Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Per- and polyfluoroalkyl substances (PFAS)

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

ECHA/SEAC/RES-O-0000007299-62-01/F

Compiled version of RAC's opinion (adopted 16 March 2023) and SEAC's opinion (adopted 07 June 2023)

Draft date: 07/06/2023

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON PFAS IN FIREFIGHTING FOAMS

16/03/2023

RES-O-0000007226-75-01/F

07/06/2023

ECHA/SEAC/RES-O-0000007299-62-01/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s): **Per- and polyfluoroalkyl substances (PFAS)**

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 https://echa.europa.eu/restrictions-under-consideration 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:

Rapporteur, appointed by RAC: **Malcolm DOAK**

Co-rapporteur, appointed by RAC: **Bridget GINNITY**

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON PFAS IN FIREFIGHTING FOAMS

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 **16/03/2023.**

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**.

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 https://echa.europa.eu/restrictions-under-consideration 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 **07/06/2023**.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

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

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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_3) or methylene (CF_2) carbon atom (without any H/Cl/Br/I attached to it). [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.]	1. Where the concentration of total PFAS is greater than 1 mg/L[1], shall not, as a constituent of a firefighting foam, be a. **placed on the market** or b. **formulated**. 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 **used** 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: a. 18 months after entry into force for training and testing (except testing of the firefighting systems for their function); 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); c. three years after entry into force for civilian ships including tankers, ferries, tugboats and other commercial vessels; d. five years after entry into force for civilian aviation (including in civilian airports) and defence; e. 10 years after entry into force for establishments covered by the Directive 2012/18/EU (Seveso

[1] Corresponding to 1 000 ppb, or 0.0001% (w/v).

Column 1	Column 2
	III)[2] (upper and lower tiers) if they are not already covered by paragraph 3.(d); 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). 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 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: a. ensure that they are only used for fires involving flammable liquids (class B fires); 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: 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). 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

[2] 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
	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 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.

Column 1	Column 2
	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

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the restriction proposed by the Dossier Submitter **on Per- and polyfluoroalkyl substances (PFAS)** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are **(changes from the DS proposal in red and strikeout)**:

Table 2: Restriction proposed by RAC

Column 1	Column 2
Per- and polyfluoroalkyl substances (PFAS) defined as: any substance that contains at least one fully fluorinated methyl (CF_3) or methylene (CF_2) carbon atom (without any H/Cl/Br/I attached to it). [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	1. Where the concentration of total PFAS is greater than 1 mg/L[3], shall not, as a constituent of a firefighting foam, be a. **placed on the market** or b. **formulated**. 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

[3] Corresponding to 1 000 ppb, or 0.0001% (w/v).

Column 1	**Column 2**
column of this entry.]	force of the restriction.
	2. Shall not be **used** 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: a. 18 months after entry into force for training and testing (except testing of the firefighting systems for their function); 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); c. three years after entry into force for civilian ships including tankers, ferries, tugboats and other commercial vessels; d. five years after entry into force for civilian aviation (including in civilian airports) and defence; e. 10 years after entry into force for establishments covered by the Directive 2012/18/EU (Seveso III)[4] (upper and lower tiers) if they are not already covered by paragraph 3.(d); 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). 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 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: a. ensure that they are only used for fires involving flammable liquids (class B fires);

[4] 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
	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: 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). 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 **national** 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. **Ensure that the collected PFAS-containing waste resulting from cleaning of firefighting equipment, where the concentration of total PFAS is greater than 1 mg/L 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 **biological wastewater treatment,** ~~sewage treatment,~~ irrespective of any pre-treatment. **If PFAS-containing waste is incinerated or co-incinerated, the temperature shall be at least 1 100 °C.** For each event of foam use or accidental spillage or leakage, proof of appropriate management and disposal of the foam concentrates, water-added

Column 1	Column 2
	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 **biological wastewater treatment,** ~~sewage treatment,~~ irrespective of any pre-treatment. **If PFAS-containing waste is incinerated or co-incinerated, the temperature shall be at least 1 100 °C.** 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 containers of firewater runoffs or other PFAS-waste in relation with the use of firefighting foams 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)". **From six months after entry into force, containers of PFAS-waste in relation to cleaning of firefighting foam equipment where concentration of total PFAS is greater than 1 mg/L 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

Column 1	Column 2
	(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.

RAC notes that the scope of the restriction proposal is based on the persistence properties of the substances within the group. Based on the available information, RAC concludes that all substances in the scope of the proposal are persistent. RAC notes that if fully substantiated evidence arises regarding the non-persistence of one or more subgroups of PFAS, these subgroups could be excluded from the scope of the restriction.

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 transitional periods may need to be extended. The relevant transitional periods include the following:

- Placing on the market of specific types of new PFAS-containing fire extinguishers dispensing alcohol resistant foam (a 18-months transitional period is proposed by SEAC), and
- Use in the marine sector (a 5-year transitional period is proposed by SEAC)
- Use at offshore installations belonging to the oil and gas sector (a 10-year transitional period is proposed by SEAC.

Because the consequences of reduced fire safety could potentially be disastrous in the case of Seveso and offshore installations in the oil and gas industry, SEAC considers that a review of the substitution status before the end of the corresponding transitional periods for these sectors would be needed. This is to address the remaining uncertainty about the successful implementation of alternatives by the end of the transitional periods.

While SEAC considers that the proposed limit value of 1 mg/l appears appropriate for mixtures placed on the market, SEAC concludes that the limit value applicable to equipment cleaning and foam discharged from already contaminated systems and equipment should be set higher at 50 mg/L for the offshore sector. SEAC highlights that the higher limit is solely intended to help avoid the high costs of cleaning and underlines that the foam concentrates used should

comply to the limit value of 1 mg/l when purchased and until fed into the equipment at the site of use.

The conditions of the restriction proposed by SEAC are **(changes from the DS proposal in red and strikeout)**:

Table 3: Restriction proposed by SEAC

Column 1	**Column 2**
Per- and polyfluoroalkyl substances (PFAS) defined as: any substance that contains at least one fully fluorinated methyl (CF_3) or methylene (CF_2) carbon atom (without any H/Cl/Br/I attached to it). [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.]	1. Where the concentration of total PFAS is greater than 1 mg/L[5], shall not, as a constituent of a firefighting foam, be a. **placed on the market** or b. **formulated**. 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), **18 months after entry into force of the restriction for a constituent of an alcohol resistant 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 **used**[6] 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: a. 18 months after entry into force for training and testing (except testing of the firefighting systems for their function); 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);

[5] Corresponding to 1 000 ppb, or 0.0001% (w/v).

[6] 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
	c. **five** years after entry into force for civilian ships including tankers, ferries, tugboats and other commercial vessels; d. five years after entry into force for civilian aviation (including in civilian airports) and defence; e. 10 years after entry into force for establishments covered by the Directive 2012/18/EU (Seveso III)[7] (upper and lower tiers) if they are not already covered by paragraph 3.(d) **and a review of the substitution status shall be implemented before the end of the transitional period to address the uncertainty about the successful implementation of alternatives (also taking into account the risk potential at neighboring sites)**; 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). g. **31 December 2030** for portable fire extinguishers as defined by EN3-7, EN-1866 and EN-16856 placed on the market before 6 months after entry into force; **h. 10 years after entry into force for installations belonging to the offshore oil and gas industry and a review of the substitution status shall be implemented before the end of the transitional period to address the uncertainty about the successful implementation of alternatives;**
	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: a. ensure that they are only used for fires involving flammable liquids (class B fires);

[7] 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
	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: 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). 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. **Ensure that the collected PFAS-containing waste resulting from cleaning of firefighting equipment shall be handled for adequate treatment where the concentration of total PFAS is greater than 50 mg/L for the offshore oil and gas industry and 1 mg/L in all other uses/sectors.** 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

Column 1	Column 2
	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 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.

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 (PFAS) in firefighting foams.

Firefighting foams are used for extinguishing fires that involve flammable liquids ("class B fires") in a variety of sectors, e.g., oil/chemicals, municipal, maritime, aviation, defence and hand-held fire extinguishers). By far the largest sector of use is the oil/chemical industry. Such foams are used both in 'live' fire incidents, ranging from small fires to large tank fires, as well as for training. An estimated 18 000 tonnes of foam - or 60 % of total foams - used annually in the EU contains PFAS.

The main function of PFAS in firefighting foams is to act as surfactants, or in other words, to form a film over the surface of a burning liquid, thus preventing flammable gases from being released and preventing reignition.

PFAS have attracted regulatory scrutiny due to their ubiquitous presence and persistence in the environment. If releases of PFAS are not prevented, humans and the environment will be exposed to progressively increasing amounts of PFAS until such levels are reached and effects become likely. Such releases are practically irreversible.

PFAS are a family of thousands of mainly persistent, 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. Where drinking water sources are affected, this is a particular concern for human health. Some PFAS are suspected carcinogens, may cause harm to the developing child and may trigger effects at low concentrations in organs such as the liver or in the immune system. There are also some indications that PFAS are potential endocrine disruptors. However, for most PFAS, there are insufficient data to adequately assess their effects on human health and the environment in a quantitative manner.

Due to the above-mentioned hazardous properties, a quantitative risk assessment is considered 'impracticable', but instead a 'case-by-case' risk assessment was performed in accordance with paragraph 0.10 of Annex I to REACH. Given the identified hazards, the Dossier Submitter contends that PFAS should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances whereby releases are taken to be a proxy for risk and that releases of PFAS should then be minimised.

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

Alternative (fluorine-free) firefighting foams are available and have been successfully used in the sectors identified above. However, the use of alternatives 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[8]. 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 periods are proposed by the Dossier Submitter for each type of use and user sector where alternatives are not yet readily implementable. 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 applicable transitional period.

Regarding an appropriate concentration limit for PFAS in foams and equipment that previously used PFAS-containing firefighting foams, consultation comments suggest 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 PFAS 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 option. 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/sector-specific 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/use-specific 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

RAC agrees with targeting the restriction to address the risks of the placing on the market and the use of the PFAS in firefighting foams. Furthermore, RAC supports including the formulation of PFAS in firefighting mixtures in the restriction to prevent PFAS-containing firefighting foams being exported outside the EU. RAC supports the Dossier Submitter assessment that all uses of firefighting foam are covered by the proposed restriction. RAC also supports the use of the OECD definition for PFAS for the purpose of grouping the substances.

[8] 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. 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).

RAC concurs with the Dossier Submitter's hazard assessment and considers that the high persistence of PFAS in combination with other hazards present grounds for significant concern. Studies have established a range of hazards for PFAS, often depending on the specific structure of the substances It is accepted by RAC that due to the very large number of PFAS, the hazards are not homogeneous and there will always be some uncertainty regarding the hazards of the entire group.

RAC notes that when estimating the emissions, the Dossier Submitter applied accepted methodology and based their assumptions on credible collation and extrapolation of available data. Overall, RAC considers the estimate of 470 tpa released to the environment are reliable and a sound basis for the risk characterisation.

RAC concurs with the Dossier Submitter that PFAS should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances whereby releases are taken to be a proxy for risk and should therefore be minimised.

RAC agrees with the justification put forward by the Dossier Submitter that all PFAS used in firefighting foams are likely to be released to the environment. RAC supports the conclusion that their release presents a risk to humans and the environment and that the risk increases with continued use due to their persistence and the consequent increase in environmental stocks over time.

The information presented by the Dossier Submitter indicates that contamination of the environment with PFAS in the vicinity of locations where firefighting use or training has taken place. This demonstrates that despite regulatory efforts over more than a decade, current risk management measures and operational conditions do not sufficiently address the risk.

RAC agrees that an EU-wide restriction under REACH that treats PFAS as a group is the most appropriate measure to reduce the risks of PFAS in firefighting foams.

RAC notes that the scope of the restriction proposal is based on the persistence of the substances within the group. Based on the available information, RAC concludes that all substances in the scope of the proposal are persistent. RAC notes that if fully substantiated evidence (i.e. covering all environmental compartments and relevant conditions) arises regarding the non-persistence of one or more subgroups of PFAS, these subgroups should be excluded from the scope of the restriction.

On the basis of effectiveness in reducing the risks, RAC concludes that restriction option RO3 is the preferred measure to discontinuing the use of PFAS in firefighting foams across the EU for the following reasons:

- The complete ban on placing on the market and/or use after 10 years offers certainty that firefighting foams are not released into the environment after that period.
- The effectiveness of RO3 is most reliant on the core conditions regarding placing on the market, formulation and use which are relatively straightforward to implement, compared with other options relying more on additional risk management measures and which are more challenging to implement.
- The ban on formulation in RO3 would prevent the export of PFAS-containing foams (including of foam concentrate) from the EU/EEA.

RAC concludes that the proposed restriction option RO3 is practical and enforceable but recommends that guidance is provided on analytical methods, on PFAS-containing firefighting foam management plans and cleaning of equipment including handling of the resulting waste.

RAC agrees with the Dossier Submitter that targeted inspection activities by enforcement authorities is a way to monitor the effectiveness of the proposed restriction. In addition, RAC recommends that reporting by formulators on their annual sales volume of firefighting foam concentrate is considered to enhance monitorability.

Overall, RAC concludes that the proposed restriction (RO3) is the most appropriate EU wide measure.

RAC has identified a number of uncertainties including the composition of PFAS-based firefighting foams, assumptions in the exposure assessment, the effectiveness of additional proposed risk management measures and the climate impact of the proposed restriction. These uncertainties do not materially affect the overall conclusions of this RAC opinion that a restriction is appropriate and that RO3 is the preferred restriction option.

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 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 consultations on the Annex XV Dossier and the SEAC draft opinion, 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 of the proposed transitional periods. The sectors/uses for which the appropriate performance of fluorine-free alternatives are considered not yet to be fully demonstrated are the use by certain types of Seveso installations and offshore installations belonging to the oil and gas industry. Because the consequences of reduced fire safety could potentially be disastrous in these contexts, SEAC considers that a review of the substitution status before the end of the transitional period for these use sectors would be needed to address the remaining uncertainty about the successful future implementation of alternatives. SEAC takes note of RAC's 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 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 and that RO3 is the restriction option which most reliably leads to the highest emission reductions because it more heavily relies on core conditions, namely, restricting formulation, use and placing on the market, rather than additional risk management measures.

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 and offshore oil and gas platforms), in order to avoid such impacts. 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 and offshore oil and gas industry 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 relevant sites and potentially relevant neighboring sites (and more generally high-fire-risk 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 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 50 mg/L) 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 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 compromise the conclusion of SEAC's 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 and offshore oil and gas industry.

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 proposal:

Some PFAS are already restricted in firefighting foams either in the EU or internationally (e.g., PFOS, PFOA and PFOA related substances, C9-C14 PFCAs) or are proposed for future risk management in the EU (e.g., PFHxS and PFHxA). However, additional PFAS have been reported by industry for use in firefighting foams and novel unregulated PFAS could be developed for this purpose in the future. The precise identities of the PFAS currently used in firefighting foams are largely unknown due to manufacturer confidentiality. Consequently, a restriction covering the whole PFAS class, rather than specific PFAS or groups of related PFAS, is appropriate to address this uncertainty and the risks from PFAS in firefighting foams. The restriction would support responsible substitution of hazardous substances as called for under REACH and the CSS. The grouping is based on structural similarity (common perfluorinated moieties) that triggers equivalent hazards and risks among the substances covered, primarily related to the 'very persistent' property of the substances.

National or regional risk management activities have led to PFAS-based foams being increasingly replaced by 'fluorine-free' alternatives. Industry best practice guidance recommends that PFAS-containing foams are not used for training and testing. However, around 18 000 tonnes of PFAS-containing firefighting foams are still used annually in the EU in applications involving flammable liquid fires (Class B fires), including for testing and training. This use leads to releases to the environment, with surface water and soil being the key receiving compartments.

Some national regulations exist that require the containment of firewater run-off, but the information available to the Dossier Submitter when preparing the Annex XV report suggested that containment is rarely 100 % effective, that the collected fire water is usually sent to waste water treatment plants (WWTP; unless prescribed differently by local/national legislation) and that the effectiveness of WWTPs to degrade PFAS is very poor. Industry best practice aims to minimise the use and release of PFAS-containing foams (e.g. ceasing its use in training and testing, as has happened in many locations already) but the Dossier Submitter notes that this best practice is not being implemented widely enough (e.g. the use of PFAS-containing foams in training and testing has been reported).

In conclusion, it has been demonstrated that the use of PFAS in firefighting foams is associated with risk to the environment – and human health via the environment – that is not adequately controlled.

RAC conclusion(s):

RAC recalls its five previous opinions (see above) recommending the restriction of various perfluorinated substances and considers that the continued production of PFAS-containing firefighting foam and the quantities involved both indicate that further regulatory controls are warranted and that restriction is a suitable regulatory instrument for this purpose.

RAC supports the grouping of PFAS, due to the their persistence and associated hazards, due to uncertainties with respect to the composition of firefighting foams, the wide availability of

candidates for substitution with similarly hazardous properties, and the impractical difficulty of evaluating on a substance by substance basis. RAC also supports the use of the OECD definition for grouping. This is based on structural similarity (common perfluorinated moieties) which gives rise to the 'very persistent' property associated with PFAS.

RAC agrees with targeting the restriction to the **placing on the market** and the **use** of the PFAS in firefighting foams to address the risks. Furthermore, RAC supports including the **formulation** of PFAS in firefighting mixtures in the restriction to prevent PFAs-containing firefighting foams being exported outside the EU. RAC supports the DS assessment that all uses of firefighting foam are covered by the proposed restriction.

Key elements underpinning the RAC conclusion:

Around 18 000 tonnes of PFAS based firefighting foams are manufactured in the EU per year by about 25 manufacturers containing 450 tonnes of PFAS. PFAS based foams are used primarily 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 fire extinguishers).

The proposed restriction bans placing on the market, formulation and use of PFAS "as a constituent of a firefighting foam". RAC concurs that this targeting is appropriate.

RAC notes with concern that the precise identities of the PFAS currently used in firefighting foams are largely unknown due to manufacturer confidentiality. The stakeholder consultation identified only 18 % of the ingredients of firefighting foam. According to input received (including comments #3560 and #3546), all foams produced today are based on C6-chemistry; C8-based foams are becoming a legacy and chain-lengths shorter than C6 PFAS have never been used as the chemistry is reported to be unsuitable.

The main PFAS that had been used in the past in firefighting foams include PFOS, PFOA (C8 chemistry), PFHxS, PFHxA (C6 chemistry). Of these, RAC notes that PFOS, PFOA, PFHxS and related compounds have been restricted under the Stockholm Convention on Persistent Organic Pollutants (POPs). Derogations allow the use of PFOS and PFOA until 4 July 2025 in firefighting foam for Class B fires already installed in systems by 4 July 2020, subject to a number of conditions. In December 2021, RAC and SEAC adopted an opinion on a restriction of PFHxA, with certain transition periods and derogations for uses in firefighting foams.

Although restriction of some firefighting foam ingredients has been implemented or is under review, individual evaluation of PFAS is not feasible due to the large number involved (about 9 000). The similarity in properties among PFAS is sufficient to provide many possibilities for substitution to equally hazardous substances. Consequently, a restriction covering the whole PFAS class, rather than specific PFAS or groups of related PFAS, is appropriate and the only efficient way to address the risks from PFAS in firefighting foams.

The proposed grouping follows the OECD definition. This is based on structural similarity (common perfluorinated moieties) which gives rise to the 'very persistent' property associated with PFAS. This will also ensure the grouping covers collectively the PFAS in its lifecycle from stock and precursors to the terminal persistent breakdown products (sometimes termed 'arrowhead'). This is the OECD definition derived in 2021 that aims to be "coherent and consistent across compounds from the chemical structure point of view and is easily implementable for distinguishing between PFAS and non-PFAS". RAC considers it appropriate to use this definition as developed by OECD.RAC acknowledges that it may be possible to

identify PFAS substances or subgroups that are not suitable for use in firefighting foams due to their inherent properties but considers exclusion of identified PFAS subgroups or substances which are not likely to be used is not warranted. If certain PFAS are not suitable, they are not impacted by this restriction and the effort required to identify such groups and substances would not be justified. Furthermore, excluding subgroups from the proposed OECD grouping gives rise to the possible inadvertent exclusion of PFAS which may be found to be suitable in future but with similar hazardous properties.

RAC acknowledges that it may be possible to identify PFAS substances or subgroups that do not share the common property of persistence associated with PFAS that is the basis for the substance scope of the proposal. Information was submitted during the consultation indicating that complete degradation of some PFAS may occur, in particular the simplest perfluorinated substances (comment #3568). However, the Dossier Submitter concluded that the information provided in the consultation was not sufficient to assess the non-persistence of these substances (Annex B.4.1.4; see also section 3.1.2.1 on persistence). RAC therefore supports the Dossier Submitter's conclusion on persistence. RAC considers that where sufficient evidence (i.e. covering all relevant environmental compartments and conditions) becomes available that specific PFAS and their degradation products are not persistent, these substances could be excluded from the scope of the restriction. RAC also notes that the trifluorinated and difluorinated PFAS referred to in the information submitted in the consultation (same comment as above) are not usually considered relevant for firefighting foams.

It is also noted the Chemicals Strategy for Sustainability suggests a group approach under relevant regulations in order to address PFAS persistency.

3.1.2. Risk assessment

3.1.2.1. Hazard(s)

Summary of Dossier Submitter's assessment:

All PFAS are considered to be very persistent, either on the basis of their own properties or those of their terminal degradation products (arrowhead; see further below under 'Persistence'). Hazardous properties in addition to persistence depend on the specific structure of a PFAS. Properties of concern identified in investigated PFAS as well as concerns resulting from specific combinations of properties as identified by the DS are listed in Figure 1 and are further described below.

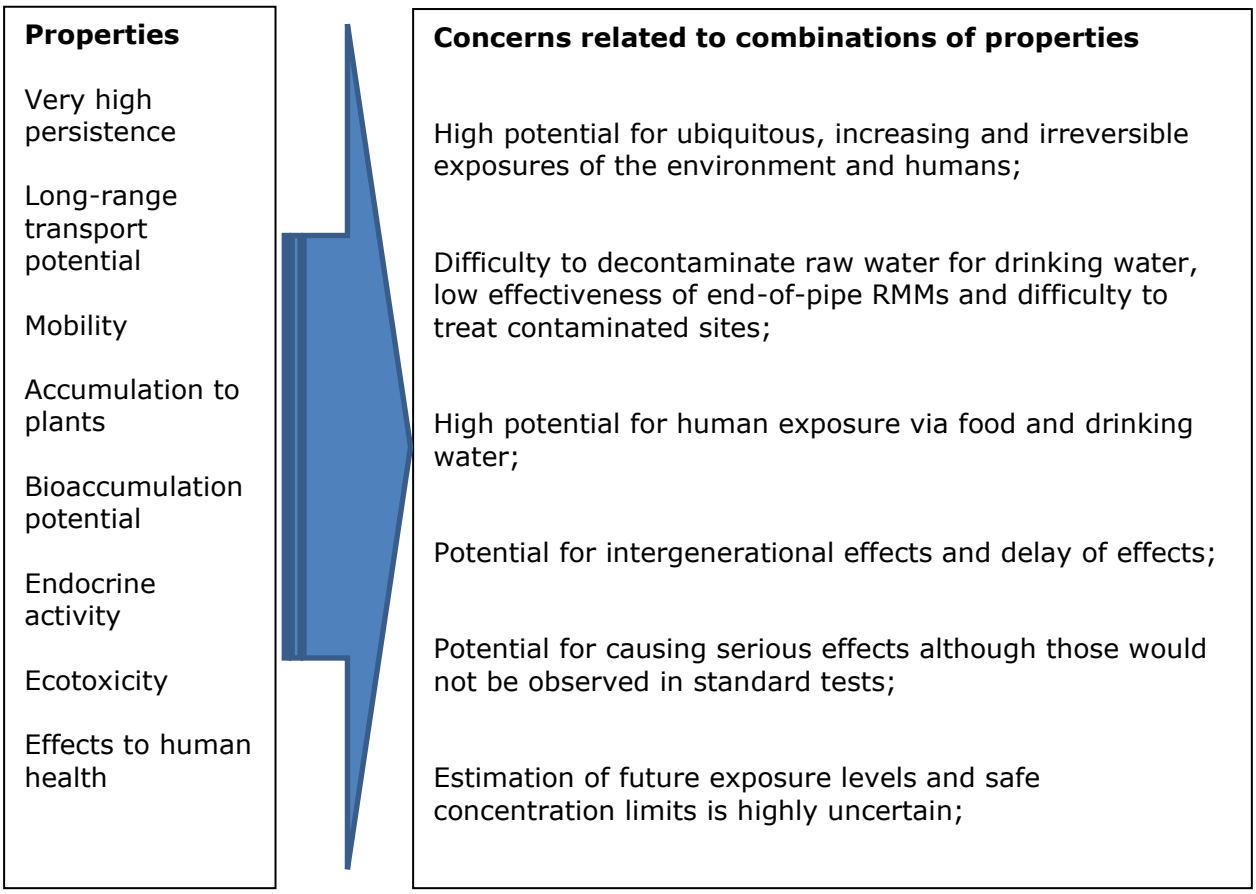

Figure 1. PFAS properties and property-related concerns resulting from combinations of the properties (Dossier Submitter schematic; Source: Background Document).

