

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

Opinion

on an Annex XV dossier proposing restrictions on

Perfluorohexane sulfonic acid (PFHxS) including its
salts and related substances

ECHA/RAC/ RES-O-0000006739-59-01/F

ECHA/SEAC/RES-O-0000006786-60-01/F

**Compiled version prepared by the ECHA Secretariat of RAC's opinion
(adopted 13 March 2020) and SEAC's opinion (adopted 11 June
2020)**

13 March 2020**ECHA/RAC/ RES-O-0000006739-59-01/F****11 June 2020****ECHA/SEAC/RES-O-0000006786-60-01/F****Opinion of the Committee for Risk Assessment****and****Opinion of the Committee for Socio-economic Analysis****on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU**

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

Chemical name(s): *Perfluorohexane sulfonic acid (PFHxS), its salts and related substances*

EC No.: *206-587-1*

CAS No.: *355-46-4*

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

PROCESS FOR ADOPTION OF THE OPINIONS

Norway 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/23404/term> on **19 June 2019**. Interested parties were invited to submit comments and contributions by **19 December 2019**.

ADOPTION OF THE OPINIONADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: *Daniel Borg*

Co-rapporteur, appointed by RAC: *Anja Menard-Srpčič*

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 **13 March 2020**.

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: *Luisa Cavalieri*

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **12 March 2020**.

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/23404/term> on **25 March 2020**. Interested parties were invited to submit comments on the draft opinion by **25 May 2020**.

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 **11 June 2020**.

The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and]⁵ 71(1) of the REACH Regulation

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

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OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

<p>Perfluorohexane sulfonic acid (PFHxS) (linear or branched), its salts and related substances¹:</p> <ol style="list-style-type: none"> a. Perfluorohexane sulfonic acids with the formula C₆F₁₃SO₃H, their salts and any combinations thereof; b. Any substance having a perfluoroalkyl group C₆F₁₃- directly attached to a sulfur atom. 	<ol style="list-style-type: none"> 1. Shall not be manufactured or placed on the market as substances on their own from [date - 18 months after the entry into force of this Regulation] 2. Shall not from [date - 18 months after the entry into force of this Regulation] be used in the production of or placed on the market in: <ol style="list-style-type: none"> (a) another substance, as a constituent, (b) a mixture, (c) an article or any parts thereof, in a concentration equal to or above 25 ppb for the sum of PFHxS and its salts or 1 000 ppb for the sum of PFHxS related substances. 3. The restriction in point 2 (c) on the placing on the market shall not apply to articles first placed on the market before [date - 18 months after the entry into force of this Regulation]. 4. Paragraph 2 shall not apply to <ol style="list-style-type: none"> (a) substances or mixtures containing PFHxS as an impurity in PFOS² in applications of PFOS which are derogated from the prohibitions in Annex I Part A of Regulation (EU) No2019/1021; (b) concentrated firefighting foam mixtures that were placed on the market before [date - 18 months after the entry into force of this Regulation] and are to be used, or are used in the production of other firefighting foam mixtures.
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Explanatory notes

Column 1

Paragraph 1 – included substances

Both linear and branched substances containing the C₆F₁₃S element are included in the scope.

Polyfluorinated substances containing partially fluorinated structural elements (e.g. C₆HF₁₂S) are not included within the scope of the restriction because they will not form PFHxS during degradation.

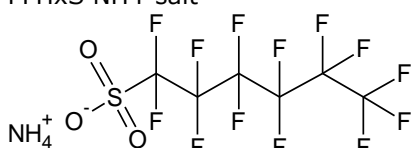
Paragraph 1(a)

Any combination of linear and/or branched perfluorohexanesulfonic acids and/or their salts are covered by the proposed entry.

¹ PFHxS related substances are substances that, based upon their structural formulae, are considered to have the potential to degrade or be transformed to perfluorohexane sulfonic acid (linear or branched). See section 2.2 of the report for more details.

² Perfluorooctane sulfonic acid and its derivatives (PFOS) C₈F₁₇SO₂X (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)

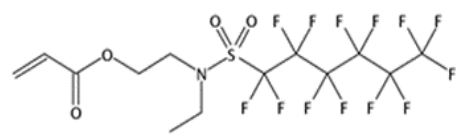
Example of a salt:

EC 269-511-6 CAS 68259-08-5	ammonium perfluorohexane-1-sulphonate; 1-hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, ammonium salt (1:1)	PFHxS NH ₄ -salt 
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Paragraph 1(b)

These are the related substances, which can degrade or be transformed to the perfluorohexane sulfonic acid (branched or linear). A definition of 'related substances' is provided as a footnote using wording based upon the definition in entry 68 to Annex XVII.

Examples of 1(b) substances include:

EC 217-581-3 CAS 1893-52-3	2-[ethyl[(tridecafluorohexyl)sulphonyl]amino]ethyl acrylate; 2-Propenoic acid, 2-[ethyl[(1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluorohexyl)sulfonyl]amino]ethyl ester	
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Column 2

The entry follows the format of existing Annex XVII entries.

Paragraph 1

"Placing on the market" includes import, see REACH article 3 no. 12.

Paragraph 2(a)

The term "constituent" includes any constituent contributing to the composition of a substance, including therefore also impurities and additives. Any of these constituents can be either unintended or intended. See ECHA guidance for identification and naming of substances under REACH and CLP:

https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d.

Paragraph 4(a)

The manufacture, placing on the market and use of PFOS and PFOS-related substances is prohibited under Regulation (EU) No 2019/1021. For the purposes of this proposal on the regulation of PFHxS, its salts and PFHxS-related substances, any specific exemptions for PFOS in Annex I Part A from the general prohibition of Regulation (EU) No 2019/1021 will apply. According to a recent report from the European Commission to the POPs secretariat (UNEP, 2019a), the countries of the European Union do not use substances or mixtures containing PFOS in photo-resist and anti-reflective coatings for semi-conductors, as an etching agent for compound semi-conductors and ceramic filters, in photo-imaging or in aviation hydraulic fluids. However, the Commission reports that there is a continuous need within the EU for PFOS used as mist suppressants for hard metal plating in closed-loop systems.

Paragraph 4(b)

The dilution of concentrated firefighting foam mixtures by an end-user is defined as manufacture of a mixture in REACH. This particular use is intended to be exempted from the restriction.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers, with one exception, that the restriction proposed by the Dossier Submitter on **perfluorohexane sulfonic acid (PFHxS), its salts and related substances CAS No.: 355-46-4 EC No.:206-587-1** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion.

RAC does not support the 18-month transitional period proposed by the Dossier Submitter in Paragraph 4(b) and is of the opinion that the transitional period should be as short as practically possible.

The conditions of the restriction recommended by RAC:

<p>Perfluorohexane sulfonic acid (PFHxS) (linear or branched), its salts and related substances³:</p> <ul style="list-style-type: none"> a. Perfluorohexane sulfonic acids with the formula $C_6F_{13}SO_3H$, their salts and any combinations thereof; b. Any substance having a perfluoroalkyl group C_6F_{13}- directly attached to a sulfur atom. 	<ol style="list-style-type: none"> 1. Shall not be manufactured or placed on the market as substances on their own from [date - 18 months after the entry into force of this Regulation] 2. Shall not from [date - 18 months after the entry into force of this Regulation] be used in the production of or placed on the market in: <ul style="list-style-type: none"> (a) another substance, as a constituent, (b) a mixture, (c) an article or any parts thereof, in a concentration equal to or above 25 ppb for the sum of PFHxS and its salts or 1 000 ppb for the sum of PFHxS related substances. 3. The restriction in point 2 (c) on the placing on the market shall not apply to articles first placed on the market before [date - 18 months after the entry into force of this Regulation]. 4. Paragraph 2 shall not apply to <ul style="list-style-type: none"> (a) substances or mixtures containing PFHxS as an impurity in PFOS⁴ in applications of PFOS which are derogated from the prohibitions in Annex I Part A of Regulation (EU) No2019/1021; (b) concentrated firefighting foam mixtures that were placed on the market before [date - transitional period should be as short as possible] and are to be used or are used in the production of other firefighting foam mixtures.
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³ PFHxS related substances are substances that, based upon their structural formulae, are considered to have the potential to degrade or be transformed to perfluorohexane sulfonic acid (linear or branched). See section 2.2 of the report for more details.

⁴ Perfluorooctane sulfonic acid and its derivatives (PFOS) $C_8F_{17}SO_2X$ (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on ***perfluorohexane sulfonic acid (PFHxS), its salts and related substances CAS No.: 355-46-4 EC No.:206-587-1*** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope or conditions are modified as stated in the RAC opinion as demonstrated in the justification supporting this opinion.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC⁵

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/emission(s) (scope)

Structural relationships of PFHxS to other perfluoroalkylated substances (PFAS) and functional characteristics

Perfluorohexane sulfonic acid (PFHxS) is part of per- and polyfluoroalkyl substances⁶ (PFAS) and therein also part of the group of perfluorinated sulfonic acids (PFSA). Other substances in this group include perfluorooctane sulfonate (PFOS), regulated under Regulation (EU) No 2019/1021 to implement the international ban of the substance under the Stockholm Convention. Another example of a substance in the group is perfluorobutane sulfonate (PFBS), which so far was not subject to regulatory action in the EU. PFBS, PFHxS and PFOS share the same functional group (SO_3^-), differing only in their respective number of perfluorinated carbons (4, 6 and 8 carbons respectively, see Figure 1).

PFAS are characterised by the extremely strong and stable carbon-fluorine (C–F) bond. A perfluoroalkyl chain has thus a high chemical and thermal stability. The perfluoroalkyl chain together with the sulfonate structure at the other end of the PFHxS molecule make it hydrophobic/lipophilic and hydrophilic (water-insoluble/fat-soluble and water-soluble, respectively) at the same time, thereby providing to it unique properties for use as surfactants and in 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.

Other PFAS subject to EU regulation include the perfluorinated carboxylic acids (PFCA) perfluorooctanoic acid (PFOA) as well as perfluorononanoic acid (PFNA) and perfluorodecanoic acid (PFDA), which are part of the C9-C14 PFCA restriction proposal. These all share the same functional group (COO^-), differing only in their perfluorinated carbon chain lengths (Figure 1).

⁵ Throughout this opinion document, all “EU” references also apply to the EEA countries, where relevant.

⁶ PFASs consist of a fully (per) or partly (poly) fluorinated carbon chain connected to different functional groups. Based on the length of the fluorinated carbon chain, **short and long chain PFASs** can be distinguished (OECD, 2020).

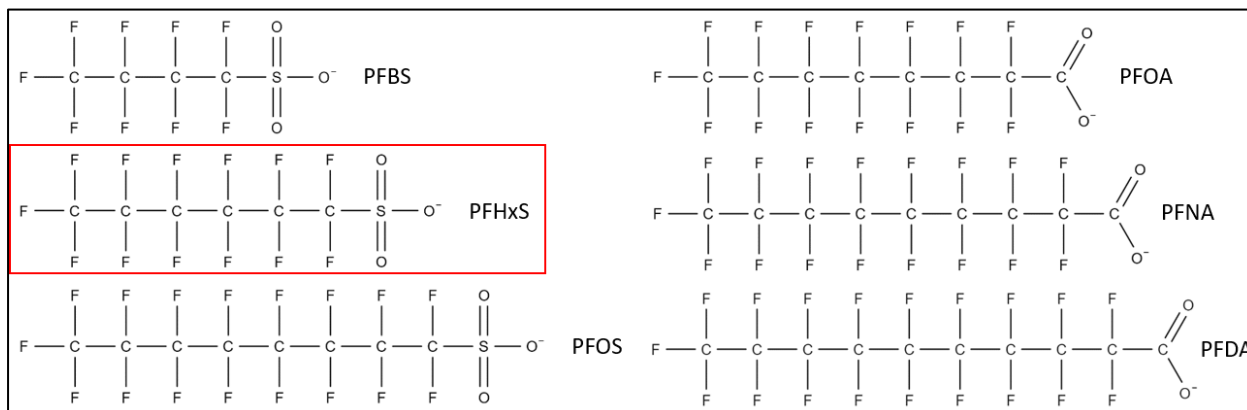


Figure 1. Structural relationships of PFHxS to the other perfluorinated sulfonic acids perfluorobutane sulfonate (PFBS) and perfluorooctane sulfonate (PFOS) and to the perfluorinated carboxylic acids perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA) and perfluorodecanoic acid (PFDA).

Summary of Dossier Submitter's proposal:

The purpose of the proposed restriction is to reduce current environmental emissions of PFHxS, its salts and related substances from imported articles and mixtures containing these substances. The restriction also aims to prevent these substances from being used as substitutes when the PFOA restriction becomes effective in 2020. Restriction at the EU-level will assist the ongoing global regulation of PFHxS, its salts and related substances under the Stockholm Convention (UNEP, 2019) by analysing the impact of an equivalent regulation in the EU. The POPs review committee (POPRC) under the Stockholm Convention decided in 2018 that PFHxS, its salts and related substances fulfil the criteria as a Persistent Organic Pollutant (POP) and are likely to lead to significant adverse human health and/or environmental effects such that global action is necessary (UNEP, 2018). The POPRC recommended in 2019 listing these substances in Annex A (elimination) of the convention without any exemptions (UNEP, 2019).

This proposal therefore aims to restrict PFHxS (linear and branched), its salts and PFHxS-related substances. PFHxS and its salts are substances of very high concern (SVHC) and are included in the REACH Candidate list due to their very persistent and very bioaccumulative (vPvB) properties. PFHxS-related substances are all those that contain the C6F13- moiety (linear or branched) directly attached to a sulphur atom and are considered to have the potential to degrade to PFHxS. Due to the successive degradation of the salts and related substances into a specific PFAS (here PFHxS) having hazardous properties and causing risk to the environment and human health, this 'terminal degradation' approach has been used in previous restriction proposals under REACH⁷.

A recent literature study (Nielsen, 2017) concluded that many substances⁸, can act as precursors, forming PFHxS via abiotic degradation. Biotic degradation of PFHxS-related substances is expected to form PFHxS via the same degradation pathways as has been demonstrated for PFOS-related substances. Furthermore, experimental data on abiotic degradation shows that the degradation of PFHxS-related substances to PFHxS may proceed via hydrolysis or via oxidative radical processes in the atmosphere (Barnes, *et al.*, 2006; D'Eon, *et al.*, 2006; Martin, *et al.*, 2006).

From the limited information available, the rate of degradation may vary for different PFHxS-related substances, is difficult to predict and in some cases the process may take years, decades or longer, while transformation of less stable precursor groups may be much faster (Rhoads *et al.*, 2008). Nevertheless, PFHxS will eventually be formed and therefore, inclusion of PFHxS-related substances in the scope of this restriction is thus warranted. Read-across of degradation characteristics from the closely related homologues PFBS and PFOS, which differ from PFHxS only in the number of CF₂-units confirms that the closely related precursor substances degrade via abiotic and biotic degradation pathways into the PFHxS.

RAC conclusion(s):

RAC agrees with the scope proposed by the Dossier Submitter, covering approximately 150 substances that can degrade to PFHxS. The use of read-across to the closely related homologues PFBS and PFOS is also supported on scientific grounds as there are no

⁷ For PFOA, its salts and related substances (ECHA, 2014) and C9-C14 PFCAs, their salts and related substances (ECHA, 2017). The approach taken in this proposal is similar to the approach taken in ECHA (2014) and ECHA (2017).

⁸ PFHxS halides, sulfonic esters (alkyl, olefinic and aryl) and sulphonamides, side-chain fluorinated polymers containing the PFHxS moiety, as well as other subclasses of PFHxS-related substances like sulfones and sulfinic acids.

indications that these homologues are different in terms of degradation and persistence. The restriction scope follows the same terminal degradation approach previously used in the EU restriction of PFOA, its salts and related substances and for C9-C14 PFCAs, their salts and related substances.

Key elements underpinning the RAC conclusion:

As stated in the ECHA REACH Guidance R.11, substances degrading into other substances with PBT/vPvB properties should be regarded as PBT/vPvB substances as well. PFHxS and its salts are vPvB substances. Linear and branched isomers of PFHxS have the same molecular formula and weight, differing only in the branching of the perfluorohexyl chain. PFHxS often consists of mixed linear and branched isomers. Therefore, it is not necessary to distinguish between them when considering their impact. PFHxS-related substances, containing the backbone C₆F₁₃-S-moiety can degrade to PFHxS and should justifiably therefore be included in the scope of the proposal. This follows the same line of reasoning that was applied in previous restriction opinions of PFOA and C9-C14 PFCA. All halides (F, Cl, Br, I) connected to the C₆F₁₃-S-moiety have the potential to degrade to PFHxS and should be considered PFHxS-related substances.

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

Information on hazard(s)

Summary of the Dossier Submitter's proposal:

In 2017, PFHxS and its salts were identified by ECHA's Member State Committee as SVHC with vPvB properties.

PFHxS-related substances can degrade to PFHxS under environmental conditions. If transformation/degradation products with PBT/vPvB properties are formed, the substances themselves are regarded as PBT/vPvB substances (ECHA, 2017c).

