

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

Opinion

on an Annex XV dossier proposing restrictions on  
undecafluorohexanoic acid (PFHxA), its salts and related substances

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

**ECHA/SEAC/Opinion N° (opinion number will be added after  
adoption)**

**9 June 2021**

3 June 2021

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9 June 2021

[SEAC opinion number will be added after adoption of the final opinion]

## Opinion of the Committee for Risk Assessment

and

## Opinion of the Committee for Socio-economic Analysis

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

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

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

**EC No.:** -

**CAS No.:** -

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

### PROCESS FOR ADOPTION OF THE OPINIONS

Germany has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/25419/term> on **25 March 2020**. Interested parties were invited to submit comments and contributions by **25 September 2020**.

## **ADOPTION OF THE OPINION**

### **ADOPTION OF THE OPINION OF RAC:**

**Rapporteur, appointed by RAC: Daniel BORG**

**Co-rapporteur, appointed by RAC: Betty HAKKERT**

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **3 June 2021**.

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

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

### **ADOPTION OF THE OPINION OF SEAC**

**Rapporteur, appointed by SEAC: Johanna KIISKI**

**Co-rapporteur, appointed by SEAC: Simone FANKHAUSER**

#### **The draft opinion of SEAC**

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **9 June 2021**.

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

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

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

#### **The opinion of SEAC**

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

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

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

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

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## OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

<p>1. Undecafluorohexanoic acid (PFHxA), its salts and related substances (including polymers)</p> <p>(a) having a linear or branched perfluoropentyl group with the formula <math>C_5F_{11}</math>- directly attached to another carbon atom as one of the structural elements;</p> <p>(b) having a linear or branched perfluorohexyl group with the formula <math>C_6F_{13}</math>-.</p> <p>2. The following substances shall be derogated from this designation:</p> <p>(a) <math>C_6F_{14}</math>;</p> <p>(b) <math>C_6F_{13}-C(=O)OH</math>, <math>C_6F_{13}-C(=O)O-X'</math> or <math>C_6F_{13}-CF_2-X'</math> (where <math>X'</math> = any group, including salts).</p> <p>(c) Any substance having a perfluoroalkyl group <math>C_6F_{13}</math>- directly attached to a sulphur atom.</p>	<p>1. Shall not be manufactured, used or placed on the market as substances on their own;</p> <p>2. Shall not be used in the production of or placed on the market in or used in:</p> <p>(a) another substance, as a constituent,</p> <p>(b) a mixture,</p> <p>(c) an article</p> <p>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.</p> <p>3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.</p> <p>4. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.</p> <p>5. Paragraphs 1 and 2 shall not apply until XX XX XXXX [five years after the entry into force] to:</p> <p>(a) hard chrome plating;</p> <p>(b) photographic coatings applied to films, papers, printing plates and inkjet photo media coatings;</p> <p>(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;</p> <p>this shall not apply to:</p> <p>(i) use of fire-fighting foam for training; and</p> <p>(ii) use of fire-fighting for testing</p> <p>unless all emissions to the environment are minimised and effluents collected are safely disposed of.</p> <p>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:</p> <p>(a) for seagoing units, air traffic facilities and storage of fuel;</p>
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	<p>(b) for training purposes provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely.</p> <p>7. Paragraphs 1 and 2 shall not apply to latex printing inks until XX XX XXXX [seven years after the entry into force]</p> <p>8. Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to:</p> <ul style="list-style-type: none"> <li>(a) concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500 m<sup>2</sup>;</li> <li>(b) semiconductors and semiconductor related equipment.</li> </ul> <p>9. Paragraphs 1 and 2 shall not apply to any of the following:</p> <ul style="list-style-type: none"> <li>(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;</li> <li>(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);</li> <li>(c) High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3</li> <li>(d) impregnation agents for re-impregnating of articles referred to in paragraph 9(b), (c), (g);</li> <li>(e) textiles for the use in engine bays in the following usage groups: Automotive and aerospace industry</li> <li>(f) epilames used in watches</li> <li>(g) medical devices as specified in Regulation 2017/745 of the European Parliament and of the Council;</li> <li>(h) filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency;</li> </ul> <p>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</p>
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calendar year a report to the European Chemicals Agency containing:

- (a) the identity of the substance(s) used in the previous year;
- (b) the quantity of PFHxA, its salts and PFHxA-related substances used in the previous year.

The European Chemicals Agency shall forward the data to the Commission by 31 March every year.

11. The concentration limit referred to in paragraph 2 shall be

- (a) 2000 ppb for the sum of PFHxA and its salts in fluoropolymers;
- (b) 150 ppm for the sum of PFHxA and its salts in fluoropolymers used in the following usage groups: Engine parts in automotive, aerospace and shipping industry.
- (c) 10 ppm for the sum of PFHxA and its salts in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force]
- (d) 100 ppm for the sum of PFHxA related low molecular substances in fluoropolymers.
- (e) 2500 ppm for the sum of PFHxA related low molecular substances in fluoropolymers used in the following groups: Engine parts in automotive, aerospace and shipping industry.
- (f) 500 ppm for the sum of PFHxA related substances in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force].

12. From (entry into force + 12 months), a natural or legal person benefitting from the derogation in paragraph 6 or paragraph 8(a) shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing:

- (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

	<p>disposed safely or emitted into the environment.</p> <p>The European Chemicals Agency shall consolidate and forward the data to the Commission by 31 March each year.</p> <p>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.</p>
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### Explanatory notes:

#### Column 1:

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

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

#### Column 2:

Paragraph 5(c): For fire-fighting foam mixtures for cases of class B fires for a period of time of five years after entry into force of the restriction paragraph 2 shall not apply. After this period of time use, production and placing on the market of fire-fighting foam mixtures shall not be allowed. The specification in 5 (c) (i) and (ii) derogates fire-fighting foam mixtures that contain or may contain PFHxA, its salts and PFHxA-related compounds that are used for training and for testing unless emissions to the environment are minimised and effluents collected are safely disposed of. Thereby only allowing use of fire-fighting foams in cases of emergency and under specific conditions use in testing. If all releases are contained when testing, paragraph 2 shall not apply to fire-fighting foam mixtures used in testing for a period of time of five years after entry into force of the restriction. Class B fires are fires of liquid substances or substances becoming liquid as specified in the European standard EN2 Classification of Fires.

Paragraph 6: While some armed forces (e.g. Denmark cf. Annex E2.3.4 Table 31) already reported transitions to fluorine free foams (FFF) and positive experiences with these foams, other armed forces reported challenges regarding a complete transition due to missing appropriate aqueous film forming foam (AFFF) alternatives in the defence sector. One of the challenges reported is, that the available FFF do not fulfil the requirements of some defence-



specific applications for 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<sup>2</sup>.

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

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

Paragraph 12: The market of fluorine free foams is rapidly developing and testing requirements for fire-fighting foams are already being reviewed, regarding changing requirements when assessing fluorine free foams. Therefore, the feasibility of a transition to fluorine free foams in the defence sector shall be possible for all armed forces in the future. That is why the efforts on substitution will be closely monitored. In the case of fire-fighting foams emissions to the environment occur mainly in the use phase. For this reason, the reporting requirement is linked to the actual application of FFF (i.e. the applicants benefitting from the derogation) and not the placing on the market. This is further supported by the fact, that FFF have a long shelf life of up to 30 years (see B.9.7).

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

## THE OPINION OF RAC

See RAC opinion.

## THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. Taking into account the available information on the proportionality of its socio-economic benefits to its socio-economic costs, SEAC considers that it has not been demonstrated that the restriction on **undecafluorohexanoic acid (PFHxA), its salts and related substances** as initially proposed by the Dossier Submitter is the most appropriate Union wide measure to address the identified risks.

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

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

Substance Identity (or group identity)	Conditions of the restriction
<p>1. Undecafluorohexanoic acid (PFHxA), its salts and related substances</p> <p>(a) having a linear or branched perfluoropentyl group with the formula C<sub>5</sub>F<sub>11</sub>- directly attached to another carbon atom as one of the structural elements;</p> <p>(b) having a linear or branched perfluorohexyl group with the formula C<sub>6</sub>F<sub>13</sub>-.</p> <p>2. The following substances shall be derogated from this designation:</p> <p>(a) C<sub>6</sub>F<sub>14</sub>;</p> <p>(b) C<sub>6</sub>F<sub>13</sub>-C(=O)OH, C<sub>6</sub>F<sub>13</sub>-C(=O)O-X' or C<sub>6</sub>F<sub>13</sub>-CF<sub>2</sub>-X' (where X' = any group, including salts).</p> <p>(c) Any substance having a perfluoroalkyl group C<sub>6</sub>F<sub>13</sub>- directly attached to a sulphur atom.</p> <p>(d) Any substance having a perfluoroalkyl group C<sub>6</sub>F<sub>13</sub> -directly attached to an</p>	<p>1. Shall not be manufactured, used or placed on the market as substances on their own;</p> <p>2. Shall not be used in the production of or placed on the market in or used in:</p> <p>(a) another substance, as a constituent,</p> <p>(b) a mixture,</p> <p>(c) an article</p> <p>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.</p> <p>3. Paragraphs 1 and 2 shall apply 36 months from entry into force of the restriction.</p> <p>4. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.</p> <p>5. Paragraphs 1 and 2 shall not apply until XX XX XXXX [five years after the entry into force] to:</p> <p>(a) hard chrome plating;</p> <p>(b) photographic coatings applied to films and in printing plates;</p>

oxygen atom at one of the non-terminal carbons.

(c) concentrated fire-fighting foam mixtures that were placed on the market before [date – 36 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:

(iii) use of fire-fighting foam for training; and

(iv) use of fire-fighting for testing

unless all emissions to the environment are minimised and effluents collected are safely disposed of.

6. Paragraphs 1 and 2 shall not apply to latex printing inks until XX XX XXXX [seven years after the entry into force]

7. Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to:

(a) concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 400 m<sup>2</sup> and their bunded areas;

(b) semiconductors and semiconductor related equipment.

8. Paragraphs 1 and 2 shall not apply to any of the following:

(a) a substance that is to be used, or is used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met;

(b) personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l);

(c) personal protective equipment specifically designed for armed forces and in the maintenance of law and order against the risk categories listed in paragraph 8(b);

(d) high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3;

(e) impregnation agents for re-impregnating of articles referred to in paragraph 8(b), (c), (d), (g);

(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.

9. From (entry into force + 36 months), a natural or legal person placing a mixture or an article specified in paragraph 8(b)- 8(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.

10. The concentration limits referred to in paragraph 2 shall be:

- (a) XXX [*information on concentration limits requested in SEAC consultation*] for the sum of PFHxA and its salts in fluoropolymers;
- (b) XXX [*information on concentration limits requested in SEAC consultation*] for PFHxA related low molecular substances in fluoropolymers.

11. From (entry into force + 36 months), a natural or legal person benefitting from the derogation in paragraph 7(a) shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing:

- (a) A description of their efforts on substitution of 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:
  - (iii) share in training and in operation
  - (iv) whether emission was contained, collected and disposed safely or emitted into the environment.

	The European Chemicals Agency shall consolidate and forward the data to the Commission by 31 March every year.
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## Explanatory notes for changes and clarifications proposed by SEAC

### Left column:

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

### Right column:

#### **Paragraph 3**

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

#### **Paragraph 5(b)**

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

#### **Paragraph 5(c)**

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

#### **Deleted: paragraph 6 from Dossier Submitter's proposal**

SEAC considers that it has not been sufficiently demonstrated in the Background Document that alternatives to fluorinated fire-fighting foams considered suitable for public uses are not applicable also for military uses over the transition period of 5 years proposed for firefighting foams for class B fires in general. Therefore, SEAC does not support a separate derogation for defence purposes from the scientific viewpoint. SEAC recalls that according to REACH

Article 2(3), Member States may allow for exemptions from the REACH Regulation in the interests of defence. This option could be taken advantage of where necessary.

### Paragraph 7(a)

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

SEAC considers that **the derogation should cover tanks with a surface area of >400m<sup>2</sup> plus their bunded areas**. SEAC notes the concern of the Dossier Submitter about the derogation becoming wider. However, the large size of the bunded area is itself a reason why a large fire could take place, making inclusion in the derogation appropriate. Although it is uncertain how many additional installations would be covered by the exemption after this modification, based on the information available, SEAC considers this is appropriate to ensure successful fire-fighting in those installations.

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

### Paragraph 8(b)

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

- substances and mixtures which are hazardous to health (a);
- harmful biological agents (c);
- ionising radiation (d);
- high-temperature environments (e);
- low-temperature environments (f);
- falling from a height (g);
- electric shock and live working (h);
- bullet wounds or knife stabs (l).

### Paragraph 8(c)

During the consultation on the Annex XV report, industry stakeholders reported that Regulation (EU) 2016/425 does not apply to PPE specifically designed for use by **the armed forces or in the maintenance of law and order** and that these uses might need a dedicated derogation. SEAC agreed that continued use for such items appears necessary and notes that there are uncertainties as to whether the derogation in paragraph 8(b) would cover also PPEs against risk category III (l) such as bullet-proof clothing or jackets for the military

and police. SEAC considers that the availability of such articles should not be affected by the proposed restriction. In relation to equipment used by armed forces, SEAC notes that where necessary in the interests of defence, Member States could make use of the possibility to allow exemptions according to REACH Article 2(3). However, this would not cover similar articles used by law enforcement. Therefore, SEAC proposes a specific derogation for PPEs for armed forces and in the maintenance of law and order.

### **Paragraphs 9 and 11**

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

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

SEAC agrees in principle that setting higher concentration limit values for fluoropolymers within the scope of the proposed restriction may be appropriate. However, more information is needed to give an opinion on the appropriateness of the proposed concentration limits. It is not clear from the Dossier Submitter's proposal how the proposed concentration limits were chosen. SEAC notes that one proposal was made by industry in the consultation on the Annex XV report (comment 3066, confidential). Based on the information available, it is not clear what the performance level of fluoropolymers complying with the concentration limits proposed by the Dossier Submitter in the different applications is. SEAC also notes that a derogation should be formulated in a way to ensure that both the manufacture of fluoropolymers and their use in articles are covered by paragraph 10.

### **Deleted: review clause from Dossier Submitter's proposal**

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

# JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

## IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

### Justification for the opinion of RAC

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

##### **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 regulated C9-C14 PFCAs. All PFCAs share the same functional group (CO<sub>2</sub>-), differing only in their perfluorinated carbon chain lengths. Figure 1 shows the structural relationships of the ionised forms of the salts and acids of PFHxA, PFOA, PFNA and PFDA.

PFASs are characterised by the extremely strong and stable C–F bond. The perfluoroalkyl moiety has a high chemical and thermal stability, together with both hydrophobicity and lipophilicity, which provides unique technical properties for use in surfactants and polymers. PFAS applications include various 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 (AFFFs) to extinguish flammable liquid fires.

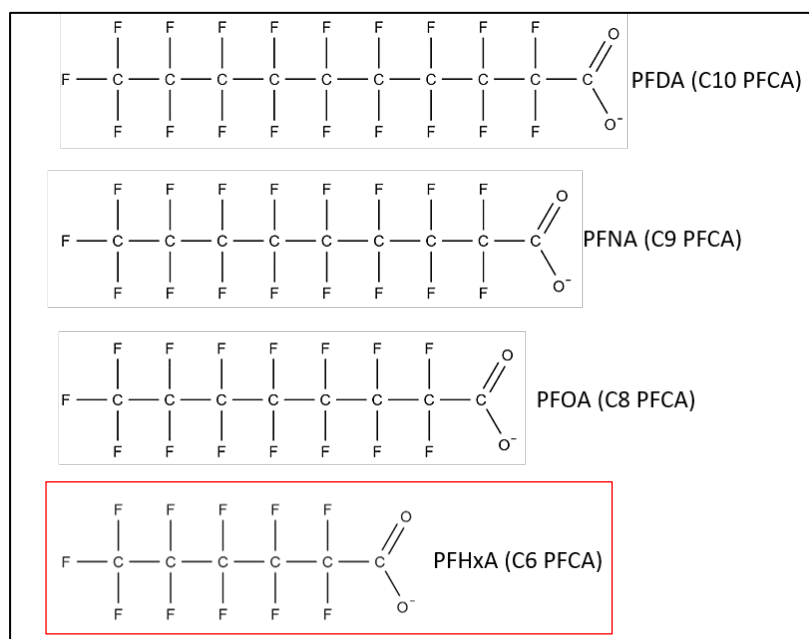


Figure 1. Structural relationship of perfluorohexanoic acid (PFHxA) to the other perfluorinated carboxylic acids perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA) and perfluorodecanoic acid (PFDA).

##### **PFHxA-related substances, side-chain fluorinated polymers and fluoropolymers**

PFHxA-related substances, i.e. substances that can degrade to PFHxA, are within the scope of this proposal. 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 this restriction proposal, unless their composition contains one or more of the substances within the scope of the proposal



as a constituent or impurity. Structural examples of each group are shown in Figure 2.

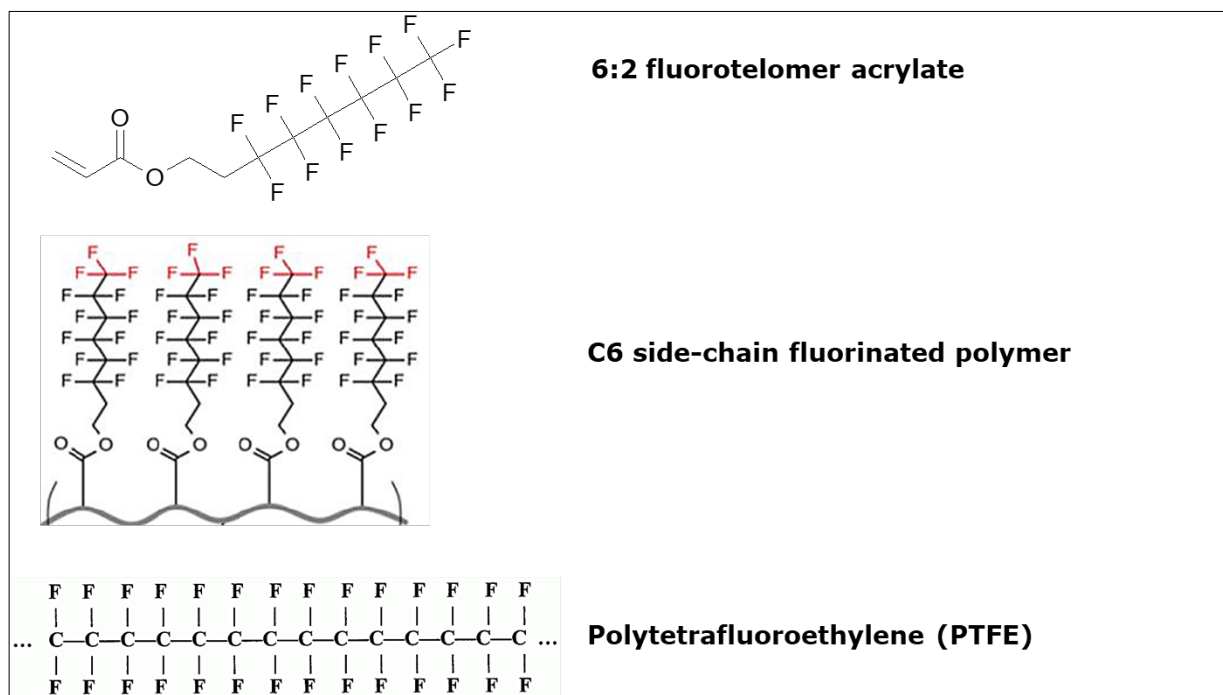


Figure 2. Structural examples of a low molecular weight PFHxA-related substance, 6:2-fluorotelomer acrylate, and a C6 side-chain fluorinated polymer (C6-SFP), i.e. a polymer with a side-chain containing 6 perfluorinated carbons that can degrade to PFHxA, that is also a PFHxA-related substance. Polytetrafluoroethylene on the other hand, cannot degrade to PFHxA and is therefore not a PFHxA-related substance.

### Summary of proposal:

The proposal aims to restrict PFHxA (linear and branched), its salts and related substances. The risk assessment of PFHxA contained in this proposal applies the 'case-by-case' approach described in paragraph 0.10 of Annex I to REACH<sup>2</sup>, i.e. where a standard risk assessment is not considered to be appropriate. The overall assessment is qualitative, but it contains several quantitative and standard elements, i.e. evaluation of data on physical and chemical properties, conclusions on hazards and related concerns and an exposure assessment.

In addition to PFHxA, the scope of the restriction also covers its salts and related substances which are known or expected to transform (salts) or degrade (related substances) into PFHxA. The 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 as well as one fully fluorinated C6 substance which is not expected to degrade to PFHxA. Excluded are also other longer-chain PFCAs, including perfluoroheptanoic acid (PFHpA) and its related substances.

<sup>2</sup> 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.

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.

Currently 45 substances within the scope of this proposal are registered under REACH, while for a further 73 substances, a CLP notification has been submitted. It is expected that even a larger number of substances are imported in articles and in formulations.

Following the restriction of PFOA (C8), perfluorinated C6 chemistry is the main substitute. The purpose of the proposed restriction is thus to reduce current environmental emissions of PFHxA, its salts and related substances from all industrial, professional and consumer uses, including imported articles.

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

See RAC opinion.

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

See RAC opinion.

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

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

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

The Dossier Submitter discussed the properties of PFHxA in relation to potential concerns for the environment and human health for the following areas: 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 substance group it seems very likely that PFHxA is as resistant to degradation as PFOA (half-life > 92 years). Thus, once PFHxA is released to the environment, it will remain there for decades to centuries because of its extreme persistence. As long as PFHxA emissions to the environment continue, also from degradation of related substances, concentrations in the environment will increase leading to a build-up of PFHxA stocks in the environment over time.

#### **Mobility**

It is expected that PFHxA predominantly stays in the aquatic compartment due to its low to moderate adsorption potential, high water solubility and low to moderate tendency to volatilise from water to air. These environmental properties will also make PFHxA mobile in the aquatic environment. Once PFHxA has entered the environment, e.g., surface waters, there is no natural barrier to prevent it from being distributed to groundwater and to the oceans.

#### **Potential for long-range transport**

Modelling data indicate that the combination of extreme persistence and high mobility lead to a high potential for long distance transport in the environment which take place via the atmosphere and with ocean 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 measured data. Thus, vulnerable remote ecosystems are currently exposed to PFHxA.

#### Removal of PFHxA contamination

Due to its physical-chemical properties, PFHxA it is difficult if not impossible to remove from already contaminated 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 be used effectively to minimise contamination and contamination already occurring 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 provides a specific route of exposure to humans and animals eating those plants.

#### Effects on human health

The Dossier Submitter reported that PFHxA caused adverse effects in subacute, sub chronic and chronic animal toxicity studies. In an available 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 of the 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 by the Dossier Submitter. 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 adverse 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, complicating any adequate prediction of ecotoxicity. The Dossier Submitter further notes that while the available data are insufficient to draw a definite conclusion, there is a concern that PFHxA is an endocrine disruptor in the environment. The same applies to two PFHxA related substances (6:2 FTA and 6:2 FTMA) that are under a REACH substance evaluation regarding their endocrine disrupting properties in the environment.

#### Bioaccumulation

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

The Dossier Submitter does consider that the strong protein-binding potential of PFHxA facilitates tissue distribution as shown by high distribution to plasma, kidney and liver in laboratory mammals.

**RAC conclusion(s):**

See opinion of RAC.

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

See opinion of RAC.

**Information on emissions and exposures**

**Summary of proposal:**

See opinion of RAC.

**RAC conclusion(s):**

See opinion of RAC.

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

See opinion of RAC.

**Characterisation of risk(s)**

**Summary of 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

In 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 similar 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 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):**

See opinion of RAC.

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

See opinion of RAC.

#### **Uncertainties in the risk characterisation**

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

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

No detailed assessment of implemented operational conditions and risk management measures regarding the use and handling of PFHxA, its salts and related substances was presented in the Background Document. Section 2.3 and Annex E.1.2 of the Background Document generally consider that measures such as improved containment in 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):**

See opinion of RAC.

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

See opinion of RAC.

**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):**

See opinion of RAC.

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

See opinion of RAC.

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

### Justification for the opinion of SEAC and RAC

#### Summary of proposal:

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

The manufacturing, placing on the market and use of PFOA, its salts and related substances (C8-chemistry) is prohibited (with some exceptions) since 2020 under Regulation (EU) 2019/1021 on persistent organic pollutants<sup>3</sup>. A large part of industry has substituted C8-based chemicals towards C6-chemistry (e.g. PFHxA and PFHxA-related substances) or fluorine free alternatives. It can be assumed that the vast majority of the remaining companies using C8-chemistry will substitute to C6 chemistry or fluorine free alternatives. Thus, the use of C6 chemistry is expected to have increased since the restriction on PFOA, PFOA-related substances and its salts entered into force.

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

#### SEAC and RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection of human health and the environment across the EU and of maintaining the free movement of goods within the Union, [RAC and] SEAC support the view that action is required on an EU-wide basis to address the risks associated with PFHxA, its salts and related substances.

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

For the substances covered by the scope of the restriction proposal, SEAC notes that PFHxA itself is not registered under the REACH regulation, i.e. it can be concluded that it is not manufactured in or imported into the EU in volumes greater than 1 tonne per year. By July 2020, 44 notifications on PFHxA have been made to the C&L inventory<sup>4</sup> by manufacturers/importers. PFHxA salts and PFHxA-related substances (precursors), which can degrade to PFHxA (whose properties are in the focus of the hazard assessment), are registered in the EU. SEAC notes that PFHxA, its salts and related substances are therefore used and placed on the market as substances, in mixtures and in articles throughout the union and respective releases and exposure take place in all EU Member States. PFHxA is

<sup>3</sup> See Commission Delegated Regulation (EU) 2020/784, OJ L 188, 15.6.2020

<sup>4</sup> <https://www.echa.europa.eu/information-on-chemicals/cl-inventory-database>

considered very persistent and mobile, it is ubiquitous in the environment and in humans, and has the potential for long-range environmental transport. Removal of PFHxA from wastewater, drinking water and contaminated sites is difficult, if not impossible, and any such remediation activities are known to be costly. The Dossier Submitter concludes that risks to human health and the environment are not adequately controlled. RAC agrees with this conclusion.

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

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

## **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**

See opinion of RAC.

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

See opinion of RAC.

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

See opinion of RAC.

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

See opinion of RAC.

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

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

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

- A **restriction** with **no concentration limit**;
- A **restriction** on **selected products**;
- A **restriction** on **specific sectors**;
- **Labelling**;
- **Voluntary** industry activities;
- The **Stockholm Convention**;



- **EU Drinking Water Directive**;
- **Operational Conditions** implemented and recommended by the manufacturers and/or importers;
- Further **international regulatory** activities.

