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/RAC opinion

Adopted

13 March 2020

13 March 2020

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

12 March 2020

[SEAC opinion number to be added after the adoption of the SEAC opinion]

Opinion of the Committee for Risk Assessment

[and

Opinion of the Committee for Socio-economic Analysis]

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

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

Chemical name(s):	***Perfluorohexane sulfonic acid (PFHxS), its salts and related substances***
EC No.:	**-**
CAS No.:	**-**

This document presents the opinion adopted by RAC and the Committee's justification for its opinion. The Background Document, as a supportive document to both 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 submitted a proposal for a restriction together with the justification and background information documented in an Annex XV report. 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 OPINION

ADOPTION 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 ***[date of adoption of the opinion]***. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by ***[number of days]*** by the ECHA decision ***[number and date]***]**[1]**.

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

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

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[1] Delete the unnecessary part(s)

CONTENT

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Perfluorohexane sulfonic acid (PFHxS) (linear or branched), its salts and related substances[2]: 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.	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: (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 1000 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 (a) substances or mixtures containing PFHxS as an impurity in PFOS[3] in applications of PFOS which are derogated from the prohibitions in Annex I Part A of Regulation (EU) No2019/1021; (b) concentrated fire-fighting foam mixtures that were placed on the market before [*date - 18 months after the entry into force of this Regulation*] and are to be used, or are used in the production of other fire-fighting foam mixtures.

Explanatory notes

Column 1

Paragraph 1 – included substances

Both linear and branched substances containing the $C_6F_{13}S$ element are included in the scope.

Polyfluorinated substances containing partially fluorinated structural elements (e.g. $C_6HF_{12}S$) are not included within the scope of the restriction because they will not form PFHxS in degradation.

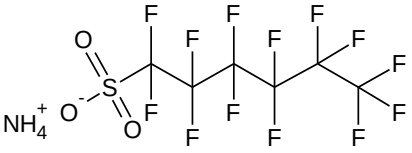
Paragraph 1(a)

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

[2] 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.

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

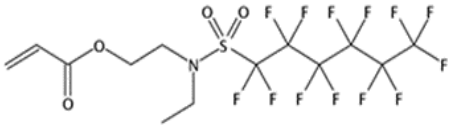
Example of a salt:

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 NH4-salt 

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	

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 fire-fighting foam mixtures by an end-user is defined as manufacture of a mixture in REACH. This particular use is exempted from the restriction in point 4 (b).

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.

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

The conditions of the restriction recommended by RAC:

Perfluorohexane sulfonic acid (PFHxS) (linear or branched), its salts and related substances[4]: 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.	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: (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 1000 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 (a) substances or mixtures containing PFHxS as an impurity in PFOS[5] in applications of PFOS which are derogated from the prohibitions in Annex I Part A of Regulation (EU) No2019/1021; (b) concentrated fire-fighting 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 fire-fighting foam mixtures.

[4] 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.

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

THE OPINION OF SEAC

See the opinion of SEAC.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

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

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

Perfluorohexane sulfonic acid (PFHxS) is a perfluoroalkylated substance (PFAS) and 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, and perfluorobutane sulfonate (PFBS). PFBS, PFHxS and PFOS share the same functional group (SO_3^-), differing only in their respective perfluorinated carbon chain lengths (Figure 1). 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), part of the C9-C14 PFCA restriction. PFOA, PFNA and PFDA share the same functional group (COO^-), differing only in their perfluorinated carbon chain lengths (Figure 1).