RAC conclusion(s):

RAC takes note of the agreement of ECHA's Member State Committee of June 2017 that PFHxS and its salts meet the criteria of REACH Annex XIII for vPvB substances.

RAC takes note that the identification of a vPvB substance as SVHC under REACH is independent of the environmental compartment in which those properties are observed. All environmental and human exposures of vPvB substances need to be minimised.

Key elements underpinning the RAC conclusion(s):

Recognising that PFHxS and its salts have been added to the REACH Candidate List of Substances of Very High Concern due to their vPvB properties and that PFHxS-related substances can degrade to PFHxS, then the latter should therefore be considered as vPvB substances. A safe concentration cannot be determined for the substances included in the scope of this restriction proposal and derivation of PNECs is not applicable (REACH Annex I, paragraph 4). According to REACH (Annex I, paragraph 6.5) exposure and emissions to humans and the environment from PBT and vPvB substances shall be minimised.

Additionally, RAC notes that the Stockholm Convention's POPs Review Committee concluded in 2017 that PFHxS fulfilled the T-criterion within the Convention and thus can

cause adverse effects.

Information on emissions and exposures

Summary of the Dossier Submitter's proposal:

Uses

The Dossier Submitter identified no current intentional uses of PFHxS, its salts and related substances in the EU. There are no REACH registrations and no information on the use of these substances was provided during the call for evidence prior to submission of the proposal. However, the Dossier Submitter considers PFHxS to be present in the EU in stockpiles of old AFFFs, as an impurity of PFOS used as a mist suppressant in functional chromium (VI) plating, in imported finished textile articles and possibly also in semiconductors. This information was provided in the call for evidence and reported in a study conducted for the Dossier Submitter (BiPRO, 2018). In addition, there are self-classifications of PFHxS, some of its salts and related substances, indicating that these substances may be in use in the EU at volumes < 1 tonne per year. Occurrence in the EU has been confirmed by the detection of PFHxS in sludge and effluents from wastewater treatment plants (WWTPs).

Articles imported into the EU containing PFHxS

Imported textiles, carpets, leather and upholstery were identified as the only area where PFHxS is intentionally present. These include jackets, outdoor gear⁹ and potentially other articles where PFHxS is used as a waterproofing/stain resistant textile treatment, for which PFOS was previously used. Based on data from 2013, the Dossier Submitter estimated the amount of PFHxS imported on waterproof jackets from China, Vietnam and Bangladesh, and an unknown quantity in other applications such as outdoor gear, to be 66 kg per year. More recent data on PFHxS in imported outdoor gear suggests less use of PFHxS in the EU today (17.4 kg per year) but continuing use of PFOA. The entry into force of the EU restriction on PFOA in 2020 could therefore lead to the increased use of PFHxS, its salts and related substances in textiles.

Uses of PFOS in the EU (containing PFHxS as an impurity)

Current uses of chemical products within the EU that can result in emissions of PFHxS were limited to uses of PFOS where PFHxS is present as an impurity:

- For stocks of older fluorinated AFFFs, produced by the electrochemical fluorination (ECF) manufacturing process, the Dossier Submitter estimated a current total EU stock at refineries, tank farms, chemical works and other installations of 0.5-3 kg PFHxS, of which 39-245 grams are estimated to be consumed or replaced annually;
- Regarding the use of PFOS in hard chromium (VI) plating, which is derogated from the EU restriction via the Stockholm Convention until 2024, and where PFHxS is present as an impurity, the Commission reports that there is a continuous need within the EU for PFOS in hard metal plating (UNEP, 2019).

Other possible uses and emission sources

⁹ E.g., tents, shoes, sport equipment needing dirt repellance.

PFHxS, its salts and related substances are used as replacements for PFOS, PFOA and their related substances in the semiconductor industry as indicated by data from Asia. Thus, PFHxS could potentially be used in the EU in imported electrical components, though no such information was provided in the call for evidence preceding the submission of the proposal and the stakeholder consultation undertaken after submission.

PFHxS is a known impurity of PFOS, and the Dossier Submitter provided information that PFHxS can be present as an impurity in PFBS as well. In effluents from wastewater treatment plants (WWTPs), a correlation between emissions of PFOS and PFHxS was found, but also between PFBS and PFHxS. Since PFHxS is chemically closely related to both PFBS and PFOS this is indeed possible. However, no information on impurity levels of PFHxS in PFBS is available.

Manufacturing in the EU and globally

Manufacturing processes may be a major source of release of PFHxS, its salts and related substances to the local environment, as has been demonstrated by elevated levels of PFHxS in water and human serum close to production plants in, e.g., Italy and the United States. Active production facilities of PFHxS in the EU have not been identified.

Most of the total emissions of PFHxS, its salts and related substances are expected to result from historic production in the United States, Western Europe and Japan. However, quantitative data are lacking and it is not clear to what extent manufacturing and use of PFHxS, its salts and related substances today contribute to current and future emissions of PFHxS. Global production of PFHxS was estimated to be approximately 700-750 kg in 2012 decreasing to less than 700 kg in 2016 (BiPRO, 2018). A further slight decrease in the global production of PFHxS is expected.

Emission estimates

Since no current intentional use of PFHxS, its salts and related substances in the EU were identified, and only the presence of PFHxS as an impurity in old stocks of AFFFs and exempted uses of PFOS in chromium plating were noted, it was not possible for the Dossier Submitter to reliably estimate emissions of PFHxS per use. Instead, estimates of total emissions were calculated based on emissions from WWTPs combined with other emission sources.

Emissions of PFHxS from WWTPs in the EU

PFHxS, its salts and related substances may enter WWTPs via industrial emission and/or emission occurring after use or disposal of products containing these substances. Conventional WWTPs have limited efficiency in removing PFAS, such as PFHxS, from aqueous waste streams. The Dossier Submitter presented data on PFHxS from 124 WWTP effluents containing an average concentration of 37.1 ng/L. Using the same strategy as in the C9-C14 PFCAs restriction opinion (ECHA, 2017), a default WWTP with an effluent concentration of 37.1 ng/L would emit 74.2 mg PFHxS/day, and all WWTPs in the EU would in total emit 5.75 kg PFHxS/day or 2.1 tonnes PFHxS/year. When further analysis of the underlying data was performed, the Dossier Submitter noted that the average value of 37.1 ng/L was primarily influenced by the uppermost 10th percentile of data. These were considered to likely represent WWTPs handling industrial wastewater with high concentrations of PFHxS, constituting around 90% of the emissions.

The Dossier Submitter referred to studies of Banjac et al. (2015), Huset et al. (2008) and Eriksson et al. (2017) that have estimated emission factors for PFHxS for releases to the environment via (industrial and municipal) wastewater per inhabitant. These range from 0.53 to 15 µg/day. If scaled up to the EU level based on 500 million inhabitants, this would result in emissions of 0.1–2.7 tonnes PFHxS/year.

The two above given approaches estimating emissions from WWTPs provide together the approximate scale of ongoing releases of PFHxS from various wastewater treatment plants to the environment based on measured data.

PFHxS does not adsorb strongly to sludge, thus most of it would pass through the WWTP. Sludge is therefore not considered by the Dossier Submitter as a major pathway for emissions of PFHxS to the environment and the focus was put on the effluent from WWTPs.

Emissions of PFHxS from landfills in the EU

Emissions of PFHxS from landfills occur after the service life of products. The Dossier Submitter reported highly variable concentrations of PFHxS in EU landfill leachates, ranging from < limit of detection to 8 900 ng/L. Since leachate volumes are highly dependent on climate (rainfall with infiltration into landfill), and may substantially vary from month to month and year to year, the Dossier Submitter considered it difficult to estimate the load of PFHxS emitted via landfill leachate in the EU and did not use such emissions in the total emission calculations.

Emissions of PFHxS, its salts and related substances from local point sources

Local point sources of PFHxS contamination in Europe and Asia have been identified. In Italy, a chemical plant producing PFHxS until 2013 caused PFHxS contamination in ground water, in surface water and in freshwater wells for human use within an area of 200 km². The contamination resulted in an average PFHxS concentration of 32.5 ng/L in drinking water. In Norway, surface water, soil and biota firefights showed elevated PFHxS concentrations (4.3 µg/L and 580 ng/kg wwt) in water and sea snails, respectively, near a company formulating and testing firefighting foam products.

Emissions of PFHxS from the use of aqueous film forming foams (AFFF) in the EU

Current and formerly used firefighting training sites in the EU and globally are contaminated with PFHxS from AFFFs. This has led to ground and drinking water contamination. In Ronneby, Sweden, AFFF used for training at an airfield since the mid-1980s had contaminated the municipal drinking water supply with PFHxS at levels up to 1.7 µg/L, which resulted in significantly elevated serum concentrations in the population consuming drinking water (Jakobson et al., 2014). A similar case has been described in Cologne, Germany (Weiß et al., 2012).

The Dossier Submitter estimated the total quantity of PFAS-containing AFFFs in the EU to be between 15 620 and 31 240 tonnes (Table 1). Based on data from the stakeholder consultation, on impurity levels of PFHxS between 31-98 ppb (µg/kg) in AFFFs in German refineries and tank farms, the total quantity of PFHxS in stocks of AFFFs in the EU was estimated to be between 0.5 to 3 kg (Table 1). Assuming in a worst case that none of the used/depleted foam was collected in a way that would allow PFHxS, its salts or related compounds to be destroyed (i.e. incineration), emissions of PFHxS were considered equal to the calculated replenishment rate of 39 - 245 g/year across the EU. Compared to the

amount of PFHxS emitted via WWTPs, this release was considered to be negligible.

Table 1. Estimated total quantity of PFHxS in the EU stockpile of foams (Table 17 in the Background Document).

	Scenario 1: 50% of PFAS foams contain PFHxS as an impurity	Scenario 2: 70% of PFAS foams contain PFHxS as an impurity	Scenario 3: 100% of PFAS foams contain PFHxS as an impurity
% of PFAS foams containing PFHxS	50	70	100
Total EU Stockpile of foams			
Total stock quantity of PFAS foam containing PFHxS (t)	15 620	21 868	31 240
Total PFHxS (g)	PFHxS content min	484	678
	PFHxS content max	1 531	2 143
	PFHxS content average	922	1 290
Annual 'use'/disposal from stockpile			
Annual use/consumption/depletion of foam containing PFHxS	1 250	1 749	2 499
PFHxS in foam used per year (g)	PFHxS content min	39	54
	PFHxS content max	122	171
	PFHxS content average	74	103

Emissions of PFHxS from continuing uses of PFOS in the EU

PFHxS is a known impurity of PFOS with concentrations between 4-14% reported in commercial formulations. The production and use of PFOS and PFOS-related substances is restricted by Regulation (EC) No 2019/1021 of the European Parliament and of the Council on Persistent Organic Pollutants (POP). One derogation is included in the restriction for mist suppressants used in non-decorative hard chromium (VI) plating in closed loop systems.

The use of PFOS as a mist suppressant for hard chromium (VI) plating is an ongoing use today (UNEP, 2019 and evidence from Applications for Authorisation of CrVI in the EU). Submissions from EU Member States to the Stockholm Convention suggest that 50 kg of PFOS is used per year (equivalent to 2 - 7 kg PFHxS, its salts and related substances, assuming that this PFOS contains such impurities). Any reduction of PFOS emissions will therefore also reduce PFHxS emissions.

Overall estimated emissions

The Dossier Submitter considered the data on specific uses to be insufficient to allow estimations of use-specific emissions of PFHxS, its salts and related substances. Instead, emission estimations on the EU-level were based on calculated emissions of PFHxS from WWTPs.

Using the average PFHxS concentration in WWTP effluents, total EU emissions of 2.1 tonnes PFHxS/year were estimated. However, 1.79 tonnes of this was associated with WWTPs handling industrial wastewater with elevated concentrations of PFHxS (10% of the WWTPs) and 0.22 tonnes from the other (90%) WWTP with lower PFHxS measured levels (comprising both industrial and public wastewater sources). Therefore, the Dossier Submitter considered these emissions to be historical, prior to the regulation/phase-out of PFOS. Thus, the current PFHxS emission was based on the 90th percentile, resulting in estimated emissions of 0.22 tonnes per year (Table 2).

In the baseline scenario, the Dossier Submitter considered the estimated imported amount of PFHxS in waterproof jackets to be the largest source of emissions, approximately 66 kg in 2013 (mean conc. 260.4 µg/kg, 9/10 clothing samples) and 17.4 kg in 2016 (estimated based on the measured concentration of 0.897 µg/kg µg/kg found in 1 out of 13 jackets tested by Greenpeace in 2016). In 2016, the use of PFHxS in jackets was much less than the use of PFOA, which was found in 9 out of the 13 jackets and several other tested consumer articles. Assuming a shift from the use of PFOA to PFHxS in jackets, emissions would increase by a factor of two compared to 2013 and a factor of 7.5 to 2016. The Dossier Submitter chose the smaller of these factors to represent the likely increase in emissions due to a shift from PFOA to PFHxS. Extrapolating this increase to society as a whole would result in a doubling of future emissions from 0.22 to 0.44 tonnes PFHxS per year.

Table 2. Summary of estimated PFHxS emissions

Time period	Estimated annual emission of PFHxS (tonnes)
1990-2010	2.1
2011-2019	0.22
2020 onwards	0.44

PFHxS is extremely persistent under environmental conditions and abiotic degradation is expected to be as low as for the homologue PFOS, with a half-life of > 42 years. Thus, the environmental stock of PFHxS is expected to increase in the future. Figure 2 illustrates the calculated change in the environmental stock of PFHxS from 1990 assuming (a) no degradation and (b) a, likely underestimated, half-life of 42 years; showing a slight decrease in stock over time.

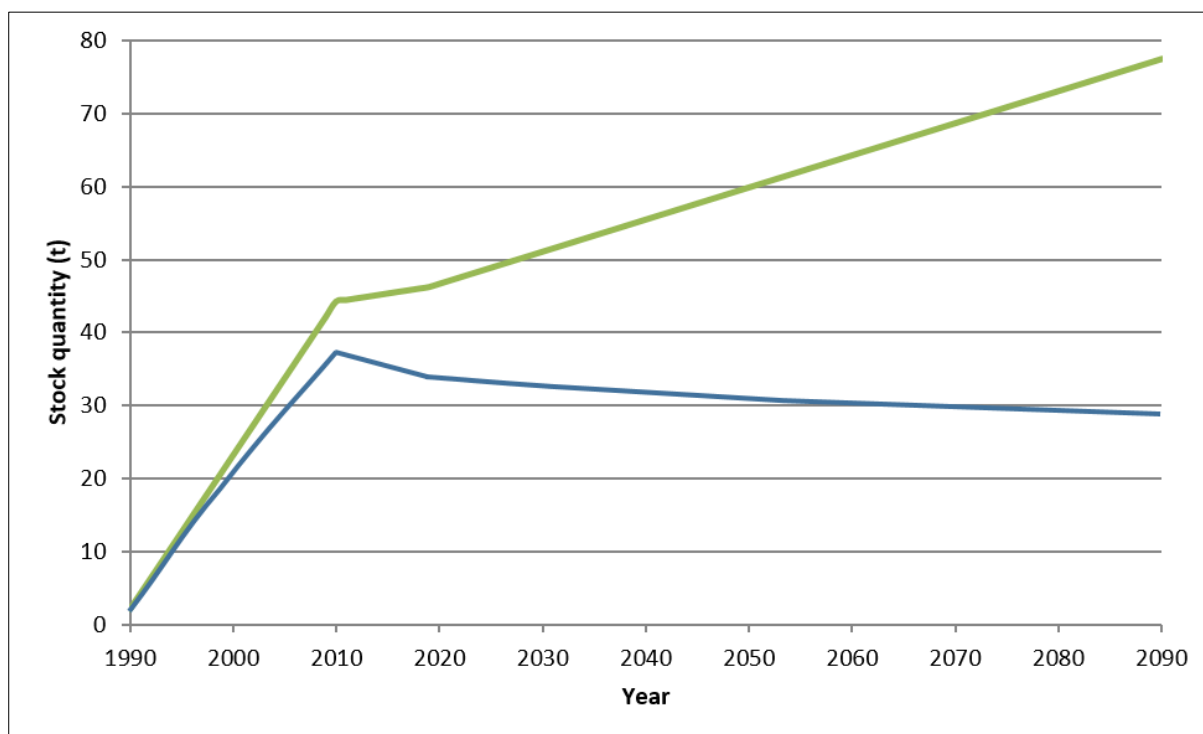


Figure 2. Estimated changes of the environmental stock of PFHxS from 1990 (a) without any degradation (green graph) and (b) with a half-life of 42 years (blue graph). (Figures 5 and 6 in the Background Document combined by the RAC Rapporteurs).