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

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

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

- PFHxA-related substances are used in **paper and cardboard (food contact materials)** for their chemical stability, heat resistance, water- and oil-repellence and their cost-effectiveness (low amounts are enough to achieve the desired effect). The Dossier Submitter reports that PFAS might be used also in paper for non-food applications (folding cartons, containers, glossy papers, carbonless forms and masking papers). This is confirmed by one comment received during the consultation on the Annex XV report reporting the use of a PFHxA-coated paper layer in an iron-based oxygen absorber used in the food packaging industry but also in pharmaceutical and medical device products.
- Fluorotelomer alcohols (FTOHs) and PFCAs are used in **textiles** mainly as durable water repellent finishing that imparts water, oil and stain resistance to the textile. Textiles treated are consumer apparel, professional apparel, including personal protective equipment (PPE), woven and non-woven medical textiles, technical textiles (including in transportation and construction uses) and home textiles (e.g. upholstery).
- **Fluorinated fire-fighting foams** are used for class B fires (flammable liquids) and in special cases for class A fires (combustible materials). They include fluorinated surfactants to lower the surface tension and allow the formation of an aqueous film between fuel and foam, thereby cooling the surface, acting as a vapor barrier, allowing a fast spreading of the foam on the fuel and preventing re-ignition. Fluorinated fire-fighting foams are used in different sectors: aviation, petrochemical industry (oil and gas platforms, refineries, fuel depots) other industrial uses (e.g. in warehouses, automotive industry), defence (seagoing military units, fuel depots, military aviation, training on ships), and in hand-held fire extinguishers.
- **Manufacture and use of fluoropolymers:** PFHxA, its salts and related substances are used as process media to produce certain fluoropolymers. APFHx (the ammonium salt of PFHxA) is used at industrial sites as processing aid to manufacture **fluoroelastomers** that are used to produce e.g. seals and tubes for the automotive or aviation sectors. PFHxA can also be found as impurity in fluoropolymers. Fluoropolymers are used in a wide array of industries such as transport, aerospace, energy (e.g. oil and gas, renewable, nuclear), chemical, telecommunications, semiconductor and electronics, pharmaceutical, food, etc.
- **Manufacture of side-chain fluorinated polymers (SFPs):** SFPs are used for several applications as finishing agents or as repellents to impart oil and water repellence in a wide range of sectors (textiles, including leather, hard surfaces or paper fabrics).
- **Semiconductors and semiconductor related equipment:** the substances are used

as process agents for the photolithography process, etching process, in cleaning fluids and in fluoroelastomers. Relevant properties for the semiconductor industry are surface activity, purity and stability.

- **Chrome plating:** PFHxA related substances are used as wetting agents for chrome baths to lower the surface tension of the plating solution. The surfactants are used in metal plating with Cr(VI) to decrease aerosol emissions to reduce emissions of the carcinogenic Cr(VI) to the air. PFHxA related substances are also added to chromo-sulfuric acid in plastic electroplating to achieve wettability of the hydrophobic plastic surface.
- **Photographic applications:** C6-based fluorinated surfactants are used in photographic equipment or in coatings when manufacturing conventional photographic films. The substances are used as surfactants, as static control agents, as dirt repellents during coating operations and as friction control agents.
- **Printing inks:** C6 based short-chain fluorinated surfactants are used in some water-based inkjet inks and latex inks. The main function is the reduction of the water surface tension when applied on nonporous substrates, thereby improving surface wetting during the printing process. In absence of a surfactant the mixture would tend to form large unequal drops that would lead to a non-uniform surface coverage of the inks.
- **Building materials/ construction products:** uses covered by this sector are e.g. treatment of hard surfaces like stone, ceramics, glass, tile ground, etc. with either solvent or aqueous based fluoropolymer or side-chain fluorinated polymer solutions or dispersions and paints to provide functional water and oil/dirt repellence. During the consultation on the Annex XV report, stakeholders submitted information on further uses: coated C6 fabric in reinforcement of roofing membranes; protection of surfaces and facades against water, moulds, mosses, soil, solvents and oil-based stains (e.g. graffiti); non-woven for construction to bring weathering resistance; water- and oil-repellent penetrating sealers for natural stone, porous tile, grout and masonry; textiles for flexible civil construction (e.g. flexible textile roofs or ceiling panels); and reinforcement fabric for wall plaster to ensure water and UV-resistant effects. C6 is used in flexible civil construction, including flexible textile roofs for sport stadiums or houses, ceiling panels, exterior paints and road marking.
- **Fragrance and flavour:** PFHxA, its salts and related substances have properties that are used for handling of fragrance and odour compounds in products and articles, as they are surface-active and inert to different chemicals. However, their use in this sector is unclear to the Dossier Submitter and no additional information was submitted during the consultation on the Annex XV report.
- **Mixtures for consumer use:** PFAS are used in various mixtures intended for end-use by consumers, including impregnating agents, ski or floor wax, cleaning products, car care and polishes. The Dossier Submitter highlights that limited and uncertain information is available regarding the use of PFHxA-related substances in these products but there is indication that the highest concentrations are found in ski waxes and in proofing products.
- 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 (polytetrafluoroethylene) and PTFE micro-powders** have desired mechanical, thermic, electrical and chemical characteristics. PTFE may contain PFHxA-related substances as residuals from the manufacturing process, and PFHxA-related substances may also be unintentionally created while producing the micro powder. PTFE micro-powders are used in the medical sector, in electronics, in the field of tribology, mechatronics and serve as an additive to different substances and liquids to enhance their attributes.
- **Electronic devices:** fluorinated polymers are used in **electronic grade coating** in order to achieve high levels of water repellence for the protection of electronic devices from water and corrosion damage. Fluorosurfactants are also applied in batteries as plating bath aids, in photoresist strippers as photoresists and in the production of flat panel displays as coating solutions, due to their anti-corrosion and electrostatic properties.
- **Filtration and separation media:** PFHxA related substances in filtration and separation media have a very broad range of applications across several market sectors. The products affected are e.g. medical devices; PPE; heating, ventilation and air conditioning (including high-purity applications for hospitals, laboratories etc.); air pollution controls; dust collectors; hydraulic systems; coalescers; gas turbines; fuel systems and many more.
- **Epilames used in watches:** C6 side-chain fluorinated polymers are used in the watchmaking industry in mixtures called epilames. Epilames are applied as coating on some internal pieces of mechanical watches and electronic quartz watches. They ensure the proper lubrication of moving parts (e.g. wheels, pivots, escapements, stones). The epilame coating is required to obtain a low surface tension for the lubricant (oil) to stay in place and not spread through the movement of the mechanical watch-parts. Furthermore, the epilame coating must be chemically compatible with the respective substrate on which it is deposited and must also not react with the components of the lubricant.
- C6 fluorinated polymers are used as a cladding material for **plastic optical fibres**. Low refractive index in the outside keeps the light within the optical fibre, minimises information loss and increases the speed of transmission. According to stakeholders, the optical fibres are mostly used for transmission media for in-vehicle data communication. They help to prevent traffic accidents and thereby save lives. In the future the properties provided by the fibres may become more important and the fibres more demanded as self-driving cars may make a rise in the market.
- **Medical devices:** different applications for PFHxA related substances exist, such as the production of detergent proof one-use washbowls, non-active medical devices in ophthalmic applications, coatings for hearing aid devices, use in implantable (e.g. catheters, drainage, stents, surgical meshes, etc.) and non-implantable (vascular/delivery catheters, extracorporeal components, wound closures, etc.) medical devices.
- **Photographic coating on paper and in printing plates:** PFHxA surfactants are also used for photographic coating on paper, inkjet photo media coatings and for photographic coating in printing plates.

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

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

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

- A longer transition period (12 years) is proposed for fire-fighting foams for class B fires in large tanks (>500m<sup>2</sup>). This is because not enough evidence is available that fluorine free fire-fighting foams perform as well as fluorinated products in these circumstances, and there are high risks arising from this uncertainty.
- A longer transition period (12 years) is proposed for **semiconductors and related equipment**. This is due to alternatives not being available at the moment, but considered possible with enough time by the Dossier Submitter.
- A longer transition period (7 years) is proposed for **latex printing inks**. This takes account of the service life of related printer hardware.
- A longer transition period (5 years) is proposed for **hard metal chrome plating**. This is because alternatives are available but have not been tested sufficiently.
- A longer transition period (5 years) is proposed for **photographic coatings** applied to film, papers, in printing plates and for inkjet photo media coatings. This is to provide enough time for phase-out of these uses. The longer transition period for inkjet photo media coatings is due to the functional losses expected and comparatively low emissions, although the Dossier Submitter considers the impacts to be poorly understood.
- **Articles placed on the market before 18 months** have passed from the entry into force of the restriction have been derogated.

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

##### **Choice of risk management option**

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

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

##### **Scope of the proposed restriction**

SEAC generally agrees with the scope as proposed by the Dossier Submitter for reducing releases of PFHxA, its salts and PFHxA-related substances. However, SEAC considers some refinements to the scope presented in the dossier necessary, mainly based on information provided during the consultation on the Annex XV report.

In particular, SEAC concludes that:

- It is appropriate to include substances causing emissions of PFHxA because of degradation (i.e. PFHxA-related substances) under the scope of the restriction. Further information is given in the respective RAC sections of this opinion.
- The proposed concentration limit values provide a balance between the need to prevent intentional use and to minimise emissions, and the availability of analytical methods.

- A general transition period of 36 months will be needed for the actors affected to adapt their operations (any respective details are given in the section below).
- SEAC notes that several derogations and sector- or use-specific extended transition periods seem necessary (mainly based on information provided in the consultation on the Annex XV report). As reported in the proportionality section of this opinion, SEAC cannot conclude on the proportionality of the overall restriction proposal due to lack of data and robust analysis and assumptions by the Dossier Submitter, based on the information available. SEAC recognises that the broad scope of the restriction proposal, covering many different sectors, posed challenges in terms of data collection, but still considers that the sectoral analysis by the Dossier Submitter was not sufficiently developed to allow a credible conclusion on the proportionality of the proposed restriction. However, SEAC has assessed if restricting the separate uses covered is proportionate in cases where sufficient information for such analysis is available. Furthermore, SEAC proposes derogations for uses for which it considers that, based on the available evidence, a restriction would not be proportionate. SEAC's conclusions on the various suggested derogations are presented in detail in Table 3 and Table 4 in Annex I of this opinion.

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

#### **Choice of risk management option**

SEAC notes that PFHxA, its salts and related substances are used widely in many different sectors and for many different uses, and emissions are occurring during every life cycle step, including manufacture, industrial use, use in consumer products, service life and the disposal phase. Furthermore, imported mixtures and articles constitute relevant emission sources (the latter cannot be targeted by any other risk management measure than a restriction). Once released, the substances will stay in the environment, be distributed on a wide scale and removal is difficult. The Dossier Submitter suggests a number of derogations from the restriction proposal (most of them time-limited, but some also not limited in time). This is regarded as necessary due to several reasons, mainly the lack of sufficiently well performing alternatives (information on a per-sector basis is given in Annex I of this opinion). The Dossier Submitter assumed that the proposed restriction would reduce emissions of the substances under consideration by approximately 50-60 % over 20 years in a comparison to the non-restriction scenario. During RAC/SEAC opinion making the Dossier Submitter further concluded that large quantities of releases occur from disposal at end of life (via landfilling) instead of actual service-life for some articles affected (e.g. for products having a rather short service life, such as grease-proof paper or clothing) i.e. the substances under consideration are emitted from landfills for many years. Therefore, the restriction is expected to be effective even beyond the 20-year timeframe. None of the other risk management measures under consideration would, in the Dossier Submitter's view, perform similarly. More information on the effectiveness of the proposed restriction is given in RAC's section above.

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

SEAC notes that the proposed restriction is in line with the existing restrictions on

perfluorinated alkyl substances (PFOA and C9-C14 PFCAs) in terms of function of the substances covered, types of uses and conditions of the restrictions. SEAC finds this approach useful in terms of consistency of legislation, clarity of the measure to the affected parties, overall practicality and monitorability.

## **Scope of the proposed restriction**

### Coverage of substances:

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

### Concentration limits:

SEAC notes that the concentration limits proposed by the Dossier Submitter are 25 ppb (i.e. 25 µg/kg) for the sum of PFHxA and its salts and 1000 ppb for the sum of PFHxA-related substances. SEAC understands that these values were chosen in order to balance several different aspects, such as preventing intentional use of the substances (and therefore protecting human health and the environment by avoiding emissions), but allowing usage of alternatives (possibly containing unintentional impurities e.g. due to trace contaminants in production facilities), preventing contradiction with other regulatory measures as well as enabling proper enforcement and guaranteeing the availability and technical capabilities of analytical methods. However, only limited information is available on unintentional impurities of PFHxA, its salts and related substances.

SEAC recognizes that the emphasis of testing will be on PFHxA-related substances as there is no direct use of PFHxA itself, and that the analysis of the related substances may be more complicated than that of PFHxA. However, the issues with testing for related substances are understood to be related to issues like the availability of C13 marked standards, and therefore changing the limit values would not affect the situation.

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

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

The higher concentration limits proposed for fluoropolymers are discussed in the use-specific assessment of derogations in this opinion (Annex I). Overall, SEAC considers that setting specific higher concentration limits for fluoropolymers is appropriate due to the largely poor availability of alternatives and the wide reliance on high-performance fluoropolymers

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<sup>5</sup> Commission Delegated Regulation (EU) 2020/784, OJ L 188, 15.6.2020

throughout industry sectors. However, more information is needed during the consultation on the SEAC draft opinion to enable SEAC to support or propose a level for those values.

Overall, SEAC considers that the proposed concentration limits seem reasonable for PFHxA, its salts and PFHxA-related substances.

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

SEAC considers that on the one hand, the transition period should be **long** enough to ensure that the producers, importers and users of substances, mixtures and articles are able to comply with the restriction, e.g. in order to **allow for required substitution activities** and respective **adaptations within supply chains**. Also, while articles already placed on the market are outside the scope of the proposed restriction, some **arrangements with regard to new articles** will be necessary in supply chains (negotiation of contracts etc.). From the comments submitted during the consultation on the Annex XV report, SEAC notes that the **time available for industry to prepare** for the proposed restriction has not been perceived as sufficiently long. Unlike for earlier PFAS restriction cases, there was no classification proposal, SVHC identification<sup>6</sup> or alike to alert affected stakeholders. According to current knowledge, PFHxA does not meet the toxic or bioaccumulative criteria in Annex XIII of REACH, and, whilst identified in the Commission's new chemical strategy for sustainability<sup>7</sup> as a potential new hazard criterion, mobility is not yet a standard hazard criterion. Therefore, phase-out had not been regarded to be necessary by some industry actors. During the consultation process, some stakeholders even highlighted that the justifications of the PFOA restriction proposal had led them to think that transition to C6 substances would be considered a viable solution, and reported having carried out **substitution of C8 by C6**. Furthermore, SEAC considers that some transition time is necessary to enable progress in the availability of and access to (preferably standard) **analytical methods**, thereby improving the enforceability and practicality of the restriction. SEAC notes that the Forum highlighted in their advice that the development of standard methods is time-consuming.

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

Several respondents to the consultation on the Annex XV report reported that they expect substitution to be possible in 2-3 years. High costs or special transition arrangements for

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<sup>6</sup> The German Competent Authority proposed in 2018 an Annex XV proposal for identification of PFHxA and its ammonium salt as SVHCs under Article 57(f) of REACH (see [ECHA website](#)). This proposal was later withdrawn.

<sup>7</sup> European Commission, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM(2020) 667 final, Brussels, 14.10.2020 (<https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>)



these uses could be avoided with a transition period of 36 months. For some uses, the necessity of a transition time of 4 years was stated (see Table 1 for an overview).

On the other hand, SEAC considers that the transition period should be **short** enough to avoid future manufacture, import or use of the concerned substances in the EU such that **emission reduction** can be achieved without unnecessary delay. SEAC also points out that a short transition period would speed up the transition to alternatives in uses where suitable alternatives are already available and add **incentive to develop alternatives** in the rest of the uses. Being at the forefront in the development of alternatives is expected to enhance the competitiveness of the EU industry in the longer term. SEAC also highlights that the ambitions to **phase out all PFASs in general have been widely advertised** in the recent years (e.g. see conclusions of the Council of the European Union "Towards a Sustainable Chemicals Policy Strategy of the Union"<sup>8</sup>), and thereby expects most actors to have been aware of the trend. Also, the time from the publication of the restriction intention until the date of application will be several years (~1 year for dossier preparation, ~1 year for opinion making, ~½ year for legislative processes, proposed 3 years general transition period).

*Table 1: Transition time needed, as reported by industry stakeholders in the consultation on the Annex XV report*

Length of the general transition period	Applications where high socio-economic impacts could be avoided if a longer (than originally suggested by the Dossier Submitter) transition period is applied as phase-out appears feasible within the period mentioned below (a non-exhaustive list based on the information available)
2-3 years	<ul style="list-style-type: none"> <li>• Consumer water-proofing sprays (comments 2968, 3033, 3049)</li> <li>• Water-repellents for outdoor, sports apparel (comments 3015, 3028, 3049)</li> <li>• Protective wear (not class 3 PPE) (comment 2962, (3015))</li> <li>• Water-repellents in construction applications (comment 2968, 3049)</li> <li>• Certain types of surfactants (comment 3030)</li> <li>• Decorative chrome plating</li> </ul>
4 years	<ul style="list-style-type: none"> <li>• (All of the applications in the row above)</li> <li>• Inkjet printing inks (comment 2987, confidential)</li> <li>• Possibly some uses in firefighting foams (comment 3010)</li> <li>• Possibly oxygen absorbers for food and medication packaging (comment 3125)</li> </ul>

SEAC also highlights that there are numerous actors in many industry sectors that stated in the consultation on the Annex XV report that the performance level of the alternatives available is not sufficient currently, and the quality of their products would deteriorate if the alternatives were introduced now, causing considerable losses. However, these respondents did not give an estimate of the time needed for transition and are not covered by the list in Table 1. It was stated in many comments that the cost of the alternatives is not the issue, but performance is. SEAC notes that a longer general transition period would also allow those companies to progress with substitution, carry out the transition in a more controlled manner and reduce costs, although the exact magnitude of these costs is not known to SEAC.

Unfortunately, no quantitative estimates of the costs avoided per application with the referred transition times are available. Several stakeholders stated in the consultation on the Annex XV report that if the transition period was too short, it would be impossible to develop fluorine-free technologies for the technically more advanced and challenging applications, and thereby the markets and the associated jobs would be lost. A short transition period might also prevent carrying out existing long-term contracts, but the welfare implications of this are not

<sup>8</sup> <http://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf>

known to SEAC. SEAC acknowledges that implementing a substitute to mass production level and requalifying the products with clients will take time even if a substitute is available in general. SEAC agrees that negative socioeconomic impacts could be expected in terms of profit losses, reduced product quality, shift of market shares to importers in cases where the substance is not contained in the finished article, etc. Further details on a sector basis are given in the cost section below.

On the other hand, SEAC keeps in mind that the longer the transition period, the larger the emissions before the restriction enters into force. The general transition period will be applied also to all uses of textiles and paper and cardboard (food contact materials), where high emissions have been observed and alternatives are mostly available. SEAC considers that four years might be too long considering that RAC recommended to keep the transition period as short as possible.

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

Derogations proposed by the Dossier Submitter: SEAC agrees that derogations are necessary for several uses where technically and/or economically feasible alternatives are not available or are still in the development phase. Applying derogations requires careful consideration with regard to uses considered by the Dossier Submitter to have high societal costs. SEAC's evaluation and conclusions on the various suggested derogations are presented in detail in Annex I, Table 3.

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

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

Applications for which derogations were requested during the consultation: during the consultation on the Annex XV report, stakeholders requested derogations for several uses. These requests have been reported and evaluated in Annex I, Table 4.

Labelling: in the consultation on the Annex XV report, NGOs stressed that articles or mixtures benefitting from a derogation or a transition period should be labelled; this way the purchaser can make an informed choice on which products to buy (PFAS-free vs. PFAS-containing) and also proper waste management can be ensured (comment 3077). SEAC acknowledges that improved flow of information would be beneficial in terms of achieving the aims of the restriction and also notes that in this way the purchasers would be better able to contribute to phase-down if they so wish, since the market would adapt to changes in behaviour. SEAC has no information on the costs associated with a labelling requirement, nor on how

purchasers would react to such labels and their effectiveness in promoting awareness and proper waste management. Therefore, SEAC cannot evaluate whether costs and benefits of such requirement would be well balanced.

### **Recycling and reuse of articles and any related issues:**

The scope of the proposed restriction includes recycled material and articles made from recycled materials. According to the Dossier Submitter, there is a concern if recycled materials contain PFHxA, its salts and related substances and a derogation for recycled materials would potentially lead to higher emissions to the environment. SEAC agrees with the Dossier Submitter that the recycling of contaminated waste contributes to environmental releases and the contaminants may again circulate through use, disposal and recycling phase of articles. SEAC notes that a recent Dutch study by Rijkswaterstaat, Ministry of Infrastructure and Water Management (see also paragraph below) seems to confirm that PFHxA was found in sludge from paper production where recycled paper was used<sup>9</sup>. Hence, excluding recycled material and articles made from recycled materials from the scope of the restriction proposal appears problematic from a chemicals risk-point of view. As to the socioeconomic consequences of restricting these uses, there is no information available to SEAC that would allow drawing a conclusion on these aspects. The dossier does not analyse a restriction option where recycled material would be out of scope, and during the consultation on the Annex XV report limited information was provided.

Notwithstanding any general socioeconomic benefits of recycling as such, SEAC highlights a few aspects:

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

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<sup>9</sup> A.C .H. Jans & R.P.M. Berbee, Sources of PFAS for Dutch surface waters, Rijkswaterstaat, 14 July 2020.

them to stores for recycling (comment 3068).

- According to the dossier, PFASs are used in many different kinds of **building materials**, and fluorinated substances are for example added in paints to improve flow, wetting, and levelling. Based on volume, construction and demolition (C&D) waste is the largest waste stream in the EU, 500 million tonnes per year.<sup>10</sup> The Waste Framework Directive 2008/98/EC aims to have 70% of C&D waste recycled by 2020. According to COM (2018) only about 50% of C&D waste is currently being recycled while some EU countries are recycling even up to 90%.<sup>11</sup> Derogation regarding recovery products<sup>12</sup> from C&D waste would help achieving the recycling goal for C&D waste. However, PFAS emissions to the environment would be avoided better without such derogation.
- E-waste recycling was also reported during the consultation on the Annex XV report as a possible source of PFHxA releases into the environment and human exposure to PFHxA, based on studies conducted in Asia (comment 3107). However, SEAC notes that evidence suggesting that these findings hold true for the EU is lacking, but recognises that many electronic articles in the EU originate from Asia.
- SEAC notes that products imported from outside the EU represent a challenge in the context of recycling, since information on their exact composition may be unavailable and this risk should also be covered in the restriction proposal regarding recycling.

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

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

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<sup>10</sup> European Commission, Circular economy, Actions for specific materials and sectors, Construction and demolition: [https://ec.europa.eu/growth/industry/sustainability/built-environment\\_en](https://ec.europa.eu/growth/industry/sustainability/built-environment_en) (30.6.2020)

<sup>11</sup> European Commission, EU Construction and Demolition Waste Protocol and Guidelines, 18/09/2018: [https://ec.europa.eu/growth/content/eu-construction-and-demolition-waste-protocol-0\\_en](https://ec.europa.eu/growth/content/eu-construction-and-demolition-waste-protocol-0_en) (30.6.2020)

<sup>12</sup> The material or articles made from recovered demolition C&D waste may have an end-of-waste status and thus are in the scope of REACH.

## Effectiveness in reducing the identified risks

### Justification for the opinion of RAC

#### Summary of proposal:

See opinion of RAC.

#### RAC conclusion(s):

See opinion of RAC.

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

See opinion of RAC.

## Socio-economic impact

### Justification for the opinion of SEAC

#### Costs

#### Summary of proposal:

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

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

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

Sector- and/or use-specific cost information, qualitative or quantitative, is provided for the sectors listed in the 'scope' section (summary of proposal) of the SEAC opinion above. Cost information provided during the consultation on sectors not initially considered by the Dossier Submitter, such as optical fibres and watches, is also discussed below.

The Dossier Submitter states that a number of further applications of fluorinated compounds have been reported in the information collection or are mentioned in the literature that do not completely fit in one of the sectors above and included in Table 7 of the Background Document, e.g. handling of fragrance and odour compounds in products, different applications in laboratories, such as the use in aerosol applications during in-house quality control of other fluoropolymer products, use in special glass for construction, automotive and the solar sector, etc. Further information on these uses is given in section 2.5.1.16 of the Background document. No socio-economic information is available for these uses, and the Dossier Submitter has therefore not identified any potential costs.

Additionally, the Dossier Submitter identifies two further categories of costs not associated with particular sectors:

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

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

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

SEAC notes that a substantial number of uses and sectors is covered by the proposed restriction and agrees with the Dossier Submitter's view that different economic impacts are expected for different uses of PFHxA and sectors accordingly. Therefore, SEAC appreciates the Dossier Submitter's attempt to assess the socio-economic impacts on a per-sector basis, where possible even at a use-specific level within specific sectors (e.g. textiles).

Substitution towards fluorine-free alternatives as a reaction to the restriction by affected parties is the main basis for the cost assessment, i.e. the Dossier Submitter mainly assessed substitution and reformulation costs as well as costs related to these processes (such as any potential reorganisation of business, potential effects on products such as reduced service life of articles, costs of disposal, etc.). More information on different types of related costs on a per-sector basis is given in Table 2 in the proportionality section below. The Dossier Submitter's approach is a combination of quantified cost estimates, where possible, and a qualitative cost assessment where the respective data do not allow for quantification.

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

In SEAC's view, similar uncertainties apply for the qualitative cost assessment. Even though qualitative information is provided by the Dossier Submitter in the restriction dossier as well as by stakeholders during the consultation on the Annex XV report, it is hardly backed-up by sufficient supporting evidence which makes it difficult for SEAC to conclude on their significance.

Overall, both, the quantified cost estimates, as well as the qualitatively described economic impacts contain several uncertainties, specifically as for some cost categories (e.g. for costs related to substitution and reformulation activities, such as reorganisation of business, unemployment effects, changes in product quality and related consequences such as reduced service life of articles, etc.) very limited information was available to the Dossier Submitter. In SEAC's view, this makes it difficult to derive a robust overall cost estimate for the restriction at hand. During the consultation on the Annex XV report, a variety of sectors responded on cost-related aspects of the proposed restriction. However, the comments provided were rather general, partly company-specific, not substantiated by supporting evidence and therefore do not allow SEAC to extrapolate the information to the sectors and/or uses affected.

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

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

*The discussion on costs here also mentions issues related to benefits and proportionality where that was considered helpful in order to better explain the issues and to keep the same structure as used in the Background Document. However, a complete overview of the impacts relating to a use is presented in the proportionality section and specifically in the use-specific analysis in Annex I.*

#### Substitution, reformulation and related cost categories:

The cost assessment performed by the Dossier Submitter covers the below discussed sectors or use-specific levels within specific sectors (the latter e.g. for textiles or firefighting foams) for which substitution, reformulation and other relevant cost categories have been discussed and assessed mainly qualitatively. Only for very few sectors, quantitative cost estimates are available and a respective cost-effectiveness analysis was performed, i.e. for the manufacture of fluoroelastomers (APFHx) as well as for food contact material and paper and partly for firefighting foams. Overall, SEAC notes that there is lack of robust information (e.g. on use quantities of affected products, alternatives, prices of alternatives, quantities of alternative substances to be used in order to derive similar product performance, share of products affected, etc.) for most sectors covered by the restriction, i.e. calculating the respective substitution and any potential related costs is difficult and uncertain. This explains the partly large cost ranges that have initially been calculated by the Dossier Submitter for some sectors. Overall, SEAC regards any robust conclusion on the qualitatively and quantitatively assessed economic costs difficult to achieve, due to lack of data, lack of sufficient supporting evidence as well as several uncertainties as pointed out within this section. Cost-related aspects for the affected sectors (either already discussed in the initial restriction dossier or brought up by stakeholders during the consultation on the Annex XV report) are discussed in this section. Any derogation-related aspects are discussed in the respective section of this opinion.

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

It is reported in the dossier that according to information provided by industry, 52 000 tons of fluorinated polymers (fluoropolymers, perfluoropolyether polymers and SFPs) were sold in the EU in 2015. SEAC notes that the tonnage information originates from a PlasticsEurope report<sup>13</sup> that covers only fluoropolymers. Therefore, SEAC understands that all of the volume (52 000 tons) refers to fluoropolymers and none of it to SFPs or perfluoropolyether polymers. Based on the available information, it is not clear which share of the ~ 52 000 tons of fluoropolymers are manufactured with PFHxA, its salts and related substances.

