EUROPEAN CHEMICALS AGENCY

Committee for Risk Assessment (RAC)

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

Adopted

3 June 2021

3 June 2021

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

[Date]

[SEAC opinion number]

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 opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document supports the RAC and SEAC opinions, and their justifications, gives the details of the Dossier Submitter's 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**.

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FIGURES

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}-.	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.
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.	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 • 2000 ppb for the sum of PFHxA and its salts in fluoropolymers; • 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. • 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]. • 100 ppm for the sum of PFHxA related low molecular substances in fluoropolymers. • 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. • 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: (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 (from the Dossier Submitter):

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 C_6F_{13}- 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:

Fire-fighting foam:
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 E.2.3.4 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 fire-fighting foams. Due to some exceptionally high risks of defence-specific fire-scenarios (e.g. fire-fighting 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 report. The restriction for 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 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.

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.

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). (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 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 [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-SFP), 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 separates 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 PFAS 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 risk management measures to minimise releases of PFHxA, its salts to related substances. Whilst 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).

1.2. THE OPINION OF SEAC

See SEAC opinion.

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 concluded 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-chain 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 concluded 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.

However as this is not achievable based on the current level of information, **RAC supports the proposed restriction for uses[1] where it is not possible to implement risk management measures to minimise emissions**, especially wide-dispersive consumer uses in food contact materials and textiles as well as in fire-fighting foams used for municipal fire-fighting. 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[2] 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. RAC does not support the justification for most of the derogations proposed by the Dossier Submitter as there was insufficient information available to conclude that releases from the uses were minimised. However, in the event that a restriction would be proposed, **RAC**

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[1] 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.

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

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), 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 all of 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 has been justified.

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

3.1.1. 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 perfluoroalkylated substance (PFAS) 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[3]. 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.

PFAS 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.

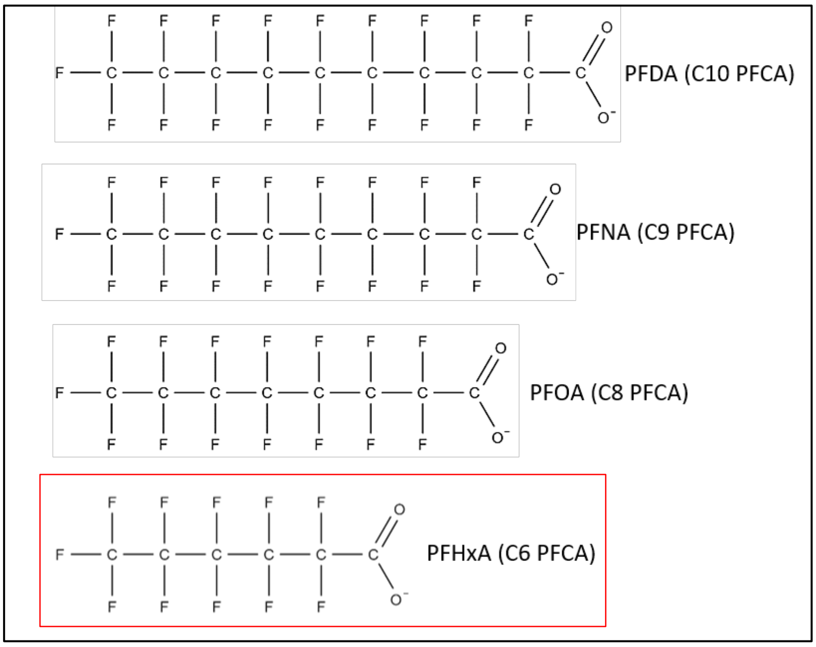

Figure 1. Structural relationship of perfluorohexanoic acid (PFHxA) to the other perfluorinated carboxylic

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

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.

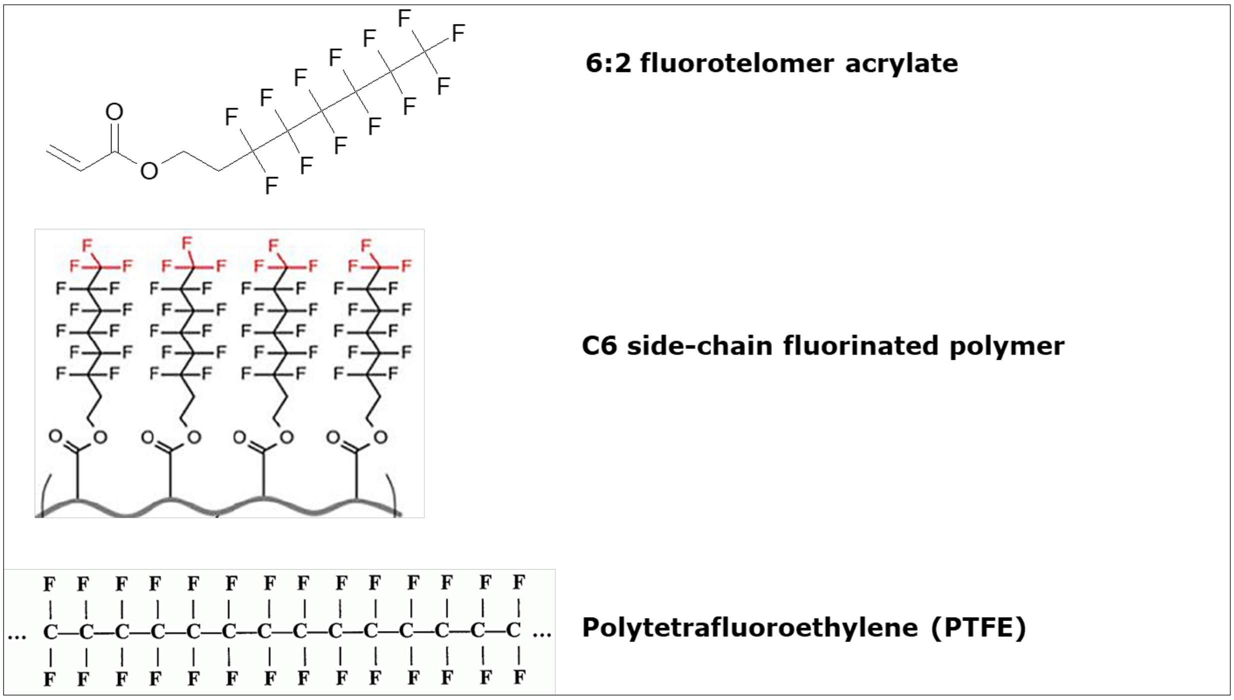

Figure 2. Examples of PFHxA-related substance: 6:2-fluorotelomer acrylate, a C6 side-chain fluorinated polymer (C6-SFP), i.e. a polymer with a side-chain containing 6 perfluorinated carbons that can degrade to PFHxA. Polytetrafluoroethylene, on the other hand, cannot degrade to PFHxA and is therefore 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 REACH[4], 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 assessment.

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[4] 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.

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 definitions included in the scope include substances that can degrade to PFHxA and exclude substances that are considered not to degrade to PFHxA (e.g. a fully fluorinated C6 carbon chain) as well as PFAS covered by previous restrictions e.g. PFOA and PFHxS (incl. their salts and related substances).

Key elements underpinning the RAC conclusion:

The substances within the 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.

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

3.1.3. 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 PFAS, 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 PFAS (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 PFAS. 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[5], 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

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)

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[5] 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.

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 m^3/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 PFAS, 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 m^3/mol is obtained. RAC notes that the HLC is far below the trigger of >250 Pa m^3/mol, which is given in REACH guidance R.16 for volatile substances, and even far below the 1 to 10 Pa m^3/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 m^3/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 PFAS 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.

3.1.4. 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 PFAS 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**: PFAS, 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.
- PFAS 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 (polytetraflouroethylene) 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.

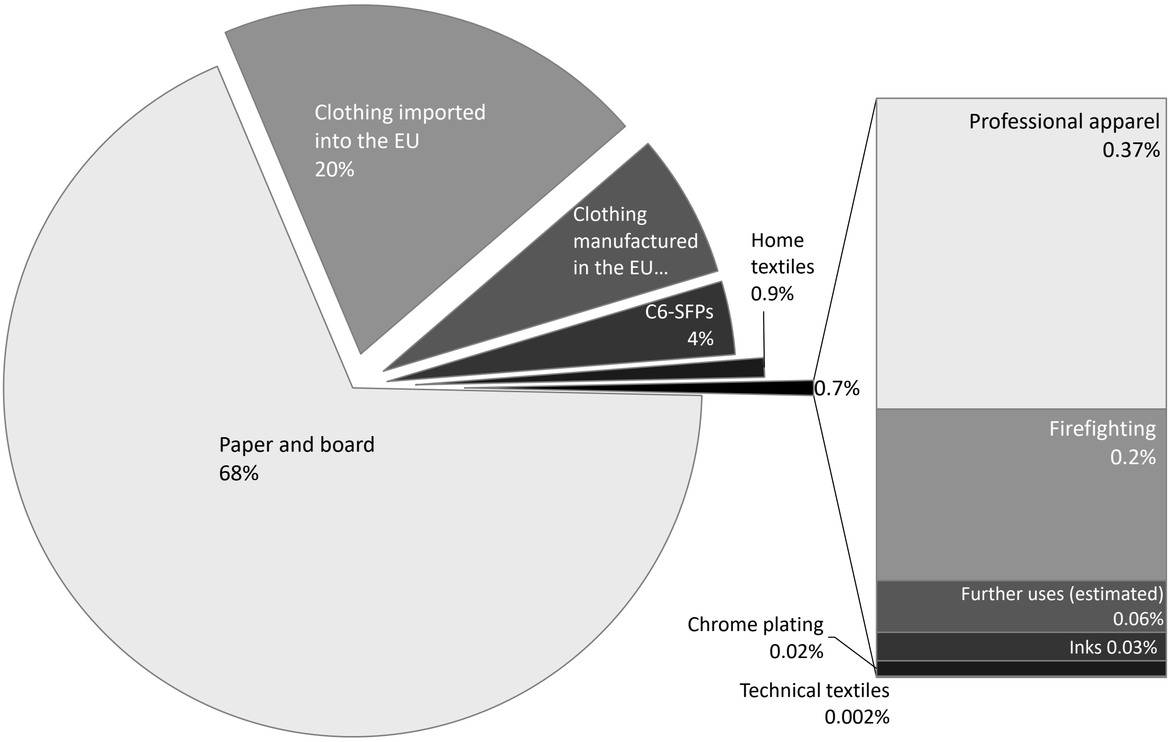

Figure 3. Current use of low molecular weight PFHxA-related substances in the European Union (Figure 1 in the Background Document. Updated after the consultation on the Annex XV dossier).

<u>Emissions</u>

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 Appendix B) 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-SFP, 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 demonstrates 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 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[6].

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[7]). 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[8], **RAC concludes that releases to the environment from wide-dispersive uses[9] 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 PFAS and in some cases PFAS related substances. 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 PFAS (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

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[6] 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).

[7] 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".

[8] 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".

[9] 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*.

widespread, and that the levels of PFHxA can be expected to increase due to the restrictions 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 PFAS is limited. The presented monitoring data generally ranges 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 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 provides 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[10] 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

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[10] i.e. non-polymeric

Document)).

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)[11], 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 was presented in the Background Document or has 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 substance 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

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[11] 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.

Details of the evaluation of the Dossier Submitter's quantitative assessment of emissions is provided in Appendix B. Further details of RAC's qualitative evaluation of released are reported in "effectiveness in reducing the identified risks".

3.1.5. 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.

3.1.6. 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. 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 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.

3.1.7. 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 fire-fighting at industrial installations. Nevertheless, for widespread uses, such as in paper and cardboard, textiles and municipal fire-fighting 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.

3.1.8. 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.

3.2. JUSTIFICATION FOR ACTION ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of the Dossier Submitter’s proposal:

The Dossier Submitter concluded that action is required on a Union-wide basis. PFHxA, its salts and related substances are used for manufacturing of materials, in articles and in 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, addressed under the hazard section, 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 pollutants12. A large part of industry has substituted C8-based chemicals towards C6-chemistry (e.g. PFHxA and PFHxA-related substances) or fluorine

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

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, PFOA-related substances and its salts entered into force.

PFHxA, the terminal degradation product, 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 initial release but potentially far away. Due to the specific properties of PFHxA, its salts and related substances local end-of-pipe technologies are not sufficient to reduce 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.

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 RAC conclusion(s):

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 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.

3.3. 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	Permanent
- Fluoropolymers in engine parts in automotive, aerospace and shipping industry	Permanent
- Fluoropolymers in coating of electronic devices	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 of 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 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 (Table 2) or by respondents to the consultation on the Annex XV report, either permanently (i.e. without a time-limit) or with a time-limit.

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:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

3.3.1. 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 to minimise exposure. 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 48 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 Table 7 in Appendix A.

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.

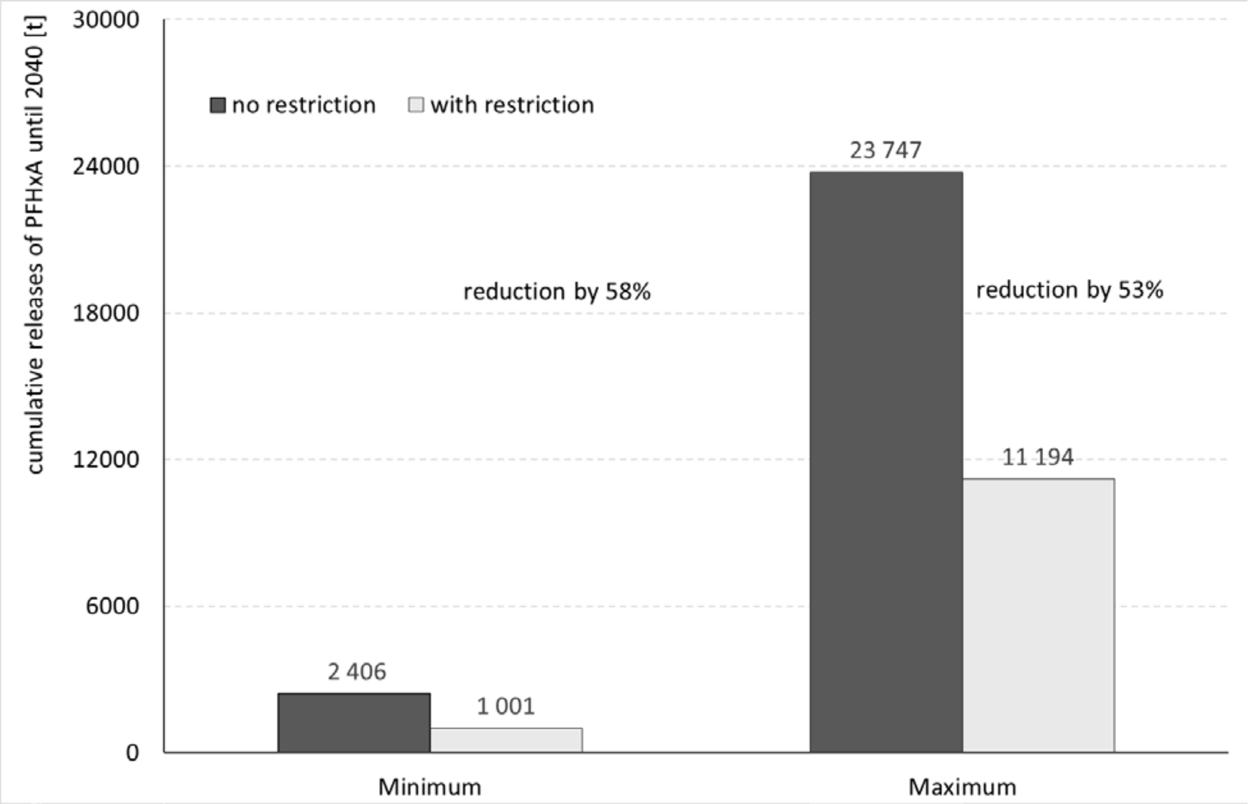

Figure 4. Estimated cumulative releases of PFHxA over 20 years (Figure 2 in the Background Document).

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 3) provides a summary of the information in the Background Document on alternatives, their availability and information on their hazards and risks.

Table 3. 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 PFAS 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 PFAS. 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 PFAS 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 PFAS, different paper refinement technologies and natural materials. No hazards/risks of alternatives are mentioned. For discussion on other PFAS, 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 PFAS. 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, fire-fighting 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 PFAS, 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[13], 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

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[13] 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, 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**.

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 10). 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 fire-fighting 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 fire-fighting 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 fire-fighting 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 PFAS 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 PFAS 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:

- 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,
- 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,
- 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 is 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.**

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, 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 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 laqueur) - 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 consider these numbers uncertain. RAC note, 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 acknowledge 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 4 and Table 5, respectively.

Table 4. 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 5	See ‘medical devices’ in Table 5	See ‘medical devices’ in Table 5
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	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

Table 5. 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

	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.

3.3.2. Socio-economic impact

Justification for the opinion of SEAC

3.3.2.1. Costs

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

3.3.2.2. Benefits

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

3.3.2.3. Other impacts

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

3.3.2.4. Overall proportionality

Summary of proposal:

See the opinion of SEAC.

RAC and SEAC conclusion(s):

See the opinion of SEAC.

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

See the opinion of SEAC.

3.3.2.5. Uncertainties in the proportionality section

See the opinion of SEAC.

3.3.3. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of Dossier Submitter's 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. 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.

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

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 1000 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.

3.3.3.1. Monitorability

Justification for the opinion of RAC and SEAC

Summary of Dossier Submitter's proposal[14]:

The Dossier Submitter considers the proposed restriction to be monitorable.

Time trend monitoring can be performed with samples from the environment, from animals or from humans. Methods and e.g. (environmental) specimen banks could be used for such a monitoring. Reductions of releases of PFHxA and related substances in the environment should result in decreasing concentrations in a trend monitoring. It might be sufficient to measure PFHxA since the related substance will be degraded to PFHxA in the environment. However, decreasing trends in releases may not be directly detected in environmental samples, due to formation of PFHxA from precursor substances.

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[14] RAC notes that the Dossier Submitter has not included a discussion on the monitorability in section 2.5.4, but in section E.7 only.

RAC and SEAC conclusion(s):

RAC agrees with the Dossier Submitter 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 6 (ECHA, 2020)).

Table 6. 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)	

3.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

3.4.1. 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 PFAS (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 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.

3.4.2. SEAC

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

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5. Appendix A

Table 7. Lifecycle steps and average service life duration used by the Dossier Submitter to derive releases and cumulative releases with and/or without restriction at 2040 for the different sectors/subsectors

Sector of use	Subsector	Lifecycle step	Average service life (years)	Cumulative release estimated		
				Fluoropolymers	C6 precursors	PFHxA and salts
1. Polymers	1.1 Manufacture of (acrylic-) polymers with C6 side chains	Manufacture	-	X (No restriction)	X (No restriction)	-
		Formulation	-	-	X (No restriction, Restriction)	-
		Service life indoor	5	X (No restriction, Restriction)	-	X (No restriction, Restriction)
		Service life outdoor	5	X (No restriction, Restriction)	-	X (No restriction, Restriction)
		Deposit	10*	-	X (No restriction, Restriction)	X (No restriction, Restriction)
	1.2 Manufacture and use of fluoroelastomers with APFHx	Service life	10	-	-	X (No restriction, Restriction)
		Deposit	10*	-	-	X (No restriction, Restriction)
2. Textiles	2.3 Clothing used in the EU	Application by professionals	-	X (No restriction, Restriction)	X (No restriction)	X (No restriction, Restriction)
		Service life	2	X (No restriction, Restriction)	X (No restriction, Restriction)	X (No restriction, Restriction)
		Deposit	10*	-	X (No restriction, Restriction)	X (No restriction, Restriction)
	2.4 Professional apparel (PPE)	Application by professionals	-	X (No restriction, Restriction)	X (No restriction)	X (No restriction, Restriction)
		Service life	2	X (No restriction, Restriction)	X (No restriction, Restriction)	X (No restriction, Restriction)
		Deposit	10*	-	X (No restriction, Restriction)	X (No restriction, Restriction)
	2.5 Home textiles	Application by professionals	-	X (No restriction, Restriction)	X (No restriction)	X (No restriction)
		Service life	15	X (No restriction, Restriction)	X (No restriction, Restriction)	X (No restriction, Restriction)

		Deposit	10*	-	X (No restriction, Restriction)	X (No restriction, Restriction)
	2.6 Technical textiles	Application by professionals	-	X (No restriction, Restriction)	X (No restriction)	X (No restriction)
		Service life	10	X (No restriction, Restriction)	X (No restriction, Restriction)	X (No restriction, Restriction)
		Deposit	10*	-	X (No restriction, Restriction)	X (No restriction, Restriction)
3. Paper and cardboard	3.1 Grease proof papers	Application by professionals	-	X (No restriction, Restriction)	X (No restriction)	X (No restriction)
		Service life	1	X (No restriction, Restriction)	X (No restriction, Restriction)	X (No restriction, Restriction)
		Deposit	10*	-	X (No restriction, Restriction)	X (No restriction, Restriction)
4. Extinguishing agents	4.1 Use by professional firefighting	Formulation	-	-	X (No restriction)	X (No restriction)
		Application by professionals	-	-	X (No restriction, Restriction)	X (No restriction, Restriction)
5. Chrome plating	5.1 Hard chrome plating	Application by professionals	1	-	X (No restriction, Restriction)	X (No restriction, Restriction)
	5.2 Decorative chrome plating	Application by professionals	1	-	X (No restriction)	X (No restriction)
	5.3 Plastics chrome plating	Application by professionals	1	-	X (No restriction)	X (No restriction)
6. Inks	6. Printing inks	Formulation	1	-	X (No restriction, Restriction)	X (No restriction)
		Application by private users	1	-	X (No restriction, Restriction)	X (No restriction)
		Service life	1	-	X (No restriction, Restriction)	X (No restriction)
		Deposit	10*	-	X (No restriction, Restriction)	X (No restriction)

*Landfill residence time

6. Appendix B

RAC evaluation of environmental release estimates

As noted in section 3.1.4 “Information on emissions and exposures”, RAC concluded that the quantitative release estimates reported in the Background Document were not reliable.

Appendix B presents further details of the Dossier Submitter’s proposal and the subsequent evaluation by RAC leading to the conclusion presented in the opinion. The RAC evaluation includes summary tables for each of the main sectors detailing the methodology, data and assumptions used by the Dossier Submitter to calculate the releases reported in the Background Document and corresponding remarks by RAC.

During the opinion making process additional information on the calculations, including calculation spreadsheets, was received from the Dossier Submitter. This information is included in the summary tables.