Environmental exposure

PFHxS is widespread in the environment. Many studies (presented in Appendix 2 in the Background Document) have reported the presence of PFHxS in different environmental compartments such as surface water, deep-sea water, drinking water, WWTP effluents, sediment, groundwater, soil, atmosphere, dust and biota globally, including remote locations such as the arctic. PFHxS is typically detected in the lower ng/L range in European surface waters and ground water, but higher concentrations (up to 217 ng/L), have also been recorded. In sediments, PFHxS has been measured in the ng/g range in urban and industrial areas in Europe. The highest environmental concentrations of PFHxS reported, both in terms of biotic- and abiotic matrices, were found in urban and/or industrial areas. Environmental monitoring from France indicates an increasing trend of PFHxS in surface waters due to increased use of products containing PFHxS as a substitute for PFOA and PFOS. Detection of PFHxS in Arctic air and snow shows that long-range transport of PFHxS and/or PFHxS-related substances through the atmosphere may occur. A significant increase in PFHxS concentrations in Arctic air in Canada and Norway between 2009 and 2015 was reported. This indicates an increase in long-range transport. Modelling predicts that environmental concentrations of PFHxS, its salts and related substances may increase in remote areas compared to the levels observed today.

PFHxS has been detected in wildlife globally, including remote areas such as the arctic, commonly in the lower ng/g range, in species such as cod, glaucous gull, ringed seal, and polar bears (Rauert *et al.*, 2018; Routti *et al.*, 2017). Recent data on polar bears from the Norwegian Arctic showed plasma levels of PFHxS up to 70 ng/mL. The highest levels of PFHxS reported were in bird eggs (range of 37-355 ng/g w/w) near a perfluorochemical plant in Antwerp, Belgium.

Human exposure

Humans are exposed to PFHxS from multiple sources and exposure routes, including food, drinking water, indoor dust and indoor/outdoor air. PFHxS has the longest human elimination half-life of all PFAS for which data are available, greater than seven years. The long elimination half-life was among the most relevant information for PFHxS being regarded as very bioaccumulative (vB). PFHxS, along with PFOS and PFOA, is the most frequently detected PFAS in blood-based samples from the general population worldwide and is present in umbilical cord blood and breast milk. A large number of studies have reported PFHxS levels in humans globally, with mean/median concentrations in the general population of 0.6-4.3 µg/L serum. Highly exposed populations, e.g., those exposed via consumption of contaminated drinking water, show elevated median serum values in the range of 2.98-277 µg/L. Biomonitoring data from European populations show comparable levels.

A temporal trend study indicates that increasing concentrations of PFHxS in humans have started to level off in recent years (Land *et al.*, 2018). However, another study reconstructing past human exposure using serum biomonitoring data from USA and Australia observed no increasing or decreasing trend for PFHxS (Gomis *et al.*, 2017). The concentrations of PFHxS followed a different age pattern compared to PFOS, indicating that global exposure to PFHxS still occurs and has not significantly declined since the early 2000s when the phase out of PFOS started.

RAC conclusion(s):

Despite the lack of currently identified intentional uses of PFHxS, its salts and related substances in the EU, emission of PFHxS in the EU has been demonstrated by means of its detection in WWTP effluents, and these data provide a sufficient basis to conclude that there are emissions to the environment and a potential for the emissions and consequently for environmental stocks to increase.

Considering the uncertainties, RAC supports the reasoning and estimations by the Dossier Submitter related to use-specific emissions from old stocks of AFFFs and textiles.

With regard to the potential increase in the use of PFHxS based on a transition from PFOA, RAC supports the use of the lower factor of two as opposed to the higher factor of 7.5.

. RAC acknowledges that the estimated emissions are associated with considerable uncertainties and that those from specific uses as well as the total emissions may be underestimated. However, the Committee considers that overall emission estimations and predictions of future emissions are plausible based on the data available.

RAC supports the two baseline scenarios (Figure 2), providing a range of possible changes in environmental stock of PFHxS based on either a degradation half-life of 42 years or no degradation. RAC considers the 'no degradation' scenario to be the most plausible, based on the lack of demonstrable degradation of PFHxS, leading to progressive accumulation over time with continued emissions.

The Dossier Submitter has demonstrated that PFHxS is widely distributed in the environment including remote locations and in human blood both in the EU and globally. The widespread occurrence in the environment provides grounds for concern.

Key elements underpinning the RAC conclusion(s):Uses

The use of PFHxS, its salts and related substances in imported articles is associated with uncertainties, e.g., the type of articles and the associated amounts. Nevertheless, the restriction proposal is aimed at preventing further import of PFHxS.

The data on textiles (Greenpeace, 2016) shows that C6-based PFCAs (that can degrade to PFHxA) were the dominant surface treatment as compared to PFOA and are a more likely substitute than PFHxS. Thus, the lower factor of two as opposed to the higher factor of 7.5 is considered more plausible when considering emission trends. PFHxA is not regulated under REACH, though a restriction proposal has been submitted by Germany (ECHA, 2019).

During the 15th POPs Review Committee meeting (POPRC-15) under the Stockholm Convention, where the risk management evaluation of PFHxS was concluded, no derogations from a global phase-out of PFHxS were proposed by the semiconductor industry present (UNEP, 2019), indicating that the use in semiconductors is low or non-existent.

In the Background Document, the Dossier Submitter presents information suggesting that approximately 11.2 tonnes of PFHxS were present in PFHxS-based AFFFs (containing 1-2.6% PFHxS) in the EU in 1999. Lifespan of firefighting foams is stated to be in the range of 10-25 years. Thus, there is a possibility that PFHxS-based AFFFs remain in the EU. However, confirmatory information was not submitted in the consultation.

Emissions

The estimated emissions are associated with uncertainties due to the lack of registered uses and limited data on the presence of PFHxS in imported articles. Emissions from specific uses may be underestimated, as there may be additional unknown sources of PFHxS, its salts and related substances from import of other articles containing these substances.

RAC notes that the combined estimated emission of PFHxS from textiles, continued uses of PFOS and firefighting foams does not add up to the estimated current baseline emission of 0.22 tonnes/year. However, no information on additional emission sources was provided in the consultation. No information on emissions of PFHxS its salts and related substances emitted as impurities from the manufacture and use of PFBS was provided in the consultation. Such emissions are thus considered unlikely.

Based on measured emissions of PFHxS from WWTPs (the upper 10th percentile of data was excluded), the Dossier Submitter calculated the current emissions to be 0.22 tonnes/year. When assuming that the emissions will potentially be twice as high in future, annual emissions of 0.44 tonnes from 2020 onwards are expected. The current emissions and estimations of future emissions are calculated based on measurements of PFHxS as free acid in WWTP effluents. RAC notes that PFHxS-related substances could also be present in WWTP effluents, but measured data on them have not been reported sufficiently in order to derive emission estimates. Due to the lack of such data, total releases of PFHxS, including formation of PFHxS in the environment from related substances have not been estimated and the release estimate may therefore be an underestimate. Nevertheless, RAC considers the emission calculations to be uncertain, but plausible, based on the available data.

Environmental and human exposure

PFHxS has been ubiquitously detected in the environment. The findings range from close to point sources, where the highest levels have been measured, to remote locations such as the Arctic. The substance has been found in the abiotic compartments and in biota. Human exposure to PFHxS has been demonstrated. PFHxS is, together with the already regulated PFOS and PFOA, the most frequently detected PFAS in blood-based samples from the general population and can also be found in umbilical cord blood and breast milk. The serum elimination half-life of PFHxS in humans is the longest of the PFAS studied (> 7 years).

Characterisation of risk(s)

Summary of the Dossier Submitter's proposal:

PFHxS and its salts are regarded as SVHC due to their vPvB properties. PFHxS-related substances can degrade to PFHxS and should also therefore be considered as vPvB substances (Annex XIII to REACH). PFOS-, PFOA- and C9-C14 PFCA-related substances have previously been treated in the same manner under REACH restriction process.

PFHxS, its salts and related substances are vPvB substances, thus no safe concentration can be determined (RAC/SEAC, 2015b) and derivation of PNECs is not applicable (REACH Annex I, para 6.5). According to recital 70 of REACH, exposure of the environment and humans from PBT and vPvB substances should be reduced as far as technically and

practically possible.

RAC conclusion(s):

RAC agrees that a quantitative risk assessment is not appropriate due to the vPvB properties of the substances. The risk to the environment cannot be adequately controlled and emissions should therefore be reduced as far as possible.

Key elements underpinning the RAC conclusion(s):

As referred to above, PBT and vPvB substances are treated as non-threshold with regard to risk assessment and therefore emissions are taken as a surrogate for risk. Due to the extreme persistence and high bioaccumulation potential of PFHxS, environmental levels and thereby exposures are expected to increase in the future. As a result, adverse environmental and health effects are expected at some point unless emissions are minimised. Environmental monitoring and human biomonitoring data have demonstrated that exposure to PFHxS, its salts, and related substances occur. Emissions are used as a proxy for risk and the Dossier Submitter has demonstrated that emissions occur, leading to environmental and human exposure, which need to be minimised.

Uncertainties in the risk characterisation

No intentional uses of PFHxS, its salts, and related substances have been identified in the preparation of the restriction proposal, during a call for evidence and in a survey conducted for the restriction process under the Stockholm Convention. However, emissions are expected to occur via imported articles such as clothing and textiles. In addition, other imported articles where PFHxS, its salts and related substances are used outside the EU, as well as other imported articles not yet identified in the process, could constitute additional emission sources. However, based on the consultations that have taken place, it is plausible that any such emissions of PFHxS would be rather small and specific.

The case for the restriction as well as the baseline emission scenario rests on the assumption that PFHxS will be used as a substitute to PFOA in e.g. textiles once the PFOA restriction enters into force in 2020. The Dossier Submitter has used the lower range of their calculations, i.e. assumed a doubling of the emissions of PFHxS due to substitution from PFOA. However, to what extent this substitution would have ultimately occurred in the absence of this restriction is uncertain.

The estimate of the historical emissions of PFHxS (1.79 tonnes/year during 1990-2010) originates from wastewater sampling performed in 2010/2011, i.e. after the restriction on PFOS entered into force in the EU. The PFOS restriction may have lowered also the emissions of PFHxS and thus the current estimate of the historical emissions of PFHxS may be an underestimation.

There are uncertainties regarding the toxic effects of PFHxS on human health and the environment. However, since the restriction is based on the vPvB properties of PFHxS, its salts and related substances, this is of limited relevance.

RAC considers that the uncertainties described above do not have an impact on the risk characterisation of PFHxS, its salts and related substances.

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

Summary of Dossier Submitter's proposal:

No intentional uses of PFHxS, its salts and related substances have been identified in the EU, thus, risk management measures and operational conditions are not discussed in the Background Document. These are vPvB substances with use in articles, for which emissions should be minimised.

RAC conclusion(s):

No intentional uses of PFHxS, its salts and related substances have been identified in the EU. However, emissions occur and the eventual risk management measures currently in place are thus not sufficient to control the risk.

Key elements underpinning the RAC conclusion(s):

The information provided on emissions, environmental monitoring and human biomonitoring of PFHxS demonstrate that current risk management measures and operational conditions do not sufficiently minimise the emissions of PFHxS, its salts and related substances.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of the Dossier Submitter's proposal:

The only existing EU regulatory risk management instrument in place is the inclusion of PFHxS and its salts on the REACH Candidate List since July 2017. As for all SVHC substances, this means there is a duty to provide information in the supply chain for articles that contain greater than 0.1% of PFHxS and its salts (REACH Article 33). However, no uses are currently registered in the EU. When detected in articles such as textiles, the measured concentrations (presented in the Background Document) are in the order of ng/kg to µg/kg, i.e. below 0.1%, which means that the duty to inform the supply chain is not applicable. In addition, PFHxS-related substances are not listed on the REACH Candidate list and therefore not covered by the information and emission minimisation requirements.

Although several legacy uses of PFHxS were identified in the EU, and there appear to be no current intentional uses in the EU, there is evidence that PFHxS, its salts and related substances have been and are being used as a substitute for PFOS and PFOA in a number of applications globally. These include applications where the current use of PFHxS in the EU appears minimal today, such as textiles and semiconductors (UNEP, 2018). Regulatory action to reduce the exposure to PFOS and PFOA may therefore result in increased use of PFHxS or PFHxS-related substances in the EU.

Even though regulatory measures for PFOS have reduced the global emissions of PFHxS as an impurity, increasing levels of PFHxS in, e.g., Arctic air have been reported. PFHxS is also amongst the most frequently detected PFAS in human blood samples in Europe and has been detected in umbilical blood and human breast milk. Modelling predicts that elevated environmental concentrations of PFHxS will remain for decades to come and that

PFHxS will reach remote areas to a greater extent than observed today. Based on the extreme persistence of PFHxS, its environmental stock will likely increase over time. Thus, existing regulatory risk management measures are not sufficient.

RAC conclusion(s):

The available data on emissions as well as environmental monitoring and human biomonitoring data demonstrate that current regulatory risk management instruments are not sufficient to minimise emissions and exposures of PFHxS, its salts and related substances.

The regulatory instrument in place today, the inclusion of PFHxS and its salts on the REACH Candidate List, is not effective for the substances in the scope of this restriction proposal. There is a possibility of increasing use of these substances when the EU restriction of PFOA, its salts and related substances enters into force in 2020.

Key elements underpinning the RAC conclusion(s):

The current regulatory status of PFHxS and the lack of regulation for the PFHxS-related substances lead to the conclusion that current risk management instruments are inadequate. There is a possibility of increasing use of these substances when the EU restriction of PFOA, its salts and related substances enters into force in 2020. Due to the extreme environmental persistence and the long elimination half-life in humans, exposures to PFHxS are difficult to reduce unless emissions are minimised.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of RAC

Summary of Dossier Submitter's proposal:

The high persistence of PFHxS implies that ongoing emissions of PFHxS, its salts and related substances will result in an increasing environmental stock of PFHxS over time. Since PFHxS persists and accumulates in humans and wildlife it may be impossible to remove if serious health concerns should be documented in the future. According to REACH Article 60(3), the risks to the environment cannot be adequately controlled for PBT or vPvB substances and no safe concentrations or threshold (PNEC) can be determined. A union-wide restriction is therefore needed to minimise emissions to the environment and human exposure to PFHxS, its salts and related substances.

The technical functions of PFHxS, its salts and related substances, i.e. high chemical and thermal stability and surface-active properties, provide the possibility for a large variety of uses.

No intentional uses of PFHxS, its salts or related substances within the EU were reported during stakeholder consultation (either by the Dossier Submitter or on the Annex XV report). The substances enter the EU via imported articles. PFHxS is a known impurity of PFOS. Whilst the production and use of PFOS and PFOS-related substances were restricted by the inclusion of PFOS on Annex B of the Stockholm Convention in 2009, there are a number of specific exemptions of PFOS and related substances listed in the Annex. PFHxS may be used as technical substitute to PFOS and PFOA. Regulatory actions to reduce the exposure to PFOA and PFOS may result in increased use of PFHxS, its salts or related

substances if no regulatory measures are taken. An important aspect of the present restriction proposal is to avoid a substitution to PFHxS and its related substances when other PFAS are restricted.

Since PFHxS enters the internal EU market via imported articles and is distributed to all parts of the European environment, via air and water transport, national regulatory action will not adequately manage the risks of PFHxS, its salts and related substances. Therefore, risk management measures need to be taken on a Union-wide basis. This need is also acknowledged by the fact that PFHxS and its salts are SVHC substances and should therefore be substituted wherever possible. An alternative to the restriction would be to list the substances in Annex XIV to REACH (authorisation). Since there are no registrations of PFHxS, the effects of this measure are expected to be minimal. Furthermore, the authorisation procedure does not apply to imported articles. Hence, listing these substances on Annex XIV could lead to ongoing emissions and to an unacceptable risk for human health and the environment due to the vPvB properties of these substances.

RAC conclusion(s):

Based on the key principles of ensuring a consistent high level of protection of human health and the environment across the EU, RAC supports the view that action is required on an EU-wide basis to address the risks associated with PFHxS, its salts and related substances.

RAC agrees that a restriction on a Union-wide basis is the best measure to reduce any potential emission of these substances into the environment and to prevent any future manufacturing, placing on the market and use. This EU-wide measure would also contribute to the parallel global restriction process under the Stockholm Convention.

Key elements underpinning the RAC conclusion(s):

A wide variety of emission sources contribute to environmental and human exposure to PFHxS, its salts and related substances. Environmental and human biomonitoring data confirm that the EU population is exposed to these substances and that they are present in all environmental media. A Union-wide restriction on PFHxS, its salts and related substances, covering imported articles, is the most appropriate way to limit the risks by effectively reducing emissions into the environment on the EU level. National regulation would not sufficiently limit the risks of this class of persistent and mobile chemicals, nor would listing in Annex XIV to REACH (authorisation) due to the lack of registered uses within the EU and because the authorisation process is not applicable to imported articles.

Justification for the opinion of SEAC

Summary of the Dossier Submitter's proposal:

PFHxS, its salts and PFHxS-related substances enter the EU internal market via imported articles and are distributed to all parts of the EU environment via air and water transport. National regulatory action will therefore not adequately manage the risks of PFHxS and PFHxS-related substances. Risk management measures need to be taken on a Union-wide basis as a step towards a global regulation of PFHxS.

SEAC conclusions:

Taking into consideration the fact that releases and exposure might take place in all Member States and that these substances have a potential for long range transport, based on the key principles of ensuring a consistent high level of protection of human health and the environment across the EU and of maintaining the free movement of goods, SEAC supports the view that national regulations are not an appropriate way to address risks associated with articles and mixtures containing PFHxS, its salts and related substances but that a more comprehensive approach is needed.