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

A quantitative cost assessment is provided for the manufacture of **fluoroelastomers**, where APFHx (the ammonium salt of PFHxA) is used as processing aid. In case of a restriction, the Dossier Submitter estimates **profit losses ranging between 2 – 16 million € per year with a central estimate of 9 million € per year** for automotive and aviation applications. Additional costs are expected for downstream users in case they have to use non-C6 fluoroelastomers. Industry stakeholders argue that continued use is beneficial with a view to CO<sub>2</sub> emissions reduction in the concerned industries. They also reported that supply shortage of fluoroelastomers that are produced with C6 polymerisation aid would lead to considerable costs: massive requalification costs and

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<sup>13</sup> Amec Foster Wheeler Environment & Infrastructure UK Limited (2017) Socio-economic Analysis of the European Fluoropolymer Industry – Executive Summary, Plastics Europe – Fluoropolymer Group <https://www.plasticseurope.org/en/resources/publications/373-socio-economic-analysis-european-fluoropolymer-industry-executive-summary>

Full version of this study was submitted as confidential attachment to comment 3082 in the consultation on the dossier.



time for downstream users and a considerably reduced international competitiveness of components suppliers as well as the EU automotive and aerospace industries. The Dossier Submitter recognises that the restriction would result in high costs in terms of CO<sub>2</sub> emissions from transport and of impacts on international competitiveness for the affected European industries. Risks from continued use (i.e. continued emissions to the environment) are said to be poorly understood.

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

- **Textiles (derogations suggested for specific applications):** the Dossier Submitter discusses different types of textiles within the restriction proposal, such as home textiles (including outdoor textiles and awnings), consumer apparel, professional apparel (including PPE) and technical textiles (including transportation applications (hoses, belts, seats, carpets, etc.), tarpaulins, conveyor belts, ropes, etc.)). The initially provided quantitative cost assessment approach was overall revised into a qualitative approach due to the lack of robust data that would allow for a meaningful quantification. Nevertheless, substitution cost estimates for textiles are presented for illustrative purposes in the Background Document. Information provided during the consultation on the Annex XV report by stakeholders as well as information available through a recently published report of the European Commission<sup>14</sup> on the use of PFAS and fluorine-free alternatives in textiles, upholstery, carpets, leather and apparel did not contribute to sufficiently eliminating the underlying uncertainties in order to apply a quantitative cost assessment. Therefore, SEAC agrees that a qualitative assessment is preferable. SEAC notes that for some aspects pointed out below an uncertain and partly scarce data basis exists as regards the following aspects (further details on these aspects are given in Annex E.2.11 of the Background Document):
  - o Alternatives, e.g.:
    - which concrete substances are used in different applications;
    - non-achievement of required technical functionalities, mainly as regards oil and dirt repellence;
    - prices and amount to be used in order to obtain the required technical functionalities (e.g. water and oil repellence properties);
    - use quantities of products affected.
  - o Any potential substitution related consequences, e.g.:
    - possible need to amend machinery and equipment;
    - reduced service life of articles.

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<sup>14</sup> European Commission DG Environment (Brussels 2020): The use of PFAS and fluorine-free alternatives in textiles, upholstery, carpets, leather and apparel ([https://echa.europa.eu/documents/10162/13641/pfas\\_in\\_textiles\\_final\\_report\\_en.pdf/0a3b1c60-3427-5327-4a19-4d98ee06f041](https://echa.europa.eu/documents/10162/13641/pfas_in_textiles_final_report_en.pdf/0a3b1c60-3427-5327-4a19-4d98ee06f041))

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

As regards any potential **substitution related costs**, the information available to the Dossier Submitter and SEAC is scarce. SEAC notes that it cannot be ruled out that costs will arise due to necessary amendments of machinery and equipment when switching to alternative substances. However, SEAC notes that for alternatives providing water repellence the EC report mentions that no or limited changes in equipment are needed<sup>15</sup>. More important seem to be the costs related to potentially reduced service life, reduced functionalities and related lower quality of articles. Whilst SEAC notes that alternatives providing water repellence properties are already available on the market (where e.g. a general trend in moving away from PFAS-containing products can be observed for the sportswear and outdoor industry), the need for fluorinated products is still high for branches and/or products where high performance levels (oil/dirt repellence, often in combination with water repellence) are required as properties such as oil/dirt repellence are not yet sufficiently provided by alternatives. The importance of providing those technical functionalities is mainly related to safety aspects (e.g. professional clothing) and to a reduced service life of or increased cleaning efforts for articles. During the consultation on the Annex XV report, the impacts of no longer being able to use fluorinated substances are said to be significant (e.g. for home textiles such as carpets, awnings, seating furniture, for textiles used in automotive and aerospace sectors and other public places, such as seats and carpets), but no robust estimates of these impacts were submitted. As regards safety aspects, the Dossier Submitter did account for these (e.g. for personal protective equipment) by suggesting respective derogations (see SEAC's discussion on derogations). As regards a reduced service life or lower quality of articles and any related impacts the Dossier Submitter notes that several comments have been provided during the consultation on the Annex XV report; however, he concludes that these claims failed to sufficiently discuss potential alternatives (e.g. washable or replaceable clip-covers for products). SEAC stresses that at the point in time when concluding on its opinion, no more specific information on any potential impacts of a reduced articles' service life than the above was available and SEAC can therefore not confirm the magnitude of such impacts.

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<sup>15</sup> European Commission DG Environment (Brussels 2020), *Ibid*, pp. 81-83

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

SEAC notes that due to lack of robust information, specifically when developing the restriction proposal and the SEAC opinion, no robust overall picture of the socioeconomic impacts of the proposed restriction could have been derived by the Dossier Submitter. However, some cost aspects (price differences between PFAS and fluorine-free alternatives, cleaning of equipment, replacement of fire extinguishers, annual replacement/procurement, etc.) have been discussed by the Dossier Submitter. SEAC notes the following:

- o The Dossier Submitter states that according to the EC/ECHA report<sup>16</sup> on the use of PFAS and fluorine-free alternatives in firefighting foams, substitution activities can be observed for all uses. For example, substitution is reported by airports, can be observed in municipal fire brigades, marine applications, etc. It can be observed that substitution is less advanced for the petrochemical industry and the defence sector (see separate discussion on derogations for further information). For the latter, however, SEAC is aware of an ongoing phasing-out of the use of PFAS in this sector in some EU-MS as well as of regulatory action to ban the use of PFAS in this sector in the US.
- o *Price differences for fluorine-free FFF (firefighting foams):* the price of potential alternatives is not expected to significantly differ for fluorine-free foams compared to fluorine-containing foams. SEAC notes that this conclusion is drawn based on expert information (IPEN 2018) and is supported by the EC/ECHA report, which reveals a weighted average price for PFAS- as well as fluorine-free foams of 3000 €/t. However, AFFF foam concentrate is claimed to be available in different qualities and concentrations and there is contradicting information that fluorine-free foams need/need not to be used in higher quantities in order to achieve the necessary functionalities (e.g. a stable performance); the range specified was between no change in volume and up to a maximum of 100% additional foam required. Based on the different responses given by stakeholders and considering their relevance and reliability, the Dossier Submitter assumed a 30% increase in volume<sup>17</sup>. The EC/ECHA (2020) report provides further discussion on potentially higher quantities to be used for different types of foams (see Annex E.2.3.5 of the Background Document), calculating any potential replacement costs based on three assumptions (0%, 50% and 100%) of required adapted use volumes. The difference in the percentage of increased volume, together with slightly different assumptions made by the Dossier Submitter compared to the EC/ECHA report as regards use volumes of fluorinated foams leads to different

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<sup>16</sup> European Commission DG Environment/European Chemicals Agency (ECHA): “The use of PFAS and fluorine-free alternatives in fire-fighting foams” ([https://echa.europa.eu/documents/10162/28801697/pfas\\_flourine-free\\_alternatives\\_fire\\_fighting\\_en.pdf/d5b24e2a-d027-0168-cdd8-f723c675fa98](https://echa.europa.eu/documents/10162/28801697/pfas_flourine-free_alternatives_fire_fighting_en.pdf/d5b24e2a-d027-0168-cdd8-f723c675fa98))

<sup>17</sup> 30% increase is regarded very uncertain by the Dossier Submitter but the most reasonable approach based on the information available (for further information see Annex E.2.3.5 of the Background Document).

cost estimates. SEAC notes that in the consultation on the Annex XV report stakeholders reported the amount of fluorine-free foams required to be 2-4 times that of AR-AFFF in IPA fires and 6-7 times that of AR-AFFF in E10 gasoline fires in certain test configurations (comment 2983). However, SEAC could not verify robustness of these estimates.

- *Replacement of foam:* the Dossier submitter assumes that (one-off) replacement costs might arise due to the proposed restriction, which are estimated to be in the range of 13 to 130 million € (using the above mentioned price of 3000€/t for AFFF and FFF and depending on the amount of replacement attributable to this restriction vs. previous regulatory action on PFOA). The Dossier Submitter concludes that stocks have to be replaced after expiry anyhow and the replacement with new foams is just an early replacement. Replacement and incineration costs (see next paragraph) would occur just a few years later. Therefore, the estimated replacement costs should be regarded as an overestimation, not considering the fair value of the foam stocks. SEAC notes that replacement costs are estimated to be higher in the EC/ECHA report, resulting in € 1bn (central estimate). The difference is mainly due to different assumptions on foam stocks, which are estimated to be 75 000 tons by the Dossier Submitter (educated guess considering the EU stock twice as high as the US stock in 2011) vs. 210 000 to 435 000 tons estimated in the EC/ECHA report (being an estimation as well). SEAC notes that no robust figure on foam stocks in the EU seems to be currently available. Also, the methodology used to calculate these costs differ (depreciation of foam stock is not considered by the Dossier Submitter).
- *Incineration costs for the replacement of AFFF:* SEAC notes that no information on the magnitude of incineration costs is available to the Dossier Submitter. For illustrative purposes, a cost of 1€/kg (information based on literature review (see Background Document, e.g. Klein, 2013, EC/ECHA report on the use of PFAS and fluorine free alternatives in firefighting foams)) was calculated by the Dossier Submitter which results in costs between 4.3 to 43 million € considering a remaining stock of 42 750 t (after the derogation of 5 years had expired). The actual amount of stock that needs to be incinerated due to the actual PFHxA restriction is, however, uncertain as the previously implemented regulatory actions on PFOA (inclusion in REACH Annex XVII and subsequent inclusion in Annex I of the POP regulation) initiated a respective replacement of affected AFFF already. The calculations provided in the EC/ECHA report reveal a central cost estimate of € 320 million for incineration costs of legacy AFFF, the discrepancy being mainly due to different assumptions on foam volumes to be incinerated (estimated in the range of 210 000 to 435 000 t in the EC/ECHA report).
- *Cleaning of existing firefighting installations and vehicles:* respective costs are assumed to be substantial by the Dossier Submitter e.g. connected to the decontamination of fire extinguishing systems. The Dossier Submitter reported that for both mobile and stationary systems the removal of contaminations after the fluorinated foam concentrate is discharged and before the fluorine-free concentrate can be used is difficult and expensive. Relevant parts of the systems have to be flushed and decontaminated flush water has to be disposed of safely. Substantial costs were also confirmed by stakeholders providing comments during the consultation on the Annex XV report. However, no reliable estimate can be given and a crucial question is the share of any potential cleaning and decontamination costs to be allocated to the PFOA restriction

within the POP-regulation already. Comments provided during the consultation on the Annex XV report confirm that the respective costs can be expected to be substantial and therefore confirm the Dossier Submitter's conclusion. A quantitative cost estimate of €1 bn is provided in the EC/ECHA report. SEAC notes that this estimate is based on the cost of €12,300 per appliance for decontamination. This technique is reported to result in all appliances achieving PFAS levels below 1000 ppt and one-third of appliances being below 70 ppt. SEAC notes that the magnitude of cleaning costs of the equipment depends on the number of equipment facilities to be cleaned but also on the type of cleaning required to comply with the concentration limits. In this respect, the EC/ECHA report indicates that if a less stringent concentration limit is used, the costs would potentially be significantly lower. SEAC has no information available to evaluate what concentration limit for contaminated installations and vehicles would be optimal considering costs and remaining decontamination.

- *Adjustments to existing extinguishing infrastructure:* according to information provided by a distributor of fluorine-free foams during the preparation of the dossier, any potential costs are expected to be low as no major adjustments to the infrastructure are expected. During the consultation on the Annex XV report, information was provided that would indicate differently, stating that any respective costs could be immense (e.g. need to retrofit bund areas in tank farms in order to cover a significantly higher volume of liquids, need for significantly increased firewater retention capacity which could cause difficulties in retrofitting operating sites). No information is available to the Dossier Submitter and SEAC as to how many installations would need to be retrofitted and what the magnitude of the related cost would be.
- *Administrative issues, training with alternative foams:* costs cannot be quantified but are expected to be minor compared to the other cost factors.
- *Handheld fire extinguishers:* costs cannot be quantified but are expected to be affordable for consumers and SMEs. Some quantified figures are provided in the EC/ECHA report, which estimates unit costs to replace fire extinguishers to be €1-5, highlighting that there are uncertainties on the exact number of fire extinguishers that would need to be replaced (number ranging from 15m to 90m). SEAC notes that fire extinguishers, like other equipment, would need to be replaced only if cleaning does not prove efficient to meet the concentration limits set in the restriction or is not applicable from a practical point of view (assumed for small mobile extinguishers).

SEAC agrees to the Dossier Submitter's view that the estimated costs presented in the dossier and summarized above are highly uncertain as a lot of input factors would need further consideration:

- Any estimates on the dimension of the EU-wide stock on AFFFs and how much of it needs to be replaced or can be used (data on use rates of firefighting foams in the EU is also limited) during the five-year transition period.
- The need to replace stocks after the expiry date anyhow and replacement by new (fluorine-free) stocks being considered as an "earlier" replacement only. The Dossier Submitter estimated that nearly half of the existing stock would be used or reach the end of shelf-life during a 5-year transition period and therefore would not be affected by the restriction. SEAC on the other hand notes that EUROFEU claimed in the consultation on the Annex XV report that about less than 10% of AFFF is actually used before end of its lifetime (comment 2983). The Fire-Fighting Foam Coalition estimated that in the EU use rates

would be 8-10% and could be as low as 3-5% for the next five years, thanks to requirements on training and testing from the PFOA restriction (comment 3010). However, SEAC could not verify the robustness of these estimates.

- o The fact that substitution is ongoing due to the entry into force of the PFOA restriction within the POP regulation. It is assumed that likely more than half of the existing stock of AFFF containing PFHxA-related substances has to be disposed of as the mixtures contain PFOA and PFOA-related substances (estimated at up to 90% by industry during the POP-listing discussion process). Also, equipment needs to be decontaminated to ensure the concentration limits for PFOA and PFOA-related substances, which are identical to the limits proposed for PFHxA.

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

It was further claimed in the consultation on the Annex XV report that the restriction proposal did not consider high extra costs for new or re-engineered systems and vehicles and foam pumping systems (comment 3023). Also, loss of revenue to foam manufacturing companies were not considered (comment 3010); however, to this end, SEAC expects that they would largely not represent social costs in the long term but would be counterbalanced by gains by manufacturers of alternative products.

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

SEAC notes the complexity of this sector and the respective uses concerned and the Dossier Submitter's difficulties to establish reliable cost figures for the overall firefighting foam sector, as robust information on the above-mentioned cost factors and any related aspects is scarce. Extensive information was provided during the consultation on the Annex XV report by stakeholders on several aspects (specific uses, specific applications and specific situations) in order to fill the information gaps. Even though the information did provide helpful insight for some cost elements and/or applications, still several major uncertainties remain (such as the amount of current stocks held, feasibility of alternative fluorine free foams, information on substitution-related costs such as negative impacts through performance issues of fluorine free foams (environmental and human health impacts)). Even though the information provided is regarded as helpful by SEAC, it did not resolve the underlying uncertainties to an extent that would allow SEAC concluding on any quantified cost estimate.

- **Paper and cardboard – food contact materials (no derogations proposed):** SEAC notes that the most important application within this sector seems to be the production of paper and board for the packaging and preparation of food. The production of water- and oil/grease-repellent paper and board products is predominantly based on fluorine technology (UBA, 2018). Alternatives as regards water repellence are, according to the Dossier Submitter, available, e.g. plastics (polyacrylates, polyvinylalcohols with fatty alcohol side-chains etc.), silicon oils/resins

or silicon elastomers, paper refinement by micro- or nanofibrillated cellulose, etc. (for further details see Annex E.2.12.4 of the Background Document). As regards oil/grease repellence properties, finding alternatives providing a performance similar to that of PFHxA and related substances is more difficult, specifically when stability at higher temperatures is needed. The Dossier Submitter states that feedback from the sector during their consultation on the restriction proposal was limited. Based on the information available, the Dossier Submitter considers it reasonable to assume that alternatives are available for certain uses and that therefore PFASs are not needed for all applications. It is also concluded that not all alternatives might be desirable from an environmental/risk point of view, e.g. those containing microplastics.

For estimating the **substitution costs** of the proposed restriction, the Dossier Submitter concludes that efficient PFAS-free alternatives are indeed overall available (based on information provided by OECD, 2020), though at higher costs for the paper production (approximately 10 – 30 %) (for any details, see Annex E.2.12.4 of the Background Document). In a report issued in 2017 (Trier, 2017) it is concluded on the costs of alternatives for all uses of paper and board that these are neutral for retailers and hence most likely for manufacturers. During the consultation on the Annex XV report, only limited information was provided on this use. Some stakeholders claimed that when using alternative substances, much higher quantities are required in order to achieve the desired functionalities. However, these claims have not been substantiated by any supporting evidence. SEAC therefore agrees to base the assessment on data available in OECD (2020). Information presented in this report is the basis for calculating the estimated substitution costs of **€ 1.45 billion/year** (central estimate) for the cheapest alternative<sup>18</sup> (i.e. chemical alternatives; other alternatives discussed and evaluated are: physical alternative, C4 alternatives (30 – 50% higher use quantities)).

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

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<sup>18</sup> The price difference between PFHxA related substances and the chemical alternative is 150€/t, which multiplied by the 9.66 million t/a quantities used (i.e. assuming that 70% of the total 13.8 million t/a products are treated) gives the total costs of €1.45bn/year.

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

- **Mixtures for consumer use (no derogations proposed):** SEAC notes that information on current and future uses of PFHxA-related substances in mixtures for consumer use is highly uncertain (only one stakeholder provided information during the development of the restriction dossier, no specific information was provided during the consultation on the Annex XV report). Publicly available information indicates that both, fluorinated as well as fluorine-free products are available to consumers for e.g. impregnating agents, ski or floor wax, cleaning products, car care and polishes and the prices are in a similar range. Whilst the Dossier Submitter regards any potential direct impacts to manufacturers and consumers as low (as alternative products are on the market already), impacts from reduced or lost functionality of the mixtures are possible (the Dossier Submitter mentions e.g. fluorine-free ski waxes to be less effective in optimising the sliding properties of skiers). The Dossier Submitter does not draw any conclusion on potential costs within this sector and SEAC notes that the above made claims are not supported by any evidence in order to draw a conclusion on socioeconomic impacts within this sector.
  
- **Electronic devices:** the Dossier Submitter notes that there are several uses of PFAS in the production of electrical devices and their components, such as semiconductors, electronic grade coating, batteries and flat panel displays. SEAC notes the Dossier Submitter's conclusion on the following uses affected.
  - o **Semiconductors and semiconductor related equipment (longer transition period proposed):** SEAC notes that according to information provided by stakeholders, no single "drop-in"-alternative is available currently (and within the next five years) for the use of PFASs as process agents for the photolithography process, etching process and in cleaning fluids. Stakeholders reported that every use needs to be re-engineered to verify if a replacement material will meet the technological requirements. Alternatives that work for one application and/or company, might not work for another. Overall, the Dossier Submitter states that only limited information on alternative substances and technologies is currently available. Substitution possibilities and respective timelines are still not fully clear to SEAC based on the information available, so more concrete information on substitution efforts and timelines for the various applications would be needed (see Table 3 in Annex I for further details). For calculating and concluding on **substitution costs**, SEAC notes that no concrete information is available: no information on any potential impacts for the European industry could be obtained. Only some general information from the US is provided by the Dossier Submitter (global revenues of the semiconductor industry (470 billion USD in 2018), cost of developing a new photoresist in the US representing 0.3 % of annual sales and therefore this not being a barrier to develop new photoresist systems). Information is also provided on the yearly revenue of Europe based semiconductor manufacturers industry, which is estimated to be 42 billion USD. Stakeholders provided limited, company-specific quantitative cost information during the consultation on the Annex XV report; generally, it was stated that the economic impacts of applying the restriction to semiconductors immediately would be severe. SEAC notes that the information provided indicates that the societal costs resulting from profit losses, the closure of manufacturing sites



and release of workforce might result in a very high cost-effectiveness ratio (no overall quantitative assessment available to SEAC though) which would indicate disproportionate high costs of a restriction. A respective derogation on semiconductors and related equipment is therefore proposed by the Dossier Submitter (see respective section of this SEAC opinion) who recommends the European Commission to monitor the situation after the entry into force of the restriction.

- o **Electronic grade coating (higher concentration limits proposed by the Dossier Submitter):** Stakeholders reported that none of the known available non-fluorinated technologies could provide the full range of desirable properties delivered by their fluorinated counterparts. No drop-in alternative is expected to be available for this use in the short-term. The Dossier Submitter was not able to provide any qualitative or quantitative cost estimates. However, SEAC notes that *costs related to substitution* will likely occur as e.g. a higher number of affected devices is expected to break down due to the lack of water and oil repellence (respective derogation suggested by the Dossier Submitter, for any details see respective section of this opinion). During the consultation on the Annex XV report, one stakeholder (comment 3007) provided estimates on potential restriction related impacts if no time-limited derogation is granted (acknowledging that substitution is not impossible, but further time is needed for transitioning to alternatives). These estimates include a significant loss of revenue for the company as well as loss of profits for the company's suppliers, significant social cost of unemployment, at least € 315 million for the replacement of broken down devices in the EU (in the period of 2021 – 2024) and impacting the sales of more than 9.5 million devices each year with a value of at least € 3.6 billion. Further impacts to manufacturers of electronic devices, medical devices and other electronic equipment as well as printed circuit boards are expected. The Dossier Submitter regards these costs as partly overestimated as several aspects, such as alternatives being available (however, no drop-in alternatives providing the full range of properties), possibilities to repair broken down devices, etc. have not been sufficiently considered. As the above claims have not been substantiated by sufficient supporting evidence, SEAC cannot conclude on the robustness and reliability of the quantified cost estimates. However, SEAC notes that economic impacts are to be expected if no transition period is considered; their magnitude, however, being unknown.
- o **Uses of fluorosurfactants, having been raised during the consultation on the Annex XV report:** The Dossier Submitter considers these uses being covered by the suggested derogation for semiconductors. No cost information, neither qualitative nor quantitative, is available to SEAC on these additional uses.

- **Printing inks (longer transition period proposed for specific uses, i.e. latex printing inks):** the Dossier Submitter states that only very little information within this sector could have been obtained on the availability of alternatives for **water-based printing inks**. However, from the information available (e.g. use of siloxanes in many coatings, replacement of long-chain PFAS by C4 PFAS, the latter posing a potential case of regrettable substitution though, use of alternative technologies such as UV curable mixtures, etc.) the Dossier Submitter concludes that alternatives are available. Even though it is claimed differently in the consultation on the Annex XV report, no such information was submitted that would allow the Dossier Submitter and/or SEAC evaluating whether or not any such additional derogations would be proportionate and if so, for which specific applications. Furthermore, some cost information has been provided during the consultation on the Annex XV report by

stakeholders, e.g. on early replacement of printing equipment which is expected to induce further negative environmental impacts in terms of additional waste, partly hazardous to the environment, and additional CO<sub>2</sub> emissions, etc. if a suitable ink is not available and decreased printing quality. SEAC notes the Dossier Submitter's conclusion that any derivation of general substitution costs for the whole industry was not possible based on the information provided.

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

Due to lack of information, the Dossier Submitter could not derive **substitution costs** for the overall industry affected. As regards **costs related to substitution** activities, the largest effect is expected through an early replacement of printer hardware, in case the longer transition period for latex printing inks would not be implemented (more information is given in the respective section of his opinion). SEAC recalls from previous PFAS restrictions (e.g. PFOA) that companies using the printers in question are typically SMEs, which are less able to absorb the costs of early printer replacement. Overall, only scarce cost information is available to SEAC, no cost assessment as such was provided by the Dossier Submitter for the overall sector affected (e.g. some cost estimates are provided, those said to vary per company, ranging up to > 10 million €, however, no information is provided to SEAC how this figure was derived). SEAC can therefore not conclude on any potential costs related to this use. No major concern was raised by third parties during the consultation on the Annex XV report.

- **Chrome plating (longer transition period suggested for hard chrome plating):** alternatives seem to be available for **decorative chrome plating and plastic electroplating** and scarce information suggests that the **cost of substitution** is affordable. However, this cost information available to the Dossier Submitter as well as several uncertainties (e.g. the possibility of phasing in a "drop-in" alternative vs. requirement of new installations (tanks, baths, etc.), reports on partly extensive modifications of plating lines, etc.) and the complexity and heterogeneity of this sector do not allow establishing a quantified cost assessment. The Dossier Submitter notes that a shift away from Cr(VI) to Cr(III) (due to Cr(VI) being included in Annex XIV of REACH) can be observed for plastic electroplating and, where feasible, decorative chrome plating and that this induces a shift away from PFAS additionally as these substances are not required for this process. The Dossier Submitter concludes that due to the diversity of the sector, the establishment of a generalised restriction scenario and any respective quantified cost assessment is not possible.

