

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

# Opinion

on an Annex XV dossier proposing restrictions on Per- and polyfluoroalkyl substances (PFASs)

# ECHA/RAC/RES-O-0000007226-75-01/F ECHA/SEAC/xxx

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted [xx Month 20xx]) and SEAC's opinion (adopted [xx Month 20xx])

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Draft date: 15/03/2023

# OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON PFAS IN FIRE-FIGHTING FOAMS

15/03/2023

ECHA/RAC/RES-O-0000007226-75-01/F

[Date]

[SEAC opinion number]

# Opinion of the Committee for Risk Assessment

and

# **Opinion of the Committee for Socio-economic Analysis**

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

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

Chemical name(s): Per- and polyfluoroalkyl substances (PFASs)

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

ECHA 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 <a href="https://echa.europa.eu/restrictions-under-consideration">https://echa.europa.eu/restrictions-under-consideration</a> on 23 March 2022. Interested parties were invited to submit comments and contributions by 23 September 2022.

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

ADOPTION OF THE OPINION OF RAC:

# OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON PFAS IN FIRE-FIGHTING FOAMS

Rapporteur, appointed by RAC: Malcolm DOAK

Co-rapporteur, appointed by RAC: Bridget GINNITY

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 **13/03/2023**.

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 of all members having the right to vote.

#### ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Jean-Marc BRIGNON

Co-rapporteur, appointed by SEAC: Johanna KIISKI

#### 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 10/03/2023.

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 <a href="https://echa.europa.eu/restrictions-under-consideration">https://echa.europa.eu/restrictions-under-consideration</a> on **15/03/2023**. Interested parties were invited to submit comments on the draft opinion by **15/05/2023**.

#### 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]]**.

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and] 71(1) of the REACH Regulation.] [No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and]<sup>Error! B</sup> ookmark not defined. 71(1)].

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.].

# OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON PFAS IN FIRE-FIGHTING FOAMS

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# 1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Table 1: Proposed restriction entry

Column 1	Column 2		
Per- and polyfluoroalkyl substances (PFAS) defined as: any substance that contains at least one fully fluorinated methyl (CF <sub>3</sub> ) or methylene (CF <sub>2</sub> ) carbon atom (without any H/CI/Br/I attached to it).	<ol> <li>Where the concentration of total PFAS is greater than 1 mg/L<sup>1</sup>, shall not, as a constituent of a firefighting foam, be</li> <li>a. placed on the market or</li> <li>b. formulated.</li> </ol>		
[The ancillary requirement in paragraph 7 of column 2 of this entry applies to all firefighting foams, whether or not they contain a substance falling within this column of this entry.]	Paragraph 1.(a) shall apply 6 months after entry into force of the restriction for a constituent of a firefighting foam in portable fire extinguishers (defined by EN3-7, EN-1866 and EN-16856) and 10 years after entry into force of the restriction otherwise.  Paragraph 1.(b) shall apply 10 years after entry into force of the restriction.  2. Shall not be <b>used</b> <sup>2</sup> as a constituent of a firefighting		
	foam, including in portable fire extinguishers (defined by EN3-7, EN-1866 and EN-16856), where the concentration of total PFAS is greater than 1 mg/L.		
	3. Paragraph 2 shall apply from:		
	<ul> <li>a. 18 months after entry into force for training and testing (except testing of the firefighting systems for their function);</li> </ul>		
	<ul> <li>b. 18 months after entry into force for municipal fire services (except if also in charge of industrial fires for establishments covered by paragraph 3.(e) and for use in these establishments only);</li> </ul>		
	<ul> <li>three years after entry into force for civilian ships including tankers, ferries, tugboats and other commercial vessels;</li> </ul>		

 $<sup>^{1}</sup>$  Corresponding to 1 000 ppb, or 0.0001% (w/v).

<sup>2</sup> Under REACH, "use" means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. Please note that, in this opinion, formulation is addressed separately from the use.

Column 1	Column 2			
	<ul> <li>d. five years after entry into force for civilian aviation (including in civilian airports) and defence;</li> <li>e. 10 years after entry into force for establishments covered by the Directive 2012/18/EU (Seveso III)<sup>3</sup> (upper and lower tiers) if they are not already covered by paragraph 3.(d);</li> <li>f. five years after entry into force for all other uses not covered by paragraphs 3(a), 3(b) 3(c), 3(d) and 3(e).</li> <li>g. five years after entry into force for portable fire extinguishers as defined by EN3-7, EN-1866 and EN-16856 placed on the market before 6 months</li> </ul>			
	after entry into force;			
	4. Without prejudice to paragraph 3, six months after entry into force users of a firefighting foam mixture, excluding in portable fire extinguishers (defined by EN3-7, EN-1866 and EN-16856), where the concentration of total PFAS is greater than 1 mg/L shall:			
	<ul> <li>a. ensure that they are only used for fires invol flammable liquids (class B fires);</li> </ul>			
	b. minimise emissions to the environment and direct and indirect human exposure to firefighting foams to the extent that is technically and economically feasible.			
	c. establish a site-specific 'PFAS-containing firefighting foams management plan' which shall include:			
	<ul> <li>i. a justification for the use of each mixture for firefighting foam where the concentration of total PFAS is greater than 1 mg/L (including an assessment of the technical and economic feasibility of alternatives).</li> </ul>			

 $^3$  Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances.

Column 1	Column 2
	ii. details of the conditions of use and disposal of each PFAS containing foam used on site specifying how paragraph 4(b) is achieved (including plans for the containment, treatment and appropriate disposal of liquid and solid wastes arising in the event of foam use, routine cleaning and maintenance of equipment or in the event of accidental leakage/spillage of foam).
	iii. The management plan shall be reviewed at least annually and be kept available for inspection by enforcement authorities on request.
	d. Ensure that the collected PFAS-containing waste resulting from the professional and industrial use of firefighting foams, where firefighting foams had a concentration of PFAS above the one mentioned in paragraph 2 shall be handled for adequate treatment. The treatment shall minimise releases of PFAS to environmental compartments as far as technically and practically possible and shall exclude sewage treatment, irrespective of any pre-treatment. For each event of foam use or accidental spillage or leakage, proof of appropriate management and disposal of the foam concentrates, water-added foams and fire run-off waters shall be documented and kept available for enforcement authorities.
	5. From six month after entry into force, a firefighting foam mixture containing PFAS above the threshold indicated in paragraph 2 which is held in stock and needs to be disposed of shall be handled for adequate treatment. The treatment shall minimise releases of PFAS to environmental compartments as far as technically and practically possible and excluding any sewage treatment, irrespective of any pre-treatment. Proof of appropriate disposal shall be documented and kept available for enforcement authorities.
	6. From six months after entry into force, packaging of a firefighting foam placed on the market or used, excluding in portable fire extinguishers (defined by EN3-7, EN-1866 and EN-16856), in concentrations above the one mentioned in paragraph 2 as well as

Column 1	Column 2	
	containers of firewater runoffs or other PFAS-waste in relation with the use of firefighting foams or the cleaning of firefighting foam equipment where the PFAS concentration in the foam was above the one mentioned in paragraph 2 shall all be labelled indicating the presence of PFAS above this threshold with the following wording: "WARNING: Contains per- and polyfluoroalkyl substances (PFAS)". This information shall be displayed in a clear and visible manner in the official language(s) of the Member State(s) where the mixture for firefighting is placed on the market, unless the Member State(s) concerned provide(s) otherwise.	
	7. From six months after entry into force, packaging of a firefighting foam placed on the market containing organofluorine substances above 1 mg/L, but where the concentration of total PFAS is not greater than 1 mg/L, shall be labelled: "Contains non-PFAS organofluorine substances with a total organofluorine concentration of (insert concentration) mg/L". This information shall be displayed in a clear and visible manner in the official language(s) of the Member State(s) where the mixture of firefighting is placed on the market, unless the Member State(s) concerned provide(s) otherwise.	

Note: The original restriction proposal has been revised by the Dossier Submitter based on comments received in the consultation, and the version above is thus the revised proposal that this opinion is referring to.

# 1.1. THE OPINION OF RAC

[Text]

# 1.2. 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. As concluded by RAC, SEAC considers that [provided that a review on the availability of alternatives for Seveso installations is carried out before the end of the time-limited derogation for this sector] the restriction proposed by the Dossier Submitter on Per- and polyfluoroalkyl substances (PFAS), CAS -, EC - Is the most appropriate Union wide measure to address the identified risks, taking into account the proportionality of its socio-economic benefits to its socio-economic costs as demonstrated in the justification supporting this opinion.

Regarding the transitional periods proposed by the Dossier Submitter, SEAC considers that some transition periods may need to be extended, however, SEAC lacks detailed enough information to recommend a specific length. The relevant transitional periods include the following:

- · Use by municipal fire brigades,
- Placing on the market of PFAS-containing fire extinguishers, and
- Use in the marine sector.

The definition of the sectors covered by a long transitional period might also need some adaptation. Further information on the advantages and disadvantages of extending these transitional periods and modifying their scope may be received in the consultation on the SEAC draft opinion.



# 2. SUMMARY OF PROPOSAL AND OPINION

# 2.1. Summary of proposal

This restriction proposal aims at reducing risks to health and the environment from the use of per- and polyfluoroalkyl substances (PFASs) in firefighting foams.

Firefighting foams are used for extinguishing fires that involve flammable liquids ("class B fires") by a variety of sectors (e.g., oil/(petro-)chemical sector, municipal fire brigades, marine, airport, defence and ready-for-use products). By far, the largest sector of use is the oil/(petro-)chemical industry. Such foams are used both for training and in a variety of 'live' fire incidents, ranging from small fires to large tank fires. Overall, an estimated 18 000 tonnes of foam – or 60 % of total foams – used in the EU annually contain PFASs.

The main function of PFASs in firefighting foams is to act as a surfactant, or in other words to form a film over the surface of a burning liquid in order to prevent flammable gases from being released from it as well as to prevent it from reigniting.

PFASs have attracted regulatory scrutiny due to their ubiquitous persistency in the environment. If releases of PFASs are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects are likely. By then, exposure is practically irreversible.

PFASs are a family of thousands of synthetic chemicals with a variety of additional hazardous properties. Most are mobile in water and therefore lead to contamination of groundwater, surface water and biota. This is in particular a concern where drinking water sources are affected. Some PFASs are suspected carcinogens, cause harm to the developing child and trigger effects at low concentrations in organs such as the liver or in the immune system. There are some indications that PFASs are potential endocrine disruptors. However, for most PFASs there are insufficient data to adequately assess their effects on human health and the environment.

Due to the above-mentioned hazardous properties, a quantitative risk assessment is not appropriate, but releases of PFASs should be minimised in accordance with paragraph 0.10 of Annex I to REACH.

Whilst some PFASs are already restricted in firefighting foams either in the EU or internationally (e.g., PFOS, PFOA, C9-C14 PFCAs and related substances) or are proposed for future risk management in the EU (e.g., PFHxS and PFHxA), additional PFASs have been reported by industry for use in firefighting foams. Novel unregulated PFASs could theoretically be developed for use in firefighting foams in the future. The precise identities of the PFASs currently used in firefighting foams are largely unknown due to manufacturer confidentiality. Consequently, a restriction covering the **whole PFAS class**, rather than specific PFASs or groups of related PFASs, is appropriate to address the risks from PFASs in firefighting foams, including those arising from so called 'regrettable substitution' in the future.

Alternative (fluorine-free) firefighting foams are available and have been successfully used in the sectors identified above. However, use of alternatives in certain specific scenarios (i.e., for fires in large flammable liquid storage tanks and at installations using multiple different flammable liquids) is not yet widespread pending the successful conclusion of performance

tests for alternative foams and application methods for these scenarios<sup>4</sup>. To minimise the adverse socio-economic impacts associated with the phase out of PFAS-containing foams, including any potential to compromise fire safety, specific transitional arrangements (i.e., transitional periods) are proposed by the Dossier Submitter for each type of use and user sector where alternatives are not yet readily available. The restriction proposal includes an obligation for users to prepare 'PFAS-foam management plans' and apply best-practice risk management measures to continue to use PFAS-containing foams during any applicable transitional period.

Regarding an appropriate concentration limit for PFASs in foams and equipment that previously used PFAS-containing firefighting foams, stakeholder input suggests that a PFAS concentration of 1 mg/L can be achieved using a relatively simple cleaning process and would avoid the majority of emissions.

The Dossier Submitter concluded that the risks from PFASs in fire-fighting foams are not adequately controlled. An analysis of several risk management options (RMO) was conducted to identify the most appropriate measure to address the risk and to define the scope and conditions of the restriction proposal. The Dossier Submitter concluded that a restriction under REACH is the most appropriate RMO. The following five restriction options (RO) were analysed:

- RO1: Restriction on the placing on the market but use continued to be allowed until expiry date of the stocks;
- RO2: Restriction on the placing on the market and use after use/sector-specific transitional periods;
- RO3: Restriction on the formulation, placing on the market and use after use/sectorspecific transitional periods;
- RO4: Restriction on the placing on the market and use after use/sector-specific transitional periods, with a derogation mechanism via a permit system to which only Seveso establishments and defence sites would be eligible;
- RO5: Restriction on the placing on the market and use for all uses after sector/usespecific transitional periods, unless adequate risk management measures are in place to capture all the emissions to the environment.

# 2.2. Summary of opinion

## 2.2.1. RAC opinion summary

[Text]

### 2.2.2. SEAC opinion summary

Based on the key principle of maintaining the free movement of goods within the Union, and also considering the need to minimize cross-border pollution within the EU, SEAC concludes

<sup>&</sup>lt;sup>4</sup> Alternatives to PFAS-containing foams have mostly been tested in small-scale tests as specified in technical standards against a limited number of flammable liquids. Fluorine-free foams behave differently to PFAS-containing foams and show more variability in their performance. However, large-scale tests have also demonstrated satisfactory technical performance under certain conditions. Additional testing with other flammable liquids in a more complete range of fire scenarios is ongoing to ensure the effectiveness of fluorine-free firefighting foams. Since large fire incidents are rare and large fire testing is costly, it requires some time to gain practical experience in such challenging fire scenarios. Importantly, it is not only the foam itself which needs to be considered, but the performance of the foam in combination with (i) the flammable liquid to be tackled and (ii) the foam application method (application system and application parameters).

that any necessary action to address risks associated with PFAS in firefighting foams should be implemented in all Member States. Furthermore, SEAC agrees with the Dossier Submitter that a restriction under REACH is generally the most appropriate approach compared to other EU-wide regulatory Risk Management Options, including previously proposed REACH Restrictions as well as other REACH-related measures and non-REACH measures.

In regard to the analysis of alternatives, SEAC concludes that the Dossier Submitter's investigation of the availability of suitable alternatives is comprehensive and complete as far as availability and accuracy of information allowed. Based on the information presented in the Background Document and considering the comments received in the consultation on the Annex XV Dossier, SEAC concludes that technically and economically feasible fluorine-free alternatives are available and can be implemented in most (but potentially not all) sectors/uses by the end on the proposed transition periods. A sector/use for which the appropriate performance of fluorine-free alternatives is considered to be not yet fully demonstrated is the use by certain types of Seveso installations. Because the consequences of reduced fire safety could potentially be disastrous, SEAC considers that a review of the substitution status before the end of the transitional period for Seveso establishments would be needed to address the remaining uncertainty about the successful future implementation of alternatives. SEAC takes note of the RAC conclusion that hazards and corresponding risk associated with alternatives are likely to be significantly lower than those associated with PFAS-based firefighting foams, with the possible exception of siloxane-based alternatives.

With respect to the cost assessment, SEAC has no major reservations about the calculation methods and finds that the cost assessment provides a reliable indication of the possible order of magnitude of costs of the different restriction options considered by the Dossier Submitter. However, SEAC has some reservations with regard to several assumptions the Dossier Submitter had to make for specific calculations because of incomplete or missing information. SEAC considers that the identified unclear aspects could have an impact on the outcome of the cost assessment, as it is possible that the sensitivity analysis carried out by the Dossier Submitter does not sufficiently address the presumably wider cost variations. Overall SEAC's analysis suggests that costs could be underestimated, maybe significantly, but SEAC believes they should reflect the correct order of magnitude.

On the topic of the benefits of the proposed restriction, SEAC agrees with the approach taken by the Dossier Submitter to assess the benefits through the consideration of the proxy of avoided emissions. SEAC notes RAC's conclusion that the estimates of avoided PFAS releases presented by the Dossier Submitter are reliable and allow to assess the effects of the proposed restriction. However, SEAC also notes RAC's finding that release reductions could be overestimated based on the assumption that all foams used are eventually discharged to the environment and the possibly optimistic assumptions about the abatement effectiveness of incineration processes. Overall, SEAC finds that relatively similar values of total emission reduction are expected to be achieved in the different ROs. Based on total emission reduction, the benefits of the different restriction options appear to be very similar. The highest potential reduction of PFAS emissions is expected for RO3 (94 %).