Key elements underpinning the SEAC conclusions:

PFHxS and its salts are vPvB substances as agreed by the ECHA Member State Committee.

According to REACH Annex I para 6.5, the risk to the environment cannot be adequately controlled for PBT/vPvB substances. There is no safe concentration for these substances, thus a threshold (PNEC) cannot be determined for PBT/vPvB substances (RAC/SEAC, 2015b).

PFHxS, its salts and PFHxS-related substances are ubiquitous in the environment and in humans, and they have the potential for environmental long-range transport.

Since releases and exposure may take place in all Member States, SEAC recognises that action is required on EU-wide basis to avoid that possible releases of these substances into the environment will result in long-term human and environmental exposure in the Member States.

SEAC notes that the main objective of the restriction proposal banning manufacturing, placing on the market and use of PFHxS, its salts and related substances is to reduce or prevent future releases and the related negative impacts of such substances on humans and the environment. In the past, PFHxS, its salts and PFHxS-related substances entered the EU via imported articles such as outdoor clothing and other textiles in which PFHxS is present as a waterproofing and a protective agent. More recently there has been no or negligible import of these substances in articles. However, as reported in the Background Document, PFHxS is a potential substitute of PFOA in some uses. Therefore, a switch to PFHxS, its salts or related substances cannot be excluded in the future once the restriction on PFOA comes into effect in 2020. The proposed restriction would ensure that the use of PFHxS does not increase as a consequence of substitution processes that will be triggered by the PFOA restriction.

SEAC 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 currently available.

Taking the above factors into account, SEAC considers that a global measure could be relevant. However, such a measure has not been assessed in the proposal and cannot be evaluated by SEAC. SEAC also notes that discussions to include PFHxS in the annexes of the Stockholm Convention are underway and that the Commission prefers that a restriction at EU level precedes and supports the global action under the Stockholm Convention. SEAC

notes that, in this specific case, discussion under the Stockholm Convention may proceed faster than the proposed restriction under REACH and, therefore, the restriction proposal and the scrutiny by ECHA's scientific Committees on the restriction proposal may serve as supportive elements for the EU negotiations in the framework of the Stockholm Convention.

In any case, SEAC considers that action on EU-wide basis is more appropriate than regulation on national level.

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

Scope including derogations

Justification for the opinion of RAC

Summary of the Dossier Submitter's proposal:

Since PFHxS, its salts and related substances are not intentionally used in the EU and imported articles and mixtures are a possible source of emissions of PFHxS, its salts and related substances, a restriction on individual uses would not result in sufficient reduction of exposure. Therefore, a broad restriction of PFHxS, its salts and related substances in manufacturing, use and in articles and mixtures (including imports) is needed. The restriction proposal includes recycled materials and articles made from recycled materials. However, second-hand articles are excluded.

The proposed concentration limits for the restriction are the same as those for the restriction of PFOA, its salts and related substances, i.e., 25 ppb for the sum of PFHxS and its salts, and 1 000 ppb for the sum of PFHxS-related substances, and similar to the proposed restriction for C9-C14 PFCA, its salts and related substances, i.e. 25 ppb for the sum of C9-C14 PFCA and their salts and 260 ppb for the sum of their related substances.

Derogations

Substances or mixtures containing PFHxS as an impurity in PFOS

PFHxS may occur as an impurity of PFOS at concentrations of approximately 4-14%. Substances or mixtures of PFOS containing PFHxS as an impurity are proposed to be derogated from the restriction for allowed uses of PFOS in the EU.

Aqueous film-forming foam mixtures used for firefighting placed on the market prior to the entry into effect of the restriction

Concentrated firefighting foam mixtures that were placed on the market before and until 18 months after the entry into force of the restriction are proposed to be allowed for use, either as such or in the production (formulation) of other firefighting foam mixtures. The Dossier Submitter motivates this derogation by the fact that PFHxS is not used for production of new firefighting foams in the EU and that it is unlikely that foams containing PFHxS will be imported to the EU during the proposed 18 months transitional period.

'Second-hand' market and articles placed on the market prior to the entry into force of the restriction

The proposed restriction does not cover articles, such as textiles, placed on the market before the restriction enters into force. One reason for this is that the second-hand market is difficult to control. In most cases, one consumer donates/sells single articles to another consumer directly or via a second-hand store. It would not be practical or effective to remove individual articles from the market. In addition, use of, e.g., a jacket as long as possible before it turns into waste is a sustainable management of resources. This derogation is in line with the previous restrictions on PFOA, its salts and related substances and C9-C14 PFCA, their salts and related substances.

RAC conclusion(s):

RAC agrees that an EU-wide restriction is the most appropriate measure to reduce the risks of PFHxS, its salts and related substances.

Substances or mixtures containing PFHxS as an impurity in PFOS

PFHxS may occur as an impurity of PFOS. RAC supports the derogation of PFHxS in substances and mixtures as an impurity to PFOS, following the allowed uses of PFOS in the EU.

Concentrated firefighting foam mixtures placed on the market prior to the entry into effect of the restriction

RAC supports the proposed derogation for existing AFFFs. The total quantity of PFHxS in AFFFs in the EU was estimated to be approximately 0.5–3 kg, with annual emissions of 39 to 245 grams. RAC agrees that this amount is low relative to the total emitted quantities of PFHxS. The estimated current total emissions are 220 kg PFHxS/year and the future emissions are 20 kg PFHxS/year under the proposed restriction. The AFFF stocks do not significantly contribute to the overall risk. **Nevertheless, RAC is of the opinion that the use of such foams for training exercises and testing should be avoided where possible and that if used for such purposes, the effluent should be collected and properly disposed of.** Furthermore, when replacing/disposing AFFFs containing PFHxS, all possible measures should be taken to properly handle and rigorously contain the substance(s) and to minimise any emissions.

Although considered unlikely in practice by the Dossier Submitter, the proposed 18-month transitional period before this derogation enters into effect would theoretically continue to allow the import of PFHxS containing AFFFs to the EU over this period. This could result in emissions of significant quantities of PFHxS if these foams are subsequently used. As PFHxS-free AFFFs are already available on the EU market, RAC does not support the need for a transitional period of this length. RAC is of the opinion that this transition period should be **as short as practically possible**.

'Second-hand' market:

RAC agrees with the Dossier Submitter's proposal to derogate articles and mixtures placed on the market before the proposed restriction becomes effective (including second-hand articles) for practical and effectiveness reasons as well as due to the difficulties related to enforcement.

Recycling:

RAC agrees that recycling should be covered in the restriction. Based on the vPvB properties of the substances, particularly the extreme persistence, PFHxS, its salts or related substances are likely to continue to be present in articles over successive life cycles.

Key elements underpinning the RAC conclusion(s):

An EU-wide restriction is the most appropriate measure to reduce the risks of PFHxS, its salts and related substances. Since the substances are not intentionally used in the EU, listing of these in Annex XIV to REACH (authorisation) would not affect the emissions. In addition, the authorisation process does not apply to imported articles. Furthermore, PFHxS, its salts and related substances are likely to be emitted from both known and possibly unknown imported articles and mixtures. Thus, a broad restriction with carefully selected derogations is from a risk perspective the most effective measure.

Substances or mixtures containing PFHxS as an impurity in PFOS

PFHxS may be present in PFOS as an impurity up to a percentage level of 4-14%. However, the main driver of the risk of these mixtures is PFOS and it would be inappropriate from a risk perspective to restrict the derogated uses of PFOS under the POPs Regulation based on impurities of PFHxS. RAC notes that any reduction in emissions of PFOS will also lead to reduced emissions of PFHxS.

Concentrated firefighting foam mixtures already placed on the market

PFHxS has historically been used as the active substance in AFFFs in the EU to extinguish flammable liquid (class B) fires. Although there appear to be no use of such AFFFs in the EU today, PFHxS-containing foams have been reported in China (Huang *et al.*, 2015). Current stocks of PFAS-based AFFFs in the EU, estimated to 31 240 tonnes, may have impurity levels of PFHxS exceeding the proposed threshold of 25 ppb. However, the total estimated amount of PFHxS in these foams in the EU equals to between 0.5–3 kg, with estimated emissions of 39-245 grams/year. RAC considers that this amount is low relative to the 11.2 tonnes of PFHxS that have been present on the EU scale in AFFFs only and in relation to the estimated future stock increase of 20 kg/year. Testing and destruction of these stocks by incineration would lead to minimal additional risk reduction. This derogation can therefore be supported by RAC. However, the use of such foams for training exercises is considered unnecessary and should therefore be avoided, unless the foam can be appropriately collected and safely disposed of (which seems unlikely). RAC notes that use of these foams for training is also advised against by the AFFF manufacturers (FFFC, 2016). The same recommendation to avoid use for training was also given in the RAC opinion on the PFOA restriction (RAC/SEAC, 2015). This should also apply to the testing of AFFF equipment/appliances containing PFHxS. Furthermore, in order to minimise the emissions of PFHxS-containing foams currently in use, where existing foams are replaced, they should be collected, rigorously contained and properly disposed of.

Transitional period of 18 months for placing new AFFFs on the market

The proposed 18-month transitional period would allow the placing of new AFFFs containing PFHxS on the market throughout this period. From a risk perspective, RAC does not support such a long transitional period and considers that this should be as short as

practically possible. PFHxS-containing foams are available in Asia and could potentially be imported to the EU. This could result in use and emissions of significant amounts of PFHxS. Since these AFFFs are not imported and used in the EU today, the need is questionable. This is also acknowledged by the Dossier Submitter in their response to the comment by the Swedish Competent Authority in the Consultation (comment 2751): *"Acknowledging that we have not identified any manufacture or placing on the market of new firefighting foams or firefighting foam concentrates containing PFHxS within the EEA, we support your view that an 18 month transitional period is not necessary"*.

Justification for the opinion of SEAC

Summary of the Dossier Submitter's proposal:

The technical function of PFHxS, its salts and related substances is based on their surface-active properties.

No current intentional uses of PFHxS, its salts or PFHxS-related substances within the EU were reported during the consultation on the Annex XV report nor from the call for evidence undertaken by the Dossier Submitter. It is believed that PFHxS, its salts and related substances mainly enter the EU mainly via imported articles. However, more recently there has been a shift away from the use of PFHxS and PFHxS-related substances as waterproofing and protective agents in imported articles, such as outdoor clothing. These data would suggest that there is currently no or negligible import of PFHxS in textiles to the EU.

Nevertheless, the same data suggest significant use of PFOA across several article types for which PFHxS is known to have been used in the past. Thus, it is possible that, once the REACH restriction on PFOA (and PFOA-related substances) enters into effect, a switch to alternatives such as PFHxS, its salts or related substances might increase imports of PFHxS via articles. The proposed restriction would ensure that the use of PFHxS, e.g. in imported textiles, does not increase as a result of the changes brought about by the restriction on PFOA.

PFHxS also occurs as an impurity in perfluorooctane sulfonic acid (PFOS). In the EU, the use of PFOS is restricted by Regulation (EC) No 2019/1021 of the European Parliament and of the Council on Persistent Organic Pollutants (POP). However, that regulation allows continued use of PFOS, containing PFHxS as impurity, as a mist suppressant for non-decorative hard chromium (VI) plating in closed loop systems. This use of PFHxS is exempted from the scope of this restriction proposal to avoid interfering with Regulation (EC) No 2019/1021.

According to the Dossier Submitter, an alternative to a restriction under REACH would be to list the substances in Annex XIV to REACH. However, this option would not cover imported articles.

Other risk management options were also considered and briefly discussed by the Dossier Submitter in the Annex XV dossier. These include a restriction on the production of PFHxS during the manufacture of PFOS or PFBS, and a requirement to remove all firefighting foams from stocks which exceed the 25ppb limit for mixtures.

SEAC conclusions:

Choice of risk management option

SEAC agrees with the Dossier Submitter that the proposed restriction:

- prevents the possibility that such substances will be in the future used as substitutes after 2020 when the PFOA restriction under REACH (or the EU POP regulation) enters into force;
- will reduce environmental emissions which could occur from imported articles and mixtures;
- is coherent with the previous restrictions on similar substances;
- contributes to global action to regulate these substances;
- is preferable to the other risk management options assessed.

Overall, SEAC agrees that among the options analysed, the proposed restriction is the most appropriate EU-wide measure to address the concern caused by releases of PFHxS, its salts and PFHxS-related substances in the environment.

Scope

SEAC and RAC agree with the scope as proposed by the Dossier Submitter for reducing releases of PFHxS, its salts as well as all the PFHxS-related substances.

In particular, SEAC agrees that:

- 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 transition period of 18 months appears to provide sufficient time for any actor potentially affected to adapt their operations.
- the derogations proposed by the Dossier Submitter are justified:
 - exempted uses in the PFOS restriction,
 - concentrated firefighting foam mixtures already placed on the market,
 - articles already placed on the market.

Key elements underpinning the SEAC conclusions:

Choice of risk management option

Prevention of unintentional use

SEAC notes that the Dossier Submitter considers that there are no intentional uses of PFHxS, its salts or PFHxS-related substances in the EEA. The outcome of the consultation

on the restriction proposal did not suggest the existence of any further uses either. However, these substances can be found in imported articles and they might be present as impurities in other substances, mixtures and articles. Notably, PFHxS and its salts and PFHxS-related substances are a known impurity of PFOS, which are present whenever PFOS is used under an exemption in the PFOS restriction. Furthermore, they occur in articles and mixtures produced with PFOS before the PFOS restriction became binding.

It is reported in the Background Document that PFHxS-based compounds have recently been developed as substitutes for PFOS and PFOA as water-proofing textile finishes, mist suppressants in metal plating and as flame retardants by two Chinese companies. According to the Background Document, a remarkable increase in PFHxS use and emissions in China have taken place in recent years. This indicates that future substitution by PFHxS is indeed a relevant potential scenario and that such substitution is already taking place in industry outside of the EEA. SEAC notes that after the entry into force of the PFOS restriction, PFOA has been mainly used as a substitute to PFOS. Therefore, based on the above-mentioned trend in China, SEAC considers that once the restriction on PFOA will become binding PFHxS substances could become the substitutes of choice for both PFOS and PFOA, inside and outside the EEA. In this context, SEAC welcomes the proposed restriction as the best regulatory measure potentially able to avoid regrettable substitution of PFOA with PFHxS, its salts or PFHxS-related substances.

Coherence with previous restrictions

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

Contribution to the global discussion

SEAC notes that at its meeting in September 2018, the **POPs Review Committee** (POPRC) of the Stockholm Convention considered that PFHxS is likely to lead to significant adverse human health and/or environmental effects, such that global action is necessary (UNEP/POPS/POPRC.14/6, 2018). In accordance with paragraph 9 of Article 8 of the Stockholm Convention, the POPs Review Committee recommended to the Conference of the Parties to the Convention to consider listing and specifying the related control measures for PFHxS, its salts and PFHxS-related compounds in Annex A (elimination) without exemptions.

In line with the view of the Commission, SEAC considers that the proposed restriction, and accompanying RAC and SEAC opinions, will contribute to the discussions on the global regulation of PFHxS, its salts and PFHxS-related substances under the Stockholm Convention for POPs and for the future update of the EU POP Regulation. Therefore, the current proposal is coherent with those activities on PFHxS by the POP Review Committee.

Choice as the most appropriate risk management option

Concerning the alternative risk management options proposed by the Dossier Submitter, SEAC agrees that listing the substances in Annex XIV of REACH Regulation (substances subject to authorisation) cannot be considered to be a suitable option. This is because

imported articles are not covered by the authorisation requirement, whereas a relevant part of the concern relates to imported articles. There are no identified intentional uses in the EEA. Therefore, to include these substances in Annex XIV of REACH would be ineffective as the consequences of such a measure would be marginal. Indeed, a restriction seems to be the only way to regulate imported articles containing PFHxS, its salts and related substances at EU wide level.

SEAC considers that neither a restriction on the production of PFHxS during manufacture of PFOS or PFBS, nor a requirement to remove all stocks of firefighting foams which exceed the 25ppb limit for mixtures can be considered an appropriate measure in the present case. These measures would not affect emissions from imported articles and they would only address single use categories.

The proposed restriction can be used to manage emissions from imported articles and to prevent substitution of other PFASs by PFHxS, its salts and PFHxS-related substances in all uses.

In conclusion, SEAC agrees with the Dossier Submitter that a restriction is a suitable tool to address the concern from potential future releases of PFHxS, its salts and the related substances. It can prevent emissions from imported articles and prevent the use of PFHxS as a substitute to PFOA.

Scope

SEAC conclusions on the scope are based on the following reasoning.

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 PFHxS and its salts and 1 000 ppb for the sum of PFHxS related substances.

SEAC considers that the limit values have to be set by balancing several different factors, such as the need protect human health and the environment by avoiding intentional and unintentional uses, the possible presence of unavoidable impurities in alternative substances, the often low concentrations of the substances in some articles, the practicality of enforcement and the availability and technical capabilities of analytical methods.