General observations

In terms of the assumptions used for constructing exposure scenarios, not all relevant life cycle stages were assessed for some uses. For instance, releases from recycling (i.e. shredding, washing and pulping of wastepaper and cardboard prior to re-use) were not covered in the Dossier Submitter’s assessment of paper and cardboard or textiles. Recycling of paper and cardboard containing PFHxA related substances could be a very relevant emission source for PFHxA-related substances. The release estimations for the waste life cycle stage assume that 60% of municipal waste are disposed to landfill (the remaining 40% of waste arising are omitted from the exposure scenario). EU data by Eurostat on the quantity of municipal solid waste disposed of via incineration, energy recovery, landfill, backfilling, recycling and other means confirm that, on average, between 55 and 60% of waste is landfilled in Europe (including backfilling; latest year available: 2018). However, the data indicated considerable differences among European member states, with some landfilling less than 10% of municipal solid waste whereas others landfilled more than 90%. More crucially, no specific data on disposal/recycling rates for paper and cardboard (food contact materials) and textiles were provided, both sectors being critical to this evaluation. Potential releases from incineration and recycling are mentioned qualitatively in the Background Document.

In terms of representativeness of assumptions, for some sectors, such as hard (functional) chrome plating, the Dossier Submitter used data from Germany that were then extrapolated to a European scale. Similarly, for aqueous film forming foams used in fire-fighting, the Dossier Submitter indicates that the vast majority of German municipal fire brigades exclusively use fluorine free foams. RAC values the use of such quantitative data, although as they mainly concern Germany their representativeness for the rest of the EU/EEA is unclear.

For two of the main sectors, paper and cardboard (food contact materials) and textiles (including imported textiles), RAC is of the opinion that the assumptions made in the release estimates represent an unrealistic worst-case and there is information available that indicates releases are likely to be significantly lower than estimated. Nevertheless, based on a qualitative evaluation, use in **paper and cardboard (food contact materials), textile and fire-fighting foams used in municipal firefighting systems will inevitably result in releases to the environment and can be considered as the main emission sources.**

While release volumes were estimated for many uses, due to the large number of uses it was not possible for the Dossier Submitter to elaborate all of them. The quantities used were not estimated for e.g.

- cosmetic products,
- building materials/ construction products,
- mixtures for consumer uses and
- semiconductors

Paper and cardboard (food contact materials)

Summary of Dossier Submitter's proposal:

According to the Dossier Submitter, 13 800 000 tonnes of paper and cardboard are produced per year for food contact materials across three main sectors: folding box board, corrugated boxes and paper bags. The total emission to the environment from paper and cardboard (food contact materials) is the sum of emissions calculated for: C6 side-chain fluorinated polymers, low molecular weight C6 related substances and PFHxA and salts or impurities.

Calculation of the emission of the C6 side-chain fluorinated polymers starts with min/max estimates of the tonnage used, calculated using the volume of the paper and cardboard (food contact materials) multiplied by the percentage content of C6 side-chain fluorinated polymers in paper and cardboard (food contact materials): 0.2 (min) and 1.5 (max) %. Releases were calculated separately for the 'industrial life-cycle stage' using ERC 12a and the 'indoor service life' using ERC 11a.

Calculation of the use tonnage of low molecular weight C6 related substances is based on data from the literature measured in paper samples (0.8 – 10 000 µg/kg of low molecular weight C6 related substances in paper) and a 'back calculation' considering a low extraction factor for low molecular weight C6 related substances when undertaking chemical analysis. Releases were then calculated separately for the 'industrial life-cycle stage' using ERC 12a and 'indoor service life' using ERC 11a. In this case, the Dossier Submitter also estimated releases from the waste life-cycle stage.

The estimated tonnage of PFHxA and its salts or impurities in paper and cardboard (food contact materials) per year was based on data from the literature as measured in paper samples and ranged from 1.40 to 180 µg/kg of PFHxA in paper. According to the Dossier Submitter, the original content of PFHxA and its salts in paper is unknown – therefore, as per C6-related substance, the use tonnage was 'back calculated' using ERC 11a for water and air. Releases were calculated separately for the 'industrial life-cycle stage' using ERC 12a and the 'indoor service life' using ERC 11a. In this case, the Dossier Submitter also added releases from the waste life-cycle stage.

To express all emission as PFHxA, the releases of the C6 side-chain fluorinated polymers and the low molecular weight C6 related substances were recalculated using degradation factors of 1% and 7%, respectively.

This use is estimated by the Dossier Submitter to result in emissions of 18 – 849 t/a of PFHxA.

RAC evaluation:

The Dossier Submitter separately assessed emissions for three life cycle stages: treatment of paper and cardboard, service life of grease proof paper and cardboard and end of life (waste disposal). As a generic assumption the Dossier Submitted uses a volume of 13 800 000 tonnes of paper and cardboard manufactured per year in the EU for food contact across three main sectors: folding box board, corrugated boxes and paper bags as representative for the annual overall use volume of PFHxA-treated paper. Between 27 600 and 207 000 t of C6-SFPs are used annually in grease proof paper and board and PFHxA itself is not used in paper treatment. Its presence in grease proof paper is due to degradation of C6-SFPs and low molecular weight PFHxA-related substances or could also be due to its presence as impurities in the products. With respect to these general assumptions RAC has the following observations:

The assumption that 100% of the EU volume of food contact paper and board is treated with C6-SFPs and/or PFHxA related substances is likely an overestimation as other PFAS may be used as well as other solutions such as silicone-based treatment which is generally applied for parchment paper.

The Dossier Submitter stated in the BD that PFHxA and 6:2 FTOH are only found in 70% of the samples, which is an indication that not all paper that is used as food contact material is treated with PFHxA precursors. Furthermore, the volume of paper used does not differentiate between different types of food packaging. PFASs are mainly used for packaging of warm and greasy food (grease proof paper). Cardboard boxes and tetra packs used for packaging of dry food stuff such as rise, cereals etc. and packaging of cold liquid products (milk, juices) are not likely to contain PFASs. Only that share of food packaging paper that is used as grease proof is potentially treated with PFAS.

However not all grease proof paper is treated with PFAS. Based on Yuan 2016 and Schaider (2017) the fraction of grease proof paper containing PFASs is 50% at the maximum and 33% as the most likely value. Verschueren (2018) indicated that of paper based greaseproof materials only 43% is chemically treated, including use of waxes and fluorochemicals. It should be noted that not all fluorochemicals used are fluorotelomer-based. According to Trier et al (2017) there seems to be a shift from telomer based PFASs towards per- and polyfluorinated polyethers on the EU market in recent years. European data on the share by end-use sector in the total demand for food contact paper and board for the year 2011 shows that liquid foods (13%), dry groceries (25%) and fresh produce (33%) together have a share of 71% in the total use of food contact paper (Europlas (2018) and Whitworth (2012)). In these sectors paper is most likely not being treated to impart water and grease repellence.

As an indication, taking a share of 50% of the total amount of food contact material that is chemically treated to make paper grease proof and about 50% of grease proof paper contains PFASs, this results in a fraction of 25% of the total volume of paper-based food contact material. Most likely this could even be lower. Via the consultation on the Annex XV report (#3064) the Alliance for Telomer Chemistry Stewardship's provided comments stating that quantities should be updated to reflect a range of usage between 30 and 70% of the market. From the information it is not exactly clear to which market this applies, which might be paper used as in food contact material as a whole, or the share in grease proof paper. RAC concludes that the fraction of grease proof paper which is treated with PFHxA related substance in the total amount of food contact paper is lower than 100%. A more reasonable estimate of 25% could be used. RAC notes that PFHxA-related substances might be used in other paper and board applications and that releases from these applications are not covered in the Background Document. Also, paper recycling is not covered in the Background Document as an emission source.

The assumption that the EU manufactured volume of 13 800 000 tonnes of grease proof paper and board for three uses (folding box board, corrugated boxes and paper bags) is representative for the EU annual use volume is inherently uncertain as import and export of such materials are not accounted for and no information is available on the representativeness of the three paper and board categories for the total amount used by the sector.

Data from the literature indicates that low molecular weight C6-related substances have been measured in paper samples at widely differing levels of 0.8 - 10 000 µg/kg. RAC notes the Dossier Submitted further assumed an extraction efficacy of 0.1% which was taken from ERC11a (sum of release factors for water and air). Based on this factor a total use volume of 11 040 – 138 000 t/a was 'back-calculated'. For PFHxA a similar approach was used starting from a concentration range of 1.40 - 180 µg/kg of PFHxA in paper resulting in 19 – 2 484 of PFHxA and salts used annually. RAC acknowledges that not all of the low molecular weight C6 related substance present in paper / board are likely to be extracted during analysis (Robel et al. 2017). However, RAC considers that the Dossier Submitter's assumption to use the default release factor from ERC 11a (which assumes that 0.1% of the substance would be extractable) is likely to overestimate the tonnage of low molecular weight C6 related substances used in paper/board as extraction will not be that low in all cases. RAC notes that Robel et al. (2017), report that the extraction efficiency from paper and textiles was in the range of 0 - 2.2%. Therefore, RAC is of the opinion that a median value of 1% would be more realistic and the above-mentioned assumption may result in the overestimation of used tonnage (and corresponding releases). For PFHxA, RAC considers a conclusion of a use volume between 19 and 2 484 t/a is contradictory to the assumption in the Background Document that PFHxA itself is not used in these materials, rather it is in the materials as a degradation product of C6-SFPs or short chain PFHxA-related substances. Using this volume in the overall release estimation may also result in some double counting as degradation from C6-SFPs and PFHxA-related substances in paper to PFHxA is already accounted for in the application of 1% and 7% degradation fractions.

Releases from the treatment of paper and cardboard (food contact materials)

The Dossier Submitter considered that releases occurring from the manufacturing of grease proof papers would be inherently low due to a closed loop of materials and the recycling of treatment emulsions. ERC12a was used to estimate the release from manufacturing but the default release factors to air, water and soil of 2.5% (processing of articles at industrial sites with low release, BD part 2 B.9.2) were reduced by 90% to reflect the closed loop assumed to be in place. This resulted in final release factors of 0.25% for air, 0.25% for water and 0.25% for soil. RAC considers ERC12a is not the appropriate ERC to use for manufacturing of chemically treated grease proof paper. According to the REACH guidance R.16, ERC12a refers to cutting and coarse grinding of materials. **RAC nevertheless considers the applied release factor as adequate**. Regarding the reduction of the release factor based on the assumption of effective manufacturing and recycling RAC considers that it is appropriate to assume closed loop manufacturing for the paper sector, but had no information to evaluate if 90% is a reasonable factor to apply for the reduction from ERC defaults. Nevertheless, RAC concurs with the choice of release factors for air, water and soil from paper treatment facilities operating at industrial scale.

Releases during service life of grease proof paper and cardboard (food contact materials)

Releases during the service life of paper and cardboard (food contact materials) were estimated from the total volume of grease-proof paper used as food contact material, the typical content of PFHxA-related substances and the resulting volumes of PFHxA-related substances and PFHxA in grease-proof paper and cardboard. The Dossier Submitter noted that the measured concentrations of PFHxA and PFHxA-related substances were highly variable for the different kind of products. Releases were estimated for air and water using ERC11b for the service life of articles used in indoor environment with a high or intended release (100% to air and water). RAC notes that the Dossier Submitter did not apply the back calculations to arrive at the use volumes of PFHxA-related substances and PFHxA in the service life stage which is inconsistent with the approach taken for the manufacture of grease-proof paper. RAC notes that the use of a release factor of 100% during service life is likely to overestimate emissions. RAC considers that it could have been more appropriate if ERC11a for widespread use of articles in indoor environment with low release (0.05% to water and air) was applied to the annual use volume. Such an approach would have resulted in a thousand-fold lower release during service life.

Releases at end of life (waste disposal)

The Dossier Submitter did not calculate releases of C6 side-chain fluorinated polymers arising from waste disposal (landfilling). Although RAC can appreciate that C6-SFPs are likely retained in the landfill degradation products could be released through the percolate. Therefore, the omission of this emission source of PFHxA from the exposure scenario has not been substantiated by the Dossier Submitter. RAC notes that the assumption of no release is not consistent with ECHA Guidance R.18. RAC concludes that release through the C6 side chain fluorinated polymers may have been underestimated.

As regards low molecular weight PFHxA-related substances, the Dossier Submitter estimated the release from the total use volume subtracted by the service life tonnage multiplied by 0.6 (based on the assumption that 60% paper waste is on average landfilled) and divided by 10-year waste “service life”. RAC considers the default assumption that all remaining low molecular C6 related substances will be released from landfill is not consistent with ECHA Guidance R.18, which states a default release factor to water of 0.032 without any wastewater/leachate treatment and a default release factor of 0.0016 to soil (assuming a lifetime of 20 years). RAC also notes that, according to ECHA R.18 Guidance, allocating a fraction of releases to a single year is not necessary and could underestimate releases (by a fraction in proportion to the length of service life applied). Furthermore, RAC considers the assumption of 60% landfilling is relatively high for the EU. The Dossier Submitter based this on a reference with limited relevance for the EU, despite the availability of granular waste disposal data for the EU via Eurostat. Therefore, based on the factors discussed above RAC considers releases as a result of waste disposal to be highly uncertain.

Conclusion on paper and cardboard (food contact materials): in view of the above-mentioned data gaps, uncertainties and inconsistencies, RAC is of the opinion that no robust conclusion can be drawn on the quantity of releases but that there is a substantial release of PFHxA-related substances from their use in paper and cardboard (food contact materials).

Table 8. Summary of emissions assessment for paper and cardboard (food contact materials)

Element	**RAC understanding of Dossier Submitter's assumptions and calculations**	**RAC remarks**
Amount of paper and cardboard produced		
	13 800 000 tonnes of paper and board are produced per year for food contact across three main sectors: folding box board, corrugated boxes and paper bags (see Annex B.9.6.1).	*RAC concludes that the fraction of grease proof paper which is treated with PFHxA related substances in the total amount of paper and cardboard is lower than 100%. As a conservative assessment, 25% could be used.*
Release estimation		
General assumptions	*Industrial life-cycle stage (treatment of paper/board):* ERC-based assessment. The default release factors to air, water and soil from ERC 12a - 2.5% (Processing of articles at industrial sites with low release, see Annex B.9.2) were further reduced by 90% to reflect effective manufacturing and recycling assumed to be in place in this sector. This resulted in final release factors of 0.25% for air, 0.25% for water and 0.25% for soil.	
	Service life: ERC-based assessment. Default release factors to air and water from ERC 11a (widespread use of articles with low release - indoor) were applied resulting in final release factors of 0.05% for air and 0.05% for water (no release to soil) - see Annex B.9.2.	
	Waste life-cycle stage: 60% of paper and board is assumed to be disposed of in landfills (Geyer et al., 2017) – see Annex B.9.2.	
Calculations of releases estimation		
C6 side-chain fluorinated polymers		

Tonnage of C6 side-chain fluorinated polymers in paper per year	Min/Max estimates of used tonnage calculated using the volume of the paper/board multiplied by content of C6 side-chain fluorinated polymers in paper: 0.2 (min) and 1.5 (max) % 27 600 to 207 000 tonnes of SFPs are used annually.	*RAC notes that in the Excel calculations tables, these are indicated as "C6 fluoropolymers". However, RAC considers that this is a mistake in terminology and the calculations refer to C6 side-chain fluorinated polymers.*
Releases calculation:		
Industrial life-cycle stage ERC 12a **Air, water and soil**	Used tonnage (min, max) x 3 (env. compartments) x release factor reduced by 90% 27 600 t/a x 3 x 0.25% = 207 t/a 207 000 t/a x 3 x 0.25% = 1 553 t/a Background Document: Release factors were further reduced by 90% to reflect effective manufacturing and recycling assumed to be in place in this sector.	
Service life **ERC 11a** **Air, water**	Used tonnage (min, max) x 2 (env. compartments) x release factor 27 600 t/a x 2 x 0.05% = 27.6 t/a 207 000 t/a x 2 x 0.05% = 207 t/a	
Waste life-cycle stage		*No calculations related to the waste life-cycle stage of C6 side-chain fluorinated polymers were reported in Annex B.9.* *RAC questions whether release of C6 side chain fluorinated polymers from waste disposal should be included. Although RAC can imagine that the C6 side chain fluorinated polymers may feasibly be retained within a landfill after disposal, while the degradation products are released through the percolate, this has not been substantiated by the Dossier Submitter. Even if that is the case, it may be questioned whether a 1% degradation followed by the proper scenario for waste disposal should be applied. RAC concludes that release through the C6 side chain fluorinated polymers may have been underestimated as the waste stage has not been considered in the calculations.*

		RAC notes that the assumption of no releases from waste disposal is not consistent with ECHA Guidance R.18, which states a default release factor to water of 0.032 without any wastewater/leachate treatment and a default release factor of 0.0016 to soil (assuming a lifetime of 20 years). Allocating a fraction of releases to a single year is not detailed in the ECHA Guidance. Therefore, releases are likely to have been significantly underestimated from this route.
Annual release	235 – 1 760 t/a of C6 side-chain fluorinated polymers would be released from paper and cardboard.	
Low molecular weight C6 related substances		
Tonnage of *C6 precursors* in paper per year	Data from literature measured in paper samples: 0.8-10 000 µg/kg of low molecular weight C6 related substances in paper. Tonnage of paper x concentration of C6 related substances in paper 13 800 000 t/a * 0.8 µg/kg = 0.0110400 t/a 13 800 000 t/a * 10 000 µg/kg = 138 t/a The Dossier Submitter assumes that not all of the low molecular weight C6 related substances present in paper/cardboard will be 'extractable', and thus would not be reflected in the calculation above. Therefore, the Dossier Submitter applied a further correction factor to account for their low extraction (this is referred to as 'back calculation'). The correction factor applied was 0.1% from ERC 11a, resulting in the	*RAC acknowledges that not all of the low molecular weight C6 related substance present in paper /cardboard is likely to be extracted during analysis (Robel et al., 2017)[15]. However, RAC considers that the Dossier Submitter's assumption to use the default release factor from ERC 11a (which assumes that 0.1% of the substance would be extractable) is likely to overestimate the tonnage of low molecular weight C6 related substances used in paper/cardboard as extraction will not be that low in all cases. RAC notes that Robel et al (2017)[16] report that the extraction efficiency from paper and textiles was in the range of 0-2.2%. Therefore, RAC is of the opinion that median value of 1% would be more realistic and the above-mentioned assumption may result in the overestimation of used tonnage (and corresponding releases).*

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[15] Robel AE, Marshall K, Dickinson M, Lunderberg D, Butt C, Peaslee G, Stapleton HM, Field JA (2017). Closing the mass balance on fluorine in papers and textiles. Environ. Sci. Technol. 2017, 51, 16, 9022–9032.

[16] *Ibidem*

	following formula: 0.0110400 t/a x 100% / 0.1% = 11.040 t/a 138 t/a x 100% / 0.1% = 138 000 t/a	
Releases calculation:		
Industrial treatment of paper/board ERC 12a Air, water and soil	Used tonnage (min, max) x 3(env. compartments) x release factor reduced by 90% 11.040 t/a x 3 x 0.25% = 0.082 t/a 138 000 t/a x 3 x 0.25% = 1 035 t/a Release factors were further reduced by 90% to reflect effective RMMs at manufacturing sites and recycling assumed to be in place in this sector.	
Service life indoor	Used tonnage (without 'back calculation' using ERC 11a) / average service life 0.011 t/a / 1y = 0.011 t/a 138 t/a / 1y = 138 t/a	*RAC notes that it would also be possible to assess releases to the environment based on ERC11a:* *used tonnage (min, max) x 2(env. compartments) x release factor*
Waste life-cycle stage	[used tonnage (min, max) – (service life tonnage (min, max) x average service life)] x 60% / average service life waste [11.040 t/a – (0.011 t/a x 1y)] x 60% / 10y = 1 t/a [138000 t/a – (138 t/a x 1y)] x 60% / 10y = 8 272 t/a	*The default assumption that all remaining low molecular C6 related substances will be released from landfill is not consistent with ECHA Guidance R.18, which states a default release factor to water of 0.032 without any wastewater/leachate treatment and a default release factor of 0.0016 to soil (assuming a lifetime of 20 years). Allocating a fraction of releases to a single year is not required by the ECHA Guidance. Therefore, releases are likely to have been significantly overestimated from this route.*
Annual release	In total, the release of low molecular PFHxA related substances is assumed to be 1- 9 455 t/a, with the main releases from landfills.	

PFHxA and salts or impurity		
Tonnage of PFHxA and salts or impurity in paper per year	Data from literature measured in paper samples: 1.40-180 µg/kg of PFHxA in paper. Tonnage of paper x concentration of PFHxA 13 800 000 t/a x 1.4 µg/kg = 0.0193 t/a 13 800 000 t/a x 180 µg/kg = 2.4840 t/a Original content of PFHxA and salts in paper is unknown. Therefore, the Dossier Submitter 'back calculated' the used tonnage using ERC 11a for water and air (0.05%+0.05%=0.1%) (explanation in the in the Excel calculations tables provided by the Dossier Submitter) 0.0193 t/a x 100% / 0.1% = 19 t/a 2.484 t/a x 100% / 0.1% = 2 484 t/a Tonnage of PFHxA and salts in paper per year: 19 – 2 484 t/a	*To estimate the amounts of PFHxA related substances and PFHxA in paper the Dossier Submitter used a so-called 'back-calculation' on the measured values to correct for extractability. RAC acknowledges that PFHxA related substances and PFHxA would not be completely extracted from paper during chemical analysis. However, RAC does not fully support the methodology applied by the Dossier Submitter to back-calculate the 'real' concentrations using ERC default release factors. RAC considers that it would be more logical to apply a general correction factor for extractability. Literature may provide an indication of extractability based on a comparison with total PFAS or total F (e.g. Robel et al 2017). Based on the data in this publication, 1% extractability seems to be a more realistic choice than 0.1%. It seems that ERC 11a (0.1%) may overestimate the amounts. RAC notes that 'back-calculation' was applied by the Dossier Submitter only for application by professionals/skilled users and waste.* *RAC notes that the impact of the 'back-calculation' is largest on the releases from waste disposal.*
Releases calculation		
Industrial treatment of paper/board ERC 12a Air, water and soil	Used tonnage (min, max) x 3(env. compartments) x release factor reduced by 90% 19 t/a x 3 x 0.25% = 0.14 t/a 2484 t/a x 3 x 0.25% = 18.63 t/a	
Service life indoor	Used tonnage (without 'back calculation' using ERC 11a) / average service life 0.0193 t/a / 1y = 0.0193 t/a 2.4840 t/a / 1y = 2.4840 t/a	*RAC notes that it would also be possible to assess releases to the environment based on ERC11a:* *used tonnage (min, max) x 2(env. compartments) x release factor*

Waste life-cycle stage	[used tonnage (min, max) – (service life tonnage (min, max) x average service life)] x 60% / average service life waste [19 t/a – (0.0193 t/a x 1y)] x 60% / 10y = 1.16 t/a [2484 t/a – (2.4840 t/a x 1y)] x 60% / 10y = 148.89 t/a	*The default assumption that all remaining PFHxA and salts or impurity will be released from landfill is not consistent with ECHA Guidance R.18, which states a default release factor to water of 0.032 without any wastewater/leachate treatment and a default release factor of 0.0016 to soil (assuming a lifetime of 20 years). Allocating a fraction of releases to a single year is not required by the ECHA Guidance. Therefore, releases are likely to have been significantly overestimated from this route.*
Annual release	In total, the release of PFHxA and salts or impurity is assumed to be 1.32-170.00 t/a, with the main releases from landfills.	
Recalculation to express releases in PFHxA		
Low molecular weight C6 related substances	From a re-evaluation of the available scientific literature, a degradation factor of 7% of PFHxA from low molecular weight related substances was suggested by RAC and applied by the Dossier Submitter in their calculations. 1 t/a x 7% = 0.07 t/a PFHxA 9455 t/a x 7% = 661.15 t/a PFHxA	
C6 side-chain fluorinated polymers	Also, fluorotelomer based SFPs can degrade to form PFHxA. The transformation factor of 1% that is used in the PFOA restriction was suggested by RAC and applied by the Dossier Submitter in their calculations. 235 t/a x 1% = 2.35 t/a PFHxA 1 760 t/a x 1% = 17.6 t/a PFHxA	
PFHxA and salts or impurity	1.32-170.00 t/a	

Total releases from paper and cardboard	0.07 t/a + 2.35 t/a + 1.32 t/a = 7.34 t/a 661.15 t/a + 17.6 t/a + 170.00 t/a = 848.75 t/a Annex B.9.6.2: in total, the release of low molecular PFHxA related substances is assumed to be 1 - 9 445 t/a, with the main releases from landfills and disposal. As far as the Dossier Submitter knows, PFHxA is not used in paper treatment. Therefore, the direct measured PFHxA concentration is assumed as a degradation product from SFPs and PFHxA related substances. Taking the measured data for PFHxA on the one hand and on the other hand the formation of PFHxA from related substances into account, about **18 to 849 t of PFHxA** may be released from paper and cardboard. Again, the vast majority is released from landfill.	*According to the Dossier Submitter, PFHxA is not used in paper treatment but calculations of the releases of PFHxA and salts or impurity are presented and included in the overall release.*

Textiles

Summary of Dossier Submitter's proposal:

The Dossier Submitter has presented their approach to release estimation for the textile sector in Annex B.9.5 of the Background Document. The release quantities expressed as PFHxA are reported in Table 25d in Annex B.9.18 of the Background Document.