Case-by-case assessment

In cases where quantitative risk characterisation or PBT/vPvB assessment are not practicable, under REACH Annex I, paragraph 0.10[9], risks can be assessed by means of a 'case-by-case' approach. The Dossier Submitter describes this general approach as well suited to the risk assessment of PFAS based on (i) their long-term persistence in the environment and (ii) the potential for this to give rise to an irreversible stock pollution that is associated with known or suspected environmental and/or human health risks (see below). Due to their persistence, PFAS will accumulate in the environment and eventually and inevitably represent a risk.

Therefore, the Dossier Submitter concluded that the risks arising from the use of PFAS in firefighting foams are not adequately controlled.

As all releases contribute to the potential for effects thresholds to be exceeded in the future, the Dossier Submitter considers that PFAS should be treated as non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment assumed to result in a risk.

To minimise the likelihood of adverse effects arising as a consequence of the exposure

[9] "*In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in sections 1 to 6* [see 0.6.1 and 0.6.2] *are impracticable, the risks associated with such effects shall be assessed on a case by case basis….*".

concentrations arising today, or that would arise in the future, the Dossier Submitter considers that a restriction under REACH should minimise releases of PFAS to the environment, similar to the existing obligations for registrants of PBT/vPvB substances under REACH. Minimisation of release would also minimise the potential for cumulative effects arising from the presence of PFAS in the environment.

HAZARDOUS PROPERTIES

Persistence

PFAS are among the most stable organic compounds. Common for all PFAS is that they have perfluoroalkyl moieties. These moieties resist environmental and metabolic degradation due to the very stable C-F bonds.

In terms of persistence, PFAS can be divided into "precursors" and "arrowheads". Based on modelling, complex precursors are known or expected to degrade on a timescale from hours to years to arrowheads such as PFCAs, PFAA, PFECAs and PFSAs. The degradation of a PFAS precursor stops (i.e., it becomes an arrowhead) when the substance contains only perfluorinated carbons or other very persistent moieties. Environmental degradation of the non-fluorinated moieties in PFAS precursors often leads to the formation of degradation products with increased mobility in water and/or air. The half-lives of arrowhead PFAS in the environment far exceed the criteria for very persistent substances in Annex XIII to REACH.

The continuous use and release of these very persistent substances leads to sustained exposure and increasing stocks in the environment. This persistence will lead, inevitably, after release to the re-distribution of PFAS from one environmental compartment to another (e.g., from soil to freshwater to marine environment). Even if releases of PFAS are minimised now, PFAS will remain in the environment for a very long time. Furthermore, precursor stocks in the environment represent a long-term source of arrowhead substances, even if the releases of precursors are stopped. The longer the stock is allowed to increase, the less effective future emission reduction will become.

The increasing stock pollution will result in increasing likelihood that known and unknown effects occur, be it by a single PFAS and/or in a mixture with other PFAS.

Long-range transport potential (LRTP)

PFAS can be transported by air, water and matrices to which they are adsorbed or absorbed, such as dust, sediments, migratory animals, or through matrices in which it is included as additive, e.g. polymers. Because of non-degradability, the movement of their carriers leads to global drift of PFAS over long distances from the point of release. Calculated characteristic travel distances (CTD) of FTOHs and PFCAs reach thousands of kilometres in air and water. For volatile PFAS, such as FTOH, the long-range transport route is expected to change from LRTP via air to water when the substances degrade to their corresponding arrowhead PFCAs. Transport pathways are also for other precursor-PFAS complex due to the change of the fate properties along the degradation.

Mobility

Degradation of precursor-PFAS in the environment to perfluoroalkanoic acids (PFCAs) also render the precursors mobile in water at some point of time. The mobility of individual PFAS varies with the water solubility and adsorption potential. Generally, short-chain perfluorinated

alkanoic acids (PFAAs) and many short and long-chain PFAAs are considered to be mobile in water. For example, fluorinated olefins, which are not necessarily mobile degrade into PFCAs and hence become mobile. The same occurs, e.g., to side-chain fluorinated polymers.

It should however be noted that short-chain perfluoroalkanes also evaporate into the air when released to the environment. The same applies to the short-chain perfluoroalkylethers without further functional groups.

Accumulation in plants

Whereas short-chain PFAS (in particular below C8) typically accumulate in above-ground plant parts, long-chain PFAS accumulate in the roots and show lower translocation factors to the above-ground plant parts. This is influenced by the higher water solubility, lower molecular size and lower hydrophobicity of the short-chain PFAS. Studies also indicate that the short-chain perfluorocarboxylic acids (PFCA) are more effectively taken up by plants compared to the long-chain PFCA.

Consumption of plant material, e.g. grains and vegetables either as roots or above ground plant parts, function as a source of PFAS to humans and animals. Accumulation of many arrowhead PFAS in plants increases the relevance of this route of exposure. Accumulation in plants is of additional relevance when agricultural soil is contaminated with PFAS, leading to the contamination of agricultural plants.

Bioaccumulation

C11-C14 PFCAs[10] and C6-PFSA[11] have been shown to fulfil the vB-criterion and C8[12]-C9[13]-C10[14]-PFCA the B criterion (vB not assessed) under REACH. From its log Kow, shorter chains, e.g. C6 PFAS such as PFHA would not fulfil the B criterion.

Based on increasing evidence from modelling, laboratory and field monitoring studies, there is a justified concern for a subset of PFAS (including C8-C14 PFCAs and C6-PFSA) of being bioaccumulative while large uncertainties remain for the majority of compounds due to lack of data. Overall, the data on the bioaccumulation potential of PFAS, which are currently available, are not sufficient to substantiate bioaccumulation in the environment for all PFAS.

Studies with mammalian species show that PFAS are readily absorbed and distributed across various tissues and that some PFAS (particularly the long-chain PFAS; i.e. C8 and longer) have a long half-life in organisms. Data for PFCAs and PFSAs and some PFECAs indicate that PFAS partition to proteins. Binding to albumin and transporter proteins, which are classes of ubiquitously expressed proteins, efficiently distributes PFAS into different tissues, and enhance passage across brain, placental barriers, and transfer via milk. Accordingly, PFAS do

[10] MSC Decision ED/169/2012

[11] Also referred to as PFHxS; MSC Decision ED/30/2017

[12] C8-PFCA also referred to as PFOA; MSC Decision ED/69/2013

[13] MSC Decision ED/79/2015

[14] C10-PFCA also referred to as PFDA; MSC Decision ED/01/2017

not follow typical accumulation patterns, i.e. partitioning into adipose tissue, but rather bind and accumulate in protein-rich organs like liver.

Furthermore, PFAS, particularly the PFAAs as arrowheads, are absorbed through diet and accumulate in air-breathing organisms as compared to gill breathing organisms, because unlike the latter, air-breathers cannot readily eliminate PFAS by passive diffusion. Elimination to water via gills is facilitated by the solubility of most PFAS, while air-breathing organisms are not able to excrete PFAS by ventilation via the lungs to air. Thus, established assessment methods of bioaccumulation based on bioconcentration testing in aquatic organisms are not an appropriate surrogate for estimating the bioaccumulation behaviour of PFAS (see Annex B.4.5) in general. Unfortunately, in comparison with freshwater species, laboratory bioaccumulation data are very limited for air-breathers.

Endocrine Activity / Endocrine Disruption

In vitro and *in vivo* data provide indications of interactions of various PFAS with the endocrine system of environmental species.

Ecotoxicity

The data on the ecotoxicity of PFAS, which are currently available, are not sufficient to substantiate adverse effects in the environment for the group as a whole. There is however evidence for a subset of PFAS (including 6:2 FTOH) that adverse effects occur. The large amount of different substances in the group of PFAS with heterogenous properties (e.g. due to different functional groups) makes the assessment of their ecotoxicity very complex. It is noted, that most recently, the fluorotelomer alcohol 6:2 FTOH was evaluated by RAC to warrant a classification of Aquatic Chronic 1.

Effects on human health

Available scientific literature on PFAS that have been investigated in animal and epidemiological studies clearly show human health hazards and concerns for many PFAS.

There is a vast amount of literature published on the health effects of PFAS, mostly on the PFAA arrowheads PFCAs and PFSAs, especially on PFOA and PFOS. Other PFAS have been less well-studied, but attention for research and the availability of hazard information is increasing. Some precursors to PFAAs may be of less concern with regard to human health effects, but will ultimately add to exposure of PFAAs due to degradation and hence, also add to the concern.

EFSA has for example established Tolerable Weekly Intake values for the sum of PFOA, PFOS, PFNA and PFHxS due to their interaction with the immune system in humans. Similar effects were found regarding the PFOS alternative 6:2 Cl-PFESA (F-53B).

Further, experimental animal studies across different groups of PFAS demonstrate that liver, kidney, thyroid, immune system, and reproduction are main targets of PFAA toxicity. For PFOS, PFOA, PFNA, and PFDA and their salts this has resulted in harmonized classifications for carcinogenicity (Carc. 2), reproductive toxicity (Repr. 1B), lactation effects (Lact.) and specific target organ toxicity - repeated exposure (STOT RE 1, except for PFDA).

Data available for less well-studied PFAA arrowheads and some PFAA precursors indicate that these PFAS can have similar effects as the well-studied ones mentioned above and a number

of other PFAAs and PFAA precursors have self-classifications for Carc., Repr., Lact. and/or STOT RE.

RAC conclusion(s):

RAC agrees with the Dossier Submitter's approach of applying the case-by-case risk assessment as outlined in Annex I 0.10 and of treating PFAS as a whole as non-threshold substances, with any release assumed to result in a risk.

RAC concurs with the Dossier Submitter's hazard assessment of PFAS in general acknowledging that neither fluorinated gases nor fluoropolymers may not be present in firefighting foams.

The property of persistence that is common to PFAS and/or their degradation products is a core concern. The half-lives of the terminal degradation products (arrowhead PFAS) in the environment significantly exceed the criteria for very persistent substances in Annex XIII to REACH and are accompanied by other properties of concern.

Many PFAS substances are highly mobile in the environment and when combined with high persistence, this leads to Long Range Transport Potential and global drift of PFAS over long distances from the point of release. RAC is of the opinion that these properties combine to present challenges to containment and remediation of pollution.

The precursor PFAS stocks in the environment represent a long-term source of break-down arrowhead substances, even if the releases of some precursors have ceased. RAC shares the concerns of the Dossier Submitter that because of the persistence of PFAS, plus in some cases their mobility and long-range transport potential, their releases into the environment might ultimately reach concentration levels that may cause an effect.

Studies have established a range of other hazards for PFAS, often depending on the specific structure of the PFAS. It is accepted by RAC that due to the very large number of PFAS, the hazards are not homogeneous and there will always be some uncertainty regarding the hazards of the entire group. RAC considers the high persistence of PFAS in combination with other hazards present grounds for significant concern.

RAC notes that EFSA reviews have established an association between PFAS exposure and adverse health effects, with immune effects as the most sensitive endpoint in humans.

Key elements underpinning the RAC conclusion:

RAC has reviewed the common property of persistence and other properties of concern that have been collated by the Dossier Submitter, and in particular considered the applicability to firefighting foams (Annex B). RAC also reviewed the input on this topic from the consultation. The existence and extent of properties of concern other than persistence are found to vary, depending on the PFAS structure, and may not apply to all PFAS that are ingredients of firefighting foams. In general, RAC accepts this uncertainty due to the extensive number of PFAS, the prevailing commercial confidentiality regarding disclosure of the ingredients of firefighting foams and their changing recipes. Nevertheless, as PFAS in the environment from firefighting foam degrade over time, the properties of those degradation products are usually applicable (usually perfluoroalkanoicacids, PFAAs),

regardless of the original composition.

Overall, RAC considers that persistence combined with additional hazards is likely to give rise to adverse impacts. Research is active in this field that is likely to increase the knowledge of such impacts, but it is unlikely to bring certainty. If any future findings increase the concern, a substantial build-up of widespread pollution from PFAS will already have occurred, remediation is challenging, if not impossible, and mitigation would not be possible.

HAZARDOUS PROPERTIES: ANALYSIS

Persistence The Dossier Submitter states that PFAS are either persistent themselves or degrade to environmentally stable end products which are still PFAS. This statement is supported by QSAR modelling of biotic degradation of three representative members of six different subgroups (Carboxylic, Sulfonic and Phosphonic acids, Perfluoroalkanes, Perfluoroalkylamines and Ethers), which predict a slow to very slow degradation of PFAS. The modelling predictions have been supported by laboratory experiments and environmental monitoring referred to in Annex B.

These selected substances and subgroups represent final degradation products, also termed "arrowhead" substances or subgroups. When PFAS's contain degradable non-perfluorinated moieties, they may not be persistent in themselves but degrade to persistent arrowheads.

RAC has previously reviewed degradation pathways and recognised the persistence of the degradation product in restriction proposals on PFOA (ECHA, 2018b), C9-C14 PFCAs (ECHA, 2018a), and PFHxA (ECHA, 2021a) all of which were found to fulfil the P and vP criteria according to REACH Annex XIII. They have been used in fire-fighting foam.

RAC considers that the structural properties of current and future PFAS ingredients in fire-fighting foam are likely to be similar to those of PFAS which have been investigated as described above and it is reasonable to conclude that they will almost certainly share the property of persistence due to the stability of the molecular structure (Siegemund et al., 2012).

RAC notes that as the stability of the PFAS is based on the stability of the carbon-fluorine bonds and the shielding effect of fluorines surrounding perfluorinated carbons, it could be argued that the most simple perfluorinated substances are less persistent than, e.g., long-chain PFCAs. However, RAC agrees with the Dossier Submitter that the available evidence is not sufficient to conclude on whether these specific PFAS subgroups are either not very persistent themselves or degrade to not very persistent PFAS. RAC therefore concludes that all substances in the scope of the proposal are persistent.

RAC supports the conclusion of the Dossier Submitter that PFAS will trigger the Annex XIII criteria for very persistent substances and thus remain in the environment for decades to centuries, and that environmental stock will continue to increase if emissions do not cease, becoming pervasive and permanent.

Regarding regulatory action and persistence, the Dossier Submitter referred to publications that recommend that PFAS are regulated on the basis of their persistence only, sometimes termed the "P-sufficient approach" to regulatory action. (Cousins et al., 2019, Mackay, 2014, Persson et al., 2013). RAC recognises that various regulatory bodies have identified that the major concern of PFAS is due to their persistence (EEA 2020, OECD/UNEP2013,

California Department of Toxic Substances Control). Overall, RAC concurs with this approach. Also, RAC notes that persistence is the core concern of a groups of scientists who have published various statements on PFAS (Helsingør 2014, Madrid 2015 and Zurich 2018).

Long range transport potential (LRTP). PFAS contamination is found ubiquitously in the environment, including in the remote polar regions (Annex B.4.2.4/appendix 10). PFAS that have been released into the environment partition into the various compartments of air, water, biotaand solid matrices, such as dust, sediments, and soil, and the partitioning depends on their specific properties such as solubility adsorption and volatility. Because of non-degradability, the movement of their carriers leads to global drift of PFAS over long distances from the point of release.

Mobility. RAC notes that the carbon-fluorine bond in any PFAS whether a precursor or arrowhead is particularly strong and offers physical properties that include high water and oil repellence, properties which mean that many PFAS substances are often highly mobile within the natural environment as well as highly persistent.

Mobility is a concern in relation to the potential for drinking water contamination and uptake in plants and crops. It is also a contributing factor for long range transport via water

Generally, short-chain PFAA and many long-chain PFAA can be considered mobile in water. Perfluoroalkanes with chain length of 4 carbons have boiling points below 0°C, hence it is more likely that these short-chain PFAS evaporate into the air when released to the environment.

Three PFAAs have been accepted as being mobile so far under REACH: PFBS[15]; HPFO-DA[16]; PFHxA[17].

Many PFAS belong to the precursors of PFAAs, which have been demonstrated to be either mobile or very mobile. Hence a large part of PFAS can be considered as mobile in water, either by themselves or as result of their degradation into PFAAs. Uncertainties remain regarding mobility of several other groups of PFAS in water.

RAC notes the many studies showing widespread distribution of PFAS in water (Sims et al 2021) and soil (Brusseau et al., 2020) which together with databases on monitoring data from Sweden, Italy, France and Austria (IPChem, NORMAN) support the finding of mobility of many PFAS.

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[15] ECHA'S MEMBER STATE COMMITTEE SUPPORT DOCUMENT FOR IDENTIFICATION OF PERFLUOROBUTANE SULFONIC ACID AND ITS SALTS AS SUBSTANCES OF VERY HIGH CONCERN BECAUSE OF THEIR HAZARDOUS PROPERTIES WHICH CAUSE PROBABLE SERIOUS EFFECTS TO HUMAN HEALTH AND THE ENVIRONMENT WHICH GIVE RISE TO AN EQUIVALENT LEVEL OF CONCERN TO THOSE OF CMR1 AND PBT/vPvB2 SUBSTANCES (ARTICLE 57F). Adopted on 11 December 2019.

[16] See footnote 15

[17] ECHA's Committee for Risk Assessment (RAC). Opinion on an Annex XV dossier proposing restrictions on undecafluorohexanoic acid (PFHxA), its salts and related substances ECHA/RAC/RES-O-0000006976-57-01/F . Adopted 3 June 2021.

RAC notes that substantial concentration gradients in groundwater have been observed in the vicinity of identified point sources from typically 20,000ng/l immediately adjacent to less than 10ng/l several km away (Filipovic et al, Liu et al., 2016). This may reflect how soil is a significant reservoir for PFAS at contaminated sites, as indicated in a meta-analysis of PFAS soil-to-groundwater concentration ratios for samples collected from 324 aqueous film forming foam (AFFF) source-zone sites across 56 military installations distributed throughout the U.S. (Hunter Anderson et al., 2019).

Another newly discovered transport pathway resulting in mobility involves accumulation of PFAS in the ocean, and transport of PFAS with deposition on the seashore from sea spray aerosol during windy conditions (Sha et al, 2022).

Accumulation in plants. RAC notes that contamination of soil with PFAS following use of firefighting foam has been established (Appendix 10.2.5). Laboratory and field data indicate PFAS have the ability to accumulate in plants although bioaccumulation processes vary with PFAS (review by Li et al., 2022). RAC agrees with the Dossier Submitter that accumulation in plants presents a hazard. While there is wide variation in the extent of accumulation in plants observed depending on the PFAS and the conditions, and the data does not include all PFAS, this does not undermine the conclusion.

Uptake in plant species at contaminated sites has been documented. For example, in wheat-grass cultivated in aqueous film-forming foam polluted soils, the ΣPFAS varied up to 6.19 µg/g wet weight (Bräunig et al., 2019). Consumption of PFAS-contaminated plant products by farm animals and humans likely causes health risks in human (Li et al., 2021). Perturbation of plant biochemical activity has also been observed.

Bioaccumulation. Field studies have found long- and short-chain PFAS in all environmental compartments in mammals, birds, fish or other vertebrates throughout Europe and globally. In aquatic food webs, freshwater exposures of fish have been linked to the proximity to airports where PFAS are emitted via firefighting foams (Ahrens et al., 2015).

Apex predators of aquatic food webs have been shown to accumulate high PFOS levels in proximity of potential point pollution sources (e.g. Badry et al., 2022). A comparison of laboratory Bioconcentration Factors (BCFs) with field bioaccumulation factors (BAFs) revealed that 60% of the BAFs are greater than their corresponding BCFs (Burkhard 2021), possibly due to multiple exposure routes taking place in field conditions. Further considerations are that BCF-studies are difficult to conduct for surfactants adhering to surfaces, and that BCFs for gill-breathing organisms may not be relevant for air-breathing organisms due to the difficulty in excretion from the lungs.

RAC notes that certain PFAS bind to proteins and accumulate in specific organs. This has a higher potential to cause adverse effects, since organ toxic effects may arise (B.5.1 on toxicity). Also, research on selected PFAS indicate they are transferred to off-spring, milk and eggs in many taxa, including livestock species (Death et al., 2021, Chen et al., 2021). Current firefighting foam formulations are usually short chain PFAS and short chain PFAS tend to be less bioaccumulative than long-chain PFAS. Nevertheless, RAC concurs that bioaccumulation presents a hazard for PFAS in firefighting foams.

Endocrine Activity/ Endocrine Disruption (EA/ED)

RAC recognises that the available dataset for establishing EA/ED for the environment and

for human health is relatively small and while this hazard is indicated, RAC acknowledges the uncertainty regarding this property. However, this does not materially influence the overall hazard posed by PFAS due to the strong evidence of other hazards.

Ecotoxicity

RAC acknowledges the uncertainty regarding the ecotoxicity of PFAS and concludes it does not materially influence the overall hazard posed by PFAS due to the strong evidence of other hazards.

Human Health. There is a large body of epidemiological and experimental research on the health effects of PFAS, as shown in Annex B.5. The human health hazard is supported by harmonised classification for PFOS, PFOA, PFNA (nonanoic), and PFDA (decanoic) and their salts. RAC notes that increasing knowledge regarding hazards of PFAS has generally led to increased concern and actions, such as the lowering of Tolerable Weekly Intake values by EFSA in 2020 due to the newly assessed endpoint of immunotoxicity.

The Committee points out that toxicity to reproduction, of which much more is known for some PFAS than the endocrine disrupting properties mentioned above, adds weight to the concern for human health for the group as a whole, noting that PFOA (C8) has harmonised classifications in Annex VI to the CLP Regulation as Repr. 1B (for development) and Carc. 2 and Perfluoroheptanoic acid (C7) as Repr. 1B (development) (published in the 18th ATP).[18] Germany has recently proposed to classify undecafluorohexanoic acid PFHxA (C6) and its inorganic salts as Repr. 1B (also for development) based on animal data from studies conducted with members of the C6 group. Despite the lack of precise data on composition of firefighting foams, both C8 and C6 chain lengths are known to have been used for this purpose.

RAC recognises that due to the large number of PFAS, it is not feasible to investigate all and that toxicity of some may be low. Lower toxicity is associated with polymeric PFAS but these are not likely to be ingredients in firefighting foams. The potential for regrettable substitution is illustrated by HFPO-DA (GenX)[19], which was initially introduced as a safer alternative to PFOA but eventually showed comparable concerns(Blake et al., 2020). Environmental and occupational exposure studies have shown that PFAS are readily absorbed by all routes of exposure - oral, inhalation and dermal.

Regarding elimination, the half-lives of PFAS are highly variable. When they are in the order of years, as with PFOA, PFOS, PFNA, PFDA, PFHxS and PFUnDA, this can result in bioaccumulation in humans and contribute to the potential for adverse health impacts. There is a potential for combined exposure both when several different PFAS ingredients are contained in the firefighting foam and due to exposure from PFAS already in the environment.

Global warming potential

The global warming potential (GWP) of a substance in air depends on the direction and extent to which that substance alters the radiation balance of the atmosphere (radiative

[18] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0692&qid=1691750979114

[19] SVHC identification: https://echa.europa.eu/documents/10162/53fa6a5b-e95f-3128-ea9d-fa27f43b18bc

forcing) and its persistence. The GWP is expressed relative to CO2 over a specified time horizon, typically 100 years.

RAC recognises that certain volatile PFAS are significant greenhouse gases with a potential high climate impact (Cousins et al. (2020)). The GWP-100 (100 years) of PFAS in the atmosphere is typically several thousand times that of CO2. (IPCC 5th Assessment report) (Say et al 2021).

Additional hazards

Additional aspects such as intergenerational effects also give rise for concern, as do both the cumulative effect of PFAS from multiple sources and the combination of properties such as volatility with LRTP.

3.1.2.2. Emissions and exposures

Summary of Dossier Submitter's assessment:

Based on an extrapolation of data provided by Eurofeu it is estimated that about 18 000 tonnes of PFAS-containing firefighting foam concentrates are sold in the EU per year, about 10 800 tonnes are estimated to be employed in fixed systems and about 7 200 in mobile systems. The oil/chemical industry is by far the largest user sector of foams (59 %), but municipal fire services (13 %), marine applications (12 %), civilian aviation (9 %) and defence applications (6 %) also account for significant volumes. Hand-held fire extinguishers only account for a very small share of PFAS-containing foams (1 %[20]), the vast majority of this category are fire extinguishers.

According to the model calculations under the baseline scenario, a total annual emission of around 470 tons of PFAS across the environmental compartments would occur (see Table 4 for a breakdown by sector). This represents a total of around 14 100 tonnes of cumulative emissions of PFAS over 30 years.

Table 4. Total emissions of PFAS to the environment under the baseline per sector or use*

Sector/type of use	**Annual emissions (t/y)**
Oil/chemical industry (Seveso establishments)	200
Other industries	<10
Civilian aviation	40
Defence	20
Municipal fire services	50
hand-held fire extinguishers	<10
Marine applications	50
Training and testing	80
All sectors	**~470**

*Note: Rounded figures. These are approximate values

[20] The number of fire extinguishers in use across the EU was corrected upwards during the consultation on the Annex XV report, but in the context of the emissions assessment the value was kept constant because it was also reported by stakeholders that only a small fraction of fire extinguishers are actually used during their service life.

Using a source-flow model and the assumptions outlined in the dossier, the material flow and emissions to the environmental occurring at different life cycle steps were calculated for the baseline (and each assessed restriction option). The sources of emissions under the baseline scenario are illustrated in Figure 2.