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

SEAC notes that the same limit values are applied in the PFOA restriction. With regard to the limit values for PFOA, SEAC notes that the draft regulation to include PFOA in Regulation (EU) 2019/1021 (the POP-Regulation) proposes a time-limited higher concentration limit of 1 ppm for PFOA and its salts in PTFE micro powders. This is to allow an affected company to modify the irradiation process to reduce unintentional production of PFOA and comply with the limit of 25 ppb.

The suitability of the proposed concentration limits was contested by three international non governmental organisations (CHEMTRUST, EEB and IPEN) during consultations on the Annex XV Dossier and on SEAC's draft opinion (ref. 492). These NGOs argued that the concentration limit values proposed by the Dossier Submitter would not be protective enough and do not take into consideration the developments in analytical methods that

could allow a lower value to be enforced. It was argued that the proposed limit values are too high to avoid intentional use, and 2 ppb was suggested instead.

SEAC considers that the available information indicates that the 25 ppb and 1 000 ppb limit values are sufficiently low to prevent intentional uses as such low concentrations do not appear to grant the desired functions. The lower concentrations found during surveillance monitoring could relate to impurities. As to analytical methods, SEAC acknowledges that there are methods that can detect and quantify concentrations lower than the suggested concentration limit values. However, according to information available, they are not applicable to all matrices, are not standardised and cannot be accessed in practice by the concerned actors.

Transitional period:

SEAC agrees with the Dossier Submitter's recommendation of a transitional period of 18 months after the entry into force of the proposed restriction.

On the one hand, in general, SEAC considers that the transitional period should be long enough to ensure that the producers and importers of substances, mixtures and articles are able to comply with the restriction. In addition, SEAC considers that some transition time should be allowed to enable progress for the availability of and access to (preferably standardised) analytical methods, thereby improving the enforceability and practicality of the restriction before its entry into force.

On the other hand, SEAC considers that the transition period should be short enough to avoid future manufacture, import or use of PFHxS, its salts and related substances in substances, mixtures or articles in the EU, including as regrettable substitution of PFOA.

No intentional uses of PFHxS, its salts and PFHxS-related substances have been identified in the EEA, and the exempted uses of PFOS will be derogated. Substitution activities would not be needed in the EEA.

Furthermore, SEAC notes that a short transition period would not have negative impacts on the supply chain because articles already placed on the market would be exempted. Sufficient time to complete administrative arrangements (negotiation of contracts etc.), potentially necessary relating to ensure the compliance of new articles, appears to be the main implication to industry.

SEAC highlights that the intention of the proposed restriction on PFHxS, its salts and related substances was announced in April 2018, and there will also be additional time before it enters into force. Therefore, SEAC considers that the concerned producers (if at all existing) as well as importers will have had a relatively long time to prepare for the restriction even by the date of entry into force.

Overall, SEAC agrees that an 18-month transitional period appears sufficiently long for industry to adapt their operations.

SEAC notes that the Forum considers that the proposed restriction will be enforceable provided that standards relating to analytical methods become available before the entry into force. Such standards are not yet available and SEAC considers that the transitional period would enable their preparation and thereby improve the enforceability and practicality of the restriction.

During the consultations of the proposal the three NGOs mentioned above commented that a transitional period of 18 months would not be justified and would only allow importers to increase PFHxS stocks in the EU. SEAC notes that, according to these NGOs, there should be no transitional period at all.

SEAC considers that 18 months is a short period in view of starting new import activities. This timeframe appears short enough to prevent regrettable substitution of PFOA by PFHxS.

Derogations proposed by the Dossier Submitter:

As mentioned above, SEAC recognises the need for the following derogations included in the restriction proposal:

- Exempted uses in the PFOS restriction;
- Concentrated firefighting foam mixtures that were placed on the market before [date - 18 months after the entry into force of this Regulation] and are to be used, or are used in the production of other firefighting foam mixtures;
- Articles placed on the market before the end of the transition period (including second-hand articles).

Exempted uses of PFOS

Perfluorooctane sulfonic acid (PFOS) is restricted by Regulation (EC) No 2019/1021 of the European Parliament and of the Council on Persistent Organic Pollutants (POP). In this Regulation, that updates the Regulation (EC) No 850/2004, the use of PFOS in mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems is the only remaining derogated use listed in the regulation.

SEAC notes that, according to recent reporting from the European Commission to the POPs Secretariat, there is a continued need within the EU for this derogated use.

SEAC also notes that, during the consultation, the German Competent Authority indicated that there are fluorine-free, chemical alternatives, e.g. alkane sulfonates, for hard chromium (VI) plating available on the market, as well as effective technical solutions to minimise aerosol emissions, e.g. galvanic bath covers or air extraction systems. While their applicability in all relevant situations is not completely clear, SEAC considers that this implies that switching to alternatives may be feasible in more and more applications in the near future, and even this exemption may soon be unnecessary.

According to the Dossier Submitter, the proposed restriction on PFHxS is not intended to affect the derogations listed in the PFOS restriction. Considering that:

- there is no information available on technical possibilities for purifying PFHxS impurities from PFOS;
- according to the Dossier Submitter, there is no indication that the negative environmental impacts of using PFHxS should be considered greater than the negative impacts of using PFOS – it would therefore make no sense to remove PFHxS impurities from PFOS; and
- the Commission already concluded that the derogations under the PFOS restriction

are justified,

SEAC agrees that as long as the respective application of PFOS is derogated from the PFOS restriction, substances or mixtures containing PFHxS as an impurity in PFOS used for that purpose should be derogated from the proposed restriction.

Firefighting foams

Point 4(b) in the entry of the proposed restriction derogates concentrated firefighting foam mixtures that were placed on the market before [date - 18 months after the entry into force of this Regulation] and are to be used or are used in the production of other firefighting foam mixtures.

PFHxS in AFFFs as an impurity vs PFHxS as the active ingredient:

SEAC notes that Aqueous Film-Forming Foams (AFFF) based on other PFAS as their active ingredients may contain PFHxS or related substances as unintentional constituents deriving from the manufacturing process. SEAC further notes that, according to the restriction proposal, based on the stakeholder consultations carried out by the Dossier Submitter, AFFFs currently manufactured and placed on the EU market (including imported foams) no longer contain PFHxS as an impurity as they are now produced by telomerisation. However, some old concentrated firefighting foams in stock in the EEA may still contain such impurities because the electrochemical fluorination (ECF) process, that yields PFHxS as an impurity, was used in the past. The Dossier Submitter estimated that the current EU stockpile of firefighting foams currently kept at refineries, tank farms, chemical plants and other installations contains around 0.5-3 kg PFHxS, of which an estimated 39-245 grams is consumed or replaced annually.

SEAC notes that PFHxS was used as an active ingredient of AFFF in the past. According to the dossier, those foams are no longer manufactured or imported into the EEA. SEAC highlights that there is no information in the Background Document on whether some legacy foams containing PFHxS as active substance might still be in stock in the EU. SEAC further notes that if such foams were to be used, emissions to the environment would be considerably higher than the potential emissions from foams where PFHxS is present as an impurity. This issue was discussed during the opinion making process and the Dossier Submitter confirmed that no information was made available to them by industry on this point. SEAC considers this this is an uncertainty factor underlying the analysis.

SEAC notes that the potential emissions and environmental contamination from firefighting foams where PFHxS is present as an impurity would be considerably lower than those in cases where PFHxS is an active ingredient, if such foams were to be used.

Concerning the costs and benefits of replacing firefighting foams containing PFHxS in stock, SEAC notes that the costs of this restriction option have not been estimated in the Background Document. Informed by the evaluation of previous restriction proposals on similar substances, SEAC expects that extending the restriction to concentrated firefighting foam mixtures already placed on the market would entail high costs over a relatively short period of time. In the restriction proposal on PFOA, costs of replacing AFFF based on PFOA were estimated taking into consideration the amount of fuel needed for the disposal of the foam by incineration (more than a volume equivalent of the foam). The emissions avoided

through the destruction of the foams in stock would be relatively low (at most, 3 kg of PFHxS).

As far as **alternatives** are concerned, SEAC notes that the available information supports the technical feasibility of fluorine-free firefighting foams in general. Based on earlier experience, specifically on the outcome of the consultation of the PFOA restriction proposal, SEAC considers that uncertainties remain on the performance of fluorine-free foams in certain types of fires. Nevertheless, since PFHxS, its salts or PFHxS-related substances are not currently used as active ingredients in firefighting foams placed on the EU market, and there are other substances that can be used as substitutes of PFOA (fluorinated and fluorine-free substances), the availability of alternatives is not considered to be a key issue in the evaluation of this restriction proposal.

Overall, SEAC agrees with the Dossier Submitter in that restricting foams that are still in stock would be disproportionate.

Concerning the use of AFFFs for testing and training, SEAC takes note that during the Ninth Meeting of the Conference of the Parties to the Stockholm Convention (COP9) in May 2019, due to the existence of firefighting foams containing alternative substances, no derogation for training or testing was recommended for firefighting foams containing PFOA.

Since testing and training can be carried out using alternative firefighting foams, SEAC agrees with such recommendation, considering that the environmental impacts of using such foams for testing and training are not compensated by socio-economic benefits related to their use for extinguishing fires.

Concerning the transitional period for concentrated firefighting foam mixtures to be used, or used in the production of other firefighting foam mixtures, SEAC considered the implications of a longer or a shorter transition period (or even no transition period at all) than the 18 months suggested by the Dossier Submitter.

- In favour of a longer transition period, one could argue that developing standard testing methods requires some transition time. The development of those tests is understood to be well underway, since the restriction on PFOA was a frontrunner, processed by ECHA already several years ago.
- Considering a shorter or no transition period, it could be argued that 18 months, as proposed by the Dossier Submitter, could leave a door open to the imports of PFHxS-containing AFFFs for an additional one and a half years, implying additional environmental emissions compared to the absence of a transitional period or the implementation of a shorter transition period. SEAC agrees with the conclusion in the Annex XV dossier and considers that the potential for future import to be quite unlikely, since it is not happening currently, and other alternatives to PFOA-based AFFFs are available and widely used (including AFFFs based on C6 chemistry). However, SEAC also notes that the purpose of a transition period is to give industry enough time to adapt to the new requirements. In this specific case, there is no use and therefore no such motivation for a transition period.

Considering the potential for significant environmental emissions, even if quite unlikely to take place, SEAC agrees with RAC that the transition period for this use should be as short

as practically possible.

Articles already placed on the market

SEAC agrees with the Dossier Submitter proposal to exempt articles already placed on the market before the entry into force of the restriction including both **articles still in the supply chain** and **second-hand articles**.

In the case of articles already placed on the market but **still in the supply chain**, SEAC considers that a derogation could be justified since it would potentially avoid high testing and enforcement costs as well as additional costs for destroying already manufactured articles as well as compliance costs for downstream operators most probably unaware of the potential emissions from the articles they are selling.

Similarly, as far as **second-hand articles** are concerned, for the seller as well as for the buyer of these articles it would be extremely difficult to know whether or not the article contains PFHxS, its salts and PFHxS-related substances and whether the conditions of the restriction are met. For enforcement authorities, it would be almost impossible to control second-hand articles that are placed on the market. Textiles which have already been washed a number of times can be expected to only have minimal potential for additional releases from subsequent washing. Moreover, enforcement would only have a very limited effect since articles containing PFHxS, its salts and PFHxS-related substances would be removed from the market one by one. Finally, continued use of second-hand articles contributes to sustainable management of resources.

Considering the arguments above, and in line with the PFOA and the C9-C14 PFCA restrictions, SEAC considers that this derogation is justifiable based on practicality and enforcement considerations.

SEAC notes that the Forum recommends that the burden of proof for demonstrating the date of first placing on the EEA market should be placed on the duty holder company. The party placing the article on the market is better placed to demonstrate this date compared to enforcement authorities. This would make enforcement easier. Therefore, SEAC agrees with the Forum recommendation. When drafting the final entry, the Commission should consider clearly indicting that burden of proof is on the companies, e.g. by mentioning in the entry that *The restriction in paragraph 2 (c) on the placing on the market shall not apply to articles for which it can be demonstrated that they had already been placed on the market before [date - 18 months after the entry into force of this Regulation].*

No derogations are foreseen for the following sectors:

Textiles: during stakeholder consultations, three textile associations indicated that PFHxS and PFHxS-related substances are not used by textile manufacturers that are their members. In fact, fluorine-free alternatives are already used by EU industry for manufacturing waterproof and stain resistant textiles. No specific challenges due to the proposed restriction were indicated by EU textile industry during the stakeholder consultations carried out during the preparation of the proposal nor during the consultation on the restriction proposal. As a result of this, the Dossier Submitter claims, and SEAC agrees, that costs for the EU textile industry can be expected to be negligible and no derogation is warranted.

Recycling: SEAC notes that the available information does not suggest that PFHxS, its salts or PFHxS-related substances (as substances or as mixtures containing them) are recycled. In the absence of information to the contrary, even after the consultations, SEAC bases its opinion on the assumption that such recycling is not taking place and concludes that no associated costs are to be expected from the proposed restriction.

Concerning articles containing PFHxS, its salts or PFHxS-related substances, there is no specific information on recycling either. SEAC notes that, according to the Background Document, in the recent years the occurrence of these substances in articles in the EU has been quite limited. In principle, textiles are considered to represent the major potential sources of emission of PFHxS. However, the data in the dossier also suggests that, at present, there is limited import of textiles containing PFHxS, its salts and PFHxS-related substances. SEAC notes that if the number of articles concerned is limited, so must be the extent of recycling, and hence also the costs of the restriction to the sector.

Moreover, SEAC notes that recycling of contaminated wastes might contribute to higher emissions to the environment than incineration, as contaminants may still circulate through use, disposal and recycling phases of articles.

Based on these considerations and on the absence of contradicting information from the consultation, SEAC concludes that, even if a ban on recycling of PFHxS-containing materials should not result in additional benefits, the recycling sector will not be affected by the proposed restriction and no exemption for recycling is needed.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of the Dossier Submitter's proposal:

No intentional uses of PFHxS, its salts or related substances within the EU were reported during the preparation of the Background Document or in the consultation on the proposal. However, the Dossier Submitter expects that PFHxS, its salts and related substances enter the EU via imported articles. There has been a shift away from the use of PFHxS and PFHxS-related substances as a waterproofing and protective agent in imported articles such as outdoor clothing with no or negligible import of PFHxS in textiles at present. The same data, however, suggest significant use of PFOA across several article types for which PFHxS has been used in the past. Thus, once the regulation on PFOA comes into effect, a switch to alternatives such as PFHxS, its salts or related substances might increase the level of import of PFHxS via articles. This restriction would ensure that the use of PFHxS in imported textiles does not increase as a result of the changes brought about by the restriction on PFOA. The proposed limit value of 25 ppb is estimated to result in total annual PFHxS emissions from textiles of 6.3 kg. However, this can be considered a "worst case" scenario, since it is based on the assumption that all textiles contain 25 ppb and that all PFHxS in the materials is emitted. A reduction of the limit value to 2 ppb (proposed in the consultation on the proposal), using the same assumptions, would reduce the annual PFHxS emissions from textiles to 0.5 kg.

The Dossier Submitter expects the restriction to result in a total reduction of the annual emissions of PFHxS by 0.42 tonnes per year. In the scenario, that no degradation of PFHxS takes place (considered most likely), the cumulative stock of PFHxS is under the restriction

expected to increase slightly by 20 kg/year, as opposed to an annual increase of 440 kg/year (Figure 3) without restriction.

Under the scenario that degradation of PFHxS takes place (considered less likely), with a half-life of 42 years, the total environmental stock quantity is expected to decrease over time regardless of whether the restriction enters into force or not, but with a more substantial decrease under the conditions of the restriction (Figure 4).