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

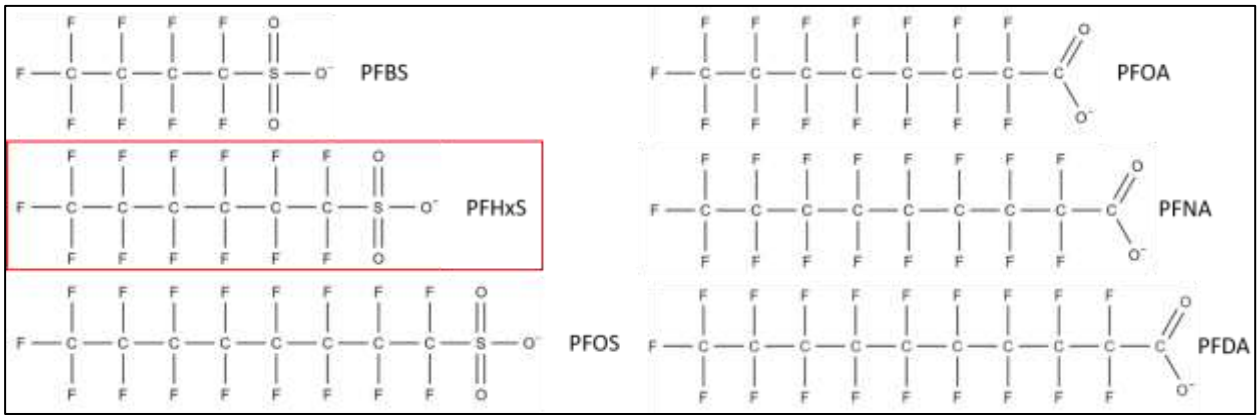


Figure 1. Structural relationships of PFHxS to the other perfluorinated sulfonic acids perfluorobutane sulfonate (PFBS) and perfluorooctane sulfonate (PFOS) and to the perfluorinated carboxylic acids perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA) and perfluorodecanoic acid (PFDA).

Summary of proposal:

The proposal 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 $C_6F_{13}^-$ moiety (linear or branched) directly attached to a sulphur atom and are considered to have the potential to degrade to PFHxS. This terminal degradation approach, referred to as the "arrowhead" approach, where the arrowhead is the final product (i.e. PFHxS), due to degradation of the more complex salts and related substances, has been used in previous restriction proposals under REACH 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).

A recent literature study (Nielsen, 2017) concluded that 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, are all precursors of 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 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). To what extent the PFHxS-related substances will end up as PFHxS may vary with the environmental conditions and is difficult to predict. The rate of degradation may vary for the different PFHxS-related substances 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). Only limited information on the degradation rate of PFHxS-related substances has been published. Nevertheless, PFHxS will eventually be formed and inclusion of PFHxS-related substances in the scope is thus warranted. Read-across from the closely related homologues PFBS and PFOS, which differ from PFHxS only in the number of CF_2-units demonstrates the abiotic and biotic degradation of closely related precursor substances.

The purpose of the restriction proposal is to reduce current environmental emissions of PFHxS, its salts and related substances from imported articles and mixtures intentionally treated or manufactured with these substances. The restriction also aims to prevent these substances from being used as substitutes when the PFOA restriction becomes effective in 2020. The restriction on an EU-level will assist the ongoing global regulation of PFHxS, its salts and related substances under the POPs Convention (UNEP, 2019) by analysing the impact of an equivalent regulation in the EU. The POPs review committee (POPRC) decided in 2018 that PFHxS, its salts and related substances fulfil the criteria as a Persistent Organic Pollutant (POP), 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).

RAC conclusion(s):

RAC agrees with the scope proposed by the Dossier Submitter, covering in total approximately 150 substances that can degrade to PFHxS. The use of read-across to the closely related homologues PFBS and PFOS is supported; there are no indications that these homologues are different in terms of degradation and persistence. The restriction scope follows the same "arrowhead" approach that was 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 C_6F_{13}-S-moiety can degrade to PFHxS and should therefore be included in the scope of the proposal. This follows the same line of reasoning that was applied in the restrictions of PFOA and C9-C14 PFCA. All halides (F, Cl, Br, I) connected to the C_6F_{13}-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 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. Due to the vPvB properties all environmental and human exposures need to be minimised.

Key elements underpinning the RAC conclusion(s):

PFHxS and its salts have been added to the REACH Candidate List of Substances of Very High Concern due to their vPvB-properties. PFHxS-related substances can degrade to PFHxS and should therefore be considered as vPvB substances. A safe concentration cannot be determined for the substances 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 of the environment and humans from PBT and vPvB substances should be reduced as much as possible.

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 proposal:

Uses

No current intentional uses of PFHxS, its salts and related substances in the EU have been identified by the Dossier Submitter. There are no REACH registrations and no information on use of the 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 of PFHxS in the EU has been confirmed by the detection of PFHxS in, e.g., 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 gear 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 per year imported on waterproof jackets from China, Vietnam and Bangladesh, and an unknown quantity in other applications such as outdoor gear, to be 66 kg. More recent data on PFHxS in imported outdoor gear suggest less use of PFHxS in the EU today (17.4 kg per year) but continuing use of PFOA. The EU restriction on PFOA in 2020 may therefore lead to increasing 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 in the EU that can cause emissions of PFHxS were restricted 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 the current total EU stockpile of such foams at refineries, tank farms, chemical works and other installations to contain around 0.5-3 kg PFHxS as an impurity, 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 in closed-loop systems (UNEP, 2019).