Regarding the emissions of PFAS-containing foams by life cycle stage, a central estimate of 10 % annual use for incident management and 2 % for training and testing is assumed, across all sectors (percentages compared to foam stock). During training exercises, aside from marine applications, it is assumed that the efficacy of bunding (use of retaining walls) and/or other control measures is 97 %. This means that for training and testing, much of the firefighting concentrate within runoff is contained and, under the baseline scenario, sent primarily to either an on-site or off-site wastewater treatment plant (WWTPs). For incidents, the collection of firewater runoffs (i.e. foam concentrate mixed with water and other on-site material) is considered to be less effective and variable among sectors and, under the baseline scenario, the collected fire waters are mainly sent to WWTPs. It is noted that municipal WWTPs are not effective in removing/eliminating PFAS.

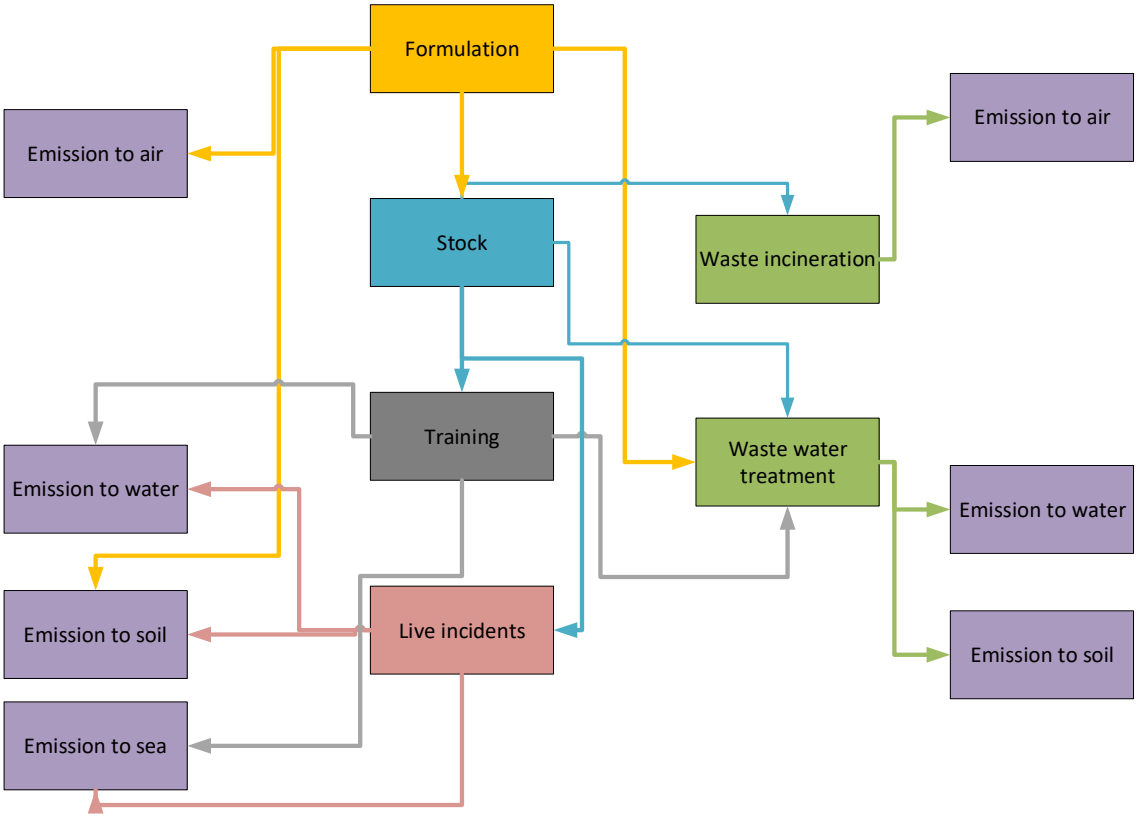

Figure 2. Material flow diagram showing the connection between the different life cycles stages of formulation, in-use, stock and waste treatment for PFAS in firefighting foams under the baseline scenario.

RAC conclusion(s):

RAC notes that when estimating the emissions, the Dossier Submitter applied accepted methodology and based their assumptions on credible collation and extrapolation of available data.

The methodology applied by the Dossier Submitter allows for the releases to different

environmental compartments to be quantified. RAC acknowledges that substantial consultation was undertaken by the Dossier Submitter to establish use and stock quantities and to identify the sectoral distribution which in turn forms a basis for the estimation of releases to the environment.

RAC considers the use and stock estimates to be sufficiently robust for the assessment and the release estimates during all stages of formulation, storage training and live incidents to be plausible.

The Dossier Submitter assumes that releases during training and live incidents are to water (including sea) and soil only. RAC considers that release to air is likely to occur during use and may also occur over time from water and soil compartments, but this was not addressed by the Dossier Submitter. However, this affects the distribution between compartments only and does not alter the overall release estimate.

Regarding disposal and treatment of PFAS-containing foams during each of the life cycle stages, RAC agrees with the assumptions and conclusions of the Dossier Submitter that studies have shown poor effectiveness of waste-water treatment in removal of PFAS from aqueous waste streams.

RAC notes that the 99% effectiveness for hazardous waste incineration assumed by the Dossier Submitter may not be achieved in practice. Correct conditions for incineration are critical for complete removal and degradation of PFAS, as short-chain PFAS are formed if the conditions are not optimal.

Overall, RAC considers the estimate of 470 tpa released to the environment are reliable and a sound basis for the risk characterisation.

Key elements underpinning the RAC conclusion(s):

A reliable estimate of the quantities in use and in stock and an estimate of the percentage released is required to establish environmental releases and a basis for the exposure assessment. Emissions occur in all of the lifecycle stages considered by the Dossier Submitter, namely formulation, storage in stock, use and disposal. The use lifecycle can further be divided into live incidents, testing and training.

Estimates of Use and Stock

The Dossier Submitter used a combination of desk studies, communication with trade organisations (Eurofeu and FFFC), interviews with foam formulators, stakeholder consultation and a commissioned study (Wood et al 2020) to obtain market data (tonnages, uses, sectors, import/export, components, shelf lives etc.). RAC considers that substantial effort was expended to gain a comprehensive view of use and stocks. RAC notes that the source-flow model developed by the Dossier Submitter is based on standard methodology, using the European Monitoring and Evaluation Programme (EMEP) air pollutant emission inventory guidebook and the OECD Emission Scenarios document for Aqueous Film Forming Foam (AFFF).

The Dossier Submitter estimates about 18 000 tonnes of PFAS-containing firefighting foam concentrates are sold in the EU each year, with a PFAS content of 2-3 % in concentrates and 1 % in portable fire extinguishers, and a sectoral breakdown as presented in their summary.

This use estimate was extrapolated from data provided by Eurofeu, an EU trade organisation for manufacturers of fire protection equipment. RAC notes that the Eurofeu website showed national trade organisation members from six EU countries (Belgium, Germany, France, Italy, Spain and Ireland) and individual members from an additional two EU countries (Netherlands and Luxembourg). Although 8 EU countries appears to be a limited base, it is reported that the market is consolidated with about 20-25 formulators, many of them major international companies and Eurofeu claims to represent 60-70 % of the market.

RAC considers it plausible to assume that customers usually purchase to replenish used stock and that the amount of foam imported into the EU and exported out of the EU are roughly equal at 3 500 to 5 000 tpa (Eurofeu).

RAC is of the opinion that the projections regarding stock levels and use quantities are reasonable, as they were established and confirmed from a range of sources and corroborated during the Annex XV report consultation. Information from a consultation during the development of the dossier commissioned by the Dossier Submitter (Wood et al 2020) is broadly consistent with the Eurofeu estimates that are used as the main basis for determining use quantities.

Annual usage rates of 10 % for live incidents and 2 % for training and testing was established by the Dossier Submitter from consultation with Eurofeu, FFFC, WFVD (the German Industrial Fire-Fighters Association, who conducted a survey during the PFHxA restriction consultation) and various foam users.

Using the annual use quantity and the usage rates, the Dossier Submitter estimates the existing stock to be 148 500 tonnes of PFAS-foam. RAC notes that a lower estimate of 62 500 tonnes of foam was provided by stakeholders. A higher estimate was provided in a study commissioned by the Dossier Submitter (Wood et al 2020) that concluded the existing stock to be 210 000 – 435 000 tonnes. The Dossier Submitter combined this initial input from the study with evidence provided by stakeholders to arrive at the stock estimate referenced above. RAC recognises the uncertainties in establishing the estimate of 148 500 tonnes PFAS-foam in stock but accepts it as a reasonable basis for the assessment. This corresponds to about 4 000 tonnes of PFAS in stock. The upper estimate by Wood et al corresponds to almost three times that figure, approximately 12 000 tonnes.

Regarding disposal of expired stock, Buser et al (2009) and Bipro (2011) suggest the quantities are insignificant. POPRC 2018 was informed it could be significant from private fire brigades, but RAC considers the stock held by private fire brigades could be expected to be a small proportion. The Dossier Submitter estimates the quantity of expired stock to be low at 84 t/a, corresponding to 2 t/a of PFAS. (Appendix 8.1.3). RAC notes that the quantity used each year is greater than the tonnage reaching the expiry date after 15 years, which supports the contention that expired stock levels are low. Furthermore, foams that reach expiry dates may be tested to establish if they can continue to be used. Due to the relatively high cost of PFAS-foam, it is reported to be common practice to test the foam at shelf life rather than to automatically dispose of it. Consequently, RAC considers that the quantity of expired stock disposed of annually is not a significant consideration.

RAC notes that portable fire extinguishers account for less than 1 % of the annual sales and the existing stock. However, this corresponds to a large number of units over many sites. RAC concurs with the increase by the Dossier Submitter in the estimate used for the installed base from 15 million units (Eurofeu 2019a) to 40 million units following the consultation input.

RAC concurs with the decision to keep the emission assessment unchanged as the issues regarding portable fire extinguishers relate to the wide dispersive use rather than potential for PFAS release from fire extinguishers, which is insignificant compared with large installations.

Overall, the estimates used are broadly consistent with data from other sources and public consultation. RAC recognises the uncertainties regarding the use estimates but considers them sufficiently robust for the assessment.

Release estimates in baseline scenario

The release estimates are established by considering the releases at each life cycle stage and the releases at waste treatment.

In the baseline scenario model, the input parameters relating to releases associated with formulation and storage are based on an OECD emission scenario document[21] and ECHA guidance R16[22]. RAC considers this to be an acceptable source of data. The formulation emissions figure of 4.5 % of total PFAS formulated per year is equivalent to 20 t/y of PFAS potentially entering into the environment. The total emissions of PFAS of 470 tonnes per year in Table 1 includes the formulation losses and consequently the quantity released during use is 450 tonnes per year.

Releases during use (i.e. live incidents, testing and training) occur primarily via the runoff water. Three potential fates for runoff water have been identified (Cornelsen 2021): direct to the soil and potentially groundwater; to the stormwater/sewage system; collection in bunded areas. The Dossier Submitter has taken releases to be 100 % of the amounts used during live incidents and 3 % during training and testing (where effective collection of 97 % is assumed) to water and soil compartments. This corresponds to about 360 t/a for live incidents and 2 t/a for training and testing. This is based on the PFOA Annex XV dossier and expert judgement (Wood et al 2020, Ramboll). Although there is a high collection rate of about 70t/a during training, the entire amount used is later assumed to be released to the environment due to ineffective treatment of collected fire water in municipal sewage treatment plants.

The assumption of extensive release to soil and water is supported by evidence of environmental contamination following firefighting incidents. PFAS have been detected in soil at contaminated sites, where the reported concentrations are generally orders-of-magnitude greater than ambient background level soil concentrations and typical groundwater concentrations (Brusseau et al., 2020).

The review by Sims et al 2021 identified firefighting foam as one of the leading contributors to surface water and ground water contamination, particularly near airports and air bases (D'Agostino and Mabury, 2017; Moody and Field, 1999, 2000). Examples include an oil depot in Buncefield (UK) (Nordic Council of Ministers, 2019) and an air base in Sweden (Jakobsson

[21] "Emission scenario document on the use of aqueous film forming foams in firefighting" available at https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)5&doclanguage=en

[22] https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf/b9f0f406-ff5f-4315-908e-e5f83115d6af

et al., 2014).

Biological wastewater treatment is the most common disposal method for collected runoff while incineration is the most common method for foam concentrates (Wood et al 2020).

RAC considers that the assumption that conventional biological wastewater treatment (WWT; i.e. sewage treatment) has 0 % effectiveness is plausible. Various studies have observed that conventional WWT has limited efficiency in removing studied PFAS. (PFCAs and PFSAs - Bossi et al., 2008; Arvaniti and Stasinakis, 2015; Eriksson et al., 2017. (PFAAs - Becker et al., 2008; Loos et al., 2013; Filipovi and Berger, 2014). Depending on the conditions, degradation products may be formed (Guerra et al., 2014, Eriksson et al., 2017).

In addition, the disposal of the waste sludge from industrial and municipal WWT can also be a significant source of some PFAS to the terrestrial environment (Washington et al. 2010; Gomez-Canela et al., 2012 Erickson et al., 2017).

RAC notes the potential of exposure to humans from drinking water. Treatment methods of coagulation, flocculation, sedimentation, filtration, disinfection with free chlorine, raw and settled water ozonation, biofiltration, and disinfection with medium-pressure ultraviolet (UV) lamps and free chlorine have not been found to be effective in the removal of all PFCAs and PFSAs from drinking water (Quiñones et al., 2009; Shivakoti et al., 2010; Eschauzier et al., 2012 ; Rahman et al., 2014 ; Appleman et al. 2014) and of PFECAs (Sun et al. 2016; Hopkins et al. 2018).

The effectiveness of incineration in the destruction of PFAS is not well understood (US-EPA, 2020b). Much of the research has been undertaken on PFAS from sources other than fire-fighting foams, including fluoropolymers, and on municipal incinerators. Municipal incinerators with combustion temperatures of about 850℃ have been demonstrated to result in incomplete destruction of PFAS (KEMI 2016, Garcia et al 2007). Even at elevated temperatures, short-chain PFAS like CF4 (PFC-14), CHF3 (HFC-23), C2F6 (PFC-116), tetrafluoroethene (TFE) may be formed from longer chain PFAS (Stoiber, 2019; NILU, 2009).

The default release factor for hazardous waste incineration given in ECHA guidance is 99.9 %[23]. The Dossier Submitter assumed a more conservative factor of 99 %. RAC considers that as temperature and conditions for incineration are critical for complete removal and degradation of PFAS and firefighting foams are challenging, existing hazardous waste incineration may not achieve the 99 % effectiveness assumed by the Dossier Submitter. As the quantity of unused stock that is incinerated in the baseline scenario is low, at 5 t/a, this does not significantly impact the the baseline release estimates.

RAC notes that the Dossier Submitter assumes release to air during formulation and from incineration only, and not from training or incidents. RAC considers that there may be aerosol generation during use, as evidenced from personal exposure measured for firefighters. There may also be release of non-volatile PFAS to air from marine environmental compartments through sea spray (Sha et al 2022). Nevertheless, RAC does not consider this to have an impact on the overall release estimates as it is assumed that all emissions are released to the

[23] Guidance on information requirements and chemical safety assessment Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage

environment, with the small exception of incineration.

RAC notes that the release estimate methodology and values are consistent with those of the PFOA and PFHxA restriction proposals.

RAC finds the estimate under the baseline scenario plausible, that a total annual emission of around 470 tonnes of PFAS across the environmental compartments occurs from formulation, training and live incidents.

Incineration is further discussed in section 0.

Worker Exposure

RAC notes that exposure of workers such as firefighters and formulation workers is not assessed in detail in the restriction dossier. Some evidence regarding firefighter exposure is presented in B.9.3.5. while no evidence is presented regarding worker exposure during formulation.

RAC acknowledges concerns about worker exposure and although additional information on exposure due to firefighting and formulation would be beneficial, considers that further analysis is not essential for the purpose of evaluating this restriction due to the sufficiency of information on risk to humans via the environment.

RAC considers that inclusion of information on worker exposure would support the comprehensiveness of the dossier but acknowledges that its inclusion is not likely to alter the conclusions of this restriction.

3.1.2.3. Risk characterisation

Summary of Dossier Submitter's assessment:

PFAS have a high potential for ubiquitous distribution and increasing and very long-term exposure of the environment. This in combination with a difficulty to decontaminate raw water for drinking water and low effectiveness of common end-of-pipe wastewater treatment trigger a potential for human exposure via food and drinking water. These together lead to a potential for intergenerational effects and delay of effects. Furthermore, due to the exposure to mixtures of PFAS in the environment, complex degradation patterns of precursor PFAS to arrowheads are due to the very high persistence and hence exposure times reaching decades if not centuries, quantification of future exposure levels and safe concentration levels is highly uncertain for PFAS. Combined effects may be expected for PFAS.

Continued emissions of PFAS will result in increasing exposures and therefore a high likelihood that effect thresholds of PFAS are exceeded and those of PFAS with yet unknown effects to occur. These would be caused by single PFAS and/or in a mixture with other PFAS. It should be noted also that for human sensitive endpoints of PFAS, such as effects on the immune system, and in highly exposed populations, effect thresholds of the most studied long-chain PFAS PFOA and PFOS are already exceeded today (EFSA, 2020).

For the above reasons, PFAS should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances. Their releases should be accordingly used as a proxy for risk. To prevent adverse effects in the future all releases should be minimised. According to REACH Annex I, paragraph 0.10, a case-by-case approach

applies for PFAS as underpinned by the available information on their high persistence in the environment in combination with the additional properties summarised above.

Current releases of PFAS from firefighting foams to the environment have been shown in the DS' exposure scenario. In addition, monitoring data for some PFAS show that they are ubiquitously distributed in the environment. Such data is only available for a limited subset of PFAS, and current monitoring results are therefore expected to provide only a partial picture of the overall exposure to PFAS. The observations of the ongoing releases and exposures together with the non-threshold nature of the hazard warrant a need for minimisation of the releases by the proposed restriction.

RAC conclusion(s):

The Dosser Submitter performed a risk assessment according to REACH Annex I, paragraph 0.10, also referred to as a case-by-case assessment. RAC concurs with the Dossier Submitter that PFAS should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances whereby releases are taken to be a proxy for risk and that all releases should be minimised.

RAC considers that sufficient evidence has been presented to conclude that PFAS in firefighting foam, including their degradation products, are potentially hazardous to human health and the environment.

RAC agrees with the argument put forward by the Dossier Submitter that all PFAS used in firefighting foams are likely to be released to the environment, either directly through use or indirectly through ineffective waste treatment, and that the annual release is about 470 t/y. RAC supports the conclusion that their release presents a risk to humans and the environment and that the risk increases with continued use due to their persistence and the consequent increase in environmental stocks over time.

RAC concludes that their release is not adequately controlled and should be minimised.

Key elements underpinning the RAC conclusion(s):

<u>Assessment methodology</u>

The case-by-case assessment approach is intended to cover risks for which the chemical safety assessment procedure outlined in Sections 1 to 6 of Annex I of REACH is 'impracticable' for quantitative and PBT/vPvB assessments.

RAC considers that a quantitative assessment is not applicable because of the large number of implicated substances, their persistence, the mobility of some and the irreversible nature of the releases. A PBT/vPvB assessment is not directly applicable because - although essentially all PFAS are persistent and many are bioaccumulative - the group as a whole has not been demonstrated to fulfil the PBT/vPvB criteria.

The examples given in REACH Annex I, paragraph 0.10 are sufficiently diverse for RAC to have confidence that the risks posed by PFAS, in particular due to the property of persistence, are well suited to a 'case-by-case' assessment as carried out by the Dossier Submitter.

Due to their persistence, RAC considers that PFAS should be assessed as non-threshold

substances in a similar way to PBT/vPvB substances. RAC notes that the emission characterisation methodology of identifying and estimating the amount of releases to the environment and identifying exposure routes by which humans are exposed used by the Dossier Submitter is consistent with the ECHA Guidance R11 for PBT/vPvB assessment[24]. The releases are then used as a surrogate for risk.

As non-threshold substances, a 'safe' concentration in the environment cannot be established using the data that is currently available. Should safe thresholds be derived in the future for all the necessary environmental compartments this would not address the key fundamental issue arising from the long-term persistence of PFAS whereby any 'safe' threshold will eventually and inevitably be exceeded over time due to the cumulative nature of the exposure.

RAC considers that there is an adverse climate impact associated with formulation, use and incineration of PFAS in firefighting foams that was not included in the assessment. This impact stems both from CO2 emissions associated with the incineration of foams and waste associated with the use and the global warming potential of PFAS and their breakdown products, which is less of an issue regarding the PFAS relevant to the use at hand.

Risk

The uncertainty regarding the identity of specific PFAS used in firefighting foam leads to uncertainty in the hazards that they and their degradation products present. Nevertheless, RAC considers that the common property of persistence together with the human health and the environmental concerns associated with many PFAS are give rise to significant concern, in particular when also combined with mobility.

The continuous exposure of wildlife and humans exposed via the environment from PFAS-foam may lead to unpredictable long-term adverse effects on the environment and human health. RAC agrees with the Dossier Submitter's contention that the longer the stock is allowed to increase, the less effective future emission reduction will become. Should additional significant hazards be identified in the future, it may be too late to take action due to the build-up of stocks in the environment.

Evidence of release having occurred is provided by the cases of PFAS contamination of groundwater, soil and surface water that have been documented near airports, military bases and fire drill sites in the EU, often sites where fluorinated fire-fighting foams have been used, for training or to extinguish a fire. (Nordic Council, Costs of Inaction 2019).

Numerous studies referred to in the background document have shown PFAS to be distributed around the world - from the Arctic to the Antarctic; in air, soil, surface and groundwater, drinking water and the ocean; in humans, plants and animals.

RAC considers that the release quantities of 470 t/y presented by the Dossier Submitter are credible, as discussed in 3.1.2.2, and that their release presents a risk to humans and the environment and should be minimised.

[24] https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

RAC compared the release quantities estimated here with estimates for other restrictions relating to firefighting foam in order to consider the relative risk. The estimated release quantities in firefighting foam in the PFOA restriction dossier was 50-100 t/a PFOA, although the estimate was considered highly uncertain. The release estimate in firefighting foam in the PFHxA restriction dossier was 7-39 t/a PFHxA and its salts.

RAC notes that the European Parliament adopted a resolution in July 2020 to "ensure the speedy phasing out of all non-essential uses of PFAS", and that specific PFAS in fire-fighting foam have been the subject of regulatory management under the POP and REACH regulations.

3.1.2.4. Existing risk management measures and operational conditions

Summary of Dossier Submitter's assessment:

A number of PFAS are already subject to the European Union POPs Regulation (EC 2019/1021), which transposes the Stockholm Convention and the Aarhus Protocol into Union law. As a result, the production, placing on the market and use of PFOS, its salts and derivatives on their own, in mixtures and in articles is restricted with no exemptions for the use in firefighting foams. PFOA, its salts and derivatives are similarly controlled by the POPs Regulation but there is an exemption for the use in Class B fires until 4 July 2025 if operators contain releases and manage stockpiles in accordance with Article 5 of the POPs Regulation. Testing and training with these substances is not exempted. Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds are currently in the process of being added to Annex A to the Stockholm Convention and it is expected that they will ultimately also be regulated at EU-level under the POPs Regulation, when its listing to the Stockholm Convention is finalised.

In December 2019, a proposal for a restriction under REACH on PFHxA was published[25]. The proposal includes certain transition periods and derogations for uses in firefighting foams. The proposal indicated that concentrated firefighting foam mixtures placed on the market until 18 months after the entry into force of the restriction could still be used in the production of other firefighting foam mixtures until five years after the entry into force, except for use of firefighting foam for training and testing (if not 100% contained). An exception was proposed for concentrated firefighting foam mixtures for certain defence applications until a successful transition to alternatives can be achieved, and for concentrated firefighting foam mixtures for cases of class B fires in storage tanks with a surface area above 500 m^2 until 12 years after the entry into force. The opinion of ECHA's Risk Assessment Committee and Committee for Socio-economic Analysis on this restriction proposal was adopted in December 2021.

The use of other PFAS in firefighting foams is currently not controlled at the European level.

The proposed restriction will not interfere with any implemented EU regulation (i.e. REACH restriction or bans under the POPs Regulation). Where individual substances or sub-groups of substances in scope of the proposed restriction are already covered by other legislation (such as PFOA or any possible future restriction on PFHxS or PFHxA), it should be noted that the restriction proposed by the Dossier Submitter 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

[25] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d

from PFAS 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 PFAS in firefighting foams at the decision phase.

In 2016, The Swedish Chemicals Agency (KEMI) published its strategy for reducing the use of PFAS (KEMI, 2016) beyond solely the implementation of EU legislation. This included specific measures to tackle PFAS in firefighting foams, including a proposal for national regulations covering, for example, legal requirement for the collection and destruction of fluorine-based firefighting foam, reporting requirements and review of exemptions.

In terms of operational conditions, no information was available to the Dossier Submitter regarding the level of implementation and effectiveness of best practice guidance to control exposure and environmental releases of firefighting foams published by various trade associations.

RAC conclusion(s):

The information presented by the Dossier Submitter indicating contamination of the environment with PFAS in the vicinity of locations where firefighting use or training has taken place demonstrates that despite regulatory efforts over more than a decade, current risk management measures and operational conditions do not sufficiently address the risk.