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

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

- **Building materials/ construction products:** Regarding water repellence, similar as for textiles, the use of fluorine-free alternatives seems feasible. Furthermore, fluorine-free alternatives are said to be cheaper than fluorinated substances. This conclusion doesn't hold for oil and dirt repellence properties. Stakeholders submitted information that these properties generate considerable benefits, such as longer lifetime, lower repairing interval, reduced paint waste from recoat preparation, or even the enhancement of protective properties of anticorrosion points by perfluorinated urethanes. However, no concrete figures on **substitution costs** or any **related costs** of the proposed restriction were provided or could be derived by the Dossier Submitter. During the consultation on the Annex XV report, stakeholders provided comments that without the use of fluorinated products, the necessity of cleaning activities of buildings (protective measure, e.g. façade maintenance) would increase from every 15 – 20 years to every 2 – 4 years with the result to use large amounts of chlorine based products (10 – 20 times) instead of using C6 once. A similar effect is reported for the painting of buildings. SEAC agrees that this may be a relevant point to consider, however, based on the available information the use may only concern a minor part of buildings, implying that other solutions exist. A further comment is referring to the use of fluoropolymer chemistry for so-called "cool roof"-systems, which reduce energy costs of large buildings and therefore reduce CO<sub>2</sub> emissions. The Dossier Submitter concludes – and SEAC agrees - that these comments have not been substantiated by any supporting evidence. Still, SEAC notes that any such effects could occur. However, the actual consequences as well as their likelihood and magnitude are unknown to SEAC.
- **Photographic applications (longer transition period proposed):** SEAC considers that information provided by the Dossier Submitter on these uses (such as use amounts and respective releases, alternatives, costs, etc.) is overall conflicting and unclear. There are diverging views by the Dossier Submitter and RAC on whether amounts of fluorinated surfactants used in photographic coatings applied to films, paper, plates and inkjet photo media coating are high (RAC's view) or low (DS's view). From the Dossier Submitter's assessment, SEAC notes that there is also conflicting information provided by stakeholders as regards the availability and feasibility of alternatives. There is some indication about potential non-fluorinated alternatives, however, this is confidential business information not available to the Dossier Submitter and SEAC; therefore, no concrete information on alternatives in the photo-imaging sector can be provided. According to another stakeholder, there is lack of suitable non-fluorinated alternatives for some specific applications. It is not clear to SEAC to which applications this statement is referring to. Overall, SEAC agrees to the Dossier Submitter's conclusion that due to the ongoing transition to digital techniques, there is a downward trend in market demand for photographic films (e.g. hobby photographers, medical or defence applications) and that partly significant investment in equipment (0.5 – 1 million € per single photographic material) would be needed to switch to alternatives (considered comparatively high compared to expected low emissions). In case a time-limited derogation is supported, the transition to digital technique is expected to be fully completed avoiding significant investments. However,

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

- **Cosmetic products (no derogation proposed):** The Dossier Submitter states that PFAS-free alternatives are available for all cosmetic products. This statement seems to be confirmed by announcements of large producers (such as L'Oréal, H&H, Lumene, Body Shop, Isadora and Kicks) to phase out all PFAS from their products. One stakeholder (L'Oréal) announced already in 2018 that reformulation processes are completed for all their trademarks. The Dossier Submitter recognises that no cosmetics producer submitted comments during their consultation process; neither in the consultation on the Annex XV report was any information provided by this sector. Overall, it is therefore concluded that alternatives are available and feasible and no functional losses of products are to be expected. However, a certain degree of uncertainty remains as regards the affordability of a restriction to small and medium sized enterprises as no information is available to the Dossier Submitter whether such companies are prepared to reformulate at affordable cost, i.e. whether the scientific expertise and financial resources are available to reformulate products. Overall, SEAC lacks sufficient information to draw a conclusion on socioeconomic costs (mainly *substitution* and any *potential related costs*) within this sector, specifically for SMEs. However, in the absence of any information provided by stakeholders during the consultation, SEAC does not expect major economic implications with the approach suggested by the Dossier Submitter.
- **Medical devices (derogation proposed):** within the medical sector, different applications for PFHxA exist and the Dossier Submitter considers medical devices to also include medical textiles. The Dossier Submitter expects that there are current (and future) uses within this sector that have not been identified by them or raised in the consultation on the Annex XV report either. They explained that it became clear from meetings with stakeholders that several of them have not been aware of the restriction proposal. As only limited cost information was available to the Dossier Submitter when developing the restriction proposal, no cost assessment was provided in the restriction dossier. During the consultation on the Annex XV report several comments for this sector have been provided, some also including information on costs. The Dossier Submitter did not provide an assessment of costs as they expect no economic impacts to occur to this sector in light of the proposed complete derogation (as stated above). However, they conclude that whether or not this information is representative for all uses is unknown. In their view, it is highly unlikely that the sample from the consultation represents reliable information in regard to all uses for medical devices. In SEAC's view, the comments provided during the consultation on the Annex XV report on any potential costs of a restriction are either very generic or company and product specific and cannot be taken forward for an assessment of the overall socioeconomic impacts for this sector, in the absence of any

such analysis by the Dossier Submitter. For example, the following cost information was provided during the consultation on the Annex XV report:

- Health costs stemming from increased thrombosis, bacterial adhesion and infection for the application in implantable, e.g. stents and non-implantable, e.g. vascular catheters medical devices (comments 3014 and 3137);
- Increase in service and repair of hearing aids by 30%, but no monetisation provided (comment 3121);
- Company specific costs for eye drops manufacturer, in terms of decreased net revenue, relocation costs and unemployment costs (comment 3153, figures claimed confidential).

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

- **Filtration and separation media (derogation proposed):** during the consultation on the Annex XV report, several stakeholders requested a complete derogation for the use of PFHxA in filters and membranes. The Dossier Submitter proposes a derogation for filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil repellence properties, even though it is well-noted in the Background Document and by SEAC that such a broad derogation leads to a certain degree of uncertainty as it might be possible that alternatives are already available or will become so in near future for some applications. Cost estimates for the uses affected are scarce, only some information was provided by stakeholders during the consultation on the Annex XV report. This information mainly indicates that specifically **costs related to substitution**, e.g. loss of effectiveness of products due to no alternatives being available currently, could be potentially very high. Stakeholders reported that appropriate filtration reduces maintenance needs, extends service life and prevents failures of equipment; they also expect energy consumption and related greenhouse gas emissions to increase in the absence of C6-treated filtration media. During the consultation on the Annex XV report, it was stated that the absence of a derogation will put manufacturing facilities located in the EU at risk and result in a supply interruption of filtration and separation media for several purposes until adequate alternative candidates are identified and requalified. SEAC agrees to the Dossier Submitter's conclusion that more information on the different applications and specifically a more detailed discussion on substitution possibilities as well as on any potential related costs would be needed in order to draw a robust conclusion on the socio-economic impacts.
- **Optical fibres (no derogation proposed):** during the consultation on the Annex XV report, requests for derogations have been submitted by stakeholders, claiming alternatives not being feasible. However, the information provided did not induce the Dossier Submitter to propose a derogation for this use (see respective section of this opinion). As regards costs, no information on **substitution** and any **potential related costs** of a restriction are available to SEAC.
- **Epilames used in watches (derogation proposed):** during the consultation on the Annex XV report, stakeholders requested a complete derogation for this use, which was taken up by the Dossier Submitter (for more information see respective section of this opinion). No specific cost information was provided by stakeholders during the consultation, even though specifically requested by the Dossier Submitter. Still, the Dossier Submitter considers that a derogation for this use is justified based on socio-economic considerations (low emissions, confirmed by RAC, that is supporting a derogation compared to potentially substantial impacts for affected companies as well as social impacts (substantial job losses for the European watch component supply

industry as stated in a comment provided by the Swiss watch industry, being a major client of the EU supply industry; however, this figure not being supported by evidence). SEAC agrees that a restriction could have socio-economic impacts (such as job losses) but notes that some uncertainties for this sector remain it is claimed that companies would no longer be able to produce watches according to international standards. However, it is not clear to the Dossier Submitter what these standards are. If these are referring to ensuring a longer service life of the products and less maintenance, then they regard the derogation as justified based on cost-risk considerations (potentially high impacts for industry, very low use/release volumes). If these standards refer to a more precise functioning of watches, then not. This is, however, not clear from the information provided in the consultation on the Annex XV report. Overall, SEAC has no qualitative or quantitative information to conclude on any potential impacts for the watch industry.

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

- Handling of fragrance and odour compounds in products and articles;
- Use of perfluoropolyethers in aerosol applications during in-house quality control of other fluoropolymer products (laboratory application);
- Use of C6 fluorosurfactants in the production of polyester films as anti-fog coatings for face shields for surgeons;
- Use of fluorinated substances in special glass for construction (external glazing and internal decorative glass), automotive (original and replacement glass) and the solar sector.

SEAC has no information on costs or any socio-economic consequences of a restriction for the above-mentioned uses. SEAC notes that it is unclear whether face shields for surgeons would fall under the definition of medical devices as per Regulation (EU) 2017/745. No such information was provided, neither in the Background Document, nor during the consultation on the Annex XV report.

### Reporting costs

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

### Enforcement costs

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

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

### Testing costs

As to the **price range of the existing tests**, the results of a survey recently carried out by ECHA<sup>19</sup> indicated that the average price for testing for PFHxA or related substances is around €350 per sample or €50 000 for 300 samples (covering many different matrices). SEAC underlines that making a relevant estimate of testing costs would also require information on the **number of tests** to be performed, and information on costs related to sampling and sample preparation (if not carried out by the laboratory and included in the price of analysis). This information is, however, not available to SEAC. Still, SEAC considers that the above-mentioned information provides some indication of the magnitude of the associated costs.

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

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

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<sup>19</sup> Available in the published collection of comments submitted to the consultation on the Annex XV dossier, comment nr 3115

## Benefits

### **Summary of proposal:**

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

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

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

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

However, even though the approach is considered appropriate in general, SEAC notes RAC's conclusion on several shortcomings within the Dossier Submitter's assessment, e.g. gaps in the description of underlying assumptions of the calculations, divergent and inconsistent release calculations for same sectors, as well as lack of or unclear and incomplete information on which substances covered by the restriction the release calculations refer to. As a consequence, RAC regards the reported quantitative release estimates as unreliable and concludes that the Background Document provides insufficient information to draw firm



conclusions on the central estimates and ranges of releases to the environment. RAC states that there is insufficient scientific data to conclude with certainty on the use volumes, source and scale of emissions from the different uses (which are in turn used as a proxy for risk) and, with the exception of a few sectors, whether the implemented OCs and RMMs are sufficient to address the risks. Further details are provided in the respective RAC section of this opinion.

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

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

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

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

- **Emission reduction used as a proxy for risk reduction/benefits assessment:** SEAC notes that the Dossier Submitter has based the benefits assessment on quantified release estimates and qualitative supportive information. SEAC in general agrees with the use of this approach that is in line with SEAC's guidance "*Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC*".<sup>20</sup> Whilst PFHxA is not a PBT or vPvB substance, SEAC notes RAC's conclusion that the hazard associated with PFHxA lead to a concern very similar to PBTs/vPvBs. RAC supports the use of a case-by-case approach where any releases and exposures are regarded as a proxy for the risk to the environment and human health and where the releases of PFHxA, its salts and related substances should be minimised. In support of the case-by-case approach is the restriction proposal on intentionally added microplastics (ECHA, 2019), where primarily the very high persistence, leading to continuously increasing environmental stocks, served as a proxy for the risk. The approach was supported by both Committees, RAC and SEAC. However, SEAC notes RAC's concern with the Dossier Submitter's specific assessment, being unclear, partly

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<sup>20</sup> [https://echa.europa.eu/documents/10162/13580/evaluation\\_pbt\\_vpVB\\_substances\\_seac\\_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3](https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpVB_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3)

inconsistent and unreproducible. SEAC therefore notes that no quantified information on emission reduction (not even ranges) is available to assess the benefits of the proposed restriction and the proportionality and derogations respectively.

- **Benefits estimation:** due to the above mentioned shortcomings in the Dossier Submitter's assessment, RAC could not establish neither quantitative emission estimates, nor any respective ranges as there is insufficient scientific data to conclude with certainty on the use volumes, source and scale of emissions from the different uses (which usually should serve as a proxy for risk). RAC provides a qualitative discussion on a per-sector basis. Even though some of the Dossier Submitter's assumptions are, according to RAC, unrealistic worst-case and generally the emission estimates are uncertain, the use areas of highest concern when it comes to potential EU emissions of PFHxA are **(imported) textiles, paper and cardboard (food contact materials) and firefighting foams** (further information is provided in the respective RAC sections of this opinion). SEAC notes RAC's conclusion that measured data in various environmental matrices convincingly demonstrate that emissions to the environment do occur. SEAC notes that overall, RAC draws the following three different conclusions, to which the single sectors/uses can be allocated to (further information is provided in table 5 and 6 of the RAC opinion as well as the proportionality section of the SEAC opinion):
  - o **RAC concludes that emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses;**
  - o **RAC concludes that emissions are minimised by means other than a restriction (e.g. through site-/use-specific RMMs) and therefore supports a derogation;**
  - o **RAC cannot conclude on the use, potential releases and the minimisation of emissions based on the information available; too many uncertainties exist.**

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

- **(Regrettable) Substitution:** SEAC highlights that **alternatives**, also fluorine-free ones, are often associated with risks. Different risk profiles may be difficult to weight against each other, and as far as the risks of alternatives are not fully elucidated (or perhaps it is not even known yet which alternatives would be adopted in each use) careful consideration is necessary when phasing out substances allowing time for the industry to find out suitable less risky alternatives for the different uses. SEAC notes that PFHxA, its salts and PFHxA-related substances are one group of substances in the family of fluorotelomer substances. Several other groups of substances (PFOS, PFOA, C9-C14 PFCAs, PFHxS and their related substances) are already subject to restrictions. Leaving this group of substances unregulated could undermine the benefits of the earlier restrictions if the other substances were substituted with these substances having similar overall concerns. SEAC highlights that, as for all restrictions, the benefits of the proposed restriction strictly depend on whether the chosen alternative substances are safer for human health and the environment. In fact, for example in terms of the quality of drinking water, the occurrence of any PFAS is a source of concern. As a consequence, the estimates of avoided remediation cost may be relevant only for evaluating a switch to non-fluorinated substances.
- **Costs of non-action:** SEAC notes that potentially high **remediation costs** for contaminated sites and drinking water could be avoided by the proposed restriction. A lot of examples on remediation costs of sites contaminated by PFASs in general can be found in literature. The Background Document reports an assessment made by the Nordic Council of Ministers which estimated that remediation costs relating to PFASs

at the European level (31 EEA Member States and Switzerland) are in the order of magnitude of hundreds of millions of euros at a minimum, ranging from 821 million to 170 billion euros. The potential costs relating to the treatment of water because of contamination by very mobile substances are indicated in the Background Document by reporting on an estimation by EurEau (2019), the European federation of national associations of drinking water suppliers and wastewater services. According to their calculation, the cost for reverse osmosis, a treatment technique against most polar compounds, would raise the price of water treatment by more than 1 €/m<sup>3</sup>, resulting in circa 200 €/year additional cost for the average household. This is highlighted to be just one element; other societal costs would also accrue but SEAC has no information on their magnitude.

- **Global efforts on a phase out of PFAS:** SEAC points out that as this restriction is part of wider European and global efforts to replace PFASs with safer fluorine-free alternatives, the actual risk reduction potential – and, therefore, benefits of these actions – will gradually materialise as the implementation of the measures advance.

## **Other impacts**

### **Summary of proposal:**

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

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

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

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

- alternative substances seem to exist for many functionalities affected or will become so in the foreseeable future; according to the Dossier Submitter, prices of alternatives lie within reasonable ranges, uncertainty exists as regards the respective amounts to be used in order to achieve the same functionalities (see sector-specific discussion on costs of this section); where the substitution process is complex or regarded as impossible to date, the Dossier Submitter suggests respective derogations (see

respective section of this opinion) which would allow industry to further use the substances for producing their products (hence, no costs expected);

- products relying on the alternative substances are available in several sectors/for several product types;
- PFAS in general are seen as a worldwide concern and early R&D as well as production of alternatives might be regarded as an advantage over other countries outside Europe when they decide to regulate C6 substances in future;
- European and non-European companies will need to keep their market shares and market position vis-à-vis their competitors, hence major increases of consumer prices of PFHxA-free articles are regarded as unlikely.

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

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

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

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

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

## **Overall proportionality**

### **Summary of proposal:**

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

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

When considering only substitution costs, the Dossier Submitter finds that the restriction is proportionate. For most uses identified, costs are said to be low due to the fact that non-fluorinated alternatives are expected to be less expensive than or similar priced as the restricted substances (for a sector- and/or use specific discussion, see respective sections of the Background Document). However, for several uses, the Dossier Submitter has identified potentially significant costs related to substitution such as reduced quality of products or functional losses, which are largely unknown and/or uncertain and evaluated only qualitatively (see section 2.5.1 on economic impacts of the Background Document).

The Dossier Submitter acknowledges the high uncertainties within the cost and benefits assessment of this restriction dossier but observes that other restriction proposals under REACH have faced large uncertainties too. As an example, the restriction proposal for intentionally added microplastics is mentioned. In their view, this case demonstrates that immediate regulatory action<sup>21</sup> might be justifiable whenever effects of a substance are uncertain but irreversible and when learning about a possible harm is expected to happen in future. In this case a "first act, then learn" approach might be preferred over a "first learn, then act" approach.

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

The Dossier Submitter provides a sector-/use-specific discussion on proportionality in the restriction dossier (see Table 8 in section 2.5.5 of the Background Document) but considers a conclusion for the overall restriction proposal as difficult, due to lack of data and high uncertainties on both costs and benefits. Therefore, instead of a cost-effectiveness analysis, the Dossier Submitter proposes to consider reasonable worst-case scenarios for costs and benefits and evaluate whether the consequences of such scenarios are affordable to society as a whole and impacted individuals or subgroups. When information is missing or incomplete and informed optimal decision-making is not possible, the Dossier Submitter regards minimisation of future regret as an adequate strategy. For some uses this approach leads to distinct and intuitively understandable conclusions for what action should result from adopting

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<sup>21</sup> No regulatory decision has been taken on the restriction proposal on intentionally added microplastics at the time SEAC agreed on its draft opinion on the restriction proposal on PFHxA, its salts and related substances.

the “first act, then learn” approach: in the first place the approach suggests to ban all uses of PFHxA, its salts and related substances because the effects of the substance are uncertain but irreversible. However, when considering reasonable worst-case consequences on human health and the environment arising from the restriction due to the lower performance of currently available alternatives (e.g. less effective products such as PPE or not being able to effectively extinguish large fires), it might be necessary to act first by granting a derogation for certain uses to prevent possibly disproportionate irreversible consequences for human health and the environment.

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

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

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

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

Instead of such an overall conclusion, the SEAC opinion comprises a sector-by-sector discussion (considering also sub-sectors) on potential alternatives, costs and RAC’s conclusion

on uses/RMMs (see Table 2 below). In particular, even in cases where SEAC cannot conclude on proportionality for a specific sector or sub-sector, SEAC provided its views on derogations considering the following aspects:

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

SEAC points out that this analysis is based on the available, overall qualitative information in the restriction dossier, information provided during the consultation on the Annex XV report as well as RAC's conclusion on uses and emission minimisation. In this respect, SEAC recognises that there are large uncertainties on the exact magnitude of the socio-economic impacts of the restriction and of the emissions for specific sectors. Therefore, SEAC acknowledges that more accurate and representative information on emissions and costs could change the outcome of sectoral analysis, for example concerning the need for a derogation or the proposed length of the transition period.

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

The following elements underpin SEAC conclusions on proportionality:

- SEAC stresses that it is not currently possible to draw a robust conclusion on the proportionality of the overall restriction proposal and any potential derogations, because the magnitude of **environmental benefits of the emission reduction** achieved is uncertain (due to large uncertainties and data gaps, no conclusions on releases and a respective release reduction through a restriction are drawn by RAC and available to SEAC). SEAC considers that the **irreversibility of emissions** is a key argument in favour of proportionality. The pollution stock is permanent, i.e. not possible to remove from the environment with the available remediation methods. If remediation would be at all possible, SEAC considers it likely to be much more costly compared to the costs of the proposed restriction.
- SEAC notes that the Dossier Submitter did try to use emissions as a proxy for risk in its assessment, which is the current standard approach applied also by SEAC in its evaluation of restrictions and authorisation applications for substances for which no standard quantitative risk assessment is possible (following ECHA's guidance on the evaluation of restrictions and authorisation applications for PBT and vPvB substances in SEAC<sup>22</sup>). However, SEAC notes that this approach does not consider any implications of **stock externalities** for the evaluation of risks and benefits of a restriction respectively. In this respect, SEAC notes that:
  - Even marginal releases contribute to the environmental pollution burden;
  - Stopping emissions does not imply that impacts disappear, neither in the short, nor in the long term (except for the case that remediation measures can be and are adopted);

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<sup>22</sup> See: [evaluation\\_pbt\\_vpVB\\_substances\\_seac\\_en.pdf \(europa.eu\)](#)

- o Benefits, in terms of avoided negative environmental impacts, can stretch over much longer time periods than cost estimates of a restriction.
- SEAC notes that an EU-wide ban on PFOA, its salts and related substances applies from July 2020 under the Regulation (EU) 2019/1021 on persistent organic pollutants. PFHxA-related substances are potential substitutes of PFOA-related substances in many uses. Indeed, during the consultation on the Annex XV report, some industry stakeholders indicated that they have already transitioned to PFHxA-related substances following the restriction on PFOA. Therefore, in the absence of the proposed restriction it could be expected that the use of PFHxA, its salts and related substances would continue in the future.

SEAC's evaluation on proportionality as well as on derogations on a per-sector basis is summarised in Table 2 below. The conclusions are based on the approach outlined in the section above. SEAC's detailed considerations, including the description of SEAC's approach for the evaluation and the underlying arguments for its sectoral conclusions, are provided in the sections 'costs' and 'benefits' of this opinion as well as in the use-specific analysis presented in Annex I (Table 3 and Table 4).



Table 2: Overview on cost estimates, alternatives, RAC's conclusion on uses, releases and emission minimisation as well as proportionality aspects and derogations per sector

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
<b>Manufacture and use of fluoropolymers</b>	Not applicable	General conclusion on alternatives not feasible due to numerous applications requiring different specific functionalities. Stakeholders reported that alternatives do not provide a combination of relevant functionalities which could lead to negative impacts on several sectors affected with possible unpredictable knock-on effects on other sectors.	Overall unknown/uncertain; societal costs are expected to be very high by STOs (e.g. severe HH impacts) due to potential functional losses of certain products.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and costs. A conclusion on the proportionality of restricting this use is therefore not possible.	<b>No</b> The main reasoning is that a justification for the choice of the higher concentration limits is missing.
<b>Manufacture and use of fluoroelastomers</b>	Not applicable	Yes, non-fluorinated alternatives are available but, according to stakeholders, do not provide heat, chemical, oil resistance as well as low-permeability	No information available on substitution costs. Information available indicates that functional losses are likely to occur and would negatively impact engine performance, safety and emissions in the automotive sector.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and costs. A conclusion on the proportionality of restricting this use is therefore not possible.	<b>No</b> The main reasoning is that a justification for the choice of the higher concentration limits is missing.
<b>Manufacture of SFPs</b>	Not applicable	Alternatives to SFPs are available for water repellence	No specific analysis provided in the dossier on manufacture of SFPs. Socio-economic impacts for the variety of applications of SFPs are described by sector.	This is considered by RAC as intermediate use.  Emissions are minimised by means	SEAC notes that RAC supports a derogation as emissions are minimised by means other than a restriction.	Derogations or longer transition periods are proposed for specific sectors of application of SFPs (e.g. textiles etc.).

<sup>23</sup> The costs' assessment reported does not include information on the number of products or individuals affected, as this is not available in the restriction dossier. However, SEAC notes that this important aspect of the socio-economic analysis is missing.

<sup>24</sup> For a more detailed discussion on derogations, please see Annex I.

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
				other than a restriction (e.g. through sire-/use-specific RMMs).	SEAC concludes that restricting this use is likely not proportionate.	A derogation is also proposed for transported isolated intermediates.
Textiles	Consumer apparel (e.g. outdoor clothing)	Yes, available and feasible as regards water repellence	Negligible substitution costs, possibly minor costs linked to changes in equipment. Limited functional losses expected, as clothing industry is already switching to fluorine-free alternatives.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates limited socioeconomic impacts only. SEAC concludes that restricting this use is likely not disproportionate.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.
	Professional apparel (PPE)	No, not yet available, nor feasible as regards repellence against oil, dirt, bodily fluids, and liquid chemicals with low surface energy	Lack of repellence against oil, stain, bodily fluids, and liquid chemicals with low surface energy would result in functional losses probably leading to decreased safety and human health costs. Functional loss for PPEs against risks resulting in death and permanent health damage (cat. III) would result in higher human health costs.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socioeconomic impacts (high human health costs). SEAC concludes that restricting the use in PPEs is likely not proportionate.	<b>Yes</b> SEAC finds that a derogation for PPEs against risk III categories a, c, d, e, f, g, h, l, and high-visibility clothing might be necessary. Furthermore, SEAC considers that PPEs for armed forces should be treated similarly to the above-mentioned PPE categories.
	Home textiles		Lack of repellence against oil, dirt and decreased UV protection would result in	Emissions cannot be minimised by means other than a	SEAC notes a lack of information on the magnitude of	<b>No</b> SEAC finds that no information that

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
		Yes, available and feasible as regards water repellence  No, not yet available, nor feasible as regards repellence against oil, dirt, bodily fluids, and liquid chemicals with low surface energy	functional losses probably leading to increased washing, reduced service life and durability of articles. No information on related costs is available to SEAC.	restriction, e.g. due to wide-dispersive uses.	emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	demonstrates the necessity of a derogation was provided.
	Technical textiles/ Industrial fabrics <sup>25</sup>		Lack of repellence against oil, stain, bodily fluids, and liquid chemicals with low surface energy would result in functional losses. The consequent impacts vary from the specific applications: <ul style="list-style-type: none"> <li>• Outdoor upholstery: reduced service life and durability.</li> <li>• Filtration and separation (see separate entry)</li> <li>• Medical textiles (see separate entry)</li> <li>• Textiles in engine bays: possible negative impacts on potentially life-saving functions.</li> </ul> No information on related costs is available to SEAC.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.  For textiles used in engine bays, some more information was provided. SEAC is unable to conclude firmly, but considers it is possible that restricting this specific use may not be proportionate.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.  SEAC considers that derogation of textiles used in engine bays might be necessary, but the information available is not sufficient to conclude.  For medical textiles and filtration - see entries for medical devices and for filtration and separation media.
<b>Firefighting foams</b>	General			<i>Municipal/mobile fire-fighting:</i> emissions cannot be minimised by means other than a restriction, e.g. due	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. SEAC concludes	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.

<sup>25</sup> Technical textiles/industrial fabrics being mainly used in automotive and aerospace applications, as filtration media and in the construction sector.

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
				to wide-dispersive uses.	that restricting this use is likely not disproportionate.	
	Production of mixtures for class B foams	Alternatives are overall regarded as available and feasible for firefighting foams. However, for some applications, (time-limited) derogations are claimed to be required due to sector-/use-specific requirements and verification of performance levels of FFFs. These are reflected in the derogation section.	Some quantified cost information was overall provided by the DS as regards replacement costs, incineration costs, cleaning of equipment, etc. (see cost section). Substitution costs are not expected to be significant due to alternatives being overall available to similar prices. However, substitution related cost might be significant; the figures provided are too uncertain to conclude on any quantified/qualitative cost estimate. No cost estimates for specific applications discussed (e.g. defence applications, large tanks) are available.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socioeconomic impacts. SEAC concludes that restricting this use is likely not proportionate at present <sup>26</sup> .	<b>Yes</b> Based on the information provided, SEAC finds that a longer transition period of 5 years would likely be necessary to avoid disproportionate socioeconomic impacts.
	Certain defence applications			Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs (no specific information provided as regards costs for the defence sector). A conclusion on the proportionality of restricting this use is therefore not possible.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided. Furthermore, exemptions may be granted by national authorities.

<sup>26</sup> Where SEAC concludes that a restriction is likely not proportionate “**at present**”, this indicates that it is considered that alternatives will become available in the timeframe indicated and a time-limited derogation is supported.

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
	Large tanks			Based on the information available/ the lack of information on RMMs, RAC cannot conclude on the use, potential releases and the minimisation of emissions and cannot support a derogation <sup>27</sup> .	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socioeconomic impacts. SEAC concludes that restricting this use is likely not proportionate at present.	<b>Yes</b> Based on the information provided, SEAC finds that a longer transition period of 12 years would likely be necessary to avoid disproportionate socioeconomic impacts. However, several uncertainties (related to size and time) still exist.
<b>Paper and cardboard (food contact materials)</b>	Not applicable	Yes, publicly available information indicates so. Some companies have fully substituted already.	Substitution costs estimated to be €1.45 bn/a (high costs linked to high used tonnages). Limited functional losses expected, as alternatives are available, industry is switching or has already switched to fluorine-free alternatives and no comments were received about functional losses during the consultation.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs and ongoing substitution activities indicate somewhat limited socioeconomic impacts. SEAC concludes that restricting this use is likely not disproportionate.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.
<b>Mixtures for consumer use</b>	Not applicable	Yes, publicly available information indicates so.	No qualitative or quantitative overall cost estimate is	Emissions cannot be minimised by means	Whilst SEAC notes a lack of information on	<b>No</b> SEAC finds that no

<sup>27</sup> To be noted that RAC recommends waiting for the restriction proposal on PFAS in firefighting foams to obtain more specific information on the effectiveness of RMMs to minimise releases from this use, which would allow a more informed decision.

