

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/[reference code to be added after the adoption of the SEAC
opinion]**

Agreed

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

PROCESS FOR ADOPTION OF THE OPINIONS

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 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

¹ Delete the unnecessary part(s)

in a separate document which has been published at the same time as the opinion.]]⁶.

Contents

OPINION OF RAC AND SEAC	1
THE OPINION OF RAC	1
THE OPINION OF SEAC.....	1
JUSTIFICATION FOR THE OPINION OF RAC AND SEAC	2
Justification for the opinion of SEAC	2
JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE	4
Effectiveness in reducing the identified risks	12
Socio-economic impact	12
Practicality, incl. enforceability	21
Justification for the opinion of RAC.....	21
Justification for the opinion of SEAC	21
Monitorability	23
Justification for the opinion of SEAC	23
<i>Key elements underpinning the SEAC conclusions:</i>	23
UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC.....	24
REFERENCES.....	27

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

<p>XX. Perfluorohexane sulfonic acid (PFHxS) (linear or branched), its salts and related substances²:</p> <ul 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 [<i>date - 18 months after the entry into force of this Regulation</i>] 2. Shall not from [<i>date - 18 months after the entry into force of this Regulation</i>] 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 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 placed on the market before [<i>date - 18 months after the entry into force of this Regulation</i>]. 4. Paragraph 2 shall not apply to <ul style="list-style-type: none"> (a) substances or mixtures containing PFHxS as an impurity in PFOS³ in applications of PFOS which are derogated from the prohibitions in Article 3 of Regulation (EC) No 1021/2019; (b) concentrated fire-fighting foam mixtures that were placed on the market before [<i>date - 18 months after the entry into force of this Regulation</i>] and are to be used, or are used in the in the production of other fire-fighting foam mixtures.
--	---

THE OPINION OF RAC

See the opinion of RAC.

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.

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)

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC

Summary of the 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 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 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 dossier, 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 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 process 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 regulations on national level.

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

Justification for the opinion of SEAC

Summary of the 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 fire-fighting 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 fire-fighting 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 the industry outside 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, inside and outside the EEA, PFHxS substances could become the substitutes of choice for both PFOS and PFOA. 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 fire-fighting 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 of PFOA.

Scope

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

Concentration limits:

SEAC notes that the concentration limits for mixtures or articles proposed by the Dossier Submitter, i.e. < 25 ppb (i.e. 25 µg/kg) and 1000 ppb, match with those included in the restriction of PFOA, its salts and related substances.

SEAC recalls that the limit values set for the PFOA restriction were established after balancing several different factors. The limit values chosen were intended to balance between the possible presence of unavoidable impurities in alternative substances, the often low concentrations of the substances in some articles, and the capabilities of analytical methods. SEAC considers that the same factors are relevant in this case. The substances covered are close relatives to PFOA with comparable properties, and the analytical methods expected to be used are similar to or the same as those 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 (POP) proposes a time limited higher concentration limit of 1 ppm for PFOA and its salts in PTFE micro powders. This is to allow a 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 not contested during the consultation of the Annex XV dossier.

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

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. 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.

SEAC considers that such a timeframe should also be sufficient for ensuring that imported substances, mixtures and articles comply with this restriction proposal. Furthermore, SEAC notes that such transition period would not have negative impacts on the supply chain because articles already placed on the market would be exempted.

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 transition time would

enable their preparation and thereby improve the enforceability and practicality of the restriction.

The restriction of PFOA enters into effect in July 2020. This restriction on PFHxS, its salts and PFHxS-related substances has been proposed well in advance of that date, such that the industry should already be aware of it, and SEAC expects that a transition period of 18 months is short enough to discourage substitution of PFOA with PFHxS compounds.

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 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;
- Articles placed on the market before the end of the transition period (including second hand articles).