In terms of other impacts of the proposed restriction, SEAC finds that several impacts are not fully captured by the assessment of costs and benefits. Some of these impacts are expected to be positive (e.g. avoided environmental remediation costs) and some could be negative (e.g. consequences of uncontrolled fire events that could theoretically occur if alternatives do not perform as well as PFAS foams by the end of allowed transitional periods). While the former kind of impacts would improve the cost-benefit relationship of the proposed restriction, the latter kind of impact prompted SEAC to recommend a review of the substitution status before the end of the transitional period for the most demanding firefighting foam uses (incl. the Seveso sector). Further considerations by SEAC in the context of other impacts cover greenhouse gas emissions, industry competitiveness and additional benefits of avoided emissions on human health and environmental quality.

SEAC finds that the proposed restriction option, RO3, appears to be proportionate (and so do all other ROs). While the proposed scope and length of the transitional periods appear to be broadly appropriate, there are some remaining reservations about a few specific cases. SEAC agrees with the Dossier Submitter that RO3 has the potential to be most effective in terms of emission reduction by a certain date in the future, but a review of the availability and technical performance of alternatives to PFAS-containing firefighting foams in the Seveso sector is recommended by SEAC in order to reduce remaining uncertainty about unwanted impacts of the restriction in terms of fire safety. This review should be based as much as possible on local information from Seveso sites (and more generally high fire hazard sites) and should be as exhaustive as possible to capture any specific circumstances requiring an extension of the transitional period. Furthermore, SEAC considers that the proposed limit value of 1 ppm (1 mg/l) appears appropriate for mixtures placed on the market, but that the limit value for cleaning of already contaminated equipment should be set higher, at least for the offshore sector.

SEAC concludes that RO1, RO2, RO3 and RO4 are in general practicable, but considers that RO5 is not practicable due to difficulties with arranging and enforcing a full containment. SEAC agrees with RAC concerning the recommendations to provide guidance, review the overlap with other restrictions and investigate the feasibility of recycling unused PFAS-containing firefighting foam. Based on the available information, SEAC further agrees that all the restriction options are monitorable.

SEAC has evaluated qualitatively the uncertainties in the cost assessment and has noted the possible magnitude of benefits other than that of emission reductions. Overall, SEAC finds that the identified uncertainties, despite being significant, do not seem to compromise the conclusion of SEAC proportionality assessment. However, the analysis of uncertainties (especially in regard to the suitability of alternatives without any reduction in their efficiency to control fires in every situation) has led SEAC to conclude that RO3 should be combined with a review of the substitution progress before the end of the time-limited derogation for the Seveso sector.

# 3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

# 3.1. IDENTIFIED RISK

# 3.1.1. Targeting of the proposed restriction

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

RAC conclusion(s):

[Text]

**Key elements underpinning the RAC conclusion:** 

[Text]

#### 3.1.2. Risk assessment

# 3.1.2.1. Hazard(s)

**Summary of Dossier Submitter's assessment:** 

[Text added by ECHA-S]

RAC conclusion(s):

[Text]

Key elements underpinning the RAC conclusion(s):

[Text]

# 3.1.2.2. Emissions and exposures

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

RAC conclusion(s):

[Text]

Key elements underpinning the RAC conclusion(s):

[Text]

#### 3.1.2.3. Risk characterisation

**Summary of Dossier Submitter's assessment:** 

[Text added by ECHA-S]

RAC conclusion(s):

[Text]

Key elements underpinning the RAC conclusion(s):

[Text]

3.1.2.4. Existing risk management measures and operational conditions

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

RAC conclusion(s):

[Text]

Key elements underpinning the RAC conclusion(s):

[Text]

3.1.2.5. Uncertainties in the risk assessment

**Summary of Dossier Submitter's assessment:** 

[Text added by ECHA-S]

RAC conclusion(s):

[Text]

Key elements underpinning the RAC conclusion(s):

[Text]

# 3.2. JUSTIFICATION THAT ACTION IS REQUIRED ON A UNION WIDE BASIS

# Summary of Dossier Submitter's assessment:

PFAS-containing firefighting foams are used throughout the EU/EEA and result in considerable releases to the environment. As indicated before, due to the properties of these substances, releases are considered as a proxy for risk to the environment and human health and should be minimised. The use of PFASs in firefighting foams is therefore associated with a risk to the environment - and human health via the environment - that is not adequately addressed by the current measures in place. Even if additional measures were introduced at Member State level, there is potential for discrepancies in the definitions and scope of any national restrictions (e.g. definition of substances covered, uses covered, concentration thresholds, transition periods, etc.). This has negative implications for the functioning of the internal market. As firefighting foams are being traded over the national borders within the EU, different restrictions in different Member States could make it very challenging to make firefighting foam products available for sale across the Member States. The principle of the internal market foresees that goods can move freely within the European Economic Area, enabling an open and competitive economic environment. It would therefore not be in the meaning of this principle to restrict PFAS-containing firefighting foams nationally. Moreover, due to their persistence and other supporting hazard concerns such as mobility, it is likely that PFASs emissions lead to cross-border pollution, making harmonised regulatory

management on EU-level even more important.

#### RAC conclusion(s):

[Text]

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

[Text]

#### SEAC conclusion(s):

Based on the key principle of maintaining the free movement of goods within the Union, and also considering the need to minimize cross-border pollution within the EU, SEAC concludes that any necessary action to address risks associated with PFAS in firefighting foams should be implemented in all Member States.

# Key elements underpinning the SEAC conclusion(s):

Considering the properties of the substances, as confirmed by RAC - including high persistence and long-range transport potential – and noting that exposure may take place in all Member States (MS), SEAC agrees that regulatory measures on a national basis would not adequately manage the risks arising from PFAS contained in firefighting foams. Although SEAC agrees that action is needed on an EU-wide basis in order to avoid releases into the environment (and resulting in long-term human and environmental exposure), it recognises the challenges related to estimating the effectiveness, efficiency and proportionality of an EUwide measure in the case of persistent and in some cases also mobile pollutants that may exhibit long-range transboundary movement if released to the atmosphere. Using emissions as a proxy for risks reflects solely the initial input flow to the environment of the substances. It ignores the implications of persistence and mobility. Furthermore, 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 within the EEA and across EEA borders and on the respective impact on actual stocks would improve the analysis on the effectiveness of the EU-wide measure. However, such information is not available, neither to the Dossier Submitter, nor to SEAC.

SEAC also agrees that an EU-wide measure is required to avoid potential national discrepancies between MS regarding the definition of PFAS, or difference in scope, that could be a cause of trade and competition distortions and could delay the reduction in emissions of PFAS compared to a union-wide measure. It is considered that an EU-wide restriction would facilitate the free movement of goods in the common market.

# 3.3. JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

## 3.3.1. Other regulatory risk management options

#### **Summary of the Dossier Submitter's assessment:**

In response to the identification of this risk, the Dossier Submitter has conducted an analysis of diverse risk management options (RMOs) to identify the most appropriate option for addressing the identified risks, including various permutations of a REACH restriction.

The Dossier Submitter notes that the Commission's choice to address the risks of PFASs, including in firefighting foams, by means of a restriction under the REACH regulation was part of the Chemical Strategy for Sustainability (CSS). As a REACH restriction is envisaged to

deliver the objectives of the CSS, the assessment of alternative **novel** Union-wide legislative RMOs was not specifically considered by the Dossier Submitter. The CSS also commits the European Commission to address PFASs via a group approach to prevent regrettable substitution, improve reporting of PFASs releases into the environment (via the Industrial Emission Directive and the European Pollutant Release and Transfer Register), address PFASs via international fora such as the Stockholm Convention and establish financial support for research and innovation of PFASs alternatives as well as remediation practices.

Aside from the above-mentioned considerations on novel RMOs, the Dossier Submitter compared the relative merits of the proposed restriction with risk management via **existing** Union-wide legislation, such as the POPs Regulation (implementing the Stockholm Convention), the Water Framework Directive, the Groundwater Directive, the Drinking Water Directive, the Marine Strategy Framework Directive, the Industrial Emissions Directive, the SEVESO Directive, and the Urban Wastewater Treatment Directive. Other analysed risk management options include voluntary industry agreements, taxation of PFASs and other forms of regulation under REACH (authorisation and Article 68.2 procedures). A main advantage of a REACH restriction is that PFASs in firefighting foams would be prevented from entering the environment by controlling emissions at the source and thus a restriction is regarded as the more effective, practicable and enforceable measure.

Other rejected RMOs include voluntary industry agreements, taxation of PFASs and other forms of regulation under REACH (e.g. authorisation and Article 68.2 procedures) due to important limitations and complicating aspects.

Dossier Submitter concluded that a new restriction under REACH is the most appropriate RMO and five restriction options (RO) were identified and analysed. Additionally, conditions to apply during transitional periods were defined. The ROs include the following:

- RO1: Restriction on the placing on the market after use/sector-specific transitional periods, but the use would continue to be allowed until expiry date of the stocks;
- RO2: Restriction on the placing on the market and use after use/sector-specific transitional periods;
- RO3: Restriction on the formulation, placing on the market and use after use/sectorspecific transitional periods;
- RO4: Restriction on the placing on the market and use after use/sector-specific transitional periods, with a derogation mechanism via a permit system to which only Seveso establishments and defence sites would be eligible;
- RO5: Restriction on the placing on the market and use for all uses after sector/usespecific transitional periods, unless adequate risk management measures are in place to capture all the emissions to the environment.

As mentioned before, it is important to note that the restriction proposed by the Dossier Submitter will not interfere with any previously **implemented** restrictions of some PFASs in firefighting foams (e.g. PFOS, PFOA, C9-C14 PFCAs and related substances).

With regard to **previously proposed** restrictions (e.g. PFHxS, its salts and PFHxS-related substances as well as PFHxA and related substances, which both propose limited derogations on uses in firefighting foams), it should be noted again that this new proposed restriction is meant to provide required additional risk management by ensuring the elimination of remaining gaps. As mentioned before, a restriction covering the whole PFAS class is considered more appropriate to address the risks from PFASs in firefighting foams, including those arising from so called 'regrettable substitution'. There may be a need for the European Commission to reconcile the various proposed restrictions on PFASs in firefighting foams at the decision phase.

Two additional ROs have also been considered but have been discarded and have not been assessed in further detail by the Dossier Submitter due to being inferior of the ones presented above. These include the following elements:

- a. Restriction of a few uses only, others derogated until suitable alternatives are found (based on a reporting requirement and a restriction review at later stage), complimented by a requirement of full containment of releases
- b. Restriction of a few uses only, other uses would be subject to authorisation under REACH Title VII

# RAC conclusion(s):

[Text]

# Key elements underpinning the RAC conclusion(s):

[Text]

## SEAC conclusion(s):

SEAC agrees that a restriction under REACH is the most appropriate approach. SEAC's conclusions on the presented restriction options are to be determined, pending the outcome of the cost/benefit/proportionality assessment

# Key elements underpinning the SEAC conclusion(s):

# Other EU-wide legislative measures

The Dossier Submitter provided an overview and assessment of several possible Union-wide risk management approaches other than a restriction under REACH. The result of the Dossier Submitter's assessment was that a REACH restriction is generally considered to be the right instrument for Union-wide regulation of PFAS in firefighting foams. The outcome of SEAC's evaluation of the applicability of other considered measures is presented in the table below.

Table 2: Outcome of SEAC's evaluation of other EU-wide legislative measures as tools to address the identified risks

Legislative approach	Summary of reasons why SEAC does not prefer this option				
Water Framework Directive (WFD)	The Dossier Submitter shows that these legislative approaches are not capable of preventing PFAS from ending up in the environment, as they are mostly relying on elimination of chemicals from the environment after emissions have taken				
Urban Waste Water Directive	place. SEAC acknowledges the WFD has a mechanism to reduce or eliminate emissions of listed chemicals, but it is less compelling and more uncertain than the one provided by a restriction under REACH. Considering the information it				
Groundwater Directive	has on the availability, performance and cost of existing remediation techniques (based on the Background Document, consultation input and also information submitted in the course of evaluation of earlier restriction cases on PFAS				
Drinking Water Directive	substances), SEAC agrees with the Dossier Submitter that minimising PFASs - that enter the environment from use in firefighting foams - at source (which can				
Marine Strategy Framework Directive	be achieved via a restriction) appears to be a superior approach.				
Industrial Emissions Directive	According to the Dossier Submitter, these measures do not cover all sectors or all types of installations/circumstances in which PFAS-containing firefighting foams are used. Their applicability to firefighting for installations that fall under				
Seveso Directive	their scope is also unclear. They are therefore not applicable to the scope as defined by the Dossier Submitter and would not be able to address all of the risks/emissions that cause the concern. SEAC agrees with these arguments.				

POPs Regulation/ Stockholm Convention	SEAC notes that the Dossier Submitter expects that with time, the risk management related to PFASs in firefighting foams will be managed under the POPs regulation. SEAC agrees that evaluation and restriction under REACH can be regarded a step in this process and expected to allow emission reduction sooner and with more certainty. SEAC also notes that not all PFAS covered by the proposed restriction necessarily meet the definition of a POP under the POPs Regulation, which is why a REACH restriction is better able to address PFASs as a group compared to the POPs Regulation.
Authorisation under REACH REACH Art. 68.2	The Dossier Submitter argues that authorisation is not available for a single use group such as firefighting foams but would cover all uses that are not specifically exempted. Also, using the authorisation approach would require that all PFASs are first formally identified as substances of very high concern, recommended for inclusion in the authorisation list and included in the authorisation list, which would be extremely resource intensive considering the number of substances. Regarding the possibility to use Article 68.2 under REACH, it is explained that PFASs are not so consistently classified as CMRs and the uses of PFASs in firefighting foams are mostly considered to be professional and industrial uses (rather than consumer uses). Given this context, Article 68.2 under REACH is of limited relevance. SEAC agrees with this analysis.
Voluntary industry agreements to restrict the use of PFASs in firefighting foams Taxation of PFASs placed on the market	The Dossier Submitter notes that there are no indications of voluntary industry agreements to restrict the relevant use, which is taken as a sign that such a scenario is considered unlikely. Regarding the option of taxation, it is noted in the Annex XV report that uniform taxes would have to be introduced across the EU to provide the needed harmonised union-wide measure and substantial effort would have to be made to develop and administer a correctly functioning taxation scheme. SEAC agrees these approaches are likely to be less efficient and may delay the general substitution of PFAS in FFF in the EU compared to a restriction under REACH.

The assessment in the Annex XV report does not go into further detail, and SEAC finds this logical, considering that the Dossier Submitter (ECHA) was precisely asked to prepare an Annex XV restriction dossier by the European Commission. In a way, a REACH restriction was already chosen as the instrument to be used by the legislator.

SEAC agrees at this stage (pending conclusions on costs, benefits, proportionality and practicality) that a restriction is generally an appropriate risk management option to be used to address the risks related to PFAS in firefighting foams considering the uses and life cycle stages. It allows to tailor the measure with regard to different uses as necessary in terms of use-specific transition times for example.

#### Other restrictions under REACH

Using a restriction as an EU-wide measure to manage the risks posed by these substances is also coherent with the approach taken for several other PFAS substances earlier (specifically PFOS, PFOA, C9-C14 PFCAs, PFHxS<sup>5</sup>, and their related substances), which appears useful in terms of consistency of legislation, clarity of the measure to the affected parties, and overall improves the practicality and monitorability of the restriction. The REACH restriction on PFASs in firefighting foams as proposed by the Dossier Submitter would confirm and extend these previous restrictions that have targeted some specific sub-groups of the PFAS chemicals. The Dossier Submitter argues that the additional restriction proposal (covering the whole group of substances) adds value by ensuring the elimination of gaps although it is pointed out there may be a need for the European Commission to reconcile the various restrictions on PFASs in firefighting foams at the decision phase.

<sup>&</sup>lt;sup>5</sup> Pending decision

A restriction proposal on PFHxA, its salts and related substances was evaluated by SEAC. Considering that the PFAS-based firefighting foams currently in use are mostly based on C6 chemistry (as reported in the Annex XV report), SEAC considers that specifically these two restriction proposals overlap widely regarding their coverage of firefighting foams. SEAC notes that the present proposal contains measures that were not included and assessed in the PFHxA dossier and which potentially better approach some key points (such as the limitation of derogations to oil and chemical industries). The present proposal also more clearly acts against regrettable substitution of one type of PFAS by other types of PFAS and avoids having to comply with several different restrictions of different PFAS in firefighting foams, potentially with different transition periods and concentration limits.

# 3.3.2. Effectiveness in reducing the identified risk(s)

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

RAC conclusion(s):

[Text]

Key elements underpinning the RAC conclusion(s):

[Text]

# 3.3.3. Socioeconomic analysis

#### 3.3.3.1. Costs

#### Summary of Dossier Submitter's assessment:

Despite previous efforts of restricting the use of specific PFASs in firefighting foams, the Dossier Submitter's analysis implies that 18 000 tonnes (60 %) of the manufactured tonnage are PFAS-containing foams. Alternative (fluorine-free) firefighting foams are available and have been successfully used. According to the Dossier Submitter, uses for training and testing, uses by municipal fire services and uses in civilian marine applications can be substituted relatively quickly without adverse impacts. However, the use of alternatives in certain specific scenarios (e.g., for fires in large flammable liquid storage tanks and at installations using multiple different flammable liquids) is not yet widespread and is pending the successful conclusion of performance tests for alternative foams and application methods for these scenarios.