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
			available. Substitution costs for manufacturers and consumers regarded as low, other substitution related costs are unknown.	other than a restriction, e.g. due to wide-dispersive uses.	the magnitude of emissions/emission reduction (benefits), information on restriction-related costs and ongoing substitution activities indicate somewhat limited socioeconomic impacts. SEAC concludes that restricting this use is likely not disproportionate.	information that demonstrates the necessity of a derogation was provided.
Printing inks	General	Only limited information available. Alternatives, however, regarded available as far as water-based printing inks are concerned. Comments provided indicating lack of alternatives are not substantiated by sufficient evidence	Overall, no information on substitution, substitution related costs or any other cost impact provided by the DS. For latex printing inks, SEAC notes the DS's conclusion that potentially high costs could be expected if no time-limited derogation would be implemented (e.g. through early replacement of printer hardware)	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.
	Latex printing inks	No simple "drop-in" substitution solutions available and feasible, substitution process regarded as complex.		Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socioeconomic impacts. SEAC concludes that restricting this use is	<b>Yes</b> Based on the information provided, SEAC finds that a longer transition period of 7 years would likely be necessary to avoid disproportionate socioeconomic impacts.

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
					likely not proportionate at present.	
Chrome plating	Decorative chrome plating/ plastic electroplating	Alternatives seem to be available for <b>decorative chrome plating and plastic electroplating</b> (voluntary substitution takes place already). Alternatives said to not having been sufficiently tested for <b>hard chrome plating</b> ; currently, it is not expected that alternatives can provide the necessary functionalities.	Overall, no information on substitution, substitution related costs or any other cost impact is available.	Based on the information available/ the lack of information on RMMs, RAC cannot conclude on use, potential releases and the minimisation of emissions and cannot support a derogation.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socioeconomic impacts. SEAC concludes that restricting this use is likely not proportionate at present.	<b>No (no specific derogation if general TP is prolonged to 36 months; otherwise, a use-specific derogation might be needed)</b> SEAC does not agree with the DS that immediate transition to alternatives is possible. Whether or not a specific time-limited derogation is necessary depends on the general TP recommended (DS's proposal of 18 months being regarded as too short by SEAC).
	Hard chrome plating		Overall, no robust information on substitution, substitution related costs or any other cost impact is available. However, alternatives claimed to be costly.		Whilst SEAC a notes lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socioeconomic impacts. SEAC concludes that restricting this use is likely not proportionate at present.	<b>Yes</b> Based on the information provided, SEAC finds that a longer transition period of 5 years would likely be necessary to avoid disproportionate socioeconomic impacts.

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
<b>Building materials/ construction products</b>	Not applicable	Alternatives seem to be available and affordable (cheaper prices) as regards water repellence functionalities. This conclusion is, however, not valid for oil/dirt repellence properties. A wide variety of products is covered, discussion and decision on alternatives likely to be product-specific.	Overall, no robust information on substitution, substitution related costs or any other cost impact is available.  Stakeholders claim that significant negative impacts are expected due to substitution (e.g. higher repairing intervals, increased paint waste from recoat preparation, etc.), their likelihood and magnitude being unknown.	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.
<b>Photographic applications</b>	Photographic coating on film	Unclear: industry stakeholders reported that non-fluorinated alternatives are not available, but other sources (UNEP, 2018b) indicate differently.	Investment for switching to alternatives estimated to be €0.5 – 1 million for a single photographic material. Negative economic impacts expected in the short-term, transition to digital techniques in the long-term.	For all photo applications (no differentiation for sub-sectors made by RAC): emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs indicates potentially high socioeconomic impacts, specifically if a respective transition time is not given. SEAC concludes that restricting this use is likely not proportionate at present.	<b>Yes</b> Based on the information provided, SEAC finds that a transition period of 5 years would likely be necessary to avoid disproportionate socioeconomic impacts.
	Photographic coating in printing plates	Unclear: industry stakeholders reported that research on alternatives is on-going.	According to the DS, negative economic impacts expected in the short-term, transition to digital techniques in the long-term. No robust information on socio-economic impacts provided in the consultation.			<b>Yes</b> Based on the information provided, SEAC finds that a transition period of 5 years would likely be necessary to avoid disproportionate socioeconomic impacts.



Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
	Photographic coating on paper and coatings on inkjet photo media	Some alternatives seem to be available but provide lower quality.	Stakeholders reported possible costs in terms of premature replacement of printing equipment (in the range of millions of €) and functional losses resulting in defects and reduced quality of printing.		SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.
<b>Electronic devices</b>	Semiconductors and semiconductor related equipment	No drop-in alternatives are available and not providing the full range of desirable properties. Substitution is regarded as process-specific for these uses; partly high length of supply chains, high quality requirements, etc. (relevant mainly for semiconductors) make a quick transition difficult. Overall conclusion is not possible.	No quantified cost assessment provided; claims that substitution is costly; some indication on high societal impacts due to profit losses, closure of business, etc.; severe economic impacts also stressed by STOs in consultation.	Emissions are minimised by means other than a restriction (e.g. through site-/use-specific RMMs); derogation supported.	SEAC notes that RAC supports a derogation as emissions are minimised by other means than a restriction, and that information on restriction-related costs indicates potentially high socioeconomic impacts. SEAC concludes that restricting this use is likely not proportionate at present.	<b>Yes</b> Based on the information provided, SEAC finds that a longer transition period would likely be necessary to avoid disproportionate socioeconomic impacts. The exact timeframe needed is, however, uncertain.
	Electronic grade coating		No quantified cost assessment provided in the restriction dossier, some quantified cost figures (loss of profits, social cost of unemployment, etc.) provided in the consultation.	Covered by the discussion on fluoropolymers.	Covered by the discussion on fluoropolymers	<b>No</b> See discussion on the higher concentration limits for fluoropolymers.

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
<b>Cosmetic products</b>	Not applicable	PFAS-free alternatives are said to be available for all cosmetic products. This is supported by the voluntary phase-out of companies.	Only negligible costs for manufacturers are expected, mainly due to reformulation. However, no qualitative or quantitative cost assessment provided by the DS. No substitution related costs (loss of functionalities) are expected. Certain degree of uncertainty on the affordability of reformulation costs for SMEs	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs and ongoing substitution activities indicate somewhat limited socioeconomic impacts. SEAC concludes that restricting this use is likely proportionate.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.
<b>Filtration and separation media</b>	Not applicable	Very broad range of applications, touching several market sectors; conclusion on alternatives sector-/use-specific, overall conclusion difficult. Alternatives are not expected to provide both, water- and oil repellence properties and are said to be not available for specific uses, for which derogations were requested and are partly supported	Cost information is scarce, no such assessment provided by the Dossier submitter. Information provided by stakeholders indicate high costs related to substitution, e.g. through loss of effectiveness of products (some in safety-critical applications).	Emissions cannot be minimised by means other than a restriction, e.g. due to wide-dispersive uses.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	<b>Unclear</b> Whilst SEAC notes that a derogation would likely be necessary, SEAC has several concerns with the current phrasing of the derogation (e.g. from an enforcement perspective) and with setting an appropriate timeframe based on current knowledge.

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
<b>Epilames used in watches</b>	Not applicable	Based on the information provided by STOs, no alternatives are available for this specific use.	No specific cost information provided by the Dossier Submitter. STOs claim during consultation socio-economic impacts to be potentially high, e.g. significant impacts on employment are expected.	Emissions are minimised by means other than a restriction (e.g. through site-/use-specific RMMs); derogation supported.	SEAC notes that RAC supports a derogation as emissions are minimised by other means than a restriction, and that information on restriction-related costs indicates potentially high socioeconomic impacts. SEAC concludes that restricting this use is likely not proportionate.	<b>Yes</b> Based on the information provided, SEAC finds that a longer transition period would likely be necessary to avoid disproportionate socioeconomic impacts. The exact timeframe needed is, however, uncertain.
<b>Medical devices</b>	Not applicable	Information on alternatives is scarce. The applications within this sector are numerous; however, these have not been explicitly evaluated by the DS. Some product-specific information provided during the consultation, but cannot be used to extrapolate information to the overall sector, as discussed by the DS.	Dossier Submitter expects no costs to occur as a complete derogation is suggested. Cost information provided during the consultation was not assessed by the Dossier submitter. This information is specific to companies/ applications and does not allow SEAC to perform an overall sector-based cost assessment. The Dossier Submitter expects potentially high substitution related costs, however, it is totally unclear what these would be and for which products these would occur. These might relate to the risks of equipment failure, need of early replacement and other unwanted consequences (as products are often supplying	Wide dispersive professional uses, possible RMMs to prevent emissions. RAC does not support a general derogation but assessed specific uses and supports a derogation for implantable medical devices (permanent) and coating for hearing aid devices (10-year TP).	Based on the information provided in the restriction dossier and during consultation, SEAC cannot conclude on the proportionality of a restriction or a full derogation (as suggested by the Dossier Submitter). SEAC doubts that both, a full restriction and an overall derogation are proportionate; however, SEAC has no information at hand on potential alternatives, emissions and costs for specific products/sectors affected.	<b>Yes</b> SEAC supports a full derogation due to potentially high HH impacts recognising the complexity of the sector. However, SEAC notes that this might not be justified for all articles covered, based on socioeconomic considerations. More information needs to be gathered e.g. through reporting, in order to reassess the need for this derogation and to be able to draw more product-/use specific conclusions.

Sector	Sub-sector	Alternatives available?	Costs <sup>23</sup>	RAC's conclusion on uses, releases and emission minimisation	Proportionality	Derogation/ longer TP/ higher concentration limits <sup>24</sup> supported?
			HH- and life-protecting functions).			
<b>Optical fibres</b>	Not applicable	Alternatives have claimed to be currently not feasible by STOs; no evaluation by the DS available to SEAC.	No information on substitution or any other/related costs (potential HH impacts due to traffic accidents or shorter service life of vehicles) are available.	Based on the information available/ the lack of information on RMMs, RAC cannot conclude on use, potential releases and the minimisation of emissions and cannot support a derogation.	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.
<b>Other uses brought forward during the consultation, such as PTFE micro powders, glass protection, thermoplastic applications, etc.</b>	Not applicable	STOs claimed that derogations are necessary due to no alternatives being available	Only very limited information provided on any potential substitution and/or substitution related costs	Not available	SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits) and restriction-related costs. A conclusion on the proportionality of restricting this use is therefore not possible.	<b>No</b> SEAC finds that no information that demonstrates the necessity of a derogation was provided.

## **Uncertainties in the proportionality section**

SEAC's detailed discussion and conclusion on uncertainties is provided in the key elements section above as well as in the use-specific analysis presented in Annex I (Table 3 and Table 4). A summary of the underlying uncertainties of this restriction proposal is given in the uncertainties section below.

## **Practicality, incl. enforceability**

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

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

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

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

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

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

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

##### Clarity of the scope

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

SEAC notes that the Forum considers that inspectors and also prosecutors dealing with sanctions would have difficulties to identify the substances covered by the restriction. While SEAC expects that industry actors may be more comfortable dealing with a chemistry-based definition, it considers that a list of the substances covered could facilitate operations at their end too, at least with regard to communication and with the smallest actors in mind. An indicative list of the substances covered by the restriction, including CAS numbers, was

published on the ECHA website<sup>28</sup> to facilitate the consultation on the Annex XV report. SEAC considers that while it will not be possible to compile an exhaustive list, an indicative list that provides examples of substances covered by the restriction will still be useful. It is not expected that a lot of new substances covered by the definition would enter the market, since there are no natural sources of these substances, but they are always intentionally manufactured. Therefore, new substances would only emerge either as deliberate breach of law, or in imported articles or mixtures. In order for a list to be helpful, the existence and location of such a list should be clear to all parties.

#### Burden of proof for the second-hand market

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

#### Reporting requirements

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

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

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

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<sup>28</sup> Annex to the information note: <https://echa.europa.eu/documents/10162/7da473c1-7f27-df34-9e6a-46152ef10d4b>

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

#### Sampling and sampling preparation

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

#### Analytical methods

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

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

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

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

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

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

#### Forum's general remark

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

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

## **Monitorability**

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

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

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

Regarding imported articles, the Dossier Submitter considers that border authorities can control compliance using the RAPEX system (Rapid Exchange of Information System) to report any violation of the restriction. A time trend monitoring can be performed with samples from the environment, from animals or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring.

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

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

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

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

Time trend monitoring could be performed with samples from the environment, from animals or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring. Long range transport, and persistence of the chemicals restricted would however complicate such monitoring. Monitoring based on verification of emission reductions should also be considered.



## UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

### RAC

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

See opinion of RAC.

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

See opinion of RAC.

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

See opinion of RAC.

### SEAC

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

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

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

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

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

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

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

- **Scope:** SEAC notes that the scope of the proposed restriction is extremely broad both in terms of substances and uses. Numerous sectors are affected and within these sectors, PFHxA, its salts and related substances fulfil specific functionalities in several different uses and products. These specific functionalities have different importance as regards any related impacts. In SEAC's view, this impacted the quality of the sectoral analysis by the Dossier Submitter, which makes a robust evaluation of the costs, benefits and the proportionality of the overall restriction and any respective derogations very difficult and uncertain; specifically, in the absence of concrete and robust information.

- **Availability of data:** SEAC notes that for most sectors and uses affected by the restriction the availability of robust and representative data is limited. Even though numerous stakeholders provided information during the consultation on the Annex XV report, this information is often product-/use- and/or company-specific and does not allow SEAC to extrapolate it for the assessment of an overall sector; specifically as the assessment of this information done by the Dossier Submitter is somewhat limited.
- **Costs** of the proposed restriction: SEAC notes that the Dossier Submitter changed their approach during the opinion making process of SEAC from a partly quantitative to an overall qualitative cost assessment. This is mainly due to lack of robust input data. An overall qualitative cost assessment approach makes it difficult for SEAC to compare costs to the potential benefits of a restriction, specifically if any respective benefits information is scarce and uncertain as well (see bullet point below). SEAC notes that overall, the qualitative cost assessment is surrounded by numerous uncertainties, specifically as substitution-related costs (their likelihood, magnitude) are concerned.
- **Benefits** of the proposed restriction: the Dossier Submitter initially followed the agreed approach for assessing the benefits of a restriction for PBT-like substances, i.e. emissions serving as a proxy for risk. SEAC notes RAC's conclusion that the emission estimates are uncertain and could be over- or underestimations. Furthermore, SEAC notes that overall, RAC was not able to verify the Dossier Submitter's emission calculations, which resulted in only general qualitative conclusions of RAC (no figures provided, not even ranges).
- **Proportionality** of the proposed restriction: SEAC notes that due to the above stated data gaps and uncertainties, an evaluation and conclusion on whether or not the restriction is overall proportionate is not possible based on socio-economic considerations. SEAC approached its evaluation and conclusion therefore differently, as pointed out in the proportionality section above. Even though any such alternative approach does not allow SEAC to draw an overall conclusion on scientific grounds, it at least allows a sector-based discussion of relevant factors surrounding the proportionality issue.
- **Enforceability, practicality** and **monitorability** aspects: uncertainties raised by the Forum relate to the definition of the regulated substances in the entry, some terminology issues, an identification of the substances within the scope of the restriction (suggesting a concrete list of substances covered), analytical methods being available and standardised for all substances covered and specifically the numerous derogations suggested (specifically where definitions of the exempted uses/user group are not given, e.g. for medical devices, concrete products being affected therefore uncertain).

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

Further information on SEAC's justification is provided in the respective sections as well as the Annex of this opinion.

## Annex I – Use-specific analysis of derogations

This annex presents additional details of SEAC’s evaluation of derogations for specific uses that were proposed by the Dossier Submitted (Table 3) or requested during the consultation on the Annex XV report (Table 4).

SEAC emphasises that RAC supports a derogation only for the following sectors/uses: transported isolated intermediates, semiconductors (12 years), epilame used in watches, coating for hearing aid devices (10 years) and implantable medical devices. This is mainly due to the fact that for these uses, emissions are minimised by other means (e.g. through use-specific RMMs) than a restriction. Further information is provided in the respective RAC sections of this opinion.

Table 3: Derogations proposed by the Dossier Submitter

Use	Para.	DS approach	SEAC conclusions
Articles placed on the market before the end of the general transition period	4	A derogation not limited in time was proposed by the Dossier Submitter, however, not separately justified in the Background Document.	<p>Derogation for articles placed on the market is a recurring issue seen in many restriction cases and the considerations made in the earlier PFAS cases apply to this case.</p> <p>The derogation would avoid destroying already manufactured articles still in the supply chain (e.g. stocks) and avoid the related costs.</p> <p>As to second-hand articles, it is specifically difficult to know whether or not an article contains PFHxA and whether the restriction is violated. Any product information or labels may be missing (and not required to contain information on potential PFHxA content anyhow), and testing would typically destroy the article. Enforcement would be difficult as well, and only of limited value, because only a single article would be removed from the market per case. A restriction may also not be necessary considering that, for example, second-hand textiles may already have been washed a number of times and the PFAS content thereby reduced to a low level. Lastly, a longer use of articles represents a sustainable management of resources.</p> <p>Considering these points, <b>SEAC supports the derogation.</b></p>
Chrome plating	5a	A longer transition period of <b>5 years</b> is proposed for <b>hard chrome plating</b> because alternatives are available in principle but have not yet been tested sufficiently.	<p><u>Costs:</u> no meaningful quantification of costs possible. Qualitative discussion provided: cost situation differs for hard chrome plating compared to decorative plating and plastic electroplating, substitution costs regarded as affordable for the latter (less complex substitution processes compared to hard chrome plating). For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> The Dossier Submitter estimated that a derogation for 5 years would result in releases of 0.6 t of PFHxA. RAC however concluded that these figures are highly uncertain and cannot be endorsed. RAC noted that no description of associated RMMs was presented and concluded that from a risk/emissions minimisation perspective they cannot support the derogation and cannot conclude on the effectiveness of a restriction for this use.</p> <p><u>Alternatives:</u> It is foreseen in the dossier that substitution can happen in two principal ways: either by transitioning from Cr(VI) electrolytic baths to Cr(III) baths, whereby the requirements relating to mist suppression are reduced, or by using an alternative efficient mist suppressant.</p> <p>The Dossier Submitter expects that a shift to <b>electrolytes based on Cr(III)</b> is an available alternative in <b>decorative plating and plastic electroplating</b>. Issues with plant approval and recertification or space limitations in the existing facilities challenging the installation of additional galvanic baths have been reported to potentially</p>

Use	Para.	DS approach	SEAC conclusions
			<p>complicate substitution in the case of plating on plastic specifically. Some users also have claimed that Cr(III) is not an appropriate substitute in decorative plating when high technical performance and strict aesthetic standards have to be met (for example in automotive industry). Furthermore, it has been highlighted by stakeholders that different substitutes may be needed for different products, possibly causing challenges for subcontractors serving diverse clients but not able to afford to run several different alternative processes. SEAC overall concludes that substitution is in principle feasible in decorative plating and plastic electroplating, but there are some issues to be solved and time will be needed for successful substitution.</p> <p>SEAC notes that for <b>functional hard chrome plating</b>, using Cr(III) does not appear to be possible currently. The hardness, corrosion and wear resistance and resistance to chemicals of the resulting coating may not be sufficient to withstand the harsh conditions that the parts are put under.</p> <p><b>Fluorine-free alternatives</b> are reported to be available but not equally effective as fluorinated surfactants. Using non-fluorinated alternatives may make an extra process step, involving additional equipment, necessary. Non-fluorinated alternatives also need to be used in higher concentrations and dosed more frequently. Also, additional risks relating to e.g. safety and device preservation have been reported by industry. Fluorine-free alternatives may be suitable where Cr(III) is used in the plating bath. Use with Cr(VI) electrolytes (specifically, in functional hard metal plating) requires further testing. Sufficient level of mist suppression appears to be challenging to achieve presently and will have to be ensured on a case-by-case basis where at all possible.</p> <p>The use of closed coating reactors was suggested in the dossier as a possible technical alternative for hard chrome plating but was not discussed further.</p> <p><u>SEAC conclusion:</u> SEAC agrees that immediate substitution is not feasible and transition time is needed. As to hard chrome plating, it is not fully clear based on the available information if the transition period of 5 years proposed by the Dossier Submitter is a sufficient time frame for successful transition. However, SEAC notes that the consultation on the Annex XV report did not yield comments claiming that the length of the transition period proposed for this use would be insufficient, and therefore SEAC assumes that specific problems are not expected by industry. As to decorative plating and plastic electroplating, substitution should be feasible sooner; however, the 18 months general transition period proposed by the Dossier Submitter may be too short for some companies to finalise the transition in a controlled manner.</p> <p>Overall, SEAC considers that a transition period of <b>5 years for functional hard chrome plating appears appropriate</b>. As to decorative plating, SEAC considers that 18 months could be too short. However, if the general transition period is extended to 36 months or more, the related problems could largely be avoided.</p> <p>During the SEAC opinion-making, industry stakeholders raised that also plating with other metals than chromium might need to be derogated. However, no information/ assessment of the related costs, emissions or alternatives was made available to SEAC and therefore no evaluation in this regard was made.</p>
Photographic coatings applied to films, papers, printing plates and inkjet photo media coatings	5b	<p>Proposes a transition period of <b>5 years</b> to provide enough time for the phase-out of these uses.</p> <p>Photographic coatings applied to paper and printing plates were</p>	<p><u>Costs:</u> no meaningful quantification of costs possible. Qualitative discussion provided: if a sufficiently long transition period is suggested, only negligible substitution costs are expected by the Dossier Submitter due to an ongoing transition to digital techniques. Overall, the Dossier Submitter expects mainly substitution-related costs (such as functional losses resulting in quality issues of affected products) if no transition period would be implemented. For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> The Dossier Submitter considers the volume used in photographic equipment or in coatings of photographic films to be small and therefore they assume the release of PFHxA and its related substances to be very low. Comments from the consultation on the Annex XV report, if considered altogether, seem to suggest that</p>

Use	Para.	DS approach	SEAC conclusions
		<p>included in the derogation after consideration of comments from the consultation on the Annex XV report</p>	<p>the use volumes from paper could be greater than those assumed for photographic coatings applied to film (confidential comments 2991, 3094). RAC concluded that no RMMs to contain the emissions have been described and that the related emissions of PFHxA could be possibly in the order of tonnes during the derogation period. Based on the information available, RAC was not able to differentiate between the uses within this sector and overall did not support a 5-year derogation for these uses.</p> <p><u>Alternatives:</u> The Dossier Submitter assumes that this use will largely phase out due to transition to digital techniques and that no more production is expected after five years after entry into force of the restriction. In some applications (hobby photographers, medical and defence applications), moving to digital imaging is claimed not possible yet and substitution of PFASs by suitable alternative substances is needed. From the Dossier Submitter's assessment, SEAC notes that conflicting information was provided in stakeholder consultation as regards the availability and feasibility of alternative substances. There appears to be some indication on availability of non-fluorinated alternatives, however, this being confidential business information not available to the Dossier Submitter and SEAC, no concrete information on alternatives in the photo imaging sector can be provided. According to stakeholders there is lack of suitable non-fluorinated alternatives for some specific applications (comments 2981, 2991, 3073, 3080, 3094). It is not clear to SEAC to which applications these statements are referring to. Anyhow, SEAC acknowledges that substances to be used in this sector require specific properties such as colloidal stability. Transition time is necessary for finalising work to develop suitable alternatives in cases where digital techniques are not suitable.</p> <p><u>SEAC conclusions:</u> regarding photographic coatings <b>applied to film</b>, SEAC notes that digital techniques are used in more and more applications and phase-out of PFASs is already underway. Some additional transition time is however required to allow the transition to proceed smoothly and for the development of suitable alternatives for specific uses where moving to digital techniques is not possible. Some stakeholders claimed that 5 years (as proposed by the Dossier Submitter) is not a sufficient transition period (comment 3080) but did not suggest and justify another length of the period. Considering the high costs (as assumed by the Dossier Submitter) falling on few sectors, some of which potentially relevant for the health care system, and the prospects with alternatives (specifically the ongoing transition to digital techniques), <b>SEAC agrees that an extended transition period of 5 years appears appropriate.</b> SEAC considers that based on similar considerations (low volumes, phase-out already underway, poor availability and high cost of alternatives), photographic coatings <b>in printing plates should be covered by the exemption.</b></p> <p>As to photographic coatings applied <b>on paper</b> and coatings applied to <b>inkjet photo media</b>, <b>SEAC does not support derogations.</b> SEAC regards that in order to be able to conclude on whether a derogation is necessary, more information is needed on the product types to be covered, the potential emissions, costs of restriction and availability of alternatives (specifically why alternatives are not considered suitable, information on the timeframe of developing alternatives and on the main impediments of developing a suitable alternative). Such information could be submitted in the consultation on the SEAC draft opinion.</p>
<p>Concentrated fire-fighting foam mixtures that were placed on the market before [date – 18 months after the entry into force of</p>	<p>5c</p>	<p>The Dossier Submitter proposes a transition period of <b>5 years</b> considering the large stocks held and the magnitude of the emissions when the stocks are used, to ensure</p>	<p><u>Costs:</u> some quantified cost figures are discussed in the Background Document, which gives an indication of the magnitude of some cost elements (such as incineration costs, cost due to adjustment of existing infrastructure, cleaning costs of existing firefighting installations, etc.). However, no overall quantified cost assessment is possible due to the complexity of the sector, lack of robust input data for a respective overall quantification and numerous further uncertainties (e.g. estimates on the dimension of the EU-wide stocks currently held, substitution activities already ongoing due to other regulatory PFAS activities, etc.). Extensive information was provided during the consultation (specific to uses/applications), however, the underlying uncertainties could not be resolved in order to arrive at a quantitative overall cost estimate for the whole sector affected. For more information, please consult the</p>

Use	Para.	DS approach	SEAC conclusions
<p>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</p>		<p>capacity for action in case of emergencies. The derogation does not apply to uses for training. For testing, the derogation applies only if all emissions to the environment are minimised and effluents collected are safely disposed of.</p>	<p>cost section of the main part of this opinion.</p> <p><u>Emissions:</u> RAC concluded that the emissions from this use may be significant, in the order of tonnes, and with a high risk of being directly emitted to the environment and possibilities of substantial local contamination. They also noted that no risk management measures have been presented for this use and emissions from extinguishing fires outside enclosed areas are also practically difficult to contain, and did not support a derogation.</p> <p><u>Alternatives:</u> According to the dossier, several fluorine-free firefighting foams (FFF) meeting the requirements of Class-B standard firefighting performance certifications as alternatives to AFFF were developed in the recent years. It is stated that fluorine-free alternatives are widely available and already in use also in some critical applications. For example, many airports in Europe have already made a transition to non-fluorinated foams. It was reported in the consultation on the Annex XV report that AFFF foam agents are nowadays predominantly used in industries holding large stockpiles of flammable liquids (i.e. chemical or petrochemical industry). Those industries are required to establish measures to retain any effluents of those facilities - including fire water run-off - as a vital part of their operating permits (comment 2983).</p> <p>SEAC notes that according to industry stakeholders, the available fluorine-free alternatives do not currently fulfil some critical requirements. They may meet the requirements of existing test standards, many of which rely on heptane as the test fuel, however, the performance level appears to be inferior to that of C6 foams on gasoline, E10 and IPA fires (comments 2983, 2990). Some respondents to the consultation also claim that there is a lack of demonstration that FFF work appropriately also in the large scale and in real-life situations (comments 3031, 3135). Also, practical incidents reported by stakeholders in the consultation on the Annex XV report demonstrate that fluorine-free alternatives are currently associated with lack of sufficient performance in some scenarios. One stakeholder claimed that in some cases insufficient performance of fluorine-free foams have led to the creation of excess toxic smoke and volumes of fire water runoff, which in turn have led to serious illness of firefighters having inhaled the smoke, and to environmental disasters (comment 2978). It was also highlighted that fluorine free foam agents show a significantly more intense interaction with liquid fuels, do not form an aqueous film suppressing vapours and fuel-pick-up, and can only extinguish as a physical foam blanket (comment 2983).</p> <p>A respondent to the consultation estimated that currently about 85-95% of worldwide class B foam sales are fluorinated foams (comment 3010). At the same time, they claim that it is largely the same companies that manufacture fluorinated and fluorine-free foams and that the choice between these products is largely performance-driven. SEAC considers that this implies that fluorinated foams still have some lead in performance level in many uses, while it does not indicate whether or not the performance level of fluorine-free foams would be sufficient in those uses. SEAC however highlights that in case the volume of fluorine-free alternatives needed for achieving a sufficient performance level is considerably larger than that of fluorinated foams, the size of the existing fire water containment areas might be insufficient, potentially leading to damages and environmental releases given limited space availability in the installations. It was pointed out in the consultation (comment 3102) that a large proportion of fire risk mitigation is covered by fixed preinstalled systems. Those systems are individually designed, can be very large by size and can be embedded deeply into the overall plant design. Consequently, changing these systems due to changing extinguishing performance, hydrodynamic properties, application types and/or density can be extremely complicated. Further challenges that industry is having with the implementation of FFF were clearly listed in the consultation (comment 3123).</p> <p>A transition period of 5 years as proposed by the Dossier Submitter is claimed to be too short by industry stakeholders (i.a. comments 3146, 2983), and 10-12 years was estimated as the minimum transition time for a complete phase-out by EUROFEU (comment 2983). In their submission they clearly list tasks that will need to be addressed to be able to manage the transition to alternatives successfully. However, no timeline for the tasks is</p>