Other possible uses and emission sources

PFHxS, its salts and related compounds are being used as replacements for PFOS, PFOA and their related compounds 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 has been provided in the stakeholder consultation and call for evidence.

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 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 was provided in the restriction proposal.

Manufacturing in the EU and globally

Manufacturing processes may constitute a major source 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.

The majority 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 is 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. One study referred to by the Dossier Submitter estimated the global production of PFHxS to approximately 700-750 kg in 2012 decreasing to less than 700 kg in 2016 (BiPRO, 2018). A further slight decrease in global production of PFHxS is expected.

Emission estimates

Since no current intentional use of PFHxS, its salts and related substances in the EU has been identified, and only the presence of PFHxS as an impurity in old stocks of AFFFs and exempted uses of PFOS in chromium plating has been noted, the Dossier Submitter could not 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 or related substances may enter WWTPs via industrial and/or urban waste emission after use or disposal of products containing these compounds. 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 (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, considered to likely represent WWTPs handling industrial wastewater with high concentrations of PFHxS, constituting around 90% of the emissions.

The Dossier Submitter referred to literature sources that have estimated emission factors for PFHxS per inhabitant, ranging from 0.53 to 15 µg/day. On an EU level, based on 500 million inhabitants, this would result in emissions of 0.1–2.7 tonnes PFHxS/year. Since the calculated emissions from WWTPs, of 2.1 tonnes, falls within this range, the Dossier Submitter considers that this strengthens the validity of the overall assessment.

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, i.e. after the service life of products. The Dossier Submitter reported highly variable concentrations in EU landfill leachates, ranging from < LOD to 8 900 ng/L. Since leachate volumes are highly dependent on the climate (rainfall with infiltration into landfill), and may vary substantially from month to month and year to year, the Dossier Submitter considered it difficult to estimate the load of PFHxS emitted via landfill leachates 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 for PFHxS contamination in Europe and Asia have been identified. In Italy,

a chemical plant producing PFHxS until 2013 caused PFHxS contamination in ground water, surface water and fresh water wells for human use over an area of 200 km^2, resulting in an average PFHxS concentration of 32.5 ng/L in drinking water. In Norway, surface water, soil and biota near a company formulating and testing firefighting foam products showed elevated PFHxS concentrations (4.3 µg/L, 580 ng/kg wwt) in water and sea snails, respectively.

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

Current and formerly used fire-fighting training sites have been contaminated with PFHxS from AFFFs in the EU, and globally, where ground water and drinking water may have been contaminated. 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 1 700 ng/L, which resulted in significantly elevated serum concentrations in the population consuming the 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 amounts of PFAS-containing AFFFs in the EU to be between 15 620 and 31 240 tonnes (Table 1). Based on data on impurity levels of PFHxS between 31-98 ppb (µg/kg) in AFFFs in German refineries and tank farms from the stakeholder consultation, the total amount of PFHxS in stocks of AFFFs in the EU was derived (Table 1) and estimated to between 0.5 to 3 kg. Choosing a worst-case assumption, assuming 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, 39 - 245 g/year across the EU. Compared to the amount of PFHxS emitted via WWTPs this 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	968
	PFHxS content max	1 531	2 143	**3 062**
	PFHxS content average	922	1 290	1 843
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	77
	PFHxS content max	122	171	**245**
	PFHxS content average	74	103	147

Emissions of PFHxS from continuing uses of PFOS in the EU

PFHxS is a known impurity of PFOS; concentrations between 4-14% have been 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: mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems.

The use of PFOS as a mist suppressant for hard chromium (VI) plating appears to be an ongoing use today (UNEP, 2019). Submissions from EU Member States to the Stockholm Convention suggest 50 kg of PFOS use in total 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, the emission estimations on an EU-level were based on calculated WWTP emissions of PFHxS.