The proposed transitional periods are set to allow the development of fluorine-free firefighting foams, their testing by the users and the adaptation of the existing firefighting systems to provide a similar level of fire protection as given under the use of PFAS-containing foams. This is to exclude the creation of fire safety risks that could have adverse impacts on human health and the environment. Consequently, the Dossier Submitter has eliminated the need to estimate costs of increased fire damage.

The following cost categories were monetised in the assessment of economic impacts:

- The cost of using alternative foams, which considers the difference in prices between PFAS-containing and fluorine-free foams, and additional volumes of fluorine-free foams needed to achieve the same level of fire protection.
- The depreciation of existing stocks, which estimates the lost value of firefighting foams already in stock.

- The cost of technical changes needed to adapt equipment for the use of alternative foams.
- The incineration/disposal costs of PFAS-containing foams, which could represent both costs (banned foams that need to be disposed of safely) or savings (alternative foams do not require incineration). Based on the assumption that existing foam is used before it expires, only the cost of incinerating existing foam stocks is considered.
- Savings for some users, which may occur in the case of avoided clean-up of contaminated land after a fire incident.
- Cost of cleaning equipment to comply with the proposed concentration threshold.
- Cost of additional RMMs required for training/testing but also real fire incidents during transitional periods.
- Producer surplus loss (i.e. lost profits from not being allowed to sell products) due to a ban on formulation including for export (only for RO3).
- Cost of full containment of the foams to minimise releases during continued use (only for RO5).

Table 3 summarises the costs for each restriction option and cost category. The results suggest that the most significant cost categories are related to technical changes needed to use alternative foams, followed by the costs of cleaning equipment. These are also the cost elements that are based on sector-specific assumptions about unit costs. The highest economic impacts are expected for Seveso establishments. This is due to high quantities of firefighting foams used in this sector, as well as more expensive technical changes needed to maintain the same level of fire safety when using alternative foams.

Table 3. Estimated economic impacts for each RO and cost category (with upper and lower bounds resulting from sensitivity analysis).

Cost category	RO1 (NPV € over 30 years)	RO2 (NPV € over 30 years)	RO3 (NPV € over 30 years)	RO4 (NPV € over 30 years)	RO5 (NPV € over 30 years)
Cleaning of equipment	2.0 billion (1 to 4 billion)	2.5 billion (1 to 5 billion)	2.5 billion (1 to 5 billion)	2.1 billion (1 to 4 billion)	1.2 billion (0.6 to 2.4 billion)
Technical changes needed	3.5 billion (2 to 11 billion)	3.5 billion (2 to 11 billion)	3.5 billion (2 to 11 billion)	2.6 billion (1 to 8 billion)	300 million (150 to 900 million)
Disposal / incineration of foams*	0	110 million (100 to 140 million)	110 million (100 to 150 million)	61 million (55 to 80 million)	67 million (60 to 80 million)
Depreciation of stocks disposed*	0	170 million (150 to 200 million)	170 million (150 to 200 million)	92 million (80 to 120 million)	100 million (90 to 130 million)
Cost of alternative foams*	260 million (-60 to 700 million)	480 million (-0.1 to 1 billion)	480 million (-0.1 to 1 billion)	330 million (-80 to 900 million)	300 million (-70 to 800 million)
Savings due to avoided clean-up*	73 million (100 to 40 million)	120 million (240 to 60 million)	120 million (240 to 60 million)	91 million (50 to 180 million)	78 million (40 to 150 million)

Cost of formulation ban including for export (producer surplus)*	not applicable	not applicable	8 million (4 to 24 million)	not applicable	not applicable	
Cost of additional RMMs for training/testing and incidents	96 million (60 to 200 million)	60 million (30 to 120 million)	60 million (30 to 120 million)	105 million (50 to 200 million)	59 million (30 to 120 million)	
Cost of full containment	not applicable	not applicable	not applicable	not applicable	13 billion (6 to 40 billion)	
SUM	5.9 billion (3 to 16 billion)	6.8 billion (3 to 17 billion)	6.8 billion (3 to 17 billion)	5.2 billion (2 to 13 billion)	15 billion (7 to 40 billion)	

<sup>\*</sup>Based on the comments received in the consultation on the Annex XV report, the Dossier Submitter has assessed changes to the cost calculation for the ready-to-use sector. Due to the negligible impact of the changed on the main conclusions of the proposed restriction, the adjustments have not been carried over into the table.

The cost analysis shows that the proposed restriction as described in RO3 would lead to a net present value of costs amounting to approximately 6.8 billion EUR. Costs are expected to be incurred during a period of 30 years and are discounted at a social discount rate of 4 %. Sensitivity analysis suggests that the lower bound of this cost estimate lies at approximately 3 billion EUR (based on best-case assumptions) and the upper bound at approximately 17 billion EUR (based on best-case assumptions).

In comparison to other restriction options, the economic impacts of RO3 are close to those of RO2 since the only notable difference between these two options is the ban on formulation including for export included in RO3. RO1 entails lower economic impacts than RO3 because the use of PFAS-containing foams would be allowed until all stocks are depleted. As a consequence, the most significant difference in costs between RO1 to RO3 is that RO1 avoids the depreciation of stocks and costs of disposal/incineration of foams. RO4 also entails lower economic impacts than RO3, mainly because in the Seveso and military sectors costs do not occur right after the transition period but only gradually up to the year 30 (discounting effect). RO5 is significantly more costly, mainly due to the cost of full containment.

# SEAC conclusion(s):

# Approach to the analysis of alternatives

SEAC concludes that the investigation on the availability of suitable alternatives was comprehensive and can be considered as complete, as far as availability and accuracy of information allowed.

#### Availability and technical and economic feasibility of alternatives

Based on the information presented in the Background Document and considering the comments received in the consultation on the Annex XV Dossier, SEAC concludes that technically and economically feasible fluorine-free alternatives are available and can be implemented in most applications by the end on the transition periods proposed.

SEAC considers that for some applications in industrial facilities and in the defence sector an appropriate performance level of fluorine-free alternatives at the end of the transition periods proposed by the Dossier Submitter has not been fully demonstrated. SEAC recognises that uncertainties always remain about whether alternatives will be available at a specific point in time even if there are indications that research proceeding well. In this particular case, there are such disastrous potential consequences of that remaining risk, that this affects the conclusion of whether availability is sufficiently demonstrated. SEAC considers that a review

of the substitution status before the end of the transitional period for Seveso establishments would be needed to address this uncertainty. This review should be based as much as possible on local information from Seveso sites (and more generally high fire hazard sites) and as exhaustive as possible, to capture any specific situation requiring an extension of the transitional period.

For portable fire extinguishers the availability of alcohol-resistant fluorine-free alternatives for all scenarios has not been fully established.

#### Risks of alternatives

SEAC takes note of the RAC conclusion that hazards and corresponding risk associated with alternatives are likely to be significantly less than those associated with PFAS-based firefighting foams, with the possible exception of siloxane-based alternatives.

#### Conclusion on analysis of alternatives

SEAC considers that a thorough analysis was presented by the Dossier Submitter.

SEAC concludes that fluorine-free alternatives appear to be suitable for most uses and also available in practice. The necessary transition times per sector are evaluated in the proportionality part of this opinion.

In case of the most demanding uses in sites covered by the Seveso III Directive, a complete setup with suitable foams, equipment and firefighting strategies is still under development. It may not be feasible to set a final date for fully completing the phase-out in these uses at this point in time.

In relation to the defence sector, SEAC recognises that some scenarios lack suitable alternatives, and finding such alternatives could be specifically challenging considering the specific use settings.

#### Cost assessment

In general, SEAC has at this stage of the assessment no major reservations about the calculation methods and simplifications (such as assuming linear trends in time to calculate annual costs) and finds that the cost assessment provides an indication of the possible order of magnitude of the costs of the restriction options. However, there are unclarities related to the rationale for several of the assumptions (several technical unit costs, and associated sensitivity analysis) the Dossier Submitter had to make for specific calculations because of incomplete or missing information. These unclarities are further described in the section on key elements below and could have an impact on the outcome of the cost assessment. It is also possible that the sensitivity analysis carried out by the Dossier Submitter does not sufficiently address the possible wider cost variations and resulting uncertainties about the level of cost-effectiveness could be significantly higher than calculated.

Overall SEAC's analysis suggests that costs could be underestimated, maybe significantly, but SEAC believes they should reflect the correct order of magnitude.

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

#### Approach to the analysis of alternatives

The Dossier builds on earlier studies on "The use of PFAS and fluorine-free alternatives in firefighting foams" and "Assessment of alternatives to PFAS-containing fire-fighting foams and the socio-economic impacts of substitution" commissioned by the European Commission

and ECHA (published as a combined final report for both studies)<sup>6</sup>. The investigation overall leaned on available literature and on consultations of stakeholders in several stages. SEAC considers the approach appropriate in the case of this restriction proposal and considers that a comprehensive review of information provided by stakeholders is an important foundation for evaluating the maturity of alternatives. Keeping in mind that several EU-wide restrictions already cover the use of some PFAS in firefighting foams and stakeholders have been involved in the course of the developments, SEAC notes that stakeholders were well informed about the restriction intentions.

#### Technical performance of alternative foams

In general, given the information provided by the Dossier Submitter and additional information from the Consultation on the Annex XV Dossier, fluorine-free alternatives appear to have similar and adequate performance levels, compared to PFAS-based foams.

Fluorine-free foams behave differently compared to PFAS-containing foams and show more **variability in their performance**. Therefore, they seem to be more specific to different types of fuel or water (Dahlbom S. et al., 2022)<sup>7</sup>, which complicates the management of fluorine-free foams by firefighting services and their co-operators, also making more uncertain the effectiveness of alternatives on the very wide range of fuels and flammables that can be found. It is recognised in the Background Document that additional testing with different flammable liquids in a more complete range of fire scenarios is currently ongoing to ensure their effectiveness.

Another issue already discussed by the Dossier Submitter and emphasized by some stakeholders is the difficulty with the **viscosity** of alternatives at **low temperatures** (comments #3543 and #3549), the latter comment raising the issue of transportation under extreme winter cold weather as a case of concern. As noted by the Dossier Submitter, one case of substitution in Norway in the oil and petroleum industry is considered to have faced and solved this issue, but it is not known to SEAC if temperatures were in this case as low as those that could be found in other locations or different applications. SEAC notes that the Dossier Submitter considers that technical solutions to viscosity issues seem to be available; however, SEAC has concern specifically relating to equipment containing small parts such as portable fire extinguishers. **Durability** of alternatives during storage at **elevated temperature** (up to 60°C) or performance level in use in high temperature could also be an issue according to some comments (#3544 and #3546). The stated lack of fluorine-free alternatives which can currently meet the fire performance requirements after long-term storage requirements at elevated temperatures is also reported in the Annex to the Background Document, section E.2.5.4.

While it is acknowledged that fluorine-free foams have potential to perform with different properties, technologies, and application strategies, SEAC recognizes that PFAS-based surfactants can provide for specific valuable properties that are unmatched by fluorine-free alternatives (as highlighted in comments from the consultation on the Annex XV Dossier, including comments #3546, #3596, #3600, #3606, #3621). These properties include for example **film-forming ability**, **fuel repellence**, and **high ambient temperature performance** and allow for an ease of operation which is currently not obtained with fluorine-free foams. This means that more precision and meticulousness is needed when fighting fires using fluorine-free foams compared to using PFAS-based foams. However, based on the

<sup>7</sup> Dahlbom, S., Mallin, T., & Bobert, M. (2022). Fire Test Performance of Eleven PFAS-Free Class B Firefighting Foams Varying Fuels, Admixture, Water Types and Foam Generation Techniques. In Fire Technology (Vol. 58, Issue 3, pp. 1639–1665). Springer Science and Business Media LLC. https://doi.org/10.1007/s10694-022-01213-6

<sup>&</sup>lt;sup>6</sup> Wood, Ramboll & Cowi 2020. The use of PFAS and fluorine-free alternatives in fire-fighting foams.

available evidence and scarcity of expressions of concern from EU actors during the external consultation, SEAC concludes that the industry has in general the ability to manage the remaining challenges before the end of transition periods. SEAC has some specific considerations related to industrial sites, defence applications and portable fire extinguishers as introduced below.

#### Industrial sites

SEAC notes that, specifically with regard to uses in the petrochemical industry the availability of suitable fluorine-free alternatives after the transition periods proposed by the Dossier Submitter cannot be fully demonstrated at this point. The information from the Background Document and the Consultation on the Annex XV Dossier overall indicates that further testing is ongoing with the objective to confirm the technical feasibility of alternatives for some specific applications, particularly large atmospheric storage tanks and sites using multiple types of flammable liquids. Considering the information made available in the Annex XV report and comments received in the consultation, SEAC regards that it may not be just testing that is needed, but also the installation of adequate firefighting systems and adoption of appropriate firefighting techniques is important (e.g. fixed systems avoiding forceful application of foam) and for some scenarios further development of firefighting foams themselves could be needed before a sufficient performance level is established. SEAC considers that the possibilities to finalise the transition to fluorine-free foams depends on the success of different factors, not all of which can be predicted at this point. SEAC notes that, for certain demanding applications, feedback from real-life use is useful and may be important to be certain that alternatives are fully providing the same level of fire protection, and SEAC does not know if such real-life feedback would occur before the end of the proposed transition periods. SEAC agrees with the Dossier Submitter that large atmospheric storage tanks and sites using multiple types of flammable liquids are key locations where further work on establishing the technical feasibility of alternatives is necessary.

### Defence Applications

Based in information in the Background Document, SEAC expects that for some use scenarios in the defence sector, alternatives used in other applications can be expected to work appropriately. However, this is not the case for all use scenarios. In the consultation on the Annex XV report, it was highlighted that there are challenges for firefighting in the military sector that go beyond civilian needs, which are related to the transport of explosives and ammunition. The presence of these products poses greater risks to security and require the highest level of efficiency in fire extinction and in the prevention of fire restart (comment #3583). It was also highlighted that during a military deployment, fire suppression must be highly efficient and reliable, so that firefighting personnel can quickly withdraw to protect themselves from hostile threats. SEAC furthermore notes that increasing the available storage space - potentially necessary when transition to fluorine-free foams is made - may be specifically difficult in some of the scenarios. SEAC takes into account that while in civilian uses it is possible to minimise the number of people on board during the shipment of the most dangerous cargo, in defence scenarios that may not be the case. Overall SEAC considers that finding suitable alternatives for these use scenarios may be considerably more challenging compared to civilian uses.

# Portable Fire Extinguishers

It was claimed in the external consultation that currently there is **no alcohol-resistant agent** that can be used for portable fire extinguishers (comment #3544). SEAC also notes that the issues with the viscosity of alternatives at low temperatures mentioned above could be emphasized in the case of portable fire extinguishers due to the limited size of the equipment. High dynamic viscosity of alcohol resistant fluorine free-foam concentrates was pointed out as a disadvantage of fluorine-free foams also in the consultation on the Annex XV Dossier (#3607). In the Background Document it is implied that non-foam extinguishers

(based on powder or carbon dioxide for example) could be used as alternatives in cases where suitable foam alternatives are not available. Recent advancement in the development of PFAS-free foam alternatives was also expected to alleviate any issues. SEAC observes that an example can be found of a product that is already marketed as usable for fires involving polar substances (alcohols)<sup>8</sup>, however SEAC does not have information on the applicability for different scenarios. Furthermore, it was stated in the Dossier that it seems that a vast majority of fire extinguishers is installed in settings that presumably do not require resistance to extreme temperature ranges (below -10°C or above 30°C). SEAC agrees with these arguments but highlights that the availability of suitable alternative extinguishers should be ensured for any cases that remain even if they are few.

#### Economic feasibility of alternatives

SEAC notes that during the evaluation of the PFHxA restriction proposal it was stated in many comments from industry stakeholders that **the cost of the alternatives is not the issue**, **but performance is**. This was confirmed by the stakeholder feedback collected for the preparation of this restriction proposal and was not challenged in the consultation on the Annex XV Dossier. The alternatives do represent an additional cost (additional unit costs and difference in volumes) that was assessed by the Dossier Submitter and SEAC reflects on this assessment in the costs-related sections of this opinion.