Exempted uses of PFOS

Perfluorooctane sulfonic acid is restricted by the 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 a 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 on the market there are fluorine-free, chemical alternatives, e.g. alkane sulfonates, for hard chromium (VI) plating available, as well as effective technical solutions to minimise aerosol emission, 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 larger than the negative impacts of using PFOS – it would therefore make no sense to purify PFOS for PFHxS impurities either; and
- the Commission already concluded that the derogations under the PFOS restriction are justified,

SEAC agrees that the proposed restriction would include the same exemption already agreed for the PFOS restriction to avoid that the proposed restriction undermines the uses exempted

under the PFOS restriction.

Fire-fighting foams

Point 4(b) in the entry of the proposed restriction derogates 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.

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

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 notes that, according to the restriction proposal, based on the stakeholder consultations by the Dossier Submitter, Aqueous Film-Forming Foams (AFFF) 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 fire-fighting 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 fire-fighting 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 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 the industry. SEAC considers this an uncertainty factor underlying the analysis.

Concerning the costs and benefits of replacing fire-fighting foams containing PFHxS in stock.

SEAC notes that the costs have not been estimated in the Background Document of this restriction proposal. Partially based on earlier experience in evaluating restriction proposals on similar substances, SEAC expects that applying the restriction to concentrated fire-fighting 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 fire-fighting 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 fire-fighting 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 these foams 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 fire-fighting foams containing alternative substances, no derogation for training or testing was recommended for fire-fighting 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 fire-fighting foam mixtures to be used, or used in the production of other fire-fighting foam mixtures, SEAC considered whether for PFHxS-containing AFFFs a longer or a shorter transition period (or even no transition period at all) than that of 18 months suggested by the Dossier Submitter would be a better solution.

- 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 year, implying additional environmental emissions compared to the situation of absence of a transition period or of a shorter transition period. SEAC agrees with the conclusion in the Annex XV dossier and considers this potential future import to be quite unlikely, since currently it is not happening, and other alternatives to PFOA-based AFFFs are available and widely used (including AFFFs based on C6 chemistry). However, SEAC also keeps in mind 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 restriction is violated. 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 have only minimal additional releases from washing. Moreover, enforcement would only have very limited effect since articles containing PFHxS, its salts and PFHxS-related substances would be removed from the market one by one. Lastly, a longer use of second-hand articles represents a sustainable management of resources.

In line with the PFOA and the C9-C14 PFCA restrictions, considering the above arguments, SEAC considers this derogation to be justified by practicality and enforcement reasons.

SEAC notes that the Forum recommends shifting the burden of proof of the date of first placing on the EEA market on to 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 industry within the EU as a waterproofing and stain resistant textile treatment. 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 differing information 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 the existence or wideness of 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

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of the 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, fire-fighting 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).

Anyway, 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 to 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 should be 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 regards 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 of the fact that currently the imports of textiles containing PFHxS 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 **fire-fighting foams**, based on the information available from stakeholder consultations and from the consultation of the Annex XV dossier, SEAC agrees with what is stated in the Background Document, 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 fire-fighting 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, currently the 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 for substituting PFOA by 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 in 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 case the Dossier Submitter referred to information in the Background Document of the PFOA restriction proposal to illustrate the possible economic costs for not being able to use C9-C14 PFCAs as substitutes of PFOA. The reasoning there was that the 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., the 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 is not 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 of 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 of administrative costs for 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 both by industry and by enforcement authorities. Specific testing costs for PFHxS have not been estimated by the Dossier Submitter.