Using the average PFHxS concentration in WWTP effluents, total EU emissions of 2.1 tonnes PFHxS/year was estimated. However, 1.79 tonnes of this was associated with WWTPs handling industrial wastewater with high concentrations of PFHxS (10% of the WWTPs) and 0.22 tonnes from the other (90%) WWTP with lower PFHxS levels (comprising both industrial and public wastewater sources). Therefore, the Dossier Submitter considered these emissions historical, prior to the regulation/phase-out of PFOS. Thus, the current PFHxS emissions 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 (mean conc. 69 µg/kg, 1/13 jackets). The samples containing PFHxS had an average concentration of 520 µg/kg. In 2016, the use of PFHxS in jackets was much less than the use of PFOA (9/13). Assuming a shift from the use of PFOA to PFHxS in jackets, emissions would increase with a factor of two compared to 2013 and a factor of 7.5 compared to 2016. The Dossier Submitter chose the lesser of these factors to represent an increase in emissions due to a shift from PFOA to PFHxS. Extrapolating this increase to society as a whole then leads to 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 overall environmental stocks of PFHxS are expected to increase during the coming decades. Figure 2 illustrate the calculated changes in environmental stocks of PFHxS from 1990 onwards without any degradation and with a, likely underestimated, half-life of 42 years, showing a slight decrease during the coming decades.

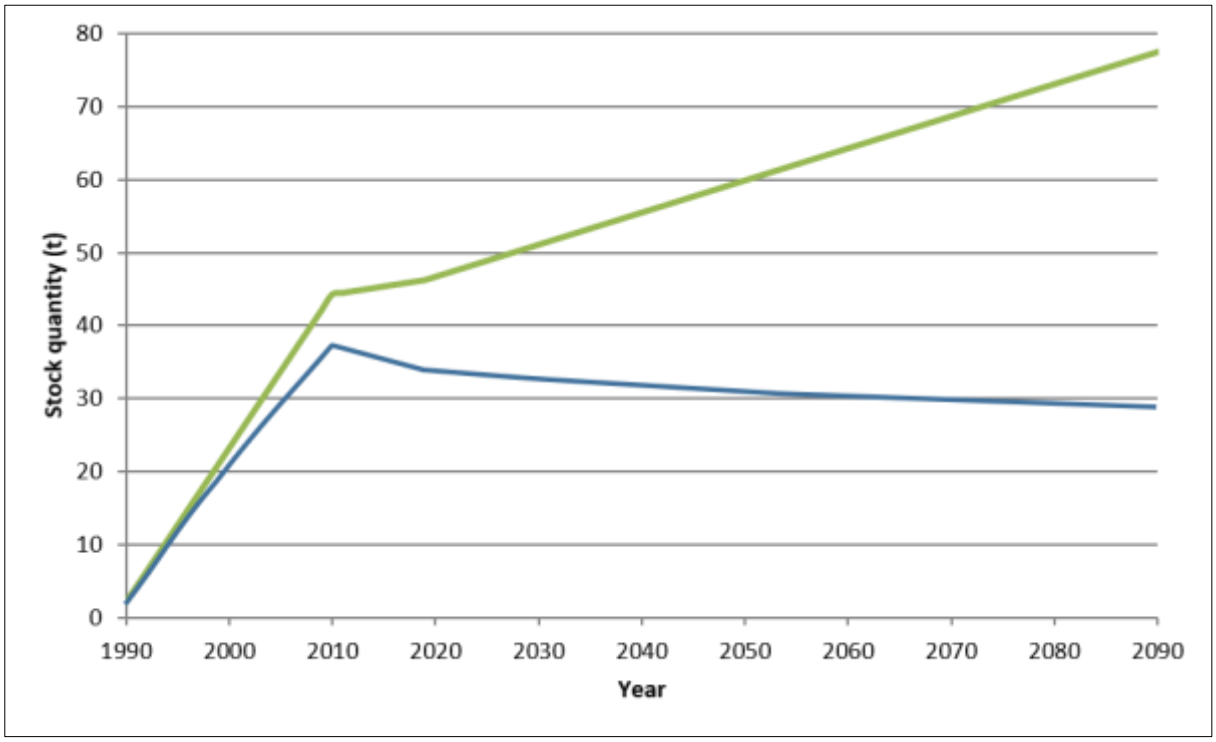


Figure 2. Estimated changes of environmental stocks of PFHxS from 1990 without any degradation (green graph) and with a half-life of 42 years (blue graph). (Figures 5 and 6 in the Background Document combined by the RAC Rapporteurs).