#### Practical availability of alternatives

The demand for fluorine-free foams could be expected to rise strongly at the time when the restriction would start to apply. SEAC notes that, based on information in the Annex XV report, the volumes of alternative surfactants needed in the foam product can be greater than those of PFAS surfactants, and also the demanded volume of fluorine-free foam to put down a fire may be greater (up to a double volume is reflected in the Annex to the Annex XV report) than the corresponding volume of a PFAS-based foam. It is estimated that around 18 000 tonnes of PFAS-containing foams and 9 000 tonnes of fluorine-free foams are currently put on the EU market each year. Fluorine-free alternatives are reported to be provided by at least 8 formulators. SEAC notes that formulators interviewed by the Dossier Submitter estimated that the necessary volumes of alternatives could be supplied within a short time (one to a few years). SEAC considers that this implies that scaling up the formulation of fluorine-free foams to replace PFAS-based foams and to supply the whole market could be feasible, considering the stepwise implementation regime (different length of transition periods per sector). SEAC notes that some challenges could arise once the sector with the highest volumes makes the transition but as this corresponds with the longest transition period (10 years) there is time to prepare. During the consultation on the Annex XV report, particular emphasis was put on the concern of limited manufacturing capacities and thus practical availability of PFAS-free fire extinguishers in the majority of placement locations (where no class B fire is expected to occur). In order to respond to the presented concerns, the Dossier Submitter proposed to lift the condition that would allow PFAS-containing foam only to be used on class-B fires starting from 6 months after entry into force of the restriction. This means that PFAS-containing extinguishers could effectively be used during the entire transitional period of 5 years in parallel to successive replacement. SEAC agrees with this proposal.

# General approach of the cost assessment

The Dossier Submitter approached the costs of the proposed restriction by estimating compliance costs, considering the following costs categories: Additional costs related to the procurement of alternatives and technical costs related to the use of procured alternatives. The Dossier Submitter applied a social discount rate of 4 % and a time horizon of 30 years

<sup>&</sup>lt;sup>8</sup> See example here: https://www.jockel.de/downloads/Fahrbare\_Feuerloescher\_Schaum.pdf (accessed 2023/02/03)

which equals double the foams' mean shelf life of 15 years. SEAC agrees that the approach followed by the Dossier Submitter to assess the costs provides a good estimation of the cost of the restriction, with the following comments:

- Using 30 years as the **time horizon** is enough to ensure that all costs associated with the restriction have been captured. On the other hand, extending further the time horizon would allow to better account for recurring benefits in terms of avoided emissions after all costs have been already incurred, and the outcome of the economic and proportionality assessment can be sensitive to the time horizon chosen. Such a sensitivity analysis was not carried out by the Dossier Submitter.
- The Dossier Submitter has not estimated the human health and environmental costs of increased fire damage, because it was considered that the transitional periods would allow that all alternatives would have at least the same performance as PFAS foams in all applications. There is some uncertainty and there are certain consequences of this assumption which this opinion discusses under "Proportionality" sections.
- In terms of costs, there could be some **overlap with previous restrictions** on some PFASs in firefighting foams either in the EU or internationally (e.g., PFOS, PFOA, C9-C14 PFCAs). This means that some substitution costs related to previous restrictions could have been counted again in the proposal. The Dossier Submitter reports information from the manufacturers' association Eurofeu that PFOA and PFOS have not been used to manufacture foams since 2010. However, there could still be PFOA-based foams in storage (noting that a derogation from the restriction on PFOA of certain firefighting uses applies until 4 July 2025) and their disposal costs should not be accounted for in the present restriction, or the potential overestimation of costs should be noted by SEAC for the rest of the assessment. SEAC also highlights that other restriction proposals addressing PFASs that have been evaluated by SEAC but not yet concluded on at the decision-making stage are not considered to be in the baseline of this restriction proposal. The cost estimates related to uses in firefighting foams reported in those proposals overlap with the cost estimates of the present restriction proposal widely. Accordingly, the estimates presented in those earlier proposals and the present proposal are only relevant when taking the first action related to one of the proposals.

Other than the above comments, SEAC has no reservations on the overall calculation methods and necessary simplifications (such as assuming linear trends in time to calculate annual costs). The text below relates more to the rationale for assumptions the Dossier Submitter had to take for specific calculations, because of incomplete or missing information.

# Substitution costs and technical costs

SEAC finds that the Dossier Submitter has used the most complete, up-to-date and relevant data sources as available to carry out cost calculations. However, there are still several unclarities regarding the rationale for choices made for some of the key parameters (unit costs for technical changes, for cleaning firefighting systems, and associated ranges used for sensitivity analysis) that were taken from the often patchy and sometime not fully consistent data reported from surveys commissioned by ECHA or the European Commission.

Since additional volumes of alternatives could be required compared to PFAS-foams, this could lead to **additional storage space requirements**, but no quantitative information was available to the Dossier Submitter in terms of costs implications. Additional storage costs could also occur during a transition when both PFASs and fluorine-free may have to be stored,

and the Dossier Submitter indicated that from stakeholder consultations these costs appeared to be "manageable", which does not necessarily mean they are negligible compared to other costs items. Overall, the impact on storage costs appears to be missing, or at least a qualitative assessment of whether they are overall negligible or not. No additional information or comment was received in the consultation on the Annex XV Dossier on storage costs, indicating that this cost is probably minor. SEAC also notes there are uncertainties in the additional volumes of fluorine-free foams needed to achieve the same level of fire protection because there is a lack of real-life feedback for certain categories of fires.

The Dossier Submitter did not consider **possible savings from the fact that alternative foams do not require incineration**, based on the assumption that existing foam is fully used before it expires. This assumption appears to be debatable since, even if the Dossier indicates that foams can be used in practice during up to 20 years, most places will not experience fires during that period and training would not exhaust the stock over that period (furthermore specific foams are used for training). There could also be uncertainties about the shelf life of alternative foams that have not always been identified for all applications so far. The Dossier Submitter carried out illustrative sensitivity analysis with 20% of avoided foams incineration as "higher" avoided cost, that looks however quite possible to SEAC, and it will be considered in SEAC's assessment of proportionality. It is also important to consider those savings because, contrary to most costs in the analysis, they would not be one-off but recurring.

According to several stakeholders who submitted comments (comments #3546 and #3549) during the consultation on the Annex XV Dossier, the number of **portable fire extinguishers** would have been underestimated by a factor 2 or 3 by initial information available to the Dossier Submitter, therefore, the substitution cost would also be underestimated. Based on these comments, the Dossier Submitter revised the assumptions on tonnages to be substituted in portable fire extinguishers based on a new number of 40 million devices instead of 15 million. The Dossier Submitter has assessed the impact of such changes on the cost calculation for the ready-to-use sector. However, these changes have a negligible impact on the total costs of the different restriction options, even under an assumption that 10% more PFAS portable fire extinguishers have to be installed than would be present in the baseline scenario.

# Cost of technical changes for industrial installations

The assessment mentions information that the total costs are (for one German industrial stakeholder) €300 million for 12 of their refineries, but the cost per Seveso installation taken forward in the analysis is assumed to be €500 000 per site, whereas it could have been €25 million based on the German data. It is likely that a refinery represents the higher bound of the cost range for Seveso installations, but it remained unclear to SEAC how the unit cost used had been derived, and it is possible that these costs are underestimated. The cost taken forward for other sites is €5000 and it is also unclear to SEAC how this unit cost had been derived since information appears to be lacking. If, as reported in the Background Document, the different viscosity of alternative foams triggers technical changes in foams distribution systems, this could also affect non-Seveso installations that possess such foam distribution systems and do not rely only on portable devices (cruise ships, warehouses, etc.). SEAC recognizes there is limited available information in this aspect in general, and especially for non-Seveso site. This uncertainty and its potential impact on total costs is important since the cost of technical changes is the main cost component for all ROs (except for RO5). SEAC is not fully convinced that the sensitivity scenarios of -50% (low-cost scenario) and +200% (high-cost scenario) are wide enough to reflect the uncertainties.

## Adaptation and training costs

Some stakeholders (comment #3546, 3548, 3596, 3614) claimed that, further to technical costs, they will also incur organisational costs (adapting firefighting related procedures) and

re-training costs (since alternative foams can require new firefighting tactics and tools), and these have not been accounted for by the Dossier Submitter. According to one comment (#3548), these costs could represent 25% of substitution cost for big industrial installations, but the claim was not further substantiated with data. Another comment stated that all firefighters in the EU would have to be re-trained, but this comment neglects that only some professional firefighters would have to do so and that many have already been re-trained given substitution has already significantly taken place for training purposes. SEAC has no reliable quantitative information regarding these costs but considers that the available information suggests they are probably small compared to other costs.

Cost of cleaning installations to reach the 1 mg/L concentration limit

The Dossier Submitter had to base the assessment on limited cost data, mainly available for fire-brigade equipment. The per-site unit cost range taken forward in the analysis by the Dossier Submitter varies between €20 000 and 200 000 per site depending on the sector of use. These figures might not apply to other and especially to industrial, ships, transportation, or defence installations for which very scarce information points to potential much higher costs. Regarding the number of sites, for Seveso, Civil aviation, Military, Municipal fire services, and marine applications sites concerned by cleaning costs, information has been taken from a report by Wood commissioned by ECHA. For non-Seveso site, information was taken from a report by Ramboll and Vito commissioned by ECHA. The number of such non-Seveso sites (10000) is only a tenth of the number of Seveso sites (10000), despite the Wood report stating that many non-Seveso sites with flammable liquids require firefighting equipment, and the origin of the assumption made by the Dossier Submitter was not found by SEAC. It was also not fully clear to SEAC whether these costs include the potential cost to incinerate or adequately dispose of hazardous waste from the cleaning processes.

SEAC therefore considers these costs as uncertain and possibly underestimated. This uncertainty and its potential impact on total costs is important since cleaning cost is the second most important cost component for all ROs (except for RO5).

### Avoided costs

SEAC agrees with the Dossier Submitter that savings for some users may occur in the case of **avoided clean-up of contaminated land after a fire incident**. The Dossier Submitter considered these annual avoided costs would linearly increase from zero up to  $\in$ 10 million per year after all PFAS foams are replaced. The figure of  $\in$ 10 million per year used by the Dossier Submitter seems to be an illustrative assumption based on remediation – and not clean-up – costs (from the Wood report) and on another illustrative and unexplained assumption regarding "tens of incidents" per year in the EU. However, one comment provided during the consultation on the Annex XV Dossier (#3622) supports high annual costs ( $\in$ 150,000 to  $\in$ 200,000) for a single clean-up site at an airport in Germany. The Dossier Submitter carried out a sensitivity analysis of these costs, but it is not clear whether the spread of the costs ( $\in$ 50% to + 100%) used for sensitivity is large enough in regard to the high uncertainty. It is also unclear what share of the clean-up costs was considered to be spent already in the baseline scenario. Given this latter consideration and the above uncertainties, SEAC choses to not consider cost savings from the proposed restriction.

### Administrative and enforcement costs

These costs have not been assessed by the Dossier Submitter, but SEAC considers they are probably low compared to other costs, except for RO4, under which a permitting system has to be run by public authorities and complied with by industry. Furthermore, such costs would likely, although only partly, be in common with previous and proposed restrictions under REACH that also target the use of some PFAS for firefighting foams.

Regarding testing costs, SEAC notes that the Annex XV Dossier does not contain quantitative

information on the cost of sampling, preparation or analysis. SEAC, however, also notes that there are already restrictions on placing on the market and use of some PFAS in firefighting foams in place in the EU. SEAC considers it likely that the enforcement of all these restrictions – the proposed one and the existing ones – will be carried out in a coordinated manner (at least considering restrictions under REACH). This would appear to mean that the additional costs relative to the baseline would be limited to the costs of adding further testing in the order made to a laboratory (a test for total fluorine) in case it is not already included in the test package offered by the relevant laboratory. SEAC further notes that, as confirmed by the Forum, an advantage of the total fluorine methods is that they are significantly faster and cheaper than targeted analyses. Overall, SEAC considers that the testing costs to be incurred from the proposed restriction will be minor relative to other costs associated with the proposal.

#### Specific points related to costs in RO1

**Under RO1**, the Dossier Submitter considered there would be no **disposal costs** since users are able to use their stocks as long as their use or expiry dates allows. However, the actors need to keep their equipment ready for use at any time, meaning that a refill will have to be made after use. Fluorine-free foams cannot be mixed with fluorine-containing foams, and this means that a transition to fluorine-free foams will have to be made at the point where the volume of stock falls below the necessary reserve stock level of that specific installation. All the respective amount would in practice need to be disposed of. This would cause some disposal costs under RO1, lower than for other restriction options, but unknown to SEAC. SEAC notes that some collaboration or trade between actors could take place, during which the ones making the substitution could potentially sell their remaining stock to the ones not yet transitioning. However, there is no information available on how wide-spread such action might be, what the preconditions for such action to work are and also to what extent this would elongate the time taken before a full transition to PFAS-free foams. The costs (and emission reductions) under RO1 could therefore be closer to those of RO3 than stated in the Annex XV report.

#### Specific points related to costs in RO4

Under RO4 (Restriction on the placing on the market and use with a derogation mechanism for Seveso establishments and defence sites), there would be some additional costs for Member State authorities who would have to set up a national system and evaluate derogation requests, and for industry actors who would have to prepare the applications. Also, national legislation would need to be adapted to include the derogation system. According to the analysis in the Annex XV report, RO4 would overall be the least costly option (see Table 3). SEAC, however, notes that the costs of the permitting system were not assessed and included in the cost calculations and considers it would have been useful to weigh them against the possible superiority in terms of ensuring no loss of performance in firefighting. The Dossier Submitter reported that the costs were not evaluated due to lack of data. SEAC considers that estimates of the expected costs could be made at the EU level building on the experience with local industrial permitting systems already in place (Seveso, IED), if required with inputs from national authorities currently in charge of supervising the Seveso sites. SEAC expects that these costs would be limited if this permitting system could be built as an extension of existing systems for Seveso and IED.

### Specific points related to costs in RO5

Under RO5 (Restriction on the placing on the market and use unless adequate risk management measures are in place to capture all the emissions to the environment), there are **costs of full containment of the foams to minimise releases** during continued use. It is unclear what is meant by "full containment" or "minimise" and if strict full containment is achievable. During opinion-making the Dossier Submitter explained that it is expected that the current types of containment do not necessarily allow to collect all of any PFAS used/leaked, and that it is expected that upgrading existing systems or building of new

systems to a level of a truly full containment would be very expensive if at all feasible in some circumstances (e.g. due to the type of terrain and infrastructure). The cost of a "full containment" or "near full containment" could be very dependent on the precise definition of the performance level, since the marginal cost of capturing last remaining emissions is likely to be a steeply increasing function of the performance level when approaching 100% capture. In the calculations underlying the Dossier it was assumed that the cost per site for implementing RMMs to meet full containment would be  $\[mathbb{e}\]$ 2 000 000. It is not described in detail what kind of measures the estimate relates to, but the estimate is reported to be based on industry information.

It is further unclear to SEAC why the costs of RO5 would necessarily be any higher than those of RO2 (depending on the exact conditions of the options). RO5 does after all assume that sector-specific transition periods apply, and the Dossier Submitter works under the assumption that suitable alternatives will be available for all uses at the end of the transition periods. SEAC infers that as far as this assumption holds, in RO5 the actors could in practice choose between substitution and arranging full containment. Where arranging full containment would be more expensive, they would pick substitution – that is, RO2 costs – unless there are some other benefits from arranging full containment, outweighing the cost. SEAC also understands that some installations may already have full containment (more or less so - depending on what level of containment is considered as "full") and for them any costs would be low.

#### Assessment of potential impacts on costs

Table 4: Main uncertainties identified by SEAC in the assessment of costs (including avoided financial costs i.e. financial benefits) of the proposed restriction

Cost (or savings) category	Summary of issue	RO concer ned	Impact on costs calculat ed in the Annex XV report	Impac t on uncert ainties (0 to +++)
Time horizon	30 years versus longer to account for recurring avoided costs (benefits)	All	Very low impact on NPVs but impacts on proportio nality  Overesti mation	++
Cleaning costs	Unit costs (per site) uncertain, number of non-Seveso industrial sites and other sites uncertain	AII	Underesti mation	++
Substitution costs	The number of portable fire extinguishers that would need to be changed is probably underestimated	AII	Underesti mation	+

Overlap with previous restrictions	Not accounted for	All	Overesti mation	+
Need for additional storage capacity	Not accounted for in cost calculations	AII	Underesti mation	+ ?
Cost of technical changes and adaptation	Possible very wide variations affecting representativity of min, max and mean  Alternatives being more specific and requiring specific training could imply training and organisational costs not taken into account by the Dossier Submitter. Some stakeholders report higher adaptation costs than used by the Dossier Submitter (oil and petroleum industry)	All (proba bly less for RO4)	Underesti mation?	+++?
Training costs	Firefighters would need to be re-trained on new foams tactics use. Not taken into account	All	Underesti mation	+
Avoided incineration costs	Not accounted for (only in one sensitivity calculation)	All except RO1	Overesti mation	++
Disposal costs	Not accounted for	RO1	Underesti mation	+
Costs of full containment	Costs of containment might highly depend on how "full" is defined/understood, and on what proportion of economic actors chose containment rather than early substitution	RO5	?	++?
Administrativ e and enforcement costs	Not quantified by the Dossier Submitter	AII	Underesti mation	+/0

#### 3.3.3.2. Benefits

# **Summary of Dossier Submitter's assessment:**

It was not possible for the Dossier Submitter to quantify the human health and environmental impacts of avoided releases of PFASs from firefighting foams. Following the SEAC approach for evaluating PBT and vPvB cases, the avoided releases of PFASs are used as a proxy of the environmental and human health risks, and thus of human health and environmental impacts of the proposed restriction.