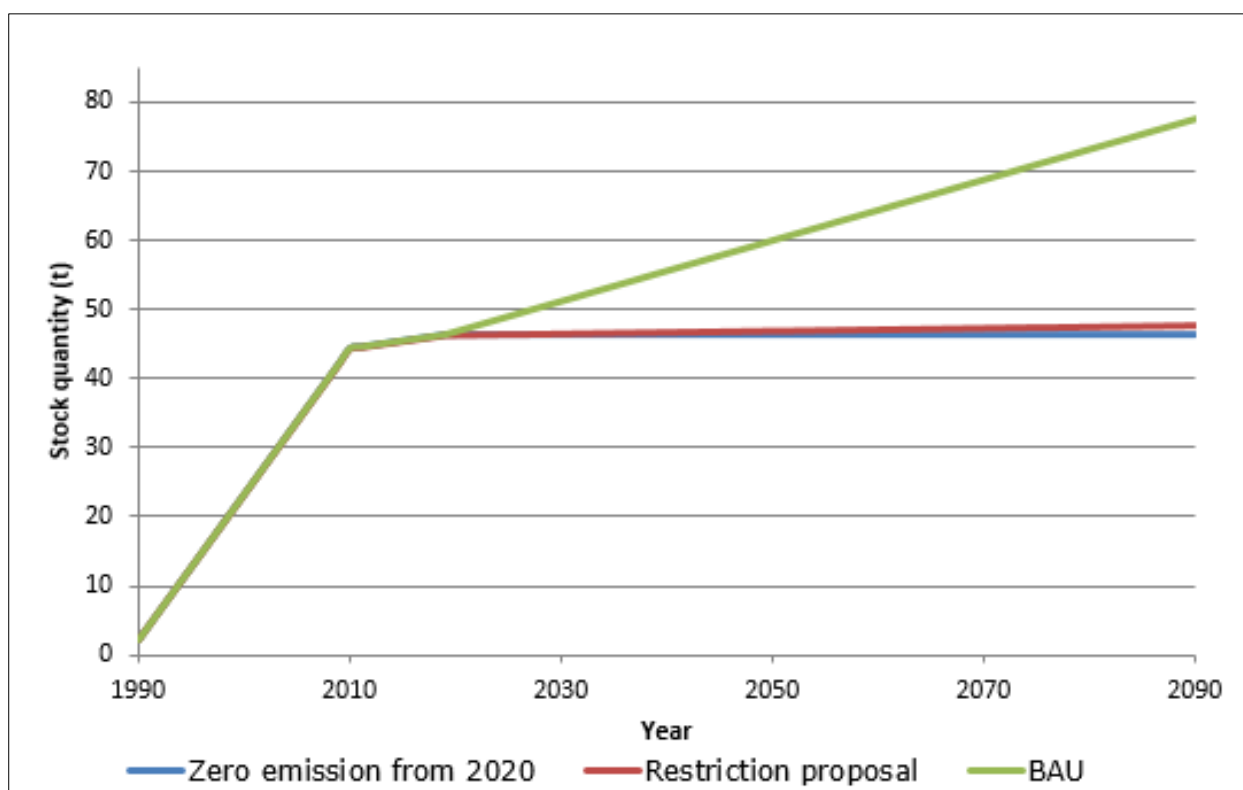


Figure 3. Environmental stock profile under the Baseline (BAU) and Restriction scenarios (no degradation)

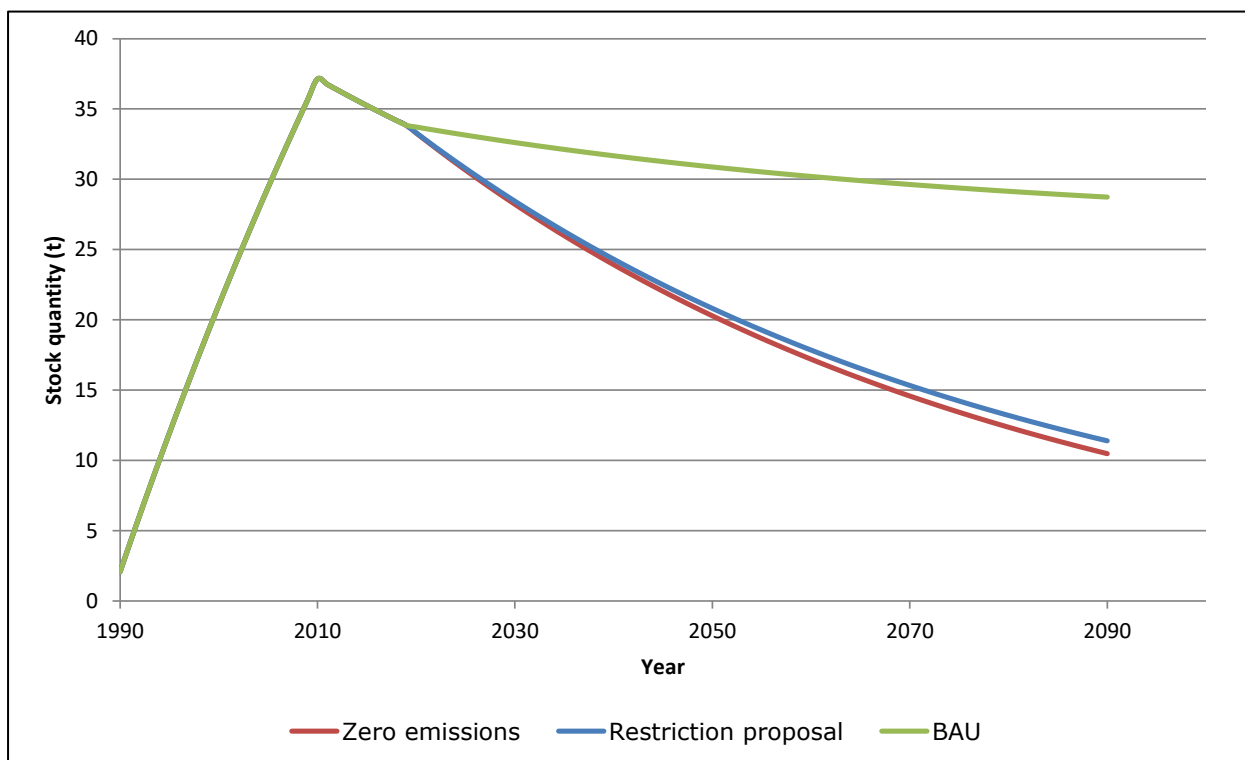


Figure 4. Environmental stock profile under the Baseline (BAU) and Restriction scenarios (half-life 42 years).

RAC conclusion(s):

RAC agrees that the proposed restriction is the most effective option for reducing the risks. A lower threshold of 2 ppb for PFHxS, as opposed to 25 ppb, may in theory reduce the total emissions by a further 6 kg/year. However, the true emission reduction is likely to be lower, and a 2 ppb limit value would have practical implications for enforcement. Thus, RAC supports the proposed limit value of 25 ppb.

RAC notes that the effectiveness in terms of reduced predicted future emissions and stock quantities of the proposed restriction are associated with uncertainties. However, based on the available information, the estimations by the Dossier Submitter are supported. RAC considers the predictions based on no degradation of PFHxS (figure 4) as the most plausible.

Key elements underpinning the RAC conclusion(s):

The proposed EU-wide restriction is the most effective option for reducing the risks. A restriction without derogations ("zero emissions") would have difficulties from a practical and proportionality point of view and would only lead to a marginal improvement in terms of emissions/risk reduction.

Textiles put on the market containing 2 ppb of PFHxS, as opposed to 25 ppb, may lower the emissions from textiles. However, the concentration of intentionally added PFHxS, its salts or related substances in such articles is likely to be much higher. The concentration of PFOS and its related substances intentionally added in textiles and upholstery was estimated to be 2-3% of the fibre weight (equal to 30 000 000 ppb) and 0.03% in synthetic carpets (equal to 30 000 ppb) (UNEP, 2017). Thus, 25 ppb should be a sufficient threshold to prevent articles with intentionally added PFHxS to be placed in the market and be

favourable from an enforcement perspective (discussed further under “Practicality, incl. enforceability”).

RAC notes that the risk reduction of the proposed restriction is associated with uncertainties. It is not known to what extent substitution from PFOA-treated textiles to PFHxS-treated textiles would occur in the absence of this restriction and to what extent these articles will be imported to the EU. However, the calculations on predicted future emissions of PFHxS by the Dossier Submitter are supported. The doubling of emissions from 0.22 to 0.44 tonnes/year in the EU is considered a small increase. Because no degradation of PFHxS has been observed under environmental conditions, the scenarios leading to an increase of the environmental stock of PFHxS over time are the most probable. However, the risk reduction when expressed as emission reductions/year are the same under both scenarios as the emission calculations are based on measurements of PFHxS in WWTP effluents (rather than future predictions). PFHxS-related substances may be present in the effluents and the provided emission estimate for PFHxS itself may underestimate the real emissions. However, the restriction as whole will reduce emissions of PFHxS, its salts and its related substances.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of the Dossier Submitter’s proposal:

No intentional uses of PFHxS, its salts and PFHxS-related substances have been identified in the EEA. As a result of this, and the fact that there are limited import of textiles containing PFHxS, its salts and PFHxS-related substances at present the Dossier Submitter concluded that substitution costs must be limited. These costs are difficult to estimate, and the Dossier Submitter decided not to try to calculate them. The Dossier Submitter considers costs associated with this restriction proposal to EU producers and importers of articles negligible. The Dossier Submitter considers the enforcement costs to be moderate and testing costs for the industry to be limited.

SEAC conclusions:

SEAC notes that the stakeholder consultation carried out by the Dossier Submitter before drafting the proposed restriction provided only limited quantitative information and, therefore, only a qualitative assessment of costs was possible. Considering that no intentional uses in the EEA were identified, SEAC agrees that the approach used by the Dossier Submitter is appropriate.

Based on the available information and on the qualitative assessment in the Dossier, SEAC concludes that the socio-economic costs to be expected from the proposed restriction should be limited.

Key elements underpinning the SEAC conclusions:

Baseline scenario

The baseline scenario that seems to emerge from the available information is the following:

- There is **no intentional production or use** of PFHxS, its salts and PFHxS-related substances in articles placed on the EU market. There is only very limited unintentional use of these substances as legacy impurities of PFOS and in AFFFs stocks.
- There are only a limited number of **imported articles** containing PFHxS, its salts and PFHxS-related substances placed on the EU market
- Concentrations of PFHxS, its salts and PFHxS-related substances in most articles and mixtures are largely below the proposed limits (if at all present)
- Other less harmful **alternative techniques, technologies and substances** (fluorinated or fluorine-free) to substitute PFOA without using PFHxS, its salts and PFHxS-related substances exist. However, substitution of PFOA by PFHxS cannot be excluded after the PFOA restriction will entry into force. There are indications that substitution by PFHxS is already taking place to some extent outside the EEA.

Historical (pre-2000) uses of PFHxS included carpets, apparel and leather, fabric and upholstery, firefighting foams and coatings. However, during the consultation carried out by the Dossier Submitter for the preparation of the proposed restriction, it was highlighted that, within the EU, PFHxS, its salts and PFHxS-related substances are now only contained in old firefighting foams, in PFOS used as a mist suppressant in non-decorative hard chromium VI plating and in imported articles.

SEAC notes that although there are no registrations, a number of self-classifications of PFHxS and PFHxS-related substances have been made. This implies that the substances might be available on the EU market and there might be uses in the EU at volumes of <1 tonne/year. However, despite extensive stakeholder consultations and directly contacting the parties that made the notifications to the C&L inventory (as confirmed to SEAC by the Dossier Submitter during opinion making), no information confirming any current use was made available to the Dossier Submitter.

Therefore, SEAC conclusions on costs are mainly grounded on the assumption that there are no intentional uses and only few unintended uses of PFHxS, its salts and related substances in the EEA. Uncertainties related to this assumption are discussed in the section on *Uncertainties in the evaluation of RAC and SEAC* (see below).

SEAC notes that it cannot be excluded that all these historical applications could become potential new uses of PFHxS as an alternative to PFOA, unless PFHxS is restricted.

Since different levels of uncertainty are associated with this baseline (current and future uses, choice of the substance that will replace PFOA), SEAC discusses the socio-economic impacts of the proposed restriction under different assumptions in the paragraph specifically dedicated to uncertainties.

Substitution and reformulation costs

No substitution costs were indicated during the stakeholder consultation carried out by the Dossier Submitter for the preparation of this Annex XV Dossier nor from the consultation on the restriction proposal. SEAC perceives this as a further confirmation of the absence of such costs in the EEA. This is also consistent with the conclusion that there are no intentional and only few unintentional current uses in the EEA.

As a consequence, SEAC considers that the proposed restriction is expected to generate no or very limited substitution costs or other reformulation costs for European manufacturers.

SEAC notes that the proposed restriction might induce some (extra-EU) manufacturers to substitute PFHxS. This could entail some costs in the EU, possibly for importers/EU citizens. In the case of textiles, fluorine-free alternatives may be more expensive, but their costs are expected to decrease over time. In fact, SEAC considers that manufacturing costs of fluorine-free alternatives could be expected to decrease with increasing know-how and economies of scale, and prices with increasing competition in the developing market. According to the information available, European industry and also parts of industry outside of the EU already use fluorine-free alternatives. As a result of this, and the fact that imports of textiles containing PFHxS currently appear to be limited, SEAC agrees with the Dossier Submitter's conclusion that any additional costs to this sector as a result of the proposed restriction will be limited or non-existent.

In terms of firefighting foams, based on the information available from stakeholder consultations and from the consultation of the Annex XV dossier, SEAC agrees with the Dossier Submitter, i.e. that AFFFs currently placed on the EU market do not contain any PFHxS. SEAC notes that if there is no PFHxS in the AFFFs currently placed on the market, there is no need to substitute PFHxS due to the proposed restriction. Therefore, SEAC agrees that there will be no costs from substituting PFHxS in firefighting foams. However, SEAC notes that when the restriction on PFOA will enter into effect, there may be a need to substitute PFOA-containing foams with other foams. In the absence of a restriction, PFHxS could be a possible substitute of PFOA, and there might be costs for having to use another alternative instead of PFHxS. This type of costs is discussed in a dedicated paragraph below.

Costs for not being able to use PFHxS as a substitute for PFOA

In general, industry is moving from C8 fluorinated compounds to shorter chain fluorinated compounds as well as to non-fluorinated alternatives. This shift has been accelerated by restrictions on PFOS, PFOA and C9-C14 PFCAs (and their related substances). During the SEAC evaluation of the restriction proposal on PFOA, C6 fluorinated compounds were considered to be the primary substitutes for PFOA and PFOA-related substances. Therefore, when considering a new restriction concerning potential substitutes to the long-chain substances, it is important to take into account the costs of not being able to use the potential substitute any longer.

The Dossier Submitter highlights that the costs of substituting PFOA with fluorine-free alternatives instead of PFHxS are not available because it appears that there are no users of PFHxS in the EEA. However, to give some indication of the possible costs, the Dossier Submitter provides information on the price difference between fluorine-containing and fluorine-free fabrics for a couple of cases. For such articles production costs appeared to be approximately 3 % higher for fluorine-free products in the case of durable water-repellent fabrics.

In the C9-C14 PFCAs restriction proposal the Dossier Submitter referred to information in the Background Document for the PFOA restriction proposal to illustrate the possible economic costs of not being able to use C9-C14 PFCAs as substitutes for PFOA. The reasoning was that industry would only substitute PFOA with C9-C14 PFCAs if it was economically more favourable than substitution with C6 substances, and the maximum

level of the associated costs was deduced based on that assumption. A similar reasoning could also be made for PFHxS and related substances; i.e., industry would only substitute PFOA with PFHxS in case it was more favourable than substitution by C6 substances. As the total cost of PFOA restriction was estimated at €35 million per year, the additional costs of not being able to substitute PFOA with PFHxS would be less than €0.35 million per percentage of PFOA substitution, or <€900 per kg of PFHxS or PFHxS-related substances potentially released.

SEAC notes that, currently, it would still be possible to use C6 chemistry or C4 chemistry for substitution. However, the use of such substances as substitutes may not be advisable as there is growing concern relating to their hazard properties and they might be subjected to further regulation in the future (i.e., not a sustainable option). For instance, an Annex XV restriction dossier has already been submitted to ECHA regarding PFHxA.

Enforcement costs

SEAC considers that the generic value of €55 600 for annual average cost per restriction proposed by ECHA is likely to overestimate the costs for enforcing the proposed restriction, 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. SEAC considers that this estimate can be seen as an indicative maximum value for the administrative costs of enforcement.

SEAC notes that the Forum considers that sampling and analytical techniques should be harmonised, and that standards would need to be developed to this end. Such activities would entail costs. SEAC notes that for PFOS a standardised method (CEN/TS 15968:2010; a method based on LC-qMS or LC-tandem/MS) already exists. The development of standardised methods for PFOA and for organic fluoride in textiles and textile products is ongoing in CEN.

Testing costs

SEAC notes that some testing activities would likely take place, mainly on imported articles, by both industry and enforcement authorities. Specific testing costs for PFHxS have not been estimated by the Dossier Submitter.

SEAC considers that testing costs for PFHxS per analysis are in principle expected to be similar to those for PFOS, PFOA and C9-C14 PFCAs; the substances and articles concerned are similar and the test methods to be used are largely the same. Regarding the number of tests to be performed, SEAC also notes that the incidence of PFHxS in articles is currently very low, and actors would mostly need to test articles based on potential risk (i.e., only when there is a suspicion that the article contains a restricted substance) which reduces the need for testing.

In case the enforcement schemes of PFHxS will be harmonised with those of the already regulated PFAS (as expected), the additional costs for testing for PFHxS might be considerably lower than otherwise expected. The analytical techniques available typically include the analysis of several PFAS (ca. 20-30 depending on the laboratory). The price is not dependent on the number of substances tested as they are covered by the testing package. Some additional costs could accrue due to the need to report one extra substance from the analysis, but those are considered to be minor by the Dossier Submitter.

SEAC notes that there is some information on testing costs applicable to the case of PFHxS available from the consultation of the C9-C14 PFCAs restriction dossier and from other public sources (such as catalogues of commercial laboratories found in the internet). As noted above, commercial laboratories currently propose packages for testing a number of perfluoroalkyl acids. For instance, a commercial laboratory offers a test for 22 PFAAs including PFHxS at the price of €485¹⁰. SEAC notes that the test in question is intended for water samples and not for articles, and it does not allow to differentiate between different PFAS (but another test can be ordered to examine substance specific concentrations). A national institute offers a test for textile or spray matrices covering 13 PFAS (including PFHxS, PFOA and PFOS), disclosing individual concentrations, at €358 (+VAT) (Personal communication). The exact price according to an offer includes sampling and sample preparation and can vary depending on working hours needed e.g. for special matrices.