SEAC regards that testing costs for PFHxS per analysis are in principle expected to be similar to those of 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 cuts down the need to do 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 for as long 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 reported 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, currently commercial laboratories 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 €485.⁴ 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

⁴ <https://analyiskatalog.euofins.se/Search/SearchView>

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 trickle down 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 emerge 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 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
- European and non-European companies will need to keep their market shares and market position in front of their competitors hence major increases of consumers prices 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 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. They accumulate in the environment, have long-range transport potential and once in the environment, are almost impossible to remove. Impacts in the long term are largely not known. The proposed restriction would prevent future accumulation of these substances 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 is challenging in case of vPvB substances such as PFHxS. 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.*⁵

While the main objective of the restriction proposal was the reduction of environmental emissions and stock, SEAC notes that also benefits for **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 firemen's blood. 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 on remediation costs of sites contaminated by PFAS can be found in literature. The dossier specifically quotes cases from Germany and Norway where the costs of remediating sites contaminated by PFAS due to fire-fighting activities rose up to 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 chosen alternative substances 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 indeed PFHxS, its salts and PFHxS-related substances are one group of substances in the family of fluorotelomer substances. 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 PFASs 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.

⁵ https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3

Other impacts

Summary of the 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 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. Most probably 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 respective actions relating to 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. These are vPvB substances for which no safe level of exposure can be established, and emissions should therefore be minimised as far as possible. 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 any regrettable substitution of PFOA with PFHxS. Even if the likelihood of this regrettable substitution happening 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 proportional.

Key elements underpinning the SEAC conclusions:

SEAC highlights that it is very complex to estimate the benefits for vPvB substances. Therefore, for the proposed restriction, as well as for other similar cases, SEAC recognises the challenges in demonstrating the proportionality.

Currently, the 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 in 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 underground drinking water sources, hence to limit high remediation costs which could incur in the future from the need of decontamination. 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

<p>Benefits</p>	<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
<p>Costs</p>	<ul style="list-style-type: none"> • Some minor costs related to substitution from PFOA to shorter chain or non-fluorinated alternatives instead of to PFHxS. <p>Some testing cost for industry (but limited if tested together with 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

Justification for the opinion of SEAC

Summary of the 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 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 contents 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 will be developed. SEAC also points out that even though suitable analytical methods with sufficiently low limits of quantification appear to be widely existent, applying them for quantifying PFHxS-related substances in a sample is not simple. Unlike for PFOA, a method capable of finding out the united content of all the related substances does not seem to be 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 content 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 establish inspections.

As to the 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 finding out the united content of all PFHxS-related substances does not seem to be 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 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 programs, cooperation with Member States' laboratories, etc.). The Forum highlights that the 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 the PFHxS substances, ensuring uniform enforcement across the EU can be challenging. SEAC finds that time is required for the development of standardised analytical methods.

The Forum also recommended to investigate possibilities to elaborate standards which combine different similar restrictions (PFOS, PFOA, C₉-C₁₄ PFCA, and PFHxS) in order to avoid excessive budgetary burden. SEAC agrees with this recommendation.

For imported articles, compliance control can be accomplished 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, earlier 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 SEAC

Summary of the proposal:

A time trend monitoring can be performed with samples from the environment, from animals or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring. It is underlined in the dossier that it may take a very long time before being able to detect downward trends in concentrations of PFHxS and related substances, due to their persistence and to the potential for on-going releases from environmental sinks such as sediment and soil.

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

Summary of the 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 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,	Dependent on the extent of avoided use, and prices of alternatives	Avoidance of future use and therefore of emissions in the EEA

placing on the market (including import) and use in EEA MOST LIKELY	Limited, because there are other alternatives in the same price range	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 price range	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 avoided imports and resulting emissions

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 it is not of a 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 regulations phasing out fluorinated substances at European and international level, would choose a safer non-fluorinated alternative whenever feasible to avoid having to substitute once again in a relatively short period of time. Therefore, SEAC considers that there is little uncertainty on the fact that substitution will be done towards safer non-fluorinated alternative substances whenever possible hence implying benefits to human health and the environment.

On the side of **costs**, 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 extremely few 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 where the observed and estimated emissions originate from. SEAC therefore views the conclusions with reservation.

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

REFERENCES

RAC/SEAC, 2015b. *Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals*. Helsinki: ECHA.

UNEP/POPS/POPRC.14/6, 2018: Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting available at <http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC14/Overview/tabid/7398/Default.aspx>