For each RO, total avoided emissions of PFASs in the environment over 30 years, compared to the baseline have been calculated. To illustrate the impact of the additional risk management measures proposed under each RO (reduction of emissions as technically and economically feasible, i.e. maximisation of collection and safe disposal for training/testing and incidents), in addition to the progressive phase out, simulations have also been done with and without these risk management measures. They are summarised in Table 5.

Table 5. Total avoided PFAS emissions over 30 years, compared to the baseline, using the best estimate scenarios (low and high scenario in brackets), with and without (tonnes of PFASs, figures rounded)

RO	Total avoided PFASs emissions over 30 years, <b>with</b> risk management measures	Total avoided PFASs emissions over 30 years, <b>without</b> risk management measures
	(t PFASs)	(t PFASs)
RO1	11 800	7 900
	(7 600 – 15 000)	(5 300 – 10 500)
RO2	13 000	11 200
	(8 000 – 16 600)	(6 900 – 14 900)
RO3	13 200	11 300
	(8 000 – 16 800)	(7 000 – 15 000)
RO4	12 600	8 800
	(7 900 – 14 500)	(5 500 – 12 500)
RO5	12 500	6 700
	(7 900 – 14 400)	(4 500 – 8 900)

Note: Baseline emissions of PFASs over 30 years are estimated at 14 100 tonnes in the EU.

RO3 is the RO which is calculated to lead to the greatest PFASs emissions reduction, up to 13 200 tonnes over 30 years. In contrast, RO1 is the RO which leads to the smallest emissions reduction with around 11 800 tonnes. The calculations also show the large impact of the proposed additional risk management measures during transitional periods on the emission reductions. The highest release reduction is achieved in the sector with highest use volumes, i.e. in the Seveso establishments.

# **SEAC** conclusion(s):

SEAC agrees with the approach taken by the Dossier Submitter to assess benefits in terms of avoided emissions. SEAC notes that RAC finds that the release estimates presented by the Dossier Submitter to assess the effects of the proposed restriction are reliable, and that RAC comments that release reductions could be overestimated because of the assumption that all foams used are currently discharged to the environment, and because the assumptions regarding incineration abatement of PFAS could be optimistic.

SEAC notes that relatively similar total emission reductions are achieved with the different ROs, with different time path, but that the significance of these differences is limited in view of the short horizon time of the analysis, compared to the extremely long timeframe of persistence and impacts of PFAS.

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

SEAC finds that the principle of using avoided emissions as a proxy for benefits follows the SEAC approach for evaluating PBT and vPvB cases, and RAC confirmed that emissions can be used as a proxy for risk for PFASs.

SEAC notes that emissions were not discounted and agrees with this approach.

SEAC notes that RAC finds the release estimates presented by the Dossier Submitter for the baseline scenario to be a reasonable estimate to assess the effects of the proposed restriction. RAC also noted that the hazards and corresponding risk of alternatives are likely to be significantly less than those associated with PFAS based firefighting foams, with the possible exception of siloxanes. Siloxanes appear to be used in a limited number of commercial products currently, but SEAC underlines that despite this being relatively unlikely, in case of increased used of siloxanes during the assessment period, actual benefits from the proposed restriction could be somewhat less than the PFAS emission reduction indicate.

SEAC also notes RAC's assessment of emission reductions for each restriction option: RAC concludes that the estimated PFAS release reductions for each restriction option RO1 – RO5 are similar (over 30 years). The biggest potential reductions of PFAS emissions are specified for restriction options RO2 and RO3 at 92 % and 94 %, respectively. The other restriction options are however estimated to result in comparable release reductions (RO1: 84 % and RO4/5: 89 %). The highest difference in total emission reductions between two different ROs is around 10 percent points, which is probably within the error margin of the emission estimates. Therefore, benefits of the different restriction options appear to be very similar in terms of emission reduction of PFAS, and the difference in benefits under the various options appears negligible compared to the significant difference between benefits in the presence or absence the additional RMMs (containment and other emission control measures) for training and incidents. However, as noted by the Dossier Submitter, the actual implementation of these additional RMMs depends on the compliance of many actors in the EU, sometimes acting under special circumstances under accidental/crisis situations, and the degree of enforcement of these RMMs is uncertain.

SEAC also notes the analysis by the Dossier Submitter of the time path of emission reductions, which shows some significant relative difference in the speed to reach the (similar) total emission reductions over the time horizon period of the analysis (30 years). However, since the concern is about the potential long and very long-term impact of these anyway irreversible risks, SEAC finds that the relative speed of emission over the short period of 15 to 30 years is a criterion of minor importance compared to the total emission reductions and proportionality of the different ROs. Which one is actually the best option between RO3 and RO4 regarding this timing issue is anyway considered to be uncertain by SEAC: under RO3 there would not seem to be a clear incentive to make the transition any sooner than by 10 years after entry into force even in cases where suitable alternatives are already available – but at 10 years there would be a clear end date. Under RO4 there would be supervision and timelines set by authorities, which could give incentive for transitioning sooner whenever possible but without a clear final end date set at the EU level.

SEAC notes RAC's concern that **incineration** of firefighting foams is challenging and under sub-optimal conditions can result in incomplete destruction and lower release reductions than calculated by the Dossier Submitter. SEAC also notes that the concern of PFAS not being fully destroyed even in high-temperature incineration has been raised more widely. In the US, the 2022 National Defense Authorization Act required the military to prohibit the incineration of PFAS-based firefighting foams, and there is an emerging practice of instituting take back programs and requiring safe storage until effective disposal techniques can be identified (highlighted in e.g. comment #3636).

The Dossier Submitter carried out a review of the technical and market maturity of alternative **PFAS-contaminated waste end-of-life treatment**, i.e. Supercritical water oxidation, Electrochemical oxidation, and Mechanochemical milling. These technologies, especially

supercritical water oxidation, which is already on the market, are promising, but there are remaining uncertainties in terms of completeness of removal of PFAS (possible formation of PFAS by-products), environmental performance (energy consumption, possible release of fluorinated greenhouse gases, etc.) and costs. It is therefore difficult to consider if they could significantly contribute to PFAS destruction capacity during the transition periods, in case incineration performance or capacity would be an issue.

## 3.3.3.3. Other impacts

# **Summary of Dossier Submitter's assessment:**

The Dossier Submitter has not identified any other significant impacts (e.g. on employment or trade) resulting from the proposed restriction. This is because many producers of firefighting foams formulate both PFAS-containing and PFAS-free foams, sufficient time is provided to develop suitable alternatives (if not available already), and because formulation (including for export) is proposed to be allowed until alternatives are available for all uses and industrial sectors.

# SEAC conclusion(s):

The proposed restriction results in several impacts that are not fully captured by the benefits assessment in terms of PFAS emission reductions. These impacts are for some of them positive (avoided environmental remediation costs), for some uncertain and could be negative for some aspects (consequences of unavoided fire events or of their consequences if alternatives do not perform as well as PFAS foams).

A quantitative assessment was not provided by the Dossier Submitter, and even a qualitative assessment of those other impacts is challenging. Overall SEAC tends to consider that emission reductions could also imply very significant avoided remediation costs, and that potential negative impacts for fire safety could be minimized through the implementation of a review of the substitution status before the end of the transitional period for Seveso establishments, based as much as possible on local information from Seveso sites (and more generally high fire hazard sites).

The proposed restriction could also have impacts in terms of emission of greenhouse gases, depending on which RO is implemented and whether RMMs are enforced, but SEAC could not assess these impacts.

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

#### Avoided environmental pollution societal costs

Avoided clean-up costs at sites after the occurrence of a fire incident und use of PFAS-containing foam are discussed in the cost section. Further to these considerations, it is becoming increasingly obvious that PFAS contamination has caused environmental contamination that represents a high societal cost (see for instance data for Sweden reported through comment #3566 in the consultation on the Annex XV Dossier), already now, and that could be growing in the future. Despite SEAC's considerations of information available at the time of dossier preparation, it is not possible to consider the presented quantitative estimation of avoided clean-up and remediation costs by the Dossier Submitter as representative for the full extent of the relevant PFAS pollution. SEAC recognizes that the restriction is extremely likely to contribute to avoided environmental remediation activities. The benefits of avoided emissions are related to avoided drinking water treatments (or switches to alternative drinking water resources) in the future (with an example of significant drinking water treatment costs caused specifically by PFAS foams contamination, provided during the consultation in Comment #3622), and also avoided economic losses due to lost agricultural production on contaminated ecosystems. The extent to which this restriction would contribute

to such societal benefits cannot be assess by SEAC. SEAC notes that in Belgium, measurements of PFAS contamination in known areas of release have been carried out. Information on the results was reported in the consultation on the Annex XV Dossier (comment #3626). Most of the releases relate to normal uses of firefighting foams and SEAC finds that this gives some insight into the wideness of the pollution problem, and therefore to potential future benefits of avoiding this contamination.

## Greenhouse gases emissions

SEAC notes that several implications of the proposed restriction could have either positive or negative effects in terms of emissions of greenhouse gases. SEAC cannot present a quantitative assessment of the CO<sub>2</sub> emissions and associated global warming potential (GWP) to compare these impacts with the avoided PFAS emissions of the proposed restriction. The different possible impacts of the proposed restriction are the following:

- Some PFAS are chemicals with high persistency and high GWP. Some of them are F-gases and are not used in firefighting foam. However, it is unknown if PFAS other than F-Gases and with high GWP are used firefighting foams and if the restriction would have any positive effect on the climate in this way
- Incineration: the proposed restriction implies an increase in incineration of: i) stocks of PFAS-containing foams that would remain usable and unused before the end of transitional periods and ii) incineration of cleaning/rinsing water of firefighting installations. However, in the long term, the substitution of PFAS-containing foams with alternatives would likely lead to a decline of the need to send water runoff from fire incidents to treatment and possibly incineration (but with the reservation that some alternatives are hazardous to the water environment according to the Dossier Submitter). Given the lack of information, it is in particular difficult for SEAC to discuss if adapting concentration limits to minimize the need to incinerate large amounts of water containing only residual amounts of PFAS might improve the overall benefits of the proposed restriction.
- Avoided remediation: the restriction will likely contribute to avoid environmental remediation activities, drinking water treatments in the future, that are sources of energy consumption and greenhouse gas emissions (until and to the extent the energy system is decarbonised).
- Redesign of firefighting systems would, in case of decommissioning and rebuild of systems, also entail greenhouse gases emissions.

## Avoided health and environmental impacts

Is it considered not to be possible, and it is not the approach taken by the Dossier Submitter, as agreed by SEAC under its approach for PBT/vPvB substances, to calculate health and environmental impacts of the proposed restriction. SEAC, however, notes that there is evidence of association of exposure to PFAS with several health outcomes (cardiovascular disease, reproductive health, etc.). Firefighters are among those workers that could experience more direct health benefits from the proposed restriction (if the performance of alternatives remains the same in every situation and does not increase risk regarding firefighting activities). SEAC also notes that there is some evidence that a subset of PFAS substances cause adverse effects on the environment.

Furthermore, the potential endocrine disrupting activity on both humans and on environmental species, could be seen as an aggravating factor further to being a PBT/vPvB class of chemicals, and strengthening these health and environmental impacts.

#### Competitiveness of industry

SEAC considers that the restriction could improve the competitiveness of the European chemicals industry through earlier innovation on PFAS alternatives, which could not be accounted for in the Dossier Submitter's assessment.

## Comparison of the different ROs in terms of other impacts

In terms of comparison of the different ROs in terms of non-quantified benefits (other than emission reductions in the EU), at this stage, SEAC notes:

- That RO3 (formulation for exports restricted), limiting emissions in other jurisdictions by avoiding exports of the substances, may benefit also the environment in the EU in terms of a lower flow-in of the substances across borders noting that some of the substances have potential for long range transport.
- That RO4 would allow to tailor the measure considering site-specific attributes such that each actor would have a timeframe that best allows them to make a controlled transition without a risk of insufficient quantity or quality of available firefighting foams. However, SEAC considers that RO3 with a review of substitution status and feasibility based on site-specific information, carried out before the end of the longest transitional period, would also address the uncertainty about future substitution success while still maintaining the advantage of definite ends to proposed transitional periods.

#### 3.3.3.4. Proportionality

## Summary of Dossier Submitter's assessment:

Table 6 summarises the cost-effectiveness (C-E) estimates for different ROs and industry sectors or types of use.

Table 6. Estimated C-E ratios for each RO and sector or type of use (with additional risk management measures during the transitional periods)

Sector/type of use	RO1	RO2	RO3	RO4	RO5
	(€ per kg)				
Seveso establishments	700 (300-3700)	800 (300-3900)	800 (300-3900)	560 (230-2800)	2300 (1200- 12000)
Other industries	160	200	200	200	200
	(40-680)	(60-850)	(60-840)	(60-850)	(60-850)
Civilian	50	70	70	70	70
aviation	(0-190)	(5-290)	(6-290)	(5-290)	(5-290)
Defence	50	70	70	30	70
	(0-190)	(4-290)	(5-280)	(1-110)	(4-290)
Municipal fire services	900	840	830	840	840
	(310-3600)	(290-3500)	(290-3500)	(290-3500)	(290-3500)
Ready-to-use applications	30	60	60	60	60
	(0-140)	(0-210)	(0-210)	(0-210)	(0-210)
Marine	320	310	310	310	310
applications	(90-1300)	(90-1300)	(90-1300)	(90-1300)	(90-1300)
Training and testing	17	60	60	60	60
	(0-60)	(0-140)	(0-140)	(0-140)	(0-140)
All sectors/types of use	500	520	515	415	1200
	(190-	(180-	(180-	(150-	(500-
	2000)	2200)	2100)	1700)	5500)

Note 1: The results for two sectors (municipal fire services and marine applications) suggests that RO2 would be less cost-effective measure than RO1. This is because of assumptions made to estimate the emission reduction from banning the use (higher reduction in these sectors) and should not be interpreted to suggest that banning use of existing foams would be cheaper per kg than banning placing on the market of new foams.

To assess the proportionality of the various restriction options with regard to the risk identified in the Annex XV report, the Dossier Submitter compared the cost-effectiveness ratios to those of former REACH actions to avoid PBT- or PBT-like substances. As shown in Table 7, the cost-effectiveness ratios of around €500/kg for RO1, RO2 and RO3 are similar compared to other recent REACH restrictions.

Table 7. Cost-effectiveness of recent REACH restrictions

Restriction under REACH	€/kg, central value
Lead in shot in wetlands	9
D4, D5 in wash-off cosmetics	415
DecaBDE	464
Phenylmercury compounds	649
PFOA-related substances	734

PFOA	1 649
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(Oosterhuis and Brouwer, 2015) investigated this issue more closely. It was concluded that, although cost estimates of previously adopted actions do not allow the derivation of a value of society's willingness-to-pay for reductions in the presence of PBT substance presence, use and emissions, the available evidence suggests that measures costing less than €1 000 per kg of PBT substance use or emission reduction would usually not be rejected for reasons of disproportionate costs, whereas measures with costs above €50 000 per kilogram PBT substance are likely to be rejected. While ECHA (2016) did not establish specific benchmarks for cost-effectiveness, the Dossier Submitter considers that the proportionality of the proposed restriction of PFASs in firefighting foams is supported by the cost-effectiveness estimates as they are similar to other recent restrictions adopted by the Commission.

The Dossier Submitter considers RO3 to be the most appropriate restriction option. Even though regulating the use of existing stocks (covered by RO2 and RO3) is more expensive per kg of emissions reduced than regulating placing on the market RO1 does not regulate the use of existing stocks), the estimated cost of €515 per kg of avoided release is still proportionate. RO4 and RO5 are not considered most appropriate as they entail lower risk reduction capacity, and they are also not considered to be practical.

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

The general approach followed by the Dossier Submitter (using cost-effectiveness ratios) is in line with SEAC approach for such vPvB/PBT chemicals.

SEAC finds that the proposed restriction appears to be proportionate (and so do all other ROs).

SEAC agrees with the Dossier Submitter that RO3 is less uncertain in terms of emission reduction at a certain date, but a review of the availability and technical performance of alternatives for PFAS-containing firefighting foams in the Seveso sector is supported by SEAC to reduce uncertainty about unwanted impacts of the restriction, in terms of consequences of fire events. This review should be based as much as possible on local information from Seveso sites (and more generally high fire hazard sites) and as exhaustive as possible, to capture any specific situation requiring an extension of the transitional period.

SEAC tends to think that given the high stakes of catastrophic risks and the low but remaining uncertainties regarding the ability of fire prevention with PFAS-free foams to provide at least the same level of protection in every challenging situation, this entails important advantages.

When addressing proportionality and the choice of a RO, SEAC also underlines that the differences of some years for the transition to alternatives for a sector will probably result in small differences in the total emission reduction (compared to the total emission reductions brought by the restriction), and even much smaller differences in view of the present total environmental stock of PFAS. Ultimately these differences are also a shift of emission reductions for a relatively short time, against the very long timeframe of past, present, and future contamination by PFAS.