SEAC underlines that making a relevant estimate of testing costs would also require information of 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). However, SEAC considers that the above-mentioned information provides some indication of the magnitude of the associated costs.

Overall, SEAC considers that, if combined with testing for PFOA and C9-C14 PFCAs as expected, the additional testing costs from this restriction should be limited.

Impacts on EU citizens

SEAC notes that some information on the possible impacts on consumers was added to the Background Document by the Dossier Submitter during opinion-making. As discussed above, in general, as a possible reaction to the proposed restriction, some non-EU manufacturers might choose to substitute PFHxS in their products by alternatives that are more expensive, and the resulting costs could be passed to EU consumers. However, as explained below, for reasons related to competition, SEAC considers that it is unlikely that the industry would include the additional costs (due to substitution, reformulation, testing, etc.) in the final prices of their articles.

Furthermore, SEAC considers that the availability or quality of articles not containing PFHxS, its salts and PFHxS-related substances is not likely to decrease as an effect of the proposed restriction.

SEAC conclusions on the impacts on consumers is based on the following arguments that arise from the baseline scenario:

- the occurrence of PFHxS, its salts and PFHxS-related substances in articles placed on the EU market is very limited
- alternative substances and techniques exist
- articles containing alternative substances are available and already dominate the market so future availability of such products should not be an issue
- the quality of PFHxS-free articles is not lower

¹⁰ <https://analyskatalog.eurofins.se/Search/SearchView>

- European and non-European companies will aim to retain their existing market share hence major increases in the price of PFHxS-free articles are unlikely

Therefore, overall, SEAC concludes that EU citizens will not suffer of any major reduction of consumer surplus since prices, availability and quality of articles are not expected to change much as a consequence of the proposed restriction.

Benefits

Summary of the Dossier Submitter's proposal:

PFHxS and its salts have been identified by the Member State Committee as substances of very high concern due to vPvB properties. The restriction is necessary to avoid the possibility that PFHxS, its salts and PFHxS-related substances are used as substitutes when the PFOA restriction becomes binding in 2020 and to reduce the environmental emissions of the substances present in imported articles and mixtures. This proposal is expected to result in a reduction of the annual emissions of PFHxS by 0.42 tonnes compared to the baseline. The Dossier Submitter considered the data on specific uses insufficient to allow estimation of total releases of PFHxS, its salts and PFHxS-related substances. Instead, the emission estimations at EU-level were based on calculated WWTP emissions of PFHxS. Half of the emissions represent an assumed increase in emissions due to a potential regrettable shift from PFOA to PFHxS.

SEAC conclusions:

SEAC notes that PFHxS and its salts have been identified as very persistent and very bioaccumulative (vPvB) substances. PFHxS-related substances can yield PFHxS through degradation and should therefore also be regarded vPvB substances. No safe level of exposure can be established for these substances. PFHxS accumulates in the environment, has long-range transport potential and once in the environment, it is almost impossible to remove. Impacts in the long term are largely not known. The proposed restriction would prevent future accumulation of PFHxS in the environment and in humans.

SEAC takes note of RAC's conclusion that all populations and environmental compartments are potentially at risk and emissions should be reduced as far as possible.

SEAC takes note of RAC's conclusion that the estimated annual emissions of 0.42 tonnes are associated with considerable uncertainties, but the overall estimations are reasonable based on the available data.

Further, according to RAC, the proposed restriction is an appropriate instrument for the minimisation of emissions, and SEAC therefore considers that benefits have been demonstrated.

In conclusion, SEAC agrees that the main benefits of the proposed restriction would derive from preventing a regrettable potential future substitution of PFOA with PFHxS, its salts and PFHxS-related substances and from preventing imports of articles containing these substances.

Key elements underpinning the SEAC conclusions:

SEAC notes that currently it appears that no intentional uses are affected by the proposed restriction. SEAC considers that the benefits of the proposed restriction mainly depend on

the avoidance of potential future substitution of PFOA with PFHxS, its salts and the related substances and on the avoidance of future imports of PFHxS in articles.

SEAC acknowledges that quantification of the benefits of a restriction on vPvB substances, such as PFHxS, is challenging. SEAC notes that the Dossier Submitter has based the analysis on quantified release estimates and qualitative supportive information. SEAC agrees with the use of this approach that is in line with SEAC's guide *Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC*.¹¹

While the main objective of the restriction proposal is the reduction of environmental emissions and stock, SEAC notes that benefits to human health can be expected. It is reported in the dossier that effect on liver metabolism, altered serum cholesterol, triglycerides and lipoproteins, and effects on the endocrine system have been observed in humans. According to the Background Document, PFHxS is detected in human blood globally. Moreover, it appears to be the dominant PFAS present in the blood of firefighters. SEAC also notes that RAC concludes that, although a clear correlation between environmental and human exposure to PFHxS and environmental/health effects are lacking, the vPvB-properties of PFHxS, its salts and PFHxS-related substances are such that adverse health effects can be expected at some point unless emissions are minimised.

SEAC notes that potentially high remediation costs for PFHxS contaminated sites and drinking water could be avoided by the proposed restriction. A lot of examples of the remediation costs for sites contaminated by PFAS can be found in the literature. The dossier specifically quotes cases from Germany and Norway where the costs of remediating sites contaminated by PFAS due to firefighting activities reached several millions of euros per site. In a comment received during the consultation, three environmental NGOs indicated that an assessment made by the Nordic Council of Ministers estimated that PFAS remediation costs at the European level are expected to be in the order of magnitude of hundreds of millions of euros at a minimum ranging from 821 million – 170 billion euros in the 31 EEA Member States and Switzerland.

SEAC highlights that, as in all other restrictions, the benefits of the proposed restriction strictly depend on if the alternatives are safer for human health and the environment. In fact, in terms of the quality of drinking water, the occurrence of any PFAS is a source of concern. As a consequence, the estimate of avoided remediation cost is relevant only for evaluating a switch to non-fluorinated substances.

SEAC notes that PFHxS, its salts and PFHxS-related substances are one group of substances in the fluorotelomer family. Several other groups of substances (PFOS, PFOA, C9-C14 PFCAs and their related substances) are already subject to restrictions. Leaving this group of PFHxS substances unregulated could undermine the benefits of the earlier restrictions if the other substances were substituted with these substances having similar properties.

SEAC notes that this restriction is part of wider European and global efforts to replace PFAS of concern with safer fluorine-free alternatives, and the actual risk reduction potential – and, therefore, benefits of these actions – will gradually materialise as the implementation of the measures advances.

¹¹ https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpnb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3

Other impacts

Summary of the Dossier Submitter's proposal:

The social and wider economic impacts of the restriction are considered to be negligible. This is due to the fact that, according to the available information, there is no manufacture or use of PFHxS in the EU at present. The impacts on the presence of PFHxS as an impurity in imported mixtures and articles should also give rise to only negligible impacts.

SEAC conclusions:

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

Key elements underpinning the SEAC conclusions:

The information received by the Dossier Submitter during the stakeholder consultations or the comments received during the consultation on the restriction proposal did not indicate any social and wider economic impacts for SEAC to consider. This fact seems to confirm the assumption that no intentional uses and only few unintended uses of PFHxS exist in the EEA and that only limited numbers of articles containing PFHxS, its salts and PFHxS-related substances are imported.

Overall proportionality

Summary of the Dossier Submitter's proposal:

In terms of proportionality, the restriction report refers to the SEAC's guide Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC which is based on estimating cost per kg of emission reduction. However, given the lack of identified intentional uses of PFHxS, its salts and PFHxS-related substances within the EU, the costs to EU actors are expected to be minimal. Costs will be incurred by authorities from undertaking monitoring and enforcement activities. However, these enforcement activities for PFHxS substances could be organised in a cost-effective manner if carried out jointly with the enforcement of PFOA and C9-C14 PFCA substances. Taking into account the low costs and estimated reduced emissions, the Dossier submitter therefore considered the proposed restriction to be proportionate.

SEAC conclusions:

SEAC agrees that the costs associated with the implementation of the proposed restriction are expected to be limited. In all probability there is no need to substitute PFHxS in the EEA as no intentional uses in the EU were identified. Activities relating to enforcement and testing can be carried out both by industry and by National Enforcement Authorities jointly with the existing restrictions on PFOA and C9-C14 PFCA. Therefore, additional costs are expected to be limited.

Benefits are expected in terms of avoided emissions of PFHxS, its salts and PFHxS-related substances to the environment. SEAC also considers the avoided remediation costs related to the avoided substitution of PFOA with PFHxS as a potential additional benefit of the proposed restriction.

SEAC finds that the proposed restriction will avoid regrettable substitution of PFOA with

PFHxS. Even if the likelihood of this regrettable substitution is not known and might be low, the benefits for society of its future prevention are worth the costs.

Moreover, also considering the similar hazard profiles of PFOA, C9-C14 PFCA and PFHxS and taking into consideration that both SEAC and the Commission already agreed on the proportionality of the PFOA and of the C9-C14 PFCA restrictions, SEAC concludes that the proposed PFHxS restriction can also be considered to be proportionate.

Key elements underpinning the SEAC conclusions:

SEAC notes that it is complex to estimate the benefits arising from restricting vPvB substances. Therefore, for the proposed restriction, as well as for other similar cases, SEAC acknowledges the challenges inherent in demonstrating proportionality.

Currently, the monetary value of avoiding exposure to PBT/vPvB substances in general or PFHxS, its salts and related substances in particular cannot be quantified. In-depth valuation studies would have to be carried out to get relevant insight. Setting up such studies would be time consuming, costly and very complex, because it would require that consumers understand the consequences of exposure to the substances in question – something that is at present difficult even for scientists.

Some uncertainty into the cost analysis derives from the fact that costs related to the inability to use PFHxS as a substitute of PFOA could not be quantified due to lack of data (see the paragraph on uncertainties for more detail). No arguments implying that PFHxS would be a better substitute compared to other similar substances were provided by the Dossier Submitter nor in the consultation. SEAC considers that this absence of comments supports the assumption that no major costs are expected from not being able to use PFHxS as a substitute of PFOA.

SEAC underlines that, with regard to the impacts relating to not being able to use PFHxS as a substitute of PFOA, the costs and benefits are equally likely/unlikely to take place. They both depend on the extent to which such a regrettable substitution from PFOA would take place in the absence of the proposed restriction.

For assessing proportionality, SEAC highlights that:

- PFHxS is an extremely persistent substance
- the impacts of exposure are not yet well known
- removing the substances from the environment may not be possible and in any case, it would be very costly.

These issues cause specific concern and are key points in the evaluation of proportionality of the proposed restriction. They describe concerns linked to PBT/vPvB substances and are also listed in Annex 1 (List of potential factors or situation for case-by-case consideration) to SEAC's PBT approach.

The SEAC conclusion on proportionality is supported by the fact that, if after the entry into force of the PFOA restriction safer alternative substances would be used instead of PFHxS, the proposed restriction has potential to avoid or at least reduce potential contamination of soils and drinking water sources, hence to limit high remediation costs which could be incurred in the future. SEAC also considers that the proposed restriction has potential to avoid further bioaccumulation of these substances in humans and the environment.

Table 1: Summary of impacts of the proposed restriction

Benefits	<p>Benefits for the environment and related economic benefits:</p> <ul style="list-style-type: none"> • Risk reduction due to reduced emission of these vPvB substances • Avoidance/reduction of contamination of water sources and soil • Avoidance/reduction of decontamination costs <p>Benefits for human health and related socio-economic benefits:</p> <ul style="list-style-type: none"> • Avoidance of further accumulation in humans and of adverse effects on human health • Avoided costs of illnesses
Costs	<p>Some minor costs related to substitution from PFOA to shorter chain or non-fluorinated alternatives instead of to PFHxS.</p> <p>Some testing costs for industry (but limited if combined with testing of PFOA and C9-C14 PFCAs).</p> <p>Enforcement cost will likely be low because enforcement will be combined with that of PFOA and C9-C14 PFCAs restrictions. However, some additional testing might have to be performed.</p> <p>Some minor costs can be expected for importers, suppliers and consumers due to presence in imported articles.</p>

Practicality, incl. enforceability

Justification for the opinion of RAC

Summary of the Dossier Submitter's proposal:

Practicality

The Dossier Submitter considers the restriction proposal to meet the requirements regarding practicality. The requirements are similar to other regulated PFAS, and the frameworks put in place with respect to C9-C14 PFCAs, PFOA and PFOS will be relevant also for the implementation of this restriction.

No intentional uses of PFHxS, its salts or related substances have been identified in the EU and alternative substances or technologies are available. The proposed transition time of 18 months should therefore be sufficient for all actors. The consultation prior to submission of the proposal indicated that relevant EU actors have foreseen the need to generally move away from PFASs and to use fluorine free alternatives or alternative technologies.

Analytical methods to analyse PFHxS and other PFASs in almost all environmental media are available. Although no standardised analytical methods exist, it is possible to use the method specified by the European Committee for Standardisation (CEN) for PFOS to determine the levels of ionic forms of PFHxS, its salts and PFHxS related substances. For volatile neutral PFHxS related substances, Herzke *et al.* (2012) reported detection of PFHxS and related substances using a different analytical method. The level of quantification in both methods is reported to be 0.06 ppb, which suggest quantification of PFHxS, its salts and related compounds at levels below the proposed threshold limit values to be possible. However, the detection level is also dependent on the sample material measured, and for some matrices (e.g. firefighting foams), a higher detection level is expected.

Enforceability

Enforcement activities involving inspections and testing of PFHxS, its salts and related substances in articles can be arranged to target the occurrence and share the costs of other regulated PFASs - PFOS, PFOA, and C9-C14 PFCA at the same time. PFHxS is one of several PFASs that are usually analysed for in one standard PFAS analysis package (up to 20-30 PFAS depending on the lab). The sampling and sample preparation will be performed together for PFHxS and other PFAS in the same sample. Some minor additional costs may be added due to the need to report one extra substance from the analysis, but these extra costs are likely to be less than the difference in costs between different laboratories for the chemical analysis itself. One stakeholder informed that the costs for the analysis of all PFAS (including PFHxS) is ca. €300 per sample, and for PFHxS alone is €110. Thus, the enforcement costs specific to PFHxS should be small.

RAC conclusion(s):

RAC agrees with the Dossier Submitter that the restriction of PFHxS, its salts and related substances is feasible with respect to practicality and enforceability. The restriction follows the same approach as for previous PFAS-restrictions and the frameworks developed for enforcement of those can be used also for PFHxS, its salts and related substances, including sampling and sharing of costs for analyses. Analytical methods with low detection limits to analyse PFHxS are currently available. RAC supports the 25 ppb concentration limit proposed by the Dossier Submitter. No standardised analytical method specific to PFHxS, its salts and related substances exists and RAC therefore recommends developing such a standardised method.

Key elements underpinning the RAC conclusion(s):

No intentional uses of PFHxS, its salts and related substances in the EU were found. Imported textiles were identified as the only emission source where PFHxS, its salts and related substances are intentionally present. Thus, the proposed transition time of 18 months should be possible to meet for all actors. No requests for derogations from the restriction were raised in the consultation. However, from a risk perspective, RAC does not support such a long transitional period for firefighting foams already on the market and considers that this should be as short as practically possible.

Methods to analyse PFHxS and other PFAS in various media have been available and used in research laboratories for more than 10 years, and commercial analyses are readily available. No standardised analytical methods have been developed, but the method specified by CEN for PFOS ("Determination of extractable perfluorooctanesulphonate

(PFOS) in coated and impregnated solid articles, liquids and firefighting foams - Method for sampling, extraction and analysis by LCMS or LC-tandem/MS”) can also be utilised for PFHxS. Analytical standards are not available for all PFHxS-related substances and given the large number of such substances (147 specified in the proposal), testing for all these is not practically possible. Analysis of PFHxS-related substances can instead be performed by Total Oxidisable Precursor (TOP) analysis, where the PFHxS-related substances are oxidised to the free PFHxS acid that is measured. Thus, in fact, no specific individual analytical standards for the analyses of PFHxS-related substances are needed.

Justification for the opinion of SEAC

Summary of the Dossier Submitter’s proposal:

This restriction proposal is similar to those proposed for PFOA and C9-C14 PFCAs. The EU regulatory approach put in place with respect to the PFCAs, PFOA and PFOS will also be relevant to the implementation of this restriction. Industry in the EU has already substituted intentional use of PFHxS and PFHxS-related substances. There are several analytical methods that can be used to measure PFHxS and other PFASs in almost any media.

SEAC conclusions:

SEAC considers that the proposed restriction is implementable, manageable and enforceable.

Key elements underpinning the SEAC conclusions:

Implementability

According to the information available, concentrations of PFHxS, its salts and PFHxS-related substances in most articles and mixtures are below the proposed concentration limits – hence it can be expected that for industry it should be possible to avoid high level of impurities. Alternative technologies, techniques and substances (including fluorine-free substances) are commercially available and economically feasible and the EU industry has already made the transition to such alternatives.

