposable alternatives to woven textiles. Uses include textiles for personal health care/hygienic products (bedding, clothing, surgical gowns, cloths, wipes, surgical curves, surgical hosiery, diapers), medical dressings and auxiliaries (wound dressing, bandage, plasters, gauge, lint wadding), implantable materials and extra corporal devices (artificial organs). Woven medical textiles are similarly used in protective and healthcare textiles, external devices, implantable materials, hygiene products and extracorporeal devices. In the consultation on the Annex XV report, stakeholders stated that there is rising demand for reusable woven medical textiles which are considered as sustainable alternative to some disposable non-woven articles. Stakeholders claim that to avoid contamination issues the use of PFHxA-related substances is necessary.

Although some of this material will be disposed as medical waste others will likely not and a significant amount of PFHxA may be emitted from treated materials. No risk management measures are presented for these sectors. Although considered uncertain by RAC, the Dossier Submitter estimated emissions in the double-digit kilogram range of PFHxA per year. **Considering the wide dispersive professional uses, RAC does not support a derogation for woven and non-woven medical textiles due to potential significant emissions.**

One company provided information that PFHxA is used as a thin nanometre coating on face shields for medical workers for its antifogging effect, important in surroundings with high humidity and/or low temperatures. The Dossier Submitter considered that this use would likely be covered by the derogation proposed for PPE. **Without additional information on emissions or RMMs, RAC does not support a derogation for this use.**

Semiconductors and semiconductor related equipment - professional uses, effective RMMs to prevent emissions

PFHxA-based surfactants are used in the semiconductor industry for photolithography and etching processes and in cleaning fluids. The Dossier Submitter considers that the emitted amounts of PFHxA from semiconductors and semiconductor related equipment to be low but not quantifiable. In the consultation on the Annex XV report (comment #3119), the European Semiconductor Industry Association state that the total use of PFHxA, its salts and related substances in the EU is less than 0.2 kg/year. Further, industry claim that any potential environmental releases are well managed due to careful collection of the used solvent liquid (constituting 80% of the amount of substances used), typically followed by solvent waste incineration, that there are minimal emissions of PFHxA, its salts and related substances to wastewater (sent to a WWTP) and that no emissions to air occur. According to the European

Semiconductor Industry Association, less than 40 grams of PFHxA, its salts and related substances are emitted per year.

In addition, obligations under Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) may reduce the release substances from semiconductors and semiconductor related equipment during and after their service life.

Based on the low level of emission in comparison to other sectors, in the order of grams per year, **RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available**. A similar (time-unlimited) derogation for the semiconductor industry was supported by RAC for the restriction of PFOA, its salts and related substances.

Epilames used in watches- professional use, effective RMMs to prevent emissions

According to the information provided by the Dossier Submitter, PFHxA-related substances are used in epilames in watches - coatings on mechanical parts that need lubrication due to their movement and where the epilame is required for the lubricant (oil) to stay in place and not spread via the movement of the watch parts. Furthermore, the epilame coating must be chemically compatible with the substrate on which it is deposited and must also not react with the components of the lubricant. The Dossier Submitter proposed a derogation for this use *(Paragraph 9f of the Dossier Submitter proposal).*

The quantities of C6-SFPs used in epilames was estimated by a stakeholder (comment #2976) to be in a total amount of 1-digit kg/year globally (laboratory scale), and considerably lower on the EU-level. As epilame coating takes place via immersion of the coated parts in a bath, around 80 % of the epilame mixtures goes to waste. According to stakeholder information waste is collected as industrial chemical waste and is properly disposed of (i.e. high temperature incineration). Using the degradation factor of 1% for SFPs, the emission is in the range of grams PFHxA/year globally. As the parts are contained in the article (watch case) the amounts emitted are likely significantly lower. The stakeholder assumes that the watches are either re-used or recycled.

Based on the low magnitude of the potential emissions of PFHxA (grams/year) and effective RMMs described (waste collection, high temperature incineration **RAC can support a derogation for this use until suitable alternatives become available**.

Manufacture of PFHxA and PFHxA-related substances at industrial sites - industrial uses, controlled conditions and effective RMMs to prevent emissions

During manufacturing of PFHxA-related substances transported isolated intermediates may be used. They are often transported via direct pipeline connections between the site where the intermediates are produced and the site where the substances are further processed. Since transportation occur in enclosed containers or the intermediates are transferred in states with lower emissions (such as gelatinous blocks instead of liquids) the emissions are assumed to be low and a time-unlimited derogation for this use has been proposed. For the transported isolated intermediates, the Dossier Submitter has proposed that PFHxA should be derogated if the conditions of Article (18(4) in REACH is met, which include:

(a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage; and

(b) procedural and control technologies shall be used that minimise emission and any resulting exposure.

The estimated emissions, which are not specified in the Background Document, are by the Dossier Submitter assumed to be low. Provided that the legal requirements of Article (18(4) in REACH is met, RAC note that the emissions should be low. Therefore, **RAC supports the proposed derogation for transported isolated intermediates**. RAC also note that a corresponding derogation has been supported by RAC for the restriction proposal for PFOA, its salts and related substances as well as C9-C14 PFCA, their salts and related substances.

Personal protective equipment *(Paragraph 9b of the Dossier Submitter proposal), high visibility clothing (Paragraph 9c), impregnation agents for re-impregnation of personal protective equipment (Paragraph 9d) – non-time limited derogations*

PFHxA-based surfactants are used for repellence of e.g. water, oil and chemicals in personal protective equipment and high visibility clothing and in agents for re-impregnation of those. For water repellence only, alternatives are available. However, for repellence of oily substances no alternatives are available today, thus the Dossier Submitter has proposed a time-unlimited derogation for certain PPE (risk category III (a), (c), (d), (e), (f), (g), (h), (l) in Regulation (EU) 2016/425), certain high visibility clothing (class 3 in EN ISO 20471) and re-impregnation of those.

From the assumption that a large percentage of personal protective equipment (PPE) are textiles (including high visibility clothing and re-impregnation agents) and that approximately 50% of the PPE need to be derogated from the restriction proposal, the Dossier Submitter estimate that 223 to 571 t of PFHxA related substances and, subsequently, 14 to 36 t of PFHxA using the 7% degradation factor will be emitted over 20 years (and more in a longer perspective). Although RAC consider the overall emission estimates from textiles to be uncertain and likely overestimated, the potential emissions from PPE, high visibility clothing and re-impregnation agents may be in the order of tons. The uses can be considered wide and dispersive and not associated with any particular RMMs for their use. Thus, based on the relatively high expected emissions and the lack of risk management measures to minimize these releases (e.g. emissions from clothing during use and/or washing) **from a risk perspective RAC does not support a derogation** for these uses.

Latex printing inks *(Paragraph 7 of the Dossier Submitter proposal) – 7 years derogation*

For latex printing inks, stakeholder information submitted stated that alternatives to PFHxA-based inks are available for new printer generations. However, for printers already placed on the market no latex printing inks will be available in case of a restriction, resulting in early obsolescence of all latex ink printers. Therefore, the Dossier Submitter proposed a 7-year derogation to avoid early replacement of current latex ink printers.

The emissions associated with this derogation were estimated jointly with photographic coatings (Paragraph 5b *of the Dossier Submitter proposal*). Annual releases of 8 to 80 t of PFHxA-related substances were estimated for these sectors together, resulting in 48 to 480 t of related substances and 3.4 to 34 t PFHxA emitted over 6 years (median of five and seven years). RAC considers these numbers uncertain. RAC notes, however, that the wide dispersive use of PFHxA-related substances in latex printing inks may lead to emissions in the order of tonnes during the derogation period. Further, no RMMs to minimize these emissions have been presented. Thus, without any appropriate RMMs described to minimize the emissions and with possible emissions of PFHxA in the order of tonnes during the derogation period, **RAC does not support a 7-year derogation for PFHxA-based latex printing inks.**

Water-based printing inks*, other than latex printing inks*

Derogations for water-based printing inks was requested in the consultation on the Annex XV

report (comments 3058, 3091) for >10 and 12 years, respectively. The use volumes and associated emissions from water-based inks are not specified but may be in the range of tonnes/year based on the Dossier Submitter emissions estimation of up to 80 t/a of PFHxA-related substances from water-based and latex inks. According to the Dossier Submitter, alternatives for water-based inks are available (e.g. siloxanes and solvent based or UV curable mixtures) and does therefore not support a prolonged transition period. No information on RMMs to minimize the emissions from this sector has been provided other than that the printed matter containing the PFHxA-related substances is expected to be handled as waste and incinerated. RAC acknowledges that in many countries paper will also be subject to recycling. Based on the likely use volumes in the range of up to tonnes, no specific RMMs presented and possible alternatives available, **RAC does not support a derogation for water-based printing inks.**

Filtration and separation media in high performance air and liquid applications *(paragraph 9h of the Dossier Submitter proposal) – time unlimited derogation*

Filtration and separation media that require a combination of water- and oil-repellency consist primarily of non-woven textiles or paper composed of natural or man-made fibres treated with C6-SFPs. These filters play a critical role in e.g. medical devices, PPE, heating, ventilation, air conditioning systems (HVAC, including EPA/HEPA/ULPA), Air Pollution Controls (APC), hydraulic systems, gas turbines, and fuel systems.

The used quantities of filtration and separation media in high performance air and liquid applications were not known to the Dossier Submitter and a quantification of releases was therefore not considered possible, although the emissions were considered as "low". In addition, no information on risk managing measures was presented for this sub-sector other than stakeholder information stating that these filters are enclosed in devices and are treated as waste after use. Confidential data submitted in the consultation on Annex XV report indicate that the emissions from production can be considered low. However, altogether, due to the unknown quantities used, possible associated emissions, and lack of information on RMMs, **RAC cannot support a derogation for this use** unless more information becomes available.

Other uses for which derogations were requested

Other uses that were raised in the consultation on the Annex XV report and where derogations were requested include the use of PFHxA, its salts and related substances in solar power, fuel cells, specialty glass, cleaning agents and waxes, stone protection, anti-graffiti, adhesives, oxygen absorbing packs and metal treatment. For these uses, however, insufficient information was provided on use volumes, emissions and RMMs and RAC can therefore not on the basis of the available information assess these derogation requests.

Derogations proposed by the Dossier Submitter and derogations requested in the consultation on the Annex XV report are summarised by RAC in Table 5 and Table 6, respectively.

Table 5. Derogations proposed by the Dossier Submitter and assessment by RAC

Sector	Sub-sector	Time-period	Use	Risk management measures (RMMs)	Derogation Supported by RAC?
Chrome plating	Hard chrome plating	5 years	Local, site-specific	No specific RMMs described.	No
Photographic applications	Photographic coatings	5 years	Wide-dispersive	No RMMs described.	No
Firefighting foams	Mixtures for class B foams (general)	5 years	Wide-dispersive	No RMMs described.	No
	Large tanks	12 years	Local, site-specific	Firewater retention systems.	No
	Aqueous film forming foams for defence applications	Unlimited	Wide-dispersive	No RMMs described.	No
Manufacture	Transported isolated intermediates	Unlimited	Local, site-specific	RMMs described. Article 18(4) of REACH need to be met.	Yes
Textiles	Certain personal protective equipment (PPE), high-visibility clothing, re-impregnation agents	Unlimited	Wide-dispersive	No RMMs described.	No
	Textiles in engine bays in the automotive and aerospace industry	Unlimited	Wide-dispersive	Unknown	No
	Filtration and separation media	Unlimited	Wide-dispersive	Filters may be collected and treated as waste	No
Medical devices	All medical devices as defined in Regulation 2017/745, including medical textiles	Unlimited	See 'medical devices' in Table 6	See 'medical devices' in Table 6	See 'medical devices' in Table 6
Semiconductors	Semiconductors and semiconductor related equipment	12 years	In manufacturing and use of electronic equipment	Solvent is collected and sent to incineration. Wastewater treated in WWTP. No emissions to air.	Yes
Printing inks	Latex printing inks	7 years	Wide-dispersive	No RMMs described.	No
Fluoropolymers	Fluoropolymers in general	Unlimited	Wide-dispersive	No RMMs associated with the use	No
	Fluoropolymers in engine parts in automotive, aerospace and shipping industry	Unlimited	Wide-dispersive	No RMMs associated with the use	No
	Fluoropolymers used in coating of electronic devices[28]	7 years	Wide-dispersive	Confidential information from one stakeholder on RMMs at production. Electronics often treated as electronic waste.	No
Watches	Epilames in watches	Unlimited	In manufacturing and use (encapsulated) of watches	Waste (80% of used amounts) is incinerated. Watches are reused or recycled.	Yes

[28] According to the information provided during the consultation on the SEAC DO, side-chain fluorinated polymers are used in coating of electronic devices. This information did not lead to opening of the RAC opinion because the outcome would not have changed.

Table 6. Derogations requested in the consultation on Annex XV report and assessment by RAC

Sector	Sub-sector	Time-period	Use	Risk management measures (RMMs)	Derogation supported by RAC?
Medical devices	Disposable washbowls	Unlimited	In hospitals/clinics	No RMMs described. Emissions after use to the drain	No
	Non-active medical devices in ophthalmic applications	Unlimited	Wide-dispersive	No RMMs described.	No
	Implantable medical devices	Unlimited	In hospitals/clinics	Collected as medical waste	Yes
	Non-implantable medical devices	Unlimited	In hospitals/clinics	Collected as medical waste	No
	Coating for hearing aid devices	10 years	Wide-dispersive?	"strictly controlled" use, including manufacturing, life cycle, and disposal	Yes
	Non-woven and woven medical textiles	Unlimited	In hospitals/clinics/ambulances	No RMMs described. Some textiles likely to be managed as medical waste	No
Fibres	Optical fibres	Unlimited	Contained in optical fibres	PFHxA-related substances expected to be contained in the fibre and subject to end-of-life waste management	No
Personal protective equipment	Antifog face shields	Unlimited	In hospitals/clinics	Confidential information from one company	No
Paper and cardboard	Food contact materials	> 5 years	Wide-dispersive	No RMMs described.	No
Building materials/ construction products	Construction material	Unlimited	Wide-dispersive	No RMMs described.	No
	Paints, surface protection, roofing	Unlimited	Wide-dispersive	No RMMs described.	No
Technical textiles	Outdoor technical textiles	Unlimited	Wide-dispersive	RMMs presented only for manufacture	No

Sector	Sub-sector	Time-period	Use	Risk management measures (RMMs)	Derogation supported by RAC?
	Home textiles	Unlimited	Wide-dispersive	RMMs presented only for manufacture	No
	Residential and commercial upholstery	Unlimited	Wide-dispersive	RMMs presented only for manufacture	No
	Automotive textiles	Unlimited	Wide-dispersive	RMMs presented only for manufacture	No
	High-performance sports equipment	Unlimited	Wide-dispersive	RMMs presented only for manufacture	No
	Textiles for construction	Unlimited	Wide-dispersive	RMMs presented only for manufacture	No
	Other	> 36 months	Wide-dispersive	RMMs presented only for manufacture	No
Printing inks	Water-based printing inks	> 10 years	Wide-dispersive	No RMMs presented other than that paper is treated as waste	No

Impact of the restriction on human health and the environment

With regard to the possible impact on human health and the environment, RAC acknowledges that the impacts are difficult to quantify. Based on the data presented in the Background Document, there is a large gap between current general human and environmental exposure levels and those levels that with the present level of knowledge would cause adverse effects. However, based on the persistency of PFHxA, the ongoing use of the PFHxA, its salts and related substances leading to continuous emissions, human and environmental exposure levels are expected to increase over time which could lead to irreversible adverse effects unless the emissions are reduced.

Availability of alternatives and their hazards/risks

For many of the described uses alternatives appear not to be available, e.g., electronic grade coatings, filtration and separation media, medical devices, epilames used in watches as well as fluoropolymers and fluoroelastomers in automotive, aerospace and shipping applications (where higher concentration limits for PFHxA and related substances are proposed), particularly if an oil-repellent function is needed. For some uses or sub-uses, alternatives technologies and/or substances may be available. These include the use of plastics of silicon materials instead of paper in FCMs, other water-repellent substances such as hydrocarbons and dendrimers for textiles, possible alternative substances/non-PFAS technologies for manufacturing of semiconductors and semiconductor related equipment, and hydrocarbon, protein, or fluorine-free detergent based firefighting foams for other uses than for large tanks and military application. For decorative and plastic chrome plating, and possible also hard chrome plating, other alternative substances such as acidic permanganate solutions, nitric acid and trichloroacetic acid mixtures and closed-loop systems can be applied according to the information in the Background Document. In mixtures for consumer uses, fluorine-free impregnating agents, ski- and floor waxes and cleaning agents are available. In cosmetics PFAS-free alternatives are available for all types of cosmetic products.

Although some possible alternatives to PFHxA, its salts and related substances for certain uses have been presented by the Dossier Submitter, no information on their hazards and risks have been presented. Therefore, due to the lack of this information, RAC cannot assess the hazards and risks of those other than that alternative substances most likely are less persistent than PFHxA, its salts and related substances. C4 PFCA (PFBA) its salts and related substances may be possible alternatives for certain specific applications although no stakeholders have indicated so in the consultation on the Annex XV report.

4.3.2. Socio-economic impact

Justification for the opinion of SEAC

4.3.2.1. Costs

Summary of proposal:

Different impacts are expected for different uses of PFHxA, its salts and related substances, and therefore the Dossier Submitter assessed the socio-economic impacts and the proportionality of the proposed restriction on a per-sector basis. Where the available information permitted, the analysis was performed at 'use-specific' level within a sector.

The Dossier Submitter attempted to obtain data for quantitative analysis for all uses and especially those where the largest quantities of PFHxA, its salts and related substances have been identified. However, robust quantitative information is limited and cost estimates are uncertain and for most uses it was necessary to rely mainly on qualitative information.

The sectors that were assessed and the costs that were identified by the Dossier Submitter are presented in Table 7 of the Background Document (section 2.5.1.19, see also section on costs and proportionality of this SEAC opinion below).

Sector- and/or use-specific cost information, qualitative or quantitative, is provided for the sectors listed in the 'scope' section (summary of proposal) of the SEAC opinion above. Cost information provided during the consultation on sectors not initially considered by the Dossier Submitter, such as optical fibres and watches, is also discussed below. The Dossier Submitter states that a number of further applications of fluorinated substances have been reported in the information collection or are mentioned in the literature that do not completely fit in one of the sectors above and included in Table 7 of the Background Document, e.g. handling of fragrance and odour compounds in products, different applications in laboratories, such as the use in aerosol applications during in-house quality control of other fluoropolymer products, use in special glass for construction, automotive and the solar sector, etc. Further information on these uses is given in section 2.5.1.16 of the Background Document. No socio-economic information is available for these uses, and the Dossier Submitter has therefore not identified any potential costs. Additionally, the Dossier Submitter identifies two further categories of costs not associated with particular sectors:

- Administrative costs: costs to some importers to test the presence of PFHxA, its salts and related substances through unintended use. No estimates were provided, but the Dossier Submitter expects testing costs could be shared with the testing needed to comply with the PFOA and C9-C14 PFCAs restrictions

- Enforcement costs: the Dossier Submitter considers that the average enforcement costs identified in connection to the restriction on lead compounds in PVC for all of the EU 28 Member State Agencies to ensure compliance with EU regulation (approximately €55 600 per year in total) are an indication of the potential magnitude of these costs. The Dossier Submitter also considers that it might be possible that enforcement costs can be reduced when some of these costs are shared with the enforcement costs associated with the restriction of PFOA and related substances (and most probably the C9-C14 PFCAs restriction).

SEAC conclusion(s):

SEAC notes that a substantial number of uses and sectors is covered by the proposed

restriction and agrees with the Dossier Submitter that different economic impacts are expected for different uses of PFHxA, its salts and related substances and sectors accordingly. Therefore, SEAC appreciates the Dossier Submitter's attempt to assess the socio-economic impacts on a per-sector basis and, where possible, even at a use-specific level for specific sectors (e.g. textiles).