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 has mostly been detected in the lower ng/L range in European surface waters and ground waters, but higher values, 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 levels of PFHxS measured are found in urban and/or industrial areas both in terms of biotic- and abiotic matrices. Environmental monitoring from France indicate increasing trends 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 during 2009 - 2015 has been reported. This indicates that an increase in long-range transport has occurred. 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 has been reported 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, which was the basis 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, via e.g. 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 than PFOS, indicating that global exposure to PFHxS still occur and has not significantly declined since the early 2000s when the phase out of PFOS started.

RAC conclusion(s):

Despite the lack of current identified intentional use of PFHxS, its salts and related substances in the EU, emissions of PFHxS in the EU has been demonstrated by 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 environmental stocks to increase.

Although uncertain, RAC supports the reasoning and estimations from 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.

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

RAC supports the two baseline scenarios (Figure 2), providing a range of possible changes in environmental stocks of PFHxS from a degradation half-life of 42 years to 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, i.e. 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 dominating surface treatments 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. PFHxA is not regulated under REACH, though a restriction proposal is in preparation (ECHA 2019).

During the 15th POPs Review Committee meeting (POPRC-15), where the risk management evaluation of PFHxS under the Stockholm Convention 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. The lifespan of fire-fighting 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 emissions of PFHxS from textiles, continued uses of PFOS and fire-fighting foams does not add up to the estimated current baseline emissions of 220 kg/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 and is thus considered unlikely.

Based on measured emissions of PFHxS from WWTPs, excluding the upper 10th percentile, the Dossier Submitter calculated the current emissions to be 0.22 tonnes/year. From a possible doubling of the emissions, annual emissions of 0.44 tonnes from 2020 onwards were derived. The current emissions and estimations of future emissions are calculated based on measurements of PFHxS as free acid in WWTP effluents. RAC notes that also PFHxS-related substances could be present in WWTP effluents, which would underestimate the estimated emissions. Due to the lack of such data, to what extent this would occur is difficult to estimate. RAC considers the emission calculations to be uncertain, but reasonable, based on the available data.

Environmental and human exposure

PFHxS has been detected ubiquitously in the environment, from close to point sources, where the highest levels have been measured, to remote locations such as the arctic, in abiotic as well as biotic compartments. 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 measured 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 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 (Regulation No 1907/2006 Annex XIII). PFOS-, PFOA- and C9-C14 PFCA-related substances have previously been treated in the same manner under REACH (Regulation No 1907/2006 Annex XVII).

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 Regulation 1907/2006, 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 for PBT/vPvB substances 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. 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. a doubling of the emissions of PFHxS due to substitution from PFOA. To what extent a substitution will occur is uncertain.

The historical emissions of PFHxS, 1.79 tonnes/year during 1990-2010, originates from sampling performed in 2010/2011, i.e. after the restriction on PFOS entered into force in the EU. This could have lowered the emissions also of PFHxS and thus underestimated the historical emissions of PFHxS.

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 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 BD. 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 any eventual risk management measures 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 data 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 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 an information flow in the supply chain for articles that contain above 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 only a few unintentional/intentional/historic uses of PFHxS has been identified in the EU, and there appear to be no current intentional uses, 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 actions to reduce the exposure to PFOS and PFOA may therefore result in increased use of PFHxS or PFHxS-related substances in the EU if regulatory measures are not taken.

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 and that PFHxS will reach remote areas to a greater extent than observed today. Based on the extreme persistence of PFHxS, environmental stocks 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 SEAC and RAC

Summary of proposal:

The high persistence of PFHxS, its salts and related substances implies that ongoing emissions of these substances will build up environmental stocks over time if no risk reducing measures are introduced. Since these substances persist and accumulate in humans and wildlife they 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 substitutes 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 therefore should 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.

SEAC and RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection of human health and the environment across the EU, RAC supports the view that action is required on an EU-wide basis to address 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 also contribute to the parallel global restriction process within the Stockholm Convention.

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

A large variety of emission sources contribute to environmental and human exposure to PFHxS, its salts and related substances. Environmental and human biomonitoring 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 for human health and the environment on an 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 that this process is not applicable to imported articles.