The Dossier Submitter split up the textile sector into different sub-sectors and assigned amounts used (t/a) to each sub-sector. Based on Table 25 in Annex B.9.18 of the Background Document, minimum and maximum use tonnages for textile sub-sectors are provided in Table 1. The Dossier Submitter assumed a share of 25% of the total amount of textiles to be produced in the EU and a 75% share to be imported based on the ECAP report[17]. It is assumed that about 60% of professional apparel, including personal protective equipment (PPE) is manufactured in Europe and that two thirds of industrial fabrics are manufactured in the EU (Annex B.9.5.2.1 of the Background Document).

Table 9. Minimum and maximum use tonnages per year for the various textile subsectors.

subsector	**Current tonnage of products / articles** [t/a]	
subsector	min	max
2.1. Clothing manufactured in the EU	1 200 000	3 600 000
2.2. Clothing imported into the EU	3 000 000	17 000 000
2.3. Clothing used in the EU	4 800 000	14 600 000
2.4. Professional apparel (PPE)	76 000	194 000
2.5 Home textiles (carpets)	620 605	1 800 000
2.6. Technical textiles (industrial fabric)	270 000	520 000
2.6. Technical textiles (medical app.)	54 000	104 000

The Dossier Submitter mentions the use of PFAS, C6 related side-chain fluorinated polymers (SFPs) and low molecular weight PFHxA related substances in different kinds of textiles but indicates that PFHxA itself and its salts are not used for textile treatment. The concentration of side-chain fluorinated polymers present in textiles was reported in a BfR study as 0.2 to 0.5 % (w/w)) and was used to calculate the total volume of PFHxA related SFPs used in the different textile subsectors (BfR, 2012). The emission calculation for low molecular weight PFHxA related substances in textiles was performed on the basis of median measured concentrations of these substances in textiles reported in the scientific literature (see Table 37 in Annex E.2.11 of the Background Document), which were considered to have been obtained by means of methods with a relatively weak extraction efficiency. According to the Dosser Submitter, the median measured concentration is the amount of PFHxA related substances, which are released into the environment from the currently assessed sub-group of textiles. The default release factors from ERC 11a for indoor or ERC 10a for outdoor uses were used to back-calculate the initially used tonnage of PFHxA related substances for textile treatment from the measured concentration of 6:2 FTOH.

The total release of PFHxA was estimated by adding the share which is formed by degradation of SFPs (1%) and by C6 PFHxA related substances (7%) to the amount released based on the

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[17] Rijkswaterstaat (2017): ECAP European Textiles & Workwear Market - The role of Public Procurement in making textiles circular, http://www.ecap.eu.com/wp-content/uploads/2018/10/ECAP-Workwear-Report.pdf

estimate of PFHxA from the scientific literature. As a worst-case scenario, the Dosser Submitter assumed that all manufactured textiles are treated with SFPs and with PFHxA related substances. The Dossier Submitter acknowledges that this assumption is likely to result in an overestimation of environmental releases because only in 70% of the investigated textile samples were both PFHxA and PFHxA-related substances detected; similarly in recent years the share of treated textiles has reported to have declined.

Disposal of 60% of the total amount of articles to landfill is assumed, based on Geyer et al. (2017), and the Dossier Submitter remarks that subsequently, together with the articles and products containing PFHxA, its salts and related substances are also disposed in the same percentage. The Dossier Submitter indicates that the releases from waste are very uncertain. Further specification is provided in Annex B.9.5.2.1 of the Background Document where the Dossier Submitter indicates that annually 1.6 million tonnes of carpets become waste. Of this, 60 % is disposed of in landfills, 37 % is incinerated and 3 % is recycled (European Public Health Alliance, 2016).

At the waste stage, the Dossier Submitter remarks that due to the short service life of clothing, the majority of the environmental releases results from disposal. From imported clothing, up to 2 882 t/a of related substances contribute to releases of 202 t/a PFHxA from landfills. Information on the released amounts is provided in Annex B.9.5 of the Background Document.

Total releases are provided for C6 side chain fluorinated polymers, the PFHxA related substances and PFHxA and salts in Tables 25b-d (Annex B.9.18 of the Background Document) and separately for the C6 side chain fluorinated polymers in Table 39 (Annex E.2.11 of the Background Document). Overall numbers are presented for C6 side chain fluorinated polymers and PFHxA related substances in the Background Document (page 55). The Dossier Submitter estimates (see Annex B.9.5 'Textiles' in the Background Document) that the use of PFAS remains constant in the future. Without a restriction, constant releases of PFHxA-related substances from textiles amount to 1 229 – 4 225 t/a. Accordingly, emissions over 20 years are expected to add up to 24 592 – 84 502 t. Additionally, release of "C6 related fluoropolymers" (RAC notes that it is unclear what this means) and SFPs of approximately 74 – 222 t/a (1 406 – 4 414 t over 20 years) also have to be considered, although the Dossier Submitter considers that these estimates are highly uncertain.

Accumulating the releases reported in Table 25b-d for the sub-sectors 'clothing used in the EU', 'professional apparel (PPE)', 'home textiles', and 'technical textiles' resulted in releases of **72 - 222 t/a for the C6 side chain fluorinated polymers, 1 229 – 4 225 t/a for the PFHxA related substances and 87 – 1 298 t/a for PFHxA itself.** Those are reported in the Background Document (Tables 25a-d).

RAC evaluation:

To assess the releases of PFHxA and related substance from textiles during service life the market volumes for different textile categories were used together with typical application rates and measured concentrations. A key assumption is that 100% of each textile category is treated with PFHxA related substances. For low molecular weight PFHxA- related substances and PFHxA the lower limit and the median value of the measured concentrations were applied to the respective minimum and maximum market volumes for each textile category to estimate the releases of PFHxA related substances. Using the minimum value of the measured concentrations implies that either none of the textile is treated, or concentrations are too low to impart dirt and water repellence functionality. RAC notes that low measured concentrations probably relate to another source or function. Applying the maximum value means that the total amount of textile is being treated to impart dirt and water repellence properties. The Dossier Submitter also calculated releases based on average values. According to the RAC average values can be considered as the most reasonable basis for estimating releases.

The assumption of that 100% of all textile categories were treated with PFHxA-related substances was also addressed in several comments submitted during the consultation on the Annex XV report.

Information from the consultation on the Annex XV report

The Alliance for Telomer Chemistry Stewardship provided information on the share of textiles treated:

- Outdoor clothing 50% (assumed only outer part of clothing is protected and treated)
- Occupational wear assumed that 80 - 100% of the items are protected using C6-SFPs.
- Carpets and textile floor coverings. Assumed 30-80%. The market has moved away from water and stain protection through dirt and water repellent treatment towards using other materials like PP and PET based fibre which have reduced requirement of dirt and water repellent treatment.
- Industrial textile fabrics assumed 30 - 80% no further substantiation provided.
- No information on the ‘clothing’ category was provided.

RAC considers that clothing is a very broad category and expects the share of material being treated to be at least less than the share for outdoor clothing i.e. <50%.

RAC concludes that the assumption that 100% of textile is treated with PFHxA related substances is unrealistic.

RAC considers that a reliable estimation of the share of textiles being treated should differentiate between each textile category and that the average value of any measured concentrations could be used.

Information on the quantities released is provided in chapter B.9.5 of the Background Document. However, most of these estimates concern subsectors and different life stages and do not provide an overall estimate of the releases. A thorough evaluation of the releases from the textiles is further hampered by lack of consistency in the BD. Outdoor clothing is mentioned frequently in the dossier, but it is not made clear to which of the three subcategories (professional apparel, incl. personal protective equipment (PPE), home textiles or technical textiles) it belongs. From the supporting information it may be deduced that it is probably included in the professional apparel sub sector. The industrial textiles mentioned in chapter B.9.5.2.1 Environmental exposure is denoted in Table 25 as Technical textiles. Furthermore, the amounts in the Background Document for the sub sectors may deviate. For example, in chapter B.9.5.2.1 (environmental exposure) mentions a share of 1.5% for the professional apparel in the total amount of used clothing (1.5% of 4.8 – 14.6 million t/a = 63 000 – 219 000 t/a), whereas Table 25a reports 76 000 – 194 000 t/a. In the comparison, Table 25 has been taken as starting point.

The Dossier Submitter assumed in the Background Document that 25% of the total amount of textiles are manufactured in the EU and 75% were imported based on the ECAP report, whereas for professional apparel it is assumed that about 60% is manufactured in Europe (chapter B.9.5.2.1 Environmental exposure). From the supporting information, RAC notes that the percentage manufactured within Europe is not taken into account in the estimations for clothes used, professional apparel and home textiles, whereas in the technical textiles a factor of 0.66 has been applied as indicated in the Background Document.

The actual estimations of the releases for textiles by the Dossier Submitter in the supplemental information deviated considerably from the description and the data in the Background Document, which could not be fully reproduced. Minimum and maximum amounts of side chain fluorinated polymers (SFPs), PFHxA related substances and PFHxA (t/a) were estimated by multiplying the amount of product (min/max in t/a) by the concentrations in most cases except for the medical textiles category. In the case of the C6-SFPs the maximum concentration applied (0.5%) was used for the release estimations from manufacturing and waste life-cycle stage. For the low molecular weight PFHxA related substances and PFHxA the median measured concentrations of FTOH 6:2 and PFHxA, respectively, from literature were used. In contrast with the description in the Background Document, the supplemental information showed that the median concentrations of measurements were only used for the emissions during service life. For the manufacturing and waste disposal life stage the so-called back calculated values to which ERC values were applied were used. To account for the limited extraction of PFHxA related substances and PFHxA from textiles the median concentrations were ‘corrected’ to what the Dossier Submitter refers to as the concentration based on a ‘back calculation’ using the default release factors from ERC11a (multiplication by factor 100/0.1 – assumption of 0.1 % extraction) or ERC 10a (multiplication by factor 100/6.45 – assumption of 6.45 % extraction) (See Table 2 for a schematic representation). The estimations for medical textiles deviated further from the Background Document description. For medical textiles the maximum amount of products was multiplied by minimum and maximum concentrations observed instead of multiplying the minimum and maximum amount by the back calculated median concentration. A factor of 0.66 was applied to represent the amount produced within Europe as described in the Background Document.

For the releases an ERC-based assessment was applied to minimum and maximum amounts. ‘Real’ (back calculated) amounts were used for the estimations of releases from manufacturing (ERC 12a) and waste disposal, whereas during service life (ERC 10a or 11a) the amounts were based on median measured amounts multiplied by volume of the product (t/a). ERC 12a (Processing of articles at industrial sites with low release) was applied to application by skilled users or application by professionals. To all releases of ERC 12a an extra factor of 0.1 was applied ‘due to effective manufacturing and recycling, about 10% of default release is assumed’, although this factor was not applied to release estimates of industrial fabric and medical textiles. In the Background Document this factor of 0.1 was only substantiated for the C6 polyacrylate production where stakeholders reliable demonstrated a high reduction of environmental releases by effective mitigation measurements.

ERC 11a (indoor) was applied to the service life volume of textiles, apart from for industrial fabrics and medical textile where ERC 10a (outdoor) was applied. The emissions to the various compartments were accumulated to a total minimum and maximum value, which were then divided by the duration of the service life. No service lifetime was applied to manufacturing, whereas 10 years was applied for waste disposal and between 2 and 15 years for service life. In most cases a service life indoor of 2 years was assumed. In the case of home textiles (carpet) 15-year service life was assumed and for industrial fabric and medical textiles where the scenario service life outdoor (ERC10a) was applied, a service life of 10 years was assumed.

As per paper and cardboard, releases from the waste life cycle stage (disposal via landfill) were only estimated for PFHxA related substances and PFHxA. It was estimated using the minimum/maximum tonnage of PFHxA related substance or PFHxA (minus the quantity released during service life) multiplied by 0.6 (assumed fraction to landfill) and divided by the service life of landfill (assumed to be 10 years). The calculations apparent in the supporting information were not clearly described in the Background Document, where only the 60% has been mentioned. RAC also notes that no reference is made to ECHA guidance R.18 (Exposure scenario building and environmental release estimation for the waste life stage).

To estimate the amounts of PFHxA related substances and PFHxA in textile the Dossier Submitter used a so-called back-calculation on the measured values to correct for extractability. RAC acknowledges that PFHxA related substances and PFHxA would not be completely extracted from textiles during chemical analysis. However, RAC does not fully support the methodology applied by the Dossier Submitter to back calculate to ‘real’ concentrations using ERC default release factors. Firstly, factors used are different for the different textile subsectors (factor 100/0.1 applied for subsectors with ERC11a applied for service life indoor and a factor of 100/6.45 for subsectors with ERC10a applied for service life outdoor). Furthermore, RAC considers that it would be more logical to apply a general correction factor for extractability instead of varying extractability factors. Literature may provide an indication of extractability based on a comparison with total PFAS or total F (e.g. Robel et al 2017). Provided the data in that publication, 1% extractability seems to be a more realistic choice than the 0.1% applied by the Dossier Submitter in some substantial subsectors. Depending on the ERCs that the Dossier Submitter took as starting point it seems that ERC 11a (0.1%) may overestimate the amounts, whereas ERC 10a (6.45%) may underestimate the amounts. Back calculation was only applied for application by professionals/skilled users and for waste. For the most important textile subsectors in volume (clothing used, home textiles) ERC11a is applied, and thus amounts released will be substantially overestimated by multiplying the concentrations measured by a factor of 1000.

The annual release of PFHxA, its salts and related substances is calculated dividing the estimated total release by the service lifetime. RAC notes that dividing releases by the article service life could be reasonably considered to represent annual releases during the 1st year of use, but would underestimate the total releases associated with the ‘use tonnage’ of a particular year as releases would typically occur over several years (and in some cases would not occur until many years after use). RAC notes that it is not common practice to apportion releases across multiple years in a simple deterministic release model. Such an approach could underestimate annual releases unless carefully considered in a dynamic cumulative release model (which does not appear to be the case here). The magnitude of underestimation would vary depending on the duration of the service life, with releases from home textiles (service life 15 years), industrial textiles and medical textiles (service life 10 years) more substantially underestimated than for articles with shorter service lives (i.e. 2 years).

The starting point for the estimations on release from the waste life-cycle stage is a 60% disposal of the product volume (t/a) and subsequently of the substance contained. RAC notes that its concerns relating to this factor in relation to the estimates of releases from paper and board equally apply to textiles. The Dossier Submitter indicated that waste is the most important route of release and from the information available in the provided supporting information it was clear that 90-95% of the total releases can be attributed to the waste life cycle stage. RAC acknowledge that waste disposal may be an important route of release for the substances. However, RAC was not able to evaluate the releases from waste disposal completely as the information provided in the Background Document was very limited and the supporting information was also not sufficient to do so. RAC is of the opinion that the Dossier Submitter assumptions, e.g. the application of C6 side chain fluorinated polymers to 100% of the textiles, the applied correction for extractability, and release of the total amount of the substances disposed of during service life instead of applying the default ERCs that the majority of assumptions would lead to an overestimation of releases. However, the correction for the duration of the service life could result in an underestimation of releases. RAC notes that the exposure assessment is highly uncertain.

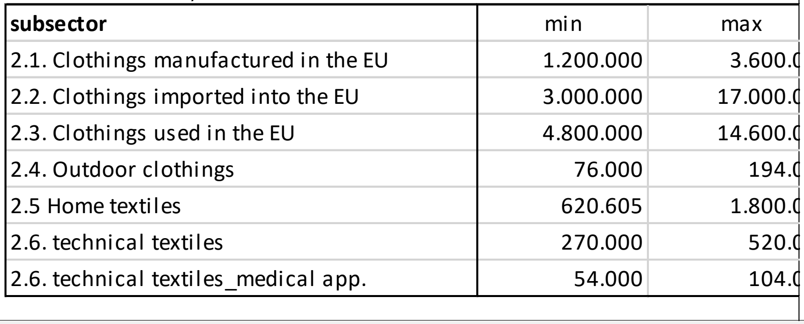
RAC questions the approach followed by the Dossier Submitter for the waste disposal estimations where total amount of the substances (back calculated) is released completely within 10 years. The default release factor from R.18 is 3.2 % (total over 20 years). As the Dossier Submitter assumes 100% over 10 years this corresponds to an annual release of 10 %. Therefore, if the model assumes a single year (see comment above) release from landfill likely to be moderately overestimated (factor ~3). If the model integrates over a period of 10 years, which it appears that it does not, release from landfill is substantially overestimated (by >90%).

The C6 side chain fluorinated polymers were not included in the waste estimation by the Dossier Submitter. As already noted in relation to the estimates for paper and board, RAC questions whether release of C6 side chain fluorinated polymers from waste disposal should also be included. Although RAC can imagine that the C6 side chain fluorinated polymers stay within the landfill, while the degradation products are released through the percolate, this has not been substantiated by the Dossier Submitter. And even if that is the case, it may be questioned whether a 1% degradation followed by the proper scenario for waste disposal should be applied. RAC concludes that release via C6 side chain fluorinated polymers is likely to have been underestimated.

By way of a sensitivity analysis, RAC applied an estimation for textile use following the R.18 Guidance and based on 1% extractability (instead of 0.1%) and applying the default release factors in R18 to the total amount of substance present (amount product x median concentration x extractability correction x ERCs). This resulted in releases being a factor of 30 lower than those calculated by the Dossier Submitter (1/10 x 3/100 x 10: with 1/10 applied for the higher extractability assumed, 3/100 for the ERCs and 10 to correct for the division by service life by the Dossier Submitter). Adding release from C6 side chain fluorinated polymers resulted finally in a value for the PFHxA release through waste that was 16-fold lower than that of the Dossier Submitter. Similarly, releases through the service life and manufacturing were also estimated by the rapporteurs. The ,main differences observed were caused by applying a lower correction factor for extractability (factor 10 lower release through manufacturing) and applying the ERCs to releases from service life instead of assuming complete release divided by 2-year service life for the PFHxA related substances and PFHxA.

Overall, applying the ECHA Guidance resulted into a 15-fold lower release, not taking into account the lower application percentage (<50% instead of 100%) mentioned earlier. **RAC concludes that the releases from textile are substantially overestimated, however on the basis of the current data the Committee is not able to provide robust quantitative estimates.** The releases can still be considered as significant taking into account the large volume of products containing C6-SFPs, low molecular weight PFHxA-related substances and PFHxA.