Key elements underpinning the RAC conclusion(s):

RAC acknowledges that existing restrictions have limited the use of specific PFAS in firefighting foam such as PFOA, while proposed restrictions (once implemented) will provide further limits, e.g. for PFHxS and PFHxA. From research undertaken by the Dossier Submitter, foams based on C6 chemistry are currently placed on the market. There is limited information available on the identity of the PFAS contained in foams currently on the market although 11 were identified from the stakeholder consultation (see Annex B1.1.2.5). It is reasonable to assume that these substances, and/or their degradation products, are likely to pose a similar risk due to persistence combined with other hazards as discussed in 3.1.2.1.

RAC considers that by its very nature, use of firefighting foam in live incidents has limited potential for collection of run-off water. Where run-off water is collected, the opportunities for adequate treatment are also limited. The diversity of potential conditions of use makes the implementation of appropriate risk management measures that could effectively reduce emissions to the environment extremely difficult.

Live incidents account for about 5 times the use compared with training, indicating that a restriction on training alone would be insufficient to control the risk.

RAC considers that there is no potential for minimisation of releases by other measures.

3.1.2.5. Uncertainties in the risk assessment

See section 3.4.1.

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 PFAS 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 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 PFAS emissions lead to cross-border pollution, making harmonised regulatory management on EU-level even more important.

RAC conclusion(s):

The use of PFAS in fire-fighting foams is widespread in the EU/EEA and presents a risk to the environment and to human health that is not adequately controlled (the latter either from direct exposure or from exposure via the environment).

Even if some Member States have already taken specific measures to limit or ban the use of PFAS in fire-fighting foams, this will not reduce the risks posed by PFAS on a Union-wide basis without further action.

Therefore, based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, RAC agrees that Union-wide regulatory measures are justified.

Key elements underpinning the RAC conclusion(s):

PFAS are highly persistent materials with a potential for environmental long-range transport via waterways, and thus becoming a transboundary pollution problem. Environmental and human monitoring data show ongoing exposure to PFAS. It is practically impossible to remove pollution once it has occurred and RAC is concerned about the increasing environmental burden. Activities associated with formulation, testing, training and use of firefighting foams have been identified as a source of release.

RAC considers that a restriction to reduce emissions of PFAS in firefighting foam is needed to limit the risks for human health and the environment. Due to the persistent and in some cases mobile properties of the substances, including their long-range transport potential, national regulatory action cannot adequately minimise emissions, so EU wide action is necessary. Furthermore, as fire-fighting foams containing PFAS are formulated, marketed, transported

and used throughout the EU, action should be taken on a Union-wide basis.

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 – in particular high persistence in combination with other properties including 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 to the environment (and resulting long-term human and environmental exposure), the committee recognises the challenges related to estimating the effectiveness, efficiency and proportionality of an EU-wide measure in the case of persistent and in some cases also mobile pollutants that may exhibit long-range transboundary movement if released to the environment. Using emissions as a proxy for risks reflects solely the initial input flow of the substances to the environment. 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 of 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 of PFAS emissions 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 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 as part of the Chemical Strategy for Sustainability (CSS), the European Commission chose to address the risks of PFAS, including in firefighting foams, by means of restriction under the REACH regulation. . As a result, **novel** Union-wide legislative RMOs were not specifically considered by the Dossier Submitter. The CSS also commits the European Commission to address PFAS via a group approach to regulate the entire class of chemicals.

The Dossier Submitter compared the relative merits of the proposed restriction with risk management via existing Union-wide legislation, such as the:

- Persistent Organic Pollutants (POPs) Regulation (and by extension the Stockholm Convention),
- Water Framework Directive (and Environmental Quality Standards Directive), WFD/EQSD;
- Groundwater Directive, GWD;
- Drinking Water Directive, DWD;
- Marine Strategy Framework Directive, MSFD;
- Industrial Emissions Directive, IED;
- Control of Major-accident Hazards Involving Dangerous Substances Directive, SEVESO, and
- Urban Wastewater Treatment Directive, UWWTD.

Other risk management options analysed include voluntary industry agreements, taxation of PFAS and other forms of regulation under REACH (Authorisation and Article 68.2 procedures). A main advantage of a REACH restriction is that PFAS 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. With regard to the POPs Regulation, it was noted that members to the Stockholm Convention can only request to add additional chemicals to the Convention by restricting them in their own jurisdiction. The proposal at hand therefore creates the conditions for controlling PFAS on a wider scale than just the EU via the Stockholm Convention and POPs Regulation in the future.

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

The 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/sector-specific 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/use-specific transitional periods, unless adequate risk management measures are in place to capture all the emissions to the environment.

RO3 represents the Dossier Submitters preferred option.

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 PFAS in firefighting foams (e.g. PFOS and PFOA).

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 PFAS 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 PFAS in firefighting foams at the decision phase.

RAC conclusion(s):

RAC agrees that an EU-wide restriction under the REACH Regulation that treats PFAS as a group is the most appropriate measure to reduce the risks of PFAS in firefighting foam. RAC notes that the Dossier Submitter suggests that RO3 is optimal and supports this option.

Key elements underpinning the RAC conclusion(s):

Due to the uncontrolled release of firefighting foams, directives such as the WFD/EQSD, groundwater directive, DWD, MSFD, IED, UWWTD are not applicable as they apply limits or controls either at specific sources or in the receiving compartments.

Control at source is the optimal approach and the EU regulatory mechanisms available to achieve this are restriction or authorisation. Restriction is an appropriate measure due to the wide dispersive use of firefighting foam. Authorisation would only be feasible if enacted in association with a restriction which limits the number of uses.

RAC notes that a number of other restrictions already apply to PFAS in firefighting foam both under the POPs convention and the REACH regulation or are currently under consideration. They are not sufficient in themselves to address the risk posed by all PFAS that are potential ingredients of firefighting foams, and a wider restriction would complement existing regulatory controls.

SEAC conclusion(s):

SEAC agrees that a restriction under REACH is the generally most appropriate approach. SEAC's conclusions on the presented restriction options are reported in later sections of this opinion taking into account the evaluation of costs, benefits and proportionality.

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 5: 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	The Dossier Submitter shows that these legislative approaches are not

Directive (WFD) **Urban Waste Water Directive** **Groundwater Directive** **Drinking Water Directive** **Marine Strategy Framework Directive**	capable of preventing PFAS from being released to the environment, as they are mostly relying on elimination of chemicals from the environment after emissions have taken place. SEAC acknowledges that 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 the committee has on the availability, performance and cost of existing remediation techniques (based on the Background Document, consultation input and also information submitted over the course of evaluation of earlier restriction cases on PFAS substances), SEAC agrees with the Dossier Submitter that minimising PFAS emissions from the use in firefighting foams at their source appears to be a superior approach and can be achieved with a restriction.
Industrial Emissions Directive **Seveso 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 activities at installations that fall under their scope is also unclear. They are therefore overall not considered applicable to the scope as defined by the Dossier Submitter and would not be able to fully address 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 PFAS 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 can be expected to facilitate 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 suited to address PFAS 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 PFAS 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 PFAS are not so consistently classified as CMRs and the uses of PFAS 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 PFAS in firefighting foams **Taxation of PFAS 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 firefighting foams in the EU compared to a restriction under REACH.

SEAC agrees 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 transitional periods 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[26], 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 PFAS 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 substance group. 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 that there may be a need for the European Commission to reconcile the various restrictions on PFAS in firefighting foams at the decision-making stage.

A restriction proposal on PFHxA, its salts and related substances was previously evaluated by SEAC. Considering that the PFAS-based firefighting foams that are 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 transitional periods and concentration limits.

3.3.2. Effectiveness in reducing the identified risk(s)

Summary of Dossier Submitter's assessment:

All PFAS are considered to be very persistent in the environment. As a consequence, if releases are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFAS until such levels are reached where effects are likely. Even if further releases of PFAS were immediately prevented, existing environmental stocks would continue to be a source of exposure for generations.

It is not possible to quantify the human health and environmental impacts of avoided releases. Instead, for evaluating PBT and vPvB cases, the released quantities of PFAS that can be avoided are used as a proxy of the environmental and human health risks, and thus the impacts of the proposed restriction.

The Dossier Submitter proposed five Restriction Options (RO1 to RO5; see section 3.3.1 above)

In addition, for all the Restriction Options, the Dossier Submitter has considered the implementation of additional risk management measures to minimise PFAS emissions during the transitional periods.

Table 6 provides an overview of the transitional periods proposed for the different use sectors.

Table 6. Proposed transitional periods for the restriction per sector/type of use

[26] Pending decision

Sector/type of use or placing on the market	**Transitional period from the entry into force**
Training and testing	18 months
Municipal fire services	18 months
Civilian ships	3 years
Other industries	5 years
Civilian aviation	5 years
Defence	5 years[27]
Ready-to-use applications	Placing on the market: 6 months Use: 5 years
Seveso establishments	10 years[28]
Formulation	10 years

The cumulative emission reductions over 30 years with and without these additional risk management measures differ significantly regardless of the Restriction Option assessed (see Table 7). They are, however, logically most pronounced for ROs with long transitional uses of PFAS-containing foams, where rigorous implementation of measures that minimise emissions have the largest relative effect.

Table 7. 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 (t PFAS, figures rounded)

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

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

[27] Not fixed under RO4 and instead subject to national permit.

[28] See footnote 15.

RO3 is calculated to lead to the greatest PFAS emissions reduction, i.e. up to 13 200 tonnes with risk management measures over 30 years and 11 300 tonnes over 30 years without risk management measures. The calculations show the large impact of the proposed additional risk management measures on the emission reductions. This is particularly the case for RO1, RO4 and RO5. These are the restriction options with continued use beyond 10 years after entry into force, where containment and other emission control measures would have a significant impact in the emission reduction make the most difference. It is noticeable that without risk management options, these three options would result in significantly lower cumulative emission reductions compared to the baseline than RO2 and RO3. Whether or not the proposed risk management measures are implemented depends on their implementation by operators and also on enforcement by Member States. The level of implementation of these measures therefore represents a significant uncertainty of the impact assessment.

One of the measures to achieve minimised emissions is the safe disposal of PFAS-containing waste. The exposure assessment assumes incineration as the primary disposal method, in order to estimate the emissions to the environment. However, it is noted that the nature and quantities of emissions of PFAS or other fluorinated substances resulting from these disposal processes are not well known and further research should be carried out in real industrial conditions to ascertain their efficiency. Also, the impact on the emissions of greenhouse gases has not been calculated.

RAC conclusion(s):

RAC notes that the five ROs considered by the Dossier Submitter differ in their core conditions regarding placing on the market, formulation, and sector-specific derogations on use. They all include the same additional risk management measures (RMMs) relating to minimising releases during use, collection and disposal of waste and unused stock.

RAC concludes that the Dossier Submitter's estimation of the avoided emissions over 30 years of each restriction option is plausible although assumptions regarding the speed of implementation and effectiveness of the risk management measures may be optimistic.

On the basis of effectiveness in reducing the risks, RAC concludes that restriction option RO3 offers the preferred route to discontinuing the use of PFAS in firefighting foams across the EU for the following key reasons:

- The complete ban on placing on the market and/or use after 10 years offers certainty that firefighting foams are not released into the environment after that period.
- The effectiveness of RO3 is most reliant on the core conditions regarding placing on the market, formulation and use which are relatively straightforward to implement, compared with other options which rely more on the additional risk management measures which could be more challenging to implement.
- The ban on formulation in RO3 stops the export of foams from the EU/EEA.

Additionally,

- RAC proposes to adjust the conditions of the restriction in para 4(d) and 5 to exclude all biological wastewater treatment as a treatment option.
- RAC considers that the assumption of 99 % effectiveness for incineration is not supported by sufficient studies to state this with certainty and is concerned that incineration, particularly of dilute waste under sub-optimal conditions may occur..

- RAC notes that the impact of incineration of waste on greenhouse gas emissions is significant and is potentially greatest with restriction options that permit continued use with corresponding incineration of greater quantities of dilute waste.
- RAC supports the 6 months restriction on placing on the market of portable fire extinguishers and agrees that they are not subject to the additional risk management measures in the restriction.
- RAC notes that the longer it takes for the restriction to be implemented, the lower its overall effectiveness because of the pollution stock accumulating during implementation periods.
- RAC concludes 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 siloxane-based alternatives.

Key elements underpinning the RAC conclusion(s):

The Dossier Submitter has used the avoided release quantities of PFAS as a proxy for the environmental and human health risk reduction, and thus of human health and environmental impacts of the proposed restriction. RAC accepts this approach and notes that it has been accepted by RAC in previous restrictions including PFHxA and microplastics.

RAC accepts the assessment timeframe of 30 years used by the Dossier Submitter as reasonable, due to the transitional period of 10 years and the shelf life of 15-20 years.

RAC notes that due to the persistence of PFAS and the consequent accumulation of the pollution stock in the environment, the overall effectiveness is enhanced by minimising the releases through transitional periods that are as short as feasible and through implementation of effective additional risk management measures during these periods.

General considerations

The baseline scenario describes the situation in the absence of any further regulatory risk management. It determines a total annual emission of 470 tonnes of PFAS or 14,100 tonnes of cumulative emissions of PFAS over 30 years.

RAC considers this is potentially a significant adverse environmental impact, and that any restriction that reduces or eliminates release of PFAS from firefighting use will reduce the likelihood of adverse impacts of PFAS on the environment and human health.

RAC evaluated the effectiveness of the proposed restriction options by comparing the derogations and conditions within the proposed options using a combination of qualitative and quantitative assessment approaches.

For the best-case scenario, the difference between the overall emission reductions for each RO ranges from 11,800 tonnes for RO1 to 13,200 tonnes for RO3. RAC considers that the difference in total avoided emissions between ROs is within a range of 10% and is not sufficient in itself to identify the preferred restriction option. Reducing the assessment period from 30 years would improve the relative performance of restriction options that permit continued use and reduce the estimated difference in avoided emissions between ROs.

Effectiveness of restriction conditions

The five ROs considered differ in their core conditions regarding placing on the market,

formulation, and sector-specific derogations on use. They all include the same additional risk management measures (RMMs), set out in paragraphs 4 to 7 of the proposed restriction. RAC compared the avoided PFAS emissions with and without the impact of RMMs in Figure 3. The difference between restriction options is more pronounced when looking at the contribution of the two elements, namely the core conditions and the RMMs.

The core conditions have the greatest impact on overall reductions for RO3. The RMMs have the greatest impact on those ROs that permit use beyond 10 years, in particular RO5 which permits continued use for sites with effective RMMs.

The implementation of the risk management measures is challenging in all sectors due to the nature of the use during fire incidents. This means that restriction options that rely more on the core conditions than on the RMMs are likely to be more effective, namely RO2 and RO3 as shown in Figure 3.

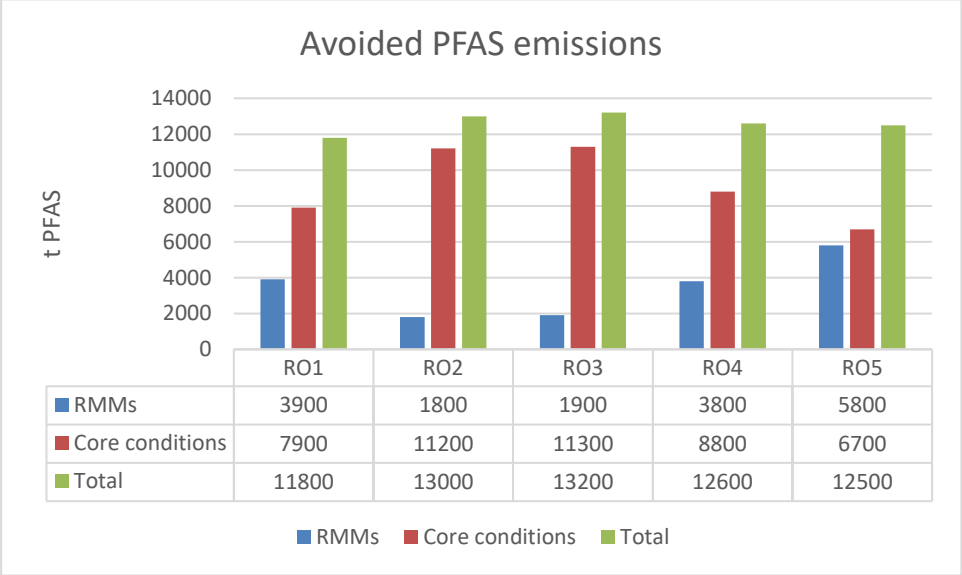

Figure 3. Avoided PFAS emissions per restriction option, and contribution of RMMs and core conditions to this reduction

Core conditions of the proposed restriction

RAC qualitatively assessed how certain it is that the core elements of the restriction would be implemented. Regarding the restriction on placing on the market and formulation, the number of formulators in the EU is low, at about 25. Consequently, it is reasonable to conclude that restrictions on placing on the market and formulation will be fully adhered to.

Regarding the restriction on use, compliance is likely to vary with sector. RAC expects that continued use beyond the derogation period may occur in sectors and organisations with poorer controls and systems for good practice. The level of enforcement activity would also influence compliance.

In modelling the releases during use, the Dossier Submitter assumed a steady state level of use and sale during the sector specific transition periods. RAC considers that an earlier decline

is more likely for those restriction options which do not permit continued use as this will stimulate earlier substitution. This increases the relative effectiveness of RO2 and RO3 compared with the other restriction options.

Regarding formulation, the Dossier Submitter estimates that about 25% of EU based formulation is exported. This indicates that all options other than RO3 would result in continued release of over 100 tonnes of PFAS per year outside the EU/EEA.

RAC considers that this is contrary to the objective of the EU Chemicals Strategy for Sustainability to "*ensure that hazardous chemicals banned in the European Union are not produced for export".* RO2 is identical to RO3, other than it permits formulation and therefore is considered unacceptable by RAC. RO1 could be adapted to include a ban on formulation. RO4 and RO5 permit continued placing on the market within the EU and so formulation and export would continue.

Additional Risk Management Measures

The additional risk management measures proposed by the Dossier Submitter to allow continued use during the transitional periods apply within 6 months of entry into force. The Dossier Submitter estimates that these will result in a significant reduction of PFAS emissions of 340 tonnes between year 1 and year 2, as shown for each sector in Figure 4.

These RMMs, described in paragraph 4 to 7, relate to:

- restricting use to Class B fires only;
- minimising releases;
- establishing a management plan;
- ensuring waste is adequately treated; and
- labelling.

The individual contribution of each of these measures to the predicted reduction is not readily identified in the Background Document. RAC considers that the immediate and dramatic impact of the additional RMMs predicted by the Dossier Submitter as shown for RO3 in Figure 4 is optimistic and not evidence based. However, industry may commence changeover prior to the entry into force of this restriction which would result in a decline in emissions.

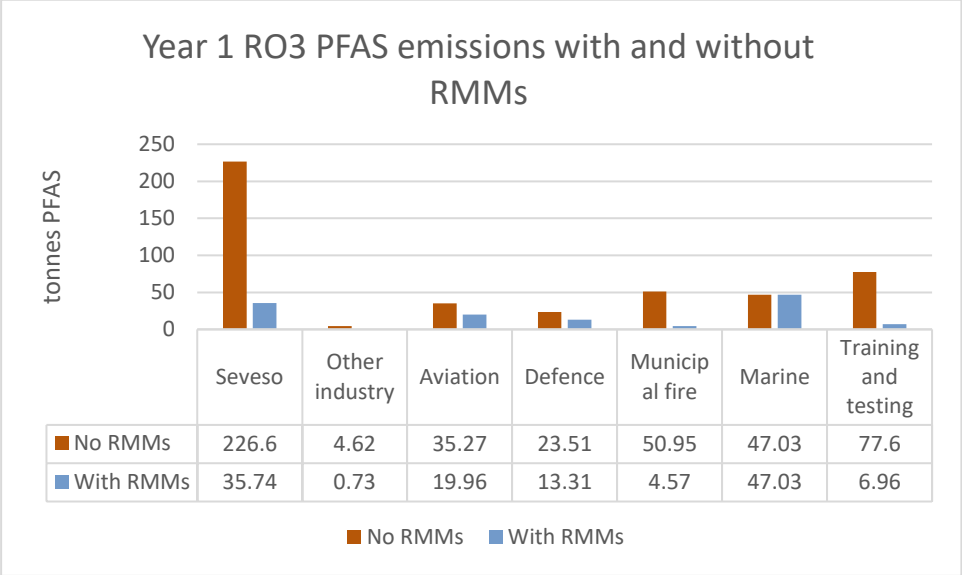

Figure 4. Estimated PFAS emissions in year 1 for RO3, indicating the impact of RMMs applicable 6 months after entry into force

Waste collection and disposal

The effectiveness of the restriction is strongly influenced by the effective collection and disposal of waste over the 30 year period of the assessment. Waste arises from runoff water following use and from cleaning but may also arise from unused stock.

Regarding collection of runoff water, the Dossier Submitter considers that collection of 97% of run-off is possible from use at Seveso sites and from training. RAC agrees with this due to the requirement for bunding at these sites. RAC also agrees with the Dossier Submitter that collection is not likely to occur in municipal and marine applications or use of portable fire extinguishers. RAC considers that the Dossier Submitter assumption of collection of 50% of run-off in all other sectors, including aviation, is optimistic and not supported by information in the Background Document.

RAC notes that the challenges associated with collection of PFAS-containing runoff compared with concentrate indicate that a restriction is more effective when use is minimised. Comparing the various ROs, RO3 does not permit continued use of foam after the transition period. Consequently 100% of PFAS stocks are sent directly to waste compared with the other RO's where PFAS stocks continue to be used in Seveso sites. Using the Dossier Submitter' assumption that stock levels have not been depleted over the derogation period, this corresponds to at least 2000 tonnes PFAS that is disposed of as stock instead of being used. RAC concludes that runoff waste collection considerations favour RO3 over RO1, RO4 and RO5.

RAC considers that effective disposal of all PFAS-based waste is challenging. For run-off, there is the added challenge of disposing of a contaminated and possibly diluted mixture compared with the foam. For cleaning waste, the concentration in the wastewater is considerably lower than in the concentrate.

The Dossier Submitter assumes that wastewater treatment is the method used for disposal of runoff water in the baseline scenario and that incineration is the disposal method for unused

stocks, collected firewater and cleaning water in all restriction scenarios. The Dossier Submitter also provides information on other disposal methods. Disposal methods are discussed in the following paragraphs.

Wastewater Treatment

Municipal wastewater treatment plants (WWTPs) have been shown to be ineffective in removal of PFAS from aqueous streams (Annex B.4.5 to the Background Document). In addition to physical treatment of wastewater (removal of solids, fats and maceration), most municipal WWTPs in Europe today rely on secondary biological treatment with the activated (sewage) sludge process to enable the oxidisation or removal of organic matter. Biological treatment exhibits low removal efficiencies of PFAS. It can degrade precursor compounds into PFCAs and PFSAs but they are then discharged into surface water or to some extent accumulate in sludge (Lenka et al., 2021). Consequently, the restriction proposal excludes "sewage treatment, irrespective of any pre-treatment" (para 4(d) and 5) as a waste treatment method.

RAC agrees that the specific exclusion of sewage treatment is justified based on these studies. RAC notes that no evidence is presented that industrial WWTPs perform better, nor is any reasoning presented by the Dossier Submitter for excluding industrial wastewater treatment from this. Such plants also rely on secondary biological treatment that is optimised for degrading certain industrial chemicals but not PFAS. Only tertiary chemical or physical treatment (e.g. reverse osmosis) could potentially remove PFAS at a higher rate (Lenka et al., 2021). Even when this is possible however, resulting sludge will require incineration, which is generally not at the temperatures required to destroy PFAS (see below for more detail on incineration).

RAC considers that conventional industrial WWTPs are likely to be as ineffective as municipal WWTPs in removing PFAS. RAC considers that the relevant issue is whether there is effective pre- or post-treatment to remove PFAS, rather than the type of WWTP.

Consequently, RAC proposes to adapt the conditions of the proposed restriction in paras 4(d) and 5 and replace "sewage treatment" is by "biological wastewater treatment".

Incineration

The Dossier Submitter states that hazardous waste incinerators and cement kilns are currently the best available techniques for PFAS disposal and assumes 1% release to air in the emission modelling. The Dossier Submitter adds that the nature and quantities of emissions of PFAS or other fluorinated substances resulting from incineration is not well known and the impact on the emissions of greenhouse gases has not been calculated.

RAC notes that municipal incinerators and low temperature hazardous waste incinerators are not permitted for handling hazardous waste with more than 1 % of halogenated organic substances and that the incinerator needs to reach temperatures of at least 1 100°C (Industrial Emissions Directive 2010/75/EU, 2010). This means that since stock concentrations generally exceed 1 % PFAS, the requirement that low temperature incinerators shall not be used for disposal would apply.

The Dossier Submitter states that the Industrial Emissions Directive would also apply to PFAS-based firefighting foam run-off and cleaning water (Appendix 2.1 to the Background

Document). RAC notes that the PFAS concentration in collected wastes would normally be well below 1% however and therefore the Directive would not apply. RAC considers that incineration at elevated temperatures (>1 100°C) of PFAS mixtures of concentration <1% is also important for destruction.

RAC notes that high temperatures are needed, to at least 1 100 °C, and conditions should be in accordance with the relevant BAT reference documents (BREFs) in order to degrade PFAS to carbon dioxide and hydrogen fluoride. RAC therefore proposes an additional condition in paragraph 4(d) and 5. RAC also notes that developments are underway on alternative destruction methods but that their practical implementation is uncertain. RAC accepts that while the effectiveness of incineration and developing methods is uncertain, they are more effective than wastewater treatment, which is currently the default approach. RAC however also notes that additional disposal techniques may be developed in the future and therefore does not propose to further define adequate treatment beyond the conditions proposed by the Dossier Submitter (see also below).