Substitution to fluorine-free alternatives as a reaction to the restriction by affected parties is the main basis for the cost assessment, i.e. the Dossier Submitter mainly assessed substitution and reformulation costs as well as costs related to these processes (such as any potential reorganisation of business, potential effects on products such as reduced service life of articles, costs of disposal, etc.). More information on different types of related costs on a per-sector basis is given in Table 7 in the proportionality section below. The Dossier Submitter's approach is a combination of quantified cost estimates, where possible, and a qualitative cost assessment where the respective data do not allow for quantification.

SEAC notes that the latter is applicable for the majority of the sectors and uses assessed. It became clear during the opinion making process (e.g. also based on the information submitted during the consultations on the Annex XV report and SEAC's draft opinion) that robust input data that would allow for a meaningful quantification of costs is not available. Even for those sectors where the Dossier Submitter was able to provide quantified cost estimates, SEAC notes that the availability of robust input data (e.g. use quantities of affected products, the identities of the alternative substances that would be used, the price of alternatives, the amount of alternative substances to be used, the share of products affected, etc.) is limited and numerous assumptions had to be taken by the Dossier Submitter. The respective derived cost figures are, in SEAC's view, therefore highly uncertain. Whilst for some sectors the derived cost figures might provide an indication on the magnitude of expected economic impacts, for others, this is doubtful and the Dossier Submitter largely refrained from using the original cost estimates for cost-effectiveness assessment purposes (emission/release estimates being a further uncertainty in this regard, please see respective section of this opinion).

In SEAC's view, similar uncertainties apply for the qualitative cost assessment. Even though qualitative information is provided by the Dossier Submitter in the Annex XV report as well as by stakeholders during the consultations, it is, on the one hand rather company and/or use specific, which does not allow an extrapolation to the overall sector affected and, on the other hand, is not backed-up by sufficient supporting evidence. This makes it difficult for SEAC to conclude on the significance of the qualitative information.

Overall, both quantified cost estimates as well as the qualitatively described economic impacts contain several uncertainties, specifically for cost categories for which very limited information was available to the Dossier Submitter (e.g. costs related to substitution and reformulation activities (including reorganisation of business), unemployment effects, and changes in product quality and related consequences such as reduced service life of articles). This makes it difficult for SEAC to derive a robust overall cost estimate for the proposed restriction. During the consultation on the Annex XV report, a variety of sectors (mainly companies and industry associations) responded on cost-related aspects of the proposed restriction. However, the comments provided were rather general, mainly company-specific, not substantiated by supporting evidence and therefore do not allow SEAC to extrapolate the information to the sectors and/or uses affected. During the consultation on the SEAC draft opinion, again, a variety of stakeholders (industry, NGOs, individuals, academia, authorities, etc.) covering almost all uses and applications discussed in the restriction proposal and the SEAC draft opinion provided comments; with some new uses also being reported to SEAC (e.g. use of the substances for the protection of porous substrates like natural stone and assimilated

substrates in the construction industry). Mainly companies and industry associations again contributed with (qualitative or semi-quantitative) cost information. SEAC very much appreciates the effort companies have taken to provide the requested cost (and overall socio-economic) information. However, SEAC notes that the situation is similar to the first consultation, i.e. an extrapolation of the information received to the overall sectors and/or uses affected is not possible.

SEAC notes that for several sectors and/or uses affected, robust cost information (on substitution costs and any further related costs and/or socio-economic impacts of the restriction) is lacking and **a conclusion on the magnitude of the overall restriction-related socio-economic costs is difficult to achieve and uncertain.**

Key elements underpinning the SEAC conclusion(s):

The discussion on costs below also mentions issues related to benefits and proportionality where that was considered helpful to better explain the issues and to keep the same structure as used in the Background Document. However, a complete overview of the impacts relating to a use is presented in the proportionality section and specifically in SEAC's use-specific analysis reported in Background Document Annex E.6, which constitutes a part of this opinion.

Substitution, reformulation and related cost categories:

The cost assessment performed by the Dossier Submitter covers the following sectors or uses (the latter e.g. for textiles and firefighting foams were assessed mainly qualitatively). Quantitative cost estimates were available for only very few sectors and, in these cases, a respective cost-effectiveness analysis was performed, i.e. for the manufacture of fluoroelastomers (APFHx) as well as for food contact material and paper and partly for firefighting foams. Overall, SEAC notes that there is lack of robust information (e.g. on use quantities of affected products, identity of alternatives, prices of alternatives, quantities of alternative substances to derive similar product performance, share of products affected, etc.) for most sectors covered by the restriction. Therefore, calculating substitution costs is difficult and uncertain. This partly explains the large cost ranges that were initially calculated by the Dossier Submitter for some sectors. Overall, SEAC regards any robust conclusion on the qualitatively and quantitatively assessed economic costs difficult to achieve, due to lack of data, lack of sufficient supporting evidence as well as several uncertainties noted subsequently in this section. Cost-related aspects for the affected sectors (either already discussed in the initial restriction Annex XV report or brought up by stakeholders during the consultations) are discussed in this section. Any derogation-related aspects are discussed in the respective section of this opinion.

- **Manufacture and use of fluoropolymers (higher concentration limits proposed by the Dossier Submitter):** Industry stakeholders reported in the consultation on the Annex XV report that **fluoropolymers** display outstanding chemical and temperature resistance, combined with favourable mechanical and electrical properties. They are used in specific, high reliability/safety critical applications. Fluoropolymers are claimed to be key enablers for the decarbonisation of the EU economy, as critical components of fuel cells, batteries, renewable energies, digital technologies, as well as many efficient industrial processes.

It is reported in the proposal that, according to information provided by industry, 52 000 tons of fluorinated polymers (fluoropolymers, perfluoropolyether polymers and SFPs) were sold in the EU in 2015. SEAC notes that the tonnage information originates from a PlasticsEurope report[29] that covers only fluoropolymers. Therefore, SEAC understands that all of the volume (52 000 tons) refers to fluoropolymers and none of it to SFPs or perfluoropolyether polymers. Based on the available information, it is not clear which share of the ~ 52 000 tons of fluoropolymers are manufactured with PFHxA, its salts and related substances.

Several uses were mentioned by stakeholders (e.g. the production of ETFE, PTFE micro-powders and certain fluoroelastomers) where a derogation is claimed to be justified based on societal benefits of continued use (more information is given in the section on derogations). Overall, only limited information is available to SEAC as regards alternatives or any potential consequences (such as functional losses and any related costs) of no longer being able to use these substances. The Dossier Submitter stresses that they are not aware of any information that would help identifying applications where technically and economically feasible alternatives are already available or in development. However, the Dossier Submitter concludes that for several uses alternatives might be already available, e.g. for cookware, textiles and food processing. For other uses, they conclude that there is insufficient evidence that society would value the benefits of continued use as highly as stakeholders claim, e.g. for construction materials and textiles. Based on the information available, the Dossier Submitter concludes that societal benefits of continued use of the substances proposed for restriction are evident for some uses, but ambivalent for others. No quantitative cost estimates were provided for these uses and accordingly no cost-effectiveness calculation was performed. The Dossier Submitter concludes that reasonable worst-case scenarios in case of a restriction imply high societal costs. SEAC notes that in the consultation on the Annex XV report, industry provided a confidential report that includes information on the socio-economic benefits of using fluoropolymers in different sectors as well as on alternatives (comment #3082). SEAC agrees with the Dossier Submitter that this report is of limited use to extrapolate any meaningful cost estimates.

A quantitative cost assessment is provided for the manufacture of **fluoroelastomers,** where APFHx (the ammonium salt of PFHxA) is used as processing aid. In case of a restriction, the Dossier Submitter estimates profit losses for automotive and aviation applications **ranging between €2 –16 million per year with a central estimate of €9 million per year.** Additional costs are expected for downstream users in case they have to use alternative fluoroelastomers. Industry stakeholders argue that continued use is beneficial with respect to CO_2 emission reduction in the affected sectors. They also reported that supply shortage of fluoroelastomers that are produced with a C6 polymerisation aid would lead to considerable costs: massive requalification costs and time for downstream users and a considerably reduced international competitiveness of components suppliers as well as the EU automotive and aerospace industries. The Dossier Submitter recognises that the restriction would result in high costs in terms of CO_2 emissions from transport and of impacts on international

[29] Amec Foster Wheeler Environment & Infrastructure UK Limited (2017) Socio-economic Analysis of the European Fluoropolymer Industry – Executive Summary, Plastics Europe – Fluoropolymer Group https://www.plasticseurope.org/en/resources/publications/373-socio-economic-analysis-european-fluoropolymer-industry-executive-summary
Full version of this study was submitted as confidential attachment to comment 3082 in the consultation on the dossier.

competitiveness for the affected European industries. Risks from continued use (i.e. continued emissions to the environment) are poorly understood.
A wide dispersive outdoor use of these articles with a low release of APFHx was assumed. Releases from articles containing fluoroelastomers into water and soil were calculated according to the expected use in automotive and aviation applications and were expected to be 120 – 160 kg/a. Based on the above, the Dossier Submitter calculated the cost-effectiveness ratio in a range of €12 500 – 133 000 /kg, with a central estimate of approximately €64 300 /kg. SEAC understands that this calculation was established based on the information from one manufacturer. However, it is not clear to SEAC on which assumptions these calculations were based and how the results were calculated. SEAC therefore cannot verify the cost estimate provided with respect to its representativeness and reliability. Moreover, SEAC notes that the Dossier Submitter's conclusions on potential alternatives as well as on economic impacts for the affected sectors due to a restriction is not supported by a sufficiently justified assessment, mainly due to lack of information. Therefore, SEAC is not able to confirm the conclusions of the Dossier Submitter.

- **Textiles (derogations suggested for specific applications):** the Dossier Submitter assessment includes different types of textiles, such as home textiles (including outdoor textiles and awnings), consumer apparel, professional apparel (including PPE) and technical textiles (including transportation applications (hoses, belts, seats, carpets, etc.), tarpaulins, conveyor belts, ropes, etc.). The quantitative cost assessment in the Annex XV report was revised during opinion making into a qualitative approach due to the lack of robust data that would allow for a meaningful quantification. Nevertheless, substitution cost estimates for textiles are presented for illustrative purposes in the Background Document. Information provided during the consultation on the Annex XV report by stakeholders as well as information available through a recently published report of the European Commission[30] on the use of PFASs and fluorine-free alternatives in textiles, upholstery, carpets, leather and apparel did not sufficiently eliminate the underlying uncertainties preventing a robust quantitative cost assessment. Therefore, SEAC agrees that a qualitative assessment is preferable. SEAC notes that for some aspects pointed out below an uncertain and partly scarce data basis exists (further details on these aspects are given in Annex E.2.11 of the Background Document):
    - Alternatives, e.g.:
        - which alternative substances are used in different applications;
        - technical performance, mainly with regards to oil and dirt repellence;
        - prices and amount to be used in order to obtain the required technical performance e.g. water and oil repellence properties;
        - use quantities of products affected.
    - Any potential substitution related consequences, e.g.:
        - possible need to amend machinery and equipment;
        - reduced service life of articles.

[30] European Commission DG Environment (Brussels 2020): The use of PFAS and fluorine-free alternatives in textiles, upholstery, carpets, leather and apparel (https://echa.europa.eu/documents/10162/13641/pfas_in_textiles_final_report_en.pdf/0a3b1c60-3427-5327-4a19-4d98ee06f041)

As regards ***substitution costs***, SEAC notes that overall, alternatives providing water-repellence properties might cost from 50% less up to 30% more compared to PFHxA, its salts and related substances. As regards the amount of alternatives that need to be used in order to achieve similar functionalities, a range from 0 up to 50 % additional amount is reported. SEAC notes that these assumptions are supported by literature reviewed by the Dossier Submitter as well as information included in the recent European Commission -report. The Dossier Submitter concludes that for textiles in general, considering alternatives providing required water repellence properties, the costs of substituting PFHxA, its salts and related substances with fluorine-free alternatives is negligible (specific applications where this conclusion does not apply are reflected in SEAC's discussion on the suggested derogations, see respective section of this opinion). Even though there might be cases where industry faces higher substitution costs, these costs are still expected to be affordable; however, these costs are not specified further. SEAC stresses that based on the information available it is difficult to draw a robust conclusion on the magnitude of substitution costs. However, based on the information available to SEAC (from the Annex XV report and the consultation comments), no major economic impacts are expected with regard to substitution costs for water repellence properties. No sufficiently justified conflicting information was provided during the consultation on the Annex XV report that would contradict the Dossier Submitter's conclusion.

As regards any potential **substitution related costs**, the information available to the Dossier Submitter and SEAC is scarce. SEAC notes that it cannot be ruled out that costs will arise due to modification of machinery and equipment required when switching to alternative substances. However, SEAC notes that for alternatives providing water repellence the European Commission report mentions that no or limited changes in equipment are needed[31]. More important seem to be the costs related to potentially reduced service life, reduced performance and related lower quality of articles. Whilst SEAC notes that alternatives providing water repellence properties are already available on the market (where a general trend of moving away from PFAS-containing products can be observed for sportswear and outdoor apparel), the demand for fluorinated substances is still high for high performance products where properties such as oil/dirt repellence are not yet sufficiently provided by alternatives. The importance of these technical functionalities is mainly related to safety (e.g. professional clothing) and non-use can lead to reduced service life or increased cleaning for articles. During the consultation on the Annex XV report, the impacts of no longer being able to use fluorinated substances were stated to be significant (e.g. for home textiles such as carpets, awnings, seating as well as textiles used in automotive, aviation and other public places), but no robust estimates of these impacts were submitted. As regards safety, the Dossier Submitter accounted for these impacts (e.g. for personal protective equipment) by suggesting derogations (see SEAC's discussion on derogations). As regards reduced service life or lower quality of articles and any related impacts the Dossier Submitter notes that several comments were provided during the consultation on the Annex XV report; however, the Dossier Submitter concludes that these comments failed to sufficiently discuss potential alternatives (e.g. washable or replaceable clip-covers for products). SEAC stresses that at the time of writing, no further specific information on the potential impacts of reduced article service life was available and SEAC can therefore not confirm the magnitude of such impacts.

[31] European Commission DG Environment (Brussels 2020), *Ibid*, pp. 81-83

- **Firefighting foams (derogations and longer transition periods proposed for several uses):** the Dossier Submitter discusses socio-economic impacts of the proposed restriction on firefighting foams for five broad categories of uses, i.e. aviation, petrochemical industry, defence, other industrial uses and other uses and states that within the last years, the following two trends have been observed: *i) a shift from long-chain PFASs in AFFFs (aqueous film-forming foams) to short-chain PFASs due to regulation (e.g. REACH restrictions on PFOA and related substances)* as well as *ii) a shift to fluorine-free foams*. Similar to the textiles sector, an annual reporting requirement on quantities used and substitution efforts undertaken is suggested by the Dossier Submitter to accompany the derogation, in order to fill data gaps.

  SEAC notes that due to lack of robust information, specifically when developing the restriction proposal, no robust overall picture of the socio-economic impacts of the proposed restriction was derived by the Dossier Submitter. However, some cost aspects (price differences between PFASs and fluorine-free alternatives, costs for cleaning of equipment, costs for replacement of fire extinguishers, annual replacement/procurement, etc.) were discussed by the Dossier Submitter and information was provided by stakeholders during the consultations. SEAC notes the following:

  - The Dossier Submitter states that according to the EC/ECHA report[32] on the use of PFASs and fluorine-free alternatives in firefighting foams, substitution activities can be observed for all uses. For example, substitution is reported by airports, can be observed in municipal fire brigades, marine applications, etc. However, substitution is observed to be less advanced in the petrochemical industry and in defence applications (see separate discussion on derogations for further information). However, for defence applications, SEAC is aware of an ongoing substitution in some EU Member States and the US.

  - *Price differences for fluorine-free firefighting foams:* the price of fluorine-free foams is not expected to differ significantly compared to fluorine-containing foams. SEAC notes that this conclusion is drawn based on expert information (IPEN 2018) and is supported by the EC/ECHA report, which reveals a weighted average price for PFAS as well as fluorine-free foams of €3 000 /t. However, there is contradicting information with respect to whether fluorine-free foams need to be used in greater quantities in order to achieve the necessary performance; the range specified was between no change in volume and up to a maximum of 100% additional foam required. Based on the different stakeholder responses and considering their relevance and reliability, the Dossier Submitter assumed a 30% increase in volume[33]. The EC/ECHA (2020) report provides further discussion on potentially higher quantities to be used for different types of foams (see Annex E.2.3.5 of the Background Document), calculating any potential replacement costs based on three assumptions (0%, 50% and 100%) of required adapted use volumes. The difference in the

[32] European Commission DG Environment/European Chemicals Agency (ECHA): "The use of PFAS and fluorine-free alternatives in fire-fighting foams" (https://echa.europa.eu/documents/10162/28801697/pfas_flourine-free_alternatives_fire_fighting_en.pdf/d5b24e2a-d027-0168-cdd8-f723c675fa98)

[33] 30% increase is regarded very uncertain by the Dossier Submitter but the most reasonable approach based on the information available (for further information see Annex E.2.3.5 of the Background Document).

percentage of increased volume, together with slightly different assumptions made by the Dossier Submitter compared to the EC/ECHA report as regards use volumes of fluorinated foams leads to different cost estimates. SEAC notes that in the consultation on the Annex XV report stakeholders reported the amount of fluorine-free foams required to be 2-4 times that of alcohol resistant aqueous film-forming foams (AR-AFFF) in IPA fires and 6-7 times that of AR-AFFF in E10 gasoline fires in certain test configurations (comment #2983). However, SEAC could not verify the robustness of these estimates.

- *Replacement of foam:* the Dossier Submitter assumes that (one-off) replacement costs might arise due to the proposed restriction, which are estimated to be in the range of €13 to 130 million (using the abovementioned price of €3 000 /t depending on the amount of replacement that would be attributable to this restriction vs. previous regulatory action (e.g., on PFOA and related substances). The Dossier Submitter concludes that stocks must be replaced after expiry in any event and that the replacement with alternative foams is just an early replacement. Replacement and incineration costs (see next paragraph) would occur just a few years later. Therefore, the estimated replacement costs should be regarded as an overestimation, not considering the fair value of the foam stocks. SEAC notes that replacement costs are estimated to be higher in the EC/ECHA report, resulting in €1bn (central estimate). The difference is mainly due to different assumptions on foam stocks, which are estimated to be 75 000 tons by the Dossier Submitter (expert judgement considering an EU stock twice as high as the US stock in 2011) vs. 210 000 to 435 000 tons estimated in the EC/ECHA report (being an estimation as well). SEAC notes that no robust figure on foam stocks in the EU seems to be available. In addition, the methodology used to calculate these costs differ (e.g., depreciation of foam stock is not considered by the Dossier Submitter).

- *Incineration costs associated with replacement:* SEAC notes that no information on the magnitude of incineration costs was reported by the Dossier Submitter. For illustrative purposes, a cost of €1/kg (information based on literature review (see Background Document, e.g. Klein, 2013, EC/ECHA report on the use of PFAS and fluorine free alternatives in firefighting foams)) was calculated by the Dossier Submitter which results in costs between €4.3 to €43 million considering a remaining stock of 42 750 t (after the derogation of 5 years had expired). The actual amount of stock that needs to be incinerated due to proposed restriction is, however, uncertain as the previously implemented regulatory actions on PFOA (inclusion in REACH Annex XVII and subsequent inclusion in Annex I of the POP regulation) already initiated a replacement of affected AFFF. The calculations provided in the EC/ECHA report reveal a central cost estimate of €320 million for incineration costs of legacy AFFF, the discrepancy being mainly due to different assumptions on foam volumes to be incinerated (estimated in the range of 210 000 to 435 000 t in the EC/ECHA report).