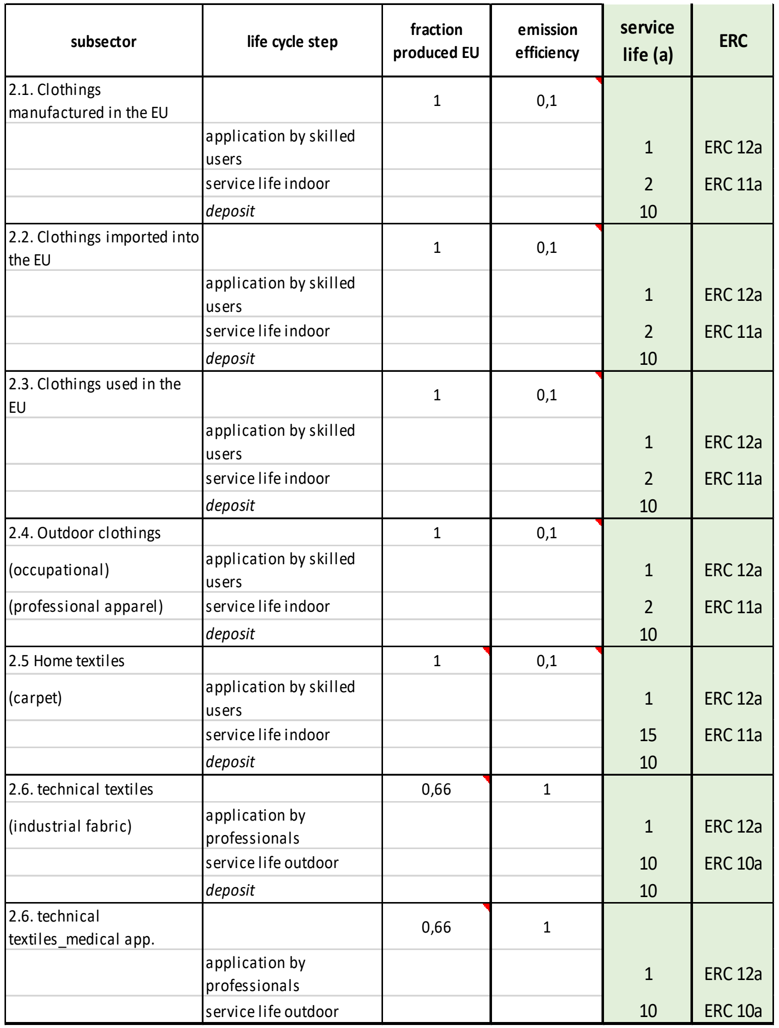
Table 10. Summary of emissions assessment for textiles

<table>
<tr><th>Element</th><th>RAC understanding of the Dossier Submitter’s assumptions and calculations</th><th>RAC remarks</th></tr>
<tr><td colspan="3"><i>Amount of textiles used</i></td></tr>
<tr><td></td><td>Tonnage of textile products/articles (t/a) reported in Annex B.9.18, Table 25a

<table>
<tr><th>subsector</th><th>min</th><th>max</th></tr>
<tr><td>2.1. Clothings manufactured in the EU</td><td>1.200.000</td><td>3.600.0</td></tr>
<tr><td>2.2. Clothings imported into the EU</td><td>3.000.000</td><td>17.000.0</td></tr>
<tr><td>2.3. Clothings used in the EU</td><td>4.800.000</td><td>14.600.0</td></tr>
<tr><td>2.4. Outdoor clothings</td><td>76.000</td><td>194.0</td></tr>
<tr><td>2.5 Home textiles</td><td>620.605</td><td>1.800.0</td></tr>
<tr><td>2.6. technical textiles</td><td>270.000</td><td>520.0</td></tr>
<tr><td>2.6. technical textiles_medical app.</td><td>54.000</td><td>104.0</td></tr>
</table></td><td><i>The amounts reported in the supporting Excel files are similar to those in Table 25a, Annex B.9.18 of the Background Document. In the Background Document the term ‘occupational wear’ is used as synonym for professional apparel or home textiles and ‘industrial fabric’ is used as a synonym for ‘technical textiles’. These terms are used throughout the Background Document. A key assumption is that 100% of each textile category is treated with C6 side-chain fluorinated polymers.</i></td></tr>
<tr><td colspan="3"><i>Releases estimation</i></td></tr>
<tr><td>General assumptions</td><td><i>Manufacture of professional apparel</i>
Applied concentration for the C6 side chain polymers was 0.2 – 0.5 % (w/w); in the estimations the maximum value of 0.5 % was used.
The applied concentration for the low molecular weight PFHxA related substances and PFHxA were the median measured concentrations of FTOH 6:2 and PFHxA, respectively, from literature. To account for the limited extraction of PFHxA related substances and PFHxA from textiles, the median concentrations were ‘corrected’ to what the Dossier Submitter refers to as the ‘real’ concentration based on a ‘back-calculation’ using the default release factors from ERC11a (multiplication by</td><td><i>To estimate the amounts of PFHxA related substances and PFHxA in textiles the Dossier Submitter used a so-called ‘back-calculation’ on the measured values to correct for extractability. RAC acknowledges that PFHxA related substances and PFHxA would not be completely extracted from textiles during chemical analysis. However, RAC does not fully support the methodology applied by the Dossier Submitter to back-calculate the ‘real’ concentrations using ERC default release factors. Firstly, default release factors are different for the different ERCs (factor 100/0.1 and a factor of 100/6.45). RAC considers that it would be more logical to apply a general correction factor for extractability. Literature may provide an indication of extractability based on a comparison with total PFAS or total F (e.g. Robel et al 2017). Based on the data in that</i></td></tr>
</table>

	factor 100/0.1 – assumption of 0.1 % extraction) or ERC 10a (multiplication by factor 100/6.45 – assumption of 6.45 % extraction). Minimum and maximum amounts of side chain polymers, PFHxA related substances and PFHxA (t/a) were estimated by multiplying the amount of product (min/max in t/a) by the 'real' concentrations in most cases except for the medical textiles. For medical textiles, the maximum amount of products was multiplied by minimum and maximum concentrations observed and a factor of 0.66 was applied to represent the amount produced within Europe. For the releases an ERC-based assessment was applied minimum and maximum amounts. 'Real' (back calculated) amounts were used for the estimations for application (ERC 12a) and waste disposal, whereas during service life (ERC 10a or 11a) the amounts were based on median measured amounts multiplied by volume of the product (t/a). ERC 12a (Processing of articles at industrial sites with low release) was applied to application by skilled users or application by professionals. To all releases of ERC 12a an extra factor of 0.1 was applied by Dossier Submitter 'due to effective manufacturing and recycling, about 10% of default release is assumed'. This factor was not applied in the case of industrial fabric and medical textiles. ERC 11a (indoor) was applied to the service life volume of textiles, apart from for industrial fabrics and medical textile where ERC 10a (outdoor) was applied. The emissions to the various compartments were accumulated to a total minimum and maximum value, which were then divided by the duration of the service life. In the case of industrial fabric, a factor of 0.66 (production within the EU) was applied to the releases for PFHxA related substances and PFHxA. (In the medical	*publication, 1% extractability seems to be a more realistic choice than 0.1%. Depending on the ERCs that the Dossier Submitter took as starting point, it seems that ERC 11a (0.1%) may overestimate the amounts, whereas ERC 10a (6.45) may underestimate the amounts. Back calculation was only applied for application by professionals/skilled users and waste.* *RAC notes that the impact of the back calculation is largest on the waste disposal releases and further remarks are made there*. *The Dossier Submitter applied an extra factor of 0.1 to* ***industrial application releases*** *to correct for effective manufacturing. RAC notes that the Dossier Submitter refers to ERC 6c for applying an extra release factor of 0.1 for the manufacturing life cycle, whereas in the estimations ERC 12a is being applied. In the Background Document, this is confirmed only for the C6 polyacrylate production: 'However, stakeholders reliably demonstrated a high reduction of environmental releases by effective mitigation measurement at C6 polyacrylate production. Therefore only 10% from the values calculated according ERC 6c are finally expected to be released into the environment.'* *RAC acknowledges that ERC default release factors are intended to be modified (as they assume that no RMMs are in place). However, the Dossier Submitter did not provide any substantiated justification for the additional factor of 0.1 % applied at the manufacturing life-cycle stage. This could lead to releases being underestimated.*

	textiles this factor was already applied to the amount used). Releases from the waste life cycle stage (disposal via landfill) were only estimated for PFHxA related substances and PFHxA. It was estimated using the minimum/maximum tonnage of PFHxA related substance or PFHxA (minus the quantity released during service life) multiplied by 0.6 (assumed fraction to landfill) and divided by the service life of landfill (assumed to be 10 years). The releases from the waste life cycle stage (i.e. disposal in landfill), based on the supporting Excel files, could be reproduced by RAC.	
	Service life The parameters used for the release estimations for the application by skilled users, or in the case of industrial fabric and medical textiles application by professionals, and the releases during service life are indicated below. For <u>releases during application by skilled users or professionals</u> ERC 12a was applied for the C6 side chain fluorinated polymers, PFHxA related substances and PFHxA. ERC 12a was modified by the Dossier Submitter with an extra factor of 0.1 *'due to effective manufacturing and recycling, about 10% of default release is assumed'*. This factor was not applied for industrial fabrics and medical textiles. For <u>releases during service life</u> in most cases an indoor service life of 2 years was assumed and ERC 11a was applied on the estimated amounts of the substance(s). In the case of home textiles (carpet) a 15-year service life was assumed. In the case of industrial fabric and medical textiles and outdoor service life of 10 years was assumed and ERC 10a was applied for estimating the releases.	*Annex B.9.2: the use of products or articles from the point of sale to the point of disposal is defined as service life.* *The use of articles containing PFHxA, its salts and related substances are considered as wide dispersive uses.* *Because there are no intended or high releases, the ERCs for widespread use of articles with low release indoor (ERC 11a) or outdoor (ERC 10a) are applied.* *The annual release of PFHxA, its salts and related substances is calculated dividing the estimated total release by the service lifetime.* *RAC notes that dividing releases by the article service life could be reasonably considered to represent annual releases during the 1st year of use, but would underestimate the total releases associated with the 'use tonnage' of a particular year as releases would typically occur over several years (and in some cases would not occur until many years after use). RAC notes that it is not common practice to apportion releases across multiple years in a simple deterministic release model. Such an approach could underestimate annual releases unless carefully considered in a dynamic cumulative release model (which does not appear to be*

	This approach was followed for the C6 side chain polymers. In case of the PFHxA related substances and PFHxA another approach was followed for service life releases. In this case, instead of the back-calculated 'real' concentration, median measured concentrations from literature were multiplied by the minimum/maximum amount of product and divided by the service life. This in contrast to the estimations for skilled users/professionals. In the case of industrial fabric, a factor of 0.66 (production within the EU) was applied to the releases for PFHxA related substances and PFHxA but not for the C6 side chain fluorinated polymers. For medical textiles, this factor was already applied to the amount used and thus applied to the release of all three substance groups. The parameters for the estimations for the releases from textile are provided below, based on the Excel files.	*the case here). The magnitude of underestimation would vary depending on the duration of the service life, with releases from home textiles (15-year service life), industrial textiles and medical textiles (10-year service life) more substantially underestimated than for articles with shorter service lives (i.e. 2 years).* *No explanation was provided on why a fraction production (0.66) was applied to the releases of PFHxA related substance and PFHxA for industrial fabric and to C6 side chain fluorinated polymers, PFHxA related substance and PFHxA, but not for the other textile subsectors. No further explanation was provided why an extra release factor (0.1) was applied to the release from application by skilled users/professionals (ERC 12a) for all subsectors except for industrial fabric and medical applications.* *The only text that could be found on textile waste is in Annex B.9.5.2.1 "Annually 1.6 million tonnes of carpets are becoming waste. Thereof 60 % are disposed in landfills, 37 % are incinerated and only 3 % of the textile floor coverings are recycled (European Public Health Alliance, 2016)." Furthermore a 60 % disposal to landfills is assumed based on Geyer et al 2017." However, the Dossier Submitter indicates that the releases from waste are very uncertain.* *RAC questions the approach followed by the Dossier Submitter for the waste disposal estimations where the total amount (back calculated) is released completely within 10 years. The default release factor from ECHA Guidance R.18 is 3.2 % (total over 20 years). As the Dossier Submitter assumes 100% over 10 years this corresponds to an annual release of 10 %. Therefore, if the model assumes a single year (see comment above) release from landfill is likely to be moderately overestimated (factor ~3). If the model integrates over a period of 10 years release from landfill is substantially overestimated (by >90%).* *The above cited paper by Robel et al. (2017) further indicates that after extraction, papers and textiles retained 64 ± 28% to 110 ± 30% of the original nmol F/cm2 as determined by PIGE,*



subsector	life cycle step	fraction produced EU	emission efficiency	service life (a)	ERC
2.1. Clothings manufactured in the EU		1	0,1		
	application by skilled users			1	ERC 12a
	service life indoor			2	ERC 11a
	deposit			10	
2.2. Clothings imported into the EU		1	0,1		
	application by skilled users			1	ERC 12a
	service life indoor			2	ERC 11a
	deposit			10	
2.3. Clothings used in the EU		1	0,1		
	application by skilled users			1	ERC 12a
	service life indoor			2	ERC 11a
	deposit			10	
2.4. Outdoor clothings		1	0,1		
(occupational)	application by skilled users			1	ERC 12a
(professional apparel)	service life indoor			2	ERC 11a
	deposit			10	
2.5 Home textiles		1	0,1		
(carpet)	application by skilled users			1	ERC 12a
	service life indoor			15	ERC 11a
	deposit			10	
2.6. technical textiles		0,66	1		
(industrial fabric)	application by professionals			1	ERC 12a
	service life outdoor			10	ERC 10a
	deposit			10	
2.6. technical textiles_medical app.		0,66	1		
	application by professionals			1	ERC 12a
	service life outdoor			10	ERC 10a

indicating that the majority of fluorine remains associated with the papers and textiles, which may indicate that release goes rather slow.

	Waste life-cycle stage Amounts disposed (termed 'deposited' by the Dossier Submitter) are only estimated for the C6 side chain fluorinated polymers and are assumed to be 60% of the total volume (based on the quantity estimated to be disposed via landfill rather than any other route). Estimations of release from the waste life cycle stage are only estimated for PFHxA related substances and PFHxA in one of the supporting Excel files, but are not estimated for C6 side chain fluorinated polymers. In some cases, the waste life cycle stage is included in the release estimations (e.g. for clothing manufactured in the EU), but in other subsectors it seems not.	*RAC was not able to evaluate the releases from waste disposal to the full extent as the information provided in the Background Document and the Excel files did not enable to do so.* *From the information provided in the Excel files, it was clear that 90-95% of the total releases can be attributed to the waste life cycle. Based on the Dossier Submitter's assumptions, e.g. the 100% application to textiles and the applied correction for extractability, the annual releases through waste disposal may be substantially overestimated.*
Calculations of releases estimation		
C6 side-chain fluorinated polymers		
Tonnage of C6 side-chain fluorinated polymers in textiles per year	Min/Max estimates of used tonnage calculated using the min/max amount of the textiles multiplied by the maximum C6 side-chain fluorinated polymers concentration applied in textiles. Min/max tonnage C6 side chain fluorinated polymers = min max tonnage products x applied concentration (0.5%) Minimum and maximum used tonnages C6 side chain fluorinated polymers (t/a), based on the additional information provided in the Excel files	*A key assumption is that 100% of each textile category is treated with C6 side-chain fluorinated polymers. RAC considers that clothing is a very broad category and expects the share of material being treated to be at least less than the share for outdoor clothing <50%. RAC concludes that assuming that 100% of the amount of textile being treated with C6 side-chain fluorinated polymers would provide unrealistic results. RAC is of the opinion that, for a sound estimation, the share of textile being treated should be differentiated for each textile category and that, as a best guess, the average value of the measured concentrations could be used. In order to calculate the releases resulting from typical concentrations of SFPs applied to treated textile, the only option is to differentiate treatment shares for each textile category. RAC is of the opinion that the 100% treatment assumption may lead at least to a 2-fold overestimation.*

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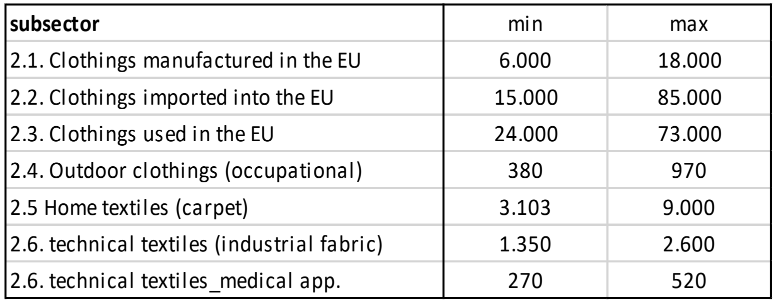
<table>
<tr><th>subsector</th><th>min</th><th>max</th></tr>
<tr><td>2.1. Clothings manufactured in the EU</td><td>6.000</td><td>18.000</td></tr>
<tr><td>2.2. Clothings imported into the EU</td><td>15.000</td><td>85.000</td></tr>
<tr><td>2.3. Clothings used in the EU</td><td>24.000</td><td>73.000</td></tr>
<tr><td>2.4. Outdoor clothings (occupational)</td><td>380</td><td>970</td></tr>
<tr><td>2.5 Home textiles (carpet)</td><td>3.103</td><td>9.000</td></tr>
<tr><td>2.6. technical textiles (industrial fabric)</td><td>1.350</td><td>2.600</td></tr>
<tr><td>2.6. technical textiles_medical app.</td><td>270</td><td>520</td></tr>
</table>
Table 25b in Annex B.9.18 reports similar amounts.
</td>
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<tr>
<td>Industrial treatment of textiles ERC 12a
Air, water and soil</td>
<td>For <u>releases during application by skilled users or professionals</u> a service life of 1 year was assumed and ERC 12a was applied for the C6 side chain fluorinated polymers. To all releases of ERC 12a an extra factor of 0.1 was applied according to the Dossier Submitter ‘due to effective manufacturing and recycling, about 10% of default release is assumed’. This factor was not applied in the case of industrial fabric and medical textiles.
The generic formula applied was: amount product*min./max. concentration*(produced within EU =1)*(∑ERC12a/100)/(service life =1)*(effectivity emissions =0,1 except for industrial fabric + medical textiles: 1).
The estimations resulted in a cumulated release of C6 side chain fluorinated polymers from textile because of application by skilled users or professionals of 465-1590 t/a.</td>
<td><i>For all textile sectors, an extra release factor of 0.1 was applied to the releases above ERC 12a assuming effective manufacturing and recycling. However, this was not applied for industrial textiles and medical textiles, which was not substantiated by the Dossier Submitter. Thus, releases of these two sectors may have been overestimated in the calculations. As these two subsectors are only a very minor part of the total releases from the textiles sector, it probably hardly affects the total release of textile.</i></td>
</tr>
<tr>
<td>Service life indoor ERC 11a
Air, water and soil</td>
<td>For <u>releases during service life</u> in most cases a service life indoor of 2 years was assumed and ERC 11a was applied on the estimated amounts of the substance(s). In the case of home textiles (carpet) 15-year service life was assumed. In the case of industrial fabric and medical textiles the scenario was service life outdoor, a service life of 10 years was assumed and ERC 10a was applied</td>
<td><i>The figures presented in the column on the left are not mentioned in the Background Document nor in its annexes. Except for the total amounts released from clothing manufactured in the EU and from service live of the imported clothing, numbers in the additional supporting information were different from those in Table 25b, Annex B.9.18.</i></td>
</tr>
</table>

	for estimating the releases. This approach was followed for the C6 side chain polymers. The generic formula applied was: amount product*min./max. concentration*(produced within EU =1)*(∑ERC11a/100 or ∑ERC10a/100) /(service life =1)*(effectivity emissions =1). The estimations resulted in a cumulated release of C6 side chain fluorinated polymers from textile during service life of 32-106 t/a.	

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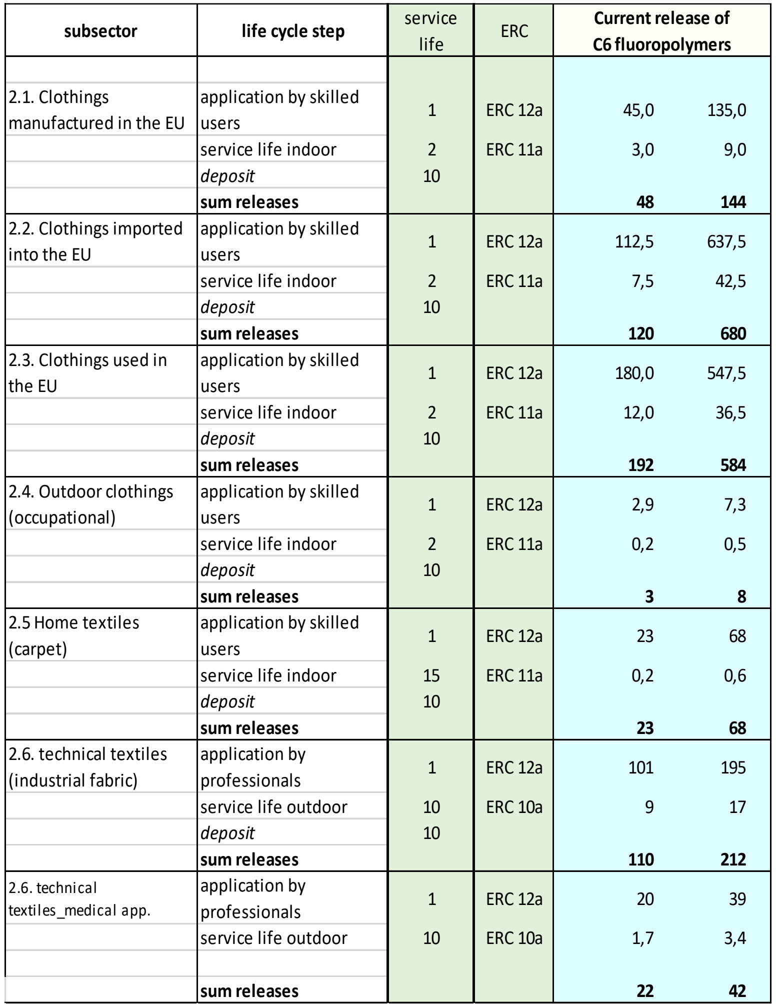
<table>
<tr><th>subsector</th><th>life cycle step</th><th>service life</th><th>ERC</th><th colspan="2">Current release of C6 fluoropolymers</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>2.1. Clothings manufactured in the EU</td><td>application by skilled users</td><td>1</td><td>ERC 12a</td><td>45,0</td><td>135,0</td></tr>
<tr><td></td><td>service life indoor</td><td>2</td><td>ERC 11a</td><td>3,0</td><td>9,0</td></tr>
<tr><td></td><td><i>deposit</i></td><td>10</td><td></td><td></td><td></td></tr>
<tr><td></td><td>sum releases</td><td></td><td></td><td>48</td><td>144</td></tr>
<tr><td>2.2. Clothings imported into the EU</td><td>application by skilled users</td><td>1</td><td>ERC 12a</td><td>112,5</td><td>637,5</td></tr>
<tr><td></td><td>service life indoor</td><td>2</td><td>ERC 11a</td><td>7,5</td><td>42,5</td></tr>
<tr><td></td><td><i>deposit</i></td><td>10</td><td></td><td></td><td></td></tr>
<tr><td></td><td>sum releases</td><td></td><td></td><td>120</td><td>680</td></tr>
<tr><td>2.3. Clothings used in the EU</td><td>application by skilled users</td><td>1</td><td>ERC 12a</td><td>180,0</td><td>547,5</td></tr>
<tr><td></td><td>service life indoor</td><td>2</td><td>ERC 11a</td><td>12,0</td><td>36,5</td></tr>
<tr><td></td><td><i>deposit</i></td><td>10</td><td></td><td></td><td></td></tr>
<tr><td></td><td>sum releases</td><td></td><td></td><td>192</td><td>584</td></tr>
<tr><td>2.4. Outdoor clothings (occupational)</td><td>application by skilled users</td><td>1</td><td>ERC 12a</td><td>2,9</td><td>7,3</td></tr>
<tr><td></td><td>service life indoor</td><td>2</td><td>ERC 11a</td><td>0,2</td><td>0,5</td></tr>
<tr><td></td><td><i>deposit</i></td><td>10</td><td></td><td></td><td></td></tr>
<tr><td></td><td>sum releases</td><td></td><td></td><td>3</td><td>8</td></tr>
<tr><td>2.5 Home textiles (carpet)</td><td>application by skilled users</td><td>1</td><td>ERC 12a</td><td>23</td><td>68</td></tr>
<tr><td></td><td>service life indoor</td><td>15</td><td>ERC 11a</td><td>0,2</td><td>0,6</td></tr>
<tr><td></td><td><i>deposit</i></td><td>10</td><td></td><td></td><td></td></tr>
<tr><td></td><td>sum releases</td><td></td><td></td><td>23</td><td>68</td></tr>
<tr><td>2.6. technical textiles (industrial fabric)</td><td>application by professionals</td><td>1</td><td>ERC 12a</td><td>101</td><td>195</td></tr>
<tr><td></td><td>service life outdoor</td><td>10</td><td>ERC 10a</td><td>9</td><td>17</td></tr>
<tr><td></td><td><i>deposit</i></td><td>10</td><td></td><td></td><td></td></tr>
<tr><td></td><td>sum releases</td><td></td><td></td><td>110</td><td>212</td></tr>
<tr><td>2.6. technical textiles_medical app.</td><td>application by professionals</td><td>1</td><td>ERC 12a</td><td>20</td><td>39</td></tr>
<tr><td></td><td>service life outdoor</td><td>10</td><td>ERC 10a</td><td>1,7</td><td>3,4</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>sum releases</td><td></td><td></td><td>22</td><td>42</td></tr>
</table>
These figures have been provided by the Dossier Submitter in the supporting information (Excel files).
</td>
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<tr>
<td>Waste (termed ‘deposit’</td>
<td><i>Waste life-cycle stage</i></td>
<td><i>RAC questions whether release of C6 side chain fluorinated polymers from waste disposal should not be included. Although RAC can imagine that the C6 side chain fluorinated polymers</i></td>
</tr>
</table>

by the Dossier Submitter)	Amounts ‘used’ in disposal are only estimated for the C6 side chain fluorinated polymers and are 60% of the total volume. Estimations of release from waste are only estimated for PFHxA related substances and PFHxA in one of the supporting Excel files, but are not estimated for C6 side chain fluorinated polymers.	*stay within the disposal, while the degradation products are released through the percolate, this has not been substantiated by the Dossier Submitter. And even if that is the case, it may be questioned whether a 1% degradation followed by the proper scenario for waste disposal should be applied. RAC concludes that release through the C6 side chain fluorinated polymers may have been underestimated.*
Annual release	Table 25b in Annex B.9.18 reports a total release of C6 side chain fluorinated polymers for the textiles of **127-409 t/a.** According to the footnote to the table 25b in the Background Document the amount released from: 2.1. Clothing manufactured in the EU* 2.2. clothing imported into the EU* are not included within the overall sum, because the number are already included in other (sub-)categories. Then, according to the Dossier Submitter, the total release of C6 side chain fluorinated polymers for the textiles is **72 - 222 t/a.**	*RAC estimations lead to a C6 side chain fluoropolymer release of 496-1696, when excluding the release due to application by skilled users from imported clothing this becomes* ***384 -1058 t/a.*** *It does not seem possible to explain the difference between the estimations by the Dossier Submitter and those by RAC based on the information provided in the Background Document.*
Low molecular weight C6 related substances precursors		
Tonnage of *low molecular weight C6 precursors* in textiles per year	The tonnage of PFHxA related substances is provided below in t/a. It is further indicated whether the median of the measured concentrations was used or the minimum and maximum concentration. Amounts were estimated by multiplying the minimum and maximum tonnages of the products, except for the medical textiles where the average was used multiplied by minimum and maximum concentration. Amounts (t/a) were back calculated using the assumed releases (ERC) (see the general	

assumptions for explanation). The back calculation was assumed to represent the total amount of PFHxA related substances in the textile as the Dossier Submitter expected that only part of the substances would end up in the measurements.