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

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of 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 material and articles made from recycled materials. However, second-hand articles are excluded from the scope.

The proposed concentration threshold for the restriction is the same as 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 PFCAs 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 levels of approximately 4-14%. Substances or mixtures of PFOS, containing PFHxS as an impurity, for allowed uses in the EU are proposed by the Dossier Submitter to be derogated from the PFHxS restriction.

Aqueous film-forming foam mixtures used for fire-fighting already placed on the market and entry into force of this regulation

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

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

The proposed restriction does not cover articles such as textiles placed on the market before the restriction becomes effective. 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 single articles from the market. In addition, to use e.g. a jacket as long as possible before it turns into waste is a sustainable management of resources. This 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 or mixtures as an impurity to PFOS, following the allowed uses of PFOS in the EU.

Concentrated fire-fighting foam mixtures already placed on the market and entry into force of this regulation

RAC supports the proposed derogation for existing AFFFs. The total amount 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 in relation to already emitted quantities of PFHxS, in relation to the estimated current emissions of 220 kg PFHxS/year and to future emissions of 20 kg PFHxS/year under the proposed restriction. These 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 minimise any emissions.

RAC does not support an 18 month transitional period for placing new PFHxS-based AFFFs on the market. RAC is of the opinion that this transition period should be **as short as practically possible**. Although considered unlikely, based on the information provided by the Dossier Submitter, a transitional period does allow import of such AFFFs, which could result in use and emissions of significant amounts of PFHxS.

'Second-hand' market:

RAC agrees with the Dossier Submitter 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 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 for imported articles. Furthermore, PFHxS, its salts and related substances are likely to be emitted from 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 is PFOS and it would thus be inappropriate from a risk perspective to restrict the use of PFOS based on impurities of PFHxS. RAC notes that any reduction in emissions of PFOS will lead to also reduced emissions of PFHxS.

Concentrated fire-fighting foam mixtures already placed on the market

PFHxS has historically been used as the active substance in AFFFs in the EU to fight 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 consider that this amount is low in relation 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 to be unnecessary, is even advised against by AFFF manufacturers (FFFC, 2016), and should therefore be avoided

unless the foam can be appropriately collected and safely disposed of (which seems unlikely). The same recommendation for training exercises was also given in the RAC Opinion for the PFOA restriction (RAC, 2015). This also should 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 or disposed 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, which 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 fire-fighting foams or fire-fighting 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 proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of 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 have 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 yearly PFHxS emissions from textiles of 6.3 kg. However, this can be considered a "worst case" scenario, since it is based on the assumptions that all textiles contain 25 ppb and that all PFHxS in the materials is

emitted. A lowering of the limit value to 2 ppb (proposed in the consultation on the proposal), using the same assumptions, may reduce the yearly 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).

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).