- *Cleaning of existing firefighting installations and vehicles:* respective costs are assumed to be substantial by the Dossier Submitter e.g. connected to the decontamination of existing fire extinguishing systems. The Dossier Submitter reported that for both mobile and stationary systems the removal of

contaminations after the fluorinated foam concentrate is discharged and before the fluorine-free concentrate can be used is difficult and expensive. Relevant parts of the systems must be flushed and wastewater has to be disposed of safely. Substantial costs were also confirmed by stakeholders providing comments during the consultation on the Annex XV report. However, no reliable cost estimate can be given and a crucial question is the share of any potential cleaning and decontamination costs that should be allocated to existing regulation rather than the proposed restriction. Comments provided during the consultation on the Annex XV report confirm that the respective costs can be expected to be substantial and therefore confirm the Dossier Submitter's conclusion. A quantitative cost estimate of €1 billion is provided in the EC/ECHA report. SEAC notes that this estimate is based on the cost of €12 300 per appliance for decontamination. This technique is reported to result in all appliances achieving PFAS levels below 1 000 ppt and one-third of appliances being below 70 ppt. SEAC notes that the magnitude of cleaning costs of the equipment depends on the number of equipment facilities to be cleaned but also on the type of cleaning required to comply with the concentration limits. In this respect, the EC/ECHA report indicates that if a less stringent concentration limit is used, the costs would potentially be significantly lower. SEAC has no information available to evaluate what concentration limit for contaminated installations and vehicles would be optimal considering costs and remaining decontamination.

- *Adjustments to existing extinguishing infrastructure:* according to information provided by a distributor of fluorine-free foams during the preparation of the Annex XV report, any potential costs are expected to be low as no major adjustments to the infrastructure are expected. During the consultation on the Annex XV report, contradictory information was provided stating that costs could be immense (e.g. need to retrofit bund areas in tank farms in order to cover a significantly greater volume of fire liquids). No information is available to the Dossier Submitter and SEAC as to how many installations would need to be retrofitted and what the magnitude of the related cost would be.

- *Administrative issues, training with alternative foams:* costs cannot be quantified but are expected to be minor compared to the other cost factors.

- *Handheld fire extinguishers:* costs cannot be quantified but are expected to be affordable for consumers and SMEs. Some quantified figures are provided in the EC/ECHA report, which estimates unit costs to replace fire extinguishers to be €1-5, highlighting that there are uncertainties on the exact number of fire extinguishers that would need to be replaced (number ranging from 15 million to 90 million). SEAC notes that fire extinguishers, like other equipment, would need to be replaced only if cleaning does not prove effective to meet the concentration limits set in the restriction or is not applicable from a practical point of view (assumed for small mobile extinguishers).

SEAC agrees with the Dossier Submitter's conclusion that the estimated costs are highly uncertain as many of the input factors appear to need further refinement:

- Estimates of the size of the EU-wide stock of AFFFs and how much of it needs to be replaced or can be used (data on use rates of firefighting foams in the EU is also limited) during the five-year transition period.

- The need to replace stocks after the expiry date anyhow and replacement by new (fluorine-free) stocks being considered as an "earlier" replacement only. The Dossier Submitter estimated that nearly half of the existing stock would be used or expire during a 5-year transition period and therefore would not be affected by the restriction. SEAC on the other hand notes that EUROFEU claimed in the consultation on the Annex XV report that less than 10% of AFFF is actually used before it expires (comment #2983). The Fire Fighting Foam Coalition estimated that in the EU use rates would be 8-10% and could be as low as 3-5% for the next five years, as a consequence of the requirements for training and testing necessitated by the restriction of PFOA and related substances (comment #3010). However, SEAC could not verify the robustness of these estimates.
- The fact that substitution is ongoing due to the entry into force of the restriction of PFOA and related substances under the EU POPS regulation. It is assumed that more than half of the existing stock of AFFF containing PFHxA-related substances already has to be replaced as the mixtures contain PFOA and PFOA-related substances above specific concentration limits (estimated at up to 90% by industry during the POPS-listing process). Also, equipment needs to be decontaminated to ensure the concentration limits for PFOA and PFOA-related substances, which are identical to the limits proposed for PFHxA.

In the consultation on the Annex XV report, stakeholders claimed that the analysis in the proposal does not give adequate consideration to many relevant cost elements, such as potential loss of life, critical infrastructure and asset damage, environmental harm, reputational damage, potential legal liabilities and national security issues (comment #2978). They expect a serious negative impact from the restriction on the level of fire safety, particularly in chemical and petrochemical industries (comment #2983). SEAC agrees that impacts on fire safety, particularly those that could potentially lead to loss of life, must not be overlooked although they are difficult to quantify.

It was further claimed in the consultation on the Annex XV report that the restriction proposal did not consider additional (potentially high) costs for new or re-engineered systems, vehicles and foam pumping systems (comment #3023). Also, loss of revenue to foam manufacturing companies were not considered (comment #3010). However, SEAC expects that loss of revenue would not represent social costs in the long term and would be counterbalanced by gains by manufacturers of alternatives.

The Fire Fighting Foam Coalition estimated that the restriction as proposed would cost EU foam manufacturers and users more than €200 million, based on loss of foam sales, the cost for procurement and disposal of foam agent and equipment (comment #3010). SEAC also notes that other (long chain) PFASs have been used in AFFFs earlier but were lately phased out because of environmental concern. This could limit the ability of affected actors to absorb the costs of further replacement over a short time period. Several of the aspects above were reiterated by stakeholders during the consultation on the SEAC draft opinion.

SEAC notes the complexity of this sector and the respective uses concerned and the Dossier Submitter's difficulties to establish reliable cost figures for the overall firefighting foam sector, as robust information on the above-mentioned cost factors and any related aspects is scarce. Extensive information was provided during the consultation on the Annex XV report and SEAC's draft opinion by stakeholders on several aspects (specific uses, specific applications and specific situations) in order to

fill the information gaps. Even though the information did provide helpful insight for cost elements and/or applications, still several major uncertainties remain (such as the amount of current stocks held, feasibility of alternative fluorine free foams, information on substitution-related costs such as negative impacts through performance issues of fluorine free foams (environmental and human health impacts)). Even though the information provided is regarded as helpful by SEAC, it did not resolve the underlying uncertainties to an extent that would allow SEAC concluding on any quantified cost estimate. SEAC notes that a restriction proposal is currently being prepared by ECHA for the use of per- and polyfluoroalkyl substances (PFASs) in firefighting foams and stresses that a possibly more robust cost assessment might be provided within that.

- **Paper and cardboard – food contact materials (no derogations proposed):** SEAC notes that the most important application within this sector seems to be the production of paper and board for the packaging and preparation of food. The production of water- and oil/grease-repellent paper and board products is predominantly based on fluorine technology (UBA, 2018). Alternatives with regards to water repellence are, according to the Dossier Submitter, available, e.g. plastics (polyacrylates, polyvinylalcohols with fatty alcohol side-chains etc.), silicon oils/resins or silicon elastomers, paper refinement by micro- or nanofribrillated cellulose, etc. (for further details see Annex E.2.12.4 of the Background Document). As regards oil/grease repellence properties, finding alternatives providing a performance similar to PFHxA and related substances is more difficult, specifically when stability at higher temperatures is needed. The Dossier Submitter states that feedback from the sector during the preparation of the restriction proposal was limited. Based on the information available, the Dossier Submitter considers it reasonable to assume that alternatives are available for certain uses and that therefore PFASs are not needed for all applications. However, the Dossier Submitter also concluded that not all alternatives might be desirable from an environmental/risk point of view, e.g. those containing microplastics.

  For estimating the ***substitution costs*** of the proposed restriction, the Dossier Submitter concludes that efficient PFAS-free alternatives are available (based on information provided by OECD, 2020), though at higher costs (approximately 10 – 30 %) (for any details, see Annex E.2.12.4 of the Background Document). In a report issued in 2017 (Trier, 2017) it is concluded on the costs of alternatives for all uses of paper and board that these are neutral for retailers and hence most likely for manufacturers. During the consultation on the Annex XV report, only limited information was provided on this use. Some stakeholders claimed that when using alternative substances, much higher quantities are required to achieve the desired performance. However, these claims were not substantiated by supporting evidence. SEAC therefore agrees to base the assessment on data available in OECD (2020). Information presented in this report is the basis for calculating the estimated substitution costs of **€1.45 billion/year** (central estimate) for the cheapest alternative[34] i.e. chemical alternatives; other alternatives discussed and evaluated are: physical alternative, C4 alternatives (30 – 50% higher use quantities).

  Regarding any potential ***related costs of substitution***, SEAC notes that information is scarce as regards the potential need for additional machinery. The Dossier Submitter

[34] The price difference between PFHxA related substances and the chemical alternative is 150€/t, which multiplied by the 9.66 million t/a quantities used (i.e. assuming that 70% of the total 13.8 million t/a products are treated) gives the total costs of €1.45bn/year.

investigated this aspect but could not identify any relevant information nor was any submitted in the consultation on the Annex XV report. SEAC notes several further uncertainties mentioned by the Dossier Submitter: no information on the share of the quantities that are re-imported as part of finished products; any potential loss of performance when alternatives are used (which could lead to reduced shelf-life of products, any potential burns from hot oil migration and any potential for soiling); no information whether the demand from non-EU buyers will change when alternatives are used for greaseproof paper (due to any potential loss of quality); no information available on whether alternative producers could meet the demand; potential undesirable impacts from some alternatives (e.g. microplastic emissions), etc. As regards technical performance, one stakeholder claimed during the consultation on the Annex XV report that standards for high grease resistance cannot be met by alternatives. However, this claim was not substantiated by any supporting evidence. On the contrary, information is available (OECD (2020) and Trier et al. (2017)) that for non-fluorinated chemical alternatives, the cost aspect rather than performance is the critical factor in determining competitiveness. Furthermore, the Dossier Submitter states that the Danish retailer Coop® has used non-fluorinated alternatives for food packaging since 2014. Furthermore, a ban on the use of PFASs in FCMs is in place in Denmark since July 2020. Neither the Dossier Submitter, nor SEAC is aware of any performance-related issues due to this ban. However, as substitution processes are still ongoing, any medium- or long-term performance issues cannot be completely ruled out.

SEAC regards the Dossier Submitter's assessment of substitution costs as a reasonable approach, specifically in the absence of any conflicting information available to SEAC. However, SEAC notes that the likelihood and magnitude of any potential substitution related costs (specifically the need for additional machinery) are completely unknown. Therefore, the calculated cost-effectiveness is regarded by SEAC as highly uncertain.

- **Mixtures for consumer use (no derogations proposed):** SEAC notes that information on current and future uses of PFHxA-related substances in mixtures for consumer use is highly uncertain (only one stakeholder provided information during the development of the Annex XV report and no specific information was provided during the consultation on the Annex XV report). Publicly available information indicates that both fluorinated as well as fluorine-free products are available to consumers for e.g. impregnating agents, ski or floor wax, cleaning products, car care and polishes and prices are in a similar range. Whilst the Dossier Submitter regards any potential direct impacts to manufacturers and consumers as low (as alternative products are on the market already), impacts from reduced or lost functionality of the mixtures are possible (the Dossier Submitter mentions e.g. fluorine-free ski waxes to be less effective in optimising the sliding properties of skis). The Dossier Submitter does not draw any conclusion on potential costs for this sector and SEAC notes that the claims above are not supported by sufficient evidence to draw conclusions on the socio-economic impacts for this sector.
- **Electronic devices:** the Dossier Submitter notes that there are several uses of PFASs in the production of electrical devices and their components, such as semiconductors, electronic grade coating, batteries and flat panel displays. SEAC notes the Dossier Submitter's conclusion on the following affected uses.
    - **Semiconductors and semiconductor related equipment (longer transition period proposed):** SEAC notes that according to information provided by stakeholders, no single "drop-in"-alternative is available currently

(and within the next five years) for the use of PFASs as process agents for photolithography, etching and in cleaning fluids. Stakeholders reported that every use needs to be re-engineered to verify if a replacement material will meet the performance requirements. Alternatives that work for one application and/or company might not work for another. Overall, the Dossier Submitter states that only limited information on alternative substances and technologies is currently available. Substitution possibilities and respective timelines are still not fully clear to SEAC based on the information available, so more concrete information on substitution efforts and timelines for the various applications would be needed (see Background Document Annex E.6 for further details). For calculating and concluding on ***substitution costs***, SEAC notes that no concrete information is available: no information on any potential impacts for the European industry could be obtained. Only some general information from the US is provided by the Dossier Submitter (global revenues of the semiconductor industry (470 billion USD in 2018), cost of developing a new photoresist in the US representing 0.3 % of annual sales and therefore this not being a barrier to develop new photoresist systems). Information is also provided on the yearly revenue of Europe based semiconductor manufacturers industry, which is estimated to be 42 billion USD. Stakeholders provided limited, company-specific quantitative cost information during the consultation on the Annex XV report; generally, it was stated that the economic impacts of applying the restriction to semiconductors immediately would be severe. SEAC notes that the information provided indicates that the societal costs resulting from profit losses, the closure of manufacturing sites and release of workforce might result in a very high cost-effectiveness ratio (no overall quantitative assessment available to SEAC though) which would indicate disproportionate high costs of a restriction. A respective derogation on semiconductors and related equipment is therefore proposed by the Dossier Submitter (see respective section of this SEAC opinion) who recommends the European Commission to monitor the situation after the entry into force of the restriction.

- **Electronic grade coating (higher concentration limits proposed by the Dossier Submitter):** Stakeholders reported that none of the known available non-fluorinated technologies could provide the full range of properties delivered by fluorinated substances. No drop-in alternative is expected to be available for this use in the short-term. The Dossier Submitter was not able to provide any qualitative or quantitative cost estimates. However, SEAC notes that **costs related to substitution** will likely occur as e.g. a higher number of devices are expected to break due to the lack of water and oil repellence (respective derogation suggested by the Dossier Submitter, for any details see respective section of this opinion). During the consultation on the Annex XV report, one stakeholder (comment #3007) provided estimates on potential restriction related impacts if no time-limited derogation is granted (acknowledging that substitution is not impossible, but further time is needed for transitioning to alternatives). These estimates include a significant loss of revenue for the company as well as loss of profits for the company's suppliers, significant social cost of unemployment, at least €315 million for the replacement of broken devices in the EU (in the period of 2021 – 2024) and impacting the sales of more than 9.5 million devices each year with a value of at least €3.6 billion. Further impacts to manufacturers of electronic devices, medical devices and other electronic equipment as well as printed circuit boards are expected. The

Dossier Submitter regards these costs as partly overestimated as several aspects, such as alternatives being available (however, no drop-in alternatives providing the full range of properties), possibilities to repair broken devices, etc. have not been sufficiently considered. As the above claims have not been substantiated by sufficient supporting evidence, SEAC cannot conclude on the robustness and reliability of the quantified cost estimates. However, SEAC notes that economic impacts are to be expected if no transition period is considered; their magnitude, however, being unknown.

- **Uses of fluorosurfactants, having been raised during the consultation on the Annex XV report**: The Dossier Submitter considers these uses being covered by the suggested derogation for semiconductors. No cost information, neither qualitative nor quantitative, is available to SEAC on these additional uses.

- **Printing inks (longer transition period proposed for specific uses, i.e. latex printing inks):** the Dossier Submitter states that only very little information was obtained on the availability of alternatives for **water-based printing inks**. However, from the information available (e.g. use of siloxanes in many coatings, replacement of long-chain PFASs by C4 PFASs, use of alternative technologies such as UV curable mixtures, etc.) the Dossier Submitter concludes that alternatives are available. Even though it is claimed differently in the consultation on the Annex XV report and SEAC's draft opinion, no such information was submitted that would allow the Dossier Submitter and/or SEAC to evaluate whether any such additional derogations would be proportionate and if so, for which specific applications. Furthermore, some cost information was provided during the consultations on the Annex XV report as well as the SEAC draft opinion by stakeholders, e.g. on early replacement of printing equipment which is expected to induce further negative environmental impacts in terms of additional waste, partly hazardous to the environment, and additional CO_2 emissions, etc., if a suitable ink is not available and decreased printing quality. Information was also received on the number of printing hardware potentially requiring early replacement due to a restriction, remaining lifetimes, emissions, economic impacts, etc. (some information was claimed confidential, some was publicly available). However, this information was not sufficient for SEAC to extrapolate it and consider it further for an overall cost assessment for this sector (further considerations are also given in Background Document Annex E.6 as regards proportionality). SEAC notes the Dossier Submitter's conclusion that any derivation of general substitution costs for the whole industry was not possible based on the information provided.

  Latex printing inks: due to a more complex substitution process compared to the above (no "drop-in" alternatives feasible for latex printing inks), the Dossier Submitter concluded that a longer transition period (seven years) was justified. This was necessary to avoid the early replacement of printing hardware. Any further information on the derogation is given in the respective section of this opinion.

  Due to lack of information, the Dossier Submitter could not derive ***substitution costs*** for the overall industry affected. As regards ***costs related to substitution*** activities, the largest effect is expected through an early replacement of printer hardware, in case the longer transition period for latex printing inks would not be implemented (more information is given in the respective section of his opinion). SEAC recalls from previous PFAS restrictions (e.g. PFOA) that companies using the printers in question are typically SMEs, which are less able to absorb the costs of early printer replacement. Overall, only scarce cost information is available to SEAC, no cost assessment as such

was provided by the Dossier Submitter for the overall sector affected (e.g. some cost estimates are provided, those said to vary per company, ranging up to > €10 million, however, no information is provided to SEAC how this figure was derived). SEAC can therefore not conclude on any potential costs related to this use. No major concern was raised by third parties during the consultation on the Annex XV report.

- **Chrome plating (longer transition period suggested for hard chrome plating):** alternatives seem to be available for **decorative chrome plating and plastic electroplating** and the limited information available suggests that the ***cost of substitution*** is affordable. However, this cost information available to the Dossier Submitter as well as several uncertainties (e.g. the possibility of phasing in a "drop-in" alternative vs. requirement of new installations (tanks, baths, etc.), reports on partly extensive modifications of plating lines, etc.) and the complexity and heterogeneity of this sector do not allow establishing a quantified cost assessment. The Dossier Submitter notes that a shift away from Cr(VI) to Cr(III) (due to Cr(VI) being included in Annex XIV of REACH) can be observed for plastic electroplating and, where feasible, decorative chrome plating and that this also induces a shift away from PFASs as these substances are no longer required. The Dossier Submitter concludes that due to the diversity of the sector, the establishment of a generalised restriction scenario and any respective quantified cost assessment is not possible.

  Hard chrome plating: a prolonged transition period of five years is suggested for hard chrome plating, as substitution processes are regarded as more complex compared to plastic electroplating or decorative chrome plating (see respective section on derogations of this opinion). Alternatives under consideration have not yet been sufficiently tested by industry. Therefore, the Dossier Submitter concluded that a longer time period is needed for completing the testing activities and procurement of new installations. Furthermore, alternatives might be costly, e.g. control devices for airflow as additional baths or additional wastewater treatment could be needed and manufacturing routines might need to be amended. The Dossier Submitter concluded that major unemployment effects are possible if no derogation would be granted for hard chrome plating. The proposal also states that loss of business to non-EU manufacturers is possible.

  SEAC notes the difficulties to establish cost estimates for this use. During the consultation on the Annex XV report, no further information was provided that would allow for a meaningful quantification of ***substitution costs***. The Dossier Submitter concludes that there is some uncertain evidence, that the costs of substitution are affordable and proportionate to the risk (high emissions to the environment). However, the Dossier Submitter further points out that the uncertainty regarding the reliability of the information used to reach this conclusion is high. SEAC agrees with this view.