RAC notes that incineration of unused concentrate and run-off is challenging due to foaming, acidity and high water content. A small proportion of current hazardous waste incinerators within the EU are capable of the safe destruction of PFAS-foam and run-off (Wood et al 2020) although it is expected that availability will increase as market demand increases in the future. There is likely to be greater availability in cement kilns. RAC is concerned that incineration under sub-optimal conditions can result in the generation of arrowhead PFAS, causing a release to air with potential exposure to humans via environment.

An additional concern of RAC relating to incineration is the high level of greenhouse gases emitted, primarily due to the high energy requirement and also due to emission of PFAS, which are potent greenhouse gasses. The global warming potential of some PFAS can be up to 24,000 times that of CO_2 (Sovacool et al. (2021)). The problem is greater with collected wastewater than concentrate as it is more dilute and requires correspondingly more energy for incineration. Consultation submission #3595 indicated that releases from incineration of firewater collected from Seveso sites has associated emissions of about 100 million tonnes CO_2 eq over the 10 year derogation period. RAC notes that the emissions are reduced if an effective pre-concentration stage is undertaken, which is likely to occur in practice. The greenhouse gas emissions from incineration of stock could result in up to 20,000 tonnes CO_2 eq emissions from fuel consumption. This is in addition to the effect of any PFAS that have not broken down in the incineration process. If 100 tonnes per year are emitted and the GWP is 10,000, this corresponds to 1 million tonnes CO_2 eq per year.

Other disposal methods

Appendix 2 and 3 to the Background Document describe additional disposal and pre-treatment measures including supercritical water oxidation, electrochemical oxidation, mechanochemical milling, precipitating agents (PerfluorAd), granulated activated carbon, ion exchange and ozonofraction. Often a combination of these methods is required, particularly with run-off water. Based on the information provided in the Background Document and during consultation, RAC agrees with the dossier submitter that these alternative methods are not currently widely available and/or fully developed for PFAS disposal. RAC agrees that incineration, possibly following pre-concentration with PerfluorAd or similar, is the most likely technique in the early period of the restriction.

Derogation periods

RAC notes that restricting the placing on the market of portable fire extinguishers 6 months after entry into force avoids the use of up to 45 tonnes of PFAS compared with a 5-year derogation period as initially proposed. This is supported by RAC.

RAC acknowledges that the large installed base of about 40 million units and wide dispersive use throughout the EU presents difficulties in ensuring their use is restricted to Class B fires and implementation of RMMs. Consequently, RAC considers that excluding fire extinguishers from restriction conditions 4-7 does not affect the overall effectiveness of the restriction.

Based on the information provided in the Background Document and during consultation of the Annex XV restriction report, RAC concludes that the proposed transitional periods offer a balance between a safe, coherent transition to non-PFAS firefighting foam and maximising the effectiveness of the proposed restriction although the Committee notes that **reducing the length of transitional periods for some or all uses would increase the effectiveness of the proposed restriction**. The use sectors identified in the restriction are clear and justified by the Dossier Submitter.

The transitional period that has greatest impact is that for Seveso sites, both because it is the longest transitional period and it is the largest use sector. RAC recognises that the risk of catastrophic fires is also greatest in that sector and that safe alternatives have not been fully tested.

Alternatives

The alternatives proposed by the Dossier Submitter have been grouped as hydrocarbons, siloxanes, protein foams and detergents.

The Dossier Submitter identified 30 fluorine free alternative products and gave more detailed hazard information on 7 of these (Annex E.2 to the Background Document). None of the constituents in these products were classified for CMR properties or meeting PBT or vPvB criteria. Regarding health effects, the most common was eye irritation. A number of products contained constituents that are classified toxic or very toxic to aquatic life, and sometime were noted as having long-lasting effects.

None of the detailed products were siloxane-based alternatives as they do not appear to be in commercial use. There are concerns in relation to PBT and/or vBvP properties of some siloxanes.

A risk assessment of alternatives was not undertaken by the Dossier Submitter. From the hazard information provided, RAC concludes that the hazards and corresponding risk are likely to be significantly less than those associated with PFAS based firefighting foams, with the possible exception of siloxane-based alternatives.

Evaluation of individual restriction options

RO1: Restrict placing on the market and allow use until depletion of stocks

From an emissions perspective, the Dossier Submitter (Appendix 8.2 to the Background Document) expects that emissions of PFAS would continue for 16 years after the transitional periods end and that any remaining stock will be incinerated. Since continued use is allowed, the restriction will not lead to early disposal of PFAS-containing foam concentrates.

RO1 has the advantage that there is not a rush to dispose of PFAS firefighting foams before adequate facilities are available, but RAC considers up to 26 years will be required to work through the stocks. This restriction option permits continued use in all use sectors while stocks last and relies heavily on implementation of risk management measures to ensure effectiveness. Implementation is likely to be good in the 59 % of sites that are in the chemical/petrochemical sector. However, the collection of firefighting foam run-off even with new RMMs, at the civilian aviation (9%) and municipal fire services (13 %) sectors are likely to be less successful. PFAS contamination of soil/groundwater will be dispersed and not easy to collect once the foam effluent hits the soil horizons and further disperses to groundwater. The modelled estimates set out in Table 13 of the Annex XV Background Document under a best estimate scenario for controlled collection of PFAS emissions is 97 % for chemical/ petrochemical/Seveso and 50% for aviation and other sectors. RAC considers that these estimates are optimistic for non-Seveso sites and that a programme of bunding and hardstands with closed drainage would be required at such sites to improve runoff collection. Furthermore, allowing continued use after the transitional periods end may reduce the impetus to finding suitable alternatives, thereby reducing the effectiveness.

Although RO1 prohibits placing on the market after 10 years, formulation could continue for export. Baseline exports are estimated at about 100 tonnes PFAS per year.

RAC agrees with the Dossier Submitter that this restriction option would avoid up to 11,800 tonnes of PFAS emissions over 30 years compared to the baseline figure for actual potential emissions of 14,100 tonnes if no restriction were to be implemented. RAC notes however that 3900 tonnes of this rely on effective implementation of additional RMMs.

RO1 represents an avoidance of PFAS emissions of 84 % over 30 years.
RAC concludes that the effectiveness of RO1 is limited because it allows extended use in all sectors while stocks last, it relies on effective implementation of additional RMMs and it permits continued formulation and associated export without time limit.

RO2: Restrict placing on the market and use

RAC agrees that this restriction option would avoid up to 13,000 tonnes of PFAS emissions over 30 years, with an additional release avoidance of 1,200 tonnes compared to RO1, triggered by requiring complete cessation of the use of the foams at the end of the transitional periods. RAC considers that the estimate of the avoided emissions within the EU are due primarily to the core conditions, and that these are more likely to be effectively implemented than the additional RMMs.

The avoided emissions are 200 tonnes lower than RO3. RAC notes that this is due to releases from formulation for export after 10 years. RAC notes that formulation and consequently export is permitted without time limit. This equates to the export of about 3000 tonnes PFAS over the assessment period. RAC concludes this is not acceptable.

Compared to the baseline figure for emissions of 14 100 tonnes if no restriction were to be implemented, RO2 has predicted emissions of 13 000 tonnes,1 800 tonnes of which rely on the additional RMMs.

RO2 represents an avoidance of PFAS emissions within the EU of 92% over 30 years. *RAC concludes that the effectiveness of RO2 is limited because it allows continued formulation and*

associated export without time limit.

RO3: Restrict placing on the market, formulation and use

Due to the complete cessation at the end of the derogation period, there is no further use permitted and consequently there is no further dependence on RMMs to minimise the emissions. RAC considers this to be a more reliable approach to achieving an effective restriction and that consequently the estimated avoided emissions of 13,200 tonnes is more credible than for other restriction options.

RO3 is the only restriction option that bans formulation. Recognising the persistence and mobility of PFAS and that contamination is a global problem, RAC supports the inclusion of a formulation ban as it would prevent export of foams (including foam concentrates) by default. If the Commission concludes that a restriction option other than RO3 is preferred, RAC strongly recommends that formulation be included in the restriction where feasible (RO4 and RO5).

The transitional period for Seveso sites is 10 years, after which placing on the market, formulation and use is prohibited. Submissions from stakeholders indicate that this is a reasonable duration in which to identify and verify safe alternatives.

RAC notes that every year less that PFAS based concentrates are placed on the market for Seveso sites equates to about 200 tonnes per year of PFAS. RAC considered whether the effectiveness could be enhanced by reducing the derogation period on placing on the market, while maintaining the 10 year period for use but concluded that the unplanned nature of the use means that this approach could result in stockpiling. The relatively onerous conditions of paragraph 4 are likely to encourage the speedy transition by users for whom safe alternatives to PFAS-based firefighting concentrates are available.

Compared to the baseline figure for emissions of 14 100 tonnes if no restriction were to be implemented, RO3 has predicted emissions of 13 200 tonnes, 1 900 tonnes of which rely on the additional RMMs.

RO3 represents an avoidance of PFAS emissions of 94% over 30 years.
RAC concludes that the effectiveness of RO3 is optimal because it stops use after 10 years, relies to a lesser extent on effective implementation of RMMs and restricts formulation.

RO4: Restrict placing on the market and use using sector-specific transitional periods with a permit system for SEVESO/defence type establishments to allow continued use*.*

Key to the effectiveness of reducing the emissions from this restriction option is the continued use at some Seveso and defence sites. The Dossier Submitter's assumptions on this are set out in Appendix 8.5, where it is modelled that there will still be some usage until year 30. RAC considers the timelines for the eradication of PFAS useunder this restriction option are unmanageable. There will be many sites with differing transition periods as agreed by local permit, and the variation of such permits will be high. RO4 may result in a key time lag to the uniform EU elimination of PFAS from firefighting foams, and will create uncertainty of the elimination timelines, specified in RO3.

As with RO1, permitting continued use after the derogation period ends may reduce the

impetus to finding suitable alternatives, thereby reducing the effectiveness. Also, reliance on RMMs including collection and disposal of waste after the derogation period ends is more liable to lead to releases than disposal of unused concentrates. About 30% of the avoided emissions depend on effective implementation of RMMs. While this is plausible for Seveso sites, it is less likely in defence applications.

As with all options except RO3, formulation is not restricted and could continue for export. Baseline exports are estimated at about 100 tonnes PFAS per year and this equates to 3000 tonnes PFAS over the 30 year period.

Notwithstanding the observations above, the Dossier Submitter notes this restriction option would avoid up to 12 600 tonnes of PFAS emissions over 30 years compared to the baseline figure for emissions of 14 100 tonnes if no restriction were to be implemented. 3 800 tonnes of these estimated emission reductions rely on effective implementation of additional RMMs.

RO4 represents an avoidance of PFAS emissions of 89% over 30 years.
RAC concludes that the effectiveness of RO4 is limited because it allows extended use in permitted Seveso/defence sectors without time limit, relies on effective implementation of RMMs and allows continued formulation and associated export without time limit.

RO5: Restrict all use of PFAS-containing firefighting foams after transitional periods, unless adequate risk management measures are in place

This restriction applies to sites with the capacity to ensure full recovery and safe disposal of all fire run-off waters. Although the use sector is not specified, this would probably apply mainly to Seveso and/or IED type permitted sites, generally in the oil/petrochemical sector. These are likely to have RMMs like bunded areas, retention basins and treatment of collected fire run-off waters.

However, large sites such as airports (covering all air strips, taxi runways, plane waiting zones, fuel storage sites, etc.), defence training sites (being mostly unpaved, irregular terrains with vegetation and obstacles) or smaller warehousing type sites will not likely have a full capture system for fire run-off waters. RAC considers it is difficult to ensure adequate RMMs are in place on an EU wide basis.

Emissions would also continue to occur at the formulation, storage and disposal stages until all uses have finally ceased. As with all options except RO3, formulation is not restricted and could continue for export. Baseline exports are estimated at about 100 tonnes PFAS per year and this equates to 3000 tonnes PFAS over the 30 year period.

This restriction option would avoid up to 12 500 tonnes of PFAS emissions over 30 years compared to the baseline figure for emissions of 14 100 tonnes if no restriction were to be implemented. This restriction option relies heavily on risk management measures being effective as these account for almost half of the avoided emissions, namely 5 800 tonnes PFAS.

RO5 represents an avoidance of PFAS emissions of 89% over 30 years.
RAC concludes that the effectiveness of RO5 is limited because it allows extended use in all sectors without time limit and relies heavily on effective implementation of RMMs in those sites. It also allows continued formulation and associated export without time limit.

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 PFAS 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 shipping/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.

Table 8. Proposed transitional periods for the restriction per sector/type of use

Sector/type of use or placing on the market	**Transitional period from the entry into force**
Training and testing	18 months
Municipal fire services	18 months
Civilian ships	3 years
Other industries	5 years
Civilian aviation	5 years
Defence	5 years
Ready-to-use applications*	Placing on the market: 6 months Use: 5 years
Seveso establishments	10 years
Formulation	10 years

*Based on the responses to the consultation on the Annex XV report, the transitional period for ready-to-use applications was split into two components: 1) a transitional period of 6 months for the placing on the market of new foam extinguishers, and 2) a transitional period of 5 years for the use of PFAS-containing extinguishers already available on the EU market. In addition, the conditions in paragraph 4 are considered not to apply to the sector of ready-to-use products.

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 Risk Management Measures (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 9 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 9. 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	not applicable	not applicable	8 million (4 to 24 million)	not applicable	not applicable

surplus)*					
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)**

*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 transitional 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 of the availability of suitable alternatives was comprehensive and can be considered complete, as far as the 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 of the transitional periods proposed.

SEAC considers that, for some applications in industrial facilities, an appropriate performance level of fluorine-free alternatives by the end of the proposed transitional periods has not been fully demonstrated. SEAC acknowledges that uncertainties always remain about whether alternatives will be available at a specific point in time even if there are indications that research is proceeding well. However, in the context of some industrial facilities, there are such disastrous potential consequences of these remaining uncertainties, that it affects the conclusion of whether technical feasibility of alternatives is sufficiently demonstrated. SEAC considers that a review of the substitution status for Seveso sites and offshore oil and gas installations before the end of the proposed transitional periods for these sectors would be needed to sufficiently address this uncertainty. This review should be based as much as possible on local information from relevant sites and potentially relevant neighboring sites

(and more generally high-fire-risk sites) and should be as exhaustive as possible to capture any specific situation requiring an extension of the transitional period for Seveso sites or installations belonging to the offshore oil and gas sector.

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.

For portable fire extinguishers, the technical feasibility of frost- and alcohol-resistant fluorine-free alternatives for all use scenarios has not been fully established.

Risks of alternatives

SEAC takes note of the RAC conclusion that hazards and corresponding risks 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.

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 the case of the most demanding uses at sites covered by the Seveso III Directive and offshore platforms, a complete setup with suitable foams, equipment and firefighting strategies is still under development. It may not be feasible to set a final date ensuring with enough certainty the full completion of the phase-out in these uses at this point in time; therefore, a review of the substitution status in the Seveso and offshore oil and gas sectors is proposed to be implemented before the end of the sector-specific transitional periods.

Cost assessment

In general, SEAC has at this stage of the assessment no major reservations about the calculation methods and simplifications (e.g. 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 (e.g. 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 of SEAC's conclusions 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 that resulting uncertainties about the level of cost-effectiveness could be significantly higher than calculated.

Overall, SEAC's evaluation 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 titled "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)[29]. 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 the Dossier Submitter's comprehensive review of information provided by stakeholders was an important foundation for evaluating the maturity of alternatives. Keeping in mind that several EU-wide restrictions already cover some of the PFAS used in firefighting foams and that stakeholders have been involved in the different assessments, 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.

However, the 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)[30], 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 wide range of fuels and other flammable liquids 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 higher **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 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 technical solutions to viscosity issues to be available; however, SEAC is concerned, specifically in relation to equipment containing small parts such as portable fire extinguishers. **Durability** of alternatives during storage at **elevated temperatures** (up to 60°C) or performance level in use under high temperatures 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 analysed 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 specific valuable properties that are unmatched by fluorine-free alternatives (as highlighted in comments received in 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 available evidence and scarcity of expressions of concern from EU

[29] Wood, Ramboll & Cowi 2020. The use of PFAS and fluorine-free alternatives in fire-fighting foams.

[30] 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

actors during the consultation on the Annex XV report, SEAC concludes that the industry is generally expected to have the ability to manage the remaining challenges before the end of transitional periods. SEAC analyses some specific considerations related to industrial sites, defence applications and portable fire extinguishers in the following sub-sections.

Industrial sites

SEAC notes that, specifically with regard to uses in the **petrochemical industry the availability of suitable fluorine-free alternatives** after the transitional periods proposed by the Dossier Submitter **cannot be fully demonstrated at this point in time**. The information reported in 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 only be testing that is needed, but also the installation of adequate firefighting systems and the adoption of appropriate firefighting techniques is important (e.g. fixed systems avoiding forceful application of foam). For some scenarios further development of firefighting foams themselves could also 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 currently be predicted. 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 lacks information on whether such real-life feedback will be available by the end of the proposed 10-year transitional period for Seveso sites. 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 on information reported in the Background Document, SEAC expects that, for some use scenarios in the defence sector, alternatives used in other sectors 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 is reported to require the same level of efficiency that is currently provided by PFAS-containing foams in fire extinction and in the prevention of fire reignition (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 transitioning to fluorine-free foams – may be specifically difficult in some of the firefighting scenarios applicable to the defence sector. Overall, SEAC considers that finding suitable alternatives for these use in the defence sector may be considerably more challenging compared to civilian uses.

Portable Fire Extinguishers

It was claimed in the consultation on the Annex XV report that there is currently[31] **no alcohol-resistant agent** that can be used for portable fire extinguishers (comment #3544). SEAC further notes that the before-mentioned issue of higher viscosity of alternatives at low **temperatures** 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

[31] The consultation period closed in September 2022.

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 is also expected to alleviate issues related to alcohol-resistance. SEAC observes that examples can be found of a few products that are already marketed as usable for fires involving polar substances (alcohols)[32], however SEAC does not have information on the applicability for different use scenarios. Furthermore, regarding resistance to extreme temperatures, it was stated in the Dossier that seemingly the vast majority of fire extinguishers is installed in settings, which presumably do not require resistance to extreme temperature ranges (below -10°C or above 30°C, e.g. not likely in indoor settings). SEAC agrees with these arguments but highlights that the availability of suitable alternative extinguishers should be ensured for all use cases that remain relevant 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 by industry stakeholders that **the cost of the alternatives is not the issue, but performance is**. This was confirmed by the stakeholder feedback collected during the preparation of this restriction proposal and was not challenged in the consultation on the Annex XV Dossier. The use of alternatives does incur 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 enters into force. SEAC notes that, based on information in the Background Document, the volumes of fluorine-free foam concentrates needed could be higher than the volumes of fluorinated foam concentrates being substituted. It was reported that fluorine-free concentrates on the market need to be applied at a higher rate when fighting a fire to achieve the desired effect (up to a double of the volume according to the Annex to the Background Document). It is estimated that around 18 000 tonnes of PFAS-containing foams and 9 000 tonnes of fluorine-free foams are currently placed on the EU market each year. Fluorine-free alternatives are reported to be provided by at least eight formulators. SEAC notes that formulators interviewed by the Dossier Submitter estimated that the necessary volumes of alternatives could be supplied within a short time period (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 lengths of transitional periods per sector). SEAC notes that some challenges could arise once the sector with the highest use volumes makes the transition but, as this corresponds with the longest transitional period (10 years), there is time to prepare for higher demand. 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 continue to be used during the entire transitional period of 5 years in parallel to successive replacement. SEAC agrees with

[32] See examples here (accessed 15/05/2023):
- S 50 J AR Externa GREEN (link)
- S 6 LJ GREEN 21, S 6 LJM GREEN 21, S 9 LJ GREEN 21 and S 9 LJM GREEN 21 (link)
- S 6 JX AR GREEN 21 and S 9 JX AR GREEN 27 (link)

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 considered a time horizon of 30 years which equals double the foams' mean shelf life of 15 years. SEAC agrees that the approach followed by the Dossier Submitter's cost assessment provides a good estimation of the cost of the restriction, with the following comments:

- Using 30 years as the assessment **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. A sensitivity analysis of a different time horizon 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 is considered that long enough transitional periods have been chosen to allow that alternatives would have at least the same performance as PFAS-containing foams in all applications. There is some uncertainty and there are certain consequences of this assumption which this opinion discusses in the "Proportionality" section.
- In terms of costs, there could be some **overlap with previous restrictions** on uses of certain PFAS 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 this proposal. The Dossier Submitter reports information submitted by the manufacturers' association Eurofeu stating 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 the use of PFOA in certain firefighting uses applies until 4 July 2025. Their disposal costs should not be accounted for in the present restriction, or, at least, the potential for overestimation of costs should be noted by SEAC when evaluating the cost assessment of this restriction. SEAC also highlights that other restriction proposals addressing uses of PFAS, that have been evaluated by SEAC but not yet concluded on at the decision-making stage (e.g., PFHxA), are not considered to be part of the baseline of this restriction proposal. The relevant cost estimates reported in those proposals widely overlap with the cost estimates of this restriction proposal.

Other than the above comments, SEAC has no reservations about 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 make 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 available to carry out cost calculations. However, there are still several unclarities regarding the rationale for choices made for some of the key parameters that were taken from the often patchy and sometime not fully consistent data reported from surveys commissioned by ECHA or the European Commission. This concerns unit costs for technical changes, for cleaning of firefighting systems, and associated ranges used for sensitivity

analysis, which will be evaluated in more detail in later sub-sections.

Since additional volumes of alternatives could be required compared to PFAS-containing 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 PFAS-containing and fluorine-free foam concentrates may have to be stored, and the Dossier Submitter indicated that, based on the results of stakeholder consultations, these costs appeared to be "manageable", which does not necessarily mean they are negligible compared to other costs items. Overall, the analysis of the impact on storage costs, or at least a qualitative assessment of whether they are overall negligible or not, appears to be missing. 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 about 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.

Furthermore, 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 an illustrative sensitivity analysis with 20% of avoided foams being send to incineration as an upper bound of avoided cost. This scenario however seems quite likely 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 of 2 or 3 by the initial information available to the Dossier Submitter and, therefore, the substitution cost would also be underestimated. Based on these comments, the Dossier Submitter revised the assumptions about the tonnages to be substituted in portable fire extinguishers and considers a new number of 40 million devices instead of 15 million. The Dossier Submitter has assessed the impacts of these changes on the cost calculation for the ready-to-use sector. However, these changes were found to have a negligible impact on the total costs of the different restriction options, even under the assumption that 10% more PFAS-free portable fire extinguishers may have to be installed compared to the baseline scenario.

Cost of technical changes for industrial installations

The Dossier Submitter's assessment mentions a case study with the information that the total **costs of technical changes** for one German industrial stakeholder are €300 million for 12 of their refineries, but the cost per Seveso installation taken forward in the Dossier Submitter's analysis is assumed to be €500 000 per site, whereas it could have been €25 million based on the German data. While it is likely that a refinery represents the upper bound of the cost range for Seveso installations, it remained unclear to SEAC how the Dossier Submitter's assumption about the unit cost used had been derived, and SEAC considers it possible that the costs per site are underestimated. The cost taken forward for other sites (non-Seveso sites) is €5 000 and here it is also unclear to SEAC how this unit cost had been derived because an explanation appears to be lacking. If, as reported in the Background Document, the different viscosity of alternative foams triggers technical changes in foam distribution systems, this could also affect non-Seveso installations that possess such foam distribution systems and do not rely only on portable devices (e.g., cruise ships, warehouses, etc.). SEAC recognizes that there is limited available information on this aspect in general, and especially for non-Seveso sites. This uncertainty and its potential impact on the 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 (comments #3546, #3548, #3596, #3614) claimed that, in addition to technical costs, they will also incur **organisational costs** (e.g. in adapting firefighting-related procedures) **and re-training costs** (since alternative foams can require new firefighting tactics and tools). These have not been accounted for by the Dossier Submitter under the assumption that costs of training and revision of firefighting procedures would also be incurred in the baseline scenario (on a regular basis). 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 attend further training (compared to the baseline scenario) and that many have already been re-trained given substitution has already significantly taken place for training purposes. SEAC does not have 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

Regarding the **cost of cleaning firefighting equipment**, the Dossier Submitter had to base the assessment on limited cost data, mainly available for fire-brigade equipment. The range of the cost per site taken forward in the Dossier Submitter's analysis 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 installations, ships, transportation settings, or defence installations, for which very scarce information points to potentially much higher costs. Regarding the number of sites, for Seveso sites, civil aviation settings, military settings, municipal fire services, and marine applications affected by cleaning costs, information has been taken from a report by Wood commissioned by ECHA. For non-Seveso sites, information was taken from a report commissioned by ECHA. The assumed number of such non-Seveso sites (1 000) is only a tenth of the number of Seveso sites (10 000), despite the Wood report stating that many non-Seveso sites handling flammable liquids require firefighting equipment. An explanation of the assumption made by the Dossier Submitter was not found by SEAC. It was also not fully clear to SEAC whether the calculated costs include the potential cost for incineration or adequate disposal of hazardous waste resulting from the cleaning process. SEAC also notes RAC's recommendation to ensure that the collected PFAS-containing waste resulting from cleaning of firefighting equipment shall be handled for adequate treatment where the concentration of total PFAS is greater than 1 mg/L. The cost implications of such a requirement may be not be integrated in the assessment carried out by the Dossier Submitter.