Use	Para.	DS approach	SEAC conclusions
			<p>given and it is difficult to see why a minimum of 10 years would be needed. Also for some tasks mentioned a restriction could actually be regarded as collaborative (e.g., push for a culture change away from AFFF-application towards a successful F3-application).</p> <p><u>SEAC conclusions:</u> The cost assessment is subject to a lot of un-knowns and the Dossier Submitter concluded that it is not possible to determine whether a restriction would be proportionate. SEAC agrees that there are relevant uncertainties surrounding the analysis and considers that any restriction should be coupled with a prolonged transition period. A longer transition period would allow more time for the execution of the tasks highlighted by the actors in the field in the consultation on the Annex XV report as necessary before a restriction is applied in an orderly manner. SEAC notes that a longer transition period would also allow more foam concentrates, firefighting vehicles and stationary extinguishing systems meet their regular end of service life without being replaced prematurely, cutting the related costs. The respondents to the consultation furthermore emphasized that time will be needed for planning, building permits, reconstruction work, adoption of operation permits, testing of foam concentrates for suitability on the risks on site, training of firefighters on optimal application of new fluorine free foams etc., at least for larger industrial sites.</p> <p>The Dossier Submitter expects that if the transition period was too long, the actors could choose to use C6 foams as substitutes of C8 foams. SEAC also notes that in light of comments received in the Consultation, many stakeholders in the firefighting industry appear to consider substitution of C6 foams not necessary at all (comments 2983, 3010, 3081). Accordingly, there may not be a commitment to phase them out any sooner than legally required. SEAC considers that this suggests that the transition period should not be very long to avoid releases if not justified. SEAC also keeps in mind that use in firefighting can lead to immense one-time release directly to outdoor environment, concentrating on a small area, and considers this another reason for keeping the transition period as short as feasible. There are many means to control the releases (measures to retain possible effluents, use AFFF only when FFF not suitable) but no evidence on their overarching effectiveness.</p> <p>Considering that the use in AFFFs is the third-highest source of emissions of PFHxA-related substances according to the dossier, SEAC regards it important for the effectiveness of the restriction that any derogations are kept as short as possible. SEAC understands based on the dossier and consultation comments that the issues highlighted by industry are largely related to the petrochemical industry, and expects that the proposed derogation for tanks (see point 8a below) will alleviate the issues such that a shorter transition period than requested in the comments will suffice. Finally, the evolution of FFF appears to be fast (and FFF already implemented for several scenarios by many stakeholders) such that their implementability can be expected to improve rapidly in the near future.</p> <p>SEAC notes that the stakeholders highlighted potential sourcing problems in the consultation on the Annex XV report; they would not be able to fully benefit from the derogation since the substances would not be available in practice (comment 2983). Considering that different foam types cannot be mixed together and that installations have to backfill containers after use, SEAC agrees that if the derogation only applies to foams placed on the market until 18 months after the entry into force of the restriction, users would be forced to make the transition and replace their entire stock as soon as their stock volume undercuts the minimum volume required on site. This means that the effective length of the transition period would be something between 18 months and 5 years depending on the user.</p> <p>SEAC considers that if the general transition period is extended to 36 months, the same should apply to this date for placing on the market (unless extended even more).</p> <p>SEAC agrees that carrying out the necessary tasks (including potential reconstruction work) over 5 years or less may be a challenge to the industry, however, does not have enough information on the overall impacts of another</p>

Use	Para.	DS approach	SEAC conclusions
			<p>length of the period to be able to evaluate another proposal.</p> <p>Overall, SEAC supports a transition period of <b>5 years</b>. SEAC however underlines that considering the magnitude of potential impacts in case a sufficiently well performing foam is not available, the prevailing performance level of FFF will have to be verified in a <b>review</b> during the transition period before a restriction will be applied.</p> <p>According to comments received in the consultation on the Annex XV report, municipal fire departments can successfully use fluorine free foam already now (comments 2983, 3155). Opposing views were not received in the consultation. SEAC agrees that a derogation for that area of application does not appear necessary.</p> <p>Industry stakeholders requested during the consultation that also the <b>manufacture</b> of the concerned foam concentrates be included in the derogation (comments 3031, 3102, 3146). They claimed that otherwise the likely response to the restriction by the fire brigades would be to build up stocks to ensure that they will be able to fill up the foam tank after using some of the foam as required; otherwise they would be forced to make an almost immediate switch (comments 3010, 3031). SEAC considers it important that AFFFs will be available in practice for the derogated uses. SEAC understands that the derogation as given now does indeed cover this and that therefore a further derogation is not necessary.</p>
Concentrated firefighting foam mixtures for defence applications	6	<p>A derogation <b>not limited in time</b> is proposed for concentrated fire-fighting foam mixtures for defence applications for seagoing units, air traffic facilities and storage of fuel, and for training purposes provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely.</p> <p>The derogation applies as long as no successful transition to military operable fluorine free foams can be achieved.</p> <p>The Dossier Submitter considers this derogation justified because alternatives are not currently available, and unacceptable risks for human health and the</p>	<p><u>Costs:</u> There is no information available on costs of substitution specific to defence uses.</p> <p>As to the costs relating to the reporting requirement, it is explained in the Background Document that the Dossier Submitter expects that the procurement of firefighting foams for defence applications is highly centralized and that the existing centralized structures can be used when reporting to ECHA. SEAC agrees that this can be expected to limit the expected costs.</p> <p><u>Emissions:</u> RAC considered that the estimated emissions from this derogation are in the magnitude of tons emitted to the environment, with possibilities of high local contamination. They also pointed out that no risk management measures for this use have been presented and also considered such measures practically difficult for the use on seagoing units and air traffic facilities. From a risk perspective, RAC did not support the derogation.</p> <p><u>Alternatives:</u> According to the dossier, fluorine-free foams still account for less than 30 percent of defence uses, and armed forces have reported challenges regarding a complete transition due to missing alternatives in the defence sector. It is explained in the Background Document that the available fluorine-free foams do not fulfil the requirements of some defence-specific applications, and that due to some exceptionally high risks of defence-specific fire scenarios (e.g. firefighting on seagoing units), a switch to fluorine-free foams is currently not possible. A restriction of the use of AFFF for defence-applications would lead to unacceptable constraints for firefighting in some defence-specific scenarios. During the consultation it was reported (comment 3079) that NATO technical standards do not currently allow the use of fluorine-free foams. SEAC notes that alternatives for public uses are expected to be available within 5 years from EIF and accordingly a transition period of 5 years is proposed for firefighting foams in general. The information available does not appear to clarify why the same alternatives would not, after that transition period, also work in defence uses. The requirements not fulfilled and the scenarios deemed problematic were not disclosed to allow scrutiny. The applicable technical standards could be reviewed. Various comments made in SEAC meetings (including industry stakeholders) and received during the consultation (comment 3077) and the fact that some armed forces (Royal Danish Airforce discussed in the Background Document) already made the transition imply that the performance level of fluorine-free foams may already be sufficient. SEAC also notes that the US appears to be planning to ban the use of PFAS in firefighting foams for defence applications (except that for use solely onboard ocean-going vessels); this also suggests that alternatives suitable for NATO members can be</p>



Use	Para.	DS approach	SEAC conclusions
		<p>environment would otherwise be expected.</p> <p>The Dossier Submitter proposes a yearly reporting requirement relative to these uses.</p>	<p>expected to be available.<sup>29</sup></p> <p><u>SEAC conclusions:</u> SEAC considers that it has not been demonstrated that alternatives considered suitable for public uses could not be made applicable also for military uses over the transition period of 5 years proposed for firefighting foams for class B fires in general. Therefore, <b>SEAC does not support a separate derogation</b> from the scientific viewpoint.</p> <p>SEAC recalls that according to REACH Art. 2(3), Member States may allow for exemptions from the REACH Regulation where necessary in the interests of defence. This option could be taken advantage of where necessary. The European Defence Agency has published guidelines to follow in case an exemption needs to be applied for.</p>
Latex printing inks	7	The Dossier Submitter proposes a transition period of <b>7 years</b> to take account of the service life of related printer hardware.	<p><u>Costs:</u> no meaningful quantification of costs is possible. Mainly qualitative cost discussion, some quantified cost figures provided. C6-based latex printing inks are needed for existing printers in use to avoid early replacement of the printers. According to the Dossier Submitter, the remaining lifetime of respective printers is 7 to 10 years. The number of printers relying on C6-based inks and the price of alternative printers are not known. Still, premature obsolescence of printers would create additional waste and not be a sustainable use of resources. SEAC recalls from the PFOA restriction case that companies using the printers in question are typically SMEs and therefore less able to absorb the costs of the earlier replacement of a printer. The Dossier Submitter considered deriving an estimate of costs for the whole industry not possible. <u>For more information, please consult the cost section of the main part of this opinion.</u></p> <p><u>Emissions:</u> RAC considered that the wide dispersive use of PFHxA-related substances in latex printing inks may lead to emissions in the order of tonnes during the 7-year period. RAC also pointed out that no appropriate RMMs to minimise the emissions were described and RAC did not support a derogation.</p> <p><u>Alternatives:</u> According to information obtained by the Dossier Submitter from a manufacturer, simple “drop in” substitution is not possible and a more extensive reformulation will be necessary to develop competitive products. The Dossier Submitter assumes that alternatives (C6-free latex printing inks) will be available in 2024. However, the new printing inks are not expected to be compatible with older printers, and therefore the Dossier Submitter assumes the availability of existing printing inks to be necessary for further 7 years.</p> <p>SEAC notes that since C6-containing inks will be needed only for legacy printers after 2024 and the need thereof will fizzle as those printers reach the end of service life, phase-out is already underway. Developing alternative inks for printers that are being phased out does not appear reasonable.</p> <p><u>SEAC conclusions:</u> SEAC supports a longer transition period for this use. 7 years appears suitable based on the remaining lifetime of printers.</p>
Concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500 m <sup>2</sup>	8a	A longer transition period ( <b>12 years</b> ) is proposed for fighting fires at large liquid tanks. This is because not enough evidence is available that fluorine free fire-fighting foams perform as well as fluorinated	<p><u>Costs:</u> A separate cost estimation for these uses was not presented in the dossier. According to the Background Document, alternatives are currently not available which results in unacceptable risks for human health and the environment in the restriction scenario. Costs of large fires that cannot be stopped could be enormous both in terms of economics, environment and potentially human suffering. <u>For more information, please consult the cost section of the main part of this opinion.</u></p> <p><u>Emissions:</u> A separate emission estimation for these uses was not presented in the dossier. It was stated during the consultation on the Annex XV report (comment 2992) that in the oil industry, all facilities for storage, filling, production, handling and usage of flammable and water hazardous substances are situated in retention basins</p>

<sup>29</sup> <https://www.congress.gov/bill/116th-congress/senate-bill/1790/text> (accessed on 09/02/2021).

Use	Para.	DS approach	SEAC conclusions
		<p>products, and there are high risks arising from this uncertainty.</p> <p>The Dossier Submitter expects that alternatives will become available within twelve years for the derogated uses in the petrochemical industry.</p>	<p>(secondary containment) or on paved surfaces so that resulting fire-fighting water can almost completely be contained. RAC concluded that this is a local, site-specific use but without specified additional information on risk management measures RAC cannot support a derogation, from a risk perspective. Generally, RAC cannot conclude on the potential releases and the minimisation of emissions based on the information available.</p> <p><u>Alternatives:</u> The dossier claims that alternatives are currently not available but are expected to be so within 12 years. It was highlighted in the Consultation that experience demonstrates that commercially available fluorine-free foams cannot deliver the required performance in certain oil industry facilities (comment 2965). In the case of tank fire of large tanks there is no proof that non-fluorinated foams are able to extinguish the fire. The application of higher water amounts is claimed to be detrimental, as it increases the risk and the severity of a boil over.</p> <p>It was stressed in the Consultation that even after over 20 years of intense development there are no commercially available fluorine-free foams that have fire performance equivalent to that of fluorinated alternatives on volatile fuels like gasoline, and especially on large scale or deep-seated Class B fires (comment 2990). It was also stated that without having a demonstrably suitable replacement, refineries and tank farms cannot comply with the requirements of the European SEVESO III Directive (comment 2992). The requirements also mean that fires have to be extinguished, i.e. not extinguishing is not an option.</p> <p>It was highlighted that the necessary properties provided by AFFFs include good burn back resistance, rapid knockdown characteristics and very good flow properties (comments 2965, 2992) and that these qualities are not easy to find in FFFs. It was underlined that the fuel-repellence and the film-forming ability of PFAS-based foams are still unmatched characteristics of PFAS-based foams (comment 3031).</p> <p>It was requested in the consultation that the size limit of <b>500 m<sup>2</sup></b> for tanks would be changed to 400 m<sup>2</sup> (comments 2965, 2992) or the tank size limit removed altogether (comments 3004, 3046). The choice of 500 m<sup>2</sup> as the size limit was not justified in the dossier. The limit of 400 m<sup>2</sup> proposed in the consultation was not justified in detail either, however, it was confirmed that according to experience, fluorine free fire-fighting foams are able to extinguish fires up to 400 m<sup>2</sup> (comments 2965, 2992).</p> <p>The respondents to the consultation furthermore stated that they consider it indispensable that the derogation covers all fires covering an area as big and not only those in tanks (comments 3081, 3114). Specifically, it was claimed that a derogation is needed for fires in secondary containment areas (or so called <b>bunded areas</b>) (comments 2965, 2990, 2992, 3031, 3081). It was highlighted that a fire may burn outside a storage tank within the bund walls, where the surface area exposed to the fire reaches a multitude of the tank surface area itself (comment 3081). It was claimed that the harm caused by a big fire, including environmental impacts, are immense. The Dossier Submitter considered that including the bund area in the derogation would widen the coverage thereof too much; they estimated that such secondary containment areas usually have an area ten times bigger than the surface area of the enclosed tanks. The Dossier Submitter however considered that a fire in the secondary containment area would be covered by the derogation in case the incident started as a tank fire.</p> <p>If was furthermore explained in the consultation that a derogation only for tanks &gt;500 m<sup>2</sup> cannot be realised because multiple foam concentrates would have to be applied within one tank farm – fluorine-free products for tanks with surface area &lt;500 m<sup>2</sup> and PFHxA-containing concentrates for tanks with surface area &gt;500 m<sup>2</sup> (comment 3046). Therefore, a general derogation for tank farms would be needed.</p> <p><u>SEAC conclusions:</u> SEAC agrees that suitable alternatives with the required performance level do not appear to be available currently or expected to be so in the near future, and therefore a longer transition time is necessary. SEAC notes that a transition period of 12 years is broadly in line with the information in a recent report (European Commission DG Environment/European Chemicals Agency 2020), that up to 10 years are required for testing of</p>

Use	Para.	DS approach	SEAC conclusions
			<p>alternatives for large atmospheric storage tanks, and that Norwegian company Equinor took about eight years from development and testing to full operation of fluorine-free alternatives. SEAC agrees that also taking into account the different circumstances at different sites, <b>12 years appears to be a suitable length for the transition period</b>. Furthermore, SEAC considers that this derogation would also allow the manufacturing of fluorinated firefighting foams to be applied for the derogated use.</p> <p>After the consultation on the Annex XV report, the Dossier Submitter proposed to cover fires in <b>all types of tanks</b> instead of only storage tanks in the derogation. Considering the information submitted and assuming that similar properties are needed from successful alternatives regardless of whether it is a storage or a process tank, SEAC agrees that this is justified. Considering the information received in the consultation on the Annex XV report SEAC however finds that the derogation should be further expanded.</p> <p>Based on the points mentioned above, SEAC considers that <b>the derogation should cover tanks with a surface area &gt;400 m<sup>2</sup> plus their bunded areas</b>. SEAC notes the concern of the Dossier Submitter about the derogation becoming wider, however, regards that the large size of the bunded area is itself a reason why a big fire could take place there, making inclusion in the derogation appropriate. Although it is uncertain how many additional installations would be covered by the exemption after this modification, based on the information available SEAC considers this is appropriate to ensure successful firefighting in those installations. Additional information on the number of installations covered by this derogation will be requested during the consultation on the SEAC draft opinion.</p> <p>SEAC notes that a similar derogation might be needed also for other types of installations than tank farms. SEAC however considers that inclusion of further types of installations would make the derogation a lot wider and the information available does not allow to estimate the related impacts. Information could be submitted in the consultation on the SEAC draft opinion.</p>
Semiconductors and semiconductor related equipment	8b	<p>The Dossier Submitter proposes an extended transition period for this sector. The scope of the derogation was extended based on comments received in the consultation on the Annex XV report from “photolithography or etch processes in semiconductor industry” to all semiconductors and semiconductor related equipment.</p> <p>After the consultation on the Annex XV report, the timeframe was extended from 7 years to <b>12 years</b>.</p>	<p><u>Costs:</u> no meaningful quantification of costs is possible. Some general cost information from the US is provided (on global revenues of the semiconductor industry and on costs of developing a new photoresist, these not being regarded as a barrier to any such new developments). During the consultation, company-specific cost information was provided, stating that the economic impacts of a restriction without a sufficiently long transition period would be severe. Based on the information provided, SEAC notes that societal costs due to a restriction (resulting from e.g. closure of manufacturing sites, release of workforce, etc.) could be severe without a respective transition period. <u>For more information, please consult the cost section of the main part of this opinion.</u></p> <p><u>Emissions:</u> RAC noted that the level of emissions is expected to be in the order of grams per year and supported a time-limited derogation for a maximum of 12 years until alternatives are available.</p> <p><u>Alternatives:</u> According to the dossier, drop-in alternatives are not available, and substitutes must be engineered on the use level or even on the company level. Alternatives are available for some processes and some companies, and research and development for finding suitable alternative techniques or substances applicable to more and more processes is ongoing. The variety of uses is large, and the information available does not reveal uses for which suitable alternatives may already be available or give estimations on how long it would take to find suitable alternatives. A stakeholder stated in the consultation on the Annex XV report that any development in finding per-fluorinated free substance alternatives for the currently used photolithography specialty formulations would require first novel chemistries to be identified (comment 3087).</p> <p>In many cases PFASs do not become a part of the final product, and EU production could be replaced by imported</p>

Use	Para.	DS approach	SEAC conclusions
		<p>The justification of the derogation was that alternatives are not available at the moment but substitution is considered possible with enough time by the Dossier Submitter.</p>	<p>articles. Accordingly, some actors could consider this as a potential way to phase out PFASs. However, considering an increasing dependence of the EU society on supply from other parts of the world this might not be optimal as a general approach, and would also represent exporting the problem (possibly somewhere with lower standards in environmental protection).</p> <p><u>SEAC conclusions:</u> SEAC agrees that considering the wide reliance on semiconductors in the electronic industry, a restriction could impart large effects on several sectors with partly unpredictable knock-on effects on other sectors. The economic impact could be very large. Considering that the emissions from the sector are very low compared to other sectors and that alternatives are not available, SEAC supports a prolonged transition period.</p> <p>In the consultation on the Annex XV report, industry stakeholders claimed that a transition period of 7 years (originally proposed by the Dossier Submitter) is too short, because PFHxA-related substances have recently been adopted as substitutes of PFOA, and it took the industry more than 10 years to substitute PFOS with largely PFOA. Also the complexity of products, the length of supply chains in the sector, high quality requirements and very long repair part requirements of the components in many applications were highlighted (comments 2986, 3120). SEAC agrees these are reasonable arguments. Some stakeholders requested a derogation not limited in time (comments 3062), however the Dossier Submitter was hesitant to that solution because they considered the information on the possibilities to substitute as not sufficient. The Dossier Submitter proposed a transition period of 12 years. The number of years was not substantiated in the Background Document; it was basically reported that substitution for semiconductors depends on feasibility testing that needs more than five years. Some comments to the dossier contain indications of the minimum period backed up with some justification: about 4,5 years needed once a substitute is known (comment 2986); 5-7 years would not be sufficient to reach every corner of the long supply chain (comment 3062); approximately 15 years for implementing new materials in the semiconductor manufacturing assuming that the specialty chemicals industrialisation process and commercialisation may take till 5 years, or 15 years to allow for invention of the alternative, material qualification and integration and verification of technical performance in company technologies (e.g., comments 3087, 3120). Many parties claimed that 15 years is necessary for substitution. SEAC notes that a suitable substitute does not appear to be known yet and therefore the highest estimates (that consider the entire substitution process) may be the ones reflecting the overall situation the best. The information provided on why exactly 15 years are needed is not very detailed. However, SEAC acknowledge that making and justifying a numerical estimate may be difficult for stakeholders where the exact substitute is not yet identified.</p> <p>SEAC understands that the variety of applications in the sector is wide and expects that suitable alternatives may be available at different times for different uses, and for some of the uses in clearly less than 15 years.</p> <p>Overall, taking into account the above-mentioned considerations, SEAC supports the proposal of 12 years by the Dossier Submitter.</p> <p>During the SEAC opinion making, industry stakeholders expressed concerns on whether the processes necessary in the semiconductor industry (such as photolithography processes) would be covered by the derogation. The Dossier Submitter confirmed in SEAC-49 that these are indeed meant to be covered by the derogation in the entry proposal.</p>
Uses as transported isolated intermediates	9a	The Annex XV dossier does not appear to include a justification for this derogation	SEAC notes that any activity taking advantage of this derogation will have to comply with the conditions of Art. 18(4) of Regulation 1907/2006 (REACH). RAC supports this derogation due to the low emissions; consequently, SEAC concludes that any cost due to a restriction would not be proportionate. SEAC therefore supports this derogation. SEAC also recalls that a respective derogation is included in the SEAC opinions on PFOA, its salts and related substances and on C9-C14 PFCAs, their salts and related substances in order to allow the manufacture of

Use	Para.	DS approach	SEAC conclusions
			C6 chemicals.
<p>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), (I);</p> <p>High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3</p> <p>Impregnation agents for articles covered by (9b, 9c and 9g)</p>	<p>9b</p> <p>9c</p> <p>9d</p>	<p>The Dossier Submitter proposes a derogation <b>not limited in time</b> for these uses.</p> <p>The Dossier Submitter concluded that it is likely that PFHxA-related substances sometimes function as important part of the risk management in several applications. They considered that a general restriction on textiles might result in very high societal costs and therefore proposed derogations for uses with risks that may cause very serious consequences such as death or irreversible damage to health.</p> <p>The Dossier Submitter proposes a yearly reporting requirement for these uses.</p>	<p><u>Costs:</u> no meaningful quantification of costs is possible. No robust information on substitution and substitution related costs is available to SEAC. For textiles in general SEAC concluded that no major economic impacts are expected with regard to substitution costs for water repellent properties. Oil/dirt repellence are not yet sufficiently provided by alternatives, and costs could be incurred from reduced service life and inadequate performance of articles. Specifically for PPE, there could be impacts in the form of health care costs and human suffering. Repellence to bodily fluids is necessary to avoid the transmission of diseases in the medical sector, and repellence towards non-polar stains is part of the hazard management in other sectors. SEAC agrees that these functions can be critical for the safety of end users. For more information, please consult the cost section of the main part of this opinion.</p> <p>SEAC also notes that PFHxA, its salts and related substances are not connected to human health hazards, and from that point of view they may be preferable in these uses compared to some of the potential alternatives.</p> <p><u>Emissions:</u> RAC concluded that the potential emissions from PPE, high visibility clothing and re-impregnation agents may be in the order of tons. RAC pointed out that the uses can be considered wide and dispersive and not associated with any particular RMMs for their use. RAC did not support a derogation.</p> <p><u>Alternatives:</u> According to the dossier, no alternative products are available that ensure the same performance as products on the market in the foreseeable future. No more detailed information is provided. Comments submitted during the consultation confirm that suitable alternatives are not available where resistance to oil, chemicals, dirt or bodily fluids or a combination thereof is needed (comments 3011, 3015, 3028, 3133). It is also highlighted that it may be difficult to find such alternatives in the future because no fluorine-free alternatives are known that would reduce the surface energy/tension to a sufficiently low level (comments 3033, 3049).</p> <p>As to high visibility clothing, it is reported in the dossier that soiling can impair the intended function severely. SEAC considers that increased washing could be regarded a potential alternative in this case. However, it could affect the length of service life of the articles and increase environmental impacts in terms of additional consumption and more use of energy and detergent. SEAC also notes that some types of dirt encountered in professional settings (such as bitumen asphalt) may be very difficult to remove.</p> <p><u>SEAC conclusions:</u> SEAC recognises that these uses provide human health and life protecting functions. Lack of products performing well could cause serious health damage and casualties, and the related impacts both in terms of human suffering and economic consequences could be large. There could also be losses relating to distress and related inability to do ones work properly due to mistrust in the available equipment.</p> <p>Based on these considerations, <b>SEAC supports these derogations.</b> SEAC agrees that considering comments received in consultation it is appropriate to include all risk categories mentioned in the revised entry text (categories of risk III (g), (h) and (I) added) in the derogation (comments 3011, 3049, 3068). Category of risk III (g) was added to cover climbing ropes, category of risk III (I) for e.g. or high voltage electricity worker suits and category III(I) for e.g. bulletproof vests. For these categories of PPEs, industry stakeholders submitted information explaining that the highest level of water- and oil- repellence is needed to ensure that the PPEs fulfil their primary function and meet industrial standards. For example, during the opinion development, industry stakeholders noted that if bulletproof vests get wet, they lose their life saving properties. SEAC furthermore considers that similar considerations could apply to <b>face shields for surgeons and other medical care workers</b> requiring unhampered visibility, even if not covered by Regulation (EU) 2016/425. However, SEAC notes that the derogation for antifog face shields was requested only by one company during the consultation on the Annex XV report, and it is therefore unclear if there are other companies already using alternatives. Moreover, the information concerning the availability</p>