SEAC also reviewed the sector-specific transition periods proposed by the Dossier Submitter and concluded that while the evidence supporting the exact numbers of years proposed (10/5/3/1.5) is scarce, noting the feedback by stakeholders, they appear broadly appropriate.

SEAC considers that the proposed limit value of 1 ppm (1 mg/l) appears appropriate for mixtures placed on the market, but that the limit value for cleaning already contaminated equipment should be set higher, at least for the offshore sector.

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

Based on Dossier Submitter figures for costs and for emission reductions and on RAC conclusions on emissions, SEAC derives the following cost-effectiveness (C/E) estimates ( $\in$ /t avoided emissions) for each of the restriction options:

Table 8: Overview of Cost-Effectiveness (€/t) of the different restriction options, taking into account sensitivity values for costs and for emissions reductions.

RO	Cost/Effectiveness central estimate	Cost/Effectiveness high estimate	Cost/Effectiveness low estimate
RO1	4,94E+05	1,93E+05	2,10E+06
RO2	5,14E+05	1,66E+05	2,12E+06
RO3	5,06E+05	1,64E+05	2,12E+06
RO4	4,05E+05	1,26E+05	1,64E+06
RO5	1,19E+06	4,76E+05	5,06E+06

Note: These C/E estimates are derived from Dossier Submitter's estimates for costs (with inclusion of RMMs, and without avoided clean-up costs, see Table 3) and emission reductions (Table 5). The "high" C/E divides lower-end estimates of cost by higher-end emissions reduction, the "low" C/E divides higher-end estimates of cost by lower-end emissions reduction, and "central" C/E divides central estimates of cost by central emissions reduction.

The cost-effectiveness value appears to vary (depending on the restriction option and the assumptions for the calculations of emission reductions and costs) between 138 €/kg and 5 000 €/kg. SEAC recognizes that there are no established cost-effectiveness benchmarks to assess the proportionality of risk management policies for PBT/vPvB chemicals, and that a comparison of the C/E ratios across restriction dossiers can only be indicative, due to e.g. differences in the persistence of the chemicals addressed but notes that this range of C/E values, and especially the range of central values appears to be within the order of magnitude of recently accepted restrictions for PBT/vPvB chemicals (less persistent than PFAS) under REACH, especially for RO1, 2, 3, and 4. The computed cost-effectiveness values are similar for RO1 to RO4 but lower for RO5 (given the lower cost-effectiveness of full foam containment).

SEAC finds that the inclusion of RMMs for training and incidents has a minor impact on the C/E ratio, and that therefore including RMMs still appears to be justified from a cost-effectiveness point of view.

SEAC noted uncertainties in the cost assessment, that costs could be underestimated, and that there are limited but actual concerns with a few alternatives. On the other hand, there are many positive impacts of the proposed restriction such as future avoided pollution costs that need to be taken into consideration. Overall, considering together the C/E figures, the uncertainties, and the other positive impacts of the proposed restriction, SEAC considers the restriction as proportionate.

#### Transitional periods

SEAC considers that, on the one hand, the transitional period should be <u>long enough</u> to ensure that the actors in the field are able to realistically comply with the restriction, e.g. in terms of carrying out the necessary research and development where suitable alternatives are not yet

available, realising substitution activities and arranging any necessary adaptations within supply chains. Some transition time may also be necessary to enable the availability of and access to (preferably standard) analytical methods to ensure the enforceability and practicality of the restriction. SEAC also underlines, as noted above, that transition times should ensure the avoidance of additional risks to human health and the environment from increased risk of fire damage. On the other hand, the transition period should be <a href="https://short.enough.com/s

According to the Annex XV report, the maturity of alternatives varies depending on sector. Based on this, the Dossier Submitter proposed several different sector-specific transition periods. The specific timeframes are evaluated in Table 9 below. Overall, SEAC agrees that considering the relatively high potential of emissions and the importance of emission reduction reflected by RAC, it is appropriate to set several different transition periods instead of one that would account for the needs of the sector where the longest time is needed.



Table 9: Evaluation of the sector-specific transition periods proposed by the Dossier Submitter.

Sector/type of use	Transitional period proposed in Dossier	SEAC considerations
Seveso establishments	10 years	In the external consultation on the Annex XV Dossier, some industry actors reported that they find the transition periods proposed by the Dossier Submitter appropriate (e.g., comments #3552, #3556, #3600). This implies that alternatives are expected to be available in this sector in 10 years after entry into force, at least in general. Some stakeholders, on the other hand, claimed that suitable alternatives are not available in all scenarios and highlighted fire cases where non-fluorinated foams were used, and which resulted in a disaster (comment #3546). SEAC notes these cases but also reasons that, for one, there is no certainty on what the outcome in these specific cases would have been if PFAS-containing foams would have been used, and also, this does not elucidate the performance level of the alternatives that will be available after a 10-year transition period.
		SEAC notes that environmental NGOs consider that especially the length of the derogation on Seveso plants is not justified (comment #3566). SEAC agrees that there is little justification for exactly 10 years in the Annex XV Dossier. SEAC notes that in the PFHxA restriction proposal, the transition time proposed was even longer; 12 years from entry into force (which has not taken place yet) for the most demanding applications. SEAC observes that some advancement has been made in the development of alternatives; however, based on the available information it is expected that full substitution for the most demanding applications in this sector may not be possible in 10 years (and that full functionality at the point of applying the restriction to these uses should be ensured). SEAC recognises that this time the long transition period covers a much larger base of applications compared to the PFHxA case. For some of the applications, alternatives could be phased in sooner. SEAC also recalls that during the evaluation of the PFHxA restriction proposal, the committee had concerns that the coverage of the long transition period might be too narrow.
		Considering all the information available, SEAC considers that it cannot be established with certainty that fluorine-free alternatives will provide for an adequate performance level in all chemical and petrochemical (or of equivalent fire hazard) scenarios in 10 years. SEAC keeps in mind that inability to fight fires successfully in this sector could lead to massive negative impacts on the environment, human health and lives, and economy. SEAC tends to think that given the high stakes of such catastrophic risks and the low but remaining uncertainties regarding the ability of fire extinction with PFAS-free foams to provide at least the same level of protection in every situation, a review should be made before the expiry of the transition period such that it is verified that suitable alternatives are available for all scenarios.
		Overall, SEAC has a preference for RO3 with a review over RO4, and this is based on the consideration of their different characteristics:

		<ul> <li>RO3 better ensures that no emissions take place after a fixed pre-set date, even if the review demonstrates that the initial transitional period needs to be extended for some installations. In contrast, under RO4, emissions could continue for some sites for an undetermined duration. On the other hand, RO4 might not necessarily lead to an actual slower pace of substitution, since (depending on the details of how it would be implemented) a permitting system could ensure that substitution is carried out as soon as it is considered feasible by the evaluating authority, contrary to sectoral fixed transitional periods. There are indications that many Seveso sites, that would be granted a long transitional period under RO3, do not need it and could be incentivised to move earlier to alternative foams under RO4. RO3 could send a clearer signal to stakeholders that substitution needs to be carried out before an end date, whereas RO4 could also promote substitution since information from first movers could be made more easily available to all stakeholders and to authorities.</li> <li>Despite lacking quantitative information, SEAC considers that RO4 would entail higher costs than RO3 due to the cost of setting and operating the permitting system, which could be higher than the cost of carrying out the review foreseen under RO3.</li> <li>The two ROs have a different approach to the risk management of risks related to industrial sites: more centralized EU approach for RO3 versus local management of industrial risks under RO4.</li> </ul>
Other industries	5 years	SEAC has some concern that other industry/economy sectors than Seveso installations could represent a challenge for fighting fires without PFAS foams (transportation of hazardous chemicals/goods; non-Seveso sites in the vicinity of Seveso sites, etc.). Conflicting comments were received on this issue during the consultation on the Annex XV Dossier. SEAC suggests that the RO option chosen for Seveso establishments also covers such installations, because this would allow to have the local information required to carry out substitution as soon as possible without creating increased risks in terms of safety.
Civilian aviation	5 years	On the one hand, SEAC considers this application as one of those where the endangerment of fire safety could have most significant impacts in terms of human life. On the other hand, SEAC also notes that the collection of firewater may be difficult depending on the site where the incident takes place, and even direct releases to the environment could be possible. It is therefore specifically important that the transition time applied is neither too short nor unnecessarily long. SEAC notes that a transition to fluorine-free alternatives has already taken place in a number of airports, and the outcome of the stakeholder survey undertaken by the Dossier Submitter did not indicate that a transition within five years would not be possible. Also, compelling evidence of any specific shorter period being sufficient at all sites has not been presented. <b>SEAC supports</b> a transition period of <b>5 years</b> . This support comes with a proposal by SEAC that a review is carried out for civilian aviation in the EU, before the end of the 5 years transitional period, to identify unforeseen substitution challenges that might create safety concerns.
Defence	5 years	SEAC acknowledges the <b>specific circumstances</b> in the defence sector. SEAC finds that the time needed for full transition in this sector might be longer than in the other sectors (even the petrochemical sector). There is no information on what the suitable length of the transition period would be. It is reported in the Background Document that based on information collected during the preparation of the Annex XV report, the acceptance of fluorine-free alternatives as technically suitable

		alternatives to PFAS-based foams – and therefore their readiness to transition to these alternatives – <b>varies greatly among countries</b> . This is explained to be due to the fact that each country has its own specificities in terms of how their military equipment is designed, their approaches to fighting a fire and the performance standards they require the foam to meet vary. SEAC concludes that a separate assessment of each scenario at a Member State level appears appropriate. REACH Art. 2(3) would provide for that.
		SEAC expects that exemptions under REACH Art. 2(3) would be set up in cases where continued use is considered necessary. It is not clear to SEAC based on the available information what the difference between a 5-year and, say, a 10-year transition period in a REACH restriction would be.
		Comments received in the consultation on the Annex XV Dossier on defence applications mostly concentrated on explaining why the continued use of PFAS-containing foams in the sector is necessary. Limited discussion was provided on the potential down-sides of using Art. 2(3) exemptions. One stakeholder claimed that the national approval of this type of exemption is associated with a great deal of effort and claimed that a legal act of the European Union would help ensure legitimacy and transparency and create legal certainty (#3621). The alleged difficulties were not further elucidated and, noting that similar points were not made by EU actors in the consultation, it is difficult for SEAC to see their relevance for actors in the Union. SEAC also considered whether using Art. 2(3) exemptions could lead to safety of supply issues for the armed forces. SEAC however finds that the viability of production should not depend on the type of the exemption. Art 2(3) exemptions could be made for formulation for defence use. SEAC notes that collaboration between Member States could be required in case formulation is carried out in a different country than use.
		Further information on potential merits and savings from realising REACH Art. 2(3) exemptions rather at 10 years after entry into force instead of at 5 years would be useful to be able to justify another length of the transition period. Such information could be submitted in the consultation on the SEAC draft opinion. At this point, <b>SEAC supports</b> the <b>5-year</b> transition period proposed by the Dossier Submitter.
Municipal fire services	18 months	Fluorine-free foams are already available and successfully used. Therefore, from the point of view of the availability and suitability of alternatives, the transition period for this sector could be relatively short and a transition period of 18 months could be justified to allow a balanced transition in terms of re-negotiating contracts, making preparations for firefighting infrastructure that has not yet been transitioned (including clean-up and adjustment of equipment and firefighting strategies/protocols), communicating, etc. Furthermore, the proposed restriction foresees that municipal fire brigades could benefit from the longer transitional periods for Seveso III sites, when they have to fight fires at Seveso III industrial installations.
		However, in the consultation on the Annex XV Dossier, some stakeholders claimed that an 18-month transition period is too short (comments #3607, #3614). It was highlighted that the need for training and gaining practical experience during emergencies has not been considered. Transition times of 8 or 10 years were requested.
		The comments do not provide more substantiation of the claim, but SEAC anyway notes that it seems legitimate to grant a longer transitional period for actual use than for training purposes, given more actions are probably to be taken to adapt for

		actual use than for only training. SEAC does not have enough information to set the duration of such a longer transitional period but considers that an extension to 2 years could be appropriate, but SEAC underline this duration is based on very limited information. Transitional periods of 8 to 10 years as requested by stakeholders do not seem justified, since municipal fire services will benefit of such long transition times when they have to fight at Seveso establishments.
Ready-to-use applications (Portable fire extinguishers, ready for use mixtures)	5 years for use; 6 months for placing on the market	Stakeholders estimated in the consultation on the Annex XV Dossier that the <b>number of units</b> that would need to be treated or replaced would be 40-50 million (comment #3557) or 41 million (comment #3579) in the EU. These estimates seem to suggest that the 15 million (taken forward in the assessment in the Dossier) is an underestimate (as was also considered by RAC). Stakeholders claimed that replacing the necessary number of portable fire extinguishers in 5 years would require an <b>unmanageable increase of manufacturing</b> of extinguishers (comment #3579). It was also pointed out that the number of extinguishers using fluorine-free alternatives needed to achieve an extinguishing capacity required by law will be larger than the number of PFAS-based extinguishers needed to achieve the same level, and this could exacerbate the manufacturing capacity issues (comments #3600, #3553, #3615). It was claimed that 10 years would be needed to manufacture a sufficient number of extinguishers. Some information on the impact of the length of the transition period on the necessary level of increase in manufacturing was provided in a confidential submission (comment #3579). However, justification for why the figures presented represent unmanageability was lacking. SEAC agrees that the necessary increase appears as notable, but without further information on the manufacturing circumstances (on potential overcapacity or standstill times, stocks, supply chain issues, etc.) and on any problems related to moving PFEs from one region to another, SEAC does not necessarily find it unmanageable. Generally, SEAC agrees that raising the manufacturing capacity temporarily for a couple of years – if necessary – might not be economically viable and could lead to excess capacity and premature retirement of capital in a few years.
		SEAC reflects that, in principle, cleaning the extinguishers or a part of them could solve or alleviate the issues with manufacturing capacity, but notes the claims by stakeholders that <b>cleaning portable fire extinguishers</b> to the level required is <b>not possible</b> (comments #3549, #3553 and #3579). SEAC understands that prospects of cleaning equipment in general were considered when setting the limit value at 1 ppm (explained in sections 2.3.8 and 2.7 in the Background Document). However, it appears that the prospects of cleaning portable fire extinguishers specifically have not been separately looked into by the Dossier Submitter.
		SEAC also notes that some other stakeholders indicated that an exemption of extinguishers of 5 years irrespective of type of fire is necessary and also sufficient to ensure that the treatment of the waste and the production of replacements are possible within the EU (e.g., comments #3556 and #3557).
		For portable fire-extinguishers, the combination of setting a low concentration limit and a short transitional period could make very challenging, and/or expensive or even impede the replacement of all the units. The reason is that possibly a significant share of portable fire-extinguishers affected is installed for dealing with both class A- and class B-fires and that the proposal would make it compulsory to replace all these.
		SEAC notes that after the consultation on the Annex XV Dossier, the Dossier Submitter proposes to restrict the <b>placing on the market</b> of PFAS in extinguishers already at <b>6 months</b> after entry into force. Existing extinguishers containing PFAS

could continue to be used and serviced. A staged substitution plan was also proposed by stakeholders, one suggesting applying a restriction on placing on the market in 2025 and on use and service in 2030 (#3621). SEAC in principle finds this kind of an approach useful. SEAC however considers that, while some alternatives to PFAS-containing portable fire extinguishers for class B fires already exist and are in use, suitable alternatives may not be available for all types of extinguishers within 6 months. SEAC also considers that a 6-month period would be very short also considering the needs to adapt operations in supply chains (communication on the new requirements, renegotiating contracts, etc.). **SEAC considers a 6-month period too short**. SEAC finds that a slightly longer transition time for placing on the market (such as 1-2 years) could be optimal but does not have information to underpin a specific length.

Further corroborated information on the factors making a 5-year transition period for use unmanageable would be necessary for SEAC to be able to potentially justify a longer transition period. Such information could be submitted in the consultation on the SEAC draft opinion. Also, information underpinning a specific length for the transition period for placing on the market would be useful to get in the consultation.

Overall, SEAC supports a 5-year transition period.

# Marine applications (civilian ships)

#### 3 years

In the consultation on the Annex XV report a stakeholder claimed that some industry sectors – mentioning separately the shipping industry – have not yet developed design standards for the implementation of converting to PFAS-free firefighting foam and stated that the transition period may be too short to enable safe transition (comment #3542). Another stakeholder highlighted that civilian ships carry many types of cargo, including flammable liquids in bulk (comment #3593). It was also reported that IMO/MED certification is needed to ensure ships are allowed to operate and that this may require additional time (comment #3600). It was furthermore pointed out that the viscosity of fluorine-free foams is typically high and claimed that transitioning to them will require significant technical changes to the on-bord fire protection system that will not be possible in 3 years (comment #3549). Detailed explanations on what those changes would be and what would be the timeframe in which the changes could be realised was not provided.