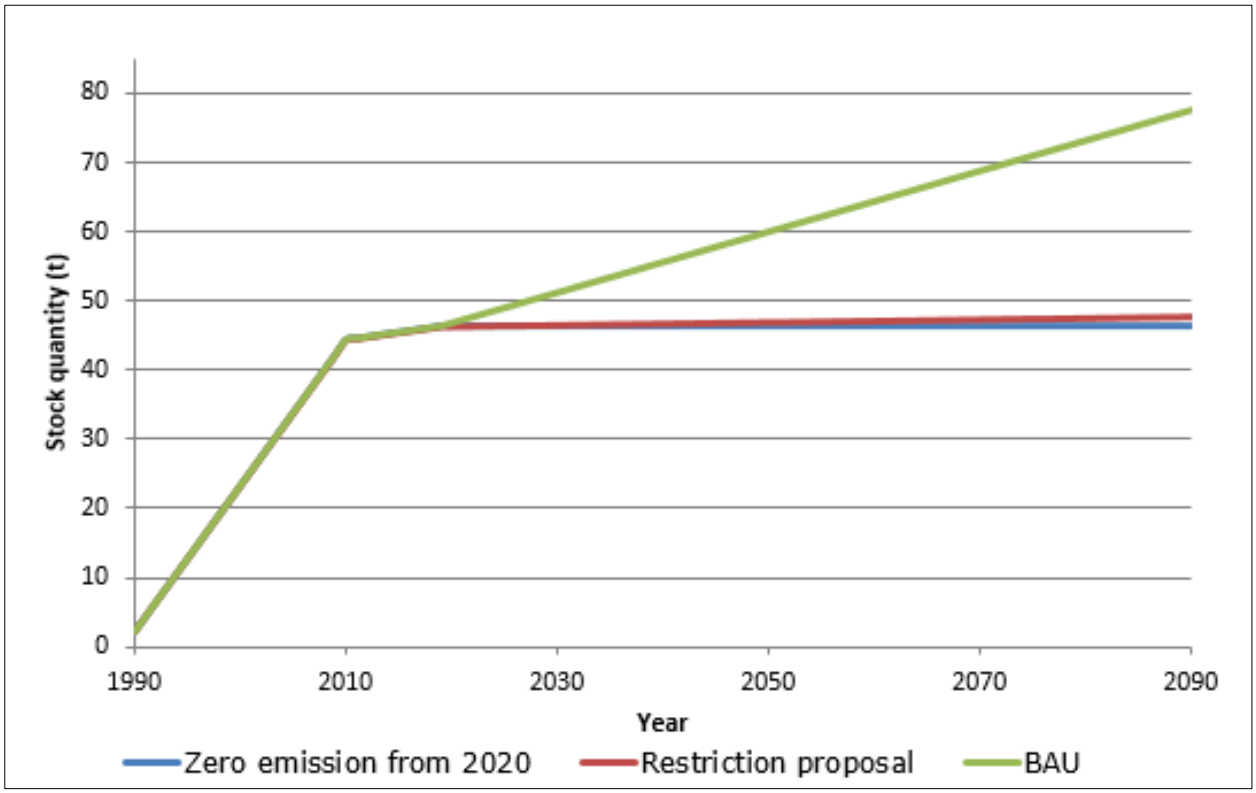


Figure 3. Environmental stock profile under the Baseline (BAU) and Restriction scenarios (no degradation)