Subsector		**min**	**max**
2.1. Clothing manufactured in the EU	concentration	median	
(man EU)	concentration	4,45E-06	
	ERC back calculation	ERC 11a	
	total amount	5.340	16.020
2.2. Clothing imported into the EU	concentration	median	
(imp EU)	concentration	4,45E-06	
	ERC back calculation	ERC 11a	
	total amount	13.350	75.650
2.3. Clothing used in the EU	concentration	median	
(used EU)	concentration	4,45E-06	
	ERC back calculation	ERC 11a	
	total amount	21.360	64.970
2.4. Outdoor clothing (occupational)	concentration	median	

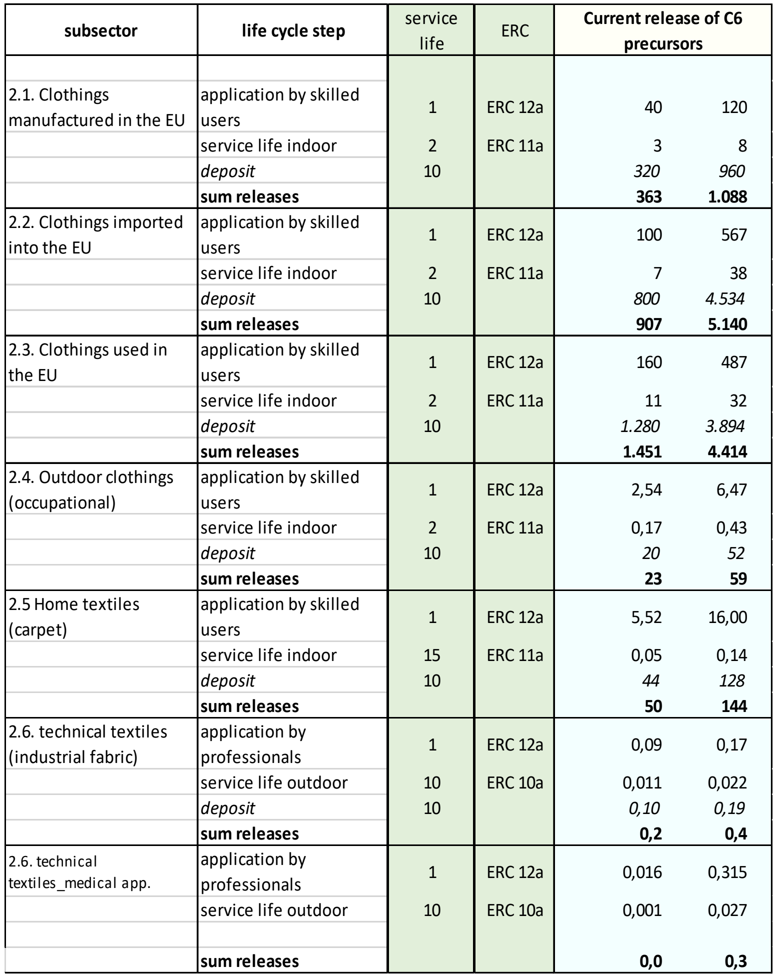
(professional apparel)	concentration	4,45E-06	
	ERC back calculation	ERC 11a	
	total amount	338	863
2.5 Home textiles (carpet)	concentration	median	
	concentration	1,19E-06	
	ERC back calculation	ERC 11a	
	total amount	735	2.133
2.6. technical textiles (industrial fabric)	concentration	median	
	concentration	4,15E-07	
	ERC back calculation	ERC 10a	
	total amount	1,74	3,35
2.6. technical textiles_medical app.	concentration	min	max
	concentration	4,00E-08	7,90E-07
	ERC back calculation	ERC 10a	
	total amount	0,21	4,20

Table 25c in Annex B.9.18 reports similar amounts than the amounts reported above from the Excel files, except for the medical textiles where a 1.5 times higher amount

	for the minimum and 5 times lower amount for the maximum are reported in Annex B.9.18.	
Releases calculated per environment compartment	The parameters used for the release estimations for both the application by skilled users, or in the case of industrial fabric and medical textiles application by professionals and the releases during service life are indicated below. For releases during application by skilled users or professionals a service life of 1 year was assumed and ERC 12a was applied for the C6 side chain fluorinated polymers, the PFHxA related substances and PFHxA. To all releases of ERC 12a an extra factor of 0.1 was applied according to the Dossier Submitter ‘due to effective manufacturing and recycling, about 10% of default release is assumed’. This factor was not applied in the case of industrial fabric and medical textiles. In case of the release of PFHxA related substances and PFHxA during service life another approach was followed compared to professional or skilled users. In this case, not the estimated amounts (based on the back calculation) were used as a starting point, but medium concentrations were multiplied by the minimum/maximum amount of product and divided by the service life. In most cases a service life indoor of 2 years was assumed. In the case of home textiles (carpet) 15-year service life was assumed. In the case of industrial fabric and medical textiles the scenario was service life outdoor, a service life of 10 years was assumed. In the case of industrial fabric, a factor of 0.66 (production within the EU) was applied to the releases for PFHxA related substances and PFHxA but not for the C6 side chain fluorinated polymers. In the medical textiles	

	this factor was already applied to the amount used and thus applied to all three substance groups.	
Industrial treatment of textiles ERC 12a **Air, water and soil**	For releases during application by skilled users or professionals a service life of 1 year was assumed and ERC 12a was applied for the C6 side chain fluorinated polymers. To all releases of ERC 12a an extra factor of 0.1 was applied according to the DS 'due to effective manufacturing and recycling, about 10% of default release is assumed'. This factor was not applied in the case of industrial fabric and medical textiles. The generic formulae applied was: amount product*min./max. concentration*100/(ERC11a = 0.1)*(produced within EU =1)*(ERC12a = 7.5/100)/(service life =1)* (effectivity emissions =0,1) The estimations resulted in a cumulated release of PFHxA related substances from textile because of application by skilled users or professionals of 309 - 1197 t/a.	
Service life outdoor ERC 11a	In case of the release of PFHxA related substances and PFHxA during service life another approach was followed compared to professional or skilled users. In this case not the estimated amounts (based on the back calculation) were used as a starting point, but medium concentrations were multiplied by the minimum/maximum amount of product and divided by the service life. In most cases a service life indoor of 2 years was assumed. In the case of home textiles (carpet) 15-year service life was assumed. In the case of industrial fabric and medical textiles the scenario was service life outdoor, a service life of 10 years was assumed. The generic formulae applied was: amount product*min./max. concentration*(produced within EU =1/(service life).	*The amount of 100 tonnes release through the medical applications over 20 years is not supported by RAC estimation neither by the numbers provided in Table 25c which are in the same range as RAC calculations.*

The estimations resulted in a cumulated release of PFHxA related substances from textile during service life of 20-79 t/a.



subsector	life cycle step	service life	ERC	Current release of C6 precursors	
2.1. Clothings manufactured in the EU	application by skilled users	1	ERC 12a	40	120
	service life indoor	2	ERC 11a	3	8
	deposit	10		*320*	*960*
	sum releases			**363**	**1.088**
2.2. Clothings imported into the EU	application by skilled users	1	ERC 12a	100	567
	service life indoor	2	ERC 11a	7	38
	deposit	10		*800*	*4.534*
	sum releases			**907**	**5.140**
2.3. Clothings used in the EU	application by skilled users	1	ERC 12a	160	487
	service life indoor	2	ERC 11a	11	32
	deposit	10		*1.280*	*3.894*
	sum releases			**1.451**	**4.414**
2.4. Outdoor clothings (occupational)	application by skilled users	1	ERC 12a	2,54	6,47
	service life indoor	2	ERC 11a	0,17	0,43
	deposit	10		*20*	*52*
	sum releases			**23**	**59**
2.5 Home textiles (carpet)	application by skilled users	1	ERC 12a	5,52	16,00
	service life indoor	15	ERC 11a	0,05	0,14
	deposit	10		*44*	*128*
	sum releases			**50**	**144**
2.6. technical textiles (industrial fabric)	application by professionals	1	ERC 12a	0,09	0,17
	service life outdoor	10	ERC 10a	0,011	0,022
	deposit	10		*0,10*	*0,19*
	sum releases			**0,2**	**0,4**
2.6. technical textiles_medical app.	application by professionals	1	ERC 12a	0,016	0,315
	service life outdoor	10	ERC 10a	0,001	0,027
	sum releases			**0,0**	**0,3**

The amounts above have been provided in the supporting information. Except for the total amounts released from clothing manufactured in the EU, releases from ∑service

	live and disposal of the imported clothing and releases from occupational wear, numbers in Table 25c in Annex B.9.18 are different. The Dossier Submitter remarks in Annex B.9.5: "It is assumed that two third of industrial fabrics are manufactured in the EU. It is further assumed that more than 20% of industrial fabrics are used for medical applications. This might result in emissions from medical textiles of up to 100 t PFHxA-related substances over 20 years. This is a very uncertain estimate.	
Waste (disposal) **Not taken into account in the estimations**	*Waste life-cycle stage* Amounts 'used' in disposal are only estimated for the C6 side chain fluorinated polymers and are 60% of the total volume. Estimations of release from waste are only estimated for PFHxA related substances and PFHxA in one of the supporting Excel files, but are not estimated for C6 side chain fluorinated polymers. For most of the subsectors they contribute most to the releases. The formula applied is the following: release through waste (t/a) =((total amount of PFHxA related substances (t/a)-(release during service life (t/a)*$service life (a)))*0,6)/service life disposal (a), and where total amount of PFHxA related substances =amount of product (t/a) * concentration µg/kg) * 100 / (∑ERC (%)). Thus, in contrast to the estimations for application and service life in the release estimations for waste the back calculated amount of PFHxA related substances was used as starting point. No further treatment of the releases is assumed. The only text that could be found on releases through textile waste disposal is in Annex B.9.5.2.1 'Environmental exposure of textile': "Annually 1.6 million	*RAC questions the use of the total volume of PFHxA related substances based on the back calculation during a 10 years' service life of the disposal without applying the default release factors in ECHA R18 guidance. RAC applied an estimation following the R18 guidance for textile use and based on 1% extractability (instead of 0.1%) and applying the defaults release factors in R18 to the total amount of substance present (amount product x median concentration x extractability correction x ERCs) which resulted in releases being a factor 30 lower than that of the Dossier Submitter (1/10 x 3/100 x 10: with 1/10 applied for the higher extractability assumed, 3/100 for the ERCs and 10 to correct for the division by service life by the Dossier Submitter). Adding release from C6 side chain fluorinated polymers resulted finally in a value for the PFHxA release through waste that was 16-fold lower than that of the Dossier Submitter. The C6 side chain fluorinated polymers were not included in the waste estimation by the Dossier Submitter.* *Although most of RAC calculations are not precisely similar to those in Table 25c, they are all in the same order of magnitude.*

	tonnes of carpets are becoming waste. Thereof 60 % are disposed in landfills, 37 % are incinerated and only 3 % of the textile floor coverings are recycled (European Public Health Alliance, 2016)”. Furthermore a 60 % disposal to landfills is assumed, based on Geyer et al. (2017) and the Dossier Submitter remarks that subsequently, together with the articles and products the containing PFHxA, its salts and related substances are also disposed in the same share. The Dossier Submitter indicates that the releases from waste are very uncertain. Although the Dossier Submitter indicates the uncertainties, the data presented show that the amounts presented in Table 25c do include the releases from waste disposal and that they are substantial.	
Annual release	Table 25c in Annex B.9.18 reports a total release of PFHxA related substances for the textiles of **2398-9882 t/a.** However, on page 57 of the Background Document, the Dossier Submitter indicates that: “Without a restriction, constant releases of PFHxA-related substances from textiles amount to **1 229 –4 225 t/a**”. RAC notes that the difference between these two values is related to the footnote to the table 25c in the Background Document: 2.1. Clothing manufactured in the EU* 2.2. clothing imported into the EU* are not included within the overall sum, because the number are already included in other (sub-)categories.	*RAC’s estimations showed that for the PFHxA related substances as well as for PFHxA waste determined between 90-95% of the releases. Thus, it contributes considerably to the total estimations following the Dossier Submitter’s approach.* *RAC estimations lead to a PFHxA related substances release of **2 794-10 845 t/a,** most of it due to the waste disposal.*
PFHxA and salts or impurity		

The tonnage of PFHxA is provided below in t/a. It is further indicated whether median of the measured concentrations was used or the minimum and maximum concentration. Amounts were estimated by multiplying the minimum and maximum tonnages of the products except for the medical textiles where the average was used multiplied by minimum and maximum concentration. Amounts (t/a) were back calculated using the assumed releases (ERC) (see the general assumptions for explanation). The back calculation was assumed to represent the total amount of PFHxA in the textile as the DS expected that only part of the substances would end up in the measurements.

Subsector		**min**	**max**
2.1. Clothing manufactured in the EU	concentration	median	
(man EU)	concentration	2,7450E-07	
	ERC back calculation	ERC 11a	
	total amount	329	988
2.2. Clothing imported into the EU	concentration	median	
(imp EU)	concentration	2,7450E-07	
	ERC back calculation	ERC 11a	
	total amount	824	4667
2.3. Clothing used in the EU	concentration	median	
(used EU)	concentration	2,7450E-07	
	ERC back calculation	ERC 11a	
	total amount	1318	4008

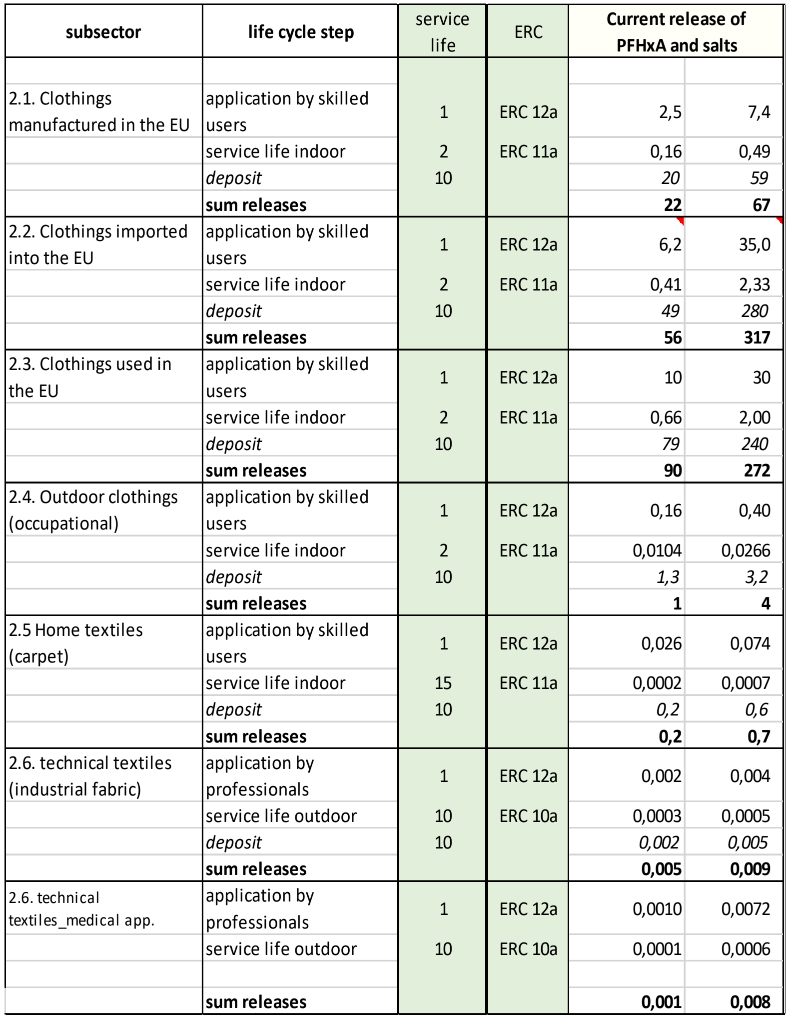
2.4. Outdoor clothing (occupational) (professional apparel)	concentration	median	
	concentration	2,7450E-07	
	ERC back calculation	ERC 11a	
	total amount	20,9	53,3
2.5 Home textiles (carpet)	concentration	median	
	concentration	5,5000E-09	
	ERC back calculation	ERC 11a	
	total amount	3,4	9,9
2.6. technical textiles (industrial fabric)	concentration	median	
	concentration	1,0200E-08	
	ERC back calculation	ERC 10a	
	total amount	0,043	0,082
2.6. technical textiles_medical app.	concentration	min	max
	concentration	2,40E-09	1,80E-08
	ERC back calculation	ERC 10a	
	total amount	0,013	0,10

Table 25d in Annex B.9.18 reports similar amounts than the amounts reported above from the Excel files, except

	for the medical textiles where Annex B.9.18 reports a 1.5-5 times lower amount.	
Releases calculated per environment compartment	The parameters used for the release estimations for both the application by skilled users, or in the case of industrial fabric and medical textiles application by professionals and the releases during service life are indicated below. The approach is similar to that for the PFHxA related substances. For <u>releases during application by skilled users or professionals</u> a service life of 1 year was assumed and ERC 12a was applied for the C6 side chain fluorinated polymers, the PFHxA related substances and PFHxA. To all releases of ERC 12a an extra factor of 0.1 was applied according to the Dossier Submitter 'due to effective manufacturing and recycling, about 10% of default release is assumed'. This factor was not applied in the case of industrial fabric and medical textiles. In case of the release of <u>PFHxA related substances and PFHxA</u> during service life another approach was followed compared to professional or skilled users. In this case not the estimated amounts (based on the back calculation) were used as a starting point, but medium concentrations were multiplied by the minimum/maximum amount of product and divided by the service life. In most cases a service life indoor of 2 years was assumed. In the case of home textiles (carpet) 15-year service life was assumed. In the case of industrial fabric and medical textiles the scenario was service life outdoor, a service life of 10 years was assumed. In the case of industrial fabrics, a factor of 0.66 (production within the EU) was applied to the releases for	

	PFHxA related substances and PFHxA but not for the C6 side chain fluorinated polymers. In the medical textiles this factor was already applied to the amount used and thus applied to all three substance groups.	
Industrial treatment of textiles **ERC 12a** **Air, water and soil**	For releases during application by skilled users or professionals a service life of 1 year was assumed and ERC 12a was applied for the C6 side chain fluorinated polymers. To all releases of ERC 12a an extra factor of 0.1 was applied according to the Dossier Submitter “due to effective manufacturing and recycling, about 10% of default release is assumed”. This factor was not applied in the case of industrial fabric and medical textiles. The generic formula applied was: amount product*min./max. concentration*100/(ERC11a = 0.1)*(produced within EU =1)*(ERC12a = 7.5/100)/(service life =1)* (effectivity emissions =0,1) The estimations resulted in a cumulated release of PFHxA related substances from textile because of application by skilled users or professionals of 19 - 73 t/a.	
Service life outdoor ERC 11a	In case of the release of PFHxA related substances and PFHxA during service life another approach was followed compared to professional or skilled users. In this case not the estimated amounts (based on the back calculation) were used as a starting point, but medium concentrations were multiplied by the minimum/maximum amount of product and divided by the service life. In most cases an indoor service life of 2 years was assumed. In the case of home textiles (carpet) 15-year service life was assumed. In the case of industrial fabric and medical textiles the scenario was service life outdoor, a service life of 10 years was assumed.	

	The generic formula applied was: amount product*min./max. concentration*(produced within EU =1/(service life). The estimations resulted in a cumulated release of PFHxA related substances from textile during service life of 1-5 t/a.	