- **Building materials/ construction products:** Regarding water repellence, similar to textiles, the use of fluorine-free alternatives seems feasible. Furthermore, fluorine-free alternatives are said to be cheaper than fluorinated substances. However, this conclusion does not hold for oil and dirt repellence properties. Stakeholders submitted information that these properties generate considerable benefits, such as longer lifetime, longer repair intervals, reduced paint waste from recoat preparation, or even the enhancement of protective properties of anticorrosion points by perfluorinated urethanes. However, no reliable estimates of ***substitution costs*** or any ***related costs*** of the proposed restriction were provided or could be derived by the Dossier Submitter. During the consultation on the Annex XV report, stakeholders provided comments that without the use of fluorinated products, the necessity of cleaning activities of buildings (protective measure, e.g. facade maintenance) would increase from every 15 – 20 years to every 2 – 4 years with the resulting use of large amounts of chlorine based products (10 – 20 times) instead of using C6 once. A similar effect is reported for the painting of buildings. SEAC agrees that this may be a relevant point to consider, however, based on to the available information the use may only concern a minor part of buildings, implying that other solutions exist. Further comments refer to uses for the protection of porous substrates like natural stone or ceramics and to the use of fluoropolymer chemistry for so-called "cool roof" systems, which reduce the energy consumption of large buildings and therefore reduce CO_2 emissions. Comments in the consultation on the SEAC draft opinion also referred to uses in fabric-based coated materials within construction (e.g. tent warehouses, roofs of shopping centres, roofs of indoor tennis courts, etc.) and in flexible composite membranes for different applications (solar protection, facade, furniture, etc.).The Dossier Submitter concludes – and SEAC agrees - that these comments were not substantiated by sufficient supporting evidence to allow the information to be taken forward to a cost assessment for the sector. Still, SEAC notes that the effects above and any related costs could occur. However, the actual consequences as well as their likelihood and magnitude are unknown to SEAC.

- **Photographic applications (longer transition period proposed):** SEAC considers that the information provided by the Dossier Submitter on these uses (such as use amounts and respective releases, alternatives, costs, etc.) is unclear and contradictory. There are diverging views between the Dossier Submitter and RAC on whether the amounts of fluorinated surfactants used in photographic coatings applied to films, paper, plates and inkjet photo media coating are high (RAC's conclusion) or low (DS's conclusion). From the Dossier Submitter's assessment, SEAC notes that there is also contradictory information provided by stakeholders as regards the availability and feasibility of alternatives. There is some indication about potential non-fluorinated alternatives, however, this is claimed as confidential business information that is not available to the Dossier Submitter and SEAC; therefore, no concrete information on alternatives in the photo-imaging sector is available. According to another stakeholder, there is lack of suitable non-fluorinated alternatives for some specific applications. It is not clear to SEAC to which applications this statement is referring to. Overall, SEAC agrees with the Dossier Submitter's conclusion that due to the ongoing transition to digital techniques, there is a downward trend in market demand for photographic films (e.g. hobby photographers, medical or defence applications) and that partly significant investment in equipment (€0.5 – 1 million per single photographic material) would be needed to switch to alternatives (considered comparatively high compared to expected low emissions). In case a time-limited

derogation is supported, the transition to digital technologies is expected to be fully completed avoiding significant investments. However, SEAC notes that for hobby photographers a complete transition to digital technologies might not be feasible or preferable . Concerning photographic paper and inkjet photographic paper, the Dossier Submitter considered that potential costs if no derogation is granted would mainly be substitution-related costs, i.e. functional losses resulting in quality issues of affected products (e.g. photo prints with impaired visual quality)). In the consultation on the Annex XV report, the need to extend the derogation to photographic coatings applied to papers and in printing plates was raised (comments #2981, 2991, 3073, 3080, 3094). Additional information to justify the need for a derogation was provided during the consultation but claimed as confidential. SEAC notes that the restriction could mean that some users would have to replace their printing equipment prematurely and that costs would be expected in the form of defects in the coating in case appropriate surfactants are not available. Based on the above information, SEAC cannot conclude on the magnitude of (substitution or substitution-related) costs for this sector.

- **Cosmetic products (no derogation proposed):** The Dossier Submitter states that PFAS-free alternatives are available for all cosmetic products. This statement seems to be confirmed by announcements of large producers (such as L'Oréal, H&H, Lumene, Body Shop, Isadora and Kicks) to phase out all PFASs from their products. One stakeholder (L'Oréal) announced in 2018 that reformulation processes are completed for all their trademarks. The Dossier Submitter recognises that no cosmetics producer submitted comments during the preparation of the Annex XV report or in the consultation on the Annex XV report. Overall, it is therefore concluded that alternatives are available and feasible and no functional or performance losses of products are to be expected. However, a certain degree of uncertainty remains as regards the affordability of a restriction to small and medium sized enterprises as no information is available to the Dossier Submitter whether such companies are prepared to reformulate at affordable cost, i.e. whether the scientific expertise and financial resources are available to reformulate products.
  Overall, SEAC lacks sufficient information to draw a conclusion on socio-economic costs (mainly ***substitution*** and any ***potential related costs***) within this sector, specifically for SMEs. However, in the absence of any information provided by stakeholders during the consultation, SEAC does not expect major economic implications with the approach suggested by the Dossier Submitter.

- **Medical devices (derogation proposed)**: within the medical sector, different applications for PFHxA exist and the Dossier Submitter considers medical devices to also include medical textiles. The Dossier Submitter expects that there are current (and future) uses within this sector that have not been identified by them or raised in the consultation on the Annex XV report. They explained that it became clear from stakeholders that several of them were not aware of the restriction proposal. As only limited cost information was available to the Dossier Submitter when developing the restriction proposal, no cost assessment was provided in the restriction proposal. During the consultations on the Annex XV report and SEAC's draft opinion, several comments for this sector were provided, some also including information on costs. The Dossier Submitter did not provide an assessment of costs as they expect no economic impacts to occur to this sector in light of the proposed complete derogation (as stated above). However, they conclude that whether or not this information is representative

for all uses is unknown. In their view, it is highly unlikely that the sample from the consultation represents reliable information with regards to all uses for medical devices. In SEAC's view, the comments provided during the consultation on the Annex XV report on any potential costs of a restriction are either very generic or company and product specific and cannot be taken forward for an assessment of the overall socio-economic impacts for this sector, in the absence of any such analysis by the Dossier Submitter. For example, the following cost information was provided during the consultations on the Annex XV report and SEAC's draft opinion:

- Health costs stemming from increased thrombosis, bacterial adhesion and infection for the application in implantable, e.g. stents and non-implantable, e.g. vascular catheters medical devices (comments #3014 and 3137);
- Increase in service frequency and repair of hearing aids by 30%, but no monetisation provided (comment #3121);
- Company specific costs for eye drops manufacturer, in terms of decreased net revenue, relocation costs and unemployment costs (comment 3153, figures claimed confidential).
- Some general information on economic impacts, mainly qualitatively, highlighting the importance (in terms of health protection, lifesaving, avoidance of infections and many more) of the substances of concern for sensitive applications within this sector provided by several stakeholder organisations (comments #819, 835, 887, 896 and some more)

Still, SEAC cannot draw any conclusion on the overall costs potentially occurring due to a restriction.

- **Filtration and separation media (derogation proposed):** during the consultation on the Annex XV report, several stakeholders requested a complete derogation for the use of PFHxA in filters and membranes. The Dossier Submitter proposes a derogation for filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil repellence properties, even though it is well-noted in the Background Document and by SEAC that such a broad derogation leads to a certain degree of uncertainty as it might be possible that alternatives are already available or will become so in near future for some applications. Cost estimates for the uses affected are scarce, only some information was provided by stakeholders during the consultations. This information mainly indicates that specifically ***costs related to substitution***, e.g. loss of effectiveness of products due to no alternatives being available currently, could be potentially very high. Stakeholders reported that appropriate filtration reduces maintenance needs, extends service life and prevents failures of equipment; they also expect energy consumption and related greenhouse gas emissions to increase in the absence of C6-treated filtration media. During the consultations on the Annex XV report and the SEAC draft opinion, it was stated that the absence of a derogation will put manufacturing facilities located in the EU at risk and result in a supply interruption of filtration and separation media for several purposes until adequate alternative candidates are identified and requalified. SEAC agrees to the Dossier Submitter's conclusion that more information on the different applications and specifically a more detailed discussion on substitution possibilities as well as on any potential related costs would be needed in order to draw a robust conclusion on the socio-economic impacts.

- **Optical fibres (no derogation proposed):** during the consultation on the Annex XV report, requests for derogations were submitted by stakeholders claiming alternatives not being feasible. However, the information provided did not induce the Dossier Submitter to propose a derogation for this use (see respective section of this opinion). As regards costs, no information on ***substitution*** and any ***potential related costs*** of a restriction are available to SEAC.

- **Epilames used in watches (derogation proposed):** during the consultation on the Annex XV report, stakeholders requested a complete derogation for this use, which was taken up by the Dossier Submitter (for more information see respective section of this opinion). No specific cost information was provided by stakeholders during the consultation even though specifically requested by the Dossier Submitter. Still, the Dossier Submitter considers that a derogation for this use is justified based on socio-economic considerations (low emissions, confirmed by RAC, support a derogation compared to potentially substantial impacts for affected companies as well as social impacts comprising substantial job losses for the European watch component supply industry (as stated in a comment provided by the Swiss watch industry, being a major client of the EU supply industry). More details on the magnitude of potential impacts for the EU and Switzerland due to a restriction were provided by the Federation of the Swiss watch industry during the consultation on SEAC's draft opinion (comment #931), e.g. information on the number of related employed workers in the EU, magnitude of export revenues due to this industry for the EU, taxes generated in the EU by the analogue watchmaking industry and many more. If no derogation is granted, the potential impacts in the EU for the analogue watchmaking industry are estimated to be between 168 000 – 218 000 job losses, lost export revenues of €3.0 billion and loss of taxes and social security contributions of €1.3 billion (SEAC assumes that these figures relate to impacts per year, however, this is not fully clear from the comment provided). A further stakeholder provided additional information on technicalities (performance implications). The Dossier Submitter was not fully clear to which standards industry is referring to when claiming that the production of watches according to international standards would no longer be possible due to the proposed restriction. Should these standards rather refer to the service lifetime of a product and increased maintenance intervals, the derogation would be justified based on cost-risk considerations (potentially high impacts for industry, very low use/release volumes and RAC's support for a derogation). However, should the standards refer to a more precise functioning of watches (i.e. time keeping precision) then the Dossier Submitter may conclude differently. As the comment on technicalities is claimed confidential (comment #937), SEAC cannot further provide information on the respective discussions. However, based on the information available, SEAC concludes that a restriction would most probably induce high economic and social costs.

The Dossier Submitter states that a number of further applications of PFHxA its salts and related substances (in addition to the above) have been reported during the consultation on the Annex XV report (see Annex E.2.13.8 of the Background Document). Some of the uses mentioned are:

- Handling of fragrance and odour compounds in products and articles;
- Use of perfluoropolyethers in aerosol applications during in-house quality control of other fluoropolymer products (laboratory application);
- Use of C6 fluorosurfactants in the production of polyester films as anti-fog coatings for face shields for surgeons;

- Use of fluorinated substances in special glass for construction (external glazing and internal decorative glass), automotive (original and replacement glass) and the solar sector.

SEAC has no information on costs or any socio-economic consequences of a restriction for the above-mentioned uses. SEAC notes that it is unclear whether face shields for surgeons would fall under the definition of medical devices as per Regulation (EU) 2017/745. No such information was provided, neither in the Background Document or during the consultation on the Annex XV report.

Reporting costs

For some uses derogated from the proposed restriction (such as for textile derogations listed under paragraph 9 of the restriction as well as firefighting foams), the Dossier Submitter suggests an annual reporting requirement; this was introduced due to currently scarce information on the use quantities for the uses proposed to be derogated. The monitoring of future use quantities is expected to lead to sufficient information to assess if further EU action is required. The costs associated with this requirement are not expected to be a major cost element of the overall restriction. The Dossier Submitter considered a one-time cost for ECHA to develop the reporting format and software to submit and process the information (unlikely to exceed €50 000) as well as ongoing costs for industry to gather the required information and submit it annually. SEAC considers that there might be also recurring costs for ECHA to process the information collected via an online tool. SEAC notes also that one company estimated reporting requirements to be in the range of €2 000 to €5 000 per year (comment #3001). However, the derivation of any robust quantified cost figure is said to be difficult as it depends on the complexity of the company structure and the number of products subject to the reporting requirement. Specifically for SMEs, any such reporting could be complex and costly. However, no concrete information on any potential impacts on SMEs is available to SEAC. In absence of any conflicting information provided, SEAC agrees to the Dossier Submitter's view that overall, no major economic impacts of introducing such a requirement are to be expected.

Enforcement costs

SEAC notes the generic estimate of €55 600 annual average cost per restriction derived by ECHA and agrees with the Dossier Submitter that this number should only be seen as an indication of the magnitude of the actual costs. Costs will indeed vary from case to case. Furthermore, in this case the figure might constitute an overestimation of enforcement costs because enforcement activities for the proposed restriction entry could be combined with activities related to the enforcement of the PFOA and C9-C14 PFCA restrictions. However, SEAC agrees that this estimate can be seen as an indicative maximum value of administrative costs for enforcement.

SEAC notes that the Forum points out that further development of analytical methods is needed to ensure the enforceability of the proposed restriction. Currently, the methods available do not cover all relevant substances (problems relating to polymers and substances bound to matrices are specifically highlighted) and are not applicable to all matrices and are not standardised. SEAC has no information about the magnitude of any related costs of developing testing methods; however, it can be expected to be mostly a one-time cost. More information on Forum advice is provided in the section on enforceability.

Testing costs

As to the **costs for analytical testing**, the results of a survey recently carried out by ECHA[35] indicated that the average price for testing for PFHxA or related substances is around €350 per sample or €50 000 for 300 samples (covering many different matrices). SEAC underlines that making a relevant estimate of testing costs would also require information on the **number of tests** to be performed, and information on the costs related to sampling and sample preparation (if not carried out by the laboratory and included in the price of analysis). This information is, however, not available to SEAC. Still, SEAC considers that the above-mentioned information provides some indication of the magnitude of the associated costs.

Testing packages available from commercial laboratories typically cover several PFASs (ca. 20-30 depending on the laboratory) including **PFHxA**. Testing for PFHxA could therefore be possible with minor or no extra costs when other PFASs are analysed. Also, some of the most commonly used **PFHxA-related substances** are included in some of the existing packages (see comment #3115 from the consultation on the Annex XV report). However, at this point, most PFHxA-related substances are not covered by the available test packages. The existing methods would need to be adjusted to enable testing for further PFHxA-related substances, and new methods (including sampling and sample preparation steps) be developed to enable testing of side-chain fluorinated polymers.

Overall, SEAC expects that after taking the one-time cost of updating the methods to make them cover the most relevant related substances, testing to ensure compliance with the proposed restriction can be combined with testing for PFOA and C9-C14 PFCAs, and thereby the additional testing costs from this restriction should be limited. SEAC however highlights that there is no information available to SEAC relating to the costs of development and use of methods for side-chain fluorinated polymers.

4.3.2.2. Benefits

Summary of proposal:

The Dossier Submitter argues that PFHxA shows characteristics complying with the concerns which are put forward to reason that a safe concentration of PBT/vPvB substances in the environment cannot be established with sufficient reliability. Therefore, the Dossier Submitter considers that PFHxA must be assessed in the same way as a non-threshold substance and had initially adopted a cost-effectiveness approach in the Annex XV dossier, as recommended by SEAC for evaluating restriction proposals for PBT/vPvB (-like) substances (see proportionality section for more details). The reduction in risk is therefore not quantified, and reduction in emissions is used as a proxy for the reduction in risk. The Dossier Submitter provides quantitative estimates of reduced emissions over 20 years for many of the uses identified and for all of the uses considered to be the major sources of emissions. For other uses, where information was particularly scarce, only qualitative considerations are made. These benefits have not been monetised.

The Dossier Submitter also considers potential health impacts that would be prevented by the restriction. Considering the absence of clear evidence regarding human health impacts from exposure to PFHxA, the Dossier Submitter concludes that there are currently no impacts to be expected. However, with a rising environmental concentration of PFHxA and due to its extreme persistence, they consider that this may change in the future and there are uncertainties on the risks to human health.

[35] Available in the published collection of comments submitted to the consultation on the Annex XV dossier, comment nr 3115

SEAC conclusion(s):

In SEAC's view, the approach taken by the Dossier Submitter is in general a reasonable way to assess the benefits of the proposed restriction. PFHxA is a stock pollutant characterised by **extreme persistence** in the environment. PFHxA is very **mobile,** and also has **long-range transport potential** and therefore contaminates remote regions. PFHxA, its salts and related substances are already ubiquitously present in the environment. The current level of understanding of effects in the environment and on human health is limited. No safe level of exposure can be established. Furthermore, once in the environment, the substances are almost impossible to be removed, i.e. any respective contamination is irreversible. Also end-of-pipe technologies to reduce releases are generally not effective and at least not cost-effective. Therefore, prevention of emissions is, in SEAC's view, a reasonable approach, because it is the only viable option to reduce or stop the increase of the PFHxA stock in the environment. RAC concludes that whilst PFHxA does not seem to have high bioaccumulation potential and hence likely not meet the criteria for a PBT/vPvB substance, the properties of concern for PFHxA warrant a case-by-case risk assessment approach where, in analogy to PBT/vPvB substances, any releases and exposures should be regarded as a proxy for an unacceptable risk to the environment and human health. Therefore, RAC also agrees that releases of PFHxA, its salts and related substances should be minimised. Taking into account the information provided by the Dossier Submitter and the assessment and conclusion of RAC, SEAC agrees that emission reduction through a restriction would have been a useful proxy for the benefits of the proposed restriction, taking into account the irreversibility of contamination and, additionally, the **possibility of irreversible adverse effects** of a growing stock on a large geographical scale in the environment and in humans.

However, even though the approach is considered appropriate in general, SEAC notes RAC's conclusion on several shortcomings within the Dossier Submitter's assessment, e.g. gaps in the description of underlying assumptions of the calculations, divergent and inconsistent release calculations for same sectors, as well as lack of or unclear and incomplete information on which substances covered by the restriction the release calculations refer to. As a consequence, RAC regards the reported quantitative release estimates as unreliable and concludes that the Background Document provides insufficient information to draw firm conclusions on the central estimates and ranges of releases to the environment. RAC states that there is insufficient scientific data to conclude with certainty on the use volumes, source and scale of emissions from the different uses (which are in turn used as a proxy for risk) and, with the exception of a few sectors, whether the implemented OCs and RMMs are sufficient to address the risks. Further details are provided in the respective RAC sections of this opinion.

In conclusion, SEAC considers that even though benefits are to be expected due to a restriction, these cannot be expressed via a standard quantified risk assessment as quantification of risks is not possible for these substances. The uncertainties in the emission reduction estimates do not allow use of emission reduction estimates for SEAC's evaluation of benefits as has been the practice in restriction proposals for similar substances. Therefore, **SEAC cannot draw a conclusion on the magnitude of the restriction related benefits.** Still, **SEAC notes RAC's conclusion that due to the wide-dispersive use of the substances in numerous sectors, substantial emissions to the environment are expected to occur.** Due to the extreme persistence of PFHxA, these emissions will lead to an increasing environmental stock, and any potential impacts and damages arising from this stock will last over decades if not centuries. **RAC's qualitative conclusion is the basis for SEAC's sector-specific discussions on proportionality and derogations.**

Key elements underpinning the SEAC conclusion(s):

- **Concern:** SEAC notes that RAC confirmed the **extreme persistence** of PFHxA. Any emissions will stay in the environment practically permanently meaning that the environmental stock will always be increasing leading to an irreversible and continuing contamination. RAC further concluded that the resulting exposures may lead to unpredictable long-term adverse effects on the environment and human health whose seriousness may increase with increasing exposures. Therefore, prevention of the build-up of further stock is, in SEAC's view, a reasonable approach. PFHxA is **mobile** in water and therefore prone to ending up in ground water and drinking water. The substances covered by the scope also have **long-range transport potential**.

  More information on substance properties and RAC's conclusion on risks as well as the risk reduction effectiveness of the proposed restriction can be found in the relevant RAC sections of this opinion.