The Dossier Submitter noted that IMO/MED certified alternatives are already being made available on the market, but that technical changes of on-board firefighting systems may be needed. It was noted that down times in harbours are costly, and that in many cases, it may not be possible at all to implement the required changes since the system is deeply embedded into the overall structure of the vessel. Still, referring to comments to an earlier survey from a shipping company highlighting that a transitional period of 3 years appears to be sufficient (Annex E.2.5.5. to the Background Document), they considered that a transition period of three years is appropriate in view of the avoided direct emissions to the environment.

SEAC takes note of the concern expressed by stakeholders in the consultation. SEAC however considers that very limited corroborating evidence was submitted to back up the requests made. Noting the challenges in controlling releases of firefighting foams into the marine environment, SEAC considers that more information on the costs and benefits depending on the transition period (why three years is not sufficient for carrying out any technical changes required; time taken for certification procedures if that is an issue) would be necessary to be able to propose a longer transition period.

More information on the costs and benefits of extending the transition period to 5 years can be submitted in the consultation

		on the SEAC draft opinion.
Training and testing (except testing of the firefighting systems for their function)	18 months	Fluorine-free foams are already available and successfully used. Therefore, the transition period for this sector could be relatively short. The exact length of 18 months was not justified in detail. SEAC, however, notes that the same has been proposed earlier for testing and training with PFAS-containing firefighting foams (e.g., PFHxA), and as such would provide for some predictability and legal certainty. Even if alternatives are already widely used, SEAC finds that some transition time is necessary to allow for adaptation and practicalities, review any contracts, etc. <b>SEAC</b> therefore <b>supports a transitional period of 18 months</b> for this use.
Formulation for export	10 years	A stakeholder highlighted in the external consultation that a 10-year timeframe for the placing on the market (addressed as formulation by the Dossier Submitter in the updated Background Document) is important in that it will allow EU foam manufacturers to maintain their international foam customers and provides a strong incentive for these manufacturers to transition their international customers to fluorine-free foams within the timeframe (comment #3552). The party believes the inclusion of this provision has the potential to reduce the use of PFAS foams in countries where there is currently no regulatory mandate to do so. SEAC agrees that in case of a transboundary pollutant, such as many PFASs, contributing to limiting emissions in other jurisdictions is specifically useful, however SEAC cannot take a stand on how successful this provision would be to that end. Overall SEAC finds however the inclusion of a measure that restricts the formulation for exports to be in harmony with the emission avoidance aim of the entire proposal.  SEAC considers that the transition period for formulation should be as long as the longest use-specific transitional period in order to maintain the availability of PFAS-containing foams for the actors concerned. SEAC also finds that setting the transitional period at the same length as for placing on the market appears to be a clear option for stakeholders.

Justifications for the choice of the exact numbers of years are not available in the Annex XV report. On SEAC's request the Dossier Submitter provided the committee with the raw data that the estimates of the suitable number of years for each sector are based on. SEAC found that little information was received in stakeholder consultations that would support any specific numbers of years. The proposals from the Dossier Submitter seem to be approximate values based on limited data and personal judgement. SEAC regrets that different lengths of transitional periods were not tested in sensitivity analysis. Such analysis would have been helpful not only to see if the chosen length is optimal, but also to see the magnitude of the impact of a too short transition period where that would be the case. Looking at all of the information provided in the Annex XV Dossier and comments from the external consultation together, SEAC however considers that the timeframes of 18 months, 5 years and 10 years appear broadly appropriate. Other, more suitable timeframes were not proposed and justified in the external consultations. Some requests of further exemptions or longer transition times for specific applications were made by specific stakeholders; these are discussed separately by SEAC later in this section.

However, as explained in Table 9, there is a concern that the transition times proposed by the Dossier Submitter might not be sufficient to ensure the development, full testing and adoption of alternatives suitable for the most challenging types of fires. Given the potential very high impacts of even a single catastrophic fire on human health and the environment, the proportionality of the proposal is uncertain if risks of such catastrophic fires are not kept as low as they are currently. SEAC recommends in this context to adopt a **no-regret strategy**; that is, a restriction option that remains justifiable whether catastrophic fires take place or not. Therefore, SEAC considers that a review of the substitution status based on local information before the end of the transitional periods for Seveso sites and industrial sites of similar risk would strengthen the proportionality of the proposed restriction. As indicated before, in comparison to other restriction options, SEAC finds that RO3 with a review before entry into force is the preferrable option.

For the potential case that a review of the substitution progress suggests that a longer transitional period would be needed, SEAC notes that extending transitional periods does not lead *per se* to the release of more PFASs to the environment, except when foams are used, and not properly collected, which should remain highly exceptional (assuming effective destruction of foams at the end of life). There could be indirect detrimental environmental effects, such as providing less incentives and therefore slowing the development of alternatives, in turn giving more time for such fire events with PFAS emissions to occur. On the other hand, longer transitional periods could (eventually more than) offset these negative impacts by lowering the occurrence of uncontrolled fires (thanks to optimized alternative foams, more preparation and training), organizing for incineration and elimination of foams, and improving the abatement of PFAS during incineration. SEAC underlines that an optimal strategy would likely combine the proposed restriction with more flexibility in terms of transitional periods.

SEAC notes that a plant fire brigade association in Germany stated that a **6-month transition period for handling** firefighting foam concentrates containing PFASs which are held in stock and need to be disposed **for adequate treatment** is **unnecessarily long** (comment #3556). SEAC agrees that it would be advisable to start collecting PFAS-containing waste for adequate treatment immediately at entry to the force. On the other hand, SEAC notes that parties not yet oriented to phase-out might not have the preparedness for it but need to organise, making some time for transition necessary. Also, other actions stipulated in entry paragraph 4 (e.g., minimise emissions to the environment and direct and indirect exposures to humans, etc.) may necessitate substantial changes in the practices and facilities. SEAC considers that if one prefers to set only one transition period for entry paragraph 4 obligations, 6 months as proposed by the Dossier Submitter appears a practical solution.

Requests of further derogations and extended transitional periods received in the external consultation

During the consultation on the Annex XV Dossier, several stakeholders expressed that the scope of the Seveso III Directive does not correctly match the scope of sectors that could face major challenges with alternatives (temporary storage and transportation of fuels, offshore oil and petroleum, ...).

Specific requests were made for the following:

- a 10-year transitional period for **offshore oil and gas industry** (not covered by the Seveso III definition) in general (comment #3546)
- a 10-year transitional period for the use of AFFF in the offshore exploration and exploitation of minerals, including hydrocarbons (comment #3544, #3570, #3621, #3546, #3596, #3606)
- a 10-year transitional period for **transportation of flammable liquids** either in pipelines or by road, rail, or ship (comment #3544, #3621, #3546, #3596)
- some further applications (such as oil and petrochemical refineries, pharmaceutical
  and chemical processing facilities & distribution terminals, offshore platforms and
  FPSOs (Floating Production, Storage, and Offloading vessels), Aviation, Defence)
  were also mentioned in the comments containing the requests related to the offshore
  exploration and exploitation of minerals and the transportation of flammable liquids
- a derogation for **offshore helipad** (comments #3543, #3546, #3550 and #3596)
- a request of a higher limit value of 50 ppm for offshore equipment already contaminated with PFAS (comment #3570) (The related SEAC evaluation is presented in the section on limit values.)

SEAC notes that a common denominator for many of the requests made was that the applications referred to are **explicitly exempted from** the application of the **Seveso** directive. Accordingly, they would not be covered by the long review period even if the uses were quite similar to those covered. SEAC notes that relatively few stakeholders highlighted these uses, and specifically, detailed justification and information on costs and emissions related to such extensions of the derogation was not provided.

The justification offered by stakeholders for extending the transitional period in the **offshore sector** was mostly limited to a claim that the offshore oil and gas industry should be given the same opportunities as similar land-based industry with similar risk potential handling large volumes of flammable and explosive liquids. One stakeholder highlighted that making offshore fit for fluorine-free foams is a challenging endeavour, as the existing systems at offshore platforms are mostly pre-installed fixed foam systems that are tailored to the specific design requirements of the site and the harsh environmental conditions (comment #3621). Also, the necessity of refitting platforms (e.g., increased storage room, larger pumping capacities, and the replacement of high technological materials) was mentioned in the same comment. Generally, SEAC notes that in the offshore sector there is typically only limited escape route in case of fires or explosions for personnel or passengers. Also, there is potential for fire causing environmental catastrophic events such as oil discharge. On the other hand, SEAC keeps in mind that in offshore applications there is limited capability to collect the firewater, making direct releases to the environment likely, which necessitates a careful consideration of any derogations.

Related to the transportation sector, the justification provided by stakeholders for an

extension of the transition period includes highlighting the importance of these uses and reminding that (densely) populated areas may be crossed. Some limitations of fluorine-free foams are listed on a general level (longer extinguishment times, higher expansion ratios, shorter extinguishing ranges, less flexibility, fuel vulnerabilities and high viscosity), but no analysis of why fluorine-free alternatives are not considered to work appropriately overall in the relevant scenarios is provided. Overall SEAC considers that the information provided is not sufficient to allow evaluation and therefore SEAC cannot make a proposal of extending the transition time to be applied to the offshore sector or to the transportation sector.

Requests to exempt offshore **helipads** were made in the consultation on the Annex XV Dossier in four submissions. The justification provided was scarce. It was claimed that this is an application where foams are often used unaspirated and use seawater, and that non PFAS agents do not offer the same level of protection as PFAS containing agents in this application. The claims were not further substantiated. SEAC considers that the information provided is not sufficient to allow evaluation and SEAC therefore cannot propose a derogation.

SEAC finds that using **coverage by the Seveso III Directive** as a **cutoff-line** between users that can or cannot benefit from a long transition period can indeed be questioned for several reasons. The coverage is considerably wider than the coverage of the long transitional period in the restriction proposal on PFHxA, its salts and related substances (where SEAC concluded that large tanks with their bunded areas should be covered). SEAC already reflected during the evaluation of the PFHxA restriction proposal that a somewhat wider scope for the long transitional period could be appropriate. In the opinion on the PFHxA restriction proposal SEAC noted that a similar derogation might be needed also for other types of installations than tank farms. At that point however the information available did not allow to estimate the related impacts and SEAC therefore could not make a related proposal. The present restriction proposal on all PFAS in firefighting foams was already in preparation, and SEAC pointed at a full evaluation to be made in the course of the processing thereof.

Table 10: Pros and cons of using being in scope of the Seveso III directive as the cutoff-line for uses that can benefit from a long transitional period.

Cons of Seveso III as cutoff- line	Explanation
A large number of users not in need of PFAS foams are covered	Actors covered by Seveso III due to other hazards than flammable liquids are covered (but need to stop using PFAS foam on class A fires after 6 months)
	As to actors storing minor volumes of or limited numbers of different flammable liquids, the decision on whether an individual qualifies or not could be partly a matter of opinion and of formulation of justification in the documentation required in entry para 4.
Some actors potentially still needing PFAS foams are still not covered (other industrial sites, offshore sector, etc.)	Applications exempted from the application of the Seveso directive (offshore sector etc.) are not covered even if quite similar land-based uses were covered
Pros of Seveso III as cutoff- line	Explanation
Fire safety better ensured than in the PFHxA restriction proposal	Industrial installations using multiple flammable liquids are covered
Practical - Easy to check if a	

certain actor qualifies or not	
Acceptable to actors in the field	The approach was proposed by stakeholders themselves (in comments to the consultation on the Annex XV restriction dossier on PFHxA, its salts and related substances) and confirmed in several comments received in the consultation on the present Annex XV Dossier

SEAC considers that the derogation should optimally be delineated in a narrower manner to avoid potentially limiting the incentive for rapid substitution for some actors under RO1-3. SEAC however agrees with the Dossier Submitter in that the obligations set in entry para 4 will help ensure that PFAS-containing foams will only be used where definitely necessary. For example, the condition limiting the use of PFAS-containing foam to the case of class-B fires starting 6 months after entry into force is considered to limit the scope for Seveso-III sites to use PFAS foams when there is not a use case on flammable liquids.

#### Limit value

SEAC notes that, in regard to **placing firefighting foams on the market**, stakeholders participating the consultation on the Annex XV Dossier generally **did not report concern** on setting the limit value at **1 mg/L**. However, stakeholders requested that the limit value to be applied to cleaning **already contaminated systems and equipment** should be set **higher**.

In the consultation on the Annex XV Dossier:

- The Norwegian Oil and Gas Association (comment #3570) proposed that the limit value should be set at 50 ppm and submitted supporting information relative to the offshore sector. They provided information on the findings after substitution at companies they represent (including information on the levels of contamination remaining years after switching to fluorine-free foam). According to them, this threshold value would be achievable by draining and eventually flushing by water before replacing with fluorine free foam. Reaching the threshold value of 1 ppm would require thorough procedures involving draining, washing with chemicals, flushing, monitoring, and potentially dismantling. They claimed that the main cost for meeting the 1 ppm requirement offshore will not be the primary cost of the cleaning operation, but the stop in production due to the unavailability of the firefighting system. They stated that the earnings lost would on average be at least €2 million per installation per day (while the cleaning costs assessed by the Dossier Submitter, not expecting extra operation standstill beyond the amount that would occur in the baseline, were up to €200 000 per site). It was estimated that drainage and cleaning of the storage tanks will need a few days stop in production, flushing of the distribution system may be achieved during a week, and any actions requiring any dismantling and replacement of parts of the deluge system would cause a stop in production for weeks. The Dossier reports that the limit of 1 ppm would lead to a minimum reduction in release of PFAS of 99.99 %, whereas a threshold of 50 ppm would represent a reduction of 99.80 %. Considering the high cost of removing the last contamination and the relatively low impact on emissions SEAC supports to set the limit value at 50 ppm for offshore already contaminated systems.
- It was also requested that the threshold would be considered separately for placing products on the market and for cleaning systems generally in **all sectors** (comment #3629). High costs of reaching the level of 1 ppm were highlighted by several stakeholders (comments #3628, #3629, #3570). It was also highlighted that large portions of the systems will require replacement to maintain a PFAS residual below a

level of 1 ppm (comment #3633). A specific level for the limit value was however not proposed and justified. In the absence of further information SEAC cannot propose any specific higher limit value. Information justifying another limit value could be submitted in the consultation on the SEAC draft opinion.

Related to the ease of cleaning procedures, SEAC notes that the Dossier Submitter stated (in the Annex XV Dossier and also the summary included at the beginning of this opinion) that a PFAS concentration of 1 mg/L can be achieved using a relatively simple cleaning process. SEAC, having also the information submitted in the consultation on the Annex XV Dossier at hand, disagrees with this view. It was explained in several comments to the consultation on the Dossier that contamination remains after several cycles of washing, potentially making it necessary to replace the part or the equipment (comments #3570, #3628, #3629, #3633).

It was argued in the comments to the consultation on the Annex XV Dossier that the lower the target level is set, the more and more expensive getting rid of more contamination rises (comment #3570). SEAC observes that the statement that it will become more costly to get rid of PBT substances (on a per kg basis) as the amounts become smaller and the concentrations lower has been also confirmed in literature.<sup>9</sup>

It was confirmed in the consultation on the Annex XV Dossier that **1 ppm of PFAS** in a foam concentrate **does not provide any increase in the effectiveness** of the foam (comments #3552, #3544). SEAC takes this as an indication of this level of the limit value as being sufficiently low to **prevent intentional use** of PFAS in firefighting foams.

In the consultation on the Annex XV Dossier, it was also reported that there are some indications that the **concentration of PFASs in new fluorine-free foam concentrates** could be higher than 1 ppm (comments #3607, #3614). The party recommended to set the limit value at 3 ppm; according to their experience the PFAS concentrations in new fluorine-free foams are under this level. The potential reasons for finding PFAS contaminations in fluorine-free foams were not elucidated in the comment.

## 3.3.3.5. Uncertainties in the socioeconomic analysis

Uncertainties related to the cost assessment and their potential impact have been highlighted in Table 4 and further discussed in the section on key elements underpinning the SEAC conclusions. Those points also have a bearing with regard to proportionality. Uncertainties related to the assessment of emissions are in the remit of RAC, but SEAC notes comments from RAC about incineration and the risks of alternatives.

## 3.3.4. Practicality, including enforceability

## Summary of Dossier Submitter's assessment:

The Dossier Submitter considers ROs 1-3 (<u>formulation</u>, <u>placing on the market</u> and <u>use</u>) to be practical (in terms of implementability, enforceability and manageability) and monitorable. The other two ROs are not considered to be practical due to possible difficulties in harmonisation of implementation in different Member States or difficulty to guarantee full containment of foam fire run-off especially for large fire accidents.