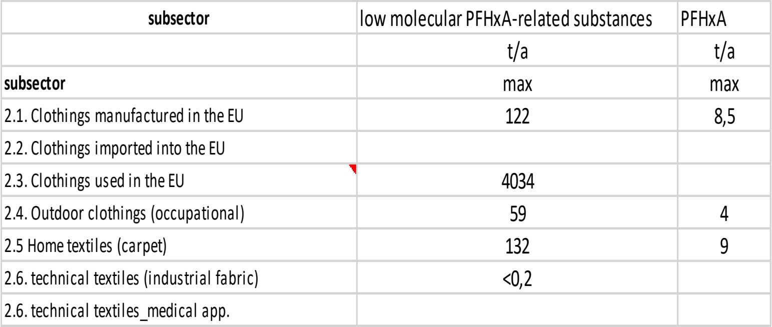


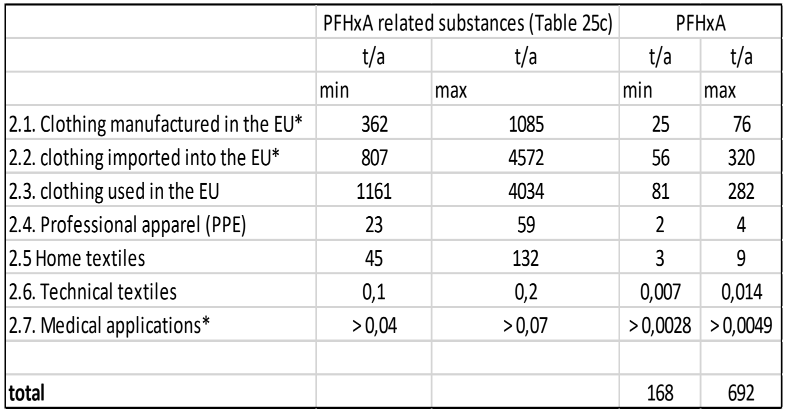
subsector	life cycle step	service life	ERC	Current release of PFHxA and salts	
2.1. Clothings manufactured in the EU	application by skilled users	1	ERC 12a	2,5	7,4
	service life indoor	2	ERC 11a	0,16	0,49
	deposit	10		*20*	*59*
	sum releases			**22**	**67**
2.2. Clothings imported into the EU	application by skilled users	1	ERC 12a	6,2	35,0
	service life indoor	2	ERC 11a	0,41	2,33
	deposit	10		*49*	*280*
	sum releases			**56**	**317**
2.3. Clothings used in the EU	application by skilled users	1	ERC 12a	10	30
	service life indoor	2	ERC 11a	0,66	2,00
	deposit	10		*79*	*240*
	sum releases			**90**	**272**
2.4. Outdoor clothings (occupational)	application by skilled users	1	ERC 12a	0,16	0,40
	service life indoor	2	ERC 11a	0,0104	0,0266
	deposit	10		*1,3*	*3,2*
	sum releases			**1**	**4**
2.5 Home textiles (carpet)	application by skilled users	1	ERC 12a	0,026	0,074
	service life indoor	15	ERC 11a	0,0002	0,0007
	deposit	10		*0,2*	*0,6*
	sum releases			**0,2**	**0,7**
2.6. technical textiles (industrial fabric)	application by professionals	1	ERC 12a	0,002	0,004
	service life outdoor	10	ERC 10a	0,0003	0,0005
	deposit	10		*0,002*	*0,005*
	sum releases			**0,005**	**0,009**
2.6. technical textiles_medical app.	application by professionals	1	ERC 12a	0,0010	0,0072
	service life outdoor	10	ERC 10a	0,0001	0,0006
	sum releases			**0,001**	**0,008**

These figures have been provided by the Dossier Submitter in the supporting information (Excel files). Except for the total amounts released from clothing manufactured in the EU, releases from ∑service live and disposal of the imported clothing and releases from

	occupational wear, numbers in Table 25d in Annex B.9.18 are different. The differences are more or less comparable with those for the PFHxA related substances and could not be resolved with the information from the Background Document.	
Waste (disposal) **Not taken into account in the estimations**	*Waste life-cycle stage* Amounts 'used' in disposal are only estimated for the C6 side chain fluorinated polymers and are 60% of the total volume. Estimations of release from waste are only estimated for PFHxA related substances and PFHxA in one of the supporting Excel files, but are not estimated for C6 side chain fluorinated polymers. Waste is included in the release estimations for the PFHxA related substances. For most of the subsectors they contribute most to the releases. The formula applied is the following: release through waste (t/a) =((total amount of PFHxA (t/a)-(release during service life (t/a)*$service life (a)))*0,6)/service life disposal (a), and where total amount of PFHxA related substances =amount of product (t/a) * concentration µg/kg)*100/(∑ERC (%)). Thus, in contrast to the estimations for application and service life in the release estimations for waste the back calculated amount of PFHxA related substances was used as starting point. No further treatment of the releases is assumed. The remarks made for waste disposal under the PFHxA related substances could be repeated here. There is little information available in the Background Document except for the 60% share of the total usage of each subsector.	

<table>
<tr>
<td>Annual release</td>
<td>Table 25d in Annex B.9.18 reports a total release of PFHxA related substances for the textiles of 159.1-1 647.3 t/a.
According to the footnote to the table 25b in the Background Document the amount released from:
2.1. Clothing manufactured in the EU*
2.2. clothing imported into the EU*
are not included within the overall sum, because the number are already included in other (sub-)categories. Then, according to the Dossier Submitter, the total release of C6 side chain fluorinated polymers for the textiles is 87 – 1 298 t/a.</td>
<td><i>RAC estimations lead to a PFHxA related substances release of 169-661 t/a, most of it due to the waste disposal.</i></td>
</tr>
<tr>
<td colspan="3">Recalculation to express releases in PFHxA</td>
</tr>
<tr>
<td></td>
<td></td>
<td><i>Taking the measured data for PFHxA plus the formation of PFHxA from C6 side chain fluorinated polymers and from related substances into account, according to RAC about 370-1 437 t/a of PFHxA may be released from textile.</i>
<table>
<tr><td colspan="2">C6 side chain fluorinated polymers</td><td colspan="2">PFHxA related substances</td><td colspan="2">PFHxA</td></tr>
<tr><td>min (t/a)</td><td>max (t/a)</td><td>min (t/a)</td><td>max (t/a)</td><td>min (t/a)</td><td>max (t/a)</td></tr>
<tr><td>5</td><td>17</td><td>196</td><td>759</td><td>169</td><td>661</td></tr>
</table>
<i>Annex B.9.18 presents a PFHxA release of 159 – 647 t/a in Table 25d. The reason for the difference with PFHxA above is small. However, the difference with the total release estimated by summing up the release of C6 side chain fluorinated polymers * 0.01 + the release from the PFHxA related substances * 0.07 and PFHxA is large. RAC noted that these are not presented in the Background Document e.g. in Table 25d.</i></td>
</tr>
</table>

<table>
<tr>
<td><i>C6 side-chain fluorinated polymers</i></td>
<td>Also, fluorotelomer based SFPs can degrade to form PFHxA. The transformation factor of 1% that was used in the PFOA restriction was suggested by RAC and applied by the Dossier Submitter in their calculations.</td>
<td></td>
</tr>
<tr>
<td><i>Low molecular weight C6 related substances</i></td>
<td>From a re-evaluation of the available scientific literature, a degradation factor of 7% of PFHxA from low molecular weight related substances was suggested by RAC and applied by the Dossier Submitter in their calculations.
Annex B.9.2 ‘General Assumptions made for environmental exposure estimations’ reports on the transfer from PFHxA related substances to PFHxA: “The resulting 70 kg PFHxA from 1 t/a related substances is used as a surrogate for the transformation of PFHxA related substances in general as a realistic worst case”. Table 25d in Annex B.9.18 summarises the equivalent PFHxA emission based on this scenario.
In the text of the Background Document the following data could be traced back for the releases of PFHxA related substances and the resulting PFHxA, where for the PFHxA the data for the realistic worst case has been taken (7% transformation rate applied):

<table>
<tr><th>subsector</th><th>low molecular PFHxA-related substances</th><th>PFHxA</th></tr>
<tr><td></td><td>t/a</td><td>t/a</td></tr>
<tr><td>subsector</td><td>max</td><td>max</td></tr>
<tr><td>2.1. Clothings manufactured in the EU</td><td>122</td><td>8,5</td></tr>
<tr><td>2.2. Clothings imported into the EU</td><td></td><td></td></tr>
<tr><td>2.3. Clothings used in the EU</td><td>4034</td><td></td></tr>
<tr><td>2.4. Outdoor clothings (occupational)</td><td>59</td><td>4</td></tr>
<tr><td>2.5 Home textiles (carpet)</td><td>132</td><td>9</td></tr>
<tr><td>2.6. technical textiles (industrial fabric)</td><td><0,2</td><td></td></tr>
<tr><td>2.6. technical textiles_medical app.</td><td></td><td></td></tr>
</table>
</td>
<td><i>Although the amounts presented for PFHxA in Table 25d are in the same range, they are not the same. The amounts presented here based on a 0.07 multiplication of the releases of the PFHxA related substances are slightly higher. Thus, RAC assumes that the data presented in Table 25d are based on the emissions of PFHxA only without taking into account the degradation from PFHxA related substances.</i></td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>In Table 25c, Annex B.9.18 releases for the PFHxA related substances are presented:

<table>
<tr><th></th><th colspan="2">PFHxA related substances (Table 25c)</th><th colspan="2">PFHxA</th></tr>
<tr><td></td><td>t/a</td><td>t/a</td><td>t/a</td><td>t/a</td></tr>
<tr><td></td><td>min</td><td>max</td><td>min</td><td>max</td></tr>
<tr><td>2.1. Clothing manufactured in the EU*</td><td>362</td><td>1085</td><td>25</td><td>76</td></tr>
<tr><td>2.2. clothing imported into the EU*</td><td>807</td><td>4572</td><td>56</td><td>320</td></tr>
<tr><td>2.3. clothing used in the EU</td><td>1161</td><td>4034</td><td>81</td><td>282</td></tr>
<tr><td>2.4. Professional apparel (PPE)</td><td>23</td><td>59</td><td>2</td><td>4</td></tr>
<tr><td>2.5 Home textiles</td><td>45</td><td>132</td><td>3</td><td>9</td></tr>
<tr><td>2.6. Technical textiles</td><td>0,1</td><td>0,2</td><td>0,007</td><td>0,014</td></tr>
<tr><td>2.7. Medical applications*</td><td>> 0,04</td><td>> 0,07</td><td>> 0,0028</td><td>> 0,0049</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>**total**</td><td></td><td></td><td>168</td><td>692</td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td>**PFHxA and salts or impurity**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>**Total releases from textiles**</td>
<td>The release estimations by the Dossier Submitter are rather complicated, they were not presented in a structured way and were not clearly reflected in the Background Document. Therefore, they could not be fully reproduced by RAC.
The release estimates by RAC for the C6 side chain fluorinated polymers were twice as high as those estimated by the Dossier Submitter, those for of PFHxA related substances for the textiles and for PFHxA were in a similar range. In some parts of the Background Document, releases of PFHxA related substances of half of the amount reported in Table 25c were reported, which has to be noted. It is also not clear whether the final data for PFHxA in Table 25d are the pure PFHxA</td>
<td>*The analysis by RAC indicated that taking all the releases estimated by the Dossier Submitter into account, release through waste disposal contributes considerably to the total releases.*
Using the data for textile use and using the amounts provided by the Dossier Submitter but applying a 1% extractability for PFHxA related substances and PFHxA (instead of 0.1%), the calculations (and not dividing by service life) resulted in 16x lower release factor of PFHxA for waste. On the total PFHxA release for textile use, the corrections applied by RAC lead to a 14-fold lower release. Assuming less than 50% for the amount of textile treated with C6 side chain fluorinated polymers would even add an extra factor of 2. Thus, RAC assumes that the</td>
</tr>
</table>

	releases based on PFHxA concentrations or whether they contain already the transformed releases of the C6 side chain fluorinated polymers (1%) and the PFHxA related substances (7%) - although this is mentioned in the text of the Background Document. The data presented above indicate that the final releases of PFHxA can mainly be attributed to the releases of PFHxA related substances and PFHxA. The C6 side chain fluorinated polymers do not contribute much to the final estimation (see Recalculation to express in PFHxA). From the estimations for the PFHxA related substances and PFHxA it appears that more than 90% of the releases are due to the releases from the waste life cycle stage, specifically disposal in landfill (see the tables presented above in the sections on PFHxA related substances and PFHxA). The data from the Dossier Submitter comes to a total PFHxA release of **159 – 647 t/a** based on Table 25d, whereas in estimations by RAC the total accumulated release (including C6 side chain polymer and PFHxA related substances degradation) to **370-1 437 t/a of PFHxA**. Thus, it is doubtful whether the data presented in Table 25d refer transformed releases. As indicated already above, more than 90% of these releases are due to waste disposal which the Dossier Submitter indicate as highly uncertain.	*PFHxA releases for textiles could be overestimated by a factor of 20-30.*

Firefighting foams

Summary of Dossier Submitter's proposal:

About 12 000 – 20 000 t of fluorosurfactant-based firefighting foam concentrates are placed on the market per year in Europe. According to EUROFEU[18], about 10% of this amount is used in fire accidents. As an alternative estimate 6 -15% of the amount of concentrate in stock is used in fire accidents. The Dossier Submitter assumed that 75 000 t are stockpiled in Europe based on data provided by FOEN[19]. For release estimation, an annual use of foam concentrates on fires of 2 000 t (10% of the maximum value of foams placed on the market) and 11 250 t (15% of stock) are used. It was estimated that the concentrate contains about 5% of fluorosurfactants. As a worst-case estimate the Dossier Submitter assumes that 100% of the foam used in fire events is released into the environment. Firefighting foams are not expected to combust during a fire outbreak. The Dossier Submitter used specific use information rather than ERCs for deriving the release estimate. The estimate of 10% of the maximum quantity of foams placed on the market, annually was assumed to represent a minimum annual release, the 15% of the stock a maximum annual release. This results in an **annual release of 100 - 563 t/a PFHxA related substances according to Table 25c and subsequently to a release of 7 - 39 t/a of PFHxA** into the European environment by professional firefighting operations. The Dossier Submitter did not distinguish between municipal and industrial fire-fighting (at fixed installations), specifically by accounting for differences in the operational conditions and risk management measures that are implemented.

PFHxA is found in firefighting foam concentrates. The presence of PFHxA was associated with remaining residues from the manufacturing process or due to storage degradation of the related substances. Concentrations vary from 76 to 14 217 µg PFHxA / kg concentrate. This results in grams of PFHxA being released in the environment.

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. The Dossier Submitter indicates that the use of perfluorinated substances in the aqueous film forming foams by volunteer fire brigades has been reduced within in the last years from 3 or 1 % to even 0.1 % foam solutions based on German data.

The formulation of firefighting concentrates at industrial sites occurs under strictly controlled conditions. In the Background Document the release of PFHxA and its related substances is assumed to be below 100 -250 kg/a during formulation.

In conclusion, a total of **7 to 39 t/a of PFHxA is likely to be released** through fire extinguishing agents by professional firefighting operations and professional workers into the European environment (Table 25d).

RAC Evaluation:

Based on information provided by sector organisations, the Dossier Submitter estimated a minimum and maximum value for the use of firefighting foams. The minimum value is based on a use rate of 10% of the amount of aqueous film forming foams placed on the market in the EU (20 000 t/a). The maximum value is derived from the amount of concentrates that is

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[18] EUROFEU- The European Committee of the Manufacturers of Fire Protection Equipment and Fire Fighting Vehicles (https://www.eurofeu.org/1/home/)

[19] FOEN – The Federal Office for the Environment (https://www.bafu.admin.ch/bafu/en/home/office.html)

stockpiled in Europe, about 75 000 t. Between 6 and 15% of this stock of concentrates is used in fire incidents. For release estimation an annual use of foam concentrates on fire of between 2 000 t and 11 250 t (15% of stock) are used. Hand-held extinguishers are considered as subset from total amount.

The Dossier Submitter assumed that firefighting foams will not be incinerated during an event of fire and 100% of the foam used is released into the environment and indicated that per- and polyfluorinated surfactants are detected in water samples after cases of fire, in water bodies, in extinguishing water and in the treated effluent of a sewage treatment plant, groundwater and surface water close to an oil storage depot, an international civilian airport, a military airport and a training centre for firefighters.

According to the Dossier Submitter, the formulation of firefighting concentrates at industrial sites occurs under strictly controlled conditions. Therefore, the release of PFHxA and its related substances is assumed to be below 100 -250 kg/a during formulation.

RAC considers that the assumption of 100 % release to the environment is a worst-case and unlikely to be representative of all applicable conditions of use[20]. Depending on the situation, especially at industrial sites and tank farms, there are risk management measures implemented (e.g. bunded areas) to control the release of fire waters to the environment. Nevertheless, foams used in fire incidents that are not contained and were discharged into the environment even in industrialised areas. Additional information on the distribution of the aqueous film forming foams among the different uses (e.g. petrochemical industry, airports, infrastructure (tunnels), municipal fire brigades etc) and data on collection in case of a fire may provide more insight in the risk management measures taken and their efficiency and enable a more realistic estimation of the release.

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[20] For instance, in the Buncefield accident about 33 million L of the 68 million L fire water were recovered after the fire despite failure of several bunds (Nicholas & Whitfield (2013). The Buncefield Accident and the Environmental Consequences for Fuel Storage Sites and other Sites in the UK, Regulated under the Seveso Directive. Chemical Engineering Transactions 31:457-462.).

Table 11. Summary of emissions assessment for firefighting foams

Element	**RAC understanding of the Dossier Submitter's assumptions and calculations**	**RAC remarks**
Amount of firefighting foam used		
	Current tonnage of products/ articles (t/a) used in the Background document: Background Document, page 31 reports that "about 12 000 - 20 000 t AFFF concentrate are placed on the market per year". Table 25a in Annex B.9.18 reports the same amount. The release estimations also take into account the about 75 000 t AFFF that are stockpiled. Annex B.9.7 (page 118) reports that "about 12 500 – 20 000 t/a AFFF concentrate are placed on the market in the EU". According to information from EUROFEU and extrapolation from European Commission DG Environment/ European Chemicals Agency (2020), these foams contain 480 - 560 t fluoro-surfactant. The amount of 480-560 t/a PFHxA and related substances is also mentioned under 'use tonnage' in Table 7 of the Background Document, pages 93-96, but Table 25c in Annex B.9.18 reports 100 – 563 t/a under 'use tonnage' of PFHxA related substances.	*The difference in the use tonnage between the Background Document and its annexes is not clear to RAC.*
Releases estimation		
General assumptions	*Manufacture of firefighting foams:* The formulation of firefighting concentrates at industrial sites occurs under strictly controlled conditions. Therefore, the release of PFHxA and its related substances is assumed to be below 100 - 250 kg/a during formulation (Annex B.9.7, page 119).	
	Service life: Estimates are based on the amount placed on the market and the amount in stock. It is assumed that 10% of the amount placed on the market is used on fire. This represents the minimum value of release in the Dossier Submitter estimations. It is assumed that about 15% of the stock is used on fire (represents the maximum	*The Dossier Submitter assumes that 100% of the fluoro-surfactants in the AFFF are PFHxA related substances, although this is not clearly stated in the Background Document and not substantiated, e.g. in Annex E.2.3.5 'Economic and other impacts' the Dossier Submitter*

	value of release). The Dossier Submitter assumes that the firefighting foam concentrates in general contain up to 5% fluoro-surfactants and that 100% of the foam used on fire is released into the environment. Furthermore, the Dossier Submitter assumes that 100% of the fluoro-surfactants are PFHxA related substances although this is not clearly stated in the Background Document or its annexes. For the further estimation, degradation to PFHxA is assumed to be 7% of the PFHxA related substances volume (Background Document, page 31, and Annex B.9.7, page 119). The Dossier Submitter only considers the PFHxA related substances. Side chain fluorinated polymers nor PFHxA itself are considered in the estimations.	*states: "With a concentration of PFAS surfactants in the foam of 2.5% this amounts to approximately 280 t/a." The assumed 5% is the maximum value of fluoro-surfactants in the foam concentrates and has been taken further in the estimation. Thus, it should be assumed as maximum. The Dossier Submitter further assumes a 100% release upon use, which has been commented by industry stakeholders during the consultation on the dossier.* *RAC notes that a clear explanation that substantiates the assumptions made by the Dossier Submitter in estimating the releases and the avoided releases is lacking in the Background Document and its annexes. RAC considers that such explanation would have improved the Background Document and RAC's insight of the assumptions considerably.*
	Waste life-cycle stage: Not considered in the Background Document and its annexes.	
Calculations of releases estimation		
C6 side-chain fluorinated polymers		
Tonnage of C6 side-chain fluorinated polymers in industrial fabrics per year	Not applicable	
Releases calculated per environment compartment	The Dossier Submitter reports in Annex B.9.18, Table 25b: no environmental release of C6 related polymers is expected.	
Industrial treatment of	Not applicable	

<table>
<tr><td>industrial fabric
ERC 12a
air, water and soil</td><td></td><td></td></tr>
<tr><td>service life indoor
ERC 11a
air, water and soil</td><td>Not applicable</td><td></td></tr>
<tr><td>Waste (deposit)</td><td>Releases from waste are not taken into account in the releases of the C6 side chain fluorinated polymers. See above under ‘Waste’.</td><td></td></tr>
<tr><td>Annual release</td><td>Not applicable</td><td></td></tr>
<tr><td colspan="3"><i>Low molecular weight C6 related substances precursors</i></td></tr>
<tr><td>Tonnage of <i>low molecular weight C6 precursors</i> in firefighting foam per year</td><td>The assumptions on volume and concentration mentioned above under general assumptions result in a release of 7- 39 t/a of PFHxA as indicated below (from the Background Document).
<table>
<tr><th></th><th colspan="2">Foam marketed</th><th>Foam stock</th><th>annual use</th><th>total use</th><th>PFHxA related fraction</th><th>release fraction to environment</th><th>release PFHxA fraction</th></tr>
<tr><td></td><td>min</td><td>max</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>t/a</td><td>t/a</td><td>t/a</td><td>fraction</td><td>t/a</td><td>0.05</td><td></td><td>0.07</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>sales</td><td>12000</td><td>20000</td><td></td><td>0.1</td><td>2000</td><td>100</td><td>1</td><td>7</td></tr>
<tr><td>stock</td><td></td><td></td><td>75000</td><td>0.15</td><td>11250</td><td>563</td><td>1</td><td>39</td></tr>
</table>
The Dossier Submitter reports the annual release of PFHxA related substances between 100 and 563 t/a in Annex B.9.7, page 119 and that applying the assumed 70 kg of PFHxA formed from related low molecular substances about 7 to 39 t/a of PFHxA is released into the environment. These amounts are also reported in Tables 25c and 25d (Annex B.9.18).
Further on in Annex E.2.3 the Dossier Submitter tries to further narrow down the amounts by applying a 50% lower fluoro-surfactant concentration (2.5% instead of 5%) and a smaller percentage to the stock used for extinguishing (10.5% instead of 15%). The Dossier Submitter finally selects the 15% amount used and the 2.5% concentration for further work and concludes that</td><td><i>The worst-case estimations in the Background Document (based on 86% transfer instead of 7%) have not been further considered by RAC as they were considered unrealistic. However, the use of different scenarios with different outcomes that still are present throughout the Background Document and the annexes hinders the transparency of the Dossier Submitter’s assessment.</i>