- **Emission reduction used as a proxy for risk reduction/benefits assessment:** SEAC notes that the Dossier Submitter based the benefits assessment on quantified release estimates and qualitative supportive information. SEAC in general agrees with the use of this approach that is in line with SEAC's guidance "*Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC"*.[36] Whilst PFHxA is not a PBT or vPvB substance, SEAC notes RAC's conclusion that the hazard associated with PFHxA lead to a concern very similar to PBTs/vPvBs. RAC supports the use of a case-by-case approach where any releases and exposures are regarded as a proxy for the risk to the environment and human health and where the releases of PFHxA, its salts and related substances should be minimised. In support of the case-by-case approach is the restriction proposal on intentionally added microplastics (ECHA, 2019), where primarily the very high persistence, leading to continuously increasing environmental stocks, served as a proxy for the risk. The approach was supported by both RAC and SEAC. However, SEAC notes RAC's concern with the Dossier Submitter's specific exposure assessment, being unclear, partly inconsistent and unreproducible. SEAC therefore notes that no quantified information on emission reduction (not even ranges) is available to assess the benefits of the proposed restriction and the proportionality and derogations respectively.

- **Benefits estimation:** due to the shortcomings in the Dossier Submitter's assessment, RAC could not establish quantitative emission estimates or any respective ranges as there is insufficient scientific data to conclude with certainty on the use volumes, source and scale of emissions from the different uses (which usually should serve as a proxy for risk). RAC provides a qualitative discussion on a per-sector basis. Even though some of the Dossier Submitter's assumptions are, according to RAC, unrealistic worst-case and generally the emission estimates are uncertain, the use areas of highest concern when it comes to potential EU emissions of PFHxA are **(imported) textiles**, **paper and cardboard (food contact materials)** and **firefighting foams** (further information is provided in the respective RAC sections of this opinion). SEAC notes RAC's conclusion that measured data in various environmental matrices convincingly demonstrate that emissions to the environment occur. SEAC notes that overall, RAC draws the following three different conclusions, to which the single sectors/uses can be allocated to (further information is provided in Table 5 and Table

36 https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3

6 of this opinion as well as the proportionality section of the SEAC opinion):

- **RAC concludes that emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses;**
- **RAC concludes that emissions are minimised by means other than a restriction (e.g. through site-/use-specific RMMs) and therefore supports a derogation;**
- **RAC cannot conclude without further information on the effectiveness of potential RMMs that a ban on the use of PFHxA, its salts and related substances is the most effective EU wide measure to reduce risks.**

No additional quantitative information is available to SEAC as regards the benefits of a restriction.

- **(Regrettable) Substitution:** SEAC highlights that **alternatives**, also fluorine-free ones, are often associated with risks. Different risk profiles may be difficult to weigh against each other, and as far as the risks of alternatives are not fully elucidated (or perhaps it is not even known yet which alternatives would be adopted in each use) careful consideration is necessary when phasing out substances allowing time for the industry to find out suitable less risky alternatives for the different uses. SEAC notes that PFHxA, its salts and PFHxA-related substances are one group of substances in the family of PFASs. Several other groups of substances (PFOS, PFOA, C9-C14 PFCAs, PFHxS and their related substances) are already subject to restrictions. Leaving this group of substances unregulated could undermine the benefits of the earlier restrictions if the other substances were substituted with these substances having similar overall concerns. SEAC highlights that, as for all restrictions, the benefits of the proposed restriction strictly depend on whether the chosen alternative substances are safer for human health and the environment. In fact, for example in terms of the quality of drinking water, the occurrence of any PFAS is a source of concern. As a consequence, the estimates of avoided remediation cost may be relevant only for evaluating a switch to non-fluorinated substances.
- **Costs of non-action:** SEAC notes that potentially high **remediation costs** for contaminated sites and drinking water could be avoided by the proposed restriction. Many examples of remediation costs for sites contaminated by PFASs can be found in literature. The Background Document reports an assessment made by the Nordic Council of Ministers which estimated that remediation costs relating to PFASs at the European level (31 EEA Member States and Switzerland) are in the order of magnitude of hundreds of millions of euros at a minimum, ranging from 821 million to 170 billion euros. The potential costs relating to the treatment of water because of contamination by very mobile substances are indicated in the Background Document by reporting on an estimation by EurEau (2019), the European federation of national associations of drinking water suppliers and wastewater services. According to their calculation, the cost for reverse osmosis, a treatment technique for most polar substances, would raise the price of water treatment by more than €1 /m^3, resulting in circa €200 /year additional cost for the average household. This is highlighted to be just one element; other societal costs would also accrue but SEAC has no information on their magnitude.
- **Global efforts on a phase out of PFASs:** SEAC points out that as this restriction is part of wider European and global efforts to replace PFASs with safer alternatives, the actual risk reduction potential – and, therefore, benefits of these actions – will gradually materialise as the implementation of the measures advance.

4.3.2.3. Other impacts

Summary of proposal:

The Dossier Submitter does not expect the proposed restriction, including the proposed derogations, to have major effects on employment, because alternatives are available and implementable or will become so in the foreseeable future at a reasonable cost for the majority of uses. The Dossier Submitter reports uncertainties concerning the impact on the manufacture of fluoropolymers and SFPs in the EU.

The Dossier Submitter also considers potential distributional impacts. They consider that any costs of the proposed restriction to EU and non-EU businesses are likely to be passed on along the supply chain. Additionally, most of the costs will consist of functional losses, which would also affect consumers. Potential impacts of functional losses include loss of convenience and associated additional costs like reduced service life or increase in cleaning processes.

SEAC conclusion(s):

SEAC notes that the information provided on social and wider (economic) impacts in the restriction proposal is scarce. The Dossier Submitter does not expect any such impacts due to the proposed restriction: no closing down or relocation of business or any major employment effects are expected. Contradictory information was provided by the Dossier Submitter whether or not companies will pass on higher costs (e.g. due to higher prices of alternatives, substitution activities, etc.) to consumers. In SEAC's view, this would require a sector- and/or use-specific discussion, which was not provided, either by the Dossier Submitter, or by third parties during the consultation on the Annex XV report or the SEAC draft opinion. SEAC notes that overall, limited information on any such wider (economic) and/or social impacts have been provided; if any such impacts will occur is likely depending on specific sectors and/or uses and is therefore discussed in the sector-specific part Background Document Annex E.6, which constitutes a part of this opinion. The reasons for expecting only negligible other impacts are explained below:

- alternative substances seem to exist for many functionalities affected or will become so in the foreseeable future; according to the Dossier Submitter, prices of alternatives lie within reasonable ranges, uncertainty exists as regards the respective amounts to be used in order to achieve the same functionalities (see sector-specific discussion on costs of this section); where the substitution process is complex or regarded as impossible to date, the Dossier Submitter suggests respective derogations (see respective section of this opinion) which would allow industry to further use the substances for producing their products (hence, no costs expected);
- products relying on the alternative substances are available in several sectors/for several product types;
- PFASs in general are seen as a worldwide concern and early R&D as well as production of alternatives might be regarded as an advantage over other countries outside Europe should they decide to regulate C6 substances in future;
- European and non-European companies will need to keep their market shares and market position vis-à-vis their competitors, hence major increases of consumer prices of PFHxA-free articles are regarded as unlikely.

SEAC notes that one uncertainty is expressed by the Dossier Submitter as regards the manufacturing of fluoropolymers and SFPs, where production facilities are expected to need restructuring if switching to alternative production processes. Information provided in the consultation on the Annex XV report indicates that a restriction on those uses would endanger production facilities in Europe. Due to limited derogations and a resulting limited use production in the EU, these processes might no longer be economically viable and a shutdown of production plants might be the most probable outcome of the restriction. However, in the Dossier Submitter's view, these claims are not substantiated by sufficient information.

SEAC notes that both information provided by the Dossier Submitter as well as information provided in the consultation on the Annex XV report on social and wider (economic) impacts is scarce and rather general and no actual assessment on any such impacts has been provided.

As regards any potential impacts on EU citizens, SEAC notes that for several products/sectors affected by the restriction, potential quality issues and related negative impacts (such as a reduced service life of articles, increased cleaning activities due to lower technical functionalities such as oil/dirt repellence, safety aspects, etc.) are noted by the Dossier Submitter and were stressed by third parties during the consultation on the Annex XV report. The likelihood and magnitude of any such restriction-related consequences are mostly unknown to the Dossier Submitter and SEAC can therefore not draw a respective conclusion on the magnitude of any such impacts. A sector and/or use-specific discussion of potential quality issues is given in the respective section of this opinion (mainly derogation, cost and proportionality sections).

Key elements underpinning the SEAC conclusion(s):

SEAC's view is given in the conclusion part above.

4.3.2.4. Overall proportionality

Summary of proposal:

The Dossier Submitter considers that the restrictions on PFOA, PFOS and C9-C14 PFCAs may not be totally adequate points of comparison when concluding on the proportionality of this restriction. This is because in the former, short-chain PFASs were considered as the most likely substitutes, whereas in this restriction, PFHxA, its salts and related substances are expected to be replaced by non-fluorinated alternatives, where it is assumed that hazard and risk will be reduced to a larger degree. In the Dossier Submitter's view, the risk reduction capacity of this restriction proposal is larger, resulting in the assumption that society's willingness to pay should also be expected to be larger than for previous regulatory measures on fluorinated substances.

Initially, the Dossier Submitter assessed the proportionality of the proposed restriction through a cost-effectiveness analysis, for sectors where quantified estimates were available. However, during the opinion making process, the Dossier Submitter changed their approach to an overall qualitative cost discussion.

When considering only substitution costs, the Dossier Submitter finds that the restriction is proportionate. For most uses identified, costs are said to be low due to the fact that non-fluorinated alternatives are expected to be less expensive than or similar priced as the restricted substances (for a sector- and/or use specific discussion, see respective sections of the Background Document). However, for several uses, the Dossier Submitter has identified potentially significant costs related to substitution such as reduced quality of products or functional losses, which are largely unknown and/or uncertain and evaluated only qualitatively

(see section 2.5.1 on economic impacts of the Background Document).

The Dossier Submitter acknowledges the high uncertainties within the cost and benefits assessment of this restriction proposal but observes that other restriction proposals under REACH have faced large uncertainties too. As an example, the restriction proposal for intentionally added microplastics is mentioned. In their view, this case demonstrates that immediate regulatory action[37] might be justifiable whenever effects of a substance are uncertain but irreversible and when learning about a possible harm is expected to happen in future. In this case a "first act, then learn" approach might be preferred over a "first learn, then act" approach.

The costs and benefits of the proposed restriction are said to be uncertain and both, environmental exposures and policy costs are irreversible. However, the Dossier Submitter concludes that most of the costs arising from a restriction on PFHxA, its salts and related substances are most likely affordable for society and the impacted industries. The possible impacts of continued emissions on the environment and human health are largely unknown but might be extremely severe. Hence, it is likely that society's willingness to pay for risk reduction is high.

The Dossier Submitter provides a sector-/use-specific discussion on proportionality in the restriction proposal (see Table 8 in section 2.5.5 of the Background Document) but considers a conclusion for the overall restriction proposal as difficult, due to lack of data and high uncertainties on both costs and benefits. Therefore, instead of a cost-effectiveness analysis, the Dossier Submitter proposes to consider reasonable worst-case scenarios for costs and benefits and evaluate whether the consequences of such scenarios are affordable to society as a whole and impacted individuals or subgroups. When information is missing or incomplete and informed optimal decision-making is not possible, the Dossier Submitter regards minimisation of future regret as an adequate strategy. For some uses this approach leads to distinct and intuitively understandable conclusions for what action should result from adopting the "first act, then learn" approach: in the first place the approach suggests to ban all uses of PFHxA, its salts and related substances because the effects of the substance are uncertain but irreversible. However, when considering reasonable worst-case consequences on human health and the environment arising from the restriction due to the lower performance of currently available alternatives (e.g. less effective products such as PPE or not being able to effectively extinguish large fires), it might be necessary to act first by granting a derogation for certain uses to prevent possibly disproportionate irreversible consequences for human health and the environment.

The Dossier Submitter concludes that in the case of very large uncertainties and few reliable data this balancing of worst-case costs and benefits of a restriction is challenging. However, the decision if PFHxA, its salts and related substances shall be restricted needs to take into account the socio-economic impacts. In the Dossier Submitters' view, for this restriction proposal, socio-economic impacts need to mostly be described qualitatively. However, if cost-benefit or cost-effectiveness cannot be described in quantitative terms it seems reasonable to discuss the proportionality mostly in terms of affordability and potential regret.

SEAC conclusion(s):

SEAC notes that the initial approach of the Dossier Submitter to assess the proportionality of the proposed restriction was a cost-effectiveness analysis (CEA). Such an analysis was

[37] No regulatory decision has been taken on the restriction proposal on intentionally added microplastics at the time SEAC agreed on its draft opinion on the restriction proposal on PFHxA, its salts and related substances.

performed for sectors, where (quantitative) cost estimates could have been established. SEAC agrees that in the absence of a standard quantified risk assessment approach, e.g. as for PBT, vPvB or similar substances, a CEA is an appropriate way forward to assess proportionality.

As noted above, during the opinion making process, the Dossier Submitter changed their approach to an overall qualitative cost discussion. Additionally, SEAC notes RAC's conclusion on the high uncertainties as regards emission estimates and restriction-related emission reductions, respectively. As described in the benefits sections, RAC can only provide SEAC with a qualitative evaluation of the effectiveness of the restriction for the different uses (e.g. wide dispersive) and whether or not emissions can be minimised by means other than a restriction on the use. For some sectors, the scarce information available in the Background Document does not allow RAC to conclude on whether OCs and RMMs can result in the minimisation of emissions for some uses. Still, RAC concludes that for wide-dispersive uses, OCs and RMMs are clearly not sufficient to control the identified risk. This situation precludes any sector-specific or overall CEA for the restriction proposal. The Dossier Submitter decided to introduce alternative concepts in order to discuss proportionality, as pointed out above and in the Background Document (e.g. "first act, then learn"-approach, worst-case/affordability/potential regret-approach, etc.). Although SEAC acknowledges the difficulties to approach the proportionality assessment of complex restriction proposals, such as the current one for PFHxA, its salts and related substances, SEAC finds that the Dossier Submitter did not demonstrate the overall proportionality of the restriction proposal, neither in a quantitative, nor in a qualitative manner. SEAC also has reservations on whether the additional aspects used by the Dossier Submitted to assess the proportionality of the restriction proposal can be considered by SEAC as a scientific basis for its opinion or should rather be in the remit of the decision maker. **As no sufficiently justified proportionality assessment was performed by the Dossier Submitter and as overall only very limited qualitative information on benefits (emissions) and costs is available to the Committees, SEAC cannot conclude on the proportionality of the *overall* restriction proposal.** Nevertheless, SEAC stresses that there are arguments in favour of proportionality, first and foremost the irreversibility related to accumulating stocks of PFHxA in the environment due to continued emissions and the extreme persistence of the substance.

Instead of such an overall conclusion, the SEAC opinion comprises a sector-by-sector discussion (considering also sub-sectors) on potential alternatives, costs and RAC's conclusion on uses/RMMs (see Table 7 below). In particular, even in cases where SEAC cannot conclude on proportionality for a specific sector or sub-sector, SEAC provided its views on derogations considering the following aspects:

- whether alternatives are available;
- where alternatives are available, any potential indication on their prices and respective substitution costs as well as the related costs in terms of changes to process and equipment as well as functional losses and reduced product quality;
- where functional losses are expected, to consider their consequences in terms of socio-economic impacts as far as information was available: human health and environmental impacts, including safety aspects, reduced service life and durability, reduced comfort or convenience; however, noting that an overall lack of information did not allow for a proper discussion.
- the comparison of mostly qualitative information on costs, including functional losses, and RAC conclusions on derogations and effectiveness.

SEAC points out that this analysis is based on the available, overall qualitative information in the restriction proposal, information provided during the consultation on the Annex XV report and the SEAC draft opinion as well as RAC's conclusion on uses and emission minimisation.

In this respect, SEAC recognises that there are large uncertainties on the exact magnitude of the socio-economic impacts of the restriction and of the emissions for specific sectors. Therefore, SEAC acknowledges that more accurate and representative information on emissions and costs could change the outcome of sectoral analysis, for example concerning the need for a derogation or the proposed length of the transition period.

Key elements underpinning the SEAC conclusion(s):

The following elements underpin SEAC conclusions on proportionality:

- SEAC stresses that it is not currently possible to draw a robust conclusion on the proportionality of the overall restriction proposal and any potential derogations, because the magnitude of **environmental benefits of the emission reduction** achieved is uncertain (due to large uncertainties and data gaps, no conclusions on releases and a respective release reduction through a restriction are drawn by RAC and available to SEAC). SEAC considers that the **irreversibility of emissions** is a key argument in favour of proportionality. The pollution stock is permanent, i.e. not possible to remove from the environment with the available remediation methods. If remediation would be at all possible, SEAC considers it likely to be much more costly compared to the costs of the proposed restriction.

- SEAC notes that the Dossier Submitter did try to use emissions as a proxy for risk in its assessment, which is the current standard approach applied by SEAC in its evaluation of restrictions and authorisation applications for substances for which no standard quantitative risk assessment is possible (following ECHA's guidance on the evaluation of restrictions and authorisation applications for PBT and vPvB substances in SEAC[38]). However, SEAC notes that this approach does not consider any implications of **stock externalities** for the evaluation of risks and benefits of a restriction respectively. In this respect, SEAC notes that:

    - Even marginal releases contribute to the environmental pollution burden;
    - Stopping emissions does not imply that impacts disappear, neither in the short, nor in the long term (except for the case that remediation measures can be and are adopted);
    - Benefits, in terms of avoided negative environmental impacts, can stretch over much longer time periods than cost estimates of a restriction.

- SEAC notes that an EU-wide ban on PFOA, its salts and related substances applies from July 2020 under the Regulation (EU) 2019/1021 on persistent organic pollutants. PFHxA-related substances are potential substitutes of PFOA-related substances in many uses. Indeed, during the consultation on the Annex XV report, some industry stakeholders indicated that they have already transitioned to PFHxA-related substances following the restriction on PFOA. Therefore, in the absence of the proposed restriction it could be expected that the use of PFHxA, its salts and related substances would continue in the future.

SEAC's evaluation on proportionality as well as on derogations on a per-sector basis is summarised in Table 7 below. The conclusions are based on the approach outlined in the section above. SEAC's detailed considerations, including the description of SEAC's approach for the evaluation and the underlying arguments for its sectoral conclusions, are provided in the sections 'costs' and 'benefits' of this opinion as well as in the use-specific analysis

[38] See: evaluation_pbt_vpvb_substances_seac_en.pdf (europa.eu)

presented in Background Document Annex E.6, which constitutes a part of this opinion.

Table 7. Overview of cost estimates, alternatives, RAC conclusions on uses, releases and emission minimisation as well as proportionality aspects and derogations per sector

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
Manufacture and use of fluoropolymers	Not applicable	General conclusion on alternatives not feasible due to numerous applications requiring different specific functionalities. Stakeholders reported that alternatives do not provide a combination of relevant functionalities which could lead to negative impacts on several sectors affected with possible unpredictable knock-on effects on other sectors.	Overall unknown/uncertain; societal costs are expected to be very high by STOs (e.g. severe HH impacts) due to potential functional losses of certain products.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**Unclear.** Information available to SEAC does not allow setting specific limit values. Further discussion is provided in Annex E.7 of the Background Document .
Manufacture and use of fluoroelastomers	Not applicable	Yes, non-fluorinated alternatives are available but, according to stakeholders, do not provide heat, chemical, oil resistance as well as low-permeability	No information available on substitution costs. Information available indicates that functional losses are likely to occur and would negatively impact engine performance, safety and emissions in the automotive sector.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**Unclear.** Information available to SEAC does not allow setting specific limit values. Further discussion is provided in Annex E.7 of the Background Document.
Manufacture of SFPs	Not applicable	Alternatives to SFPs are available for water repellence	No specific analysis provided in the Background Document on manufacture of SFPs. Socio-economic impacts for the variety of applications of SFPs are described by sector.	This is considered by RAC as intermediate use. Emissions are minimised by means other than a	SEAC notes that RAC supports a derogation as emissions are minimised by means other than a restriction. SEAC concludes that	Derogations or longer transition periods are proposed for specific sectors of application of SFPs (e.g. textiles etc.).