Use	Para.	DS approach	SEAC conclusions
			<p>and performance of alternatives was limited and there was no information on the search for alternatives. Therefore, SEAC does not propose a separate derogation for antifog face shields used in medical settings.</p> <p>It was highlighted in the consultation on the Annex XV report that Regulation (EU) 2016/425 does not apply to PPE specifically designed for use by <b>the armed forces or in the maintenance of law and order</b> and that these uses might need a dedicated derogation (comment 3068). SEAC agrees that continued use for such items appears appropriate. SEAC notes that there are uncertainties on whether the derogation applies also to PPEs against risk category III (I) such as bullet-proof clothing or jackets for the military and police. This is because the scope of Regulation (EU) 2016/425 excludes PPEs designed and manufactured for military or police purposes and intended to be used exclusively for such purposes. SEAC considers that the availability of such articles should not be endangered by the restriction. As comes to equipment used by armed forces, SEAC notes that where necessary in the interests of defence, Member States could make use of the possibility to allow exemptions according to REACH Art. 2(3). However, this would not cover similar articles used by law enforcement. Therefore, SEAC supports a specific derogation for PPEs used by armed forces or in the maintenance of law and order.</p> <p>Some <b>further types of equipment/ uniforms</b> were also raised in the consultation on the Annex XV report as potentially requiring a derogation (military, specific types of professional workers; comments 3011, 3015, 3068). SEAC considers that further information on costs of restriction, potential emissions and availability of alternatives would be necessary to allow an evaluation of whether further derogations are necessary.</p> <p>The information available on the availability of alternatives, the specific issues with potential alternatives and on the extent of the search made to find suitable alternatives is very scarce. The information available does not allow SEAC to estimate and suggest a suitable length of a transition period. The derogation should therefore be reviewed in due time. SEAC considers that the reporting requirement proposed could be useful for making sure that more information will be available at that time and also that PFASs will only be used when necessary for the functioning of the equipment.</p> <p>SEAC considers that it should be made more clear which articles are covered by the derogation on personal protective equipment. The wording provided in the proposed entry may not be clear enough for implementation and enforcement purposes.</p>
Textiles for the use in engine bays in automotive and aerospace industry	9e	<p>The Dossier Submitter proposes a derogation <b>not limited in time</b> for this use.</p> <p>The Dossier Submitter concluded that it is unknown whether a derogation is justified however the potential costs to society are very high.</p> <p>The Dossier Submitter proposes a yearly reporting requirement for</p>	<p>A stakeholder proposed a derogation to allow a continuing use of polyfluorinated hydrocarbon in automotive engine bay liners and similar related liner materials with similar needs on the grounds of safety and the lack of suitable alternatives (comment 2996).</p> <p><u>Costs:</u> no meaningful quantification of costs is possible. It was claimed in the consultation on the Annex XV report that treatment with C6-related substances provides potentially life-saving functions. The Dossier Submitter considered that although the impact is unknown it is likely that PFHxA-related substances function as important part of the risk management in these applications. It is concluded in the Background Document that the potential costs of the restriction to society are very high.</p> <p><u>Emissions:</u> due to unknown quantities used, where possible emissions cannot be quantified, and lack of information on RMMs, RAC did not support a derogation.</p> <p><u>Alternatives:</u> The stakeholders explained that textiles in the engine bay provide sound and heat isolation. PFAS are used as a part of the flame-retardant system to prevent the build-up of flammable deposits / liquids in the substrate's lattice. It was claimed that without fluorocarbon, the deposits of flammable materials can overload the flame-retardant properties of the substrate when ignited (comment 2996).</p>

Use	Para.	DS approach	SEAC conclusions
		this use.	<p>Stakeholders reported that they know alternatives for hydrophobic treatment, but not for oleophobic (comments 2996, 3124). SEAC acknowledges that oleophobic treatment may be critical in the engine compartment. It is reported in the comments submitted that some search for alternative substances has been carried out, however, there is no information on how wide that search has been, and the impression from the comments to SEAC is that the search may not have been very extensive.</p> <p><u>SEAC conclusions:</u> The Dossier Submitter considered it likely that PFHxA-related substances function as important part of the risk management in these applications. SEAC agrees that based on the limited evidence submitted, the treatment with C6-related substances appears to provide potentially life-saving functions. SEAC however notes that no evidence is available regarding the actual risk reduction resulting from the use of PFHxA-related substances as opposed to potential alternatives.</p> <p><b>SEAC does not find the information available sufficient to conclude on a derogation.</b> The information received in the consultation on the Annex XV report is fairly generic. Further information on the costs of the restriction, related emissions, the search made to find alternatives and on the reasons why it is specifically difficult to find alternatives for this use could be submitted in the consultation on the SEAC draft opinion. This could include information on the volume of the use, the proportion of the related end products (cars etc.) requiring this use, availability of alternatives (for the textile product or for the PFAS treatment), costs of non-use and the emissions related to continued use.</p>
Epilames used in watches	9f	<p>The Dossier Submitter proposes a derogation <b>not limited in time</b> for this use.</p> <p>The Dossier Submitter finds that considering the low emissions and the potential impact for companies of no longer being able to produce mechanical watches according to international standards, a derogation is justified from a socio-economic perspective</p> <p>The Dossier Submitter proposes a yearly reporting requirement for this use.</p>	<p>According to comments received in the consultation on the Annex XV report, a mechanical watch or a quartz watch cannot function properly without an efficient epilame (comments 2976, 3005, 3130, 3154). The industry considers the restriction disproportionate for this use since exposure of consumers or the environment is considered very unlikely and they expect high costs from not being able to use C6-containing epilames. An exemption request was made for epilame-coatings applied to internal watch parts, and epilame -coated internal watch parts.</p> <p><u>Costs:</u> no meaningful quantification of costs is possible. It was claimed in the consultation that without an exemption, it will not be possible to ensure the manufacturing and sales of watches, or the servicing of watches already on the market. Federation of the Swiss Watch Industry highlighted in the consultation that the Swiss watch industry is a major client of the European watch component supply industry and estimated that tens of thousands of jobs in the retail trade in the EU are indirectly dependent on the Swiss watch industry and the sale of its products. SEAC agrees that a restriction could potentially have an impact on employment (substitution-related costs, as partly assessed by the Dossier Submitter within this restriction), but underlines that no information was provided that would allow to verify the number of job losses claimed by stakeholders. It was also highlighted in the comments received that currently no analytical methods are available for the determination of PFHxA in epilames, and therefore the restriction would jeopardize the production of C6 epilames and watches in Europe while not being able to control imported watches. For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> A company provided an estimate on the overall mass of C6 polymers used by the watch industry worldwide (2 kg/yr globally, less in the EU, and only 0.4 kg going onto the watch parts; comment 2976). RAC concluded that based on the low magnitude of potential emissions of PFHxA (grams/year) and the RMMs described (waste collection, high temperature incineration) RAC can support a derogation for this use until suitable alternatives become available.</p> <p><u>Alternatives:</u> According to the comments received, no suitable alternative substance is available for the C6 substance used in the production of epilame mixtures. Silicone-based coatings have been investigated as potential alternatives, but they do not meet some technical requirements. Some other unsuccessful research made was also reported in</p>

Use	Para.	DS approach	SEAC conclusions
			<p>the consultation (comment 3154, confidential).</p> <p>Furthermore, the prohibition to use epilames would lead to premature wear of the components and consequently a shorter service life of mechanical watches and quartz watches. Performance level of the products employing another technology might also be lower.</p> <p>The specific properties that are required for an efficient epilame and difficult to achieve with other substances were clearly documented by stakeholders (comment 2976). SEAC notes that specifically as comes to very low surface tension it is also more generally recognised that it may be difficult to achieve with fluorine-free alternatives (“UNEP, 2013” reference to the dossier).</p> <p>Also no alternative for using epilame mixtures in depositing antispread coatings on the surface of internal watch components (or spare parts) has been identified.</p> <p>It is pointed out in the comments received (comment 2976) that the implementation of an entirely new technology to replace the fluorinated chemistry is complex and risky, and it would require many years to evaluate its feasibility and to proceed to its implementation. A suitable technology is also not yet known at the moment.</p> <p><u>SEAC conclusions:</u> SEAC agrees that costs to the concerned actors can be expected. The magnitude and share of the costs that would be borne by EU actors are not clear; comments were provided mostly by extra-EU actors and only one actor based in the EU. Volumes used and the potential resulting annual emissions are low compared to other uses. Some search for suitable fluorine-free alternatives has been made but has not been successful so far. Considering all this, specifically the low emissions, <b>SEAC supports a derogation</b>. There is no information available allowing to estimate a suitable length of a transition period for this use, however, considering the low emission potential, the timing of substitution may be less critical for this use and could be looked into later in the context of a potential review of the entire restriction.</p> <p>SEAC considers that the reporting requirement proposed could be useful in making sure that related information will be available at a later point for a review and also that PFASs will only be used when necessary for the functioning of the equipment.</p>
<p>Medical devices as specified in Regulation 2017/745</p> <p>including woven and non-woven medical textiles</p>	<p>9g</p>	<p>The Dossier Submitter proposes a derogation <b>not limited in time</b> for this use.</p> <p>The Dossier Submitter proposes a yearly reporting requirement for this use.</p>	<p><u>Costs:</u> no meaningful quantification of costs is possible for the overall sector affected. Dossier Submitter did not provide a cost assessment as a derogation is suggested and therefore, no economic impacts are expected. Several stakeholders provided use- and company specific cost information during the consultation. This does not allow SEAC to draw an overall conclusion on the costs for this sector. For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> RAC noted that the information available is relatively unspecific, with no specific information on RMMs, and concluded that RAC cannot support a derogation for medical devices in general, from a risk perspective. However, RAC assessed specific derogation requests submitted during the consultation on the Annex XV report and supports a 10-year derogation for coatings of hearing devices and a derogation for implantable medical devices.</p> <p><u>Alternatives:</u> Discussion on alternatives is very scarce in the Background Document; not very much information was received from stakeholders during stakeholder consultations and only product-specific information was received during the consultation on the Annex XV report.</p> <p>In the consultation on the Annex XV report, several actors in the field reported a wide variety uses in which C6 substances are used. They highlighted the value that the applications provide to society and explained the responsible practices that are followed when handling these substances or articles containing them, but mostly did not report having looked for fluorine-free alternatives.</p>



Use	Para.	DS approach	SEAC conclusions
			<p>It was highlighted that a long period of quality confirmation and application to administrative organs is a characteristic of the medical device industry (comment 3159).</p> <p>SEAC notes that so far there are only relatively few human health hazards and risks recognised for PFHxA, its salts and PFHxA-related substances, and their continued use in medical devices creates overall a societal value. While SEAC recognises the importance of reducing emissions and related environmental impacts, this is a use group where it may be specifically important to recognise the benefits of continued use of the substances.</p> <p>Some search of alternatives was reported relating to <b>detergent proof washbowls</b> (comment 3016). The alternatives studied did not provide the requested properties. It was claimed that fluorine-free alternatives cannot be used, because there will be a failure of the washbowls as soon as they come into contact with detergents. It is further stated that fluorine-free alternatives are not an option due to the method of manufacture and handling; however it was not clarified why it is so and why those methods (i.a. collection of used articles in a certain type of container) cannot be changed. The respondent also noted that alternative solutions are available, such as the use of reusable plastic or stainless-steel washbowls, pointing out that require more time from medical staff for cleaning and that they have a higher risk of infection if not washed or sterilized properly. They cite one study showing that introduction of disposable washbowls is part of the reason <i>clostridium difficile</i> infections reduced at an NHS Hospital<sup>30</sup>. The Dossier Submitter stated that there actually seem to be fluorine-free alternatives which allow the production of detergent-proof washbowls. SEAC assumes that the Dossier Submitter refers to the above-mentioned alternative solutions.</p> <p>As to <b>hearing aids</b>, it was reported in the consultation that currently the coating suppliers do not have a fluorine-free coating with comparable hydrophobic performance in place, and the development of a new coating is necessary (comment 3121). Some requirements of a successful coating were listed in the submission. It was claimed that developing, qualifying and introducing a new coating would require approximately ten years.</p> <p>Manufacturers of medical devices for <b>dry eyes</b> disease (comments 2997, 3055, 3132, 3153) reported also that no alternatives providing the same functions are available for this use and provided detailed confidential information on alternatives (comment 3153).</p> <p>One respondent reported the use of PFHxA related substances in <b>implantable and non-implantable medical devices</b> (e.g. catheters, stents etc.) and provided confidential information on the lower performance of alternatives (comments 3014, 3137).</p> <p><b>Medical textiles</b> are also considered by the Dossier Submitter to be covered under medical devices. Comments in the consultation on the Annex XV report highlighted that C6 chemistry is necessary to meet the standards required in EU legislation (comments 2995, 2971). Generally, stakeholders pointed out that fluorine-free alternatives only provide water repellence; alternatives do not provide repellence against oil, liquid chemicals and bodily fluids and C6 chemistry is considered necessary to provide resistance to viruses and bacteria (e.g. comments 3028, 3049, 3070, 3161). The lack of alternatives for repellence against oil, liquid chemicals and bodily fluids is confirmed by the Commission report on "The use of PFAS and fluorine-free alternatives in textiles, upholstery, carpets, leather and apparel".</p> <p><u>SEAC conclusions:</u> SEAC recognises that these uses provide <b>human health and life protecting functions</b>. Lack of products performing well could cause serious health damage and casualties, and the related impacts both in</p>

<sup>30</sup> Power, M. et al. (2010), Reducing Clostridium difficile infection in acute care by using an improvement collaborative, BMJ 2010; 341:c3359 doi: <https://doi.org/10.1136/bmj.c3359>

Use	Para.	DS approach	SEAC conclusions
			<p>terms of human suffering and economic consequences could be large.</p> <p>The Dossier Submitter noted that most probably the derogation covers articles where the continued use of PFHxA-related substances is not justified. However, based on the information available they found it impossible to identify use categories for exclusion. Limited, use-specific derogations could also leave out uses that merit to be exempted (ones not identified in the consultations). In order to avoid negative impacts from the restriction affecting such uses the Dossier Submitter proposed a <b>general derogation</b> of medical devices. SEAC agrees with the Dossier Submitter that considering possible negative impacts from limited use-specific derogations, a broad derogation of medical devices can be expected to be an appropriate approach at this point. However, SEAC considers that it would be good to review the possibility to restrict the derogation to the most critical applications as phase-out advances and the availability of alternatives improves. Currently the information available is not sufficient for suggesting use-specific derogations nor to propose a specific timeframe for a time-limited derogation.</p> <p>SEAC concluded that the information available does not allow to reach a conclusion on proportionality of a restriction on this use group (see the proportionality section of the opinion). Considering the potential consequences of situations where the equipment used does not work properly, and the apparent limited availability of suitable fluorine-free alternatives, <b>SEAC supports the derogation</b>. For example, one stakeholder suggested that at least 5 years are required for medical devices to be approved and used in clinical practice (comment 3159). However, the exact timeframe of transition to alternatives cannot be estimated based on the current information but will have to be assessed at a later point. SEAC considers that a reporting requirement as proposed could be useful in making sure that related information will be available at that time and also that PFASs will only be used when necessary for the functioning of the equipment.</p> <p>SEAC surmises based on the information available that many uses in medical devices might be covered by other derogations, such as the derogation (higher concentration limits) for <b>fluoropolymers</b>, however cannot be certain without more specific information on the uses and the related concentrations.</p> <p>SEAC would like to highlight that medical devices are assumed by the Dossier Submitter to cover <b>medical textiles</b>, but SEAC cannot confirm this. During the SEAC opinion making, industry stakeholders representing non-woven producers highlighted that medical devices, as defined by Regulation 2017/745, do not cover all the non-woven medical textiles. Therefore, uncertainty remains on the scope of this derogation. In case stakeholders consider that some type of medical textiles should be derogated but is not covered by Regulation 2017/745 and by this derogation, information on the product type, costs expected from the restriction, emissions related to the use and availability and timelines of alternatives could be submitted in the consultation on the SEAC draft opinion.</p>
Filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellence	9h	<p>The Dossier Submitter proposes a derogation <b>not limited in time</b> for this use.</p> <p>The Dossier Submitter proposes a yearly reporting requirement for this use.</p>	<p>Different derogation requests were made by stakeholders for filtration and separation media. Several of the actors supported the derogation request made in comment 3024 (on which the Dossier Submitter bases the derogation they propose).</p> <p><u>Costs</u>: no meaningful quantification of costs is possible. SEAC notes that several concerned applications fulfil important functions, some in safety-critical applications. According to stakeholders, suitable alternatives are not available (comments 3024, 3070, 3096 and more) and a restriction would therefore lead to a large loss of functionality and effectiveness, i.e. mainly substitution-related costs could be high. Appropriate filtration reduces maintenance needs, extends service life and prevents failures of equipment. Energy consumption and related GHG emissions are expected by stakeholders to increase in the absence of C6-treated filtration media. It was stated in the consultation that the absence of a derogation will put manufacturing facilities located in the EU at risk (comments 3024, 3070). It would result in a supply interruption of filtration and separation media for several purposes until</p>

Use	Para.	DS approach	SEAC conclusions
			<p>adequate alternative candidates are identified and requalified. SEAC agrees to the Dossier Submitter's conclusion that more information on the different applications and specifically a more detailed discussion on substitution possibilities as well as any potential related costs would be needed in order to draw a robust conclusion. For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> Stakeholders indicated that emissions are low during production and highlighted that the substances are enclosed in devices/ bound in matrices during service life, keeping emissions down. Information available on emissions from the waste phase is however very limited, and since use quantities are expected to be high (possibly several hundreds of tonnes per year), emissions may be significant. RAC noted that confidential data submitted during the consultation on the Annex XV report indicates that the emissions from production can be considered low. However, altogether, due to the unknown quantities used and possible associated emissions and lack of information on RMMs, RAC cannot support a derogation for this use.</p> <p><u>Alternatives:</u> The stakeholders claimed in the consultation on the Annex XV report that suitable alternatives combining water and oil repellence are not available (comments 3024, 3070, and more). Also other key properties provided by C6, which are challenging to achieve with alternatives, including glue repellence and ensuring reduced pressure drop across the filter device, were highlighted. Some fluorine-free repellents currently used in the EU were introduced and the related problems briefly described. Stakeholders also clearly listed the specifications that a successful alternative should meet (comment 3070).</p> <p>It was stated by stakeholders that C6 perfluorinated polymers are the only substance class available for filtration media that are chemically resistant to hydrogen fluoride arising in industrial waste incineration (comment 3049). It was also highlighted that in technical textiles for oil and gas filtration, e.g. filters for wasted air/incineration plants, oil repellence is crucial to comply with sectoral testing standards (comment 3109).</p> <p>The Dossier Submitter noted that more detailed information on the different applications and a more detailed discussion on substitution possibilities for individual applications is missing. Information on estimated substitution costs and planned activities would be helpful to better understand the difficulties of the substitution process. 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 for some applications.</p> <p><u>SEAC conclusion:</u> SEAC agrees that considering the expected loss of appropriately functioning filtering applications, and the related societal costs, <b>a derogation appears necessary.</b></p> <p>A suitable length of a <b>transition period</b> is difficult to estimate, since the technical requirements, and therefore the timelines with the development of suitable alternatives, vary widely by application. SEAC notes that requalification of equipment and third-party certifications are also required in many applications. Therefore, setting one timeline does not appear appropriate. On the other hand, setting a high number of different review periods, assuming the necessary information was available, might not be practical. Considering that suitable alternative materials have not been identified yet for most applications; that there is a multitude of concerned uses across the economy; and that the timelines indicated by stakeholders are very long (10 years and up), SEAC considers that an exact timeline cannot be set yet but the issue should be looked into again at a later point in time in the context of a potential review of the restriction.</p> <p>SEAC considers that the present <b>formulation of the proposed derogation</b> is problematic from the enforcement point of view, since it is difficult for enforcement authorities to know which articles qualify for "a high performance air and liquid application" and whether both water and oil repellence are required in each case. The coverage of the derogation should therefore be better defined.</p>

Use	Para.	DS approach	SEAC conclusions
			<p>With the current wording it is also difficult for SEAC to verify whether all applications meriting a derogation are covered by the proposed text. To this end, further information could be submitted in the consultation of the SEAC draft opinion. However, SEAC presumes that some of the applications might be covered by other proposed derogations, such as the separate provisions for fluoropolymers or those for specific product groups such as PPE or medical devices, and considers that the stakeholders, having the exact technical information on their application, should investigate also this possibility.</p> <p>Also information on applications now unnecessarily covered by derogation would be welcome in the consultation (from alternatives providers for example).</p>
Fluoropolymers	11	The concentration limit referred to in paragraph 2 shall be...	
	11 a,d	<p>(a) 2000 ppb for the sum of <u>PFHxA and its salts</u> in fluoropolymers</p> <p>(d) 100 ppm for the sum of <u>PFHxA related low molecular substances</u> in fluoropolymers</p>	<p><u>Costs:</u> overall, no meaningful quantification of costs is possible. The Dossier Submitter concludes that reasonable worst-case scenarios in case of a restriction imply high societal costs. During the consultation, stakeholders provided information on the socioeconomic benefits of using fluoropolymers in different sectors, this information, however, being claimed confidential. SEAC agrees to the Dossier Submitter's view that the report is of limited use to extrapolate any meaningful cost estimates. A quantitative cost assessment was provided by the Dossier Submitter for the manufacture of fluoroelastomers, where APFHx is used as processing aid. A restriction is expected to lead to profit losses ranging between 2 – 16 million € per year, additional (partly substantial) costs expected for DU, due to requalification processes and considerable reduced international competitiveness of component suppliers as well as the EU automotive and aerospace industries. Whilst SEAC acknowledges costs to occur due to a restriction, SEAC cannot verify the cost calculation provided as it is not supported by a sufficiently justified assessment. For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> uncertain emission quantities, but believed to be comparably low by the Dossier Submitter. Emissions from waste phase are very uncertain. RAC pointed out that a higher concentration limit will allow some emissions, but noted that the amounts are not presented. As fluoropolymers are widely used in various forms, RAC concluded that it is unlikely that another measure than restriction of the concentration of PFHxA, its salts and related substances in fluoropolymers, would be effective in preventing further emissions to the environment. RAC did not support higher separate concentration limits, from an emissions minimisation perspective.</p> <p><u>Alternatives:</u> Fluoropolymers are used in a wide variety of applications in several sectors. They are used in specific, high reliability/safety critical applications. Therefore, performance requirements are tight. This issue was highlighted by stakeholders in the consultation on the Annex XV report (comments 2999, 3066, 3082 and many more). Stakeholders claim that fluoropolymers display i.a. outstanding chemical and temperature resistance, combined with mechanical and electrical properties. The properties and specifically the combination thereof are claimed difficult to find in alternative products.</p> <p>SEAC understands that the specific performance requirements in each of the numerous applications are different, and therefore general conclusion on the availability of alternatives is not feasible or overall helpful. Carrying out separate assessments for each use then again would be arduous, and considering the assumed comparably low emissions, potentially not reasonable. Stakeholders did not provide information on alternatives for specific applications.</p> <p>Alternatives could be sought among fluoropolymers purified of PFHxA-related substances, fluoropolymers</p>

Use	Para.	DS approach	SEAC conclusions
			<p>manufactured with low volumes of or without PFHxA-related substances, or completely different products. Being manufactured using PFHxA-related substances or containing PFHxA-related substances affects the quality of the fluoropolymer.</p> <p>Based on the information available, fluoropolymers compliant with the proposed restriction can be manufactured, even ones not containing any PFHxA-related substances at all (where other types of processing aids have been used). However, the performance level of such products is claimed to be lower. Specifically as to fluoroelastomers, SEAC notes that there are fluoroelastomers compliant with the 1000 ppb limit value on the market. However, the performance level of such fluoroelastomers is considered by industry as not sufficient for many applications. Stakeholders argue that standards in automotive industry can only be fulfilled by using high performance fluoroelastomers.</p> <p>SEAC notes that a technology for the purification of fluoropolymers was highlighted in the consultation (comment 2960). The comment does not contain information on the performance level of the purified products and accordingly on the possibility to use them successfully in the more demanding applications. Other information on the performance of this technology is not available to SEAC.</p> <p>The Dossier Submitter concluded that alternatives are most probably available for some uses; however, information is scarce. The Dossier Submitter on the other hand concluded that a restriction is most likely not proportionate for several uses, and as no way to differentiate between uses meriting a derogation and those not meriting a derogation was found, they proposed a general derogation of fluoropolymers in terms of higher concentration limits.</p> <p><u>SEAC conclusions:</u> SEAC agrees that considering the wide reliance on fluoropolymers in a wide variety of industrial applications, a restriction could have large effects on several sectors with partly unpredictable knock-on effects on other sectors. SEAC agrees that suitable alternatives do not appear to be available for many applications and it may take a lot of further work and a long time to develop suitable alternatives.</p> <p>SEAC in principle agrees that setting higher limit values for fluoropolymers may be appropriate. However, more information is needed to give an opinion on the appropriateness of the proposed limit values. It is not clear from the Background Document how the limit values were chosen. SEAC notes that one proposal was made by industry in the consultation on the Annex XV report (comment 3066 (confidential)). Based on the information available, it is not clear what the performance level of fluoropolymers complying with the limits proposed by the Dossier Submitter in the different applications is.</p> <p>Information on current levels of PFHxA-related substances in fluoropolymers and specifically on the lowest levels that are reachable in the short term by optimising the current techniques is invited in the consultation on the SEAC draft opinion.</p> <p>SEAC considers that a derogation should cover the import or manufacture and use of the process media and solvents necessary for the production and use of fluoropolymers.</p> <p>The Dossier Submitter considered that due to the very high underlying uncertainties, the derogations should be re-evaluated in the future. SEAC agrees to this conclusion. Information on the availability of compliant fluoropolymer products or substituting products and their performance in the different applications would be welcome also in the consultation on the SEAC draft opinion to enable further scrutiny already at his stage.</p> <p>The Dossier Submitter expected that this derogation will address concerns relating to <b>PTFE micro powders</b>. SEAC notes that C6 substances are included therein as unintentional ingredients produced during the production process and as impurities resulting from the initial manufacture of the PTFE used for the manufacture of the micro powder.</p>

Use	Para.	DS approach	SEAC conclusions
			<p>SEAC does not have exact information on the concentrations of C6 substances in PTFE micro powders but agrees that the Dossier Submitter's conclusion appears reasonable.</p> <p>SEAC notes that PTFE micro powders are covered by the scope of the restriction proposal on microplastics, and the use thereof may be banned by a restriction on microplastics in the near future.</p>
	11 b,e	<p>(b) 150 ppm for the sum of <u>PFHxA and its salts</u> in fluoropolymers used in the following usage groups: <b>Engine parts</b> in automotive, aerospace and shipping industry</p> <p>(e) 2500 ppm for the sum of <u>PFHxA related low molecular substances</u> in fluoropolymers used in the following groups: Engine parts in automotive, aerospace and shipping industry</p> <p>This is due to low emissions and high costs expected in the sector (loss of profits to the European manufacturers), as well as because there is some evidence that the automotive and aerospace industries rely on these specific fluoroelastomers to comply with international safety standards (and cannot use alternative materials arbitrarily).</p>	<p><u>Costs:</u> for cost information, see section above as well as the cost discussion in the main part of the opinion document.</p> <p><u>Emissions:</u> RAC did not support higher separate concentration limits for fluoropolymers, including fluoroelastomers, from an emissions minimisation perspective.</p> <p><u>Alternatives:</u> It is noted in the dossier that excellent heat and chemical resistance are necessary for smaller, higher performance engines to meet the EU car emission standards. Stakeholders argue that standards in the automotive and aerospace industries can only be fulfilled by using high performance fluoroelastomers (comments 3048, 3069).</p> <p>The components suppliers in automotive industry have to supply according to requirements listed for example in ISO/TS 16949. Stakeholders argue that these requirements can only be fulfilled with fluoroelastomers with C6 polymerisation aids. The Dossier Submitter reports that it was not able verify whether all uses of C6-fluoroelastomers in automotive and aerospace industry are necessary to meet the requirements of ISO/TS 16949.</p> <p>It is stated in the Background Document that there is another way to produce fluoroelastomers, called soap-free emulsion polymerization. It was explained that the resulting fluoroelastomers do not reach the same performance levels. The underlying reasons or the wideness of the gap between the necessary and achieved performance level were not elucidated.</p> <p><u>SEAC conclusions:</u> Justification for choosing limit values of specifically 150 ppm/ 2500 ppm is missing. The information available is not sufficient to evaluate the proposed limits, and more information is needed to be able to give an opinion on setting specific higher limit values for this use. Information on current levels of PFHxA-related substances in fluoropolymers and specifically on the lowest levels that are reachable in the short term by optimising the current techniques is invited in the consultation on the SEAC draft opinion.</p>
	11 c,f	<p>(c) 10 ppm for the sum of <u>PFHxA and its salts</u> in fluoropolymers used in <b>coating of electronic devices</b> until XX XX XXXX [7 years after entry into</p>	<p><u>Costs:</u> no meaningful quantification of costs is possible. SEAC notes that mainly costs related to substitution are expected to occur as e.g. a higher number of affected devices is expected to breakdown due to lack of required properties (see discussion on alternatives below). Some quantitative cost information was provided during the consultation by stakeholders (e.g. loss of profits, significant social cost of unemployment), however, SEAC cannot conclude on the robustness, reliability and overall applicability of these quantified cost estimates. SEAC acknowledges economic impacts to occur in case no transition period is considered, their magnitude, however, being</p>