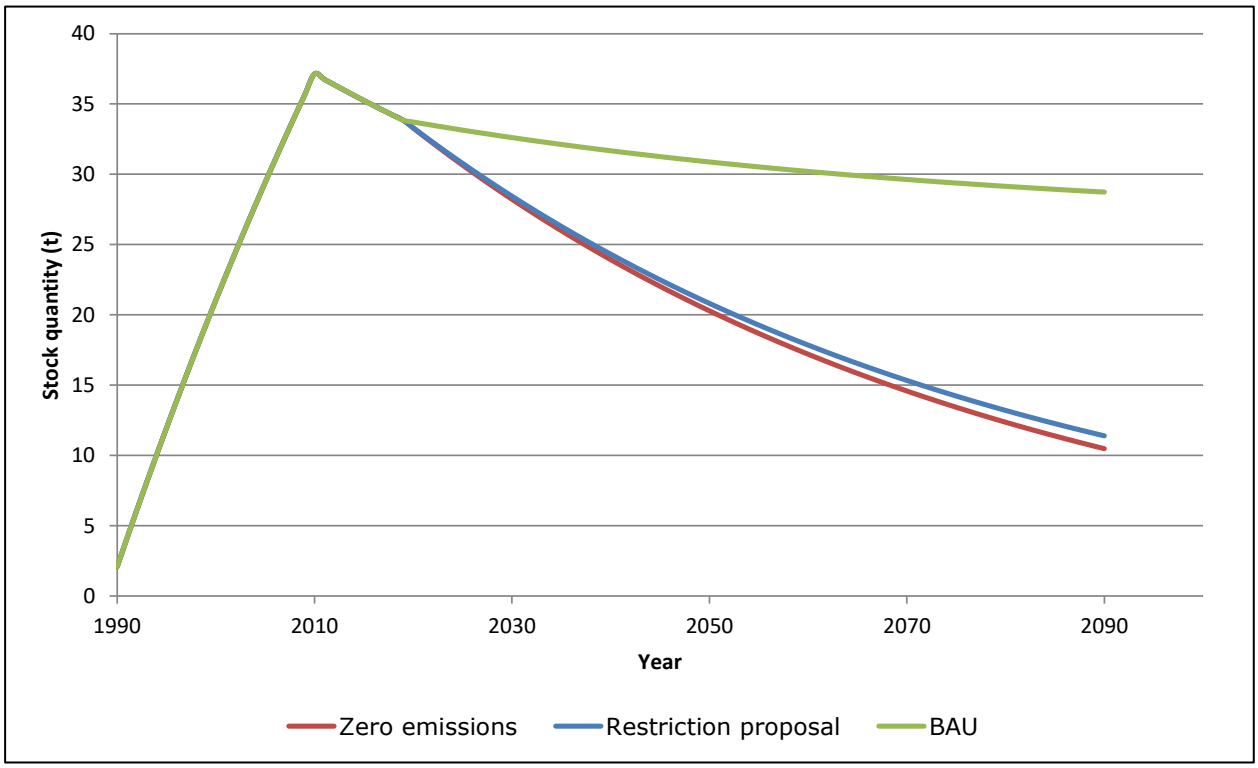


Figure 4. Environmental stock profile under the Baseline (BAU) and Restriction scenarios (half-life 42 years).

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 approximately 6 kg/year. However, the true emission reduction is likely lower, and a 2 ppb limit value has 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 sufficient 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 will occur 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 is supported. The doubling of emissions from 0.22 to 0.44 tonnes/year in the EU are still on a relatively small scale. Based on the fact that 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 for both scenarios. The emission calculations are based on measurements of PFHxS in WWTP effluents. Any PFHxS-related substances present in the effluents, not included in the measurements, would underestimate the 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 proposal:

See the opinion of SEAC.

SEAC conclusion(s):

Add conclusion of SEAC

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Benefits

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Other impacts

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Overall proportionality

Summary of proposal:

See the opinion of SEAC.

RAC and SEAC conclusion(s):

See the opinion of SEAC.

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

See the opinion of SEAC.

Uncertainties in the proportionality section

See the opinion of SEAC.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

Practicality

The Dossier Submitter considers the restriction proposal to meet the requirements regarding practicality. The requirements are similar to those for 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. However, the detection level is also dependent on the sample material measured, and for some matrices (e.g. fire-fighting 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 and SEAC 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 available today. Of the threshold limits discussed; RAC supports the 25 ppb threshold as 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 and SEAC 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 was raised in the consultation. 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 fire-fighting foams - Method for sampling, extraction and analysis by LCqMS or LC-tandem/MS") can be utilised also 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.

Monitorability

The level of quantification for PFHxS (0.06 ppb) is sufficiently low to allow quantification of PFHxS, its salts and related compounds at the proposed threshold limit values. With a threshold of 2 ppb, reliable results can be difficult to achieve for analyses of some matrices. A threshold of 25 ppb is anticipated to provide more reliable results (CRO, 2020). RAC supports the view of Forum that development of an EU-standard for analysis of PFHxS (incl. sampling and extraction) is needed to ensure a uniform enforcement in the EU of the restriction. PFASs are routinely analysed together and commercial analyses are available as analysis packages of groups of PFAS. Thus, RAC support the view of the Dossier Submitter that the enforcement of this restriction can be performed together with enforcement of other existing PFAS restrictions.

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, its salts and PFHxS-related substances and the potential for on-going emissions from environmental sinks such as sediment and soil.

RAC and SEAC conclusion(s):

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

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

Methods are available to measure PFHxS in various environmental matrices and in human blood and there is ongoing environmental monitoring and biomonitoring. RAC agree that due to the extreme persistence of PFHxS, decreasing levels may take a long time to detect in some matrices.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of 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 sufficient to 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 that were not revealed in the data collection process. The potential for this was mitigated by repeated attempts by 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 to identify and consult potential users (including the BiPRO, 2018 study) before the extensive consultation and the

ECHA call for evidence prior to submission. Through these efforts, the Dossier Submitter considers that sufficient opportunities to provide a response have been provided to users, but these consultations have identified either no use or no interest (also implying no use).

Emissions and environmental stocks of PFHxS

The predicted emissions and environmental stocks 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 acted to reduce the industrial component (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. However, the Dossier Submitter does not consider the need for a restriction to entirely depend on this substitution. The thresholds to be implemented on articles (and mixtures) would still provide a reduction in imports 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, that affect the magnitude of the risk and the effect of the suggested risk reduction measures, and does 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 is 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 from "long-chain" PFASs (PFSAs with ≥6 perfluorocarbons, PFCAs with ≥7 perfluorocarbons) to "short-chain" PFASs (PFSAs 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 proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

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