[39] The costs' assessment reported does not include information on the number of products or individuals affected, as this is not available in the restriction dossier. However, SEAC notes that this important aspect of the socio-economic analysis is missing.
[40] For a more detailed discussion on derogations, please see Background Document Annex E.6.

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
				restriction (e.g. through site-/use-specific RMMs).	restricting this use is likely not proportionate.	A derogation is also proposed for transported isolated intermediates.
Textiles	Consumer apparel (e.g. outdoor clothing)	Yes, available and feasible as regards water repellence No, not yet available, nor feasible as regards repellence against oil, dirt, bodily fluids, and liquid chemicals with low surface energy	Negligible substitution costs, possibly minor costs linked to changes in equipment. Limited functional losses expected, as clothing industry is already switching to fluorine-free alternatives.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates limited socio-economic impacts only. SEAC concludes that restricting this use is likely not disproportionate.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.
	Professional apparel (PPE)		Lack of repellence against oil, stain, bodily fluids, and liquid chemicals with low surface energy would result in functional losses probably leading to decreased safety and human health costs. Functional loss for PPEs against risks resulting in death and permanent health damage (cat. III) would result in higher human health costs.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socio-economic impacts (high human health costs). SEAC concludes that restricting the use in PPEs is likely not proportionate.	**Yes** SEAC finds that a derogation for PPEs against risk III categories a, c, d, e, f, h, l, and high-visibility clothing fulfilling the requirements of EN ISO 20471 Class 3 might be necessary. Furthermore, SEAC considers that PPEs and protective clothing designed for armed forces and in the maintenance of law and order or other emergency response workers should be treated similarly to the above-mentioned PPE categories.

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
	Home textiles	Yes, available and feasible as regards water repellence No, not yet available, nor feasible as regards repellence against oil, dirt, bodily fluids, and liquid chemicals with low surface energy	Lack of repellence against oil, dirt and decreased UV protection would result in functional losses probably leading to increased washing, reduced service life and durability of articles. No information on related costs is available to SEAC.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.
	Technical textiles/ Industrial fabrics[41]		Lack of repellence against oil, stain, bodily fluids, and liquid chemicals with low surface energy would result in functional losses. The consequent impacts vary from the specific applications: • Outdoor upholstery: reduced service life and durability. • Filtration and separation (see separate entry) • Medical textiles (see separate entry) • Textiles in engine bays: possible negative impacts on potentially life-saving functions. No information on related costs is available to SEAC.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible. For textiles used in engine bays, some more information was provided. SEAC is unable to conclude firmly, but considers it is possible that restricting this specific use may not be proportionate.	**General: No** SEAC finds that sufficient information to demonstrate the necessity of an overall derogation for technical textiles was not provided. **Specific applications: Yes** Based on the information provided in the consultation on SEAC's draft opinion, SEAC considers that a derogation of textiles for the use in engine bays in transport and non-road mobile machinery is necessary. For medical textiles and filtration - see entries for medical devices and

[41] Technical textiles/industrial fabrics being mainly used in automotive and aerospace applications, as filtration media and in the construction sector.

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
						for filtration and separation media.
Firefighting foams	General	Alternatives are overall regarded as available and feasible for firefighting foams. However, for some applications, (time-limited) derogations are claimed to be required due to sector-/use-specific requirements and verification of	Some quantified cost information was overall provided by the DS as regards replacement costs, incineration costs, cleaning of equipment, etc. (see cost section). Substitution costs are not expected to be significant due to alternatives being overall available to similar prices. However, substitution related cost might be significant; the figures provided are too uncertain to conclude on any quantified/qualitative cost	*Municipal/mobile firefighting*: emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. SEAC concludes that restricting this use is likely not disproportionate.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.
	Production of mixtures for class B foams			Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socio-economic impacts. SEAC concludes that restricting this use is likely not proportionate at present[42].	**Yes** Based on the information provided, SEAC finds that a longer transition period of 5 years would likely be necessary to avoid disproportionate socio-economic impacts. A derogation for training and testing is considered warranted only if emissions are minimised and effluents are collected and disposed of safely.
	Certain defence applications			Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs (no specific	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.

[42] Where SEAC concludes that a restriction is likely not proportionate "**at present**", this indicates that it is considered that alternatives will become available in the timeframe indicated and a time-limited derogation is supported.

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
		performance levels of FFFs. These are reflected in the derogation section.	estimate. No cost estimates for specific applications discussed (e.g. defence applications, large tanks) are available.		information provided as regards costs for the defence sector). A conclusion on the proportionality of restricting this use is therefore not possible.	Furthermore, exemptions may be granted by national authorities.
	Large tanks (with a surface area > 400 m2 and the bunded areas they are in)			RAC cannot conclude without further information on the effectiveness of potential RMMs that a ban on the use of PFHxA, its salts and related substances is the most effective EU wide measure to reduce risks and cannot support a derogation[43].	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socio-economic impacts. SEAC concludes that restricting this use is likely not proportionate at present.	**Yes** Based on the information provided, SEAC finds that a longer transition period of 12 years would likely be necessary to avoid disproportionate socio-economic impacts. However, several uncertainties (related to size and time) still exist.
Paper and cardboard (food contact materials)	Not applicable	Yes, publicly available information indicates so. Some companies have fully substituted already.	Substitution costs estimated to be €1.45 bn/a (high costs linked to high used tonnages). Limited functional losses expected, as alternatives are available, industry is switching or has already switched to fluorine-free alternatives and no comments were received about functional losses during the consultation.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs and ongoing substitution activities indicate somewhat limited socio-economic impacts. SEAC	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.

[43] To be noted that RAC recommends waiting for the restriction proposal on PFASs in firefighting foams to obtain more specific information on the effectiveness of RMMs to minimise releases from this use, which would allow a more informed decision.

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
					concludes that restricting this use is likely not disproportionate.	
Mixtures for consumer use	Not applicable	Yes, publicly available information indicates so.	No qualitative or quantitative overall cost estimate is available. Substitution costs for manufacturers and consumers regarded as low, other substitution related costs are unknown.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs and ongoing substitution activities indicate somewhat limited socio-economic impacts. SEAC concludes that restricting this use is likely not disproportionate.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.
Printing inks	General	Only limited information available. Alternatives, however, regarded available as far as water-based printing inks are concerned. Comments provided indicating lack of alternatives are not substantiated by sufficient evidence	Overall, no information on substitution, substitution related costs or any other cost impact provided by the DS. For latex printing inks, SEAC notes the DS's conclusion that potentially high costs could be expected if no time-limited derogation would be implemented (e.g. through early replacement of printer hardware)	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.
	Latex printing inks	No simple "drop-in" substitution solutions available and feasible,		Emissions cannot be minimised by means other than a restriction, e.g. due	Whilst SEAC notes a lack of information on the magnitude of emissions/emission	**Yes** Based on the information provided, SEAC finds that a

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
		substitution process regarded as complex.		to wide-dispersive uses.	reduction (benefits), information on restriction-related costs indicates potentially high socio-economic impacts. SEAC concludes that restricting this use is likely not proportionate at present.	longer transition period of 7 years would likely be necessary to avoid disproportionate socio-economic impacts.
Chrome plating	Decorative chrome plating/ plastic electroplating	Alternatives seem to be available for **decorative chrome plating and plastic electroplating** (voluntary substitution takes place already). Alternatives said to not having been sufficiently tested for **hard chrome plating;** currently, it is not expected that alternatives can provide the necessary functionalities.	Overall, no information on substitution, substitution related costs or any other cost impact is available.	RAC cannot conclude without further information on the effectiveness of potential RMMs that a ban on the use of PFHxA, its salts and related substances is the most effective EU wide measure to reduce risks and cannot support a derogation.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socio-economic impacts. SEAC concludes that restricting this use is likely not proportionate at present.	**No (no specific derogation if general TP is prolonged to 36 months; otherwise, a use-specific derogation might be needed)** SEAC does not agree with the DS that immediate transition to alternatives is possible. Whether or not a specific time-limited derogation is necessary depends on the general TP recommended (DS's proposal of 18 months being regarded as too short by SEAC).
	Hard chrome plating		Overall, no robust information on substitution, substitution related costs or any other cost impact is available. However, alternatives claimed to be costly.		Whilst SEAC a notes lack of information on the magnitude of emissions/emission reduction (benefits), information on	**Yes** Based on the information provided, SEAC finds that a longer transition period of 5 years would likely be necessary to avoid

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
					restriction-related costs indicates potentially high socio-economic impacts. SEAC concludes that restricting this use is likely not proportionate at present.	disproportionate socio-economic impacts.
Building materials/ construction products	Not applicable	Alternatives seem to be available and affordable (cheaper prices) as regards water repellence functionalities. This conclusion is, however, not valid for oil/dirt repellence properties. A wide variety of products is covered, discussion and decision on alternatives likely to be product-specific.	Overall, no robust information on substitution, substitution related costs or any other cost impact is available. Stakeholders claim that significant negative impacts are expected due to substitution (e.g. higher repairing intervals, increased paint waste from recoat preparation, etc.), their likelihood and magnitude being unknown.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.
Photographic applications	Photographic coating on film	Unclear: industry stakeholders reported that non-fluorinated alternatives are not available, but other sources (UNEP, 2018b) indicate differently.	Investment for switching to alternatives estimated to be €0.5 – 1 million for a single photographic material. Negative economic impacts expected in the short-term, transition to digital techniques in the long-term.	For all photo applications (no differentiation for sub-sectors made by RAC): emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socio-economic impacts, specifically if a respective transition time is not given. SEAC concludes that restricting this use is likely not proportionate at present.	**Yes** Based on the information provided, SEAC finds that a transition period of 5 years would likely be necessary to avoid disproportionate socio-economic impacts.
	Photographic coating in printing plates	Unclear: industry stakeholders reported that research on alternatives is on-going.	According to the DS, negative economic impacts expected in the short-term, transition to digital techniques in the long-term. No robust information			**Yes** Based on the information provided,

Sector	**Sub-sector**	**Alternatives available?**	**Costs[39]**	**RAC conclusion on uses, releases and emission minimisation**	**Proportionality**	**Derogation/ longer TP/ higher concentration limits[40] supported?**
			on socio-economic impacts provided in the consultation.			SEAC finds that a transition period of 5 years would likely be necessary to avoid disproportionate socio-economic impacts.
	Photographic coating on paper and coatings on inkjet photo media	Some alternatives seem to be available but provide lower quality.	Stakeholders reported possible costs in terms of premature replacement of printing equipment (in the range of millions of €) and functional losses resulting in defects and reduced quality of printing.		SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
Electronic devices	Semiconductors and semiconductor related equipment (considering also anti-adhesive coatings for semiconductor microelectromechanical systems (MEMS)	No drop-in alternatives are available and not providing the full range of desirable properties. Substitution is regarded as process-specific for these uses; partly high length of supply chains, high quality requirements, etc. (relevant mainly for semiconductors) make a quick transition difficult. Overall conclusion is not possible.	No quantified cost assessment provided; claims that substitution is costly; some indication on high societal impacts due to profit losses, closure of business, etc.; severe economic impacts also stressed by STOs in consultation.	Emissions are minimised by means other than a restriction (e.g. through site-/use-specific RMMs); derogation supported.	SEAC notes that RAC supports a derogation as emissions are minimised by other means than a restriction, and that information on restriction-related costs indicates potentially high socio-economic impacts. SEAC concludes that restricting this use is likely not proportionate at present.	**Yes** Based on the information provided, SEAC finds that a longer transition period would likely be necessary to avoid disproportionate socio-economic impacts. The exact timeframe needed could not be fully clarified due to the complexity of the sector/applications and the variety of applications. However, SEAC finds that the DS's proposal of 12 years seems most appropriate based on current knowledge Furthermore, alternative wording proposals have been provided by stakeholders during the consultation in order to ensure an appropriate coverage of products affected (for a detailed discussion, please see the explanatory note and Annex E.7 of the Background Document).

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
Cosmetic products	Not applicable	PFAS-free alternatives are said to be available for all cosmetic products. This is supported by the voluntary phase-out of companies.	Only negligible costs for manufacturers are expected, mainly due to reformulation. However, no qualitative or quantitative cost assessment provided by the DS. No substitution related costs (loss of functionalities) are expected. Certain degree of uncertainty on the affordability of reformulation costs for SMEs	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs and ongoing substitution activities indicate somewhat limited socio-economic impacts. SEAC concludes that restricting this use is likely proportionate.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.
Filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency for filters used in industrial settings or by professionals.	Not applicable	Very broad range of applications, touching several market sectors; conclusion on alternatives sector-/use-specific, overall conclusion difficult. Alternatives are not expected to provide both, water- and oil repellence properties and are said to be not available for specific uses, for which derogations were requested and are partly supported	Cost information is scarce, no such assessment provided by the Dossier submitter. Information provided by stakeholders indicate high costs related to substitution, e.g. through loss of effectiveness of products (some in safety-critical applications).	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**Yes** Based on the information provided SEAC finds a longer transition period would likely be necessary to avoid disproportionate socio-economic impacts. The exact timeframe is, however, uncertain.

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
Epilames used in watches	Not applicable	Based on the information provided by STOs, no alternatives are available for this specific use.	No specific cost information provided by the Dossier Submitter. STOs claim during consultation socio-economic impacts to be potentially high, e.g. significant impacts on employment are expected.	Emissions are minimised by means other than a restriction (e.g. through site-/use-specific RMMs); derogation supported.	SEAC notes that RAC supports a derogation as emissions are minimised by other means than a restriction, and that information on restriction-related costs indicates potentially high socio-economic impacts. SEAC concludes that restricting this use is likely not proportionate.	**Yes** Based on the information provided, SEAC finds that a longer transition period would likely be necessary to avoid disproportionate socio-economic impacts. The exact timeframe needed is, however, uncertain.
Medical devices, incl. medical textiles and *in vitro* diagnostics	Not applicable	Information on alternatives is scarce. The applications within this sector are numerous, some potentially even not known to SEAC; no explicit evaluation was provided by the DS. Some product-specific information was provided during the consultations, but cannot be used to extrapolate information to the overall sector, as discussed by the DS.	Dossier Submitter expects no costs to occur as a complete derogation is suggested. Cost information provided during the consultation was not assessed by the Dossier submitter. This information is specific to companies/ applications and does not allow SEAC to perform an overall sector-based cost assessment. The Dossier Submitter expects potentially high substitution related costs, however, it is totally unclear what these would be and for which products these would occur. These might relate to the risks of equipment failure, need of early replacement and other unwanted consequences (as products are often supplying	Wide dispersive professional uses, possible RMMs to prevent emissions. RAC does not support a general derogation but assessed specific uses and supports a derogation for implantable medical devices (permanent) and coating for hearing aid devices (10-year TP).	Based on the information provided in the restriction dossier and during consultation, SEAC cannot conclude on the proportionality of a restriction or a full derogation (as suggested by the Dossier Submitter). SEAC doubts that both, a full restriction and an overall derogation are proportionate; however, SEAC was neither provided with a complete picture of the applications and products affected, nor with information on potential alternatives, emissions and costs for specific	**Yes** SEAC supports a full derogation due to potentially high HH and socio-economic impacts recognising the complexity of the sector. However, SEAC notes that this might not be justified for all articles covered, based on socio-economic considerations. More information needs to be gathered e.g. through reporting, in order to reassess the need for this derogation and to be able to draw more product-/use specific conclusions.

Sector	Sub-sector	Alternatives available?	Costs[39]	RAC conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits[40] supported?
			HH- and life-protecting functions).		products/sectors affected.	
Optical fibres	Not applicable	Alternatives are claimed to be currently not feasible by STOs; no evaluation by the DS available to SEAC.	No information on substitution or any other/related costs (potential HH impacts due to traffic accidents or shorter service life of vehicles) are available.	RAC cannot conclude without further information on the effectiveness of potential RMMs that a ban on the use of PFHxA, its salts and related substances is the most effective EU wide measure to reduce risks and cannot support a derogation.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.
Electrical and electronic devices	Flat panel displays	Alternatives are claimed to be currently not feasible by STOs; no evaluation by the DS available to SEAC	No information on substitution or any other/related costs (potential impacts on reduced quality of equipment used in e.g. automobiles, aircraft, and medical settings) is available to SEAC. However, SEAC notes that products are used in the everyday life of practically all EU citizens and the market for EEE products hold a considerable economic value. Furthermore, for some products (medical equipment, aircraft, etc.) also impacts in terms of health and safety could be expected. No evaluation by the DS has been performed.	Not available	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**Yes** Based on the information provided, SEAC finds that a longer transition period of 7 years would likely be necessary to avoid disproportionate socio-economic impacts.

Sector	**Sub-sector**	**Alternatives available?**	**Costs[39]**	**RAC conclusion on uses, releases and emission minimisation**	**Proportionality**	**Derogation/ longer TP/ higher concentration limits[40] supported?**
	Coatings		Only limited information on costs is available to SEAC, mainly provided by industry during the consultations (e.g. loss of profits, significant social cost of unemployment, etc.). No cost evaluation by the DS is available to SEAC.	Not available. RAC, however, did not support higher concentration limits for fluoropolymers used in coating of electronic devices.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**Yes** Based on the information provided, SEAC finds that a longer transition period of 7 years would likely be necessary to avoid disproportionate socio-economic impacts. However, SEAC notes the high uncertainties around emissions.
	Lubricants	Only very limited information was provided by stakeholders during the consultation.	Only very limited information was provided by stakeholders during the consultation.	Not available.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.
Other uses brought forward during the consultation, such as PTFE micro powders, glass protection, thermoplastic applications, etc.	Not applicable	STOs claimed that derogations are necessary due to no alternatives being available	Only very limited information provided on any potential substitution and/or substitution related costs	Not available	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	**No** SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.

Uncertainties in the proportionality section

SEAC's detailed discussion and conclusion on uncertainties is provided in the key elements section above as well as in the use-specific analysis presented inAnnex E.6 of the Background Document. A summary of the underlying uncertainties of this restriction proposal is given in the uncertainties section below.

4.3.3. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers the proposed restriction to be practical because it is affordable, implementable, enforceable and manageable.

A yearly reporting requirement has been proposed in Paragraph 10 for the derogated uses without a time-limit (Paragraph 9b-h) where the identity and quantity of PFHxA, its salts and related substances shall be reported by the natural or legal person placing an article in the EU-market. In addition, Paragraph 12 proposes that for the derogations related to firefighting foams (Paragraphs 6 and 8a), quantities used as well as the efforts of substitution from PFHxA, its salts and related substances shall be described, and the share of quantities used for operation and training and whether the emissions were contained, collected, and safely disposed of or emitted to the environment. The Dossier Submitter also proposes that the Commission after 6 years after entry into force of the restriction shall carry out a review of the derogations in paragraph 6 and paragraph 8(a), related to firefighting foams, in the light of new scientific information, including the availability of alternatives, and propose amendments if indicated by the outcome of the review. As long as the Commission concludes that there is still need for these derogations this review shall be carried out every three years (Paragraph 13). The reporting requirements will allow the European Commission to gather data on the use of the substances in these sectors and to monitor the development of alternatives. This proposed reporting requirement also aim to signal that substitution of PFHxA, its salts and related substances is desirable.

Regarding enforceability, the Dossier Submitter considers that enforcement authorities can set up efficient supervision mechanisms to monitor industry's compliance with the proposed restriction and that methods easily can be adapted from the methods to analyse PFOA and C9-C14 PFCAs. Given that such methods exist, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.

A joint approach for enforcement activities such as inspections and testing for the occurrence of already regulated PFASs (PFOS, PFOA, C9-C14 PFCAs and PFHxS, incl. their salts and related substances) at the same time would lower costs. Thereby, cost effectiveness is enhanced and enforcement costs for PFHxA, its salts and related substances are reduced. Regarding imported articles, border authorities can control compliance using the RAPEX system (Rapid Exchange of Information System) to report any violation of the restriction.