<i>The Dossier Submitter’s estimates of 100-563 t/a for the PFHxA related substances and 1-39 t/a for PFHxA could be reproduced by RAC. The upper bound estimate of 280 t/a could also be reproduced by RAC. However, the origin of the lower bound estimate of 48 t/a is not clear to RAC as it is not substantiated. RAC can agree with the assumptions on the percentage used per year and the PFHxA related substance concentration although the 5% should be considered as a maximum. RAC considers that the choice for concentration values used by the Dossier Submitter (15% amount used instead of 10.5% and of 2.5%</i></td></tr>
</table>

	therefore estimates that without a restriction emission to the environment amount to 48 – 280 t/a of PFHxA-related substances. In Annex E.2.3, Table 33 this is summarized: "Avoided PFHxA-related emissions: Unknown, but most likely in the range of **48 – 280 t/a** PFHxA related substances after transition period". RAC notes that these amounts are not yet recalculated to avoided PFHxA emissions.	*instead of 5%) could have been substantiated more clearly to underpin what data have been used in the estimations on avoided emissions.*
Releases calculated per environment compartment		
Industrial treatment of industrial fabric ERC 12a air, water and soil		
Service life outdoor ERC 11a		
Waste (deposit) Not taken into account in the estimations	Not considered in the Background Document and its annexes.	
Annual release	Two ranges were reported by the Dossier Submitter: **100 and 563 t/a** in Annex B.9.7, and **48 – 280 t/a** PFHxA related substances in Annex E.2.3.	
PFHxA and salts or impurity		
Tonnage of PFHxA and salts or impurity in firefighting foam per year		

Releases calculated per environment compartment		
Industrial treatment of industrial fabric **ERC 12a** **air, water and soil**		
Service life outdoor **ERC 11a**		
Waste (deposit) **Not taken into account in the estimations**	Not considered in the Background Document and its annexes.	
Annual release	The Dossier Submitter reports the annual release of PFHxA related substances between **100 and 563 t/a** in Annex B.9.7, page 119 and furthermore that applying the assumed 70 kg of PFHxA formed from 1 tonne of related low molecular substances about **7 to 39 t/a of PFHxA** is released into the environment. These amounts are also reported in Tables 25c and 25d (Annex B.9.18).	*RAC notes that the Dossier Submitter has followed a conservative approach taking worst-case assumptions for their estimations. The Dossier Submitter assumed the fluoro-surfactants to be 100% PFHxA related substances, took the maximum amount of 5% surfactants present in the concentrate and assumed a 100% release at use. Thus, it is likely that releases are overestimated severalfold.*
Recalculation to express in PFHxA	The original released amount of PFHxA related substances estimated by the Dossier Submitter results in emissions of about **7 to 39 t/a of PFHxA**.	
Low molecular weight C6 related substances **From a re-evaluation of the**	Not applicable	

available scientific literature, a degradation factor of 7% of PFHxA from low molecular weight related substances was suggested by the rapporteurs and agreed upon by RAC.		
C6 side-chain fluorinated polymers **Also, fluorotelomer based SFPs can degrade to form PFHxA. The transformation factor of 1% that is used in the PFOA restriction was suggested by RAC.**		
PFHxA and salts or impurity		
Total release releases from firefighting foam		*RAC notes that in the text on uncertainties (Annex E.2.3.8 ‘Uncertainties and sensitivity analysis’, Table 33), half of the emissions estimated above were presented.*

Inks and photographic uses

Summary of Dossier Submitter's proposal:

Small tonnages (15 t/a of C6-SFPs as worst-case estimation) are used in photographic equipment or in coatings when manufacturing conventional photographic films. Furthermore, short chain perfluorinated substances are used as surfactants in some water-based inkjet inks and latex inks. For the purpose of calculations, the Dossier Submitter assumed that 10-100 t/a of C6 precursors are used in ink applications. The releases from the formulation for this use was estimated with sector specific SPERCs (SpERC CEPE-4 for formulation and CEPE-20 for consumer use) by the Dossier Submitter. Furthermore, release from landfilled material (60 % of used material) was also considered by the Dossier Submitter. In Annex B.9.12.2 of the Background Document a release of PFHxA related substances of 8-80 t/a is reported. **A total amount of PFHxA released is estimated to 0.6-6 t/a PFHxA**

RAC evaluation:

C6 based short-chain fluorinated surfactants are used in some water-based inkjet inks and latex inks. These fluorinated surfactants provided the required performance of the inks. The Dossier Submitter assumed as worst-case a use of about 15 t/a of these substances in Europe.

According to the Dossier Submitter, many PFHxA-related substances are volatile. Therefore, for estimation of PFHxA release from printing inks, the CEPE SpERCs[21] for volatiles are used. According to SpERC CEPE4 (formulation of water borne coatings and inks in large scale; CEPE SPERC 2.2a.v1), 2.2 % of the used tonnage, 330 kg/a PFHxA- related substances are released to air during formulation. At the stage of consumer application, the Dossier Submitter assumed 1% (150 kg/a) into the air referring the SpERC CEPE 20 (application for indoor consumer use volatiles with brush/roller; CEPE SPERC 8a.1a.v1). The Dossier Submitter assumed that 50% of the remaining surfactants is released during service life stage of the imprinted paper (7.4 t/a). 60% of the amount that remains in paper of service life is landfilled (4.5 t/a).

RAC notes that according to CEPE 20 the total amount of the volatile surfactant is lost to air instead of 1% as assumed by the Dossier Submitter at the ink application stage. According to RAC the consequence of 100% release during ink application is that there are no releases at the subsequent service life stage and the waste stage. Instead of approximately 80% release to the environment, the release would be 100%. This affects the effectiveness of the restriction for this specific use (no release at service life and from landfills).

Overall, RAC concludes that taking into account the above-mentioned considerations the release estimates of inks during formulation, application, service life and disposal remain uncertain.

The information below is based on Annex B.9.12 "Inks and photographic uses" and one excel table provided by the Dossier Submitter to RAC during the opinion making process.

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[21] SpERCs developed by the European Council of the Paint, Printing Ink, and Artist's Colours Industry (CEPE), See Use maps - ECHA (europa.eu)

Table 12. Summary of emissions assessment for inks and photographic uses

Element	**RAC understanding of the Dossier Submitter's assumptions and calculations**	**RAC remarks**
Amount of Low molecular weight C6 related substances		
	During the stakeholder consultation, it was confirmed that C6 based short-chain fluorinated surfactants are used in some water-based inkjet inks and latex inks. Only these fluorinated surfactants provide the required performance of the inks. The use of about 15 t/a of these substances in Europe is assumed as worst-case estimation by the Dossier Submitter. In their calculations, the Dossier Submitter assumes that 10-100 t/a of C6 precursors is used in inks applications.	*The Background Document does not explain how the Dossier Submitter has calculated the tonnage of 10-100t/a of C6 precursors used in inks applications per year as in Table 25a, Annex B.9.18 the Dossier Submitter reports that no data are available on the current manufacture of inks (t/a).*
Releases estimation		
General assumptions	Many PFHxA-related substances show certain volatility. Therefore, for estimation of PFHxA release from printing inks, the CPA SpERCs for volatiles are used.	
	According to SpERC CEPE4 (formulation of water borne coatings and inks in large scale), 330 kg/a PFHxA-related substances (0.022 % of the used tonnage) are released to air during formulation.	
	With the consumer applications (according CEPE 20) about 150 kg/a of the related substances are released into the air.	
	When a loss of about 50 % of the surfactants during the life cycle of the imprinted papers (service life) is assumed, about 7.4 t/a of the related substances are released into air and from air into water in a further step.	
	Considering a deposit of 60 % of the imprinted papers to landfills and a total release of the perfluorinated surfactants, an annual release of 4.5 t of the C6 based short-chain fluorinated surfactants (= 174 kg/a PFHxA) could be assumed.	

Calculations of Releases estimation		
Formulation	Min/Max estimates of used tonnage x 0.022% (SpERC CPE4) 10 t/a x 0.022% = 0 t/a 100 t/a x 0.022% = 0.022 t/a	
Application by private users	Min/Max estimates of used tonnage /100 10 t/a / 100 = 0.1 t/a 100 t/a / 100 = 1.0 t/a	*The Background Document does not explain how the Dossier Submitter concluded that 1% of the Min/Max estimates of used tonnage are used by private users.*
Service life	(Min/Max estimates of used tonnage – Min/Max release during formulation - Min/Max release during application by private users) x 50% (10 t/a – 0 t/a – 0.1 t/a) x 50% = 4.95 t/a (100 t/a – 0.02 t/a – 1 t/a) x 50% = 49.49 t/a	
Deposit	Min/Max during release service x 60% 4.95 x 60% = 2.97 t/a 49.49 t/a x 60% = 29.69 t/a	
Annual release	0 t/a + 0.1 t/a +4.95 t/a + 2.97 t/a = 8t/a 0.022 t/a + 1.0 t/a + 49.49 t/a + 29.69 t/a = 80 t/a Considering a tonnage band from 10 to 100 t/a of C6 related substances used in printing inks an environmental release between 8 and 80 t/a could be assumed.	
Recalculation to express in PFHxA	Annual releases per activity x 7% (degradation factor)	
Formulation	0 t/a x 7% = 0 t/a 0.022 t/a x 7% = 0 t/a	
Application by private users	0.1 t/a x 7% = 0.01 t/a 1.0 t/a x 7% = 0.07 t/a	

Service life	4.95 x 7% = 0.35 t/a 49.49 x 7% = 3.46 t/a	
Deposit	2.97 x 7% = 0.21 t/a 29.69t/a x 7% = 2.08 t/a	
Total release	0 t/a + 0.01 t/a + 0.35 t/a + 0.21 t/a = **0.6 t/a** 0 t/a + 0.07 t/a + 3.46 t/a + 2.08 t/a = **6 t/a**	*The Background Document, Annex B.9.12 'Inks and photographic uses' refers only to the release C6 related substances used in printing inks. These are also reported in Annex B.9.18, Table 25c, while Table 25d contains release estimates in PFHxA (considering degradation factor 7%).*

Chrome plating

Summary of Dossier Submitter's proposal:

6:2 FTS is used in hard (functional) chrome plating as well as decorative chrome plating as a surfactant to lower the surface tension of the plating solution. According to the Dossier Submitter, emissions of 6:2 FTS during plating processes originate e.g. from the rinsing steps between the electrolytes and from the replacement of used solutions (Blepp, et al., 2017). In Germany up to 11.8 t/a of fluorosurfactants are used for decorative and hard chrome plating (Willand et al., 2019). Based on the German share of European GDP, in total approximately 30 t/a 6:2 FTS (min 2 t/a, max 57 t/a) is estimated by the Dossier Submitter to be used in chrome plating processes across the EU. 20 % of the applied surfactants are assumed to be lost over time and all losses are released to the environment. The effectiveness of risk management measures was not specifically accounted for.

For hard chrome plating 9 t/a, for decorative chrome plating 18 t/a, and for plastics products chrome plating 2 t/a of 6:2 FTS is used in Europe annually. The amount of 6:2 FTS used in chrome plating was then recalculated to express in PFHXA by using the degradation factor of 7%.

The Dossier Submitter has estimated that in total **between 0.04 to 0.85 t/a PFHxA may be released from chrome plating.**

RAC evaluation:

The volume of 6:2 TFS used in chrome plating in the EU is unknown. The Dossier Submitter derived the EU use volume from the amount of fluorosurfactants used in Germans (11.8 t/a) based on Germanys share of the European GDP (~21%), resulting in a total EU use volume of up to 57 t/a for the different chrome plating processes.

Emissions of 6:2 FTS during plating processes originate e.g. from the rinsing steps between the electrolytes and from replacement of used solutions. Chromate solution containing the mist suppressing agent has a limited usage lifetime and has to be changed regularly. The used solution is treated as chemical waste, where chromium is isolated. The wastewater is treated in wastewater treatment plants. 6:2 FTS has a low adsorption potential and is difficult to remove during water treatment processes and will be released in receiving waters. Exposure to the environment is also possible via waste from the chrome plating processes (e.g. chromium hydroxide sludge), which may contain 6:2 FTS. As these agents as well as the rinsing waters from these processes are mostly not treated PFAS-specific, 6:2 FTS will be released to wastewater. Beside release of 6:2 FTS from chrome plating process into the environment via industrial wastewater, emission to air is possible.

The German national metal plating association (ZVO) states that in the case of Germany 20% of the applied surfactant is lost in the plating processes annually. The Dossier Submitter considered these losses as environmental releases of 6:2 FTS.

RAC considers it worst case but justifiable to assume that all losses are released into the environment, based on the described operational conditions. Used solutions are not treated specifically to remove used PFASs and due to the low adsorption potential 6:2 FTS is difficult to remove from the wastewater generated from the treated solutions.

RAC recognises that as mentioned by the Dossier Submitter another, in the literature so far barely mentioned, emission source of 6:2 FTS could be the process of dechroming. 6:2 FTS was detected in demetallisation agent and degreasing agent (Willand et al., 2019). Due to the lack of information, a quantification of the 6:2 FTS release by dechroming is not possible.

The loss of the applied surfactant in the plating processes over time is taken to be 20%. These losses are considered as environmental releases of 6:2 FTS. The rapporteurs note that using 20% loss over time might be a worst-case assumption because it is not fully clear how to understand ‘over time’. If this is the loss over a period longer than a year, annual losses might actually be smaller. In addition to that not all losses might end-up in the environment, which is currently assumed, as part of the losses are expected the be treated as hazardous waste.

Overall, RAC concludes that a quantitative estimation of the releases of PFHxA-related substances due to chrome plating is highly uncertain. Firstly, it is not clear whether the German circumstances are representative for Europe as a whole and also the extrapolation of the amount of fluorosurfactants used based on GDP is questionable. Without further clarity on the RMMs taken throughout Europe, RAC is not able to draw a firm conclusion on the amount emitted.

Table 13. Summary of emission assessment for chrome plating

Element	**RAC understanding of the Dossier Submitter's assumptions and calculations**	**RAC remarks**
Amount of 6:2 FTS is used in chrome plating		
	For chrome plating 6:2 FTS is used as a surfactant mainly as a mist suppressing agent. Emissions of 6:2 FTS during plating processes originate e.g. from the rinsing steps between the electrolytes and from replacement of used solutions (Blepp, et al., 2017). In Germany up to 11.8 t/a of fluorosurfactants are used as well for decorative as for hard chrome plating (Willand et al., 2019). Based on Germany's share of the European GDP, a use up to **57 t/a** was derived for the EU. In total, considering the different chrome plating processes, about 30 t (min 2, max 57 t/a) of 6:2 FTS are estimated to be used in the EU, annually.	
Releases estimation		
General assumptions	Release of 6:2 FTS from chrome plating process into the environment is possible via industrial wastewater and air.	
	The German national metal plating association (ZVO) states that in the case of Germany **20%** of the applied surfactant is lost in the plating processes annually (Brunn Poulsen et al., 2011).	*RAC notes that it is unclear whether any wastewater treatment or treatment of the air ventilation takes place, as assumed in the estimations for other product sectors of use.*
Use of 6:2 FTS	- hard chrome plating - 9 t/a (min 0.4, max 18 t/a), - decorative chrome plating - 18 t/a (min 0.8, max 36 t/a) - plastics products chrome plating 2 t/a (min 1.1, max 3 t/a)	
Calculations of releases estimation		
	Min/Max estimates of used tonnage x 20% (surfactant is lost in the plating processes annually)	
Releases calculation		

5.1 hard chrome plating	0.4 t/a x 20% = 0.08 t/a 18 t/a x 20% = 3.64 t/a	
5.2 decorative chrome plating	0.8 t /a x 20% = 0.16 t/a 36 t/a x 20% = 7.2 t/a	
5.3 plastics chrome plating	1.1 t/a x 20% = 0.22 t/a 3 t/a x 20% = 0.6 t/a	
Annual release	These losses are considered as environmental releases of 6:2 FTS. Based on this assumption, **min 0.5 max 11.4 t/a** 6:2 FTS are released into the environment wide dispersive.	
Recalculation to express in PFHxA	Annual release x 7% (degradation factor)	
5.1 hard chrome plating	0.08 t/a x 7% = 0.01 t/a 3.64 t/a x 7% = 0.25 t/a	
5.2 decorative chrome plating	0.16 t /a x 7% = 0.01 t/a 7.2 t/a x 7% = 0.5 t/a	
5.3 plastics chrome plating	0.22 t/a x 7% = 0.01 t/a 0.6 t/a x 7% = 0.04 t/a	
Total release	0.01 t/a + 0.01 t/a + 0.01 t/a = 0.03 t/a 0.25 t/a + 0.5 t/a + 0.04 t/a = 0.8 t/a Calculating with the assumed surrogate for the annual degradation of related substances to PFHxA, it is assumed that about 0.45 t/a of PFHxA **(min 0.04 t/a, max 0.85 t/a)** are released into the environment. A subsequent service life is not relevant.	*RAC noted that these estimates provided in the Excel table by the Dossier Submitter are in line with Table 25d, Annex B.9.18.*

Manufacture of low molecular weight PFHxA-related substances

Summary of Dossier Submitter's proposal:

According to the proposal (Annex B.9.3.1 of the Background Document), the EU manufacture of PFHxA-related substances takes place under strictly controlled conditions using mitigation measures (total manufacturing volumes not presented). Residues in wastewater and air are captured with e.g. activated carbon or absorber resins. The Dossier Submitter estimated the releases using the default release estimates of ECHA Guidance (ERC 1), which result in releases of up to several hundred tonnes per year to air and water. Due to release mitigation measure at production, the release of low molecular C6 fluorochemicals via wastewater treatment plants (WWTPs) and into the air is considered less than 10 t/a according to industry information. As well the absorber materials, the sludge from the WWTP, as the air from the processes are exhausted and incinerated. Consequently, the Dossier Submitter assumed **releases from manufacturing of low molecular related substances to be between 1-10 t/a, corresponding to a release of 0.07-0.7 t/a PFHxA**.

The low molecular weight PFHxA-related substances are mainly (87%) used as process intermediates (incl. monomers) for the manufacture of fluoropolymers and C6-SFPs or as polymerisation aid. 7% of low molecular weight PFHxA-related substances are used in firefighting foams as surfactant. Other direct uses are considered minor.

RAC Evaluation:

Both 6:2 fluorotelomer iodides and 6:2 fluorotelomer-alcohols are intermediates to produce 6:2 acrylates (like 6:2 FTA as of 6:2 FTMA). Fluorotelomer iodides are used to produce the telomer-alcohols which are then used as intermediates for the production of the telomer acrylates. According to industry, this is an integrated process, and the reaction takes place at the same site in an enclosed system. The outcome of one production step, like the produced 6:2 fluorotelomer-alcohols, is immediately used in the next reaction step. Therefore, environmental releases of the acrylate precursors, the respective iodides and the alcohols are not expected. These 6:2 acrylates are monomers for the manufacturing of acrylate polymers with C6 fluorinated side chains. According to Table 22 in Annex B.9.3.1 of the Background Document, 6:2 fluorotelomer acrylates are produced in the EU in a volume of between 1 000 and 10 000 t/a.

The Dossier Submitter considered the standard worst-case scenario according to the REACH guideline not feasible because the production of the monomers occurs under strictly controlled and enclosed conditions and emission mitigation measures are applied. According to the Dossier Submitter the release of low molecular C6 fluorochemicals via WWTPs and into the air are much less and based on information provided by industry, the release was considered to be less than 10 t/a. For exposure estimations, the release of low molecular C6 fluorochemicals during manufacture lies in the range of 1–10 t/a.

RAC considers it difficult to robustly judge the assumed emissions without proper contextual information. Furthermore, RAC considers that in the case of strictly controlled and enclosed conditions as described in the REACH regulation, no emissions will take place. Under these conditions the use is exempted from the restriction and in the case of transported isolated intermediates a derogation is proposed by the Dossier Submitter. RAC further notes that, although these emissions are described in the Background Document in B.9.3 it is not made clear whether these emissions are taken up further in the Background Document. The

Dossier Submitter concludes in B.9.3 that the release of PFHxA, its salts and related substances seems to be low during manufacturing process of these substances and that they are not taken up in the overview in Table 25.

Manufacture of C6 side chain fluorinated polymers (C6-SFPs)

Summary of Dossier Submitter's proposal:

A large group of C6-SFPs are polyacrylates with C6 perfluorinated side chains. Based on data evaluated from 2016 to 2018, 1 000 to 10 000 t C6 side-chain fluorinated acrylates were manufactured annually in the EU. According to the Dossier Submitter, manufacturing 1 000 to 10 000 t/a of polymers with a C6 perfluorinated side chain, 5 to 50 t/a of PFHxA-related substances are released into air and water respectively. The Dossier Submitter concludes in chapter B.9.4.2.1 that 10 to 100 t/a of PFHxA-related substances are released into the environment via C6 side chain (co-) polymers at manufacturing (Table 25c). The Dossier Submitter has estimated that during manufacture of acrylic polymers with C6 side-chains **between 0.6 to 6 t/a PFHxA may be released** (Table 25d). The Dossier Submitter also estimated the release due to service life and attributed 75% of the production to service life indoor (ERC11a) and 25% to service life outdoor (ERC10a). For service life indoor (5 years) for these articles, 0.15 to 1.5 t/a of the C6 side-chain polyacrylates are released to water and air, respectively. For the articles with an outdoor service life the Dossier Submitter estimated that annually 3.23 to 32.25 t/a polymers are released to water and soil respectively. Finally, the Dossier Submitter concluded that 7 to 68 t/a of SFPs are released into the environment by articles containing these polymers during their service life. The rationale for the conclusion has not been given.

Concerning waste disposal, the Dossier Submitter reports that applying the default for waste disposal (60%) to articles containing or treated with C6 side chain acrylate polymers, together with the respective articles 600 to 6 000 t/a of these polymers are disposed in landfills. On average, per tonne acrylate polymers containing C6 side chains, up to 425 mg PFHxA are released mainly to water per year from landfills. According to the Dossier Submitter, before summing the total release from the manufacture of side chain fluorinated polymers, the amount of 6 t/a from waste disposal was derived by multiplying 6 000 t/a by a degradation fraction of 1% and dividing by 10-year service life of the disposal. Then the release due to service life multiplying tonnage of the release by a degradation fraction of 1% and dividing by 5-year service life to express the tonnage in PFHxA. That according to the Dossier Submitter results in releases in range 0.6-6 t/a of PFHxA.

RAC evaluation:

The Dossier submitter only considered manufacturing and assumed that, based on the manufacturing, import and export for the whole group of fluoropolymers, that import and export of the C6 side chain fluorinated polymers would be in balance. For the use of 6:2 acrylate monomers in polymerisation processes at industrial sites the Dossier Submitter applied the default release factors according to ERC 6c for environmental release estimation (5% release to air and 5% to water). Between 1 000 and 10 000 t/a of side chain fluorinated acrylates are used for the emission calculation. RAC notes that the Dossier Submitter used the manufactured tonnage of C6-SFPs as the starting point for the calculation of the release of the C6 precursors (PFHxA related substances) assuming these tonnages to be similar. RAC concludes this may have resulted in overestimation of the release. The Dossier Submitter lowered the estimated releases by a factor of 10. Releases into the environment of PFHxA related substances from the use of monomers are therefore calculated to be between 10 to

100 t/a. RAC considers for the use of monomers in polymerisation processes at industrial site (inclusion or not into/onto article) it is in general appropriate to apply the default release factors according to ERC 6c for environmental release estimation. However, stakeholders during the consultation on the Annex XV report demonstrated a high reduction of environmental releases by effective mitigation measurement at C6 polyacrylate production. Although RAC considers the representativeness of this information for the fluoropolymer sector as a whole uncertain, it may be expected that mitigation measures are generally applied by industry and therefore RAC agrees with reducing the release estimates with a factor of 10. RAC further notes that data provided by Wang et al. (2014) on the release of fluorotelomer-based species from production sites suggest much lower emission factors 0.0025% instead of 5% (or 0.5%). This would result in emissions < 1 t/a.