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

Avoided clean-up costs

SEAC agrees with the Dossier Submitter that cost savings for some users may occur in the case of **avoided clean-up of contaminated sites after a fire incident**. The Dossier Submitter considered that these annual avoided costs would linearly increase from zero up to €10 million per year after all PFAS foams are replaced. The figure of €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[33]) and on another illustrative and unexplained assumption regarding "tens of incidents" per year in the EU. One comment provided during the consultation on the Annex XV Dossier (#3622) supports high annual costs (€150,000 to €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 (-50% to + 100%) used for sensitivity analysis is wide 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 all of these considerations, SEAC chose to not consider quantitative estimates of assumed cost savings related to avoided clean-up costs at incident sites, but qualitatively takes them into account.

Administrative and enforcement costs

Administrative and enforcement 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 would have to be operated by public authorities and complied with by industry. Furthermore, such costs would likely, although only partly, be addressed by 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 and analysis. SEAC, however, notes that there are already restrictions in place regulating the placing on the market and use of certain PFAS substances (historically) used in firefighting foams in the EU. SEAC considers it likely that the enforcement of 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 mean that additional costs relative to the baseline would be limited to the costs of adding further testing (a test for total fluorine) to the order that is made to a laboratory (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 additional testing costs incurred due to 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 that there would be no **disposal costs** for PFAS-containing foam concentrate since users would be able to use their stocks as long as their use or expiry date allows. However, the actors need to keep their equipment ready for use at all times, meaning that a refill of foam concentrate tanks will likely 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 when the volume of stock falls below the necessary reserve stock level of that specific installation. The respective residual amount at the time of the transition may 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 use of residual amounts or trade between actors could take place, in which the ones making the substitution could potentially use or sell their remaining stock to the ones not yet transitioning. However, there is no information available on how wide-spread such a solution might be adopted, what the preconditions are and, also, to what extent this would elongate the time needed to realise 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.

[33] Wood, Ramboll & Cowi 2020. The use of PFAS and fluorine-free alternatives in fire-fighting foams

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 incurred by Member State authorities who would have to set up a national system to evaluate derogation requests, and costs incurred by 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 Background Document, RO4 would overall be the least costly option (see Table 9). SEAC, however, notes that the **costs of the permitting system** were not included in the Dossier Submitter's cost assessment due to lack of data. SEAC considers it would have been useful to weigh them against the possible advantage of ensuring no loss of performance in firefighting and finds that estimates of the expected costs could be made at EU level building on the experience with local industrial permitting systems already in place (Seveso, IED). If necessary, input by national authorities currently in charge of supervising the Seveso sites could be sought. SEAC expects that these costs would be limited if the 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 to SEAC 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 the PFAS releases, and that it is expected that upgrading existing systems or building new systems to a level of 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 "full containment" or "near full containment" could be very dependent on the precise definition of the performance level, since the marginal cost of capturing the last remaining emissions is likely to be a steeply increasing function of the performance level when approaching 100% PFAS capture. In the calculations underlying the Dossier, it was assumed that the cost per site for implementing RMMs to ensure full containment would be €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 assumes that sector-specific transitional periods apply, and the Dossier Submitter works under the assumption that suitable alternatives will be available for all uses at the end of the transitional 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 achieved full containment (more or less so depending on what level of containment is considered "full") and for these installations any costs would be low.

Assessment of potential impacts on costs

Table 10: 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 concerned	Impact on costs calculated in the	Impact on uncertainties (0 to

			Annex XV report	**+++)**
Time horizon	30 years versus longer to account for recurring avoided costs (benefits)	All	Very low impact on NPVs but impacts on proportionality Overestimation	++
Overlap with previous restrictions	Not accounted for	All	Overestimation	+
Need for additional storage capacity	Not accounted for in cost calculations	All	Underestimation	+ ?
Avoided incineration costs	Not accounted for (only in one sensitivity calculation)	All except RO1	Overestimation	++
Substitution costs	The number of portable fire extinguishers that would need to be changed is probably underestimated	All	Underestimation	+
Cost of technical changes	Possible very wide variations affecting representativity of min, max and mean	All	Underestimation?	+++ ?
Adaptation and training costs	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	Underestimation	+
Cleaning costs	Unit costs (per site) uncertain, number of non-Seveso industrial sites and other sites uncertain	All	Underestimation	++
Avoided costs for site clean-up after fire	Very uncertain estimate, some assumptions unexplained	All	?	+++
Administrative and enforcement	Not quantified by the Dossier Submitter	All	Underestimation	+/0

costs				
Testing cost	Dossier does not contain quantitative information on the cost of sampling, preparation and analysis.	All	Underesti mation	+/0
Disposal costs	Not accounted for	RO1	Underesti mation	+
Cost of permitting system	Not accounted for due to lack of data	RO4	Underesti mation?	+/0
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	?	++?

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 PFAS from firefighting foams. Following the SEAC approach for evaluating PBT and vPvB cases, the avoided releases of PFAS 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 PFAS 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 11.

Table 11. 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 RMMs (in tonnes of PFAS, figures rounded)

RO	Total avoided PFAS emissions over 30 years, **with** risk management measures (t PFAS)	Total avoided PFAS emissions over 30 years, **without** risk management measures (t PFAS)
RO1	11 800 (7 600 – 15 000)	7 900 (5 300 – 10 500)
RO2	13 000 (8 000 – 16 600)	11 200 (6 900 – 14 900)
RO3	**13 200** (8 000 – 16 800)	11 300 (7 000 – 15 000)
RO4	12 600 (7 900 – 14 500)	8 800 (5 500 – 12 500)

RO5	12 500 (7 900 – 14 400)	6 700 (4 500 – 8 900)

Notes:
(1) Baseline emissions of PFASs over 30 years are estimated at 14 100 tonnes in the EU.
(2) The emission assessment for the ready-to-use sector has not been changed although a revision has been considered on the cost side. While stakeholder comments imply that the number of PFAS-containing fire extinguishers is higher than initially reported by them, it is also reported that only 1-5% of extinguishers are actually used during their service life. As the Dossier Submitter cautiously assumes that all volumes sold are eventually released, a further increase of the emission estimate for this sector was not considered warranted.

RO3 is the RO which is calculated to lead to the greatest PFAS 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 RAC's finding that the release estimates presented by the Dossier Submitter to assess the effects of the proposed restriction are reliable. However, SEAC also notes RAC's comment that release reductions could be overestimated because of the assumption that additional proposed RMMs are fully implemented and effective.

In this respect, SEAC notes RAC's assessment that total emission reductions achieved with the different ROs are most reliable when they are achieved via core conditions (placing on the market, formulation, sector-specific derogations on use) rather than additional RMMs. SEAC further notes that the timing of emission reductions per se is of limited significance compared to the extremely long timeframe of persistence and impacts of PFAS. SEAC agrees that RO3 is the reliable restriction option regarding the reduction of emissions.

SEAC also notes RAC's comment that assumptions regarding incineration abatement of PFAS could be optimistic.

Key elements underpinning the SEAC conclusion(s):

SEAC finds that the principle of using avoided emissions as a proxy for the benefits of the restriction follows SEAC's approach for evaluating PBT and vPvB substances. 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 and notes that RAC confirmed that the estimated emissions can be used as a proxy for the risk of PFAS releases in the context of the use in firefighting foams.

SEAC takes into account that emissions were not discounted and agrees with this approach.

As noted by SEAC, RAC also finds that the hazards and corresponding risk of alternatives are likely to be significantly lower 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, in case of increased used of siloxanes during the assessment period, actual benefits from the proposed restriction could be somewhat lower than the PFAS emission reduction indicate. SEAC notes certain siloxanes are identified as SVHC based on their PBT and/or vPvB properties (cyclic D4, D5, D6) and octamethyltrisiloxane are undergoing PBT-assessment. This situation could make siloxanes less attractive as alternatives, but SEAC lacks information to assess to what extent these four siloxanes are representative of the whole possibilities offered by the large number of siloxanes.

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 to RO5, are similar over 30 years. The highest potential reductions of PFAS emissions are specified for restriction options RO2 and RO3 with 92 % and 94 %, respectively. However, the other restriction options are still estimated to result in comparable release reductions with 84 % for RO1 and 89 % for RO4 and RO5. The greatest difference in total emission reductions between two different ROs is approximately 10 percent points, which is probably within the error margin of the emission estimates. Therefore, the benefits of the different restriction options appear to be very similar in terms of emission reduction of PFAS, and the difference in the benefits of the various options appears negligible compared to the significant difference between benefits in the presence or absence the additional RMMs for training and incidents (i.e., containment and other emission control measures). However, RAC notes that the different restriction options presented by the Dossier Submitter differ in their core conditions regarding placing on the market, formulation and sector-specific derogations. Moreover, RAC considers that a full implementation of additional RMMs is challenging due to the nature of the use during life incidents. RAC therefore found RO3 to be the most reliably effective restriction option because core conditions contribute the greatest to the reductions of this restriction option. Indeed, 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 in 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 timing and the speed with which each RO is expected to reach the (overall similar) total emission reduction over the time horizon of the analysis (30 years). However, since the concern is about the potential long- and very long-term impacts of the irreversible risks of PFAS releases, SEAC finds that the relative speed of emission reduction over the period of 15 to 30 years is a criterion of lower importance compared to the total emission reductions and the proportionality of the different ROs.

SEAC further notes RAC's concern that **incineration** of firefighting foams is technically challenging and under sub-optimal conditions can result in incomplete destruction and lower release reductions than calculated by the Dossier Submitter. RAC therefore proposes an additional condition in paragraph 4(d) and 5 that requires a minimum incineration temperature of 1100°C. SEAC has no information on possible costs resulting from this condition additional to those already assessed by the Dossier Submitter (such as related to technology change or adaptation, higher energy consumption, temporary storage of PFAS foams if incineration capacity at that higher temperature is limited) and therefore this remains an uncertainty in SEAC's assessment.

The Dossier Submitter carried out a review of the technical and market maturity of alternative **end-of-life treatment for PFAS-contaminated waste**, such as 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 PFAS removal (due to the possible formation of PFAS by-products), uncertainties about environmental performance (energy consumption, possible release of fluorinated greenhouse gases) and uncertainties about costs. It is therefore difficult to conclude on whether these technologies could significantly contribute to PFAS destruction capacity during the transitional 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 assessment of costs and benefits, the latter being focused on PFAS emission reductions. Some of these other impacts are positive (e.g., avoided environmental remediation costs and increased competitiveness of the industry) and some are uncertain or could be negative (e.g., impacts on greenhouse gas emissions and consequences of unprevented fire events if alternatives do not perform as well as PFAS foams).

A detailed quantitative assessment of these impacts was not provided by the Dossier Submitter, and even a qualitative assessment of those other impacts is challenging. Overall, SEAC tends to consider that PFAS emission reductions could also imply very significant avoided remediation costs.

Furthermore, SEAC finds that potential negative impacts on fire safety could be minimized by the implementation of a review of the substitution status before the end of the transitional period for Seveso establishments. This review should be based as much as possible on local information collected from Seveso sites (and more generally high-fire hazard sites).

The proposed restriction could also have impacts on the 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 societal costs of environmental pollution

As a positive result of the proposed restriction, avoided clean-up costs at sites after the occurrence of a fire incident and after the use of PFAS-containing foam are discussed in the cost section. However, SEAC concluded that it does not have enough confidence in the quantitative assessment and thus SEAC does not take these cost savings into account. Yet, SEAC considers these avoided costs should be kept in mind as qualitatively analysed benefits when assessing the proportionality of the restriction proposal.

In addition to the avoided costs related to clean-up after local fire incidents, another benefit category has been identified by the Dossier Submitter, which is related to avoided remediation activities. It is becoming increasingly obvious that PFAS contamination has caused wide-spread environmental contamination which represents a high societal cost already now, and which could be increasing further in the future. An example of such contamination is provided by Swedish data reported in the consultation on the Annex XV Dossier (comment #3566).

Despite SEAC's evaluation 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 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. For instance, the benefits of avoided emissions are related to avoided drinking water treatments or avoided shifting to alternative drinking water resources that may be required in the future. An example of significant drinking water treatment costs caused specifically by PFAS foam contamination was provided during the consultation on the Annex

XV report (comment #3622[34]). Moreover, avoided economic losses due to foregone agricultural production on contaminated ecosystems was considered as an example. The extent to which this restriction would contribute to such societal benefits cannot be assess by SEAC, given that the restriction only addresses part of the PFAS emission sources contributing to environmental contamination (only use of PFAS in firefighting foams). However, SEAC notes that in Belgium, measurements of PFAS contamination in known areas of historic release of firefighting foams have been carried out. Information on the results was reported in the consultation on the Annex XV Dossier (comment #3626). Most of these releases relate to uses of firefighting foams and SEAC finds that this gives some insight into the wideness of the pollution problem, and 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 on emissions of greenhouse gases. SEAC cannot present a quantitative assessment of the change in CO_2 emissions and associated global warming potential (GWP) nor can SEAC compare these impacts with the benefit of avoided PFAS emissions of the proposed restriction. The different possible impacts of the proposed restriction on greenhouse gas emission can be summarised qualitatively as follows.

- 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 whether PFAS other than F-gases with a high GWP are used in firefighting foams and whether the restriction would have any positive effect on the climate in this way.
- Incineration: the proposed restriction implies an increase in i) the incineration of stocks of PFAS-containing foams that would remain usable and unused before the end of transitional periods, and ii) the incineration of cleaning/rinsing water used in the cleaning 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 (with the reservation that some alternatives are hazardous to the water environment according to the Dossier Submitter). Given the lack of information, it is particularly difficult for SEAC to discuss whether adapting concentration limits in order to minimise the need for incinerating large amounts of water containing only residual amounts of PFAS would increase the overall benefits of the proposed restriction.
- Avoided remediation: the restriction will likely contribute to avoid environmental remediation activities or drinking water treatment in the future, which are sources of energy consumption and greenhouse gas emissions (until and to the extent the energy system is decarbonised).
- Redesign of firefighting systems would also entail greenhouse gases emissions in case of decommissioning and rebuilding of these systems.

Avoided health and environmental impacts

It is not considered possible, and it is not the approach taken by the Dossier Submitter, to quantify health and environmental impacts of the proposed restriction in line with SEAC's approach for assessing PBT/vPvB substances. SEAC, however, notes that according to RAC,

[34] SEAC also took note of the following report: "PFAS in Nederlands drinkwater vergeleken met de nieuwe Europese Drinkwaterrichtlijn en relatie met gezondheidskundige grenswaarde van EFSA" – (PFAS in Dutch drinking water compared to the new European Drinking water Directive and relation with EFSA's health-based limit value) RIVM-briefrapport 2022-0149. This report highlights potential health impacts of PFAS exposure due to current concentrations found in drinking water in the Netherlands.

there is evidence of exposure to PFAS being associated with several health outcomes (e.g., 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 of 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 effect on humans and other species could be seen as an aggravating factor in addition to PFAS being a PBT/vPvB class of chemicals, which may represent an additional health and environmental benefit of the proposed restriction.

Competitiveness of industry

SEAC considers that the restriction could improve the competitiveness of the European chemicals industry by incentivising earlier innovation of PFAS alternatives. This was not accounted for in the Dossier Submitter's assessment.

Comparison of the different ROs in terms of other impacts

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

- RO3 (restricting formulation for exports), limits emissions in other jurisdictions by avoiding exports of the substances. This may also benefit the environment in the EU through lower flow-in of the substances across borders, noting that some of the substances have potential for long range transport.

RO4 would allow to tailor the regulation based on the consideration of site-specific attributes so that each actor would have a timeframe that best allows them to make a controlled transition without increasing the risk of insufficient quantity or quality of available firefighting foams. However, SEAC considers that RO3 with a review of the substitution status and technical feasibility based on site-specific information, which should be 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 endings to proposed transitional periods.

3.3.3.4. Proportionality

Summary of Dossier Submitter's assessment:

Table 12 summarises the cost-effectiveness (C-E) estimates for different ROs and industry sectors or types of use.

Table 12. 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 (€ per kg)	RO2 (€ per kg)	RO3 (€ per kg)	RO4 (€ per kg)	RO5 (€ per kg)
Seveso establishments	700 (300-3700)	800 (300-3900)	800 (300-3900)	560 (230-2800)	2300 (1200-12000)
Other industries	160 (40-680)	200 (60-850)	200 (60-840)	200 (60-850)	200 (60-850)
Civilian aviation	50 (0-190)	70 (5-290)	70 (6-290)	70 (5-290)	70 (5-290)
Defence	50 (0-190)	70 (4-290)	70 (5-280)	30 (1-110)	70 (4-290)
Municipal fire services	900 (310-3600)	840 (290-3500)	830 (290-3500)	840 (290-3500)	840 (290-3500)
Ready-to-use applications	30 (0-140)	60 (0-210)	60 (0-210)	60 (0-210)	60 (0-210)
Marine applications	320 (90-1300)	310 (90-1300)	310 (90-1300)	310 (90-1300)	310 (90-1300)
Training and testing	17 (0-60)	60 (0-140)	60 (0-140)	60 (0-140)	60 (0-140)
All sectors/types of use	**500 (190-2000)**	**520 (180-2200)**	**515 (180-2100)**	**415 (150-1700)**	**1200 (500-5500)**

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.
Note 2: The outcomes of the cost-effectiveness analysis show negligible sensitivity to the adjustments made in the cost assessment for the ready-to-use sector. This is related to the relatively small share of the PFAS use in this sector compared to the total use across all sectors.

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 13, the cost-effectiveness ratios of around €500/kg for RO1, RO2 and RO3 are similar compared to other recent REACH restrictions.

Table 13. 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

(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 PFAS 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.

SEAC conclusion(s):

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

Considering the cost-effectiveness analysis and the identified benefits of the proposed restriction, SEAC finds that the proposed restriction (RO3) appears to be proportionate (and so do all other ROs).

SEAC agrees with the Dossier Submitter that RO3 is less uncertain than RO4 in terms of the achieved emission reduction by the sector-specific end date of the use. However, a review of the availability and technical performance of alternatives for PFAS-containing firefighting foams in the Seveso sector is supported by SEAC as a measure to reduce uncertainty about unwanted impacts of the restriction, in terms of consequences of fire events. The recommended review should be based as much as possible on local information collected from Seveso sites (and more generally high-fire-hazard sites). Thereby, the review should be as exhaustive as possible, to capture specific situations requiring an extension of the transitional period. SEAC finds that this entails an important advantage, given the high stakes related to catastrophic fire events and the low, but remaining, uncertainties about the performance of PFAS-free foams in providing the same level of protection in every challenging situation.

When addressing proportionality and the choice between different ROs, SEAC also underlines that the differences between ROs in terms of the total environmental stock of PFAS is likely small. Ultimately, the differences between ROs with regard to the shift of emission reductions are relatively short, against the very long timeframe of past, present, and future contamination by PFAS.

SEAC also evaluated the sector-specific transitional 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, they appear broadly appropriate.

SEAC considers that the proposed limit value of 1 mg/l for PFAS concentration in foams 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.

Key elements underpinning the SEAC conclusion(s):

Based on the Dossier Submitter's figures for the costs of the restriction and emission reduction

as well as RAC's conclusions about emissions, SEAC derives the following cost-effectiveness (C/E) estimates (in €/t avoided emissions) for each of the restriction options.

Table 14: Overview of cost-effectiveness (in €/t) of the different restriction options, taking into account sensitivity analysis of costs and emission 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 the costs (with inclusion of RMMs, and without avoided clean-up costs) and emission reductions. The "high" C/E divides lower-bound estimates of costs by upper-bound emission reduction. The "low" C/E divides higher-bound estimates of costs by upper-bound emission reduction. The "central" C/E divides central estimates of costs by central emission reduction.

The cost-effectiveness values appear to vary (depending on the restriction option and the assumptions made for the calculations of emission reductions and costs) between 138 €/kg and 5 000 €/kg. SEAC acknowledges that there are no established cost-effectiveness benchmarks for the assessment of the proportionality of risk management policies for PBT/vPvB chemicals, and that a comparison of the C/E ratios across different restriction dossiers can only be indicative. This is for example due to differences in the persistence of the chemicals addressed. However, SEAC notes that the 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 to RO4. The estimated cost-effectiveness values are similar for R01 to R04, but lower for R05 (given the lower cost-effectiveness of complete foam containment).

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

SEAC noted that, due to some uncertainties in the cost assessment, the costs of the restriction could be underestimated and that there are limited but actual concerns about the performance of alternatives in a few sectors. At the same time, there are many positive impacts of the proposed restriction, such as future avoided pollution abatement costs, that need to be taken into consideration. Overall, considering the C/E figures, the uncertainties, and additional benefits of the proposed restriction, SEAC considers the restriction to be proportionate.

Transitional periods

On the one hand, SEAC considers that the transitional periods should be long enough to ensure that stakeholders are able to realistically comply with the restriction. For example, this means that there is sufficient time to carry out the necessary research and development where suitable alternatives are not yet available, to implement substitution activities and arrange any necessary adaptations within the supply chains. Some time may also be necessary to enable the availability of and access to (preferably standard) analytical methods,

which is also important for the enforceability and practicality of the restriction. SEAC further underlines, as noted above, that transitional periods should ensure the avoidance of increased risks to human health and the environment related to increased risk of fire damage.

On the other hand, the transitional periods should be short enough to achieve emission reduction without unnecessary delay. SEAC also points out that a relatively short transitional period would increase the incentives for the development of and transition to alternatives. Being at the forefront of the development of alternatives is expected to enhance the competitiveness of the EU industry in the longer term.

According to the Annex XV report, the maturity of alternatives varies depending on the sector. Based on this, the Dossier Submitter proposed several different sector-specific transitional periods. The specific lengths of these transitional periods are evaluated in Table 15, below. Considering the relatively high potential of emissions and the importance of emission reduction reflected by RAC, SEAC overall agrees that it is appropriate to set several different transitional periods instead of one that would only account for the needs of the sector in which the most time is needed.

Table 15: Evaluation of the sector-specific transitional periods proposed by the Dossier Submitter.