The Dossier Submitter acknowledges a lack of EU-standardised analytical methods for PFHxA, its salts and related substances but considers that the analytical methods (including a few standard methods) available for monitoring PFOA and C9-C14 PFCAs can be adapted to measure also PFHxA, its salts and related substances. A lack of an EU standard method for the substances in the scope of the restriction should not be considered a hindrance to the enforceability or monitorability of the restriction. Detection limits of the standards for PFCAs and PFSAs reach for water samples down to 0.0001 ppb. The Background Document highlights

the high variety and sometimes unknown identity of related substances as a challenge for the monitorability. The so called Total Oxidisable Precursor assay (TOP assay), oxidizing the PFHxA-related substances to the free PFHxA-acid that can then be measured, do not identify the related substances as such but detect their presence indirectly, and is hence useful for enforcement and monitorability. It is noted that the method has some uncertainties. Furthermore, the measurement of the related substances from products and articles is in general considered as a challenge by the Dossier Submitter despite of several methods available. A development of a CEN standard for measuring PFASs in textiles is ongoing.

The restriction proposal also covers recycled materials based on that recycling potentially leads to emissions. No stakeholder information has been received on the effects of the proposal to include a specific assessment for recycling. For background information, it is noted that the restriction opinions of PFOA, C9-C14 PFCAs and PFHxS also included recycling in the restriction. The Dossier Submitter further elaborates for paper recycling that with it might be argued that the vast majority of releases is emitted during the waste stage. Consequently, repeated service-life through recycling would not be a major source of additional emissions. The Dossier Submitter notes that he is not aware of information with regard to emissions of PFHxA, its salts and related substances from the process of wastepaper recycling (e.g. deinking, effluent, air emissions). However, emissions might be significant. Considering this risk, the Dossier Submitter proposes no derogation for recycling.

RAC and SEAC conclusion(s):

RAC considers the restriction of PFHxA, its salts and related substances feasible with respect to practicality and enforceability. The restriction follows the same approach as previous PFAS restrictions and the frameworks developed for enforcement of those can be applied also here.

SEAC agrees that the proposed restriction is in general practicable and enforceable. This is based on the information provided in the Background Document and Forum's advice. However, SEAC notes Forum's opinion that the restriction can be regarded as enforceable, as long as it is clear which substances are in the scope of the restriction and that reliable normative test methods are defined covering all types of regulated substances. SEAC agrees that these are relevant points to clarify to improve the enforceability.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC

RAC supports the proposal to include reporting requirements on the identity and quantities used of PFHxA, its salts and related substances for the time-unlimited derogations for articles (Paragraph 8) to allow ECHA and the Commission to collect information on the use of the substances. For articles, RAC acknowledges, however, that substance identity and exact quantities may be difficult to specify for downstream users placing an article on the market as this information may not be transferred within a supply-chain. RAC supports reporting requirements on quantities and efforts for substitution related to the derogations on firefighting foams, if these uses would be allowed by the Commission, including how the substances were used and if they were contained/emitted, as well as the proposed review by the Commission every 3 years on the need of these derogations.

For enforcement, frameworks have been developed in relation to previously regulated PFASs, i.e. PFOS, PFOA, C9-C14 PFCAs and PFHxS, incl. their salts and related substances. These frameworks can also be applied in this restriction. Enforcement activities involving inspections and testing of PFHxA, its salts and related substances in articles can be arranged to target the occurrence and share the costs of the other regulated PFASs at the same time. PFHxA is

one of several PFASs that are usually analysed for in standard PFAS analysis packages (up to 20-30 PFAS depending on the lab). The average cost in the EU for analysing one individual PFAS in a sample was estimated to approximately €169 and for a total of 32 PFASs in a water sample between €280 - 350, depending on the limit of quantification (ECHA, 2020). The sampling and sample preparation of PFHxA, its salts and related substances can also be performed together with other regulated PFASs. Thus, the enforcement costs specific to PFHxA its salts and related substances can therefore be considered small.

Analytical methods with low detection limits to analyse PFHxA and its salts (as free acid) are available today. RAC acknowledges that the proposed threshold of 25 ppb for the sum of PFHxA and its salts, the same threshold as for PFOA, C9-C14 PFCAs and PFHxS, is feasible for certain matrices (e.g. LOQ of 0.5 – 10 ppb for cosmetic products (ECHA, 2020)) but in the lower range of the possible limit of quantification of other (LOQ of ~ 20 - 50 ppb for textiles and firefighting foam (ECHA, 2020c)). In the consultation, a method (the FFFC/AXYS method) was reported that consistently and accurately can measure PFOS and PFOA in foam concentrates to a limit of 10 (ppb) is under validation for 29 PFASs, including 6:2 FTS and PFHxA (FFFC, 2019).

For analysis of PFHxA-related substances, RAC recognizes that measurements in products and articles can be challenging. Analytical standards are not available for all PFHxA-related substances and given the likely large number of such substances (at least 73 as specified in the Background Document), testing for all these is not practically possible. Analysis of PFHxA-related substances can be performed by the TOP assay followed by targeted PFHxA-analysis, i.e. the PFHxA-related substances are oxidised to the free PFHxA acid that is subsequently measured. Thus, no specific individual analytical standards for PFHxA-related substances are needed. Analytical uncertainties related to the TOP-assay would primarily lead to an underestimation of the true concentration of PFHxA-related substances in a sample (Robel et al. 2017) while the risk of false positives is considered to be very low. Analysis of "lead substances", e.g. 6:2 FTOH, as representatives for PFHxA-related substances, similar as proposed for PFOA (ECHA, 2015), is another option. The threshold of 1 000 ppb for the sum of PFHxA-related substances is in line with the threshold for PFOA-related substances and PFHxS-related substances and slightly higher than the threshold of 260 ppb for C9-C14 PFCA-related substances.

Since no EU-standardised analytical methods are yet available to analyse PFHxA, its salts and related substances, RAC strongly recommends the development of standardisation of such methods (analysis of PFHxA and TOP assay), including the extraction process, in line with the recommendations and activities for previously regulated PFASs. RAC takes note that a standardised method for analyses of PFASs, including PFHxA, its salts and related substances in textiles is under development by CEN (European Committee for Standardization) within the technical committee TC248/WG26, "EC restricted substances in textiles". RAC agrees with the Dossier Submitter that a lack of standard methods for the substances in the restriction should not be considered a hindrance to the enforceability or monitorability of the restriction as the situation mirrors the same circumstances as for the previously adopted PFAS restrictions.

No information regarding the practicality of including recycling in the scope of the restriction has been obtained from stakeholders during the process. RAC therefore interprets this as including recycling is manageable, in line with the previous restrictions on PFOA, C9-C14 PFCAs and PFHxS.

SEAC

Clarity of the scope

As regards the scope of the proposed restriction, Forum raises several aspects to be clarified in order to remove any potential uncertainties, e.g. on the **definition of the regulated substances in the entry** (using the same approach applied in the PFOA restriction), any **terminology issues** (first placing on the market vs. placing on the market and respective burden of proof (authorities vs. duty holders)), on **exemptions** (expressing a concern on the high number of derogations from an enforceability perspective), and on **identifying substances within the scope** of the restriction (suggesting a concrete list of substances to be added to the Annex XVII entry).

SEAC notes that the Forum considers that inspectors and also prosecutors dealing with sanctions would have difficulties to identify the substances covered by the restriction. While SEAC expects that industry actors may be more comfortable dealing with a chemistry-based definition, it considers that a list of the substances covered could facilitate operations at their end too, at least with regard to communication and with the smallest actors in mind. An indicative list of the substances covered by the restriction, including CAS numbers, was published on the ECHA website[44] to facilitate the consultation on the Annex XV report. SEAC considers that while it will not be possible to compile an exhaustive list, an indicative list that provides examples of substances covered by the restriction will still be useful. It is not expected that a lot of new substances covered by the definition would enter the market, since there are no natural sources of these substances, but they are always intentionally manufactured. Therefore, new substances would only emerge either as deliberate breach of law, or in imported articles or mixtures. In order for a list to be helpful, the existence and location of such a list should be clear to all parties.

Burden of proof for the second-hand market

According to the proposed restriction entry, the burden of proof on the date of first placing on the market would lie on enforcement authorities. The Forum emphasized in their advice that the burden of proof needs to be shifted on the duty holders. SEAC agrees that the market actor is better able to know and demonstrate that date than the enforcement authority.

Reporting requirements

For derogated uses, the reporting requirements have been justified in order to gain information on quantities used and any substitution and/or research and development activities, but also as a way to signal that substitution is desirable. SEAC regards that the restriction alone (along with all respective recent activities relating to PFASs) is a clear signal of desirable substitution, also regarding the applications suggested to be derogated at this point. Forum considered that developing a new reporting system is a complicated way to send signals that substitution is desirable.

[44] Annex to the information note: https://echa.europa.eu/documents/10162/7da473c1-7f27-df34-9e6a-46152ef10d4b

Due to the lack of alternatives and the shortage of information on the possible substitution timelines for some uses referred to in paragraph 9 of the entry proposal, it was not possible to set a specific transition period in those cases. SEAC considers that the transition periods should therefore be decided on at a later point in time with more information at hand. SEAC regards a reporting requirement in principle as a useful way to collect information necessary to that end. It is not clear though if the information requirements specified in paragraph 9 (information on the identities and volumes of substances used) are optimal for gathering information useful for such an evaluation, or whether information on the availability of alternatives and efforts made to substitute would need to be collected also, as is done in paragraph 11. However, SEAC assumes that the actors whom the requirement in paragraph 9 concerns may not possess such information. At the same time, RAC considers that reporting requirements are useful to collect information on the use of the substances. Therefore, it would also improve the data basis for the impact assessment.

SEAC notes that the reporting obligations would partly fall on small actors, including importers and distributors. Fulfilling the obligation requires specific technical information and know-how that the actors in question may not have. It is noted in the Background Document that a significant number of articles concerned may be imported into EU, and the exporters might not be prepared to deliver the required information; supply chains may be long and it may be difficult for the exporter to obtain complete information on quantities and identities of the relevant PFHxA-related substances. SEAC concludes that high efforts may be needed to comply with the obligation. As it is not clear how and when (if ever) the miscellaneous information derived from this exercise would be utilised, SEAC considers that it is not clear that the costs and benefits are well balanced. Any further information is given in the respective cost section.

A similar type of reporting requirement is included in the restriction proposal on intentionally added microplastics. SEAC expects that this enhances the practicality of the requirement as there is a precedent on how the collecting of information should be managed. Authorities and some industry actors will also already have experience in carrying out the necessary tasks.

In the consultations the challenges of the proposed requirements were highlighted by actors in the supply chains. Specifically the non-availability of the relevant information for actors at different levels of supply chains were highlighted:

- To *downstream users*, information on the presence of the substances is not available. There is currently no requirement to report the content of PFHxA, its salts or related substances to the recipients; the substances have not been identified as an SVHC substances or classified as hazardous substances. Some suppliers are not willing to give this information voluntarily, arguing that it is confidential business information. Even if they gave the information, investigating through all of the supply chain in case of complex articles would be difficult. Establishing contractual arrangements, claimed to be necessary to make exchange of information with suppliers outside of the EU work, was stated to be disproportionate at least in some uses where volumes are low. Analytical methods to measure the content of the concerned substances in different matrices are not widely available, and even where available, their costs would be very high considering that the concerned companies are often small (comments #822, 840, 907, 917, 918, 937 and others).
- *Upstream actors* then again do not have the information on the final use and are therefore not able to report the requested information; i.e. it was recommended that reporting should be done at the end-user level as supply chains are long and complex and manufacturers of PFHxA, its salts and related substances do neither have the

information on the final use, nor whether or not the end use benefits from a derogation (comments #868, 917 and others).

- Also, it was claimed that it is not clear which party in the supply chain should do the reporting, and this could bring about confusion and double counting of the volumes used. A clear guidance on what needs to be reported as well as who is obliged to report is requested by several stakeholders; additionally, the need for developing specific reporting templates is raised (comments #855, 873, 946, 947 and others).

SEAC finds that it might be the most practical to set a **communicating requirement** of the content of the substances in question on each actor in the supply chain and clarify that the reporting requirement is on the final downstream actor. That way the volumes used in the different applications along the supply chain could be made separate. Such a communication requirement could be comparable to the one proposed in paragraph 7 (the final part) in the entry text of the proposed restriction on intentionally added microplastics[45]. SEAC notes that the microplastics restriction did not include an obligation to report the exact identity of the substance but that there are ways of dealing with the confidentiality aspect, for example by using unique identifiers (similar to what is done in poison centre notifications). SEAC underlines that the costs of such measure have not been estimated. The committee expects that those could potentially be relatively low compared to other costs caused by the restriction, since the information should be already there (at the top and along the chain) and what is necessary is mostly calculation and paperwork. The costs of the communication requirement discussed in the microplastics restriction may also give some indication of the possible magnitude (please see p. 139-141 of the final opinion for the microplastics restriction). SEAC notes that it could be difficult for importers of articles to get the information on the presence of the substances since actors outside of the EU would not be bound by the communicating requirement (also highlighted in comment #914). SEAC notes that the availability of some products on the EU market might decline as a consequence.

Sampling and sampling preparation

Forum noted that some guidance on sampling methods is available, e.g. outlined in ISO 25101 and concludes that whilst sampling by inspectors should be feasible without relatively extensive training, some guidance may be required to avoid sample contamination. Furthermore, Forum stressed that proper sampling of some products being in the scope of the restriction might be challenging, e.g. the elastomers listed in paragraph 11 of the restriction proposal by the Dossier Submitter.

Analytical methods

The availability of testing methods in general is discussed under the paragraph on testing costs above. In short, methods for PFHxA itself are available, while testing for related substances requires adaptation of the existing methods, and may be difficult for side-chain fluorinated polymers and substances bound to matrices.

In their opinion, the Forum reiterates the need to develop standard methods for the analytical testing of the content of the substances covered by a proposed restriction. In the present case, so far, standard methods are only available for water matrices.

[45] At the time of writing, the European Commission had not yet made a decision on the microplastics restriction. More information on that restriction, including the final RAC and SEAC opinion, can be found here: https://echa.europa.eu/fi/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

The Forum also underlines that the methods to be developed should provide for possibilities to combine different related restrictions (PFOS, PFOA, C9-C14 PFCA, PFHxS, PFHxA) to avoid excessive budgetary burden for public authorities involved in the enforcement of these restrictions. SEAC fully agrees to this view.

SEAC notes that the Forum highlights that it remains unclear how the restriction of PFHxA related substances of higher molecular weight should be enforced. Problems relating to those PFHxA related substances which are polymers and substances bound to matrices (such as treated textile fibres) are underlined. Currently no analytical method is available. SEAC expects that the enactment of a restriction will give incentive to develop the required methods such that they will be available in due course.

SEAC further notes that the Forum considers that it should be specified that the limit value applies to the concentration expressed in "free PFHxA" or in "free PFHxA related substances", such that the counter ion would not need to be determined to be able to derive the concentration of the restricted substances. SEAC notes that the determination of the counter ion may be difficult to impossible and comes with a cost without a respective benefit, and therefore supports the Forum view.

SEAC highlights that successful implementation and enforcement of a restriction requires that suitable analytical methods are also available in practice to NEAs and industry actors. The Forum raised a similar issue in their advice, pointing out that the techniques need to be transferable to commercially or public laboratories when the restriction entries into force.

Forum's general remark

Forum stresses that in recent PFAS restriction proposals, it is common approach to refer to the existing restriction provisions on PFOS and PFOA in order to claim successful implementation of a PFAS restriction, especially in terms of enforceability and the availability of analytical methods. Forum notes that from the practical experience of an enforcement authority, this seriously has to be put in question especially with regard to applicable analytical methods addressing restricted compounds that are salts and compounds of PFHxA related substances.

Overall, SEAC can support the recommendations made by the Forum and agrees that solving the before mentioned aspects (any details can be found in the final Forum advice) would improve the enforceability of the proposed restriction.

4.3.4. Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers the proposed restriction to be monitorable and proposes a joint approach for different enforcement activities such as inspections and testing for the occurrence of several regulated PFASs as PFOS, PFOA, C9-C14 PFCAs and PFHxA, its salts and related substances at the same time, as it would lower costs.

Regarding imported articles, the Dossier Submitter considers that border authorities can control compliance using the RAPEX system (Rapid Exchange of Information System) to report any violation of the restriction. 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.

RAC and SEAC conclusion(s):

RAC agrees with the Dossier Submitter that the restriction is monitorable.

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

Key elements underpinning the RAC and SEAC conclusion(s):

Analytical methods with low detection limits applied to previously regulated PFASs can also be applied to analyse PFHxA, its salts and related substances. There is ongoing environmental monitoring and biomonitoring (e.g. HBM4EU) that can be used for the purpose of monitoring the effects of the restriction. Due to the extreme persistence of PFHxA, and the formation of PFHxA from PFHxA-related substances, decreasing levels may, however, take a long time to detect in some matrices. The threshold of 25 ppb for PFHxA in serum/blood/tissues and in abiotic matrices in various monitoring programmes, appear to be feasible (Table 8 (ECHA, 2020)).

Table 8. LOQs for PFHxA in different matrices (adapted from ECHA, 2020)

Matrix	LOQ (range: minimum stated value – maximum stated value)	Comment
Aqueous matrices	~ 0.1 - 10 ng/L (0.0001 – 0.01 ppb)	Differences between clean water and wastewater
Sediment/Soil	~50 - 200 ng/kg (0.05 – 0.2 ppb)	
Plasma/Serum/Blood	~50 - 500 ng/L (0.05 – 0.5 ppb)	
Dust	~ 5 - 10 µg/kg (5 – 10 ppb)	
Biota/Food	~2 - 200 ng/kg (0.002 – 0.2 ppb)	

SEAC agrees that as regards contents in articles, monitoring of the proposed restriction can be conducted through regular enforcement activities. The necessary analytical methods exist for PFHxA and its salts and can be adapted to cover related substances, whilst the situation with polymers and substances bound to matrices may be more challenging. Monitoring of notifications gathered via Safety Gate (earlier: Rapid Exchange of Information System, RAPEX) appears to be a useful complementary approach.

Time trend monitoring could 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. Long range transport, and persistence of the chemicals restricted would however complicate such monitoring. Monitoring based on verification of emission reductions should also be considered.

4.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

4.4.1. RAC

Summary of the Dossier Submitter's proposal:

Related to the overall **scope** of the restriction, two uncertainties are highlighted related to the indicative list of substances, (a) the list of related substances may be wider, and (b), it is not certain whether the consultation on the Annex XV report has reached all relevant industries and hence it may be that some uses have not been addressed by the proposal.

The uncertainties in relation to **the hazard and risk** have been elaborated in more detail in

the Background Document sections 1.3.4, 1.3.5 and 1.3.7. These include uncertainties in relation to bioaccumulation potential, fate and prediction of future exposures and future effects. The Dossier Submitter concludes that, i.e., due to these uncertainties the non-threshold approach for qualifying the risks (releases and exposure as a proxy of risk) and the release minimisation approach for risk management have been followed in the proposal. In brief, the selection of the approach addresses the uncertainties related to fate, effects and future exposures. Consequently, uncertainties in the assessment of the presence of risk are mainly related to the uncertainties in estimation of releases and exposures, see below.

The Dossier Submitter considers the evidence of releases and risk to be clear and substantial based on the presented broad set of **measured exposure data** from the environment, general population and some point sources (e.g. Annexes B.4.2.4 and B.9.18). There is depending on the sample type, region and compartment a large variation in the concentrations measured and the mass estimates use maximum measured values. The current pollution stock in the European coastal waters and receiving marine water bodies has been estimated based on the measured data in Annex B.9.18. RAC considers the current pollution stock to be overestimated, which is based on the Dossiers Submitters assumption that PFHxA is evenly distributed in the water column. Monitoring data have shown vertical gradients for PFASs (including PFHxA) in the water column with the highest concentrations in surface water decreasing with increasing depth (Yeung et al., 2017; Gonzales-Gaya et al., 2019). However, it is certain that PFHxA is ubiquitously present in the European environment and general population.