Hence, RAC concludes that considering the additional information on release factors the estimated release of PFHxA-related low molecular weight substances at C6-SFPs manufacture could be a significant overestimation. It also indicates the high uncertainty of the release estimates from industrial sources.

Manufacture and use of fluoropolymers and fluoroelastomers

Summary of Dossier Submitter's proposal:

The Dossier Submitter makes a distinction between fluoropolymers and C6 side chain fluorinated polymers. The use of fluoropolymers is discussed extensively in Annex E.2.1 of the Background Document. The Dossier Submitter indicates that fluoropolymers as such do not contain structural moieties like FTOHs and PFCAs. A potential source of PFHxA, however, could be residues of fluorinated processing aids. The Dossier Submitter has, however, not estimated releases for the use of the substances in actual fluoropolymer manufacture but only for manufacture of side chain fluorinated polymers and specific monomers (see below). More importantly, in Annex E.2.13 of the Background Document the presence of PFHxA in PTFE micro-powders is discussed. The side-chain fluorinated polymers are also mentioned in Annex E.2.1 of the Background Document. For the restriction proposal, an important difference between the side-chain fluorinated polymers and the fluoropolymers is that the first fall directly under the definition in the restriction proposal as they are considered as PFHxA-related substances, whereas the second falls within the restriction proposal in case the PFHxA, its salts or related substances surpass the concentration limits as being present as constituent/impurity in a fluoropolymer.

A large sector of use is fluoroelastomers containing APFHx as an impurity. Fluoroelastomers are used as seals and tubes in automotive and aviation. Ammonium perfluorohexanoate (APFHx), the ammonium salt of PFHxA, is imported to the EU in amounts of 10-100 t/a. APFHx is used at industrial sites as a processing aid for the manufacture of polymers, leading to inclusion into articles. According to the Dossier Submitter, the release from fluoroelastomers manufacturing is considered to be very low (< 10 kg/a). APFHx may occur as an impurity in fluoroelastomers. Assuming the used tonnage to appear in the products and applying the default release factors for service life (ERC10a) and dividing by a 10-year service life, up to 650 kg/a of the ammonium salt may be released to the environment. From landfills up to 390 kg/a may be released to water annually using a disposal fraction of 60% and the same scenario. Concluding, the Dossier Submitter estimates that **0.1 to 1.0 t/a APFHx is released to the environment from fluoroelastomers**.

RAC evaluation:

Use as processing aid in the manufacture of elastomers

Starting point for the release estimation are the registration data for APFHx. The amount registered have been lowered from 10-100 t/a to 1-10 t/a recently, which result in a 10-fold lower release than estimated by the dossier submitter. Ammonium perfluorohexanoate (APFHx), the ammonium salt of PFHxA is imported as an aqueous solution into the EU and is used at industrial sites as a processing aid to manufacture fluoroelastomers, leading to inclusion into articles. According to the Dossier Submitter, the environmental releases of APFHx from the manufacturer of fluoroelastomers is below 10 kg/a. This is realised by multiple reuses of monomer solution and by removal of APFHx from wastewater at the production sites, using multiple and specific filtering steps. Using the new registration data would result in releases below 1 kg/a.

Goldenman et al (2019) investigated the current number of sites within Europe where production of fluorochemicals and/or fluoropolymers took place in 2018; he identified 7 sites. However not all these sites produce fluoroelastomers. At least three companies have been identified to produce fluoroelastomers. Emissions are still below 100 kg/a if the releases at remaining sites are comparable if the production volumes and the implementation of release control measures and process conditions are similar throughout the sector.

A mass balance for the use of HPFO-DA in the production of PTFE at the Chemours site in Dordrecht, the Netherlands revealed that from the 50 tonnes used (2017) 1% is emitted to air and 4% is emitted to water. 40 % of the processing aid is recovered and re-used and 55% ends up in various waste streams. 0.55% of the processing aid remains in the end products and 5% is released at the production of powders through spray drying of PTFE dispersions[22].

Based on this, the release to air and water amounts to 2 500 kg/a in 2017. Recently Chemours announced to reduce the HPFO-DA emission further to 2 kg/a to water and 3 kg to air by installing additional active carbon filters and other technical measures. As of this moment these measures are not yet implemented. These future emissions result in a release factor of 5/50 000 = 0.01%. This release factor represents a situation with very stringent release control measures.

Using this release factor as a surrogate for the release of APFHx would result in an annual release of 1 - 10 kg, representing a very high level of release control. It is unknown to which extend this is representative for the whole sector. Very recently, 2017/2018, releases at the Chemours site using a similar process, were substantially higher.

RAC concludes that the estimated release of about 1 kg/a for the whole sector represents a very high level of control at all sites. Depending on the extent to which this level of control applies across the sector and the whole use volume, releases could possibly be substantially higher, tons rather than kilograms. RAC therefore concludes that the quantitative assessment by the Dossier Submitter is uncertain.

Fluoroelastomers containing APFHx

Residual APFHx can be released from fluoroelastomers articles. Applying the default release factors for this release category (ERC 10a) and a service lifetime of 10 years. Concluding, 0.1 to 1.0 t/a APFHx could be released into the environment by the use of APFHx in the production of fluoroelastomers.

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[22] Netherlands Ministry of Infrastructure and Water Management, Inspectie Leefomgeving en Transport (2018). Afvalstromen van Chemours (Waste streams of Chemours). Den Haag, Inspectie Leefomgeving en Transport.

In these calculations the Dossier Submitter assumed that 100% of the amount of APFHx used as polymer processing aid is present in the elastomer articles. As indicated by industry in the consultation on the Annex XV report, this is an overestimation. From the mass balance of the amount of HPFO-DA used in the production of PTFE it appears that only small fraction, 0.55%, of the processing aid remains in the final end products. The end-products mainly cover PTFE dispersions. Both fluoropolymers as elastomers are produced by aqueous emulsion polymerisation. The dried PTFE powders contain about 0.05%, 0.5% being lost to the atmosphere at drying. Wang et al. (2014) reported that approximately 15% of the polymer processing aids used to make polymers remained as residuals in aqueous dispersion products. However major producers developed technologies to reduce residual levels in their dispersion products. They also mention that residual levels in solid products such as granular resins and powers are generally 2-3 orders of magnitude lower than in dispersions.

From this information it seems that most likely only a small fraction of the processing aid will remain in the end product, and hence, the assumption of the Dossier Submitter that 100% remains in the final elastomer is an overestimation. The reduction of the registered amount of APFHx result in an emission reduction of a factor of 10.

RAC concludes that the 100% residual amount is an overestimation and release from residual amounts in fluoroelastomers articles might potentially be a factor of 100 or more lower than proposed by the Dossier submitter. The current data presented does not allow RAC to draw a firm conclusion on the emitted amounts.

Table 14. Summary of emissions assessment for polymers

Element	**RAC understanding of the Dossier Submitter's assumptions and calculations**	**RAC remarks**
1.1. Manufacture (Acrylic-) Polymers with C6 side chains (SFPs)		
	Based on data evaluated from 2016 to 2018, in the EU **1 000 to 10 000 t** C6 side chain acrylates were manufactured annually.	
Releases estimation		
General assumptions	Many articles made or treated with perfluorinated substances are imported into the EU in large quantities from the Asia Pacific region. Therefore, the import of articles containing C6 side chain acrylates is much higher than the manufacture of such articles in Europe. As a consequence, a higher release of C6 side chain acrylates than the release calculated using the above stated tonnage range is expected.	
	For the use of monomers in polymerisation processes at industrial site (inclusion or not into/onto article) the default release factors according to **ERC 6c** can be applied for environmental release estimation.	
	Stakeholders reliably demonstrated a high reduction of environmental releases by effective mitigation measurement at C6 polyacrylate production. Therefore, only **10 %** from the values calculated according ERC 6c are finally expected to be released into the environment.	
	About **75 %** (treatment of textiles and paper) of the C6 side chain acrylate polymers are used widely dispersive for indoor products with low releases. Thus, a use of 750 – 7 500 t/a of these SFPs could be assumed in this sector. **ERC 11a** and **ERC 10a** have been used respectively for service life indoor and service life outdoor.	
	About **60 %** of articles are deposited in landfills globally (Geyer et al., 2017).	

Calculations of releases estimation		
Low molecular weight C6 related substances ***(RAC note:* C6 precursors *in calculations tables)***		
Min/Max used tonnages of C6 precursors	1000-10000t/a	
Releases calculation		
Formulation **ERC 6c** **air, water**	used tonnage (min, max) x 2 (env. compartments) x ERC6a release factor x 10% 1000 t/a x 2 x 5% x 10% = 10 t/a 10000 t/a x 2 x 5% x 10% = 100 t/a	
Annual release	Background Document: manufacturing 1 000 to 10 000 t/a of polymers with a C6 perfluorinated side chain, 5 to 50 t/a of PFHxA-related substances are released into air and water respectively at a service life of ten years. Concluding, 10 to 100 t/a of PFHxA-related substances are released into the environment via C6 side chain (co-) polymers at manufacturing.	
C6 side-chain fluorinated polymers ***(RAC note: C6 fluoropolymers in calculations tables)***		
Min/Max used tonnages of C6 precursors	1000-10000 t/a	*RAC notes that the Dossier Submitter has used the amount of tonnage produced of the C6 side chain fluoropolymers as the starting point of the calculation of the release of the C6 precursors (PFHxA related substances) and assumes these tonnages to be similar. This may result in overestimation of the release.*
Overall tonnage split in two live cycle steps:	service life indoor 75%: 750-7500 t/a service life outdoor 25%: 250-2500 t/a	

service life indoor 75% service life outdoor 25%		
Releases calculation		
service life indoor ERC 11a air, water	used tonnage (min, max) x 2 (env. compartments) x release factor / an average service life 750 t/a x 2 x 0.05% / 5y = 0.15 t/a 7500 t/a x 2 x 0.05% / 5y= 1.5 t/a	
service life outdoor ERC 10a air, water, soil	used tonnage (min, max) x no of env. compartment x release factor / an average service life air: 250 t/a x 1 x 0.05% / 5y = 0.025 t/a water, soil: 250 t/a x 2 x 3.2% / 5y = 3.2 t/a air: 2500 t/a x 1x 0.05% / 5y = 0.25 t/a water, soil: 2500 t/a x 2 x 3.2% / 5y = 32 t/a	
Annual release	In total, the release of *C6 side-chain fluorinated polymers (C6 side-chain fluorinated polymers in calculations tables)*: 0.15 t/a +0.025 t/a+ 3.2 t/a = **3.375 t/a** 1.5 t/a + 0.25 t/a + 32 t/a = **33.75 t/a** Background Document: annually 3.23 to 32.25 t/a polymers are released to water and soil respectively during articles service life. In sum, **7 to 68 t/a of SFPs** are released into the environment by articles containing these polymers during their service life.	*RAC notes that some values reported in the Background Document do not seem to be correct, based on RAC analysis of the additional information provided in the Excel files. In particular, RAC notes that the Dossier Submitter might have doubled the release without justification.*
PFHxA and salts or impurity		
Min/Max used tonnages of C6	1000-10000t/a	

precursors		
	Background Document: Waste management includes sewage treatment systems, landfills, incineration and recycling. About 60 % of articles are deposited in landfills globally (Geyer et al., 2017). Applying this amount to articles containing or treated with C6 side chain acrylate polymers, together with the respective articles 600 to 6 000 t/a of these polymers are deposited in landfills.	*The Dossier Submitter is using the amount of tonnage produced of the C6 side chain fluoropolymers as the starting point of the calculation of the release of C6 precursors (PFHxA related substances) and assumes these tonnages to be similar. RAC notes that this may result in overestimation of the release.*
Releases calculation		
	600 t/a x 425mg/a = 0.000255 t/a of (PFHxA) 6000 t/a x 425mg/a = 0.00255 t/a of (PFHxA) Background Document: In average, per tonne acrylate polymers containing C6 side chains, up to 425 mg PFHxA are released mainly to water per year from landfills deposits.	
Annual release	0.000255-0.00255 t/a (PFHxA)	
Recalculation to express in PFHxA		
	Due to the lack of other reliable studies describing the degradation of C6 related SFPs directly and not in combination with treated articles, the worst-case assumption of 1% release of PFHxA from C6 related SFPs was carried over from the restriction of PFOA.	
C6 side-chain fluorinated polymers (C6 fluoropolymers in calculations tables)	used tonnage (min, max) x degradation factor / an average service life 7 t/a x 1% / 5y = 0.014 t/a 68 t/a x 1% / 5y = 0.136 t/a deposited tonnage (min, max) x degradation factor /an average service life	*The Dossier Submitter second time divides in the same line of calculations per an average service live what means underestimation 5x. It was done the first time in the calculation of the releases from C6 side-chain fluorinated polymers and then the second time here while doing recalculation of release from 6 side-chain fluorinated polymers to express in PFHxA.*

	600 t/a x 1% / 10a = 0.6 t/a 6000 t/a x 1% / 10a = 6 t/a ***Release of C6 fluoropolymers expressed in PFHxA*** 0.014 t/a + 0.6 t/a = 0.61 t/a 0.136 t/a + 6 t/a = 6.1 t/a	*It is not clear why the Dossier Submitter has added the release from the deposit stage only in case of C6 fluoropolymers release. Additionally, releases are calculated based on full tonnage of deposited articles instead of the tonnage of C6 fluoropolymers, which may result in overestimation.*
Low molecular weight C6 related substances (RAC note: C6 precursors in calculations tables)	BD: Concluding, 10 to 100 t/a of PFHxA-related substances are released into the environment via C6 side chain (co-) polymers at manufacturing. Release from C6 precursors deposited in landfills were considered negligible by the Dossier Submitter but relevant calculations were not explained.	*10-100 t/a seems to be the tonnage of C6 precursors released to the environment. There is no information if the Dossier Submitter has used the degradation factor agreed by RAC to express the release in PFHxA. Also, fluorotelomer based SFPs can degrade to form PFHxA. The transformation factor of 1% that is used in the PFOA restriction was suggested by RAC. Consequently, an overestimation by a factor of 100 is possible.*
PFHxA and salts or impurity	0.000255-0.00255 t/a (PFHxA)	
Total release from Manufacture (Acrylic-) Polymers with C6 side chains *(SFPs)*	0.6-6 t/a Table 25d of the BD part 2	*It seems that the release of PFHxA from C6 precursors has not been considered. If this is taken into account, RAC considers that the release should be 0.7-7 t/a.*

Element	**RAC understanding of the Dossier Submitter's assumptions and calculations**	**RAC remarks**
1.2 Manufacture of fluoroelastomers containing Ammonium Perfluorohexanoate (APFHx)		
APFHx used in the EU	10 to 100 t	*The Dossier Submitter does not explain how the used tonnage of 10 to 100 t/a APFHx has been*

	Background Document: for manufacturing a subset of fluoroelastomers, APFHx is used as processing aid. Therefore, APFHx 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 like in automotive or aviation. So, a wide dispersive outdoor use of these articles with a low release of APFHx could be assumed. Applying the default release factors for this release category (ERC 10a) and a service lifetime of 10 years, up to 0.65 t/a of the ammonium salt from the 10 to 100 t APFHx used in the EU are released to the environment.	*calculated.*
Releases estimation		
Releases calculation		
service life **ERC 10a** **air, water and soil**	air: used tonnage (min, max) x release factor / an average service life 10 t/a x 0.05% /10y = 0.0005 t/a 100 t/a x 0.05% /10y = 0.005 t/a water and soil: used tonnage (min, max) x 2 (env. compartments) x release factor/ an average service life water, soil: 10 t/a x 2 x 3.2% / 10y = 0.064 t/a water, soil: 100 t/a x 2 x 3.2% / 10y = 0.64 t/a release to all compartments: 0.0645 - 0.64 t/a	
Deposit **(60 % of articles are deposited in landfills)**	air: used tonnage (min, max) x release factor 10a / an average service life 6 t/a x (0.05%) /10y = 0.0003 t/a 60 t/a x (0.05%) /10y = 0.003 t/a Water, soil: used tonnage (min, max) x release factor 10a / an average service life water: 6 t/a x 3.2% /10y = 0.0192 t/a	

	water: 60 t/a x 3.2% /10y = 0.192 t/a soil: 6 t/a x 3.2% /10y = 0.0192 t/a soil: 60 t/a x 3.2% /10y = 0.192 t/a Release to all compartments: 0.039-0.387t/a	
Annual release	0.0645 t/a + 0.039 t/a = **0.1 t/a** 0.64 t/a + 0.387t/a = **1.0 t/a**	
Total release from Manufacture of fluoroelastomers (APFHx)	Background Document: Assuming a low release of APFHx by leachate from landfills (60 % of articles are deposited in landfills), up to 390 kg may be released into water annually. Concluding, **0.1 to 1.0 t/a APFHx** could be released into the environment by the use of APFHx in fluoroelastomers.	*RAC noted that these estimates provided in the Excel table by the Dossier Submitter are in line with the Table 25d, Annex B.9.18.*

Semiconductors and semiconductor related equipment

Summary of Dossier Submitter's proposal:

The semiconductor industry uses PFASs as processing agents for photolithography, etching process and in cleaning fluids.

The overall amount of PFASs used in semiconductor industry is assumed to be < 10 t/a. Short-chain PFASs possibly may be emitted from the process of microchip manufacture. The amount of PFHxA, its salts and related substances released into the environment is not reported by the Dossier Submitter. However, the Dossier Submitter considers **the release from the semiconductor industry to be "very low" (< 10 t/a)**.

RAC Evaluation:

The overall amount of PFASs used in semiconductor industry is assumed to be < 10 t per year (Stakeholder Consultation, 2018). According to the Dossier Submitter short-chain PFASs possibly may be emitted from the process of microchip manufacture. The Dossier Submitter indicates that releases of PFHxA, its salts and related substances into the environment is unknown. However, they considered the release as very low but not negligible considering the process and the fact that PFASs are measured in effluents from semiconductor plants. For service life of semiconductors and semiconductor-related equipment, the Dossier Submitter concluded that regarding low concentration levels of perfluorinated substances in the coatings used, the release of PFHxA, its salts and related substances can be considered as very low.

RAC is of the opinion the there is insufficient information to assess releases from uses in semiconductors and semiconductor related equipment quantitatively. The information however is sufficient to allow for a qualitative indication of low expected release during service life and during manufacture of semiconductors and semiconductor related equipment.

Building materials/ construction products

Summary of Dossier Submitter's proposal:

Several uses of fluorinated substances in building materials/ construction products have been identified. Fluorinated substances are, e.g., added in paints to improve flow, wetting, and levelling. They are also used as additives in some adhesives and glues. A use in oil and water repellents in special glass for construction and in the solar energy sector has been identified, too. The substances have also been detected in treated floor waxes and stone/wood sealants and wood insulation materials. The main use of coatings with fluorosurfactants is as impregnation agents, especially on roofs and on frontages of buildings. As no sufficient information on the use volumes are available, the Dossier Submitter has **not quantified releases from building materials/ construction products**. **However, they consider that releases could potentially be significant as they are often associated with outdoor uses with direct release into the environment**.

RAC evaluation:

Several uses of fluorinated substances in building materials/ construction products have been identified. Fluorinated substances are, e.g., added in paints to improve flow, wetting, and levelling. They are also used as additives in adhesives and glues. A use in oil and water repellents in special glass for construction and in the solar sector has been identified, too. The substances have also been detected in treated floor waxes and stone/wood sealants and wood insulation materials. The main use of coatings with fluorosurfactants is as impregnation agents, especially on roofs and on frontages of buildings.

The Dossier Submitter indicated that no sufficient information on the use volumes is available to quantify the releases from building materials/ construction products.

RAC agrees with the Dossier Submitter that coatings with fluorosurfactants, including impregnation agents, especially are used outdoors and a direct release in significant amounts of perfluorinated surfactants from the building and construction sector into the environment can be considered as very likely. Based on limited information available quantification of such releases is not possible.

Mixtures for consumer uses

Summary of Dossier Submitter's proposal:

Perfluorinated substances are used in various mixtures intended for end-use by consumers such as (water)proofing agents, ski or floor waxes, car care and polishes and cleaning products. The substances most commonly used in products are fluorotelomers as stated during stakeholder consultations. They are used either as independent active ingredients or as a component in more complex matrices (like in waterproofing agents).

Only limited information is reported in the Background Document on tonnages of the mixtures and of the identity of the PFAS used. However, as stated in the Background Document, the potential release of PFCAs from mixtures for consumer uses should not be underestimated because use quantities may be high and use could lead to direct release into the environment.

There are currently **insufficient data available on tonnages used in mixtures for consumer uses to make a quantitative exposure assessment feasible**.

RAC evaluation:

The Dossier Submitter provided convincing data that PFHxA related substance are used in large variety of mixtures intended to be used by consumers. Such mixtures for consumer uses are, for example, (water)proofing agents, ski or floor waxes, car care and polishes and cleaning products. The Dossier Submitter indicated that there is only limited information available about used tonnages of such product formulations and the concentrations and volumes of PFHxA(-related) substances applied.

RAC agrees with the Dossier Submitter that due to large number of different kinds of products and the application of these mixtures for consumer uses and the potential widespread use across the EU leading to direct release into the environment, emissions to the environment can potentially be significant.

Cosmetic products

Summary of Dossier Submitter's proposal:

PFHxA is not identified as an intentionally added ingredient of cosmetic products. Other perfluorinated substances e.g. polyfluoroalkyl phosphonic acids (PAPs) and perfluorinated polymers, ethers and esters are used in cosmetic products such as foundation, concealer and sunscreen. According to a recent study by the Danish Environmental Protection Agency, 0.7 % (78 out of 11 108) cosmetic products contained fluoroalkyl substances or other fluorinated compounds (Brinch et al., 2018). The Dossier Submitter considers that there are currently **insufficient data on tonnages used in cosmetic products to make a reliable quantitative exposure assessment**.

RAC evaluation:

PFHxA is not identified as an intentionally added ingredient of cosmetic products. Other perfluorinated substances, e.g., polyfluoroalkyl phosphonic acids (PAPs) and perfluorinated polymers, ethers and esters are used and have been identified in a variety of cosmetic products such as foundation, concealer, and sunscreen. According to one study covering a large number of cosmetic products (> 10 000), only as small fraction (0.7%) of cosmetic products, contains fluoroalkyl substances or other fluorinated compounds. The Dossier Submitter states that there are currently no sufficient data available on tonnages used in cosmetic products which makes a quantitative exposure assessment not feasible.

RAC considers the information on actual use of PFHxA or PFHxA-related substances in cosmetic products too limited to draw firm conclusions on use and (magnitude of) potential releases. Based on known use of related PFASs in various cosmetic applications RAC considers that the use of PFHxA, its salts and related substances in cosmetic products is not unlikely.