Sector/type of use	Transitional period proposed by the Dossier Submitter	SEAC's evaluation
Seveso establishments	10 years	In the consultation on the Annex XV Dossier, some industry actors reported that they find the transitional periods proposed by the Dossier Submitter appropriate (e.g., comments #3552, #3556, #3600). This implies that technically and economically feasible alternatives are expected to be available in this sector by the end of 10 years after entry into force, at least in general. Some stakeholders, on the other hand, claimed that suitable alternatives are not yet available in all scenarios and highlighted cases of fires in which non-fluorinated foams were used resulting in a disaster (comment #3546). SEAC notes these points but also reasons that, firstly, there is no certainty about what the outcome in these specific cases would have been if PFAS-containing foams would have been used, and secondly, this does not elucidate the performance level of alternatives that will be available after a 10-year transitional period. SEAC notes that environmental NGOs consider that especially the length of the derogation for Seveso establishments is not justified (comment #3566). SEAC agrees that there is little justification for choosing exactly 10 years in the Annex XV Dossier. SEAC notes that in the PFHxA restriction proposal, the transitional period proposed was even longer with 12 years after 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 before the end of 10 years and that full functionality of alternatives at the point of applying the restriction to these uses should be ensured. SEAC recognises that, in this restriction, the long transitional period covers a much larger base of applications compared to the PFHxA restriction. For some of the covered applications, alternatives could be phased in sooner. SEAC also recalls that during the evaluation of the PFHxA restriction proposal, the committee was concerned that the coverage of the long transitional 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 an adequate performance level in all scenarios affecting the chemical and petrochemical sector (or scenarios of equivalent fire hazard) by the end of the 10-year transitional period. SEAC takes into consideration that the inability to successfully fight fires in this sector could lead to very high negative impacts on the environment, human health and lives, and the economy. SEAC therefore thinks that, given the high stakes of such catastrophic risks and the low but remaining uncertainties about the ability of fire extinction with PFAS-free foams, a review of the substitution status should be implemented before the expiry of the transitional period. This is to ensure that suitable alternatives are available for all high-risk settings. Overall, SEAC has a preference for RO3 with a review over RO4, which is based on the consideration of their different

		characteristics: • RO3 better ensures that no emissions take place after a fixed date, even if the review should demonstrate that the initial transitional period needs to be extended for certain installations. In contrast, under RO4, emissions could continue for an undetermined duration at some sites. However, SEAC notes that RO4 might not necessarily lead to a slower pace of substitution, since a permitting system could ensure that substitution is carried out as soon as it is considered feasible by the evaluating authority depending on the details of how it would be implemented. This aspect of substitution pace is considered a weakness of fixed transitional periods because there are indications that many Seveso sites, which would be granted a long transitional period under R03, do not need it and could be incentivised to switch earlier to alternative foams under RO4. Furthermore, RO4 may further promote substitution by allowing information sharing between first movers and other stakeholders or authorities. Yet, it is considered by SEAC that RO3 sends a clearer signal to stakeholders that substitution needs to be carried out before the specified end date. • Despite lacking quantitative information, SEAC considers that RO4 would entail higher costs than RO3 due to the cost of establishing and operating the permitting system, which could be higher than the cost of carrying out the review foreseen by SEAC under RO3. • The two ROs take a different approach to the management of risks related to industrial sites, a more centralized EU approach in RO3 compared to local management of industrial risks under RO4. SEAC expects that, where the decisions on whether the continued use of PFAS-based foams is appropriate at a certain point is made by local authorities, they would be impacted by differing levels of rigorousness or expertise.
Other industries	5 years	SEAC is somewhat concerned that industries or sectors other than Seveso installations could represent a challenge for fighting fires without PFAS-containing foams (e.g., non-Seveso sites in the vicinity of Seveso sites referred to as "neighbouring sites" in the Seveso Directive, etc.). Conflicting comments were received on this topic during the consultation on the Annex XV Dossier. On the issue of "neighbouring sites", SEAC asked specifically and received the same comments from two stakeholders representing the fire safety and security industry in Europe and Australia, and one comment from a global organization of C6 fluorotelomer-based products manufacturers during the consultation. The comments overall claimed that neighbouring installations can present significant hazards and represent a risk to Seveso III installations, and that it can create a risk if neighbouring installations and Seveso III installations do not use the same foams and therefore cannot share foam resources during an incident. SEAC finds that the comments do not substantiate enough the claim in order to propose a longer transitional period than proposed by the Dossier Submitter. However, SEAC recommends that the survey carried out to inform the review of the transitional period for Seveso III installations also covers the case of neighbouring installations.
Civilian	5 years	On the one hand, SEAC considers the aviation sector to be one of those sectors in which 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

aviation		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 especially important that the transitional period applied is neither too short nor unnecessarily long. SEAC notes that a transition to fluorine-free alternatives has already taken place at a number of airports, and that the outcome of the stakeholder survey undertaken by the Dossier Submitter indicates that a transition within five years would be possible. Also, compelling evidence of a shorter period being sufficient at all sites has not been presented. **SEAC thus supports** a transitional period of **5 years**.
Defence	5 years	SEAC acknowledges the **specific circumstances** related to fire fighting in the defence sector. SEAC finds that the time required for full transition in this sector might be longer than in the other sectors (even the petrochemical sector). However, there is not enough information on what the suitable length of the transitional 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 in the defence sector – and therefore the readiness of national defence operations to transition to these alternatives – **varies greatly among countries**. This is explained to be due to the fact that each country has its own specificities in terms of how military equipment is designed, approaches to fighting a fire and the performance standards required to be met. SEAC concludes that a separate assessment of each scenario at Member State level seems appropriate. REACH Art. 2(3) would provide for that and SEAC expects that exemptions under REACH Art. 2(3) would be granted in cases where the continued use of PFAS-containing firefighting foams is considered necessary. It is not clear to SEAC based on the available information what the benefit of a 10-year TP would be over a 5-year TO with the possibility to use REACH art. 2(3). 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 information was provided on the potential disadvantages 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 other EU actors in the consultation, it is difficult for SEAC to evaluate their relevance for all actors in the Union. SEAC also considered whether using Art. 2(3) exemptions could lead to supply issues for the armed forces. SEAC however finds that the viability of production should not depend on the type of the exemption and that Art. 2(3) exemptions could be granted for the formulation of foams 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. In the consultation on the SEAC draft opinion, it was claimed that from the perspective of foam manufacturers, if EU member state militaries are going to be purchasing PFAS foams beyond 5 years from entry into force, it would be better if a derogation for such use is provided in the restriction (#1214). This claim was not substantiated further. It was also stated that the national approval of an exemption according to Art. 2(3) is associated with a great deal of effort and creates a need for European harmonization, and that legal act of the European Union would help ensure legitimacy and transparency and create legal certainty (#1202). Information on the difference in impacts between starting to use Art. 2(3) exemptions at 5 or 10 years after entry into force – such as information on uses where substitution in 10 years would be possible, meaning that Art. 2(3) exemptions could be avoided – was not provided, and therefore it is difficult to SEAC to evaluate the benefits of applying the 10-year transitional period also to defence uses. Overall, **SEAC supports the 5-year transitional period**

		proposed by the Dossier Submitter.
Municipal fire services	18 months	According to the information available to SEAC, fluorine-free foams are already available and successfully used by municipal firefighting services. Therefore, from the point of view of the availability and suitability of alternatives, the transitional period for this sector could be relatively short and 18 months could be sufficient to allow a balanced transition, including communication, re-negotiation of contracts, and preparations for firefighting infrastructure that has not yet been transitioned (e.g. cleaning and adjustment of equipment and firefighting strategies/protocols). Furthermore, the proposed restriction foresees that municipal fire brigades could benefit from the longer transitional period proposed for Seveso III sites, if such fire brigades have to fight fires at Seveso III industrial installations. However, this means that fire brigades would need to keep separate equipment for firefighting at Seveso sites and other fire incidents. However, in the consultation on the Annex XV Dossier, some stakeholders claimed that an 18-month transitional 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. Transitional periods of 8 or 10 years were requested. During the consultation on its draft opinion, SEAC received a comment from an industrial chemicals manufacturer claiming that plenty of non-Seveso plants have hazardous chemicals being protected by foam systems as well, to prevent major safety and environmental issues. The comment states that in their case, they have remote sites where municipal fires services have to intervene in case of fire. In their view, this would require that municipal fire brigades have the same transitional period for all industrial sites. The comment was not further substantiated and only covered the submitter's particular case. Therefore, SEAC finds that it does not support the alignment of the transitional period for municipal services fighting industrial fires on non-Seveso installations to that for Seveso III installations. SEAC has no information whether municipal fire services are involved in fighting fires at neighbouring sites from Seveso III installations. In that case, the transitional period and conditions of the restriction for municipal fire services should be consistent with the transitional periods and conditions of the restrictions that apply for neighbouring sites.
Ready-to-use applications (Portable fire extinguishers, ready for use mixtures)	5 years for use; 6 months for placing on the market	Stakeholders submitted updated information to the consultation on the Annex XV Dossier, reporting that the **number of foam fire extinguishers** that would need to be replaced in the EU is 41 million (comment #3579) or perhaps even up to 50 million (comment #3557). These estimates suggest that the number of 15 million units that was initially reported by stakeholders and taken forward in the Dossier Submitter's assessment had been underestimated. Stakeholders claimed that replacing the necessary number of PFAS-containing portable fire extinguishers within 5 years would require an **unmanageable increase of manufacturing capacities** for extinguishers (comment #3579). In this context, it was pointed out that the number of PFAS-free extinguishers needed to achieve the extinguishing capacity required by law will be larger than the number of PFAS-based extinguishers needed to achieve the same level, and that this could exacerbate the manufacturing capacity issues (comments #3600, #3553, #3615). Stakeholders also explained that a significant share of currently installed portable fire extinguishers is intended for dealing with both class A and class B fires and that the proposal would make it compulsory to replace all of these (even those predominantly used on class A fires), which would further contribute to the issues of insufficient supply (comment #3549, #3621). SEAC finds that, in principle, cleaning of the PFAS-containing extinguishers or a part of them could solve or alleviate the issues of manufacturing capacity but notes the claims by stakeholders that **cleaning of portable fire extinguishers** to the level required is **not possible** (comments #3549,

		#3553 and #3579). SEAC understands that the prospects of cleaning firefighting equipment were generally considered by the Dossier Submitter when setting the limit value at 1 mg/L (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 at by the Dossier Submitter. SEAC also notes that some types of PFEs include a separate **inner container**/cartridge/bag holding the foam concentrate, which is only mixed with water upon activation of the extinguisher. SEAC expects that the replacement of the entire unit would thus not be necessary in such cases, which would reduce the number of required new units. In the consultation on SEAC's draft opinion, different opinions were expressed to this end. Some stakeholders agreed that converting such existing PFE into a PFAS-free PFE is possible in case the PFE was provenly not used (even though in addition to the container also some other parts would need to be exchanged) (#1181, #1183) while one stated that this is not possible because the approvals are different (#1189). However, the respondents agreed that this would not impact the necessary substitution timeline; the ones agreeing that conversion is possible stated that the market share and the share of PFEs that could be converted are too low. Some stakeholders claimed that a transitional period of 10 years would be needed to manufacture a sufficient number of PFAS-free extinguishers. Some information on the necessary increase of manufacturing capacity for different transitional periods was provided in a confidential submission (comment #3579). However, sufficient justification for why the figures represent an unmanageable increase was lacking. In the consultation on the SEAC draft opinion, the figures regarding the use of existing portable fire extinguishers were further explained. It was demonstrated with calculations that a transition period of 7 years would mean a temporary capacity increase of 36 % for concerned local industry compared to the 70% raise to accomplish a 5-year transition (#1189). All respondents discussing the transition period for use agreed that a suitable (although tight according to some) timeline would be either 7 years from now or 5 years from entry into force (expecting decision making to take 1.5 to 2 years) (#1181, #1183, #1189). It was highlighted that a longer transition period would slow down the substitution process whereas shorter timeframes could result in chaotic conditions in supplying and treatment of the upcoming waste (#1183) or lead to importing PFEs from outside the EU with the effect to destroying industrial capacities currently located in EU (#1189). Based on the information collected, **SEAC supports a transition period lasting until end of 2030** (i.e. corresponding to at least 7 years from now, and this end date is expected to lie approximately 5 years after entry into force of the restriction depending on the length of the decision-making process). 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). SEAC notes that, after the consultation on the Annex XV Dossier, the Dossier Submitter proposed to restrict the **placing on the market** of PFAS in extinguishers already at **6 months** after entry into force. Existing extinguishers containing PFAS could continue to be used and serviced until the proposed transitional period for the use of PFAS extinguishers has passed (5 years after entry into force). Such a staged substitution plan was also proposed by stakeholders, with one comment suggesting to apply 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. In the consultation on the SEAC draft opinion some industry stakeholders stated that they find a 6-month transition period after entry into force reasonable in general but reported concern on the availability of technically feasible alternatives in the case of alcoholic fluids or polar fluids more generally (#1181, #1183). The stakeholders mentioned a necessary transition time of 12 or 18 months after entry into force but it was not further substantiated or clarified whether the time relates to inventing the foams or being able to place finished products on the market. Some concern was also reported related to low temperature environments and frost-proof agents, but there the work appears to be already close to completion (#1181, #1183). One stakeholder claimed that a transition period of 18 months after entry into force would be necessary for all PFEs to avoid interfering with a fair global competition amongst manufacturers (#1189). Based on the available information, **SEAC supports a transitional period until end of 2030 for use of PFAS-containing PFE.** Regarding placing on the market, **SEAC proposes a transitional period of 18 month (after entry into force) for the placing on the market of PFEs specifically for alcohol resistant foam dispensing**. For other types of PFEs, SEAC supports a transitional period of 6 months for the placing on the market.
Marine applications (civilian ships)	3 years	In the consultation on the Annex XV report, a stakeholder claimed that some industry sectors, including the shipping industry, have not yet developed design standards for the implementation of substitution to PFAS-free firefighting foam and that the transitional period may be too short to enable a 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 further pointed out that the viscosity of fluorine-free foams is typically high and that transitioning to such alternatives will require significant technical changes to the on-bord fire protection system, which will not be possible within 3 years (comment #3549). Detailed explanations on the nature of those changes and 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 also noted that downtimes in harbours are costly, and that in many cases, it may not be possible to implement the required changes at all since the system is deeply embedded into the overall structure of the vessel. Still, referring to the comments to an earlier survey, the Dossier Submitter considered that a transitional period of three years is appropriate in view of the avoided direct emissions to the environment. In the above-mentioned survey a shipping company highlighting that a transitional period of 3 years appears to be sufficient (Annex E.2.5.5. to the Background Document). In the consultation on the SEAC draft opinion, stakeholders brought up new arguments on why a 3-year transitional period is not considered appropriate. It was pointed out that vessels carry wide ranging bulk flammable fuel cargos which may change with different voyages including hydrocarbons and polar solvents (#1204). SEAC observes that the availability of fluorine-free foams able to extinct fires in different flammable liquids or on polar solvents specifically have been recognised as a challenge also more widely across applications and considers this a valid point. Also noting that fire systems may be integral to the ships and are designed for foams of a specific type, it would not seem possible to change the firefighting medium carried depending on cargo. It was also claimed that since different fluorine-free foams cannot be mixed, it may be

		difficult to make a refill at the next harbour after a fire at sea (#1204). It was also explained that at sea, forceful non-aspirated application of firefighting foam is often necessary due to effects of wind, whereas the appropriate performance of fluorine-free foams often requires that they are applied well aspirated; furthermore, it was reported that using sea water for firefighting is less effective when fluorine-free foams are used (#1204, #1205). One stakeholder pointed out that many containment measures, such as bunding, fire detection systems, and deluge systems to extinguish the fire rapidly, are in place in vessels to maximize fire water clean-up (#1202). Unfortunately, no information on the effectiveness and frequency of such systems or on the fate of the waste is available, and estimations on their impacts on the extent of potential emissions cannot be made. SEAC notes that the circumstances of use in this sector resemble those at the offshore sector to a large extent. However, in this case the transition does not appear quite as demanding as in the case of oil rigs for example, and indeed some actors stated that even a 3-year transitional period would be suitable in their case. Taking into account all arguments provided, **SEAC supports a 5-year transitional period**.
Training and testing (except testing of the firefighting systems for their function)	18 months	According to information available to SEAC, fluorine-free foams are already available and successfully used for training and testing. Therefore, the transitional 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 length has been proposed earlier for testing and training with PFAS-containing firefighting foams (e.g., PFHxA restriction), and as such, it would provide for some predictability and legal certainty. Even if alternatives are already widely used, SEAC finds that some time is necessary to allow for adaptation and practicalities (e.g., review any contracts, etc.). **SEAC** therefore **supports a transitional period of 18 months** for this use.
Formulation for export	10 years	A stakeholder highlighted in the consultation on the Annex XV report that a 10-year timeframe for the placing on the market (formulation) is important because 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 stakeholder believes that the inclusion of this provision has the potential to reduce the use of PFAS foams in countries where there is currently no regulatory need to do so. SEAC agrees that in case of a transboundary pollutant, such as many PFAS, 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 transitional period for formulation should be as long as the longest use-specific transitional period in order to maintain the availability of PFAS-containing foams during the substitution process. SEAC also finds that setting the transitional period to the same length as for placing on the market appears enhance regulatory clarity 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 SEAC with the raw data on which the estimates of the suitable number of years for each sector are based. SEAC found that little information was received in stakeholder consultations that would support any specific numbers of years. The proposals by the Dossier Submitter therefore seem to be approximate values based on limited data and personal judgement. Furthermore, SEAC regrets that different lengths of transitional periods were not tested in sensitivity analysis. Such an analysis would have been helpful not only for evaluating whether the chosen length is optimal, but also for evaluating the magnitude of the impact of a too short transitional period where applicable. **Looking at all of the information provided in the Annex XV Dossier and comments received in the consultation on the Annex XV report, SEAC however considers that the timeframes of 18 months, 5 years and 10 years appear broadly appropriate.** Other, more suitable timeframes were not proposed or justified in the consultations. Some requests for further exemptions from the restriction or longer transitional periods for specific foam applications were made by specific stakeholders; these are discussed separately by SEAC later in this section.

However, as explained in Table 15, a concern is raised that the transitional periods 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 offshore oil and gas installations 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 of the restriction is the preferrable option.

In case the 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 PFAS to the environment, except when foams are used, and not properly collected, which should remain highly exceptional (since effective RMMs including destruction of foams at the end of life are included in the proposed restriction). The principle followed by SEAC in recommending a review, finding a compromise between accelerated completeness of substitution and minimising the risk of catastrophic fires, should be followed when using the results of the review.

SEAC notes that a German association of fire brigades operating on industrial sites stated that a **6-month transitional period for adequate disposal** of PFAS-containing firefighting foam concentrates held in stock is **unnecessarily long** (comment #3556). SEAC agrees that it would be useful to start collecting PFAS-containing waste requiring adequate treatment immediately at entry to the force as proposed in the comment. On the other hand, SEAC notes that actors not yet familiar with the phase-out process might not have the preparedness for it and may need some time to organise themselves. Also, other actions stipulated in entry paragraph 4 (e.g., minimisation of emissions to the environment and direct and indirect exposures to humans, etc.) may necessitate substantial changes of the practices and facilities. SEAC considers that, if one prefers to set only one transitional period for entry paragraph 4 obligations, 6 months as proposed by the Dossier Submitter appears to be a practical solution.

Requests of further derogations and extended transitional periods received in the consultation on the Annex XV report

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 in the transition to alternatives. Examples of additional high-risk areas include temporary storage and transportation of fuels, offshore oil and petroleum, and other

use areas of firefighting foams.

The following specific requests were made:

- a 10-year transitional period for the **offshore oil and gas industry** not covered by the Seveso III definition (comment #3544, #3570, #3546, #3596, #3606, #3621)
- 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 were mentioned in the comments containing the requests related to the sector of offshore exploration and exploitation of minerals and the transportation of flammable liquids, including oil and petrochemical refineries, pharmaceutical and chemical processing facilities and distribution terminals, offshore platforms and Floating Production, Storage, and Offloading vessels, aviation, defence
- a derogation for **offshore helipad** (comments #3543, #3546, #3550 and #3596)

SEAC notes that a common denominator for many of the requests made was that the uses referred to are **explicitly exempted from** the applicability of the **Seveso III directive**. Accordingly, the potential foam uses in the mentioned settings would not be covered by the long review period proposed for the Seveso sector, even if the uses were quite similar.

At the time of the SEAC draft opinion, the justification offered by stakeholders for extending the 10-year transitional period to the **offshore sector** was mostly limited to a claim that the offshore oil and gas industry should be given the same opportunities as comparable land-based industrial facilities with similar fire risk due to handling large volumes of flammable and explosive liquids. One stakeholder highlighted that making the offshore sector fit for fluorine-free foams is a challenging endeavour, as the existing firefighting 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-tech materials) was mentioned in the same comment. Generally, SEAC notes that in the offshore sector there are typically only limited escape routes for personnel or passengers in case of fires or explosions. Also, there is potential for a fire causing extensive environmental pollution such as extensive oil discharge. On the other hand, SEAC considers that, in the context of offshore uses of PFAS foam, there is limited potential to collect the firewater, making direct releases of PFAS to the environment likely. This necessitates a careful consideration of any derogations.

In the consultation on the SEAC draft opinion, stakeholders provided further underpinning to claims made earlier and also presented further arguments to justify applying a 10-year transition period (with a review at the end) also to the offshore sector. It was reported that to use fluorine-free foams effectively requires gentle applications, **well aspirated** (not non-aspirated), slower (not rapid) attack, and closer engagement with the fire (#1192, #1204). It was explained that for fluorine-free foams, higher expansion ratios compared to fluorinated firefighting foams are often required, resulting in lighter foams, making them more sensitive to wind conditions (#1202). It was also pointed out that **high winds** are prevalent in the offshore setting and stated that therefore forceful, non-aspirated application is however typically necessary in practice (#1204). It was explained that fluorine-free foams are typically highly viscous under **winter temperatures,** and this impedes their use (#1192, #1204). Also challenges with using **sea water** were highlighted (#1204, #1179). It was explained that the hardness of water used to prepare the foam solution negatively affects the quality of the expanded foam, i.e., expansion ratio and drain time (#1202). It was also highlighted that only seawater is available for firefighting operations in winter temperatures that often drop to -18°C in North Sea and Baltic areas (#1192). The claim that to date no PFAS-free foam concentrates providing **both alcohol resistance and high freeze protection level** seem

to be available was repeated (#1189, #1214). It was also claimed that larger **storage capacity** will be needed after transition, because higher application rates are required with fluorine-free foams, and this may be difficult due to space and weight limitations (#1192, #1204, #1208). It was reported that **a variety of flammable fuels** are stored and used on these offshore installations (incl. crude oil, condensate, Jet A1, methanol, diesel) which increases the difficulty for a single fluorine-free foam to be adequately effective on all fuels (#1204). Furthermore, it was explained that fluorine-free foams require **system designs dedicated to a specific fluorine-free foam agent**, and therefore different fluorine-free foams cannot be used in one site. This could have major implications on re-supply following a fire event. Also, this could prevent mutual aid collaboration amongst platforms during emergencies, which is reported to be the practice currently, even across different operators (#1204, #1192, #1208). It was highlighted that **containment basins**, floor dividers and other coaming devices reduce the risk of leakage of both firewater runoff and hydrocarbon liquid fuels into the environment (#1202). Unfortunately, SEAC has no information on the types and extent of use of this kind of measures in the relevant installations and therefore cannot make estimations on their impacts on the extent of potential emissions. Finally, it was reported that many offshore installations are scheduled for **decommissioning before 2030** and it was claimed that the costs of transition and re-training would be disproportionate in these cases (#1192, #1204). SEAC considers that based on the information received, the challenges of the transition are clear. SEAC agrees that relative to installations to be decommissioned before 2030 the cost of transition would indeed be disproportionate considering that the remaining time after the 5-year transition period would be very short. Considering the specific challenges affecting the transition to fluorine-free foams in the offshore sector, SEAC finds that a long transition time is required. SEAC notes that it took eight years to by the actor that reported having already carried it out. Overall SEAC concludes that it would be appropriate to apply the same timelines as for the similar onshore activities (i.e., a 10-year transition period with a review).

In relation to the **transportation sector**, the justification for an extension of the transitional period that was provided by stakeholders highlighted the importance of these uses and emphasized that (densely) populated areas may be crossed. Some limitations of fluorine-free foams were listed on a general level (incl. longer extinguishment times, higher expansion ratios, shorter application ranges, lower flexibility, higher fuel vulnerabilities and higher viscosity), but no analysis of why fluorine-free alternatives are not considered to work appropriately in the relevant scenarios was provided. In the consultation on the SEAC draft opinion, it was claimed that no fluorine-free alternatives can currently meet the long-term storage requirements at elevated temperatures, i.e., 30-60°C (#1202). SEAC agrees that high temperatures can be relevant for some transport scenarios but also notes that heat-resistant fluorine-free alternatives have been reported to be available (see Background Document, Annex E.2.4., p. 309ff). Also, in transport scenarios the volumes of flammable liquids simultaneously present are expected to be lower than, e.g., in tank farms, and therefore the risks may not be comparable. Other comments received discussing transport seemed to actually relate to temporary storage (#1204, #1196).

Overall SEAC considers that the information provided is not sufficient to allow further evaluation and, therefore, SEAC cannot make a proposal for an extension of the transitional period time to be applied to the transportation sector.

Requests to completely exempt offshore **helipads** were also made in the consultation on the Annex XV Dossier in four submissions. However, the justification provided was scarce. It was claimed that this is a context in which foams are often used unaspirated and with 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 further evaluation and SEAC, therefore, cannot propose a derogation[35].

SEAC finds that using **coverage by the Seveso III Directive as a cutoff-line** between users that can or cannot benefit from a longer transitional period can indeed be questioned for several reasons. The coverage provided by the Seveso Directive is considerably wider than the coverage of the longest transitional period proposed in the restriction on PFHxA, its salts and related substances (where SEAC concluded that large tanks with their bunded areas should be covered). During the evaluation of the PFHxA restriction proposal, SEAC however also considered 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 16: 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 the Seveso III Directive 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 paragraph 4.
Some actors potentially still needing PFAS foams are still not covered (other industrial sites, offshore sector, etc.)	Uses exempted from the applicability 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 because easy to check if a certain actor qualifies or not	
Acceptable for actors in the	The approach was proposed by stakeholders

[35] Sources indicating availability of alternatives for helidecks in the marine environment can be found online, see for example: https://www.sthamer.com/wp-content/uploads/2023/03/PD-9146-V09-STHAMEX-IAF-MARINE-1-F-10-9146-EN.pdf and https://www.sthamer.com/wp-content/uploads/2023/03/PD-9275-V09-STHAMEX-IAF-MARINE-2-F-10-9275-EN.pdf

field	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. Some dissenting views were repeated during the consultation on the SEAC draft opinion. SEAC proposes a time-limited derogation to alleviate the impacts on the offshore sector, where difficulties were reported and justification for derogating provided.

SEAC considers that the derogation should optimally be delineated in a narrower manner to avoid potentially limiting the incentives for rapid substitution for some actors under RO1-3. SEAC, however, agrees with the Dossier Submitter that the obligations set in entry paragraph 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. It is important to note at this point that the Dossier Submitter only relaxed this requirement in the case of fire extinguishers, keeping the condition applicable in all other cases.

Overall SEAC finds that using coverage by the Seveso III Directive as a general cut-off line is an appropriate solution if obligations in paragraph 4 are adhered to (specifically, the use of PFAS-containing foams is limited to fires involving flammable liquids) and if a longer transitional period is proposed for the offshore sector as presented above.