In relation to the estimation of the **degradation/transformation** of related substances into PFHxA, a simplified approach has been taken in the Background Document (see section 1.3.6 and Annex B.4.1.2). The Dossier Submitter notes that the approach introduces an uncertainty into the estimation of releases expressed as PFHxA but on the other hand that other approaches considered would encompass even higher uncertainties and would be more elaborate. The fact that PFHxA is formed is, however, certain from the experimental and modelling data. A very similar approach has been taken in the previous PFAS restrictions.

The Background Document (section 3) highlights specific information gaps in **use volumes** of PFHxA, its salts and related substances. The gaps are especially large for imports and exports and it is thus not possible to derive exact quantities of the substances in articles in the EU. Correspondingly, the releases have in the Background Document been estimated very roughly. The Dossier Submitter concludes in section 1.2 that despite of these uncertainties it is possible to state that paper and cardboard (food contact materials) is the largest use sector, followed by textiles.

As explained in the Background Document Annex B.9.2 on the general assumptions of the **release assessment**, the releases have been estimated either by using default ERCs or, in few cases, with SPERC. It is noted that the use of ERCs generally deploy default release factors and distribution between release routes. They are conservative (provide worst case estimations) and should only be used where no sector specific data for release estimation is available. The Dossier Submitter has not received specific release data for most sectors despite of several consultations carried out by the Dossier Submitter at the preparatory stage and the consultation on the Annex XV report. The use of default release factors is noted as a source of uncertainty.

As noted in section 2.4 of the Background Document, the consideration of the various **restriction scenarios** was complicated by the large uncertainties with regard to specific uses within larger fields of use, use quantities, release quantities, availability and applicability of alternatives and affordability of alternatives.

The Dossier Submitter mentions in section 2.5.3 that it can be questioned whether emission reduction is an adequate proxy of risk reduction (**effectiveness**) when substitutes are SVHCs or otherwise of substantial concern. The risk profile of potential alternatives sometimes is poorly understood or unknown for PFHxA substitutes. Often it is not known which of the potential alternatives will be used in case of a restriction. Therefore, it is not possible to predict where regrettable substitution will happen. It is apparent that the uncertainties related to effectiveness are also closely related to the uncertainties in release estimations (see above).

The Background Document also concludes that most of the information received during the stakeholder consultation during the Annex XV dossier preparation, consultation on the Annex XV report and publicly available information is highly aggregated. While the collected facts sufficiently demonstrate, according to the Background Document, that a general ban would not be proportionate, it has been for the Dossier Submitter difficult to determine, based on the consultation comments, which **derogations** would be justified.

RAC conclusion(s):

RAC agrees with the Dossier Submitter that there are uncertainties in the information provided in the Background Document. The uncertainties are primarily related to uses, use volumes, emissions, and the impact of the proposed restriction (i.e. effectiveness). However, RAC is of the opinion that the uncertainties do not change the overall conclusion that there is a risk from PFHxA, its salts and related substances that is not adequately controlled.

Key elements underpinning the RAC conclusion(s):

The main uncertainties in the restriction proposal are related to the use volumes and associated emissions of PFHxA, its salts and related substances as well as the proposed impact (Effectiveness) of the restriction.

The RAC evaluation of emissions pointed out **significant limitations and uncertainties in the Dossier Submitter's assessment of uses and associated releases.** Therefore, RAC adopted a qualitative approach, rather than a quantitative, to evaluate the emissions. **Nevertheless, RAC considers the information on emission as whole to point towards substantial releases of PFHxA, its salts and related substances, further supported by measured environmental concentrations and by modelling.**

A cross-check of the release estimates can be carried out by using the current pollution stock in European coastal waters and receiving marine water bodies (section B.9.18). It has been calculated by the Dossier Submitter based on measured concentrations and using default region and water body sizes. The total aquatic pollution stock of PFHxA would be 17 357 tons (German Bights 7 t, European coastal surface waters 144 t, North Atlantic Ocean 16 500 t, Mediterranean 700 t and Baltic Sea 6 t of PFHxA). If assumed that this stock has been accumulating over the last 20 years in equal amounts, it would imply a release (and formation of PFHxA from release of related substances) of 868 t PFHxA/a. RAC notes that also this point of reference encompasses some uncertainties (e.g., the choice of the measured data for the mass calculations, development of the market and releases during the past 20 years, the stock in surface waters, soil and groundwater, and long-range transport not considered, assumptions on the sizes of the water bodies). However, the result is within the overall release estimates of 113 – 1200 t PFHxA/year by the Dossier Submitter.

Related to uses, RAC agrees that the **indicative list may not fully cover all substances that are part of the restriction**. There is therefore a risk that not all relevant industries may have been reached and that not all uses may have been covered. RAC notes, however, that information on many new uses and associated derogation requests have been received

in the consultation on the Annex XV report, which to some extent decrease this concern.

RAC acknowledge that there is a risk to be addressed with PFHxA, its salts and related substances due to primarily the persistence of PFHxA in combination with its mobility in the environment. The persistence will lead to an ever-increasing environmental stock of PFHxA, and, subsequently, increasing environmental and human exposure. At one point, exposure levels causing adverse effects may be reached if the uses of PFHxA, its salts and related substances are not restricted. However, it is not certain at what time point in the future this may occur. In addition, any estimations are based on the current available data, and yet unknown more sensitive endpoints may exist. The uncertainties related to the **effectiveness of the restriction** are related to the methodology and assumptions used by the Dossier Submitter to derive the estimated emissions reductions under the conditions of the restriction. These calculations (including underlying assumptions) are not sufficiently described in the Background Document and have not been possible to validate by RAC. However, RAC considers the estimations to be reasonable (to some extent based on clarifications via personal contact with the Dossier Submitter). The measured exposure data are due to the challenges of **analytical methods** still mainly available on PFHxA as most of the related substances cannot be either identified at all or quantified (see "Monitorability"). Therefore, the measured current exposures and the estimated current pollution stock based on measured data can be considered as clear underestimates of the **future exposures** of PFHxA even though all releases of PFHxA, its salts and related substances would be ceased today. This is because the releases mainly take place and can be assumed to have taken place in the near past as related substances and hence have not been caught by measurements. The exposures of PFHxA will increase even in case of immediate, complete ban due to the formation of PFHxA over time from related substances which already can confidently be assumed to be present in the environment, as most of the uses and releases take place in form of related substances.

Uncertainties related to the monitorability by measured data: although it is possible to monitor time trends of environmental and human exposures of PFHxA and some related substances as such, RAC notes that monitoring of the implementation of the restriction by measured data encompasses some uncertainties due to the transformation of the various related substances over long time periods into PFHxA. PFHxA may not be the most suitable indicator to measure for that purpose. The least uncertainty in the monitoring of the implementation might be achieved by selecting such related substances which are most representative of the actual releases and choosing the suitable sample types for those representatives.

4.4.2. SEAC

Summary of proposal:

The Dossier Submitter considers that the main uncertainties in the analysis are due to knowledge gaps regarding the tonnages of PFHxA, its salts and related substances affected by the proposed restriction and where relevant, the availability and or functionality of alternatives.

Knowledge gaps are especially large with regard to the impact of this restriction proposal on imports and exports. On the basis of available statistical data (from EU and OECD) it is not possible to derive quantities of imports and exports for articles that contain PFHxA, its salts or related substances. Product groups are often broad and do not differentiate between fluorine-free and fluorinated articles. Additionally, the Dossier Submitter lacks information on the nature of international commodity chains. Therefore, no information is available on whether exported /imported articles are further processed and then imported /exported

again.

Regarding cost data, the Dossier Submitter emphasises large uncertainties regarding the uses for firefighting foams, photographic applications, printing inks and chrome plating. Additionally, for many uses costs have been identified which the Dossier Submitter has not been able to quantify due to lack of data, or considers it is not possible for them to quantify (loss of functionality).

The Dossier Submitter also identifies large uncertainties regarding the potential benefits of the restriction.

SEAC conclusion(s):

SEAC's conclusion on uncertainty aspects of the assessment and the corresponding justification is given in the respective sections of this opinion and its Annex. In summary, SEAC notes the following:

- **Scope:** SEAC notes that the scope of the proposed restriction is extremely broad both in terms of substances and uses. Numerous sectors are affected and within these sectors, PFHxA, its salts and related substances fulfil specific functionalities in several different uses and products. These specific functionalities have different importance as regards any related impacts. In SEAC's view, this impacted the quality of the sectoral analysis by the Dossier Submitter, which makes a robust evaluation of the costs, benefits and the proportionality of the overall restriction and any respective derogations very difficult and uncertain; specifically, in the absence of concrete and robust information.
- **Availability of data:** SEAC notes that for most sectors and uses affected by the restriction the availability of robust and representative data is limited. Even though numerous stakeholders provided information during the consultation on the Annex XV report, this information is often product-/use- and/or company-specific and does not allow SEAC to extrapolate it for the assessment of an overall sector; specifically as the assessment of this information done by the Dossier Submitter is somewhat limited.
- **Costs** of the proposed restriction: SEAC notes that the Dossier Submitter changed their approach during the opinion making process of SEAC from a partly quantitative to an overall qualitative cost assessment. This is mainly due to lack of robust input data. An overall qualitative cost assessment approach makes it difficult for SEAC to compare costs to the potential benefits of a restriction, specifically if any respective benefits information is scarce and uncertain as well (see bullet point below). SEAC notes that overall, the qualitative cost assessment is surrounded by numerous uncertainties, specifically as substitution-related costs (their likelihood, magnitude) are concerned.
- **Benefits** of the proposed restriction: the Dossier Submitter initially followed the agreed approach for assessing the benefits of a restriction for PBT-like substances, i.e. emissions serving as a proxy for risk. SEAC notes RAC's conclusion that the emission estimates are uncertain and could be over- or underestimations. Furthermore, SEAC notes that overall, RAC was not able to verify the Dossier Submitter's emission calculations, which resulted in only general qualitative conclusions of RAC (no figures provided, not even ranges).
- **Proportionality** of the proposed restriction: SEAC notes that due to the above stated data gaps and uncertainties, an evaluation and conclusion on whether or not the restriction is overall proportionate is not possible based on socio-economic considerations. SEAC approached its evaluation and conclusion therefore differently,

as pointed out in the proportionality section above. Even though any such alternative approach does not allow SEAC to draw an overall conclusion on scientific grounds, it at least allows a sector-based discussion of relevant factors surrounding the proportionality issue.

- **Enforceability, practicality** and **monitorability** aspects: uncertainties raised by the Forum relate to the definition of the regulated substances in the entry, some terminology issues, an identification of the substances within the scope of the restriction (suggesting a concrete list of substances covered), analytical methods being available and standardised for all substances covered and specifically the numerous derogations suggested (specifically where definitions of the exempted uses/user group are not given, e.g. for medical devices, concrete products being affected therefore uncertain).

Key elements underpinning the SEAC conclusion(s):

Further information on SEAC's justification is provided in the respective sections as well as the Annex E.6 and E.7 of the Background Document (containing SEACs evaluation).

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Appendix A Changes to the proposed restriction

The table below reports parts of the proposal where changes were introduced and compares the initial and final proposal by the Dossier Submitter, by RAC, and by SEAC. To facilitate the comparison, changes compared to the initial proposal by the Dossier Submitter are in italics.

Topic	Initial DS proposal (AXV report)	Final DS proposal (BD)	RAC proposal	SEAC proposal
General transition period	18 months	18 months	18 months	*36 months*
Derogation for photographic applications	Photographic coatings applied to films (5 years)	Photographic coatings applied to films, *papers, printing plates and inkjet photo media coatings* (5 years)	No derogation proposed	Photographic coatings applied to films *and in printing plates* (5 years)
Derogation for fire-fighting foams	Concentrated fire-fighting foam mixtures placed on the market before [date –18 months after entry into force] and used or to be used in the production of other fire-fighting foam mixtures this shall not apply to use of fire-fighting foam for training and for testing unless all releases are contained.	Concentrated fire-fighting foam mixtures placed on the market before [date –18 months after entry into force] and used or to be used in the production of other fire-fighting foam mixtures *for cases of class B fires* this shall not apply to use of fire-fighting foam for training; and use of fire-fighting for testing unless all emissions to the environment are minimised and effluents collected are safely disposed of	No derogation proposed	Concentrated fire-fighting foam mixtures that are used or are to be used in the production of other fire-fighting foam mixtures *for cases of class B fires* this shall not apply to use of fire-fighting foam for training; and use of fire-fighting for testing unless all emissions to the environment are minimised and effluents collected are safely disposed of
Derogation for fire-fighting foams: defence applications	Derogation for seagoing units, air traffic facilities and storage of fuel, for training if emissions in enclosed areas - until substitution is feasible	Derogation for seagoing units, air traffic facilities and storage of fuel, for training if emissions in enclosed areas - until substitution is feasible	No derogation proposed	No derogation proposed
Derogation for fire-fighting foams: tanks	Derogation for class B fires in storage tanks with a surface area above 500 m^2 (12 years)	Derogation for class B fires in *tanks* with a surface area above 500 m^2 (12 years)	Significant uncertainties on minimisation of emissions, uncertain if derogation justified	Derogation for class B fires in *tanks* with a surface area above *400 m^2 and the bunded areas they are in* (12 years)
Derogation for semiconductors	Derogation for photolithography or etch processes in semiconductor industry (7 years)	*semiconductors and semiconductor related equipment (12 years)*	*semiconductors and semiconductor related equipment (12 years)*	*semiconductors and semiconductor related equipment (12 years)*

Topic	Initial DS proposal (AXV report)	Final DS proposal (BD)	RAC proposal	SEAC proposal
Derogation for PPE	PPE against risk categories III (a), (c), (d), (e), (f) and impregnation agents for these articles	PPE against risk categories III (a), (c), (d), (e), (f), *(g), (h), (l)*	No derogation proposed	PPE against risk categories III (a), (c), (d), (e), (f), *(g), (h), (l)*
Derogation for PPE for armed forces	No derogation proposed	No derogation proposed	No derogation proposed	*PPE specifically designed for armed forces and in the maintenance of law and order against the risk categories listed above and protective clothing specifically designed for armed forces and in the maintenance of law and order or other emergency response workers;*
Derogation for protective clothing	No derogation proposed	*High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3*	No derogation proposed	*High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3*
Derogation for medical applications	Non-woven medical textiles	*Medical devices as specified in Regulation 2017/745*	*Coating for hearing aid devices (10 years); implantable medical devices*	*Medical devices as specified in Regulation 2017/745; woven, knitted and nonwoven medical textiles as specified in Regulation 2017/745 with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795; in vitro diagnostic medical devices as specified in Regulation 2017/746 as well as parts thereof*
Derogation for filtration and separation media	No derogation proposed	*Filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency*	No derogation proposed	*Filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency for filters used in industrial settings or by professionals.*
Derogation for watches	No derogation proposed	*Epilames used in watches*	*Epilames used in watches*	*Epilames used in watches*
Derogation for textiles in engine bays	No derogation proposed	*Textiles for the use in engine bays in the following usage groups: automotive and aerospace industry*	*No derogation proposed*	*Textiles for the use in engine bays in the following usage groups: transport and non-road mobile*

Topic	Initial DS proposal (AXV report)	Final DS proposal (BD)	RAC proposal	SEAC proposal
				machinery;
Derogation for fluoropolymers, including fluoroelastomers	Concentration limit of 150 ppm for the sum of PFHxA and its salts in fluoroelastomers used in automotive and aerospace industry	*Concentration limits* *Fluoropolymers in general:* *2 000 ppb for the sum of PFHxA and its salts in fluoropolymers* *100 ppm for the sum of PFHxA related low molecular substances in fluoropolymers* *Fluoropolymers used in engine parts in automotive, aerospace and shipping industry:* *150 ppm for the sum of PFHxA and its salts in fluoropolymers* *2500 ppm for the sum of PFHxA related low molecular substances in fluoropolymers* *Fluoropolymers used in the coating of electronic devices (7 years):* *10 ppm for the sum of PFHxA and its salts in fluoropolymers* *500 ppm for the sum of PFHxA related substances in fluoropolymers*	*No derogation proposed*	*Concentration limits proposed for fluoropolymers considered not sufficiently justified by Dossier Submitter nor industry. The concentration limits have therefore been left open in the SEAC proposal. In the SEAC draft opinion consultation, it was confirmed that the coating of electronic devices relates to side-chain fluorinated polymers and not to fluoropolymers. See the separate derogation proposed for that use in the following row.*
Derogation for coating of electronic devices	No derogation proposed	*Covered in fluoropolymer derogation above*	*No derogation proposed*	*Functional coatings used in electrical and electronic equipment (7 years)*
Derogation for flat panel displays	No derogation proposed	*No specific derogation proposed but the use was said to be believed to be covered by the proposed derogation for semiconductor manufacturing and related equipment*	*No derogation proposed*	*Flat panel displays used in electrical and electronic equipment (7 years)*
Reporting requirements for non-time limited derogations	Who: natural or legal person placing an article on the market for the first time and benefiting from derogation To whom: reporting to Member States competent authorities, which will forward data to COM by 31	Who: natural or legal person placing *a mixture or* an article on the market for the first time and benefiting from derogation To whom: *reporting to ECHA*, which will forward data to COM by 31	Who: natural or legal person placing *a mixture or* an article on the market for the first time and benefiting from derogation To whom: *reporting to ECHA*, which will forward data to COM by 31	Who: natural or legal person placing *a mixture or* an article on the market for the first time and benefiting from derogation To whom: *reporting to ECHA*, which will forward data to COM by 31

Topic	Initial DS proposal (AXV report)	Final DS proposal (BD)	RAC proposal	SEAC proposal
	March What: identity of substance used in previous year; quantity of PFHxA, its salts and PFHxA-related substances used in previous year When: by 31 January each year Start of reporting: entry into force + 12 months	March What: identity of substance used in previous year; quantity of PFHxA, its salts and PFHxA-related substances used in previous year When: by 31 January each year Start of reporting: entry into force + 12 months	March What: identity of substance used in previous year; quantity of PFHxA, its salts and PFHxA-related substances used in previous year When: by 31 January each year Start of reporting: entry into force + 12 months	March What: identity of substance used in previous year; quantity of PFHxA, its salts and PFHxA-related substances used in previous year When: by 31 January each year Start of reporting: entry into force + *36 months*
Reporting requirements for fire-fighting foams	Who: natural or legal person benefiting from derogation To whom: reporting to Member States competent authorities, which will forward data to COM by 31 March What: substitution efforts; quantity of PFHxA, its salts and PFHxA-related substances used in previous year, info on use for training and whether emissions collected and disposed of safely When: by 31 January each year Start of reporting: entry into force + 12 months	Who: natural or legal person benefiting from derogation To whom: *reporting to ECHA*, which will forward data to COM by 31 March What: substitution efforts; quantity of PFHxA, its salts and PFHxA-related substances used in previous year, info on use for training and whether emissions collected and disposed of safely When: by 31 January each year Start of reporting: entry into force + 12 months	*No reporting requirements proposed as RAC did not propose derogations for fire-fighting foams.*	Who: natural or legal person benefiting from derogation To whom: *reporting to ECHA*, which will forward data to COM by 31 March What: substitution efforts; quantity of PFHxA, its salts and PFHxA-related substances used in previous year, info on use for training and whether emissions collected and disposed of safely When: by 31 January each year Start of reporting: entry into force + *36 months*
Review clause	Review clause (6 years after entry into force) for derogation proposed for fire-fighting foams in defence applications	Review clause (6 years after entry into force) for derogation proposed for fire-fighting foams in defence applications *and for class B fires in tanks. Then, review every 3 years, as long as there are derogations.*	*No review clause proposed as RAC did not propose derogations for fire-fighting foams.*	*No review clause proposed but highlights large uncertainties associated with the restriction proposal and with derogations for fire-fighting foams, and for non-time limited derogations (PPE, high visibility clothing, epilame in watches, medical devices, filtration and separation).*