Manufacturers, as well as retailers of articles will need to seek confirmation from their suppliers about the content of PFHxS in the substances, mixtures or products they purchase. Also National Enforcement Authorities (NEAs) may request information about the product composition from the suppliers of the consumer products.

Analytical methods allowing the determination of the concentration of PFHxS are reported to be available for almost any media; monitoring the compliance of products should therefore be feasible. There are methods that cover the analyses of several different PFASs, such that it is possible to monitor compliance with restrictions on several substances (including PFOS, PFOA, PFHxS) by a single test. However, these methods are not standardised. Also, for some matrices testing could be problematic until new analytical methods are developed. SEAC also points out that even though suitable analytical methods with sufficiently low limits of quantification appear to be widely available, applying them for quantifying PFHxS-related substances in a sample is not simple. Unlike for PFOA, a method capable of determining the total concentration of all related substances does not

seem to be currently available.

Considering the ongoing phase-out of fluorotelomer substances and specifically the identification of PFHxS as a substance of very high concern, SEAC understands that industry actors are already getting prepared for using different substances and technologies.

SEAC concludes that, within the timeframe of 18 months, the proposed restriction is implementable by the actors involved.

Enforceability

Standardised EU analytical methods to measure the concentration of PFHxS, its salts and PFHxS-related substances in articles and mixtures are not yet available. However, several analytical methods allowing the measurement of PFHxS and PFASs to the desired level in certain media exist and they could also be used as a basis for standardisation. Therefore, NEAs should be able to enforce the proposed restriction.

In terms of PFHxS-related substances, SEAC notes that the determination of their concentrations in an unknown sample could be challenging. Also, as mentioned above, a method capable of determining the total content of PFHxS-related substances in a sample does not seem to be currently available. However, as already noted, there are methods that cover the analyses of several different PFASs, such that it is possible to monitor compliance with restrictions on several substances (including PFOS, PFOA, PFHxS) by means of a single test.

According to the Forum, the proposed restriction will be enforceable provided that standards become available before the entry into force of the proposed restriction. The Forum proposes the European Commission to promote the development of those standards in the EU if the restriction is adopted (i.e. CEN standards, research programmes, cooperation with Member State laboratories, etc.). The Forum highlights that methods should be transferable to commercial or public laboratories when the restriction enters into force. In line with the Forum advice, SEAC recognises that until the establishment of EU standard analytical methods for PFHxS substances, ensuring uniform enforcement across the EU can be challenging. SEAC considers that time is required for the development of standardised analytical methods.

The Forum also recommended to investigate the possibility to elaborate standards that combine several similar restrictions (PFOS, PFOA, C₉-C₁₄ PFCA, and PFHxS). SEAC agrees with this recommendation.

For imported articles, compliance can be checked by customs control and notification of any violation of the restriction can be reported in Safety Gate (the rapid alert system for dangerous non-food products, previously RAPEX).

Even in the absence of an EU standardised method, SEAC considers that the content of PFHxS can be measured and that the restriction can be enforced.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of the Dossier Submitter's proposal:

The level of quantification for PFHxS (0.06 ppb) in the available analytical methods is sufficiently low to allow quantification of PFHxS, its salts and related compounds at the proposed concentration limit values. With a concentration limit of 2 ppb, reliable results can be difficult to achieve for analyses in some matrices. A concentration limit of 25 ppb is anticipated to provide more reliable results (CRO, 2020).

The Dossier Submitter proposes monitoring of the results of the restriction would be cost effective and consistent with, and complementary to, the strategy put forward for other regulated PFAS. This would comprise time-trend monitoring and monitoring of emissions suited to very persistent substances, for example with respect to emissions from waste water treatment facilities. Time-trend monitoring should, as proposed for C9-C14 PFCAs, include sampling from the environment, from animals and from humans. Methods and instruments available in environmental specimen banks could be used for such a monitoring. However, it should be recognised that it might take a very long time to detect downward trends in concentrations, due to the persistence of PFHxS and due to the potential for redistribution of PFHxS, its salts and related substances from environmental sinks such as sediment and soil.

RAC conclusions:

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

Key elements underpinning the RAC conclusions:

Methods are available to measure PFHxS in various environmental matrices and in human blood and environmental monitoring and biomonitoring are currently being carried out. RAC agrees that due to the extreme persistence of PFHxS, decreasing levels may take a long time to detect in some matrices.

RAC supports the view of Forum that development of an EU-standard for the analysis of PFHxS (incl. sampling and extraction) is needed to ensure a uniform enforcement of the restriction in the EU. PFASs are routinely analysed together and commercial analyses are available as analysis packages of groups of PFAS.

SEAC conclusions:

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

Key elements underpinning the SEAC conclusions:

SEAC agrees that 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.

Monitoring notifications gathered via Safety Gate appears to be a useful complementary approach for monitoring imported articles. Controls can also be carried out by customs authorities.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of the Dossier Submitter's proposal:

There are uncertainties in the estimations and assumptions provided in the Background Document. The Dossier Submitter considers these to primarily affect the socio-economic analysis. The uncertainties are not anticipated to be of such scale that they would alter the conclusions and, where this potential existed in principle, this has been mitigated in the analysis by a conservative treatment of data and emissions.

Manufacture or use of PFHxS, its salts or related substances

No manufacture or use of PFHxS, its salts or related substances in the EU were identified other than in stocks of AFFFs, as an impurity of PFOS, and in imported textiles. It is, however, possible that other uses exist which were not revealed in the data collection process. The potential for not identifying all uses was mitigated by repeated attempts of the Dossier Submitter to engage potential users and user groups, by reviews of the international literature and data (including PFOS) to identify potential uses and through several other studies made to identify and consult potential users (including the BiPRO, 2018 study). All this was preceding the ECHA call for evidence prior to the submission of the restriction proposal and the subsequent stakeholder consultation after the submission. The Dossier Submitter considers that several opportunities to provide a response have been offered to the users. However, these consultations have identified either no use nor interest towards the restriction process (also implying no use).

Emissions and environmental stock of PFHxS

The predicted emissions and environmental stock of PFHxS in the baseline scenario are based on emissions via WWTPs. The estimate of 1.79 tonnes/year of PFHxS via WWTPs from industrial sources is based on water samples taken in 2010/2011. This time-period coincides with action on PFOS under Directive 76/769/EEC that applied from 2008. The regulation of PFOS may have triggered a reduction of the industrial share (1.79 tonnes/year) of the total (2.1 tonnes/year) emissions. Thus, the baseline may have underestimated the real situation.

Substitution from PFOA

The underlying basis for the restriction rests partially on the likelihood that the restriction on PFOA will trigger substitution to PFHxS. The Dossier Submitter provides sufficient evidence to support this assumption. However, the Dossier Submitter does not consider the need for a restriction to entirely depend on this substitution. The concentration limits to be implemented on articles (and mixtures) would still provide a reduction of PFHxS, its salts and related substances in imported articles.

Toxicity

The Dossier Submitter states that there are some uncertainties regarding the toxic effects on the environment and human health from PFHxS, its salts and related substances. One such uncertainty is the cause and effect relationship between PFHxS and different health impacts and outcomes. However, these uncertainties together with the very persistent nature of PFHxS also provide a strong motivation for a restriction on PFHxS, its salts and related substances.

RAC conclusion(s):

RAC agrees with the Dossier Submitter that there are uncertainties in the underlying estimations and assumptions. However, these uncertainties are primarily related to uses and emissions, and affect the understanding of the magnitude of the risk and the effect of the suggested risk reduction measures. The uncertainties do not alter the conclusion that there is a risk from PFHxS, its salts and related substances that is not adequately controlled.

Key elements underpinning the RAC conclusion(s):

There are uncertainties related to the uses of PFHxS, its salts and related substances in the EU. No intentional uses were identified in the preparation of the dossier and via stakeholder consultations other than those presented. No additional information and requests for derogations have been provided in the consultation. Thus, the information provided in the Background Document can be considered to likely represent the major uses/emission sources, any other uses/emission sources are expected to be minor.

The emission estimations and predictions are also associated with uncertainties. However, RAC considers the estimations reasonable based on the available data. It is possible that the phase-out of PFOS may have underestimated the baseline emissions of PFHxS. However, the effectiveness of the restriction in terms of reduction in emissions of PFHxS, its salts and related substances will remain the same.

The restriction rests to some extent on the assumption that PFOA will be substituted to PFHxS. It is, however, uncertain to what extent this substitution will occur. Industry has generally substituted "long-chain" PFASs (PFASs with ≥ 6 perfluorocarbons, PFCAs with ≥ 7 perfluorocarbons) to "short-chain" PFASs (PFASs with < 6 perfluorocarbons, PFCAs with < 7 perfluorocarbons). Thus, the likelihood of substitution from PFOA to a short-chain PFASs (e.g. perfluorohexanoic acid (PFHxA)) is considered more plausible than to a long-chain PFAS such as PFHxS. Nevertheless, the restriction proposal also aims to prevent emissions of ongoing uses of PFHxS and the extent of substitution from PFOA to PFHxS does not affect the underlying reasons for the restriction.

Although a clear correlation between environmental and human exposure to PFHxS and environmental/health effects are lacking, the vPvB-properties of PFHxS, its salts and related substances are such that adverse health effects can be expected at some point unless emissions are minimised.

SEAC***Summary of the Dossier Submitter's proposal:***

The major uncertainties for the socio-economic assessment identified by the Dossier Submitter are the following:

- **Uses:** Whether there are some uses that were not discovered during dossier preparation
- **Substitution** after the PFOA restriction applies: Whether and to what extent PFOA would be replaced with PFHxS in the non-existence of the proposed restriction
- **Cause and effect relationship**

SEAC conclusions:

SEAC agrees that the uncertainties presented by the Dossier Submitter appear to cover the most relevant sources of uncertainty. However, SEAC highlights also the following additional sources of uncertainty that stem from the lack or scarcity of available information:

- identity and risks of the alternative techniques, technologies and substances chosen as substitutes
- volumes of PFHxS, its salts and related substances in imported articles

The potential level of each of these uncertainties, as well as their socio-economic implications under different scenarios are described below.

However, overall, SEAC considers that the level of uncertainty brought about by these elements is not of a magnitude to challenge the conclusions made by SEAC above.

Key elements underpinning the SEAC conclusions:

SEAC based its conclusions on uncertainties on the following elements.

Current intentional and unintentional uses

SEAC notes that the Dossier Submitter concludes that currently PFHxS, its salts and PFHxS-related substances are not produced nor intentionally used in the EEA.

Taking into account the available information found through literature review or gathered during the stakeholder consultation carried out by the Dossier Submitter, the assumptions made by the Dossier Submitter seem to be associated with a low level of uncertainty. The conclusion of a lack of intentional uses is supported by the fact that the substances under the scope of the proposed restriction are not registered under REACH. However, it cannot be completely excluded that some current uses were not caught during dossier preparation and opinion-making on the proposal. The existence of some self-classifications of the substances in scope seems to suggest that there might be some use at volumes below one tonne per year. This possibility, coupled with the uncertainty on potential future substitution from PFOA, could imply, on one hand, costs for the industry to replace these substances and, on the other hand, benefits of the proposed restriction.

No information on any further uses of PFHxS, its salts or related substances in the EEA was received during the consultation of the Annex XV dossier.

SEAC concludes that the uncertainty concerning uses is of small magnitude and does not affect the SEAC conclusions.

Substitution and future uses after the entry into force of PFOA restriction

In the absence of the proposed restriction, SEAC notes that uncertainty exist on whether and on to what extent, once the PFOA restriction becomes binding, PFOA would be replaced by PFHxS, its salts and related substances. Moreover, SEAC notes that this uncertainty has high implication on the substitution costs for the industry and on the potential benefits of the proposed restriction.

In general, before proceeding with substitution, companies would check the regulatory framework, e.g. the SVHC-listing, in order to avoid a regrettable substitution. Also, no arguments implying that PFHxS would be an exceptionally good substitute in certain uses

compared to other similar substances were provided by the Dossier Submitter nor in the consultations. Therefore, SEAC concludes that this uncertainty is of small magnitude since such shift is rather unlikely even in the absence of the proposed restriction.

The following tables prepared by SEAC illustrate what the socio-economic impacts of the proposed restriction would be with or without a switch from PFOA to PFHxS taking into consideration the estimated level of uncertainty of the different elements of the baseline scenario.

Table 2: Costs and benefits in case of entry into force of the proposed restriction and no switch from PFOA to PFHxS, its salts and related substances in the baseline

	Costs	Benefits
No or very limited current production, placing on the market (including import) and use in EEA MOST LIKELY	very limited	Very limited; future production, placing on the market (including import) and use in EEA would be prohibited
placing on the market (including import) and use in EEA LESS LIKELY	High if a large share of the industry will have to adapt limited if only a few companies will have to adapt (largely borne by actors outside the EU)	Avoidance of emissions from imported articles Dependent on the extent of avoided imports and resulting emissions

Table 3: Costs and benefits in case of entry into force of the proposed restriction and switch from PFOA to PFHxS, its salts and related substances in the baseline

	Costs	Benefits
No or very limited current production, placing on the market (including import) and use in EEA MOST LIKELY	Dependent on the extent of avoided use, and prices of alternatives Limited, because there are other alternatives in the same price range	Avoidance of future use and therefore of emissions in the EEA Dependent on the extent of avoided use and emissions, and whether the alternatives are less harmful
Presence of current production, placing on the market (including import) and use in EEA LESS LIKELY	High if a large share of the industry will have to adapt Limited if only a few companies will have to adapt Dependent on the extent of avoided use, and prices of alternatives Limited, because there are other alternatives in the same	Avoidance of future use and therefore of emissions in the EEA Avoidance of emissions from imported articles Dependent on the extent of avoided use and emissions (and therefore comparable to costs), and whether the alternatives are less harmful Dependent on the amount of

	price range	avoided imports and resulting emissions
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Cause and effect relationship between release and environmental and health effects

The evaluation of the proportions of impacts caused by emissions and exposure to PFHxS, its salts and related substances is complicated by the lack of information on the cause and effect relationship. The impacts are nonspecific and could be caused by exposure to other agents as well.

Lack of clarity on the cause and effect relationship is common to many PBT/vPvB restriction proposals. While it is a point to be kept in mind, SEAC considers that it is not of particular concern in this case.

Identity and risks of the chosen alternative substances

If unable to use PFHxS, its salts and related substances instead of PFOA due to the proposed restriction, some companies could choose to shift either to other (short chained) fluorinated alternatives such as C4 or other C6 substances, or to non-fluorinated substances. The extent of a potential switch to other fluorinated substances is unknown.

SEAC notes that the proposed restriction would imply benefits to human health and the environment only if alternative substitutes to PFOA will be safer than PFHxS, its salts and PFHxS-related substances.

SEAC considers that companies, aware of the ongoing and future initiatives for phasing out fluorinated substances at European and international level, would choose a non-fluorinated alternative whenever feasible. Therefore, SEAC considers that there is little uncertainty on the fact that substitution will be to non-fluorinated alternative substances whenever possible; hence implying benefits to human health and the environment.

SEAC notes that the magnitude of costs of the proposed restriction would depend on the extent to which industry would switch to more expensive alternative techniques, technologies or (fluorinated or non-fluorinated) alternative substances instead of switching to PFHxS substances. However, SEAC recalls that, according to the available information, alternative substances appear to be available in the same price range with PFHxS (for durable water repellent textiles, roughly 3% higher production costs were estimated for fluorine-free products). Furthermore, the EU industry appears to already use fluorine-free alternatives, which SEAC considers to signal economic feasibility.

SEAC prepared the following table to better illustrate costs and benefits of a substitution from PFOA to a fluorinated or to a fluorine free alternative substance.

Table 4: Costs and benefits in case of entry into force of the proposed restriction depending on the alternative chosen to substitute PFOA after its restriction

	Costs	Benefits
Use of a safer technique, technology or substance (even without restriction on PFHxS) MOST LIKELY	No costs due to the proposed restriction	No benefits due to the proposed restriction
Use of PFHxS or other fluorinated substances (without restriction on PFHxS) LESS LIKELY	High if a large share of the industry will have to adapt limited if only a few companies will have to adapt	Avoidance of future use and therefore of emissions in the EEA Dependent on the extent of avoided use and emissions

Volumes of PFHxS, its salts and PFHxS-related substances in imported articles

The data collected by the Dossier Submitter on the content of PFHxS, its salts and PFHxS-related substances in articles suggest no or negligible import of these substances in textiles at present. SEAC notes that the conclusions on the incidence of PFHxS in articles are based on limited data. The data seem consistent and appear reliable as such. However, available information is indeed very scarce to enable sound scientific analysis. SEAC notes that the total estimated emissions (and emission reductions) are much higher than the specifically estimated emissions from imported textiles (as well as from AFFFs). There is a gap of knowledge between observed and estimated emissions.

If the prevailing incidence and content of PFHxS, its salts and related substances were higher than expected, both costs and benefits of the proposed restriction would be higher than what is indicated in the analysis.

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For further references, please, see the Background Document.