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 applicable to cleaning and foam discharged from **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** (equivalent to 50 mg/L) and submitted supporting information relevant 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 transitioning to fluorine-free foam). According to them, the higher requested threshold value would be achievable by draining and eventually flushing by water before transitioning to fluorine free foam. Reaching the threshold value of 1 ppm (1 mg/L) 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 require a few days of interrupted production, whereas flushing of the distribution system may be achieved during a week, and any actions requiring dismantling and replacement of parts of the deluge system would cause a stillstand of production for weeks. The Dossier reports that the limit of 1 ppm (1 mg/L) would lead to a minimum reduction

in concentrations of PFAS of 99.99 %, whereas a threshold of 50 ppm (50 mg/L) would represent a reduction of 99.80 %. SEAC notes that RAC acknowledges that the additional risk associated with this lower reduction is relatively small but does not support a derogation to ensure releases are indeed minimised across all sectors. Considering the high cost of eliminating the last units of contamination and the relatively low impact on emissions, **SEAC supports to set the limit value at 50 mg/L for already contaminated systems in the offshore sector**. SEAC highlights that the higher limit is solely intended to help avoid the high costs of cleaning and underlines that the foam concentrates used should comply to the limit value of 1 mg/L when placed on the market or used. SEAC also points out that in case the offshore sector will be allowed a long transition period similar to the corresponding onshore activities (covered by the Seveso directive), the higher limit value would be expected to be relevant at the point in time that the derogation period would expire. The cleaning of the equipment would likely be likewise difficult and costly at that point in time.

- It was also requested that the concentration 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 (1 mg/L) were highlighted by several stakeholders (comments #3628, #3629, #3570). It was also highlighted that large sections of the systems will require replacement to maintain a PFAS residual below a level of 1 ppm (1 mg/L) (comment #3633). A specific alternative 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.

Regarding 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. Based on the information submitted in the consultation on the Annex XV Dossier, SEAC 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 expensive it will be to eliminate contamination (comment #3570). SEAC observes it has been confirmed in literature that it will become more costly to get rid of PBT substances (per kg) as the amounts become smaller and the concentrations lower.[36]

Furthermore, it was confirmed in the consultation on the Annex XV Dossier that **1 ppm (1 mg/L) 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 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 PFAS in new fluorine-free foam concentrates** could be higher than 1 ppm (comments #3607, #3614). The stakeholder recommended to set the limit value at 3 ppm because, according to their experience, the PFAS concentrations in new fluorine-free foams are below this level. The potential reasons for finding PFAS contaminations in fluorine-free foams were not elucidated in the comment.

[36] Oosterhuis, F. H., & Brouwer, R. (2015). Benchmark development for the proportionality assessment of PBT and vPvB substances. Institute for Environmental Studies, Vrije Universiteit Amsterdam.

3.3.3.5. Uncertainties in the socioeconomic analysis

Uncertainties related to the cost assessment and the potential impact of such uncertainties on the overall results of the assessment have been highlighted in Table 10 and are further discussed in the key elements underpinning the SEAC conclusions in section 3.3.31 of this opinion. These points also have a bearing on the proportionality of the proposed restriction.

Uncertainties related to the assessment of emissions are in the remit of RAC, but SEAC notes RAC's comments about incineration efficiency and the risks of alternatives.

3.3.4. Practicality, including enforceability

Summary of Dossier Submitter's assessment:

The Dossier Submitter considers ROs 1-3 (formulation, placing on the market and use) 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 PFAS in laboratories. In addition to specific analysis methods, the total oxidizable precursor (TOP) assay has been used by several laboratories in recent years to analyse PFAS 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 organochlorine 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 PFAS 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):

RAC concludes that the proposed restriction option RO3 is practical and enforceable with the following recommendations to the Commission:

- that guidance is provided on analytical methods and on PFAS-containing firefighting foam management plans and cleaning of equipment including handling of resulting waste.
- that a requirement for adequate treatment of cleaning waste be included, and a PFAS concentration limit of 1 mg/L be applied both to this and to the labelling requirement.

RAC concludes that RO3, as proposed by the Dossier Submitter, is the preferred option regarding practicality and enforceability.

Key elements underpinning the RAC conclusion(s):

Analysis

RAC considers that grouping of PFAS in this restriction is a practical approach and offers significant advantages compared with specific identification of likely ingredients. A grouping approach presents challenges with respect to chemical analysis however as there is currently no standardised method for total PFAS, as identified also during the consultation.

Information provided in the Background Document and during the consultation indicates that a number of analytical methods are commercially available. The opinion of the Dossier Submitter that a total fluorine-based method is appropriate is considered reasonable.

RAC considers 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. Furthermore, there is considerable focus on analysis of PFAS in the scientific community, so it is reasonable to expect greater standardisation in the future.

RAC supports the conclusion by the Forum that clear guidance on the analytical method is essential for enforceability. RAC considers that advice on sampling (timing, location etc.) is also required when establishing the contamination level of substitute foam.

Concentration Limit

The proposed restriction applies *"where the concentration of total PFAS is greater than 1mg/L…as a constituent of a firefighting foam."* The rationale in Table 5 of the Background Document clarifies that this "*applies to foam concentrates before they are mixed with the application medium as well as to firefighting foam*."

The proposed concentration limit of 1mg/L or 0.0001% for placing on the market, use and formulation is well below the lowest concentration of 0.1% that provides functionality for PFAS in concentrates and ready-to-use firefighting foams. RAC notes that there is further dilution of concentrates by a factor of about 10-100[37] with water before application as foams. RAC considers this concentration limit to be practical as all PFAS-containing firefighting foam and concentrate will be included in the scope.

RAC notes that this concentration limit also applies where non-PFAS based foams are added to equipment previously filled with PFAS-containing foams and therefore potentially contaminated with PFAS.

Regarding the concentration limit referred to in para 1 and 2, RAC notes comment #3570 which includes a proposal to elevate the limit for PFAS in firefighting foams for the offshore oil and gas sector from 1 mg/L to 50 mg/L . . RAC acknowledges the relatively small additional risk associated with this but does not support a derogation to ensure releases are indeed minimised across all sectors.

The sensitivity of current analytical techniques is adequate to measure this concentration level and hence it is considered enforceable.

Collected firewater

[37] Confirmed by the Dossier Submitter to be most commonly between 33 to 100.

The proposed restriction requires collection and adequate treatment of firewater run-off following use if the concentration of PFAS in the original firefighting foam exceeds 1mg/L (Para 4(d)). RAC agrees with basing the limit on the PFAS content of the foam rather than a concentration limit in the collected runoff water as originally proposed by the Dossier Submitter. The practical advantages are that it removes the need for analysis of the runoff water and any potential for pollution by dilution. RAC notes that the concentration limit in this instance applies to either the foam or the concentrate.

Cleaning water

Another source of PFAS containing waste is from cleaning tanks and equipment when changing to a non-PFAS based foam. RAC notes that para 4(d) of the original restriction proposal required adequate treatment of "collected PFAS-containing waste". This followed the reference in 4I(ii) to "…wastes arising in the event of foam use, routine cleaning…." And so clearly included cleaning waste.

RAC notes that the amended para 4(d) refers to "collected PFAS-containing waste resulting from the professional and industrial use of firefighting foams". This appears to exclude waste from cleaning. RAC proposes that the proposed restriction be amended to include a requirement for adequate treatment of cleaning waste.

Although there is currently no requirement for collecting cleaning waste, there is a requirement for labelling containers of PFAS-waste from "…cleaning of firefighting foam equipment where the PFAS concentration in the foam was above" 1mg/L (para 6).

RAC has concerns about this concentration limit when applied to cleaning waste. From information contained on cleaning procedures in Appendix 1, the concentration in the collected cleaning waste can be several orders of magnitude less than the concentration in the PFAS foam. Waste treatment of such dilute solution is not practical, taking energy requirements and greenhouse gas emissions into consideration. RAC concludes that, unlike for collected firewater, it is not appropriate to base the concentration limit for labelling of collected cleaning water on the concentration of the foam.

RAC recommends that the concentration limit in Para 6 is stated with reference to the PFAS concentration in the cleaning water instead of the PFAS concentration in the firefighting foam. For consistency, it is recommended that the same limit is applied as was included in the PFOS restriction, namely 1mg/L. RAC acknowledges however that without a mass limit, there is potential for pollution by dilution.

If, as RAC recommends, Para 4(d) of the restriction is amended to include a requirement for adequate treatment of collected cleaning waste, RAC recommends that the same concentration limit as assigned for labelling is assigned here.

RAC also recommends that guidance be provided on cleaning, with a view to minimising the waste generated and consequently minimising the greenhouse gas emissions from incineration. I

PFAS-containing firefighting foams management plan

RAC considers that the proposed PFAS-containing firefighting foams management plan is an essential element of the proposed restriction and is likely to be an effective deterrent to continuing unnecessary use. RAC supports a proposal by the Forum that guidance be

developed and that a requirement be added to retain the plans and records for a number of years, to facilitate investigations into any contamination identified in the future.

RAC has concerns about the availability and adequacy of disposal options and considers that guidance is required on this aspect. The Dossier Submitter refers to current guidance available from a range of trade associations (Fire Fighting Foam Coalition (FFFC), the Fire Protection Association Australia) and regulatory authorities in some countries including Germany.

RAC is particularly concerned about the practicality of transportation and incineration of wastewater. Transport distances may be long, due to the small number of sites offering the facility and high temperature incineration of very dilute mixtures is both costly and technically problematic.

Use Sectors

RAC considers that the use sectors identified in the restriction are clearly defined. Regarding the Seveso transitional period, RAC notes that the restriction to use on Class B fires substantially reduces the number of Seveso sites that fall within the derogation.

RAC considered if limiting the definition within Seveso sites (such as upper tier only/specified hazardous categories etc.) would enhance the restriction proposal but concluded that the broad definition of Seveso site is practical and widely used.

Portable fire extinguishers

During the opinion development process, RAC had substantial concerns about the practicality of the proposed requirements regarding portable fire extinguishers and the long period of 5 years during which they could still be placed on the market. Similar concerns were also identified by the Forum and other stakeholders.

The Dossier Submitter made substantive amendments to the proposed restriction while the Committees' opinion was being development. These include restricting placing on the market within 6 months of entry into force and excluding PFE's from the requirements of para 4 (use for Class B fires only, minimising emissions and emissions management plan) and para 6 (labelling re. PFAS content).

These amendments have fully addressed the concerns of RAC and RAC supports them.

Practicality of Restriction Options (ROs)

The practicality, including enforceability, of factors common to all restriction options is addressed in the preceding paragraphs. The practicality of aspects that differ between restriction options is addressed here. RAC considers that practicality considerations support the selection of RO3 as the preferred option.

Restriction Option 1 provides for continued use after the derogation period until depletion of stocks. A practical drawback is that this extends the enforcement requirements over a much longer period. It also increases the possibility of customers overbuying stock before the deadline and removes the incentive for substitution.

Restriction Options 2 and 3 are identical except RO3 includes the restriction on formulation. Neither RO provides for continued use after the derogation period. RO3 is the preferred option

on practicality grounds as well as effectiveness (Section 3.3.2).

Restriction Option 4 includes a derogation mechanism via the local environmental permit system to which Seveso establishments and defence sites would be eligible to continue use if permitted after 10 years. Eurofeu proposed an implementation process as part of the consultation process and this is included in Appendix 7. RAC supports the Forum opinion that a permit system could be challenging to implement and time consuming. RAC concurs with the Dossier Submitter that it could remove the incentive for substitution.

Restriction Option 5 allows placing on the market and use without time limit if full recovery and safe disposal of all fire run-off waters are demonstrated and implemented. The enforcement mechanism is not clear. RAC supports the Forum opinion that proving no emissions is difficult and that assessments could differ between different authorities. RAC considers that this RO could remove the incentive for substitution.

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 of arranging and enforcing a full containment.

SEAC agrees with RAC concerning the recommendations to the Commission to provide guidance and review the overlap with related restrictions.

SEAC considers that the changes made to the restriction proposal during opinion making relieve the concerns that SEAC originally had on the practicality and enforceability of the proposal, specifically the changes include:

- making the labelling requirements and risk management measures for transitional 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.

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 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 about some details affecting the practicality, such as:

- the lack of a definition of the analytical methods or cleaning methods to be used,
- limited practical availability of analytical methods at this point in time,
- the lack of a definition of terms used (adequate treatment),
- the lack of a prescription on how to handle fire water, and
- the lack of a definition of 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 provides a strong indication of the

practicality of the present proposal which is similar to those previous restrictions in many regards.

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

SEAC notes that the **risk management measures** to be applied during the transitional periods are **not very clearly described** in the restriction proposal. Making the description of the tasks to be performed more detailed would improve practicality. In the absence of more detailed instructions, different actors could have different understandings of what the obligations are exactly. SEAC considers that guidance would be needed specifically on the level of emission reduction that is 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 necessary to ensure the avoidance of adverse environmental and health effects under the long transitional 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 (section 2.8 of the Background Document). 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 would be needed on how to achieve the threshold level of 1 ppm during cleaning of equipment(comments #3543, #3550).

In the original dossier, the concentration limit designating whether the **PFAS-containing waste** generated and collected should be handled for adequate treatment referred to the PFAS concentration in the waste itself. It was highlighted by stakeholders in the consultation on the Annex XV Dossier that, as also implied in the Dossier itself, the concentration of PFAS in most fire water would likely be well below the concentration threshold of 1 ppm (1 mg/L) (comment #3595) and the fire water would therefore not require treatment according to condition 4.d. A complication could also arise if in a part of the effluent the concentration was above 1 ppm (1 mg/L) and in the rest it was not; 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 water. During SEAC's opinion making, the proposed restriction was modified by the Dossier Submitter such that the **concentration limit** does not **refer to** the waste but to **the firefighting foam concentrate**. SEAC considers that this change removes the problems mentioned and supports the change.

During SEAC's opinion making, the initial version of the proposed restriction was modified by the Dossier Submitter also in terms of the coverage of the requirements such that **PFEs** were **excluded from all the requirements** of paragraph 4. Related to **use on class B fires only**, this was already briefly discussed in section 3.3.3.1. of this opinion (related to Practical availability of alternatives). To that end, SEAC notes that PFEs currently in use are typically installed for fighting both class A and class B fires. Limiting use only to cases of class B fires starting 6 months after entry into force would therefore necessitate the replacement of all the existing PFEs in premises where only type A fires can be expected, and potentially adding separate PFEs for class A fires in premises where both of the types of fire could possibly take place. SEAC notes that this would not be feasible in terms of the numbers of new PFEs needed. SEAC considers that also complying to the other requirements under point 4 (i.e., minimising emissions, establishment of a firefighting foams management plan, collection and adequate treatment of waste) would be very challenging for many types of users of PFEs (including, e.g., office buildings and even private homes) and might not provide any real benefits. Overall, SEAC supports the change.

Labelling requirement (paragraph 6 in the restriction entry)

In principle, SEAC finds a requirement to label the packaging of PFAS-containing materials related to the use of PFAS in firefighting foams 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.

Labelling of packaging of a mixture for firefighting containing organofluorine substances (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 determine 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 of the product. 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, retrieving 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 **not** be **possible to verify** whether a company claiming 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 does not seem to confirm the presence of non-PFAS organofuorine substances in firefighting foam products (Background Document, Forum advice, comments from the consultation on the Annex XV report). The lack of information could be due to the lack of obligations to report; however, SEAC expects that the substances are only added to products for specific purposes (adding further substances would be a cost element) and based on 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 expressed in 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 not to be 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.

Regarding practicality for industry actors, the Dossier 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 (Annex E.1.1.). 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 limited information on whether this represents all types of organisations concerned (also those not represented by 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 consider it 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 problematic specifically 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 PFAS.

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):

RAC agrees with the Dossier Submitter that targeted inspection activities by enforcement authorities can be used to monitor the effectiveness of the additional RMMs of the proposed restriction.

RAC considers that time trend monitoring proposed by the Dossier Submitter is not likely to provide results that are readily interpreted, due to the extensive number of sources of PFAS and their persistence.

The Dossier Submitter did not propose measures to monitor the implementation of core conditions regarding placing on the market, formulation and use. If a restriction option that permits continued placing on the market is implemented (RO4 or RO5), RAC recommends that reporting by formulators on their annual sales volume of firefighting foam concentrate is considered to enhance monitorability. RAC further recommends that SEAC evaluates the impacts of such reporting.

RAC concludes that the proposed restriction RO3 is the most appropriate EU wide measure with regard to monitorability as well as effectiveness and practicality.

Key elements underpinning the RAC conclusion(s):

Monitorability considerations that relate to compliance and enforcement were addressed in section 3.3.4 on Practicality, including aspects relating to analysis. No issues affecting monitorability were identified.

For monitoring how effective the restriction is in practice, there are two aspects, namely how effective the additional RMMs are in reducing emission and how quickly the sales and use of PFAS based foams will decline.

The Dossier Submitter proposes targeted inspection activities by national enforcement authorities as a way of monitoring the level of implementation and effectiveness of the additional RMMs of the proposed restriction. RAC concurs that this can be effective and is in line with approaches for already regulated PFAS like PFOA. RAC further notes that targeted inspection activities can focus 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.

The Dossier Submitter also proposes time trend monitoring of contaminated sites and exposure monitoring of firefighters following use of firefighting foams.

Monitorability by time trend monitoring was evaluated by RAC in previous related opinions, namely PFOA (2016), PFCAs (2019), PFHxS (2020) and PFHxA (2022). In all cases, RAC acknowledged that the restriction was monitorable with the caveat that due to the high persistence of the substances in question, it could take a very long time for environmental monitoring to demonstrate significant declines and that decreasing trends in releases will not be directly measurable.

In this restriction, RAC still considers that time trend monitoring is not likely to indicate changes in emissions over time. RAC also considers that due to the extensive number of sources of PFAS and their persistence, ambient environmental concentrations would not be expected to decrease in the 30 year assessment period even with the implementation of this restriction.

The Dossier Submitter also proposes firefighter exposure monitoring as a means of monitoring the restriction. Personal exposure and biomonitoring exposure data is not generally made widely available and a specific data reporting system would be required to obtain significant amounts of data with contextual information.

The Dossier Submitter does not elaborate other exposure monitoring approaches. RAC considered the ways in which environmental exposure monitoring could aid monitorability of the effectiveness of risk management measures. At sites where PFAS based firefighting foams were used, comparison between sites of RMMs and associated contamination levels could illustrate the effectiveness of various control measures. This would be challenging due to the large number of variables and the EU-wide cooperation required. Comparison between published historical contamination levels with contamination levels after entry into force could indicate the effectiveness of the additional RMMs. This would be possible but challenging.

Consequently, RAC concludes that the effectiveness is not directly monitorable through time trend or personal exposure monitoring and, in the absence of further information, that other exposure monitoring approaches are likely to be challenging.

Regarding monitorability of the core conditions regarding placing on the market, formulation and use, RAC considers that a requirement on formulators to report their sales quantities annually could provide information on the implementation of the restriction. This would be more relevant if a restriction option that allows continued placing on the marker is enacted (RO4 or (RO5). According to the Background Document, the number of formulators within the EU is relatively small, with approximately 20-25 formulators of class B firefighting foams in the EU. A number of consultation inputs drew parallels with a similar requirement that is included in other the PFHxA proposed restriction. RAC therefore suggests that such a reporting requirement be considered and that SEAC evaluates the impacts of such a requirement.

Effective monitorability is similar for all restriction options but needs to be implemented for a longer period for options RO1, RO4 and RO5, due to continued placing on the market and/or use after 10 years. This favours RO3 as the preferred option with respect to monitorability.

SEAC conclusion(s):

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

Key elements underpinning the SEAC conclusion(s):

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 PFAS 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.

SEAC notes that RAC recommends that a requirement to report sales quantities annually would be laid on formulators and that SEAC would evaluate the impacts of such a requirement. SEAC agrees in principle that such a requirement could aid monitorability, especially if the use sectors are reported according to the categories used in the proposed restriction. SEAC also notes that care should be taken so that this requirement does not create an incentive to carry out formulation outside of the EU. SEAC wonders whether this kind of a requirement would be better placed on the party responsible for the first placing on the market in the EU in order to cover all quantities sold but avoid double reporting. Overall, SEAC cannot evaluate further this proposal since no related assessment or comprehensive set of information is available to the committee.

3.4. UNCERTAINTIES

3.4.1. Uncertainties evaluated by RAC

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 emission calculations contain a range of more or less uncertain assumptions. Among them, the annual use rates, the nature and efficiency of the risk management measures already in place, and the efficiency of the RMMs proposed in the restriction have been identified as entailing the highest uncertainties which can potentially significantly affect the results. In addition, there is in-build uncertainty in using the reduced emissions as a proxy of the risk reduction and reduced negative human health and environmental impacts.

For calculation of the baseline, the same amounts were assumed to be used each and every year during the 30 years assessment period without regulation. It cannot be excluded that a decrease could be observed because alternative foams are under development and thus, the Dossier Submitter may overestimate the emissions.

RAC conclusion(s):

RAC has identified uncertainties regarding:

- The typical composition of PFAS-based firefighting foam concentrate and associated hazards, including degradation products formed, and combined effects
- Estimates for PFAS-foam stocks and releases to the environment
- The effectiveness of avoided releases from the proposed additional risk management measures (RMMs), set out in paragraphs 4 and 5 of the proposed restriction
- The impact of the proposed restriction on climate due to associated greenhouse gas emissions from incineration of foam stock and collected waste

These uncertainties do not materially affect the overall conclusions of this RAC opinion that a restriction is appropriate and that RO3 is the preferred restriction option.

Key elements underpinning the RAC conclusion(s):

Composition and hazards

RAC notes uncertainty regarding typical composition of PFAS-based firefighting foam concentrate and associated hazards, including degradation products formed and combined effects. RAC acknowledges the investigation and consultations undertaken by the Dossier Submitter to reduce this uncertainty and the comments received during opinion formation.

The approach of the proposed restriction is to address PFAS as a group. This is an all-encompassing approach and was previously supported by RAC in the opinion on the restriction proposal for intentionally added microplastics (ECHA 2020). It is not certain that all substances that fall within the group definition and that are potential ingredients in fire-fighting foams are hazardous. Despite this uncertainty, the concern for persistency and other properties remains.

RAC acknowledges contributions during consultation that highlight uncertainty with respect to aspects such as persistence and mobility for some specific PFAS subgroups. RAC accepts this uncertainty and notes that the persistence and mobility of most PFAS will lead to an ever-increasing environmental stock of PFAS and subsequently, increasing environmental and human exposure.

Emissions and exposures

RAC considers the stock and release estimates to be based on extensive consultation and sufficiently robust for the assessment, as outlined in section 3.1.2.2. RAC acknowledges the uncertainty in the release estimates due both to uncertainties in the quantities used annually and the effectiveness of control measures. The sensitivity analysis undertaken by the Dossier Submitter shows an impact of no more than 2% when changing any one input parameter between the low and high input estimates, which indicates that the results are not highly dependent on input assumptions.

RAC considers that regulatory and environmental concerns regarding PFAS based firefighting foams over the last few years combined with the development and testing of alternatives is likely to lead to an overestimate in the stock and release figures.

Evidence presented on contamination of soil and groundwater in the vicinity of locations where

use of fire-fighting foams had taken place supports the assumptions that significant releases occur in practice, albeit that there cannot be absolute certainty regarding the source of contamination in the absence of monitoring before the event.

RAC notes the uncertainty relating to the distribution between environmental compartment and considers that distribution to the air may be underestimated. However, as the transfer between compartments is complex and depends on the properties of the PFAS or sub groups, RAC considers that it is not possible to establish this with certainty, and also that it does not materially influence the conclusion reached regarding the need for regulatory risk management.

Effectiveness of the additional proposed RMMs

The effectiveness of the additional proposed risk management measures (RMMs), set out in paragraphs 4 and of the proposed restriction is uncertain:

- Class B fires: the restriction condition that limits use to Class B fires only may be challenging to achieve within 6 months after entry into force due to practical constraints. The justification for the derogation period for non-Seveso use sectors is that practicalities related to transition to suitable alternatives will delay changeover. If this is the case, it is reasonable to expect that the same practical challenges will apply when limiting use to Class B fires. Nevertheless, despite this uncertainty, RAC agrees with this condition of the restriction and it is likely that industry commences changeover prior to entry into force
- Minimising emission: Due to the crisis nature of the use, the feasibility of minimising emissions during use is uncertain, particularly in non-Seveso sites
- PFAS-containing firefighting foams management plan: Due to the wide variety of sites and variations between EU member states, the consistency of enforcement and effectiveness is somewhat uncertain.

Greenhouse Gases

RAC notes the uncertainty regarding the impact on global warming and that this was not addressed by the Dossier Submitter. The high global warming potential of PFAS is likely to lead to an adverse impact during formulation and use. Incineration of PFAS wastes, including disposal of existing stocks, can release greenhouse gases (Stoiber et al. 2019) due to emissions from both energy usage and from incomplete destruction of PFAS.

Such greenhouse gas emissions would contribute to an adverse impact on climate from continued use that was not addressed by the Dossier Submitter and hence is uncertain.

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 those related to emission reductions.

Overall, SEAC finds that these uncertainties, despite being significant, do not seem to compromise the conclusion of SEAC's 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 (incl. Consideration of neighbouring sites) and for the offshore oil and gas 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, at this time, a similar performance level by the end of the respective transitional period may not be possible to ensure for in 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 are released to 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. 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

This list of references includes only references cited in addition to those already contained in the reference list in the accompanying Background Document. Additional references can be found there.

List of additional references:

EC (2007). Guidance Document No. 17 Common Implementation Strategy for the Water Framework Directive (2000/60/EC). Guidance on Preventing or Limiting Direct and Indirect Inputs in the Context of the Groundwater Directive 2006/118/EC. ISBN 978-92-79-06277-3.

Sha et al. 2022 Sea Spray Aerosol (SSA) as a Source of Perfluoroalkyl Acids (PFAAs) to the Atmosphere: Field Evidence from Long-Term Air Monitoring. Environ. Sci. Technol. 2022, 56, 28-238.