Targeted PFAS analysis is used to quantify around 40 different PFASs in laboratories. In addition to specific analysis methods, the total oxidizable precursor (TOP) assay has been

<sup>&</sup>lt;sup>9</sup> Oosterhuis, F. H., & Brouwer, R. (2015). Benchmark development for the proportionality assessment of PBT and vPvB substances. Institute for Environmental Studies, Vrije Universiteit Amsterdam.

used by several laboratories in recent years to analyse PFASs in firefighting foam concentrates and foam container rinse water. The dossier Submitter considers more practical to use 'total fluorine' methods which measure the overall amount of (organic) fluorine in a sample. The total fluorine methods would also detect and quantify organic fluorine from non-PFAS (i.e. not restricted) organofluorine substances in firefighting foams therefore, an additional ancillary requirement for labelling the presence (and concentration) of non-PFAS organofluorine at concentrations greater than 1 mg/L in firefighting foams is included in the conditions of the restriction. The Dossier Submitter recognises the importance of developing a European (or internationally) standardised analytical method for PFASs in firefighting foams although the absence of such method is not considered as a hindrance to the enforceability of the proposed restriction. The enforceability of the additional RMMs required by the proposed restriction (RO3) may be challenging for enforcement authorities but is considered feasible.

## RAC conclusion(s):

[Text]

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

[Text]

#### SEAC conclusion(s):

SEAC concludes that RO1, RO2, RO3 and RO4 are in general practicable. SEAC considers that RO5 is not practicable due to difficulties with arranging and enforcing a full containment.

SEAC agrees with RAC concerning the recommendations to the Commission to provide guidance, review the overlap with related restrictions and investigate the feasibility of recycling unused PFAS-containing firefighting foam.

SEAC considers that the changes made to the restriction proposal during opinion making, specifically

- making the labelling requirements and risk management measures for transition periods not cover portable fire extinguishers, and
- deciding on the coverage of the obligation to ensure that the collected PFAS-containing
  waste shall be handled for adequate treatment based on PFAS concentration of the
  firefighting foam used instead of the PFAS concentration of the waste generated

relieve the concerns that SEAC originally had on the practicality and enforceability of the proposal.

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

The SEAC conclusion is based on the information provided in the Background Document, Forum's advice and comments received in the external consultation on the Annex XV Dossier. SEAC notes that the Forum considers the proposed restriction generally practicable, but considers some clarifications and amendments necessary, specifically related to the method to be used to analyse the total amount of organofluorine substances. There are different types of methods available, and it should be made clear to the concerned parties which one should be used.

In the consultation on the Annex XV Dossier, stakeholders expressed concern on some details affecting the practicality, such as not defining the analytical methods or cleaning methods to be used, limited practical availability of analytical methods at this point in time, lack of definition of terms used (adequate treatment), lack of prescription on how to handle fire

water, lack of definition regarding how compliance with limit values will be checked by authorities. However, SEAC agrees with the Dossier Submitter that experience with already existing restrictions on PFAS-containing firefighting foams provide a strong indication of practicality of the present proposal that is similar to those in many regards.

#### Risk management measures for transition periods (paragraph 4 in the restriction entry)

SEAC notes that the **risk management measures** to be applied during the transition periods are **not very clearly described**. Making the description of the tasks to be performed more precise would improve practicality. In the absence of more detailed instructions, different actors could have different understandings of what the obligations exactly are. SEAC considers that guidance would be needed specifically on the level of minimising emissions that is to be considered technically and economically feasible and on how the foam management plans should be implemented. SEAC considers that the appropriate implementability and enforceability of the requirements in entry paragraph 4 is an essential condition of the proper functioning of the demarcation of the long transition period in RO1-3 (i.e., coverage by the Seveso III Directive).

Also, the Dossier Submitter appears to expect that **additional guidance**, based on best practices existing in some sectors and countries, will be developed for the industry to ensure enforceability. SEAC finds this a useful idea as such and agrees that guidance, or even prescriptive documents at EU level (similar to IED/BREF documents) should be developed by the European Commission. In the consultation on the Annex XV Dossier, stakeholders also implied that guidance on how the cleaning of equipment to meet the restriction level of 1ppm can be achieved would be needed (comments #3543, #3550).

It was highlighted by stakeholders in the consultation on the Annex XV Dossier that, as also implied in the Annex XV Dossier itself, most fire water would likely not reach the concentration threshold of 1 ppm (comment #3595). It was pointed out that therefore condition 4.d would generally not apply to fire water. Other complications with the formulation of this obligation were also recognised during opinion making. SEAC considers that recognising and separating the part of fire-extinguishing water that contains PFAS in a concentration surpassing the limit might be challenging. Furthermore, a scenario of some actors potentially just diluting fire water to lower the PFAS concentration in order to technically comply with the limit cannot be ruled out if the concentration limit relates to the fire extinguishing water. During SEAC opinion making, the proposed restriction was modified by the Dossier Submitter such that the concentration limit does not refer to the fire- extinguishing water but to the firefighting foam concentrate used. SEAC considers that this change removes the problems mentioned. However, SEAC reflects whether it might create a new one: obligation to users of fluorinefree alternatives to carry out actions to comply with the 4.d obligations. It was stated in the consultation on the Annex XV Dossier that some fluorine-free foam concentrates may contain PFAS above the level of 1 ppm (#3607). SEAC does not have information on why there would be PFAS present in fluorine-free firefighting foams, noting that PFAS are not naturally occurring substances. A reason could be contamination at the manufacturing site. This should be reasonably easy to resolve at the site(s) in question (through replacement of equipment if cleaning not possible); also, since the reported concentration (less than 3 ppm) is already close to the limit, the contamination level could possibly decrease sufficiently before the application of the restriction even without any dedicated action. However, to cover for the case where there were further origins to the PFAS contamination in fluorine-free foams, a possibility for the legislator could be to raise the limit of PFAS content in foam used that leads to the requirement to comply with paragraph 4.d obligations to a higher value, still keeping it under the level at which PFAS provides functionality to the foam.

#### Labelling requirement (paragraph 6 in the restriction entry)

SEAC finds a requirement to label the packaging of PFAS containing materials related to the use of PFAS in firefighting foams in principle useful to enable the parties coming across such

packaging to handle it appropriately. Applying the labelling requirement to portable fire extinguishers was criticized by stakeholders in comments received during the consultation on the Annex XV Dossier (#3549, #3600) and also by the Forum. SEAC welcomes that this requirement was removed from scope by the Dossier Submitter.

<u>Labelling of packaging of a mixture for firefighting containing organofluorine substances</u> (Ancillary paragraph 7 in the restriction entry)

SEAC agrees with RAC that the proposed labelling requirement of paragraph 7a is a pragmatic way of addressing any possible non-PFAS fluorine content in the foam and improves enforceability.

SEAC however notes the following **complications** with the proposed requirement and the endeavour to find out the PFAS content of the foam concentrate via this route:

- It might be **difficult to get information** on the content of non-PFAS organofluorine substances from the party responsible for placing on the market. There is no requirement currently to report these substances in the safety data sheet, unless the substance is classified as hazardous and present in a certain concentration. Not even the manufacturers may have information on the content of non-PFAS organofluorine substances in case they were not intentionally added (but included as an ingredient of another substance, or formed as a side product). Also, getting the information via analysis could be difficult, since total fluorine methods do not differentiate between PFAS and non-PFAS substances, and for targeted analysis, information on the identity of the substance searched for would be needed beforehand.
- The lack of a common definition of PFAS could make it difficult for the stakeholders to know what they should label according to entry paragraph 7.
- The Forum pointed out that, for the enforcement authorities, it might be not possible
  to verify whether a company that claims that their product contains non-PFAS
  organofluorine substances above 1 mg/L is providing accurate information. SEAC notes
  that this would potentially make the restriction less efficient and could also create an
  uneven playing field for more or less environmentally friendly or law obedient actors.

The Forum raises the question **how likely it is that paragraph 7 will be relevant** for any products in scope. SEAC reflected on the same issue. The available information (Background Document, Forum advice, comments from the external consultation) do not seem to confirm the presence of non-PFAS organofuorine substances in firefighting foam products. The lack of information could be due to the lack of obligation to report; however, SEAC expects that substances are only added to products for specific purposes (adding further substances would be a cost element) and from the information available it is not clear for what purpose the formulators would add such substances to their firefighting foam products.

In their advice, the Forum reiterated their view from earlier cases that they consider it desirable that **a standard method** for the analytical testing is developed before the restriction applies. Otherwise, **guidance stating what kind of a method to use** should be provided. SEAC agrees that the availability of a standard method could be expected to improve the practicality and enforceability of the restriction considerably. However, as in previous PFAS restriction cases, SEAC does not consider the absence of a standard method as a hindrance of the practicality of a restriction. SEAC also considers that developing a guidance document as proposed by the Forum would be helpful as a first approach during the development of a standard method.

#### Points related to RO4

The Dossier Submitter discarded RO4 because they considered it to be not practical. It is not completely clear to SEAC what the factors making RO4 not practical are. SEAC notes that local permitting is already widely used and established under the Seveso and IED Directives.

As to practicality for industry actors, the Dossier (Annex E.1.1.) reports that RO4 has been built from a proposal made by Eurofeu in their submission to the consultation on the SEAC draft opinion on the PFHxA restriction proposal. The Dossier Submitter considers that since the proposition came from industry, it can be assumed to be feasible for industry. SEAC agrees with this view. SEAC however points out that there is a limited view on whether this represents all types of organisations concerned (also those not represented in the umbrella organisation).

As to practicality for authorities, the practical organisation of the participation of the different national authorities is not elucidated in the Annex XV Dossier, neither for permitting authorities nor enforcement authorities. The concerned parties could therefore arrange their actions as they see it the most practical. It however appears to SEAC that collaboration between authorities working with different legislative frameworks (REACH, Seveso) might be called for. The practicality thereof would depend on the Member State in question and on the division of obligations under different legislative acts between authorities. In addition, it is noted that permitting only works if the parties involved in the decision making are well enough informed and trained.

It is pointed out in the Dossier that adapting national or sub-national legislation to include the necessary derogation system would not be practical. In the absence of further discussion or related analysis it is difficult for SEAC to evaluate the claim. During opinion making the Dossier Submitter expanded the discussion on why they consider RO4 not practicable in the Background Document but focused on explaining the ways in which non-harmonisation may show (notably, Member State authorities opting for less stringent measures). The Dossier Submitter considered that potential local differences in the implementation of the permit system could undermine the goal of an EU-wide harmonised regulation. SEAC agrees that harmonisation would not be achieved at a clearly predictable point in time with RO4 for the sectors exempted and agrees that there are disadvantages but considers that they are not clearly undermining practicality (in terms of implementability, enforceability and manageability) but maybe rather risk reduction capacity for example.

#### Points related to RO5

The lack of detail in the description of the required risk management methods could be expected to be specifically problematic in the case of RO5, which relies on adequate risk management measures being in place. Clarification of what can be considered "adequate" would be of key importance for making this RO practical.

SEAC expects that the enforcement of full containment might be difficult and at least not in the core of competence of REACH inspectors, considering the division of responsibilities in many Member States.

SEAC finds it problematic that the level of containment considered as sufficiently high is not specified in the Annex XV Dossier. The discussion appears to reflect an assumption that a sufficiently high level of containment is not possible in practice, which situation then again would render the entire restriction option irrelevant.

## 3.3.5. Monitorability

#### **Summary of Dossier Submitter's assessment:**

The Dossier Submitter considers the proposed restriction to be monitorable. Enforcement authorities can set up supervision mechanisms to monitor industry compliance including by adapting those used to monitor compliance with regulation around PFOA and long-chain PFASs. Enforceability and analytical methods are covered under practicality and enforceability

as summarised above.

The implementation of the proposed restriction is considered monitorable via targeted inspection activities that rely on PFAS-containing firefighting foam management plans and proper labelling of PFAS-foam stocks as well as waste resulting from the use of such foams.

In addition, the Dossier Submitter suggests that time trend monitoring could be performed with relevant samples from the environment (i.e., those from around sites using firefighting foams) or humans (e.g., firefighters). A reduction of PFAS emissions to the environment (and human exposure) resulting from this restriction should register when performing this type of trend monitoring.

#### RAC conclusion(s):

[Text]

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

[Text]

## SEAC conclusion(s):

Based on the information provided in the restriction dossier, SEAC agrees that all the restriction options are monitorable.

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

SEAC notes and acknowledges the reservation expressed by RAC related to the monitorability of the proposed restriction. SEAC agrees that the actions proposed by RAC are useful and would greatly benefit monitorability. Information could, however, also be collected as part of a monitoring project or, e.g., in course of enforcement projects (with extra effort and time) and therefore SEAC considers the proposed restriction in principle as monitorable. SEAC recalls that in the evaluation of earlier restriction proposals, arranging for the collection of information for monitoring upfront has not been considered a prerequisite to concluding that a proposed restriction is monitorable.

As to the points raised by RAC, SEAC considers that requiring reporting of use of PFAS-containing firefighting foam would be specifically useful, since that way the authorities would get the information on locations of potential major local emissions and would be able to influence whether clean-up of the environment and/or targeted monitoring activities are necessary. SEAC however notes that reporting requirements would come with costs; information on those are not available to SEAC. SEAC considers that reporting would be specifically useful in case of RO4, since this would allow to monitor the use in the long term in cases where use might continue for a longer period of time. Under RO3 the usefulness would be more limited if there was a full stop of use at 10 years after entry into force (but more useful again if the possibility to use the foams will be extended in a review).

SEAC expects that monitoring of the proposed restriction could be conducted through regular enforcement activities. Monitoring of sales could also be used as an instrument, if feasible.

The Dossier Submitter suggested that time trend monitoring could be performed with relevant samples from the environment (i.e., samples from around sites using firefighting foams) or humans (e.g., firefighters) to monitor the effectiveness of the proposed restriction (RO3). SEAC agrees that time trend monitoring is in general useful as an instrument to monitor the effectiveness of restrictions. SEAC considers that since most existing uses of PFASs would not be affected by the proposed restriction, making conclusions on the effectiveness of the restriction based on results from environmental monitoring would not be simple in this case;

however, there are methods that can be used, as is demonstrated by the database on environmental pollution around sites with past and present firefighting foam use in Flanders. Moreover, biomonitoring of firefighters would appear to be a useful measure.

SEAC points out that the cost of monitoring would have to be borne by some actor, and it is not clear which actor that would be. Applying the "polluter pays" approach could be an appropriate measure.

## 3.4. UNCERTAINTIES

## 3.4.1. Uncertainties evaluated by RAC

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

RAC conclusion(s):

[Text]

Key elements underpinning the RAC conclusion(s):

[Text]

## 3.4.2. Uncertainties evaluated by SEAC

#### **Summary of Dossier Submitter's assessment:**

For each RO, sensitivity analyses were carried out to describe the magnitude of uncertainty in the results and to understand the contribution of each input parameter to the overall uncertainty. The level of uncertainty for each parameter was labelled low, medium or high based on the Dossier Submitter's judgement. Based on this, reasonable assumptions for low and high scenarios were made. However, the intention was not to determine the lowest and highest possible values for each parameter.

The uncertainty analysis of the cost assessment has been presented as an in-built component of the result tables (see low and high scenarios). The input parameters taken for the quantitative and cost calculations are described in detail in section 3 of the Annex XV report. This includes the sources of the data, level of uncertainty and the values used for the calculations in the low, best and high estimate scenarios.

The most uncertain parameters used in the cost assessment are related to the cost of technical changes needed to use alternative foams. A revision of the cost assessment for the ready-to-use sector (based on a correction of the number of extinguishers in use across the EU, information received during the consultation on the Annex XV report) did not result in changes of the aggregated cost per RO, and therefore also did not impact the cost-effectiveness calculation. This is related to the still relatively small share of the use in this sector compared to the total amount of PFAS-containing foams used across all sectors.

#### SEAC conclusion(s):

SEAC has evaluated qualitatively the uncertainties in the cost assessment and has also noted the possible magnitude of benefits other than that of emission reductions.

Overall, SEAC finds that these uncertainties, despite being significant, do not seem to compromise the conclusion of SEAC proportionality assessment. However, the analysis of

uncertainties (especially of the suitability of alternatives without any reduction in their efficiency to combat fire in every situation) has led SEAC to conclude that RO3 with a review of the substitution progress before the end of the time-limited derogation for the Seveso sector is the preferable restriction option.

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

Uncertainties in the assessment of costs, benefits and proportionality have been analysed in the respective sections. Some additional considerations are provided here:

The Dossier Submitter assumes that there will be no impacts of any **reduced fire protection capacity** related to the use of alternative foams. SEAC considers that a similar performance level has not been ensured for all applications and that therefore impacts on fire safety cannot be excluded if a fixed end date is set without a review before applying the obligations.

The assumption that 100% of foams placed on the market end up in the environment is not well justified. SEAC presumes that this was a very conservative assumption made by the Dossier Submitter due to unavailability of data, and that it was expected that information to allow assessment would be submitted in the consultation on the Annex XV Dossier. Unfortunately, such data was not received, and this remains as a major uncertainty factor underlying the analysis. For instance, some stakeholders indicate that only 1-5% of extinguishers are actually used (#3621), and it is unlikely that all the remaining foam reach the environment. SEAC did not assess the level of uncertainty this brings about because it is considered to fall into the remit of RAC. However, there may be a notable impact on the costs (for implementing article 4.b of the restriction) and benefits of the restriction and therefore the issue is highlighted by SEAC.

## 4. REFERENCES

Not applicable.