Use	Para.	DS approach	SEAC conclusions
		<p>force]</p> <p>(f) 500 ppm for the sum of PFHxA related substances in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force]</p>	<p>unknown. For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> According to information submitted by stakeholders in the consultation on the Annex XV report, the use volume appears to be low. Emissions from this use are expected by manufacturers to be low considering the low amounts of C6 fluorinated polymers and also the closed loop recycling of electronic articles. RAC noted that the available information on use volumes and RMMs described is company specific and difficult to extrapolate to this use generally. Moreover, RAC noted that the use volumes provided in the consultation are significant and RAC did not support higher concentration limits in fluoropolymers used in coating of electronic devices, from a risk perspective.</p> <p><u>Alternatives:</u> It was claimed in the consultation on the Annex XV report that the performance level of the available non-fluorinated alternatives is not sufficient at this point and C6 polymers for nano-coating are needed to achieve high levels of water repellence to protect electronics from water and corrosion damage (comments 2977, 3007). It is claimed that water repellents are less well available for this sector compared to textiles. Stakeholders explained that where a combination of different key properties is required, the performance of fluorine-free alternatives does not match that of fluorinated chemistries. Also, some confidential information on the alternatives assessed was provided.</p> <p>Taking into account all the information available, SEAC notes that technically feasible alternatives actually appear to exist. From the SEAC perspective it might be appropriate to apply a longer transition period based on an alternative being economically not feasible, however, more substantiation on the infeasibility would be necessary. Furthermore, there was only one party requesting a derogation for this use in the consultation on the Annex XV report, which might indicate that other companies may have found a suitable alternative.</p> <p>Further information on alternatives could be submitted in the consultation on the SEAC draft opinion.</p> <p><u>SEAC conclusions:</u> More information on alternatives and the requested higher limit values that can be used in justifying a derogation (i.e., non-confidential) is necessary to be able to evaluate and report whether setting higher concentration limits for this use is appropriate.</p> <p>SEAC also has doubts on whether this derogation proposal actually derogates the use it intends. The use highlighted in the consultation may not be a fluoropolymer use at all. Therefore, it is even more important to receive additional information through the consultation before SEAC can give an opinion in this regard. SEAC notes that there were several requests for a derogation relating to coating materials made in the consultation and wants to see if there are possibilities to find a common ground for all the applications where SEAC concludes that a derogation would be justified.</p>

Table 4: Derogations requested by stakeholders during the consultation on the Annex XV report

Other uses where derogations were requested during consultation	SEAC discussion and conclusions
Optical fibres	<p>A stakeholder requested a derogation for the use of C6 fluorinated polymers as cladding material for plastic optical fibres in the consultation on the Annex XV report claiming that alternatives are not available (comment 3002). The Dossier Submitter considered a derogation might be appropriate for future use in cars (e.g. self-driving cars) but considered that the information available was not sufficient to allow an evaluation on whether a derogation is justified.</p> <p><u>Costs:</u> No information on substitution and any potential related costs of a restriction are available to SEAC. SEAC notes that if there are no suitable alternatives, the speed increase and lower information loss achieved by using the targeted substances would be lost. This could lead to traffic accidents not being avoided and therefore to costs in terms of human suffering and shorter service life of vehicles. However, there is no information on the relative deterioration of performance and on the expected related number of accidents, and thereby no indication of the magnitude of costs.</p> <p><u>Emissions:</u> Claimed to be low from finished articles because the substances are inside a jacket. It is claimed that collection in the waste phase should be possible under the End-of-Life Vehicle Directive. RAC considered that PFHxA-related substances are expected to be contained in the fibre and subject to end-of-life waste management. RAC acknowledged that with proper waste-management emissions to the environment from this use could be low, but without further information on emissions or RMMs, RAC cannot support a derogation and cannot conclude on the effectiveness of the restriction, from a risk perspective.</p> <p><u>Alternatives:</u> It is highlighted in the comment that the low refractive index, providing for the desired function, is an inherent property of fluoropolymers and cannot be achieved with other polymers. SEAC agrees that such inherent properties are difficult to mimic, however, further clarification and backing to the claim as relates other materials would be necessary. It is claimed that other materials compatible with the plastic optical fibre core do not have the low refractive index, however it is difficult to know how wide the search has been.</p> <p><u>SEAC conclusions:</u> SEAC considers that <b>the information available is not sufficient to suggest a derogation</b>. More information on the availability of and requirements for alternatives and costs of non-use could be submitted in the consultation on the SEAC draft opinion (for vehicles or other uses as relevant).</p>
Paper and cardboard (food contact materials)	<p>In the consultation on the Annex XV report stakeholders requested a derogation or a longer transition period to develop alternatives that provide for an equivalent functional performance and that do not contain plastics (comments 2966, 3064).</p> <p><u>Costs:</u> some quantified cost figures have been provided by the Dossier Submitter. Based on information provided in a report (OECD 2020), substitution costs are estimated to result in 1.45 billion €/year (central estimate), when using the cheapest alternative that is said to be available feasible. As regards potential substitution related costs, no quantified cost figures are available. Any such costs might arise due to loss of functionalities of products and consequently reduced shelf life of articles, potential burns from hot oil migration, the need for additional machinery/equipment, etc. Whilst the calculated substitution costs seem to be based on a reasonable approach, the likelihood and magnitude of any potential substitution related costs is completely unknown to SEAC. For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> SEAC notes that according to the dossier this use is connected to very high emissions. Emission reduction from paper, together with textiles and to a lesser extent firefighting foams, is key to the effectiveness of the restriction. Based on the high volumes of substances used, that may end up in landfills and constitute a major emission source, from a risk perspective RAC does not support a derogation.</p> <p><u>Alternatives:</u> According to the dossier, water repelling properties can be achieved by several techniques. Information from industry suggests that alternatives that provide oil- /grease-repelling properties are less effective than fluorinated substances, especially where stability at higher temperatures is needed. A recent report from the OECD on paper FCM (OECD 2020) concluded that efficient PFAS-free alternatives are available for all applications, though higher costs for the paper production of 11-32% might result. The report also noted that the current market share of non-fluorinated alternatives appears to be approximately 1% or less.</p>



Other uses where derogations were requested during consultation	SEAC discussion and conclusions
	<p>The report acknowledged that there are some technical challenges to the transition, however it was concluded that the key reason for the current lack of market share is the higher cost.</p> <p>It is reported in the dossier that some articles for baking and frying, such as baking “papers”, can be made from silicone. For food packaging, specially adapted micro- or nanofibrillated cellulose-fibres could be used to achieve water- and oil-repelling properties. Furthermore, intensive pulp refinement can offer some solutions, and certain natural alternatives exist such as bamboo, palm leaves or elephant gras. The alternatives may carry risks of their own; some of the substances are suspected reprotoxicants or have PBT and vPvB properties, and the risks of the possible migration of the nanomaterials into food are still under investigation. It was noted that also plastics or products containing a plastic layer in contact with the food could be used as packaging materials, however, it was pointed out that this might not be desirable considering the strategy of the EU to reduce plastics.</p> <p>It was reported in the consultation on the Annex XV report by a company that the phase-out of C6 used in FCMs has already been initiated and that they will stop imports by the end of 2023 (comment 3109).</p> <p>SEAC notes that several actors in the field, such as some fast-food chains, have committed to phase out the use of PFASs from its customer packaging<sup>31 32</sup>. Also other well-known companies have publicly announced intentions to transition away from using PFAS in food packaging.<sup>33</sup> In addition, according to the US FDA, in 2019 one manufacturer already phased out short-chain PFAS and in 2021 three manufacturers are beginning a 3-year phase-out of their sales of certain substances that contain 6:2 FTOH for use as food contact substances.<sup>34</sup></p> <p>SEAC considers that all this strongly indicates that there are alternatives available that are technically and economically feasible and the actors in the field also expect them to be implementable in the next couple of years.</p> <p><u>Conclusions:</u> SEAC regards that considering the high emissions from the paper sector, in view of the effectiveness of the restriction, evidence on substantial negative socio-economic impacts is needed to support further derogations. Considering that alternatives appear to be available and some manufacturers and food producers are already switching to these alternatives, <b>SEAC does not support any derogations for these uses.</b></p>
Building materials/ construction products	<p>Derogations were requested in the consultation on the Annex XV report for paints (comments 2964, 2969 (confidential)), C6 fluorinated polymers in general for the construction sector (comment 2968), agents for the protection of hard surfaces (comments 2969 (confidential), 3049) and for coating additive for products being used in the roofing industry (comment 2973 (confidential)).</p> <p><u>Costs:</u> no meaningful quantification of costs is possible. Overall, any qualitative or quantitative cost information is scares for this use/sector affected. It was claimed during the consultation that without fluorinated products, protective measures and cleaning activities for buildings will increase, (e.g. from 15 – 20 years to 2 – 4 years); the same goes for painting of buildings. Also the “cool-roof”-system functionality of fluoropolymer chemistry was mentioned to reveal a benefit in terms of reduced CO<sub>2</sub> emissions (through a reduction of energy costs). SEAC notes that the before mentioned claims weren’t substantiated by supporting evidence. For more information, please consult the cost section of the main part of this opinion.</p>

<sup>31</sup> <https://saferchemicals.org/2021/01/13/mcdonalds-announces-global-ban-of-toxic-chemicals-in-food-packaging/> (Accessed 03/02/2021)

<sup>32</sup> <https://saferchemicals.org/2020/01/10/taco-bell-to-phase-out-toxic-chemicals-in-food-packaging/> (Accessed 08/02/2021)

<sup>33</sup> <https://sustainability.aboutamazon.com/environment/packaging-and-products/chemicals> (Accessed 03/02/2021)

<sup>34</sup> <https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-agreement-manufacturers-phase-out-certain-short-chain-pfas-used-food> (accessed 05/02/2021)

Other uses where derogations were requested during consultation	SEAC discussion and conclusions
	<p><u>Emissions:</u> Quantitative exposure assessment was not feasible for the Dossier Submitter due to lack of data. Considering that the products in question are largely used outdoors, a direct release of perfluorinated surfactants into the environment in significant amounts was considered as very likely. The Dossier Submitter assumes that use in paints and inks in the range of 50 - 100 t/a within the EU from the PFOA restriction applies also to shorter chain PFAS like PFHxA. RAC considered that taking into account the in large outdoor use of these applications a direct release to the environment is likely. Based on a lack of information on associated volumes or expected/confirmed large volumes and direct emissions to the environment, RAC does not support a derogation for building/construction materials.</p> <p><u>Alternatives:</u> Regarding water repellence, the use of fluorine-free alternatives seems feasible, however, higher amounts of the chemicals may need to be used and the service life of finished articles may be shorter.</p> <p>As to repellence to oil and some other materials, substitution appears more challenging. Claims were made in the consultation that suitable fluorine-free alternatives are not available (comments 2968, 2973 (confidential), 3049, 3085, 3109). However, the claims were generally not supported by information on the R&amp;D carried out to find suitable alternatives, or other corroborating evidence. Some indications of insufficient performance against other agents than water was submitted relating to surfactants and to stone protection agents (comment 2969, confidential). Silane/siloxane-based agents were recognised as potential fluorine-free alternatives of C6 perfluorinated polymers in the protection of hard surfaces however, it was claimed that those do not provide stain and oil repellence and, moreover, are less durable due to their poor UV resistance (comment 3049).</p> <p>Increased cleaning could be an alternative in the case of facades of buildings, but according to comments received would lead to the use of large amounts of chlorine-based products and would require a lot more workforce (comment 2964). Also painting would need to be repeated more often. SEAC notes that there is no information on the number of buildings that this use relates to, but considering the low number of actors raising this use in the consultation SEAC understands that the protection of facades by C6 technology may not be a very widely used application, implying that other solutions exist.</p> <p>As to textiles for flexible civil construction (e.g. flexible textile roofs or ceiling panels), it was mentioned that with fluorine-free alternatives a maximum dynamic water repellency and dirt repellency cannot be achieved, and manufacture standards are failed to meet (comment 3109). Information on the time needed to develop alternatives was not provided for SEAC.</p> <p><u>SEAC conclusion:</u> There is a wide variety of products covered, and accordingly the availability and stage of development of alternatives varies. Only very rough estimates on the timelines needed for the transition to alternatives were presented by stakeholders and the estimates were not substantiated. For the protection of facades, it was claimed that developers will need at least 10 years to achieve equivalent effects and durability (comment 2964), and for water-repellent agents some stakeholders stated that substitution would be possible in 2-3 years without specifying a product type (comments 2968, 3049).</p> <p><b>SEAC considers that the information provided on costs, emissions and availability of alternatives (where included) is not sufficient to allow a conclusion on whether a derogation or a longer transition period would be appropriate for any of the product groups covered.</b></p>
Textiles: apparel, home textiles, technical textiles not covered by point 9e (e.g. outdoor upholstery, automotive)	<p>The textiles category covers many different sub-categories. The analysis presented here covers textiles in general (except non-derogated PPEs, see below, and uses for which derogations were proposed by the Dossier Submitter), specific information by sub-category is provided where relevant.</p> <p>During the consultation on the Annex XV report, derogations were requested for further several types of textiles, such as fabrics used in outdoor clothing, home textiles, upholstery for residential, commercial and automotive settings, high-performance sports equipment, nonwovens used in transport [i.a. Comments 3028, 3040, 3070, 3076, 3109, 3140]</p> <p><u>Costs:</u> no meaningful quantification of costs is possible. SEAC notes that any potential costs (specifically substitution related costs) are dependent on which functionalities are sought: whilst alternatives seem to be available and feasible as regards water repellence properties, this is not valid for oil/dirt repellence properties and respective negative economic consequences can be expected through a reduced service life of articles, increased cleaning effort for products, etc.</p>

Other uses where derogations were requested during consultation	SEAC discussion and conclusions
	<p>However, their likelihood and magnitude are unknown to SEAC. For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> RAC considered that it is probable that use volumes and emissions will be substantial, and likely to most extent directly to the environment during the service life. RAC did not support a general derogation for specialised and technical textiles, from a risk perspective.</p> <p><u>Alternatives:</u> As far as water repellence is concerned, suitable alternatives with high performance level appear to be widely available. This was also confirmed in the consultation [i.e. Comments 3015, 3033]. Phase-out of PFASs is already ongoing at least in the sportswear and outdoor clothing industry due to increasing pressure from the public, implying technical feasibility.</p> <p>As regards oil or dirt repellence, the situation with alternatives is not as good. It was stated in the consultation that perfluorinated polymers are currently the only class of substances able to repel liquids such as oil, blood, solvents, petrol and other liquid chemicals with low surface energy [i.a. Comments 3015, 3028, 3033, 3049]. It was highlighted that the superiority of C6 is manifest where a combination of repellence to different agents (water, oil, stain, chemicals) is required (comment 3019, 3109, 3133). It was also stated that due to the physico-chemical properties required, this situation is not expected to change (comment 3049). The properties in question and the reasoning why it would not be possible to find them in any fluorine-free alternatives were not clarified though. In another comment it was explained that these properties relate to the unique low surface tension provided (comment 3070).</p> <p>Some stakeholders also highlighted the low flammability and flame retardant properties provided by perfluorinated polymers as an additional virtue (comment 3044, 3049). Also, it was claimed that UV resistance can be provided by fluorine-containing finishing but not by fluorine-free alternatives (comment 3161 (confidential)).</p> <p>SEAC notes that stain repellence may have a significant impact on consumer satisfaction, since otherwise the fabric may need to be washed more often and may have a reduced service life. Increased washing could also affect water emissions specifically considering that fluorine-free alternatives need to be used in larger quantities to achieve a comparable performance and are usually less resistant to washing compared to fluorine ones (comments 2969 (confidential), 3049). Increased washing could also be not feasible on some cases if for example the fabric is affixed to a furnishing or laundering would damage the fabric (comment 3019). However, as to customer satisfaction, according to the dossier, in a recent consumer survey on important purchasing factors to consumers of outdoor apparel, 'green' chemical use was found out to be three times more important as a purchasing factor than stain resistance.</p> <p>It was highlighted by industry actors in the comments received in the consultation that the necessary recertification processes to meet industrial standards is an additional burden for them and requires time. The actors further stated that alternatives won't allow them to meet the required standards for their products and claimed that if there are no alternatives allowing to meet industrial norms, a derogation should be granted [e.g. Comments 3049, 2962].</p> <p>For <b>home textiles and textiles used in public places</b> (seats, carpets, etc.) the main benefit of use of C6 appears to be stain repellence. C6 treated articles do not need washing so often and this can provide for a longer service life. Based on the information in the dossier, water repellents appear to be available also for this use. SEAC notes that other materials are also available for these uses.</p> <p>For several types of <b>technical textiles</b> repellence to oil and chemicals may be an important property and there is a lack of alternatives (comment 3049). Derogations have been proposed for some applications considered the most critical by the Dossier Submitter (medical textiles, filtration, textiles used in engine bay). For other applications some fall in performance level could be expected. Stakeholders highlighted in the consultation on the Annex XV report that technical non-woven materials e.g. in the automotive industry are subject to extreme wear and soiling. Hence, the materials used must be resilient, highly durable and easy to clean but also light-weight to keep the consumption of fuels down. Those expectations were claimed to currently be met only by textile treatments with C6 perfluorinated polymers. For certain parts also diesel repellence may be necessary (comment 3049). Transition time of 10 years for technical textile applications was requested (comment 3049), however the choice of the number of years was not substantiated.</p> <p>It was highlighted in the consultation on the Annex XV report that the upholstery supply chain is complex, and that it is common that an upholstery producer does not know in advance whether the fabric will have the option to be laundered, or where the finished fabric will ultimately reside (i.e. hotel, residence, restaurant, etc.) (comment 3109). It was explained that therefore fabric manufacturers need the option to apply C6 repellent to all types of upholsteries, not just upholstery</p>

Other uses where derogations were requested during consultation	SEAC discussion and conclusions
	<p>for selected end-uses. SEAC considers this kind of practice potentially problematic from the emissions point of view.</p> <p><u>SEAC conclusion:</u> SEAC regards that considering the high emissions from the textile sector, in view of the effectiveness of the restriction, evidence on substantial negative socio-economic impacts is needed to support further derogations. PPEs and medical textiles have been recognised as applications where societal costs in terms of reduced health and safety would be high, and SEAC agrees with the Dossier Submitter that derogations should be applied to these uses (see Table 3). The scopes of the derogations were made wider based on information received in the consultation. As to the other product types, e.g. carpets, functional losses may result in more frequent washing or less durability, which is assumed to lead to low/medium economic impact for consumers and low/medium impact for the environment (if e.g. carpets are thrown away earlier as a result, but no clear evidence that this would be the case).</p> <p>Overall, SEAC notes the concerns raised by stakeholders in the consultation on the Annex XV report, but considers that the requests for further derogations made in the consultation on the Annex XV report were not accompanied with sufficient corroborating evidence on costs, emissions and availability of alternatives to enable to conclude on derogations. <b>Based on the evidence available at this point SEAC does not support further derogations in this sector.</b> Further information justifying further derogations could be submitted in the consultation on the SEAC draft opinion.</p>
Textiles: PPE (other than those intended to protect users against risks in Risk Category III) and professional apparel	<p>Derogations were requested during the consultation on the Annex XV report for a large number of uses in PPE (in addition to the derogations proposed by the Dossier Submitter covered in Table x) and professional apparel such as uniforms for law enforcement and military authorities and emergency responders, and different types of occupational clothing such as apparel for bad weather and with requirement of high durability [i.a., Comments 3011, 3018, 3019, 3109, 3068].</p> <p><u>Costs:</u> Please see above for information on textiles in general as well as the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> See above for technical textiles in general.</p> <p><u>Alternatives:</u> Like for textiles in general, alternatives are available to achieve water repellence, but not a sufficient level of repellence against stain, oil, bodily fluids and other liquids. It was reported that fluorine-free alternatives do not offer any oil repellence at all (comment 3015, 3049). Still, repellence to oil and stain may be specifically important in this product group, since it reduces the risk of fuels or oils soaking into clothing, potentially creating a fire risk. Furthermore, it was reported that in case there is no effective oleophobic protection, contact with environmental and body oils will lead to early failure of water beading performance, leading to loss of breathability, heaviness and the risk of cold-related injury (comment 3015). SEAC notes that it was stated in the consultation on the Annex XV report that alternatives in the case of protective wear could be expected in 2-3 years (comment 2962, 3015).</p> <p><u>SEAC conclusion:</u> For these uses, potential problems in terms of lack of alternatives providing the same or required performance levels were highlighted in the consultation and derogation requests were made. SEAC notes the issues reported, however, finds that considering the high emissions from the textile sector, in view of the effectiveness of the restriction, evidence on substantial negative socio-economic impacts is needed to support further derogations. Specifically, it has not been demonstrated that it is necessary to have a high level of oil and stain repellence in uniforms. Specialized equipment for situations where protection is required could be a solution.</p> <p>SEAC considers that adequate protection of workers carrying out tasks involving a risk of exposure to oil or hazardous chemicals must not be jeopardized. In case suitable equipment would not be foreseen to be available and materials containing PFASs are necessary, more information would be needed to allow proper evaluation. SEAC however notes that according to PPE regulation guidelines<sup>35</sup> for example "<i>Clothing and/or accessories (whether or not detachable) designed and manufactured to protect against liquid chemicals</i>" for example are assigned to category III and therefore covered by the exemption proposed.</p> <p><b>The information provided on costs, quantities used, emissions and feasibility of alternatives (where included) is not sufficient to allow a proper evaluation and therefore SEAC cannot conclude on the necessity of any further derogation.</b></p>

<sup>35</sup> Guide to application of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC

Other uses where derogations were requested during consultation	SEAC discussion and conclusions
	Extension of the general transition period from 18 months would be a way to reduce the related impacts. More information may also be submitted in the consultation of the SEAC draft opinion.
Water-based printing inks, other than latex printing inks	<p><u>Costs:</u> no meaningful quantification of costs possible, despite efforts made by the Dossier Submitter to collect information, specifically as regards a calculation of potential substitution costs. The largest effect due a restriction would be expected through an early replacement of printer hardware in case a suitable ink is not available. SEAC notes that this represents negative environmental impacts in terms of additional waste, partly hazardous to the environment, and additional CO<sub>2</sub> emissions. However, it appears that fluorine-free alternatives exist and could be implemented, at least partly avoiding those costs. SEAC notes the Dossier Submitter's conclusion that any derivation of general substitution costs for the whole industry was not possible based on the information provided. For more information, please consult the cost section of the main part of this opinion.</p> <p><u>Emissions:</u> It is assumed by the Dossier Submitter that up to 80 t/a of PFHxA-related substances are released into the environment in using either water-based or latex inks. The share of water-based printing inks in those figures is not clear from the dossier. RAC considered that the likely use volumes are in the range of up to tonnes and noted that no specific RMMs are presented. RAC did not support a derogation, from a risk perspective.</p> <p><u>Alternatives:</u> The Dossier Submitter states that only very little information could have been obtained on the availability of alternatives for water-based printing inks. However, from the information available (e.g. use of siloxanes in many coatings, use of alternative technologies such as UV curable mixtures, etc.) they conclude that alternatives are available. Comments from the consultation can be seen to confirm the availability in principle, however, time would be needed for further evaluation (comment 2987). It was claimed in the consultation that the quality of the print made using alternatives is worse, however, it was not clarified what the value of the better appearance compared to the worse appearance is.</p> <p>During the consultation, stakeholders requested an extended transition period for some water-based printing inks to avoid disruption of supply to printers currently used or already imported into the EU (comments 2987, 3058, 3091). The requested length of the period varies widely (up to 12 years, the lowest estimates claimed confidential). The justifications are narrow such that it is not possible to evaluate the requests and find a precise length.</p> <p><u>SEAC conclusion:</u> Considering that suitable alternatives seem to exist, even though work with implementation is still needed, SEAC considers that if the general transition period for the restriction is extended to 36 months, a separate derogation for this use is not needed. This would also allow many more printers to reach the end of their service life, reducing the need of premature replacement in cases where alternative inks may not yet be implemented. <b>Therefore, SEAC does not support any derogations for this use.</b></p> <p>Further information, such as on the types and numbers of printers potentially requiring replacement in case inks containing PFHxA-related substances would not be available, on their remaining lifetimes, on the emissions related to their continued use, on the reasons why alternatives are not appropriate, and on other economic impacts, could be submitted in the consultation on the SEAC draft opinion.</p>
Others	<p>Potential problems for further uses, including the following ones, were highlighted in the consultation on the Annex XV report and derogation requests were made. It was claimed that suitable alternatives are not available.</p> <ul style="list-style-type: none"> <li>• PTFE micro powders (considered by the Dossier Submitter to be covered by the higher concentration limits proposed for PFHxA, its salts and related substances in fluoropolymers)</li> <li>• PFHxA coated paper for oxygen absorbers used in sealed container (comment 3125)</li> <li>• Glass protection (comment 2969 (confidential))</li> <li>• Use of fluorinated substances in special glass for construction (external glazing and internal decorative glass), automotive (original and replacement glass) and the solar sector.</li> <li>• Handling of fragrance and odour compounds in products and articles;</li> </ul>

Other uses where derogations were requested during consultation	SEAC discussion and conclusions
	<ul style="list-style-type: none"> <li>• Use of perfluoropolyethers in aerosol applications during in-house quality control of other fluoropolymer products (laboratory application).</li> <li>• Coating of mechanical parts (short chain SFP anti-staining agents) other than in watches, such as in engine parts (e.g., comment 3112)</li> <li>• C6 surfactants as a corrosion inhibitor at the electrodes in battery cells (e.g., comment 3112)</li> </ul> <p><u>SEAC conclusion:</u> The information provided on costs, quantities used, emissions and availability of alternatives (where included) is scarce and not sufficient to allow a conclusion on whether a derogation or a longer transition period would be appropriate. Extension of the general transition period from 18 to 36 months could be a way to reduce the related impacts at least to some extent. SEAC notes that uncertainties remain on whether PTFE micro powders would benefit from the higher concentration limits proposed for PFHxA, its salts and related substances in fluoropolymers. SEAC also notes that the use of PFHxA coated paper for oxygen absorbers was reported only by one company and therefore, it remains unclear whether alternatives are available and already in use by competitors for oxygen absorbers. More information may also be submitted in the consultation of the SEAC draft opinion.</p>

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